Robotics in Genitourinary Surgery

Second Edition

Ashok K. Hemal
Mani Menon
Editors

Springer

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Preface

It has been our privilege and honor to edit the second edition of *Robotics in Genitourinary Surgery* which comprises 70 chapters, 11 more than its forerunner. Most of the chapters have been revamped, and many fresh faces have enriched this process. The authors include established pioneers of the field, the busiest practitioners of robotics, and the sharpest innovators of this generation. It also features two seminal urologists who express a warm, witty, and highly personal experience in dealing with prostate cancer.

Several new chapters have been added focusing on training, simulators, development of program, innovation in surgery, collaborative quality initiatives, health services research, besides newer techniques of robotic surgeries and newer tools including robots.

The editors are eternally grateful to all the individual contributors with their insightful contributions toward this book. Your work is what has made this edition possible.

We would also like to appreciate our tireless coaches and cheerleaders.

For Hemal and Menon, it has been a labor of love, but labor, nonetheless.

Winston-Salem, NC, USA — Ashok K. Hemal
Detroit, MI, USA — Mani Menon

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Part I

History, Basics, and Development of Program

The History of Robotic Surgery

1

Michael E. Moran

Abstract

The rise of digital, intelligent technologies is just beginning to have the widespread and projected paradigm shifting effect that many futurists have predicted. The history of robots and mechanical methods of emulating our human activity began early in humanities civilization, perhaps with the Antikythera mechanism that was discovered in a ship wreck off the shores of the Greek island of the same name. This mechanism contained 30 interlocking gears that could calculate accurately the Sun, moon, eclipses, planetary locations and the dates of Olympiads. This represents some of the detailed history of the mechanisms of the past that have formed the foundation of current robotic surgery. It traces in some detail the foundations of this fascinating process of mechanizing human work, including that of surgery.

Keywords

Robotics · History · Surgery · Technology · Capek and Asimov

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Introduction

If you will have the precision out of them, and make their fingers measure degrees like cogwheels, and their arms strike curves like compasses, you must inhumanize them. (J. Ruskin, The Stones of Venice [1]).

We stand at the threshold of the *information age* rapidly integrating the next technologic wonders into our everyday lives [2]. For instance, who would have thought that with little difficulty, we can go *online*, purchase an airline ticket halfway around the world, and return before the weekend is over. Certainly no one would have considered this even a remote possibility at the turn of the twentieth century or even by the end of World War II. Think about this for 1 min, *to go online* implies that we can immediately communicate to a travel agent or directly with the airline carrier, reserve and pay for our ticket, select our seat and any dietary preferences without leaving the office or home. Coupled to this is the fact that the aviation has come a long way from Orville and Wilbur's sensational but expected powered flight at Kitty-Hawk, SC, just over 100 years ago!

For millennia, one of the humanity's fondest dreams was to fly like birds. Aeronautics engineering has not only allowed this to happen but also exceeded anything possible from nature in a span of less than a century. Certainly, the primitive notions by such brilliant men as Leonardo da Vinci thought that powered flight might be

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possible by flapping wings; however, wind tunnel experimentation and wing designs coupled with innovations in jet propulsion have made the supersonic flight a reality. The technology of flight is now an everyday expectation, and no one could foresee going backward. We have landed a man on the moon with computer technology that is equivalent to an Intel® 286 processor which many younger urologists cannot now remember; we have several autonomous, robotic rovers on Mars, and our expectations of continued advances in aeronautics remain undaunted. Robots are another one of humanity's dreams.

The definition of the word "robot" can be debated, but according to The Robot Institute of America (1979), it is defined as follows: "a reprogrammable, multifunctional manipulator designed to move materials, parts, tools, or specialized devices through various programmed motions for the performance of a variety of tasks." Webster's dictionary states: "an automatic device that performs functions normally ascribed to humans or a machine in the form of a human." Mankind has been enthralled by the possibility of mechanizing human actions from the earliest recorded times; in fact, some evidence for this is seen in Homer's *Iliad*. A historical perspective on the coming of age of robotics is appropriate for any knowledgeable discussion and forms a basis for understanding the intense perceptions our patients have about this form of therapy. Consider this is an intellectual introduction to a rapidly expanding research effort that is applying the power of computer technology to the engineering of mechanical actuators with a significant past. In fact, the history of robotic technology is almost as compelling as the technology itself.

History of Robotics

Any sufficiently advanced technology is indistinguishable from magic. (Arthur C. Clarke [3]).

The word *robot* was introduced from a play written by the Czech author Karel Capek in the work *Rossum's Universal Robots* (RUR) in 1920. In this satire, all unpleasant manual labor is performed by manufactured biologic beings [4]. Robots have gradually morphed into our machines and have assumed a more human mantra, even undergoing anthropomorphitization, such as the computer HAL in Stanley Kubrick's interpretation of Arthur C. Clarke's tale *2001: A Space Odyssey* [5]. Isaac Asimov, in fact, goes much further in his classic work *Runaround.* Here he generates three basic laws of robots: first law—a robot must not harm a human being or, through interaction, allow one to come to harm; second law—a robot must always obey human beings unless it is in conflict with the first law; third law—a robot must protect itself from harm unless it is in conflict with the first or the second law. Asimov first explored the notion of robotic potential in the short story *Runaround* in 1942 but later added his zeroth law—a robot may not injure humanity or, through inaction, allow humanity to come to harm [6]. The recent motion picture adaptation of the science fiction potential for robotics was seen in *Bicentennial Man*, where Robin Williams plays the robot seeking to become human, or in *The Terminator*, where Arnold Schwarzenegger (ex-governor of the State of California!) is a robot out to change the future [7, 8]. These highly publicized but currently erroneous expectations of robots have an intriguing history, and several recent books have discussed early prototypic robots, or automatons. These will be presented in detail because it allows the user of current systems to better understand their implications and to better understand human-robotic interactions and mankind's desire or attraction/repulsion toward robotic technologies. Uniquely, there are two quite distinct histories that lead to different cultural perceptions of robots, the Western and the Eastern historic legacies. They will be presented separately.

Western Robotics

About 3.4 billion years ago, an anaerobic organism developed the capacity to reproduce, and life arrived on this Earth, the third planet from the sun. The earliest solution to storing data, replicating information, and developing along a pathway of growth potential to self-awareness commenced.

Deoxyribonucleic acid (DNA) became a biomolecular method of storing vast amounts of genomic data that allowed for the adaptive proliferation of life forms [9]. The Cambrian explosion possibly represents the most unprecedented time where the potential of this biomolecular database was allowed full expression. At the inception of the Paleozoic era, an intense period of biologic diversification occurred producing a massive outpouring of multicellular animals about 530 million years ago [10]. Our subspecies *Homo sapiens* probably arrived geologic moments ago, perhaps 40,000 years or so, and tool making was one of our distinguishing features. Our earliest accounts of technology are based on our mythologies and religious beliefs. According to Hebrew Scripture, the first human being, Adam, was created by God on the sixth day of creation. In rabbinic lore, Adam begins his existence as a golem. On the third hour of the sixth day, God assembles virgin dirt from all corners of the Earth, thus linking the first human to all of the planets. In the fourth hour, God kneads the dirt and in the 5th hour shapes the form of man. In the sixth hour, God makes this lump of clay into a golem. By the seventh hour, God breathes a soul into the creature and the golem becomes a self-aware human being [11]. This in ancient Judaic context suggests that the act of creation itself is infused into humanity. "If the righteous desired it, they could create worlds, for it is written, 'your iniquities have distinguished between you and your God'" [Isaiah 59:2].

Greek mythology tells us that Prometheus stole fire from Zeus to give to mankind and was punished for this. Icarus flew with wings made of lightweight wax that melted as he arose closer to the sun. Dedalus is also known to have animated statues so that they could move about and appeared lifelike. These mythical illustrations reinforce the contention that mankind has always been interested in technology and augmented function with inventions. In 250 BC, Ctesibius of Alexandria, a Greek physician and inventor, developed a mechanical water clock, or clepsydra [12]. In the thirteenth century, Albertus Magnus, a Dominican monk who is most well known as Thomas Aquinas's mentor, probably built an artificial man that apparently could move [13].

It was not until 1495 that one of the least known inventions of Leonardo da Vinci was drawn and the first real automaton can be verified. Leonardo was in his late twenties about this time and was experimenting with his painting technique on wet plaster. In the 1950s a researcher interested in the rare drawings and writings of this Renaissance master noted what appeared to be mechanical notations on one of Leonardo's works. At the Florence Museum of the History of Science, they have now shown that this drawing is a scale version of a mechanized, armored knight. It should be noted that at this time, there was no method of rendering mechanical drawings for craftsmen to work from, there were no motors, no electricity, no steam engines, and springs were only in their infancy. In fact, rubber had not yet been found by the French explorers in Honduras. From da Vinci's writings, it appears he was aware of the writings of Homer and a "mechanized cart" enthralled him. He had developed a mobile automaton that could be programmed to turn and had rack-and-pinion front wheel drive. This foundation became the basis for another of his famous automatons, a mobile, movable lion that was used to welcome King Francis I from France [14]. Though da Vinci's discoveries would not come to light for centuries, there is strong evidence that his drawings were widely distributed. Another tinkerer and inventor from Spain, Gianello Torriano mechanized an automaton referred to as the Japanese tea server.

In the early eighteenth century, Jacques de Vaucanson (1709–1782) would follow in the path of the ancients but improved the mechanisms of animation and would become world renowned. He was thought of as the master "toy maker" of Europe and attracted the royal attention of Louis XV. His finest creation was a mechanical duck with hundreds of moving parts. This duck could eat, drink and apparently "digest," and excrete although this is known to have been a preformed paste. He went on to construct musical automatons, the most famous being the "drummer and fife" player and a "flutist." What is remarkable about these automatons was the anatomical similarity they had to the real

things (humans). In fact, the flutist could be seen to breathe, with a bellows-like device inserted into the chest cavity that would draw in air and express it toward the devices' mouth so that it could play the flute. Vaucanson had studied the anatomy of animals and humans extensively and created in his "flutist's" mouth all representations of a normal human. His machines were unparalleled in their complexity and decades would pass before anyone could duplicate his efforts [15]. René Descartes, the father of the Enlightenment, believed that animals, man included, were nothing more than biologic machines. His disquisitions on consciousness is related in his "*cogito ergo sum.*" There now is no sure proof, but it has been recounted that during his last trip to the Norway, he took with him a mechanical doll, thought to look like his dead daughter Francine [16].

Largely due to the success of Vaucanson, other machinists and watchmakers became interested in making mechanical automatons. In fact, it had become quite fashionable for the aristocracy to collect sophisticated mechanical devices for entertainment. Particularly to our discussion, two more European individuals deserve mention. Jaquet-Droz, a Swiss inventor, in the 1770s made moving and musical androids. In fact, some of these machines still enchant audiences in Neuchâtel, Switzerland. Mary Shelly, the author of *Frankenstein: The Modern Prometheus*, was delighted by these automatons [17, 18]. These devices appeared like children and were mechanized only to draw (usually king's portraits) or write (commonly would quote Descartes). But Jaquet-Droz was most interested in musical automatons. He had one automaton that could play the harpsichord and appeared to consider the audience and breathe. The other Frenchman was Roulet-Descamps, who became famous for his intricate, smaller mechanical pieces. Collectors vied with each other to obtain his most sophisticated automata. By the 1800s there were whole shows of such "mechanical wonders." [19]

In what was then thought as the ultimate attempt at automata, von Kempelen developed a sophisticated machine that could play chess against a human opponent. It widely toured all of Europe and eventually made its way to the New World. The *Turk*, as it was referred to, was an immediate sensation. His touring would make von Kempelen famous and wealthy, for crowds of people would pay just to observe this mechanical device usually beat the most gifted chess players of the time. In fact, it is known that Benjamin Franklin played against the *Turk* and lost [20]. Scholars were attracted to these shows in an attempt to understand the inner workings of this automaton but were never able to figure how it was done. A book published in 1773 about this mechanical device was titled *Inanimate Reason*. Recall that this device appeared just as the "Industrial Revolution" was beginning. The average person of that period had almost unlimited expectations of mechanical wonders. The steam engine was on the horizon, and mechanized factories were being discussed. The mechanical workings of this machines' left arm were extraordinary, but in reality, it was indeed a magic trick with von Kempelen's accomplices coming from the best chess players of the age. Maelzel, another tinkerer, eventually bought this machine and brought it to America. Here, as was true in Europe, it attracted large crowds and prompted Edgar Allen Poe to write a famous essay on the impossibility of a mechanical device to reason or think [21]. It would be another 200 years before Poe's essay would be proven false when IBM's computer, Deep Blue, beat Garry Kasparov, the world's Master chess player, in 1997 [22].

Between 1805 and 1871, Jean Robert-Houdin, the father of modern magic, became well known. One of his passionate interests was automata. He became famous for his ingenious gadgets and machines, many of which would be used in his magic shows. He eventually developed a whole "menagerie" of these devices including a moving pasty cook, "Fantastic Orange Tree," "Diavolo Antonio," and "the Writer." [23] People would come to his shows and would remain spellbound when these mechanical devices would perform in ways that even trained animals could not. Many of his creations were later used by Georges Méliès, the father of modern cinematography and master of special effects, and are now in museums in Paris [24].

At the onset of the twentieth century, the famous inventor Nikola Tesla, who developed alternating current, generators, the radio, and many other devices, also turned his attention to automata [25]. He proposed that autonomous mechanical devices could be used to eliminate the need for soldiers in war. He designed, built, patented, and demonstrated the first autonomous, programmable, remote-controlled submarine. Tesla's device was mobile, autonomous, interactive with its human controllers via radio and so advanced that it did not even attract the interest of the armed services or any other scientists of the time [26]. Tesla's main contemporary Thomas Edison was likewise at work upon an early mechanized device, the Edison talking doll. Unlike Tesla's huge expectations, Edison thought only to sell the product to the huge doll market at the turn of the century. The idea was to incorporate his new phonograph into a realistic appearing doll that could talk. His prototype device appeared on the cover of *Scientific America* in April 1890. Edison created a whole division near his research facility in New Jersey, but like Tesla, this product was not ready for the time, and the Edison doll was quickly withdrawn from the market [16].

Approximately 20 years and one World War later, Karel Capek, the Czech playwright, wrote *Rossum's Universal Robots* which became a success playing throughout Europe, England, and the United States in 1921 [4]. Capek probably took a suggestion from his brother to use the Czech word "robot" meaning peasant or worker as a title for his automata. In *RUR*, the brilliant scientist Rossum manufactures a line of biologic humanoids designed to save mankind from work. The plot becomes sinister when the robots are used in a war to kill humans. The robots are given emotions and become no longer tolerant of humans and wipe mankind from the face of the earth, except one. Capek's word "robot" has stuck and has replaced all others in discussing such machines [4].

In May of 1950, W. Grey Walter and his wife built a mobile robot to investigate the way it learns. *An Imitation of Life* appeared in *Scientific America* in May 1950 (pp. 42–45) describing his first two efforts to build robots [27]. He stated that the human brain has 10,000 million cells, but his robotic "tortoises" had only two miniature radio tubes. In addition, these little machines that he gave mock biologic names *Machina speculatrix* were mobile and sought light. These robots had two sense organs, two motors, and an onboard 6-V hearing aid battery. Later, Walter built more advanced circuits for his robots because he wanted them to learn [28]. He called the advanced machines *Machina docilis* that demonstrated conditioned reflex learning, and he published his second paper "A Machine that Learns" (Sci. Am. Aug 1951, 60–63). During the 1940s, electronic data processors were just beginning to be investigated. Vannevar Bush published his classic work "As We May Think" in July's *Atlantic Monthly*. Bush was a well-known scientist who essentially spells out the coming of the *Informational Age*. In this article, he predicts the rise of computers, digital photography, the FAX machines, the Internet, digital word processors, voice recognition, automatic language translation, scanners, advanced mathematics programs, cellular phones, and much more [29]. Ted Nelson in 1965, the father of "hypertext," credits most of his ideas to Bush from having read "As We May Think."

Eastern Robotics

There is little doubt that the ancient Chinese were culturally adept and developed many technologic advances. Mechanical engineering was quite advanced as early as the empire of King Wu (976–922 BC) of the Western Zhou Dynasty. It is written that one such skilled artisan named Yan Shi made a humanoid robot that could sing and dance like a real human being [30]. This device is said to have possessed lifelike organs such as bones, muscles, joints, skin, and hair. At the beginning of Emperor Tang Xuan Zhong's rule and the Tang Dynasty, there were numerous accounts of such fetes of automation. One other gifted designer was Daifeng Ma, who built and repaired lead carriages, drums that recorded the mileage of the carriage on journeys, and birds that measured the wind's direction. His most

famous automated device was a dresser for the queen. Through ingenious levers and switches, when the queen opened the mirror, the doors beneath automatically opened as well. He devised a robotic woman servant for the queen that would bring washing paraphernalia and towels. When the towel was removed from the servant's arm, it automatically triggered the machine to back away back into the closet.

One later Chinese book, *Stories of Government and the People* or *Chao Ye Qian Zai*, contains several accounts of other robotic technologies during the Tang Dynasty [31]. King Lan Ling (550–577 AD) is said to have possessed a humanoid robot that looked like a non-Chinese ethnicity that could both dance and serve drinks. Ling Zhao was a monk from the northern regions of China who is reported to have built a pool for the Emperor Wu Cheng. Ling, in addition, built a miniature boat that self-propelled itself to the Emperor and automatically served wine. Detailed accounts of the boat include a little wooden man that could clap its hands, and the boat would start to play music. Another skilled mechanical engineer was Yin Wenliang from Luozhou. He created an automated man that could propose a toast to his guests at banquets. He also animated a wooden woman that could play the sheng (a Chinese pipe with 13 reeds) and sing. The final artisan of note was Yang Wulian, who created a wooden monk in Qinzhou City. The monk held a wooden bowl to collect alms. Amazingly, when the bowel had been filled, it triggered the monk to proclaim "alms solicited!" [31]

The most well documented of all of the automata comes from Han Zhile, who was actually a Japanese craftsman who moved to China between 806 and 820 C.E [32]. He is known to have created mechanical birds, phoenixes, cranes, crows, and magpies. Though made of wood, some of the ornithologic prototypes could be made to pretend to eat, drink, chirp, and warble like real birds. He is reported to have installed mechanical devices inside some of the birds to drive their wings to make them fly. He is reported to have also created a mechanical cat. One of the most marvelous creatures was an automated bed for the Emperor Xianzong named "a dragon on demand." It was activated by someone applying their weight to the bed, thus triggering the release of an intricately carved dragon.

Arising much later than the ancient Chinese automata were the Japanese Karakuri. The word Karakuri means a mechanical device to tease, trick, or take a person by surprise [33]. There are three main categories of Karakuri. Butai Karakuri are puppets used to entertain people in theaters. Zashiki Karakuri are small and used to entertain people in rooms and small groups. Dashi Karakuri are automatons that performed on wooden floats and could be much larger. The Japanese typically used these automata for religious festivals for performing re-enactments of Japanese myths and legends as a form of entertainment. There are several museums in Japan with collections of these intricate mechanical devices such as the Arashiyama Orgel Museum outside of Kyoto. In addition, many of these truly beautiful devices can be viewed "online" with brief descriptions of the device, how they worked, who built them, and what they represent to the Japanese people. Most were built in the seventeenth century [34].

By the twelfth century, tales of Konjaku Monogatari Shu had developed crude robotic devices for irrigating rice paddies. The most famous nearly-modern robotic device from Japan is the 1927 Gakutensoku [35]. It was presented from the people of Japan for the International Exposition that was supposed to have a diplomatic role. Therefore, it was designed to exhibit features from all races. It was actuated by compressed air and could write fluidly and raise its eyelids. Gakutensoku means "learning from divine reason" and was not designed as a laborer but to think, write, and entertain.

By the 1950s, Japanese cultural infatuation with robots underwent an epiphany from the unlikely source of a comic book character [36]. This character would become a cultural icon and eventually spawn enough resolve by these people to spur the Japanese government into funding future robotic research on a scale only comparable to the effort the US government used in the Apollo program. The cartoon character is the Mighty Atom, or better known to the West as Astro Boy. His first black and white appearance

occurred on Japanese television in 1963. Many of Japan's top roboticists grew up immersed in the Astro Boy era and can relate their interests in this career from early exposure to this cartoon character.

Osamu Tezuka, the creator of Astro Boy, could not have predicted the outcome of his little cartoon boy would have on the ideals and future of the Japanese people. First conceived and printed in 1951, the series begins with the death of roboticist Dr. Boynton's son Aster in a car accident set in the year 2000. The distraught Boynton sets out to make the robot boy in his son's image, but disappointed with his creation, he soon disowns him. The robot boy is passed off but is found by Dr. Elefun, who schools him in humanity and trains him to battle against anything that might threaten mankind [35].

Most importantly, Dr. Elefun teaches Astro Boy human feelings such as love, courage, compassion, friendship, and self-doubt. But Astro Boy is not human and struggles with finding the bridges between being a robot and trying to be human. Tezuka's portrayal of this robot boy who struggles with being a partner with his human colleagues continues throughout the series. The robot is never a drone or pure worker for the whim of humanity but assists with his own abilities. This more closely parallels the Japanese vision of the future of intelligent technologies in general. Corporate Japan echoes these themes to this day; robots are an immensely worthwhile endeavor to companies, and they expect their robotic products to be helpmates to their human counterparts, not slaves or potential threats as we saw from Western versions. This modern example can best be seen in Sony's newest entertainment robot QRIO (pronounced CURIO) [36].

The first industrial robot was introduced into Japan in 1967. It was a Versatran robot from American Machine and Foundry (AMF). The following year, Kawasaki licensed the hydraulic robot designs from Unimation and started production in Japan. From that time onward, Japan has rapidly become the global leader in the design, development, and distribution of robots of all types (particularly industrial). The whole of the now European Union did bypass Japan in the number of industrial robotic installations in 2001. But, no single country even comes close to Japan in the number of robotic applications. The International Federation of Robotics estimates that Japan (approximately the size of California) installed three times the number of industrial robots than did the US in 2001 (28,369 vs. 10,824). Germany which is also a very industrialized country installed 12,524 robots in the same year. According to the World Fact Book 2002, Japan possesses 410,000 of the world's 720,000 "working robots." These trends highlight a fundamental difference that technology is perceived from East to West.

But don't stop there, Sony Corp. unleashed a robotic dog in 1999 named Aibo. They have since sold approximately 100,000 of these robotic companions. Humanoid robots are the next major desire of the Japanese corporate giants. The Japanese government recently planned to spend ¥30 billion (about $258 million) annually on a 30-year program to develop a humanoid robot with the same mental, physical, and emotional capacities of a 5-year-old human; it is called the Atom Project [37].

This commitment to this technology is already bearing fruit. Every year, Japan hosts ROBODEX, an exposition that exposes corporate prototypes to the people and the media. The third event, ROBODEX 2003, was held on April 3–6. In 4 days, 66,264 people attended; there were 393 press, 29 speakers, 24 vendors, and 13 universities at the event. There were 90 types of robots exhibited at ROBODEX 2003, most of which were personal assist-type machines. Most of these robots were humanoid in appearance, were small, unimposing, with large heads and eyes. If speech was added, it was usually high-pitched and childlike. The goal according to some technologic enthusiasts is that Japan expects to have a robot in every household in the twenty-first century. If robots can be made to be intelligent, feeling and mobile, they can be more interactive and become personal partners. Some feel that Japan's market for human-friendly robots will soon outstrip the domestic PC market, which generated ¥1.67 trillion ($14.3 billion) in shipments in 2002. Japan's current robot market, ¥400 billion,

could grow to ¥3 trillion by 2010 and 8 trillion by 2025 according to some projections [38]. The next Robodex is planned for 2017 in Tokyo.

Engineering Modern Robots

When a scientist states that something is possible, he is most certainly right. When he states that something is impossible, he is very probably wrong. (Arthur C. Clarke's three laws of technology [3]).

From Greek Myths to Reality

Our modern Western thought is inexplicably linked to ancient Greek civilization and thought. Greek mythology represents some of the earliest writings that have been preserved as were the folk tales written by Homer. One needs to look no further to the implications of technology and society than the myths recounted by him and the events surrounding the Greek gods. Hephaestus was the Greek god of fire, particularly the blacksmith's fire, as he would become the patron of craftsmen, artisans, and manufacturers. He was depicted in ancient works of sculpture and paintings as the lame god, born from Hera, who despised him because of his weak and crippled form. As the story goes, he is cast out of Mount Olympus by the repulsed Hera and falls for an entire day before landing in the sea. He is rescued by nymphs, who carry him to the island of Lemnos where he builds a palace and his forges under a volcano. Hephaestus creates a golden thrown as a present to Hera, but his intentions are sinister, and she becomes entrapped. Dionysus is sent by Zeus to intoxicate and bring Hephaestus back to Mount Olympus in order to entreat him to release his mother. This is of course attended to with a bribe and Aphrodite is promised to Hephaestus as his wife [39].

Hephaestus was the great craftsman for the gods and supposedly created many wonderful devices out of metal. His primary helpers were the Cyclopes, who assisted him as workmen. He made weapons and armor for the gods and their heroes. He made Athena's shield and Aros' arrows. He manufactured the chariot for the sun god Helios and the invincible armor for Achilles. In the Greek creation myth, it is Hephaestus who is given the ingenuity of creating the female gender by shaping Pandora (meaning, "all gifts") out of clay. It is also Hephaestus who is ordered by Zeus to chain Prometheus to the rock in Mount Caucasus. "Against my will, no less than yours, I must rivet you with brazen bonds… Such is the prize you have gained for your championship of man." [40] In addition, some of Hephaestus other creations include an animated bull given to King Aeetes that could breathe fire from its mouth. He wrought the famed necklace of Harmonia and Oengrioun's fabulous underground house. But for the sake of our discussion here, his most poignant creation was Talos [39]. Zeus asks Hephaestus to create a bronze humanoid creature for Europa (Zeus' lover), the queen of Crete. Talos is a gigantic automaton whose task is the warder of Crete. He guards this island country by running around it three times daily to drive pirates or invaders off with volleys of stones. But Talos is no ordinary automaton. His secret for life is apparently an infusion of god's blood, or ichor by Hephaestus. Talos, the man of bronze, had beneath the metallic sinew of his ankle "a red vein with its issues of life and death" covered by his skin. It is this part of his invulnerable body where a nail was used to fashion the cover and protect its secret vitality. The Argonauts from Homer's Odyssey were to be the downfall of the mythical creation. Medea, who was with Jason on his return trip from Troy, enchants Talos promising to make him immortal. While enchanted by her, the nail is removed allowing the ichor to gush out toppling the mechanical man [40].

The first encounter with technology is as a robot, or an automaton infused with some god-like fluid for animation. This first robot is meant to be a guardian or a protector to the people of Crete. But there is another ancient Greek myth, just as powerful technologically speaking, that continues to have an influence on our modern era, the story of Pygmalion. These myths, as we shall see, can have a profound effect on the human

psyche, society's expectations, and the creative spirit, at least by Western standards.

Pygmalion is either a gifted Cyprian sculpture or a king, or both. As the myth is told, Pygmalion finds the women of Cyprus so impossibly flawed that he resolves to create a statue of his ideal woman [41]. He embodies this statue with every feminine grace and virtue he can devise and sculptures his masterpiece from the finest virgin ivory (or perhaps marble). After months of labor, he completes the most exquisite art ever created and, of course, he falls in love with it. He is depicted standing in his studio kissing its ivory lips, holding the stone hands, dressing, and grooming the figure like a large doll [42]. But Pygmalion becomes despondent as the lifeless statue could not return his affections, and the cold stone could not fathom his love. It is lost in the mists of time, but Pygmalion's statue eventually assumes a name, Galatea (sleeping love). Pygmalion presents gifts and prayers to Aphrodite, who hears and animates his statue. He goes on to marry his statue and is blessed by Aphrodite with a long life and a son, Paphos [43].

Both of these ancient Greek myths have founded their modern technologic legacies, respectively. Talos has created the image of an automaton being constructed for the benefit of humanity. This myth will be recreated and changed throughout the history of the Western world. When Sir Artegall fell under the power of Radigund, the queen of the Amazons, it is Talus that brings Britomart to the rescue [44]. This word also finds itself evolved to the word talismans. The four talismans from the *Oriental Tales* (1743) were a little golden fish, which could get from the sea anything that it was bidden; a poniard, which made the person wearing it invisible; a ring of steel, which allowed the wearer to read the secret desire of men's hearts; and the fourth a bracelet, which protected the wearer from poisons [45]. The current iteration of the Greek myth of Talos, the protector, is utilized in the US Department of Defenses modern missile defense system [46].

The Pygmalion myth is much more ingrained into our modern psyches. William Schwenk Gilbert, better known as the first half of the great operatic comedy duo, Gilbert and Sullivan, wrote a three-act comedy called Pygmalion and Galatea. In addition, a great deal of modern Hollywood stereotypic activity has gone into a Pygmalion-like movie theme. Pygmalion fantasies abound in Hollywood images and in literature. Whenever man seeks to make the woman of their lives into the likeness thought to be archetypical, the myth of Pygmalion is perpetuated.

The roots of artificial intelligence, however, can be found linked to the myth of Pygmalion. The first programming by demonstration research was David Smith's Pygmalion, which was inspired by the question: "Can a programming environment be constructed to stimulate creative thought?" He identified various aspects of creative thought and concluded that programming systems should support visual and analogical aspects of creative thought and that programming should be less tedious. The design of Pygmalion was inspired by the ease of use of text editors, especially in comparison with programming languages. Pygmalion became that system. Unlike later systems which tried to add programming to otherwise typical user interfaces, Smith constructed a special user interface which contained the typical operations of a programming language. This user interface was the first to make use of *icons*, which he used to subsume the notions of variable, reference, data structure, function, and picture. Icons have since become Smith's most well-known contribution to computer science and represent his attempt to bring computer programming to life. This represents modern computing's symbol of its Pygmalion legacy [47].

This urge to create something living is common among artists. Artists have consistently reported an exhilaration during the act of *creation*, followed by depression when the work is completed. "For it is then that the painter realizes that it is only a picture he is painting. Until then he had almost dared to hope that the picture might spring to life." This is also the lure of programming, except that unlike other forms of art, computer programs do "come to life" in a sense [48].

By the fourth century, Aristotle postulated that mechanical contrivances could reduce the amount of human labor. "If every instrument could accomplish its own work, obeying or anticipating the will of others…if the shuttle could weave, and the pick touch the lyre, without a hand to guide them, chief workmen would not need servants, nor masters slaves." This classic thinker of ancient Greece would have known of the story of Daedalus, the master craftsman of classic lore, who is said to have animated dolls and statues. Daedalus was also the designer and builder of the fantastic mazes on Crete. In order to escape, he built wings for his son Icarus and himself to fly away from the land where they were held hostage. Of course, Icarus would fly close to the sun and fall to his death, as would most "would-be" inventors of mechanized flight until the Montgolfier brothers flew aloft in a hot air balloon in 1783 [49]. And even they were predicted to do so by Professor Black at the University of Edinburgh in 1767, who announced to his class that a vessel, filled with hydrogen, would rise naturally into the air [50]. Aeschylus wrote about such "living statues" and no less of an authority than Socrates is quoted "that if they were left untethered, they might take off, giving you the slip like a runaway slave." A remarkably creative individual who lived during Plato's lifetime was Archytas of Tarentum. He designed great cranes that could help in building magnificent structures with less human effort. He is thought to have constructed wooden pigeons that could fly using power from steam. The most amazing reference to the ancient world might be applied to Hero of Alexandria around 150 BC. Hero is credited with the invention of the syringe in medicine. He is also thought to have created a humanoid automaton that had a head that could not be severed from its neck. It achieved motion by utilizing an ingenious system of cogs and wheels. The most widespread technical wonders of that long-ago era were the complex water clocks or clepsydra that could be found in many of the city centers [51].

But the Greek's greatest contribution to the advancement of technology was recorded in the works of Ctesibius, Philon, and Heron regarding hydraulic machines. Ctesibius is given credit for inventing the hydraulic organ. This is an ingenious method for using water power through pipes to create music. Fabulous fountains with enchanting statuaries could also produce music and provide power to animate moving sculptures [52]. Heron would eclipse even these with his works on hydraulics and pneumatics. These masters of engineering would vanish for about 1500 years, but their work was transcribed and propagated by Arabs and the Byzantines [53]. In fact, one Arab engineer is credited with several hydraulic mechanized devices, but also the modern flush toilet, Al-Jazari. By 1501, Heron's works on hydraulics and pneumatics were translated into Latin by Giorgio Valla. Future mechanical enthusiasts would find numerous wonders from these ancient Greek thinkers, and the rise of complex mechanical automata would follow directly [54, 55].

Lastly, one cannot finish a tale about Greek lore without ending with the great, blind poet–laureate Homer. In his *Iliad*, Homer recounts the use of automated carts that could be used by the gods:

…since he was working on 20 tripods which were to stand against the wall of his strong-founded dwelling. And he had set golden wheels underneath the base of each one so that of their own motion they could wheel into the immortal gathering, and return to his house: a wonder to look at. (Homer the *Iliad*, book 18 [56]).

World's Fair Robots

It is possible that in the recent history of the world, only wars have had a more dramatic impact upon our society than expositions. The first industrial exposition occurred in Paris in 1798 and allowed the public to witness progress and technologies that could change the lives of everyone [57]. Steam-powered machines became all of the rage during the Industrial Revolution [58]. In short order, fictional writers began to concoct stories with steam-powered men, *The Steam Man of the Prairies* [59]. The Columbian Exposition presented the first steam engine-powered version of this type of robot built by

Professor George Moore from Canada [60]. Within 5 years, Zadock Deddrick, a machinist from Newark, developed a working "Steam Man" that pulled a carriage [61]. This process continued into the nineteenth century when the extraordinary potential of remote-controlled robotic devices was clearly demonstrated to an unsuspecting public at the 1898 Electrical Exhibition in Madison Square Garden, New York City [25]. Nicola Tesla was at the height of his inventive prowess when he brought upon the unprepared world a fully automated, remote-controlled robotic submersible boat. "Teleautomata will ultimately be produced, capable of acting as if possessed of their own intelligence, and their advent will create a revolution." [26]

It would be 37 years and one World War later at the San Diego Exposition that the next robotic device would greet the public. A little known and not widely regarded demonstration of a 2000-lb mechanical man was demonstrated by its inventor Professor Harry May. Alpha, the robot's name, was 6′2′′ tall and could roll its eyes, open and close its mouth, sit and stand, move its arms, and fire a revolver [62]. By 1939, the super secret and far more popular mechanical man was introduced at the New York World's Fair by the electronics giant Westinghouse. Elektro was a spectacular hit at the Westinghouse Pavilion. Elektro would stand high above the audience on a platform and supposedly respond to English-spoken commands. Elektro was able to perform far more complex tasks than Alpha; he was able to move about on the stage with a strange sliding gate. Elektro was about 7′ in height and costs several hundred thousand dollars for the Westinghouse Corporation to make in Mansfield, Ohio. Records of the company show that they in fact manufactured eight robots from 1931 to 1940. These robots could all move actuated arms and walk. Elektro used a 78-rpm record player to simulate conversation and had a vocabulary of more than 700 words [63]. Elektro was captivating; he enthralled millions of visitors and went on tour following the World's Fair and even appeared in a bad "B" movie, "Sex Kittens Go to College," subtitled Beauty and the Robot [64]. Most curious of all, these mechanical men were not called robots yet, because Karel Capek's play *Rossum's Universal Robots* had not achieved the notoriety and cultural conversion of this word at this time [4].

The electronics in these early metal men were primitive with loud electrical motor drivers and vacuum tube relays. They would be replaced with microcircuits and far more rapid, efficient, and quiet mechanics in the not too distant future. The World's Fair phenomenon and robots continue to this day. The last Worlds Expo 2005 was held in Aichi, Japan, and closed in September with over 22,000,000 in attendance [65]. The theme was "Nature's Wisdom," but the technology was definitely center stage. The robot assumed a key role with "We Live in a Robot Age." Working robots roved around the grounds and performed routine chores about the grounds including the following: sanitation, garbage collection, security, guide robots, child care duties, and handicapped aid robots. Multiple prototype robots were demonstrated for 11 days in June. In addition, the exhibition had a "Robot Station" where visitors were able to interact with a whole host of robotic-based venues. As is the core of most such industrial expositions, manufacturers were present to show off their future technologies, including Toyota, Honda, SONY, Mitsubishi, and Brother Industries [65]. The latest World's Fairs and Expos have not the Japanese commitment for robotics (2015, Milan; 2016 Antalya, Turkey; 2017 Astana, Kazakhstan), but perhaps Dubai in the United Arab Emirates in 2020 might see the return of the next famous automaton.

The Legacy of Raymond C. Goertz

At this midpoint in discussing engineered robots, it is appropriate to give credit to the engineer who perhaps has done more for modern robotic development than any other, but who is seldom, if ever mentioned, Raymond C. Goertz [66]. Almost every graduate textbook on robotics mentions Goertz, yet surgical papers fail to recognize this man's truly monumental influence on this field [67].

Ray Goertz was part of the World War II effort euphemized as the Manhattan Project. As a young engineer, he worked at Enrico Fermi's experimental site outside of Chicago called Argonne National Laboratories (ANL). Part of Goertz's obscurity relates to the politically volatile issues surrounding nuclear materials. In September 1944, Manhattan Project's 100-B plutonium reactor began outputting enough of this substance to achieve criticality at Hanford, and Ray Goertz developed the first unilateral manipulator to handle this hazardous material for the Atomic Energy Commission. By 05:29:45 AM, Mountain War Time on July 16, 1945, the successful results of "handling" this material culminated in the explosive crescendo called the Trinity test. Goertz and co-workers at ANL demonstrated the first mechanical, bilateral master–slave manipulator device (MSM) in 1949 [68]. Goertz had become acutely aware that the haptic senses were necessary to manipulate delicate objects and had incorporated force-feedback systems that greatly improved deftness of the human–machine combination [69]. By the height of the Cold War years, 1954, Goertz had improved the teleoperations by applying principles of cybernetics and constructing the first electronic master–slave manipulator systems [70].

Goertz applied modern engineering skills with an ancient mechanical device, the pantograph, to create the first MSM. He also codified the terms that university and industrial developers could follow. Not only did Goertz improve his master–slave manipulators, he also performed the primordial research regarding degrees of freedom necessary for smooth motion by remote manipulation. He developed teleoperated systems that are the direct forerunner of modern robotic surgical systems. He even developed one of the first head-mounted displays as a prototype for virtual reality. Goertz incorporated nautical terms such as pitch, yaw, and roll into the lexicon of robotics. Finally, the efforts of this incredibly prolific individual led to the creation of a spin-off company, Central Research Labs (CRL) in Red Wing, Minnesota. By 1953, Ray Goertz was ultimately replaced by Demetrius Jelatis at CRL which has made over 8000 MSMs for over 26 different countries [71]. Goertz's legacy lives on, and his first principles of an MSM are as applicable to our own robotic surgical systems [66]. They are as follows:

- The motion of the slave arm must possess six independent degrees of freedom, three of translation and three of rotation to position gripping devices, and a tong squeeze motion to grip items.
- The motion of the slave arm must be coupled to the master arm so that the position and the direction of the two arms correspond.
- The coupling of the two arms must be bilateral. This important concept means that forces at the slave end must be reflected to the master end and displacements produced at the slave end must be able to produce a displacement at the master end. Another way to state this important concept is to say the manipulator must be back-drivable or compliant. This means that the slave arm must be able to align itself in response to the constraints imposed by the task being done. A classic example of this concept is the ability of an MSM to rotate a crank which follows a constrained path.

The University of Robotics

Concurrent with the revolution in computer technology, the robotics effort gained momentum especially in our centers of higher learning. Early robotic prototypes arose in research laboratories at some US universities, particularly Stanford (SRI), Carnegie Mellon, and MIT. Others were industrial, such as General Electric's prototype "walking vehicle" or colloquially referred to as the "elephant" by Ralph Mosher [72]. Others were developed for the dangerous environments of US nuclear-powered facilities. But serious federal funding for Stanford's mobile robot "Shakey" evolved from an Advanced Research Projects Agency (ARPA) grant for artificial intelligence and from these humble beginnings a whole network of robotic centers would evolve. Shakey was a mobile, intelligent robot that could search for objects within its environment [73]. It had an "off-

board" PDP-10 computer linked to the robot by radio. It certainly had difficulty working independently and was incredibly slow. One of the early investigators from this SRI team was a young Australian, Rodney Brooks. He would move on to MIT's Artificial Intelligence Laboratories to continue building and investigating robotics. Brook's labs now have many prototypes utilizing computer strategies that were significantly different to any type of previously available programming. Based upon an investigational autonomous robot called "Genghis," Brook's new computerized algorithms were termed subsumption programs. The idea was to build robots with programs that were intelligent, situated, embodied agents that could interact with their environment. The computation is organized asynchronously with network active elements in a layered architecture. Sensors and actuators are connected to this control program so as to modify the robot's "behavior." Genghis thus became a hunter-seeker. Some of the first sensors given to these robots were sonar and light sensors. Genghis demonstrated surprising adaptability to his environment and a life-like quality not previously accorded to advanced robots (except the Turk). Genghis weighed just about one kg., had six legs for mobility, walked, and sought all under its subsumption programming. It could negotiate even rough terrain using 12 motors, 12 force sensors, six pyroelectric sensors, one inclinometer, and two whiskers [74].

The MIT program sought to investigate the known robotic dogma. Do complex robotic behaviors need to be a product of complex control systems? They believed that things should be simple, interface systems and subsystems. Do robots need to be expensive? They sought to build cheap robots that worked in human environments. The world is 3D, and the robot must function in 3D. Do coordinate systems have to be very sophisticated? They noted that coordinate systems for robots are the source of a large number of errors. The real world is not constructed of simple polyhedra. They noted that visual data are necessary for high-level tasks, but sonar might be good for low-level tasks such as object avoidance. Their robots must perform even if one or more of its sensors fail or give erroneous information. To quote Brooks, "we are interested in building 'artificial beings'—robots that survive for days, weeks and months without human assistance, in a dynamic and complex environment. Such robots must be self-sustaining." [74] The MIT robotics labs came up with a method to solve this complex control problem that had faced roboticists since the beginning. Their method is nothing like human neurologic control systems; it is organized asynchronously with network-active elements. They called their robotic control systems subsumption programs. The computations are fixed topology of unidirectional connections. Messages are sent over connections with semantics of small numbers (typically 8–16 bits) with dynamics designed into both the sender and the receiver. Sensors and actuators are connected to this via asynchronous two-sided buffers. "Allen" was their first subsumptive robot and it was almost entirely reactive—using sonar readings to keep away from people and other objects. Allen also had a non-reactive higher level which attempted to head toward a goal. Next came Genghis, whose primary program is to search for a moving object and track and chase it. It is amazingly insect-like and really interacts with the environment to complete its programmed task. The laboratory has pursued more sophisticated behaviors and have begun to downsize the robots (recall their goal of reducing cost). "Herbert" uses a laser scanner to find soda cans, infrared proximity sensors to navigate, and a magnetic compass to maintain its global sense of orientation. Its task is to wander around the laboratory looking for things to clean up and bring them back to where Herbert started. "Squirt" followed with a diminutive weight of 50 g and measured only 5/4 cubic inches. Squirt incorporates an 8-bit onboard computer, battery, three sensors, and a propulsion system. Its normal activity is bug-like hiding in dark corners and venturing out to investigate noises. Squirt's control system fits 1300 bytes of code into its computer [74].

There are many problems with subsumption systems, especially when adaptive learning is necessary for the robot. More research into sensors, computational algorithms, and actuators are all necessary, but as with computing costs are

dropping. There are now sophisticated robotic kits that your children can purchase from LEGOTM. Multiple parallel fields of research are beginning to merge with robotics technologies. More degrees of freedom are possible from robotic systems [75]. More computer horsepower is available, to make even the most sophisticated interactive systems work smoothly. The roles of robotic systems are beginning to be systematically evaluated. Robots are proving vital in the hazardous industry sector. Robots are used routinely in nuclear reactor facilities. Robots are expected to play a significant role in precursor missions to Mars. Robotic morphology is being evaluated. Vehicular-mobile-payload-carrying devices are just beginning to be utilized. Humanoid devices are planned for future space shuttle missions. Robotic control systems are tackling such problems as the balance of control issues. Can a single human control many robots at once? Robots can be used to augment human functions. Funding and vigorous research is ongoing to alleviate the handicaps of deafness, blindness, and motor dysfunction from limb loss or nerve damage. Robotic exoskeleton devices are being investigated, robotic "prosthetic" wheelchairs that interact with the environment are being tested, and cochlear implant technology is advancing [76]. Robotic systems are gradually creeping into our daily lives with toys such as the "My Real Doll," AIBO, and smart appliances (vacuum cleaner and lawnmowers). Human–robot relationships are being investigated. AIBO, Sony's first robotic pet, has already generated many interesting observations by observing responses from its owners. Robotic appearance will establish the social expectations of these systems in our society. Honda, the auto company, is investing millions of dollars into its automated, walking robotic system, named Asimo walked to the grave of Karel Capek. Robotics programs at universities are increasing at a rapid rate. Born of Stanford's Shakey work, Brooks went to MIT, Moravec joined the team at Carnegie Mellon, and the modern run to advanced machines ensued. Some researchers are working on matching robotic morphology with task and environment. The most significant work is being done at MIT and in Japan using humanoid facial expressions to study robotic–human interactions [77].

Out of the Laboratory

George Devol and Joe Engelberger in the early 1950s thought that machines could be manufactured that could take the place of skilled workers in factories [78]. They developed the first modern industrial robots, called "unimates." Engelberger went on to develop the first robotics company, called "Unimation." Robots in the workplace are thought to have many potential advantages. The robot can work in a potentially dangerous place without risk of injury. Thus, the mechanical worker is safer. In addition, the robot's program makes each movement always with the same specifications and, it can perform very fast depending upon the servo-motors. The machines are reliable and can perform for prolonged periods of time before requiring service. When parts wear out, they are simply replaced. Some types of industrial robots can be reconfigured and redeployed to perform several tasks [79].

In 1961, the UNIMATE was introduced to the automotive industry as the first industrial robot. In 1971, the first microprocessor was introduced, allowing computer mass to be reduced to postage stamp-sized circuits that cost about as much as dinner. By 1996, 6 million components were placed upon a single silicon chip adding to the speed and power of the integrated circuit. In 1997, Sojourner, the first automated, autonomous robotic space rover, explored the surface of Mars [2].

Finally, surgical applications of robotics are just beginning to be realized. Our expectations for robots is somewhat jaded by our Hollywood stereotypes [80]. This burgeoning technology is in its infancy and the future will probably not be quite as we have thought to be.

Surgical Robotics

His latest achievements in the substitution of machinery, not merely for the skill of the human hand, but for the relief of the human intellect, are

founded on the use of tools of a still higher order. (Charles Babbage [81]).

Technology and microelectronics are revolutionizing every aspect of our society. Polymer science, micro-computerization, optical engineering, bio-engineering, and many other technologic arenas are being focused upon advanced health-care delivery [2]. Surgery has not been immune to such technologic advancement. But as we have already seen, there exists a great deal of historical precedent. At the dawn of the Enlightenment, technology began to focus on healthcare, and surgeons, in particular, attempted to simulate surgery using machines. Jacques de Vaucanson, Francois Quesnay, and Claude-Nicolas LeCat represent seventeenth-century proponents of simulators in medical education; but there is no evidence that any of these three luminaries had any substantive success. De Vaucanson whom we have already mentioned actually presented some type of mechanical device to the Royal Academie [82]. LeCat, a noted lithotomists, also devised a crude surgical simulator. But a little-known midwife outdid all of these great inventors. Le Boursier du Coudray epitomized the enlightenment attitudes toward broadening knowledge to the common man. She ceaselessly sought to bring education to the woman in villages and towns throughout France in response to the population crisis and the very high birth morbidity and mortality (approx. 200,000 infant mortalities in France in 1729, some areas reached 25%) [83]. Her original textbook *Abrégé* utilized some of the first color anatomical illustrations, her method of teaching complex birthing techniques to peasant woman throughout France, and her birthing simulator was a complex machine, complete with fluids [*wet ware*] to aid learning. Her techniques and methods are surprisingly modern in context and her plan to use every method available to improve the performance of her pupils is poignant. The color illustrations in *Abrégé* remain profoundly effective, but the only existent models of her simulator are even more remarkable [84]. She developed influential support from the likes of lithotomist Frére Côme. Her teaching methods affected untold thousands of medical practitioners, from midwives to surgeons, and she received royal support from Louis XV. Voltaire wrote about her, and she became an icon of progressive France, but remained ostracized by much of the conventional medical practitioners. She continued to educate midwives and physicians for 23 years before retiring at the age of nearly 70 after training an estimated 10,000 pupils [85].

Automation represents the most advanced capacity for minimal access intra-abdominal surgery. In 1985, a robotic engineer began to develop feasibility studies into the possibility of a neurologic robot in the Department of Mechanical Engineering of Imperial College in London [86]. Brian Davies joined the urologic team headed by J.E.A. Wickham and turned his attention to the prostate. By 1987, this team collaborated with Roger Hibberd and guided by Anthony Timoney proceeded from the laboratory to clinical trials with a six-axis Unimate PUMA robot. They called their device the PROBOT [87]. Pneumatic robotic arms were already available for holding the laparoscope better than can the trusted medical student by the mid-1980s [88]. Precision, computerized response devices that interact with the human hand–eye coordination capacity are utilized by the military for weaponry. Children's games are already utilizing this same technology for amazing games of video skill. It is foreseeable that this same capacity will evolve into micro-robotic intra-abdominal devices that will work on remote radio signal commands. Such systems for surgical intervention are already being developed. Complete, remote surgical interaction with the endoscopic camera and robotic instruments coupled with computer-mediated feedback (auditory, visual, and tactile) provides a near "virtual reality" for the surgeon. RobodocTM is one such computer-controlled, robotic, interactive orthopedic device. It can rapidly and reproducibly make total joint replacement a precision tooled, automated procedure [89]. But this represents just the initial surgical application of a whole host of robotic technology. The Massachusetts Institute of Technology is proposing new computerized intelligence chips that allow small, mobile robotic devices to learn and interact. Such GNAT robots combine distrib-

uted real-time control with sensor-triggered behavior. Currently, insect-like mobile robots have been constructed but are limited in their capacity to perform dexterous surgical maneuvers by inadequacies of the micro-engines. The University of California, Berkeley, and AT&T Bell laboratories are independently investigating micro-engines that could power small robotic devices. Nippondenso, one of the world's largest auto manufacturers, has devised an electromagnetic wave engine, utilizing microwave energy "beamed" into it from a distance. Where this technology shall lead, no one can quite predict. These micro-robotic, computer-controlled, intra-abdominal surgical devices are sure to become more advanced [90]. This leads us to our current state of robotic surgery.

Complete Robotic Surgery

The United States Department of Defense has long been interested in the development of front-line methods of improving care to injured soldiers. Life-threatening injuries occurring immediately during battle might be salvageable if surgical care could be instantly instituted. In addition, after George Bush's announcement of the United States' intention of getting a man on Mars, the National Aeronautics and Space Administration (NASA) Ames Research Center began to fund proposals for the eventual need for possible surgical intervention on astronauts remote from a hospital [2]. A team of investigators led by Michael McGreevey and Stephen Ellis began to investigate computer-generated scenarios that could be perceived on head-mounted displays (HMDs) [91]. To this team eventually came Scott Fisher, who added 3D audio and came up with the concept of "telepresence." This was the notion that one person could be projected with the immersive experience of another (real or imaginary). Joseph Rosen, a plastic surgeon at Stanford University, began to experiment with Philip Green from Stanford Research Institute (SRI) to develop dexterity-enhancing robots for telemanipulation [92]. These two teams would eventually collaborate, and together Joe Rosen and Scott Fisher produced the fundamentals of telepresence surgery. This combined the dexterity-enhancing robotics of Green and the "virtual reality" systems of NASA for an immersive surgical experience. The initial systems conceived that the surgeon would be in a helmeted immersive sight/sound environment wired electronically to "data gloves" that would digitally track the surgeon's motions and reproduce them at remote robotic instruments. The notion of the data glove came from Jaron Lanier, a computer scientist interested in virtual reality. The initial targeted surgery was on the hand.

Many of the initially designed features of Green's Telepresence System were at the time unworkable from an engineering standpoint. The HMD was subsequently replaced with monitors, and the data gloves were replaced with handles for controllers at the surgeon's console. Since the imperative at this time was for space and/or military application for acute surgical care, the end effectors were substantially similar to open surgical instruments. This was all occurring in the late 1980s. By 1989, then Colonel Richard Satava stationed at Silas B. Hayes Army Hospital in Monterey became involved in this project and more Federal aid became available [93]. Serendipitously, that same year found Jacques Perissat of Bordeaux presenting on the technique of laparoscopic cholecystectomy at the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) in Atlanta. Upon returning from this meeting, the team of investigators began to consider developing a system that could be applied to minimally invasive laparoscopic surgery. Satava presented a videotape of a bowel anastomosis using the telepresence surgery system to the Association of Military Surgeons of the United States. The results of this single demonstration of this technology resulted in a July 1992 Defense Advanced Research Projects Agency (DARPA) grant for further investigation and development. In addition, Satava became the program manager for Advance Biomedical Technologies to aid funding of technologically advanced projects. With the funding now possible, by 1995, the robotic system was in prototype mounted into an armored vehicle (the Bradley 557A) that could "virtually" take the surgeon to

the front lines and immediately render surgical care to the wounded, called MEDFAST (Medical Forward Area Surgical Team) [93]. The technology caught the attention of Alan Alda (aka Hawkey Pierce from the TV drama M.A.S.H.), now the voice of *Discovery Channel*, who filmed a piece on this technology.

The primordial "team" began to split apart; however, Satava was transferred to DARPA, Joe Rosen left Stanford for a position in plastic surgery at Dartmouth-Hitchcock Hospital and an engineering affiliation with the department of engineering. Jon Bowersox was recruited to join the team as a replacement for Rosen and furthered the research by performing the first remote telesurgical procedure, another intestinal anastomosis, in an ex vivo porcine model in 1994. He later turned his attention to vascular surgical research interests [93]. Also in 1993, Yulyn Wang, Ph.D., from the University of California, Santa Barbara, developed software for control motion of robotic systems and founded a company called Computer Motion. Wang succeeded in developing a robotic camera holder called automated endoscopic system for optimal positioning (AESOP). He became interested in complete robotic surgery and obtained DARPA funding and money from the entrepreneurs to develop ZEUS, a modular robotic system to be integrated with AESOP. HERMES was the integrated operating room control system that allowed the complete integration of Computer Motion's robotic system [94]. It was the ZEUS robotic system that made history during the performance of the first remote surgery across the Atlantic Ocean (surgeon in New York City, patient in Brussels) [95].

In 1995, surgical entrepreneur Frederic H. Moll, MD (formerly started three other successful surgical enterprises, but then medical director of Guident), Rob Younge (an engineer who had co-founded Acuson), and John Freund (an MBA from Harvard) became interested in the potential of the "telepresence" work from SRI. Fred saw that this technology could be applied specifically to the area of burgeoning laparoscopic surgeries with some modifications. They arranged a group of scientists from the SRI group, from International Business Machines (IBM), and the Massachusetts Institute of Technology (MIT) in a fledgling company. Two people particularly would influence the design and development of the robotic surgical instrument, J. Ken Salisbury, who was working in Rodney Brooks' Artificial Intelligence Laboratory, and graduate student Akhil J. Madhani both left to join the start-up company of Moll's called *Intuitive Surgical* [96]. From the outset, they formed the belief that the focus of robotic-assisted surgery should be compatible with minimally invasive surgery and they licensed the rights to patents to build a system with three basic components:

1. A master–slave software-driven system that would provide intuitive control of a suite of seven-degree-of-freedom robotic instruments.
2. A computerized vision system that would be three-dimensional and immersive (Green's legacy).
3. A redundant method for ensuring safety consisting of sensors to allow maximum safety during the robotic procedure.

The team now at Intuitive Surgical experimentally chose to locate the surgeon's hands below the console as the optimum position. Next, the tip-to-tip control idea was evolved to get maximum dexterity from the surgeon's fingers at the master console to the virtual jaws of the instruments themselves. It was felt that the tip-to-tip method allowed the surgeon to always remain oriented to the jaws of the robotic via a software interface allowed true surgical intention [97].

Intuitive tested the first prototype in March of 1997 using their robotic system with a then available stereo endoscope. By 15 April 1997, the first robotic surgery was performed by Jacques Himpens and Guy Cardiere of Brussels, Belgium, a robotic cholecystectomy [98].

For the bulk of 1998, Intuitive focused intensely on the development of a better binocular, computer-enhanced imaging system so as to achieve superior resolution and three-dimensional perception for the advanced robotic surgical procedures intended. In 1999, the company developed the system architecture for the da Vinci

Surgical SystemTM. da Vinci was equipped with an elaborate safety system that checks its position every 750 μs, using at least one motherboard for each active arm and another for the imaging systems [96]. The first 200-patient trial was completed on cholecystectomy and Nissen fundoplications leading to Food and Drug Administration (FDA) approval of this robotic system in July 2000. In December 2002, the FDA also approved the use of the next generation da Vinci System with the addition of a fourth robotic arm to the tower. This fourth arm is identical to the other two, and the surgeon can toggle with a foot pedal between control of any two of the three surgical instrument robotic arms. Late in 2003, Intuitive also introduced a new highly magnifying panoramic computer-enhanced digital video system that toggles with a foot switch from close-up, 3D view and wide-angle 2D views to aid in the surgery of complex sutured repairs. In addition, the company is actively investigating "downsizing" of their current 8-mm robotic actuators to 5 mm and smaller [96]. The FDA currently requires that the American surgeon performs the telerobotic operation within the same operating room as the patient, but this is not necessary with this technology as we have already seen.

Micro-robotic Surgery

Scale down the size of the robots, add more intelligent software, and the micro-robotic systems become possible. The technology for creating working clinical devices is in its infancy, but such devices are already available in children's toys. Clinical interest for such systems already exists for stereotactic brain surgery. In one futuristic system, Wieneke and Lutze utilize a micro-endoscopic trocar system with miniaturized electronically orienting instruments with outer diameters of 0.63 mm [99]. New steering mechanisms such as microfluidics (no cables or mechanical structures) allow the device to be electronically steered toward the site of the pathology. The optics were produced micro-technically by the LIGA process for fabrication of freely movable microstructures. A host of electronically controllable micro-instruments from graspers to scissors have been made from the super-elastic behavior of materials such as nickel–titanium alloys or plastics [100].

One can envision the basic robotic surgical instrument of the future that will be introduced through very tiny portals or via an endoluminal route. The head of the device will be similar to an insect with small, paired optical sensors for guiding the robotic intervention. The end effectors will be mounted upon the "head" with other sensors much like feelers that will monitor the local–regional environment [101]. The mouthparts will be dexterous darning apparatus to reapproximate any structure that needs to be repaired. There will be retractable-powered devices such as laser fibers for hemostasis or soldering.

Autonomous Microrobotic Surgery

One step further removed from the microrobots just mentioned are the autonomous microrobots that interest basic scientists around the world. These will have the capacity to learn from mistakes and might be capable of self-replication and recruitment. If more than one device is needed, it will attract another. They will be capable of orienting themselves for purposeful cooperative behavior and controlling the environment to accomplish whatever task is given to them [102]. Sound too far-fetched, think again. The ability to micromanufacture component parts and integrate intelligent technologies is in its infancy. Autonomous robotic technologies are rapidly advancing and medical/surgical applications will be sought [103, 104].

Nano-robotic Surgery

Go one final step and you come to the realm of nanotechnology. This shall be discussed in the final section of this chapter.

Human–Robot Interface (Cyborgs)

My robots were machines designed by engineers, not pseudo-men created by blasphemers. (Asimov, 1994 [105]).

The exact beginning of cybernetics is perhaps difficult to ascertain, but the article *An Essay on the Origins of Cybernetics* from a 1959 article by D.L. Stewart is the best place to start [106]. He notes that the word *cybernetics* was derived from the Greek *kubernetes* or "steersman" and was coined by Norbert Wiener, a professor of mathematics at MIT. In 1948, Wiener started meeting with other young scientists monthly at Vanderbilt Hall in the early 1940s. One of the first investigators he met was a Harvard Medical School professor of physiology Arturo Rosenblueth. This pair would later team up during the war years to investigate a machine's ability to predict voluntary control (desperately needed for wartime anti-aircraft design systems). By 1943 these investigations were published in the *Philosophy of Science* called *Behavior, Purpose, and Teleology* [107]. They specifically defined behavior as any change of an entity with respect to its surroundings. This began the scientific understanding of mechanized actions or the understanding of human behavior with mechanized processes. Their first classification separated *active behavior*, in which the object is itself the source of energy in the output, and *non-active behavior* or *passive behavior*, in which all the energy in the output come from the immediate output. The essence of their theories was based upon feedback loops for control; the mathematics was just beginning at this time. They stated, "the broad classes of behavior are the same in machines and in living organisms…while the behavioristic analysis of machines and living organisms is largely uniform, their functional study reveals deep differences." Wiener and Rosenblueth's ideas would begin to stimulate formal scientific investigation when the Josiah Macy, Jr. Foundation organized a series of scientific meetings to fertilize new methods of investigation throughout the 1940s. By the 1950s, the term *cybernetics* was increasingly utilized to describe much of the scientific investigation of control mechanisms, digital processing, and of course computer technologies and intelligent systems [106]. This brings us to Norbert Weiner's final legacy- the famous "triple revolution." There was a federal ad hoc committee that consisted of two Nobel laureates including Linus Pauling and Gunnar Myrdal in 1974 that identified two revolutionary forces- nuclear weapons and the civil rights movement, but they spent the bulk of their investigation on a third, less well publicized "cybernation" or automation that would be equally disruptive.

Artificial intelligence (AI) uses computer technology to strive toward the goal of machine intelligence and considers implementation as the most important result; cybernetics uses epistemology (the limits to how we know what we know) to understand the constraints of any medium (technological, biological, or social) and considers powerful descriptions as the most important result [108]. The computer chip comes from germanium or silicon solid-state transistors that were the first of two Nobel Prizes for John Bardeen [109]. In 1950, ENIAC at the Moore School of Electrical Engineering at the University of Pennsylvania was the first modern electronic computer with the essential features found on current computers. By the early 1950s, microprocessors began to be conceptualized, and computers began to make their way into scientific and business accounting. In the summer of 1956, John McCarthy, who founded the Stanford Artificial Intelligence Laboratory (SAIL) along with Marvin Minsky, started a 6-week workshop at Dartmouth College on "Artificial Intelligence." There were 12 original participants in this prophetic group. The field of AI came into being when the concept of universal computation [110], the cultural view of the brain as a computer, and the availability of digital computing machines were combined. The field of cybernetics came into being when concepts of information, feedback, and control [Wiener 1948] were generalized from specific applications (e.g., in engineering) to systems in general, including systems of living organisms, abstract intelligent processes, and language. We have already talked about Vannevar Bush's vital contributions with his view of the information revolution (1945 article *As We May Think*). In the early 1960s, Ted Nelson conceived and designed hypertext and the systems for storing and transferring information. Tim Berner-Lee followed by delivering the World Wide Web to his employers, built it, and placed it on the nascent Internet of the early 1990s [2].

It has been said that computers will be 1000 times more powerful than they are currently within 20 years [111]. At that point, it is expected that our electronic machines will be more intelligent than us. What will we be able to do with so much computing power? Let us explore just some of the intriguing possibilities in light of some of the today's cutting edge, fusion work on man and machines [112]. Cochlear implants were some the first fusions of electronics engineering and human neurophysiologic function. The pioneering work of Georg von Bekesy in 1950 demonstrated that the basilar membrane in the inner ear was responsible for analyzing signal input into different frequencies. William House working closely with 3 M company had developed a working unit consisting of three mechanisms: signal processor, signal transmitter/receiver, and implanted electrodes. By the 1980s, the Technical University of Vienna, also working with 3 M, improved this design and added automatic gain controls. Multichannel implants became available in the mid-1980s [113].

The next obvious digital–neurobiologic interface would help correct blindness. Such advanced technologies are rapidly progressing in such labs at Johns Hopkins University and the University of Tübingen. There are currently two types of retinal implants, subretinal and epiretinal. These electronic microchip processors such as the *Optobionics* 2-mm device are composed of tiny electrodes, powered by 3500 microscopic solar cells. Thus the light coming into the eye both powers the chip and transfers the signal for processing to the brain [114].

Now go one step further into amputees and spinal cord-injured patients and the next possible cybernetic applications can be appreciated [115]. Miguel Nicolelis at Duke University published a classic article in *Nature Neuroscience* in 1998. He implanted multi-site neural ensemble electrophysiology monitors into the cerebral cortex of three adult owl monkeys (*Aotus trivirgatus*) [116]. He studied and sought specific cortical areas that had neuronal responses to tactile stimulation, particularly on the animals' hands and arms. He developed a computerized artificial neural network to train and derive the responses. Once the computer's neural network was trained (after 360 stimulus runs with derived values from linear discriminant analysis), they were able to replicate the same responses as predicted from the monkey's cortex. For 2 years, they monitored the signals and modeled them using the computer's neural network. Taking this a step further, they were next able to attach the computer's neural network to a robotic arm. Whenever the monkey would reach for food, the robotic arm would now reach for food in a similar fashion. Wired via the Internet to a similar arm at Boston's MIT, the monkey could also perform the same task in both places at once [117].

Using the human nervous system and fusing information transfer with digital technologies is in its infancy. There is ongoing work with robotic artificial legs and arms that can connect or communicate with nerve endings from the stump of a lost limb [118]. In addition, computer–brain interface technologies that can directly interpret EEG brain waves are already functionally being tried at advanced research centers. At MIT, a select group of handicapped individuals are being trained to directly interface with a computer's mouse-like device to aid these individuals in connecting to the Internet, writing, controlling other mechanical devices within their environments, and generally trying to improve their existence [119]. Many of these advanced technologies can be expected to have "spin-off" devices that could become widely available in the next 10 years. Man–machine interface issues will become an increasingly sophisticated issue in the very near future.

Future Considerations (Nanotechnology)

In 1997, one of the seminal battles between the human brain and artificial intelligence was fought and lost…the world shivered. (TIME [22]).

The Nobel physicist Richard Feynman predicted in a 1959 talk entitled "There's plenty of room at the bottom" that the theoretical possibility of manipulating things on a molecular scale [120]. Prior to this prophetic lecture, Albert

Einstein as part of his doctoral dissertation calculated that the size of a single sugar molecule was about 1 nm in diameter (for scale imagine that ten hydrogen atoms side by side, it is one thousandth the length of a typical bacterium, one millionth the size of a pinhead) [121]. The first living cells housing nanoscale bio-machines evolved 3.5 billion years ago. In 400 BC, Democritus coined the word "atom," which was thought to be the basis of all matter. In 1905 Albert Einstein calculated the diameter of the sugar molecule described previously. In 1931 Max Knoll and Ernst Ruska developed the electron microscope for sub-nanometer imaging. In 1959 Richard Feynman gave the prophetic lecture predicting the rise of nanotechnologies. In 1968 Alfred Y. Cho and John Arthur of Bell Labs invented molecular-beam epitaxy, to deposit single atomic layers on a surface. In 1974 Norio Taniguchi conceived the word "nanotechnology." In 1981 Gerd Binnig and Heinrich Rohrer created a scanning tunneling microscope, which can image individual atoms. By 1985 Robert F. Curl Jr., Harold W. Kroto, and Richard E. Smalley discovered buckminsterfullerenes, also known as buckyballs, which measure about 1 nm in diameter. D. Eric Drexler published his futuristic book *Engines of Creation* in 1986 that popularizes nanotechnology. In 1989, Donald M. Eigler of IBM wrote the company's name using individual xenon atoms. In 1991, Sumio Iijima of NEC in Tsukuba, Japan, discovered nanotubes. In 1993, Warren Robinett of the University of North Carolina and R. Stanley Williams of the University of Southern California at Los Angeles devised a virtual-reality system connected to a scanning tunneling microscope that lets the user see and touch atoms. In 1998 Cees Dekker's group at the Delft University of Technology created a transistor from a carbon nanotube. In 1999, James M. Tour at Rice University and Mark A. Reed of Yale University demonstrated that single molecules could act as molecular switches. In 2000 the Clinton administration announced the National Nanotechnology Initiative, which provided a big boost in funding to nano-research. Later in that same year, Eigler and others devised a quantum mirage with a magnetic atom, proving a possible means of transmitting information without wires at a molecular level [2].

Currently, there are several proposals to the National Nanotechnology Initiative for medical applications. Some are for diagnostic possibilities including the use of artificial magnetic crystals that detect particular biologic entities such as pathogens. Other applications include the use of semiconductor nanocrystals, a quantum "dot." These dots owe their special properties to quantum mechanics and emit photons of light in only one specific wavelength. These quantum "dots" can be attached to DNA sequences which when scanned can act like a genetic bar code, looking for flaws. A dendrimer is a branching molecule roughly the size of a protein that has a large internal surface area. They can be created in a variety of sizes and might be able to transmit DNA sequences into cell's nuclei much safer than virus particles. Other dendrimers might be able to act as micro-drug delivery vectors. Nanoshells are small beads of glass coated with gold that can absorb light, particularly near-infrared which can be beamed into the body. These nanoshells could then be induced from an extracorporeal strong infrared source to be heated. Buckyballs can be made from just a few dozen carbon atoms. The potential for the future of nanotechnology like many other futuristic applications to medicine is unknown. But it is intriguing to speculate about the possibilities. Using artificial scaffolds that nanotechnology might conceive cancerous tumors at the cellular range might be identifiable and destroyed. Using synthetic scaffolds, we might be able to regenerate bones, cartilage, skin, or more complex organs [122].

Conclusions

At the dawn of the next millennium and the rise of the information age, intelligent technologies (ITs) are beginning to affect every aspect of surgical practice. It will be expected that products of this age will be essential in areas of diagnosis, therapy, and education. The same three aspects of medical science that have been thought to be essential for the advancement of medicine will be strongly influenced by intelligent technologies: com-

puters, telecommunications, robotics, microrobotics, and virtual reality simulation. Diagnosis is already beginning to show signs of the intelligent technology invasion with virtual colonoscopy, 3D imaging systems, micro-endoluminal probes, real-time teleconferencing and consultation, and tele-mentoring and tele-proctoring. Therapy cannot be far behind these initial diagnostic endeavors. The tools to perform surgery remotely already exist and are being refined, miniaturized, and increasingly more autonomous. The trend in the surgical realm includes a paradigm shift from minimally to noninvasive procedures (i.e., percutaneous lithotripsy to shock wave lithotripsy); from direct hands-on to direct hands-off (i.e., laparoscopic, catheter stenting, robotic-assisted to robotic performed) procedures; and from single modal therapy to multimodal therapies (i.e., resection and reconstruction to biologically tagged, image-guided, dexterity-enhanced). Education will be substantially aided by the infusion of ITs by the creation of computer-aided skill development. One would hope that an acceptable degree of surgical error could rival or improve upon the current standards accepted by the aviation industry (FAA) for pilots trained continuously on flight simulators (<0.0001%) [123].

Some other trends might be expected from this technologic influx. There will be more procedures performed with endoscopic guidance. There probably will be a trend toward interdisciplinary cooperation. Much of the ability to minimize the trauma of surgery further will require fusion image processing. The pathology identified with advanced magnetic image devices and computerized tomography will be targeted similarly to stereotactic brain surgery currently. The endoscopic view will provide a stable position to monitor the robotic ablation or reconstruction necessary to obviate the patient's pathologic process. Newer imaging modalities will likely exist such as MR/PET hybrid devices. MRI already possesses the ability to observe thermal gradients within tissues. Image-guided thermal ablation or cryoablation might not even require endoscopic control. Most likely, patients will be diagnosed at even earlier stages of disease processes, thanks to advances in proteomics [124]. Therefore, the extent of disease to be treated will likely be less, and the interventions might not need to be as drastic, but the precision robotic controls will be mandatory and such robots are in pipeline research stages [125].

The explosive and sometimes experimental development of laparoscopic surgery has certainly not been all straightforward. In urology, the early 1990s were all enthusiasm over laparoscopic pelvic lymphadenectomy and varicocelectomy. Interest waned by 1993–1994. Only those urologic laparoscopists comfortable with the more complex types of laparoscopic surgeries pursued the technology, and general surgery rapidly became the leader of technologically advanced surgery where it currently remains. But as technologies come, so might they go as predicted by F. Mosteller in 1980. New technology has an apparent life cycle with five stages: (1) feasibility (technical performance, applicability, safety complications, morbidity, mortality); (2) efficacy (benefit for the patient demonstrated in centers of excellence); (3) effectiveness (benefit for the patient under normal conditions, reproducible with widespread application); (4) costs (benefit in terms of cost-effectiveness); and (5) gold standard [126].

To understand how humanity will deal with the coming maelstrom of technologic wonders that our science is about to spew forth into our lives, we must as Winston Churchill once advised, "the further backwards you look, the further forward you see." The relevance of looking to the myths and lore that are the foundations of modern thoughts and perceptions is where to begin to understand technology and the changes that will affect *all* aspects of our civilization and not just the way we practice urology. The history of robotics is almost as intriguing as the robots themselves, almost!

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Robotic Instrumentation and Operating Room Setup

2

Matthew J. Ziegelmann and Matthew T. Gettman

Abstract

Robotic surgery, performed via the da Vinci® Robotic System (Intuitive Surgical; Sunnyvale, CA), has revolutionized the field of urology. Over the past 15 years, five separate da Vinci® models have been introduced. Despite technologic advanced with each model, the three integral components remain standard and include the surgeon console, patient cart, and vision cart. Additionally, various sterile accessories and multiple EndoWrist® (Intuitive Surgical; Sunnyvale, CA) instruments have been developed for use with robotic surgery. Here, we describe in detail the components of the da Vinci® Robotic System Robotic System and robotic instrumentation, including the multiple technologic advances that have been implemented. We also provide a basic overview of operating room setup and execution of robotic surgical procedures.

Keywords

Robotic surgery · da Vinci® · Operating room · EndoWrist® · Technology

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Abbreviations

3D	Three dimensional
CCU	Camera control units
da Vinci© S	da Vinci© streamlined
da Vinci© Si	da Vinci© streamline integrated
HD	High definition
LED	Light-emitting diode

Robotic Instrumentation

Introduction to the da Vinci® Surgical System

Robotic surgery has revolutionized the field of Urology over the past 15 years. Multiple platforms have evolved, and ongoing innovative technologic advances allow urologists to deliver state of the art care to patients undergoing complex surgical interventions. Today, the da Vinci® Robotic System (Intuitive Surgical; Sunnyvale, CA) remains the most commonly used platform for robotic surgery, and is utilized by surgeons in multiple subspecialties. Intuitive Surgical has released five da Vinci® models including the standard, streamlined (S), S-high definition (HD), S integrated (Si)-HD, and Xi systems. Each system consists of three separate but integral components including the surgeon console, patient cart, and vision cart [1, 2]. In addition,

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Table 2.1 Instruments for robotic-assisted surgery

Laparoscopic instruments	Robotic instruments
• Veress needle • VisiportTM (Ethicon Endo-surgery, Cincinnati, OH) • 12-mm OptiviewTM and 12-mm XcelTM (Ethicon Endo-surgery, Cincinnati, OH) • 6-mm Ternamian EndoTIP trocarsTM (Storz, Culver City, CA) • Fascial closure device • 10-mm ENDOCATCH® entrapment sac (Covidien, Norwalk, CT) • Curved Endo Metzenbaum scissors • Maryland dissector • Hook cautery • Needle driver • Endoscopic clip applier • Suction irrigator • 0° and 30° laparoscope lens • Camera and fiber-optic cords • 5- and 10-mm Hem-o-lock® clips (Teleflex Medical, Research Triangle Park, NC) • Hot water bath for endoscopes	• da Vinci® Surgical System • 8-mm robotic trocars (2–3 depending on the number of instrument arms) • EndoWrist® instruments • Sterile drapes for camera and instrument arms, camera, and telemonitor • Sterile camera mount and camera trocar mount (depending on the system) • Sterile trocar mount (depending on the system) • Sterile instrument adapter (comes attached to the drape for the S) • Sterile camera adapter

each model has several associated sterile accessories and multiple EndoWrist® (Intuitive Surgical; Sunnyvale, CA) instruments available for use (Table 2.1). Multiple advances have been introduced with each new model, and these will be discussed in turn.

The original standard model contained only three arms, but an optional fourth arm became available with later models or as an add-on to the original systems. Seven years later, in 2006, the S-system was released with advanced optics, touch screen displays, and improvements in patient cart ergonomics such as a drive motor and improved robotic arm range of motion. An HD camera was subsequently introduced in 2007, followed by the introduction of the Si-model in 2009 with upgrades to the surgeon console. Also, for the first time, dual console technology was available, providing for enhanced teaching opportunities with robotic surgery. Finally, the Xi system was released in 2014, with the incorporation of multiple upgrades to the patient cart and surgeon console such as a new optic system for enhanced visualization, lighter robotic arms, and changes to the endoscope and patient cart to enhance multi-quadrant surgery.

The goal of the current chapter is to describe the components of the da Vinci® surgical system and robotic instrumentation as well as to provide a basic overview of operating room setup and execution of robotic surgical procedures.

The Surgeon Console

Examples of the surgeon consoles can be seen in Figs. 2.1 and 2.2. The surgeon should be considered the pilot of the da Vinci® system, and the surgeon console is the cockpit. Through the stereoviewer, the surgeon is able to observe a three-dimensional (3D) view of the operating field while utilizing a combination of hand controls ("master-controllers") and foot pedals to manipulate the instruments and endoscope [1, 2]. Power, electrosurgical inputs, and audiovisual connections are located on the back side of the surgeon console, thereby minimizing clutter for the OR personnel.

Right and left pod controls, located on the armrests, are present in the standard and S-systems (Fig. 2.1). Major system error communications and system on/off switches are located on the right-side, while system faults and configuration settings are controlled by the left-sided pod. The surgeon is able to control the height of the surgeon console arm-rest and head positioning via controls located near the left-side pod as well. With the Si and Xi-models, the majority of right and left-sided pod functions have been integrated into a single central touch pad (Fig. 2.2). Central touchpad features include the ability to store surgeon-specific profile settings such as the height of the armrest and stereoviewer, motion scaling control (see below), and utilization of the

Fig. 2.1 Photograph of da Vinci® S and S-HD surgeon console (**a**) and side pod controls (**b**, **c**)

FireflyTM technology. Improved ergonomics are facilitated by the ability to adjust the console in four different directions with a control located on the left side of the armrest, and the power controls are housed on the right side of the armrest.

The stereoviewer projects a magnified 3D image of the surgical field. The 3D image is created by capturing two independent views from separate endoscopes fitted into the stereo endoscope (Fig. 2.3). The images are then displayed into right and left optical channels in the stereoviewer to give the 3D image [2]. Messages are displayed to communicate changes with the system and provide guidance for correcting system faults. On the sides of the stereoviewer, near the surgeons head, there are sensors that allow for activation/deactivation of the robotic instruments. Additionally, on some models, there is a microphone located within the stereoviewer to improve communication with bedside assistants. With the Xi model, there is also a speaker located within the stereoviewer that allows the OR personnel to more clearly communicate back with the surgeon. Other features include adjustable knobs for ocular distance, brightness/contrast settings, and microphone volume control. The available controls differ between models.

Manipulation of the robotic instruments and endoscope is performed with the master controllers, which are grasped with the surgeon's thumb and index (standard and S models) or middle finger (SI and Xi models) (Fig. 2.4). These controllers allow the surgeon to manually exert control over the instruments and camera by movements that are relayed to the EndoWrist® instruments [1]. Remarkably there is no measured delay, and a filtering function prevents the relay of surgeon tremor. The system also allows

Fig. 2.2 Photograph of da Vinci® Xi system with surgeon console (**a**) and center touch-pad (**b**). (Reproduced with permission from Intuitive Surgical; Inc© 2017 Intuitive Surgical, Inc.)

the surgeon to adjust a scale factor (2:1, 3:1, and 5:1) so that 2, 3, or 5 cm of movement in the master controllers translates into 1 cm of movement in the instrument arm [3]. Working space adjustments are made by activating the master clutch (see below) in order to avoid interference with the contralateral master controller. When the master controllers have been repositioned, the surgeon must position his or her grip to match that of the tip of the instrument. "Matching grips", as it is known, is necessary to prevent tissue damage and inadvertent activation of the robotic arm. A finger clutch, located on the top of each master controller, is present with the later models (Si-HD and Xi). The clutch is activated by depressing the button with the ipsilateral index finger, and unilateral or bilateral clutching can be performed.

The foot panel (Fig. 2.5) has multiple pedals that are used by the surgeon in coordination with the master controllers. Functions associated with the pedals include clutch, camera, focus, bipolar/auxiliary, and cautery. The clutch function, which allows the surgeon to adjust the working distance of the master controllers, is employed by fully depressing the clutch pedal in order to disengage the master controllers from the instrument arms. This allows the surgeon to adjust the master controllers to a more comfortable working position. For instance, we recommend that the surgeon adjust the working distance when his or her elbows start to lift off from the armrest, or there is a collision between the master controllers. For the S system, if the clutch pedal is quickly and gently tapped, the designated master controller will switch to the third robotic arm. To restore the

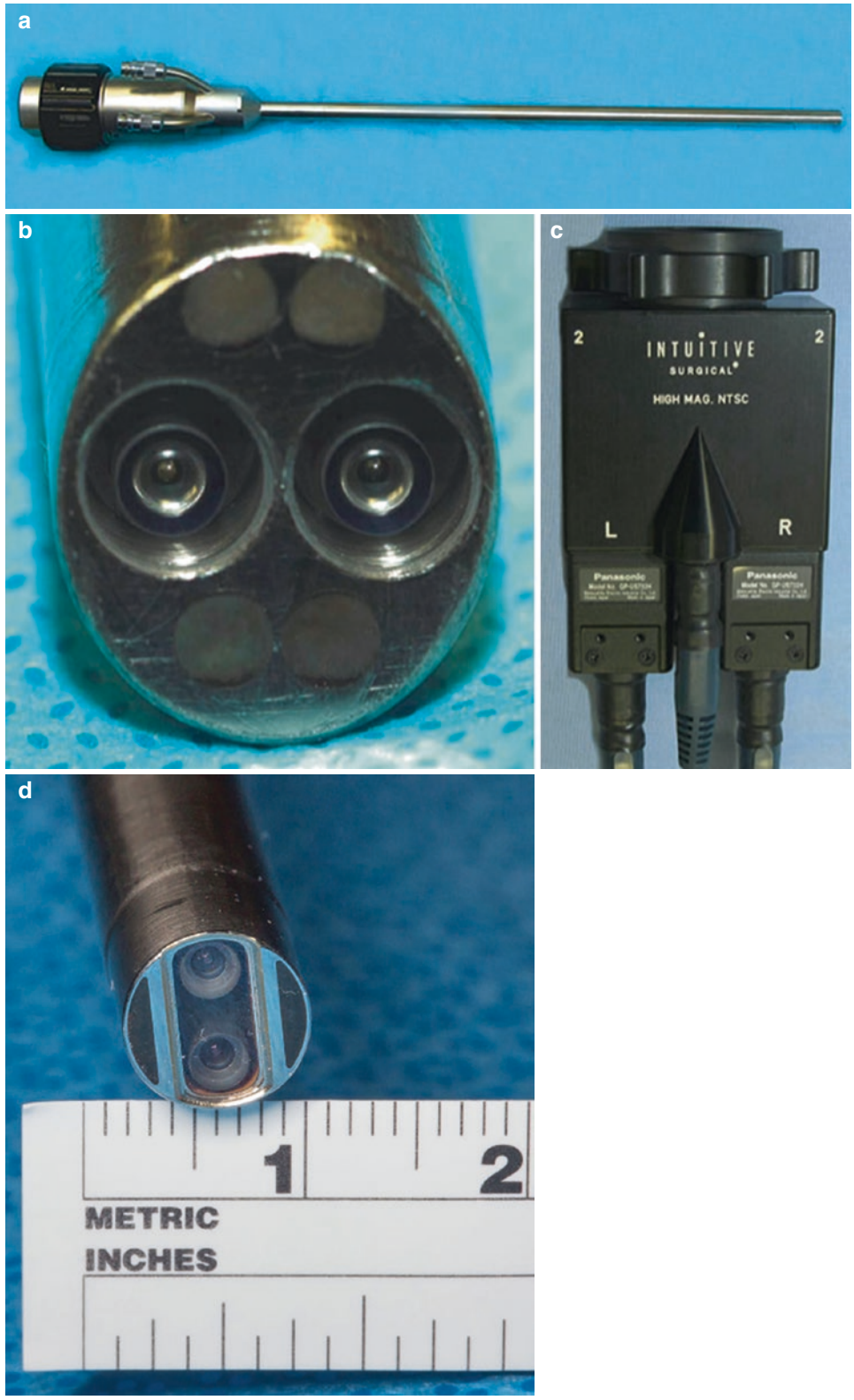

Fig. 2.3 Photograph of the da Vinci® stereo endoscope (**a**) showing the two individual 5-mm endoscopes (**b**) and camera (**c**) with *right* and *left* optical channels, as well as the new da Vinci® Xi stereo endoscope with updated optics (**d**)

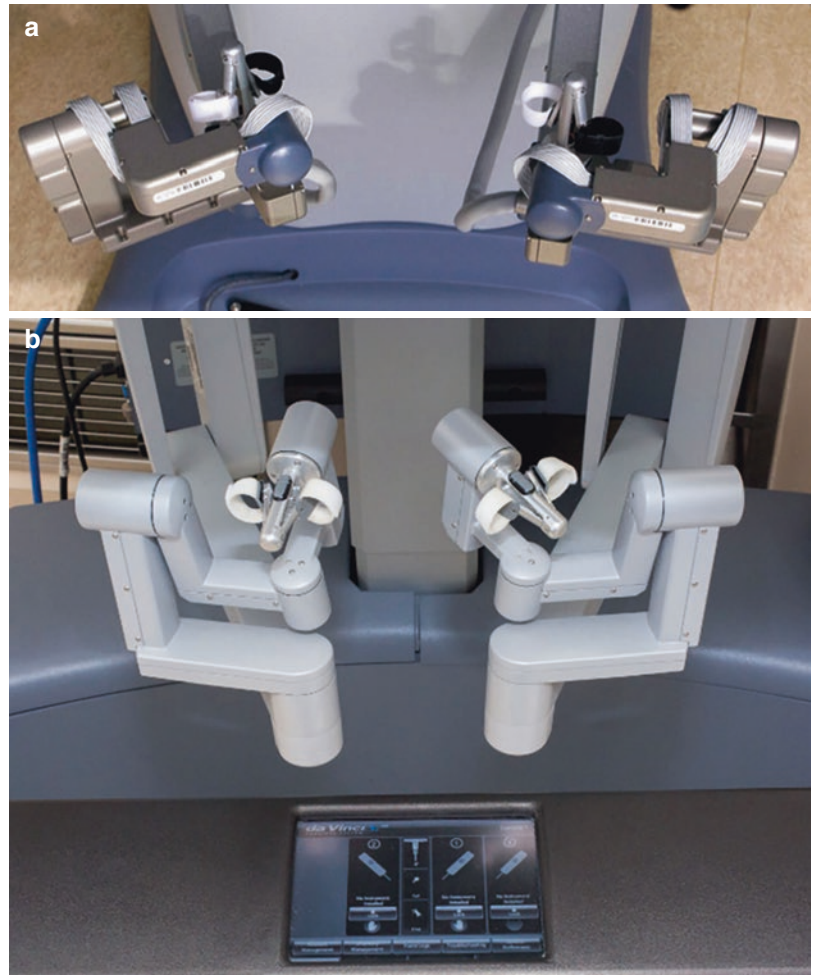

Fig. 2.4 Photograph of master controllers from the da Vinci® S (**a**) and Xi (**b**) systems

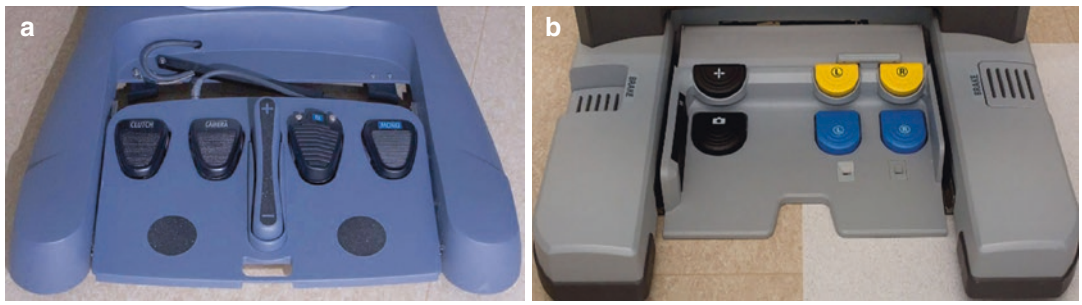

Fig. 2.5 Photograph of the surgeon console foot pedals for the da Vinci® S (**a**) and Xi (**b**) systems

original settings, the surgeon simply taps the clutch pedal once again. In the Si and the Xi-models there are separate pedals for the clutch and instrument switch functions.

A separate camera pedal exists on all models. Completely depressing the pedal allows the surgeon to seamlessly engage the endoscope and adjust the field of view as seen through the stereoviewer. Additionally, by moving the master controllers together or apart with the camera pedal depressed on the S-HD, Si, and Xi systems, a digital zoom function can be activated. The presence of other pedals is model-specific. For instance, a stand-alone auxiliary pedal is present

on the standard system, while the S system has a specific bipolar pedal. The coagulation pedals, when present, must be connected to an appropriate electrosurgical unit in order to be used safely and effectively. The Xi-system does not need a separate electrosurgical unit, as an ERBE® electrosurgical unit is built-in the patient cart. Interestingly, the Si-HD and Xi systems have a two-tiered "foot panel (Fig. 2.5b). The right-sided foot panel contains coagulation and cut pedals that correspond to each of the robotic arms being used. Within the stereoviewer, the surgeon is able to identify the energy type (monopolar, bipolar, and cut currents) associated with each arm. On the left side of the foot panel, pedals to facilitate clutch and movement of the endoscopic camera are present. There are many additional features present with the newer operating systems, and the reader is referred to the Intuitive Surgical website and instructional courses for further information.

The Patient Cart

The patient cart houses the robotic arms, which seamlessly facilitate movement of the laparoscopic instruments based on maneuvers carried out by the surgeon at the level of the master controllers (Fig. 2.6). The cart itself is mobile, allowing it to be positioned adjacent to the operating room table at the time of robotic docking. The S, Si, and Xi systems contain a motor drive that assists with cart maneuvering. Several clutch buttons are present on each robotic arm (Fig. 2.7). The proximal port clutch buttons are depressed to produce gross movements of the robotic arms. Additionally, a specific camera/instrument clutch button is located on the top of the distal aspect of each arm, allowing for fine movements during robot docking. The S, Si, and Xi models contain LED indicators just below this clutch to aid bedside assistants with camera/instrument insertion. A trocar mount is also present to secure the

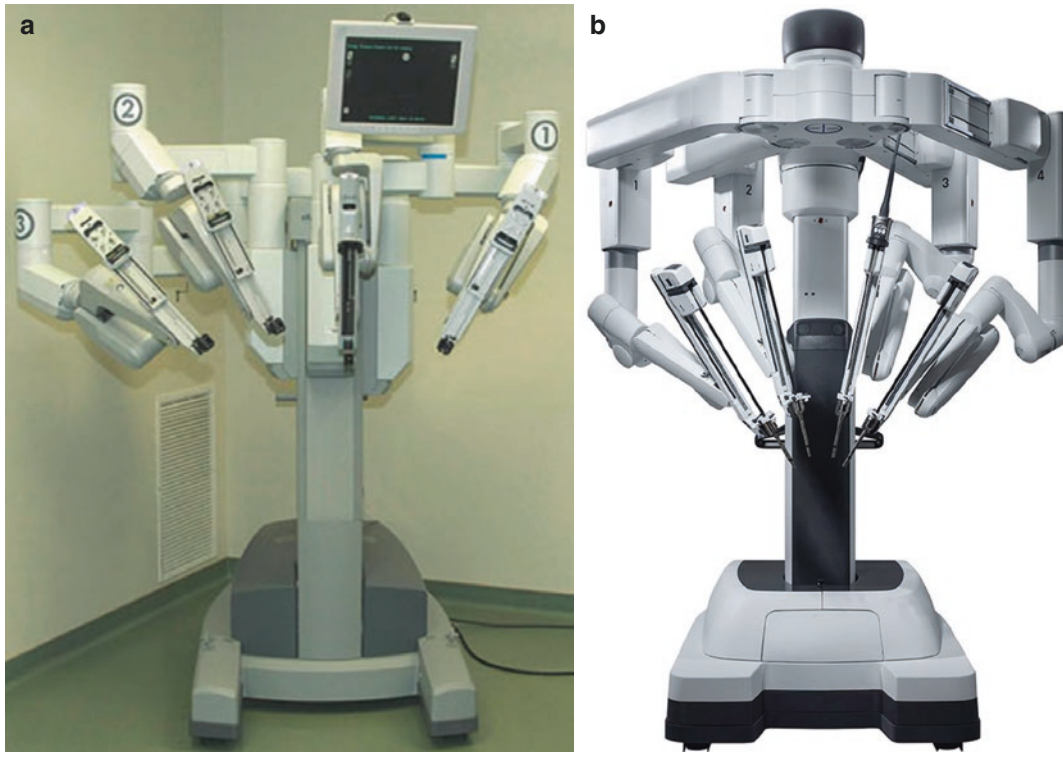

Fig. 2.6 Photograph of the da Vinci® S (**a**) and Xi (**b**) patient (Reproduced with permission from Intuitive Surgical; Inc© 2017 Intuitive Surgical, Inc.)

Fig. 2.7 Photograph of the da Vinci® S instrument arm including the port clutch buttons (arrows), showing camera/instrument clutch buttons (*arrows*) and trocar mount (*arrowhead*)

robotic arms to the laparoscopic trocars. The patient cart, including individual robot arms and multiple sterile accessories, is draped in a sterile fashion prior to each procedure (Fig. 2.8).

The original systems contained two instrument arms and a camera arm, with a third working arm available as an add-on. However, the third instrument arm is standard with the newer systems. A touch screen monitor is also present, and this is often mounted to the patient or vision carts. This feature allows OR personnel to see the same view that the surgeon sees through the stereoviewer. The Telestration function can also be used with this touch screen, allowing team members to create real-time drawings that can be seen by the operating surgeon within the stereoviewer.

Several additional features are available with the Xi model including an adjustable boom height, laser-targeting of the specific anatomy to more effectively position the robotic arms, and the ability to interchange the endoscope between all four arms for increased ease when performing multi-quadrant surgery.

The Vision Cart

The vision cart houses the endoscopic light source, visual processing equipment, and camera accessories (Fig. 2.9) [1, 2]. Storage bins are available for insufflators and the electrosurgical unit. The optics consist of a xenon fiber system, connected to the endoscope via a sterile bifurcated cable that illuminates the right and left cables. The lamp on the S systems can be changed by a member of the surgical team, while the standard system requires a service visit. The Si system has single light cable instead of the bifurcated light cable in the S model. The Xi-model has in integrated camera and light cable, so there is only one cable connecting the patient cart to the endoscope.

For the standard, S, and Si-models, 0° and 30° endoscope lenses are available (Fig. 2.3). We utilize the 30° downward lens for the majority of procedures in the pelvis, while the 0° and 30° upward lenses are more useful for procedures with the upper tract. However, lens choice is highly user dependent, and the surgeon's ability to quickly flip from one lens view to another with the Xi-endoscope, for instance from 30° upward to zero or 30° downward, without the need to remove the endoscope from the patient is a helpful new feature. Of note, with the smaller 8-mm endoscope that is available with the Xi-model, more frequent lens cleaning during the procedure seems to be required.

The S-HD system added a high-definition camera and technology that improved the resolution and aspect ratio. While the first generation HD system carried a resolution of 720p (1280 × 720), the Si-HD system came with an increased resolution of 1080i (1920 × 1080), a marked improvement from the standard NTSC (720 × 480). Other improvements include a digital zoom function. While further advances in imaging technology have been implemented with the new models, additional software enhancements are needed to more closely emulate open surgical visualization.

The EndoWrist® Instruments

The surgeon's motions are relayed from the master controllers on the surgeon console to the robotic arms on the patient cart, and the tasks are carried out through the EndoWrist® instruments within the patient (Fig. 2.10). These instruments

Fig. 2.8 Photographs of sterile accessories placed during the draping procedure. (**a**) Camera sterile adapter (*left*) and camera arm sterile adapter (*right*) and camera trocar mount (**b**). da Vinci® standard instrument arm sterile adapter (**c**) and trocar mount (**d**). The standard instrument arm adapter can be used 50 times before being discarded compared to the S models (**e**), which can be used only one time before being discarded

Fig. 2.9 Photograph of vision cart for the da Vinci® Xi system. (Reproduced with permission from Intuitive Surgical; Inc© 2017 Intuitive Surgical, Inc.)

restore the degrees of freedom (DOF) lost by standard laparoscopy by adding three DOF at the end of the instrument, giving a total of seven DOF with 180° of articulation and 540° of rotation [3]. Each instrument has a fixed lifetime, with a limited number of uses, and a function exists to prevent the arm from functioning if an outdated instrument in installed [1]. However, we have identified variability in the lives of some instruments, and non-functional instruments should be discarded.

EndoWrist® instruments contain an instrument housing, shaft, wrist, and tip. The da Vinci® standard instruments are 52 cm with gray housing compared to the S systems which are 57 cm with blue housing (Fig. 2.10). Be aware that instruments are not interchangeable between the standard and S systems. EndoWrist® provides over 40 separate instruments in both diameters. "Angled joints", which allow instrument tips to rotate with a shorter radius, are present on 8-mm instruments, while "snake joints" are present on the 5-m instruments (Fig. 2.11). Prograsp forceps, monopolar curved scissors, a large needle driver, and Maryland bipolar forceps are the most common instruments used in our robotics practice.

Operating Room Personnel

A firm foundation in robotic-assisted surgery is mandatory for each member of the surgical team, and an emphasis should be placed on clear com-

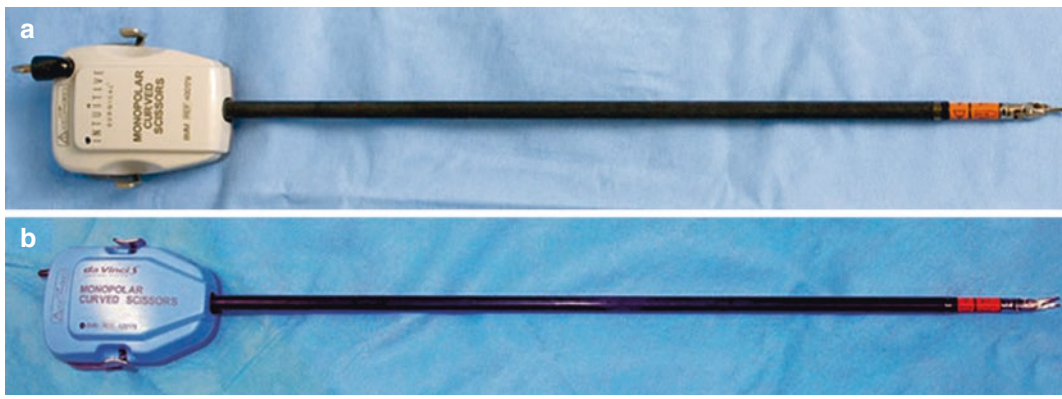

Fig. 2.10 Photograph of an EndoWrist® instrument for the standard (**a**) and S (**b**) systems

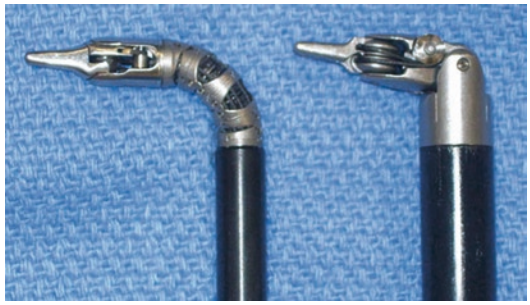

Fig. 2.11 Photograph of EndoWrist® needle drivers. The "*snake joint*" (*5-mm*) is seen on the *left*, compared with the "*angled joint*" (*8-mm*) that is seen on the *right*

munication [4, 5]. Intuitive Surgical offers multiple training courses specifically designed for each role, and these courses should be completed prior to starting with the robotic team. Additionally, separate courses are available for each da Vinci® model. Consistent OR personnel, especially during the learning curve, is recommended [4].

As the team leader, the surgeon should be knowledgeable in setup, basic operation, and system troubleshooting, in addition to piloting the robot. The circulating nurse must be an expert in system startup and control of the patient cart, while the surgical technician needs expertise in draping, docking, instrument exchange, and intraoperative troubleshooting. In addition to a thorough understanding of robotic surgical principles, the surgical assistant should also be familiar with the basics of laparoscopic surgery to include trocar placement, clipping, suction, irrigation, retraction, and cutting [4, 6].

Robotic Operating Room Setup

With the robotic system up and running, the surgeon should have a clear view of the patient from the console. In addition, walkways should be clear for efficient movement about the operating theater (Fig. 2.12). Ideally, the operating room should be spacious enough to allow docking of the robot from several angles, although the ability of the Xi patient cart to facilitate four-quadrant procedures makes this a less stringent requirement.

With a standard operating room that is intermittently used for robotic cases, additional laparoscopic towers may be necessary to store accessories such as the insufflator, electrosurgical units, and additional monitors (Fig. 2.13a). An ideal scenario involves the use of a dedicated robotic/laparoscopic surgical suite, wherein CO_2 is piped directly into the room for insufflation, monitors and other pieces of equipment are mounted from ceiling booms, and capabilities for DVD recording and telemedicine exist (Fig. 2.13b).

Approach to Robotic-Assisted Surgery

Specific surgical procedures are beyond the scope of this chapter. However, the basics of robotic surgery are described here. Before the patient enters the room, the surgical team must prepare the da Vinci® Surgical System using the sterile accessories (Fig. 2.8), which is described in detail during the training sessions offered by Intuitive Surgical and by Bhandari et al. [1]. Once the patient has been anesthetized and positioned properly, we secure a face shield plate (Fig. 2.14) to protect the patient's face and endotracheal tube from inadvertent damage or dislodgement from the endoscope. Robotic-assisted surgery can then begin with abdominal or retroperitoneal access. Techniques for establishing pneumoperitoneum vary by surgeon preference. The Veress needle or Hassan techniques are most commonly used for robotic surgery [5, 7, 8]. Here, we briefly describe our technique for abdominal access with the Veress needle. After a small skin incision is made, tracheal hooks elevate the fascia, and the Veress needle is inserted. Proper location is verified by visualizing a small drop of saline fall rapidly into the abdominal cavity, confirming intraperitoneal location. For the standard, S, and Si-models, the VisiportTM (Covidien, Inc., Dublin, Ireland) is used to place the initial 12-mm trocar under direct visualization. This will serve as the camera arm, which is compatible with the majority of 12-mm laparoscopic trocars. In contrast, with the Xi-system,

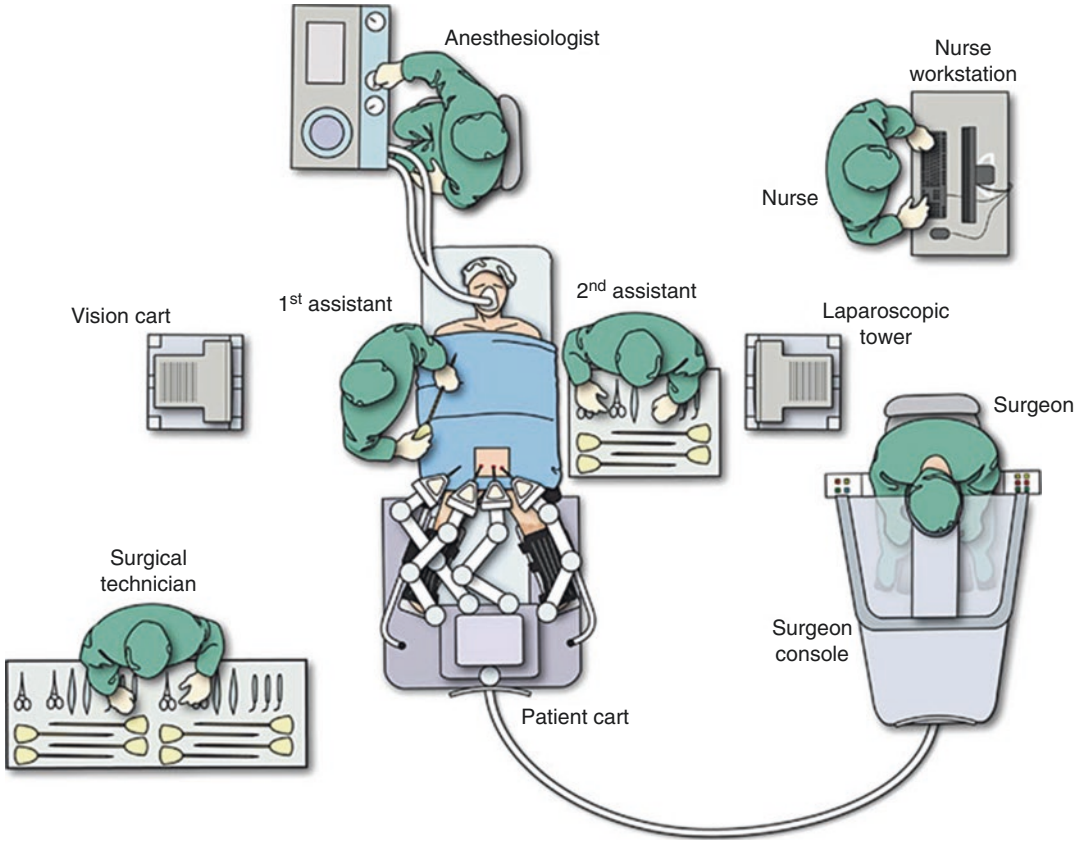

Fig. 2.12 Schematic of the operating room personnel and set up for robotic surgery with the da Vinci® Surgical System

Fig. 2.13 Photograph of operating room for da Vinci® standard (**a**) with additional laparoscopic tower and available seating for a second surgical assistant; and (**b**) da Vinci® S system operating room with ceiling-mounted telemonitors and laparoscopic tower

pneumoperitoneum is established with the Veress needle, and the smaller 8-mm camera trocar is placed blindly. The da Vinci® endoscope is then placed through the trocar, and the abdominal wall contents are evaluated for evidence of injury or other abnormalities such as carcinomatosis. We recommend that the camera trocar is placed 15–18 cm from the target anatomy. However, obese patients may require adjustments based on the degree of abdominal girth, especially when using the standard system [8]. While the camera is held by the surgical assistant, the remaining robotic trocars are next placed under direct laparoscopic vision.

Fig. 2.14 Photograph of patient with face shield plate secured to the operating room table

The robotic metal trocars, which are placed using blunt or sharp obturators, need to be inserted with the thick black band at the level of the abdominal fascia (Fig. 2.15). This acts as the pivot point for the trocar and the robotic instrument arm. Ideally, the trocars should be placed 8–10 cm way from the camera trocar in order to minimize instrument collisions during the case [4, 6]. Multiple laparoscopic instruments should be readily available for the first assistant and to facilitate lysis of adhesions by the surgeon at the time of initial port placement (Table 2.1).

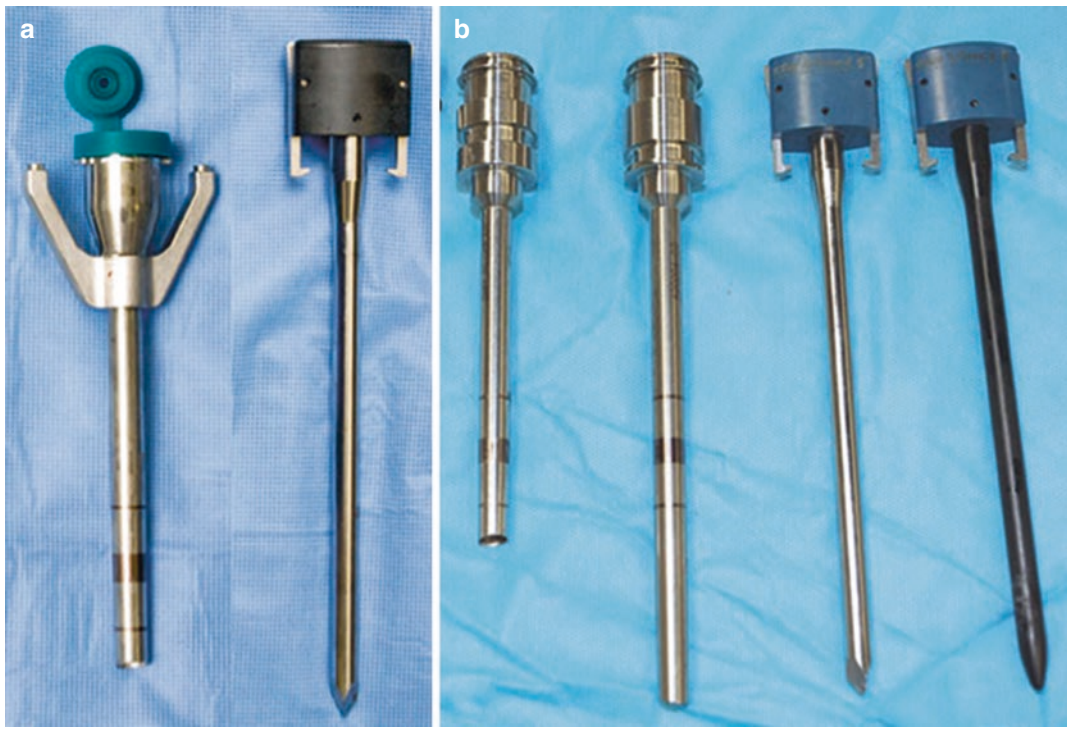

Fig. 2.15 Photograph of 8-mm trocar for the da Vinci® standard (**a**) and S systems (**b**). Also shown are the sharp and blunt obturators used for trocar placement

Docking the Patient Cart

When all ports have been placed, the patient cart should be positioned with the tower aligned to the target anatomy. The Xi patient cart includes a laser guidance system to assist with patient cart alignment. The standard system patient cart lacks a motor driver, and the wheels must be manually locked into position. In contrast, the S, Si, and Xi systems all contain a motor to assist with movement, although this is not mandatory for the docking process. There are switches located on the base of the cart that must be turned to the "drive" mode, and the cart contains a throttle that is engaged to activate the motor. If manual cart maneuvering is desired, the switches should be turned to "neutral". Unlike with the standard system, setting the mechanical break is not necessary.

The camera arm should be placed first and locked in place by the trocar mount. The proximal robotic port arm clutches are useful for gross movements of the camera arm, while the distal camera clutch should be used for fine-tuning the positioning of the arm (Fig. 2.7). Use of the camera clutch without adjusting the port arm clutches may prevent an adequate range of motion during the procedure. The instrument arms are then placed in turn. Securing the robotic trocars to the mounts differs slightly, depending on the system being used. Prior to placing the robotic instruments, the team should ensure that adequate space is available between arms to prevent clashing. Also, it is of the utmost importance to verify that no working elements such as the more proximal portion of the robotic arm, are in contact with the patient, as this can result in severe injury.

The endoscope can be placed into the appropriate trocar, and advanced into the surgical field using the camera clutch button. The instruments are then advanced into the surgical field in a similar manner under direct visualization. When inserting or removing EndoWrist® instruments, the surgeon and assistant must ensure that the tips are straight in order to prevent inadvertent abdominal injury or damage to the instrument. The S and Si systems feature a safety function known as the guided tool change. With this tool, a new instrument can be replaced with the tips advanced to a depth approximately 1-mm short of the previous position. When using this feature, it is imperative that the instrument tips are straight prior to removal and replacement, as this can alter the trajectory of the instrument, resulting in devastating consequences.

Once the robot is docked, the surgical team can take their positions for the procedure. The surgeon sits at the console, circulating nurse at his or her workstation, and surgical technician and assistant at the patient bedside. Depending on the type of surgery, two or three instrument arms will be utilized. Using a third instrument arm may eliminate the need for a second surgical assistant during certain procedures.

Shutting Down the da Vinci® Surgical System

At the cessation of the robotic portion of the case, all instruments and the endoscope are removed. Next, the robotic arms are disconnected, and the patient cart is moved away from the surgical table. Sterile accessories are removed, and drapes are appropriately discarded. It is not necessary to power the system off between surgical procedures. If needed, the specimen can be delivered by extending one of the trocar incisions. Fascial closure must be performed on all 12-mm trocar sites made with a cutting trocar, while 8- and 5-mm trocars do not generally require closure [4, 5]. The skin can then be approximated with suture, and sterile surgical dressings can be applied.

Conclusions

Numerous advances in technology have led to the development of robotic-assisted surgery using the da Vinci© Surgical System. To date, robotic-assisted surgeries have been described for almost every genitourinary organ, and the use of robotics continues to increase. A successful robotics program requires a complete understanding of the robotics system, instrumentation, and operating room setup. Selection of a specific robotic system is beyond the scope of this chapter, but is certainly an important consideration.

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Port Placement in Robotic Urologic Surgery

3

Kyle A. Blum and Ketan K. Badani

Abstract

The emergence of a robotic platform has revolutionized urological surgery and paved the way for more advanced operations to be performed using this minimally invasive modality. In the years following its debut, robotic procedures have become ubiquitous within the field of urology as indications for its use have expanded considerably. In this chapter, we present the principles of port placement, operative setup and proper patient positioning for robotic urological surgery in additional to details pertaining to commonly practiced robotic urological procedures.

Keywords

Port placement · Patient positioning · Docking · Robotics · Trocar

Introduction

In 2001, the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) was approved for use in urology (www.fda.gov), and the technological improvements have translated to a paradigm shift, especially in the field of urologic oncology. Robotic-assisted laparoscopic prostatectomy (RALP) has quickly become the minimally invasive surgical procedure of choice at most centers of excellence, and robotic-assisted laparoscopic radical and partial nephrectomy (RALN/RALPN) and cystectomy (RALC) are also increasing in numbers. More recently, there has been an extension of the use of minimally invasive surgery in reconstructive urology, with robotic-assisted laparoscopic pyeloplasty and ureteral stricture management; in female urology with robotic-assisted laparoscopic sacrocolpopexy (RALSC), and to benign urologic conditions, such as robotic-assisted laparoscopic simple prostatectomy for prostatic hyperplasia, and robotic-assisted laparoscopic pyelolithotomy for stone disease.

The impetus for the robotic approach to surgical management is based on a combined need for minimally invasive treatment with optimal surgical outcomes. Historically, conventional laparoscopy has been at the forefront of minimally invasive surgical technique, and the fundamental principles of robotic surgery are founded upon those used in laparoscopic surgery. However, the advanced technology utilized in robotics has required modifications of these techniques to capitalize on the enhanced capabilities of robotic surgery. Whereas laparoscopic surgery is limited by counterintuitive movement, 2D visualization, and a decreased range of motion, robotic surgery

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offers high-definition 3D visualization with up to ten times magnification, seven degrees of freedom, and is a natural reflection of the surgeon's movement. Robotic surgery, therefore, offers enhanced capabilities for visualization, surgical dexterity, and exposure to the surgical field, but these are ultimately dependent on the proper placement of the ports used for access. This chapter will provide a comprehensive overview of the standard techniques for access and port placement in a number of major robotic urologic procedures focusing on the nuances of prostate, renal, bladder, and female robotic urologic surgery.

General Principles of Port Placement

Pre-operative assessment and planning is critical, and mastery of surgical anatomy is imperative to success as the exposure and access to the surgical field will dictate the progress and outcome of any operation. The majority of robotic urologic procedures are performed transperitoneally and are therefore based on the creation of pneumoperitoneum as done in laparoscopic surgery. A significant difference between laparoscopy and robotic port placement is the remote presence of the surgeon with only a single bedside assistant, whereas laparoscopy requires both surgeon and assistant at the bedside.

In addition, the da Vinci Surgical System requires three or four ports for the robotic arms and, depending on the procedure, one or two assistant ports. Therefore, for a given procedure, one must consider a total number of ports ranging from 4 to 6 for placement. As with conventional laparoscopy, angulation toward the surgical site while preventing the crossing of instruments or "rolling" is essential although this is less important with daVinci Xi. Special consideration is given to abdominal wall anatomical landmarks, particularly the rectus muscles and epigastric vessels. These landmarks can change with body habitus and prior abdominal surgery. Therefore, patient selection for robotic procedures should consider these pre-operative factors as well.

In general, contraindications to laparoscopic procedures are the same as those for robotic procedures which include the inability to tolerate pneumoperitoneum, extreme obesity, intestinal obstruction or distention, massive hemoperitoneum, generalized peritonitis, extensive prior abdominal surgery, abdominal wall hernias, and advanced intra-abdominal malignancy [1].

Location of the robotic system is another added variable to port placement when compared to that of conventional laparoscopy. The field must be accessible to the robotic system which, for a transperitoneal urologic procedure, typically requires the robot positioned at the foot of the operating table and patient in the dorsal lithotomy position with steep Trendelenburg. Other variations of robotic positioning will be discussed in detail with each procedure later in the chapter.

Establishing Pneumoperitoneum and Primary Access

The site of primary access for establishing pneumoperitoneum is periumbilical, approximately 1 cm away, though variations will exist for different procedures. The Veress technique utilizes a needle with a spring-loaded inner sheath that retracts as the needle advances through the tissue then springs forward once tension is released upon entering the peritoneal cavity. Once intraperitoneal, the sheath covers the needle, thereby preventing injury to intra-abdominal organs.

After identification of the site for primary access, an incision is made through the skin followed by cautery using the cutting current through the dermis. The abdominal wall is then raised away from the intra-abdominal organs by firmly grasping the skin and fat on either side of the incision and lifting upwards perpendicularly to the body with one hand (surgeon and assistant) (Fig. 3.1). With the other hand, the surgeon then places the Veress needle ensuring a plane of entry that is perpendicular to the patient's body (see Fig. 3.1). For patients in steep Trendelenburg, a common mistake is to enter perpendicular to the floor as opposed to the patient's body, thereby

"skiving" the needle entry. During advancement of the Veress needle, one should hear three "clicks" which correspond to the sheath's spring slightly releasing with passage through the following abdominal wall layers: Scarpa's fascia, anterior rectus sheath, and posterior rectus sheath (Fig. 3.2). Occasionally there may be only two clicks, particularly below the arcuate line where the anterior and posterior rectus sheaths are fused. A Cochrane database review of the literature looking at 17 randomized controlled trials of laparoscopic access demonstrated no significant disadvantage of Veress needle access over other techniques except for an increase in extraperitoneal insufflation and increased rate of failed entry when compared to direct trocar access [2].

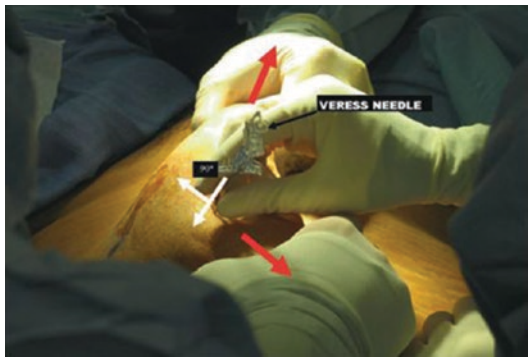

Fig. 3.1 Correct angle of entry for Veress needle insertion. The plane of entry for the Veress needle and an imaginary horizontal line corresponding to the patient's abdominal wall should be perpendicular. The surgeon and the assistant should simultaneously lift the abdominal wall up and away from the abdominal contents to prevent intra-abdominal injury from the Veress needle

Following needle placement, there is a sequence of steps that must be performed ritually to confirm correct passage of the Veress needle and to prevent injury [3]:

1. Aspiration of the needle—air should be easily aspirated. If blood or succus is aspirated, there may be vascular, or bowel injury and the needle should *not* be removed so as to identify the site of injury. Bowel contents typically appear as small particles in the syringe. An alternative access site should then be attempted, and location of the injury site sought out.
2. Drop test—apply a drop of 1–2 mL of saline into the needle. If the saline drop falls easily and rapidly, then it is highly likely that the needle is correctly positioned in a low-pressure space. In performing the drop test, we prefer not to screw the needle onto the

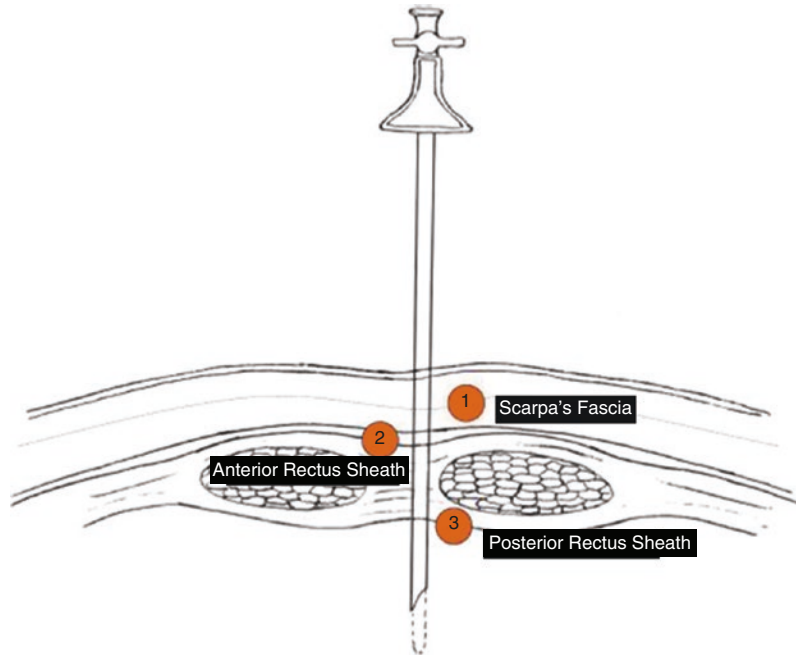

Fig. 3.2 Passage of the Veress needle through the abdominal wall. Three distinct "clicks" of the retractable spring-loaded needle can be heard as the Veress needle traverses: (*1*) Scarpa's fascia, (*2*) the anterior rectus sheath, and (*3*) the posterior rectus sheath then finally entering the peritoneal cavity. Occasionally there may be only two clicks, particularly below the arcuate line where the anterior and posterior rectus sheaths are fused

syringe as this may cause the needle to retract back into the tissue when the syringe is screwed off or disconnected.

3. CO_2 insufflation and opening pressure—the insufflation cord is connected to the needle, while holding the Veress needle steadily in place, and the opening pressure is read aloud. Opening pressure should typically range from 2 to 7 mmHg and is always <10 mmHg. If the pressure is >10 mmHg, then the needle should be withdrawn slightly as it may be up against intra-abdominal contents. If the pressure remains high, then the needle may be in the abdominal wall or an intestinal cavity. In the former case, remove the needle and restart the Veress algorithm. In the latter case, stop insufflation and aspirate to inspect for bowel contents. If the opening pressure remains low, then continue insufflation at 1–2 L/min for a total of 3–5 L and relax the grasp on the abdominal wall allowing intra-peritoneal pressure to reach 15 mmHg. The abdomen should appear uniformly distended, and the patient's ability to tolerate pneumoperitoneum should be confirmed with the anesthesiologist. The Veress needle may then be withdrawn.

Primary access is then performed after pneumoperitoneum has been established and the patient stable. A trocar is an instrument used to establish primary access. Trocars vary in size and style and will be discussed in detail later in this chapter. The skin incision used for the Veress needle should be made sufficiently large enough for passage of the primary trocar. The trocar is held with two hands: the dominant hand is used for the driving force behind the trocar, and the non-dominant hand is used to serve as a guard for smooth advancement through the tissue with the thumb and forefinger placed around its distal portion to gently guide and stabilize trocar insertion. The incision is engaged, as always, with the trocar tip at an angle perpendicular to the patient's body and a gentle twisting motion with steady pressure is applied until a slight release of tissue is felt. The stopcock is then opened, and the "whoosh" of gas is used to confirm intraperitoneal placement. The insufflation cord is then connected to the trocar stopcock and pressure and flow are again noted. The camera is then inserted through the trocar, and the abdominal viscera in the trajectory of the Veress insertion site is inspected for signs of injury followed by the surrounding organs, and lastly the intra-abdominal cavity is inspected for adhesions.

Direct open access via the Hasson technique is another operative approach for primary access. A small infra-umbilical incision is made, and two stay sutures (typically 0 Prolene) are placed on opposite sides of the fascia. With the fascia tented, an incision is made through this layer exposing the peritoneum which is then grasped with a forceps and opened using a Metzenbaum scissors. A blunt-tipped trocar is then passed directly into the peritoneum, and the stay sutures are secured to the arms of the trocar to hold it in place. A balloon trocar may also be used which has a small balloon around the trocar to secure it within the fascia once filled with air. The Hasson technique is typically used in patients with multiple prior abdominal surgeries or extremely obese patients.

Types of Trocars Used for Robotic Surgery Port Placement

There are two main classes of trocars: cutting trocars and dilating (axial or radial) trocars. Cutting trocars utilize a blade to cut fascia while advancing through the tissue simultaneously. Dilating trocars penetrate tissue without the use of a blade, but have a sharp tip which helps with advancement through the tissue. The diameter of the defect created by a dilating trocar is one-half the size of the trocar whereas the cutting trocar creates a defect that is equal to the size of the defect and requires closure when trocars larger than 5 mm are used [3]. The coaxially dilating trocars employ a Veress needle passed through an expandable mesh. After Veress access into the intra-abdominal cavity, the needle is then removed, and a blunt-tipped coaxially dilating trocar is passed through the mesh sheath. The advantage of this trocar is that after removal, the fascia contracts, thereby avoiding the need for

closure [2]. The da Vinci robot has 5- and 8-mm dilating bladeless trocars available for the robotic arm ports.

Additionally, longer (bariatric) trocars exist that may be used in obese patients or to allow for the more flexible use of the fourth robotic arm, which will be discussed later in this chapter.

Port Placement Troubleshooting

Port placement during robotic surgery is critical to the success of the procedure. If the ports are incorrectly placed, the robotic arms will collide externally making the operation extremely challenging. The goal of port placement is also to provide sufficient distance between the camera and working ports to prevent rolling and crossing of instruments internally. One particular challenge to robotic port placement is the obese patient as the anatomical landmarks are difficult to identify and the distance from the surgical site is challenging to estimate [4]. Typically, during RALP, the larger abdomen requires ports to be placed more cephalad from the pubic symphysis and deeper into the body with lateral deflection of the robot arms [4].

During port placement, the correct angle for entry into the peritoneum is important as an incorrectly positioned port can impede movement of the robotic arm. The correct angle of entry is always perpendicular to the plane of the patient and, after entry is confirmed on camera, the angle is directed toward the surgical site away from bowel and adjacent organs. When using STEP (bladeless) trocars, a common mistake is to angle incorrectly on entry and puncture the mesh of the sheath with the trocar. If this occurs, remove the trocar and re-attempt placement at the correct angle. The port should always be inspected to ensure that it is freely mobile and not "skived" (inappropriately positioned at a fixed angle upward or downward away from the surgical site). If the port is "skived," then it should be removed and again repositioned with the help of the sharp-tipped trocar as previously described.

Adhesions and prior abdominal surgery pose another significant challenge to robotic port placement. If the patient has visible external scars, care is taken to avoid placing the ports directly through the scar or in a trajectory that involves the scar when feasible. We recommend the use of the Hasson technique for placement of the camera port in patients with extensive prior abdominal surgery. After placement of the camera port, the abdominal cavity is inspected for adhesions. If adhesions are present, the first ports to be placed for any procedure would be those that are outside of the field of the adhesion but in a position that would permit manual laparoscopic lysis of adhesions. After adhesiolysis, the remainder of the ports can then be safely placed. Occasionally, an alternative access port site may be necessary solely for adhesiolysis when there are extensive adhesions that block the position of all conventional port sites.

Robotic-Assisted Laparoscopic Radical Prostatectomy (RALP)

After the patient is prepped and draped and positioned in dorsal lithotomy with steep Trendelenburg, the bladder is drained with a 20-Fr Foley catheter to ensure that it is completely decompressed and outside of the field of port placement. For the four-arm approach, we typically place six ports: two assistant ports (12- and 5-mm, for suctioning, passing sutures, and retraction), three robotic ports (8 mm including the fourth arm for retraction), and the 12-mm camera port. For the three-arm standard da Vinci system, we omit the fourth arm robotic port for a total of five ports (Fig. 3.3).

The 12-mm camera port is placed slightly left of the umbilicus using the Veress technique, as previously described. After pneumoperitoneum is established, primary inspection of the intraperitoneal cavity is performed to ensure that no injuries to the bowel or adjacent organs have occurred and attention is then turned to the lateral (assistant) port. The right anterior superior iliac spine (ASIS) is identified, and a point which is approximately 2 to 3 finger breadths superior and 1 to 2 finger breadths medial to this landmark is marked out. The camera is then used to confirm, from an intra-peritoneal

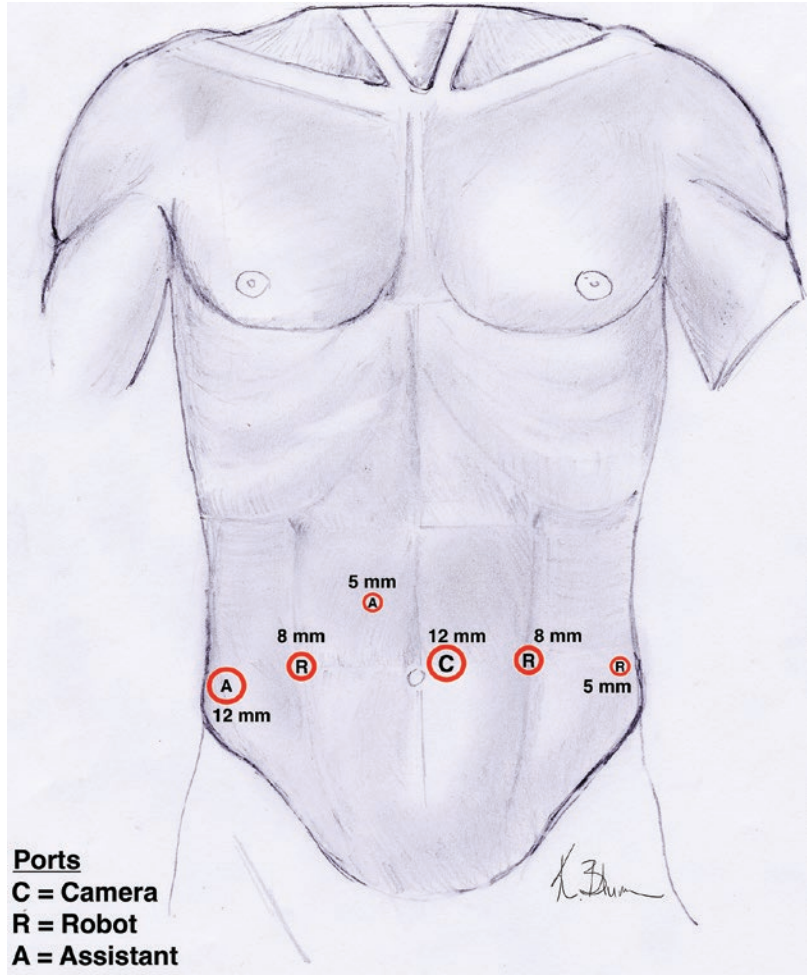

Fig. 3.3 Port placement for robotic-assisted laparoscopic prostatectomy. (Illustration by Kyle A. Blum)

standpoint that there are no adhesions or bowel in the trajectory of the incision and port site. If there are any adhesions noted, contralateral port placement is then undertaken, and laparoscopic adhesiolysis is performed as previously described.

A skin incision is made parallel to Langer's lines to expose the dermis, and the cutting current from the Bovie is then used to incise this layer. For assistant ports, we prefer to use the radially dilating STEP trocars. The STEP trocar is inserted via the Veress technique under direct visualization. A 12-mm blunt-tipped trocar is then inserted through the mesh sheath with special attention at aiming the trajectory toward the pelvis. After placement of the 12-mm port, the insufflation tube is then moved from the camera port to this port.

Attention is then turned to the right-sided 8-mm robotic arm port, which is placed approximately 10 cm away from the midline camera port slightly below the level of the umbilicus and just lateral to the edge of the rectus muscle. The robotic arm port has a sharp plastic trocar which can directly pierce the fascia. After confirmation of the appropriate port site, the trocar is inserted, perpendicular to the plane of the patient and with gentle rotation and pressure, under the aid of direct visualization from the camera. After the sharp tip is visually identified on camera coming through the peritoneum, the port is angled toward the pelvis, and the sharp trocar is removed. The robotic port is then advanced to the level of the thick 1-cm black mark.

For the second assistant suction port (5 mm), an imaginary line is drawn connecting the right-sided 8-mm robotic port and the midline camera port and, at the midpoint of this line, the port is then inserted under visualization using a STEP trocar and Veress needle as described for the 12-mm assistant port.

On the left side of the patient, for the fourth-arm model, an 8-mm fourth robotic arm port is placed using the same landmarks as the 12-mm right-sided lateral assistant port (2–3 fingerbreadths superior and 1–2 fingerbreadths medial to the ASIS). For the three-arm da Vinci model, a 5-mm assistant port may also be placed at this location for a second bedside assistant for retraction [4]. Finally, another 8-mm left-sided robotic working port is then placed in a position which is an exact mirror image of the 8-mm right-sided robotic port (lateral to the edge of the rectus muscle, approximately 10 cm and slightly inferior to the camera port).

The final RALP port configuration has a fan-like appearance with all ports aiming toward the pelvis and with sufficient distance between the robotic arms (Fig. 3.4).

Robot Docking

The patient should be positioned with their arms tucked at the sides, ensuring adequate padding of pressure points, and all intravenous lines and anesthesia monitors are functioning appropriately. The patient is in the low lithotomy position in steep Trendelenburg. The robot is "driven" toward the patient (the robot is usually docked at the patient's feet), ensuring that the alignment of the center column of the cart is with the camera port. As the robot is brought towards the patient, the table is lowered, and the robot arms are positioned high enough to clear the patient as it is advanced.

To lower the robot arm, hold the clutch button located behind the cannula mount. The port is stabilized with one hand while docking, and once the cannula and mount are flush, the clutch

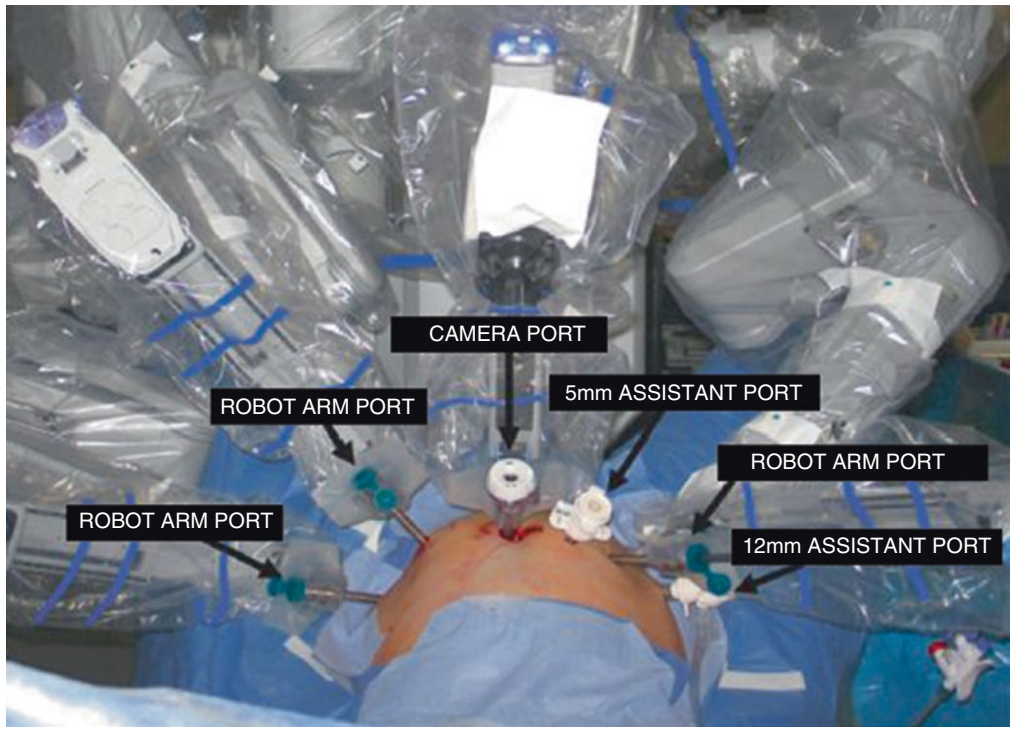

Fig. 3.4 The final appearance of ports after docking the robot for robotic-assisted laparoscopic prostatectomy

is released and "wings" are closed on the cannula mount to lock the port in place. Care is taken to not withdraw or advance the port during docking. The camera arm is docked first. The "sweet spot" of the camera arm can be confirmed by ensuring that the arrow is within (preferably in the center) of the blue zone. Once all cannulas are locked within the robot arms, the instruments are placed into the ports, and advanced into the patient's body, under direct endoscopic visualization using the camera one at a time, by pressing the arm clutch button. If needed, the robot arms can be "burped" upward to allow for more space between the arms, by holding instrument arm in one hand and robotic port and clutch with the other.

The cannula should be held with one hand each time an instrument or the camera is removed to secure it from being dislodged or removed.

Port Site Closure

After de-docking the robot, the robotic camera is manually placed through the lateral right-sided 12-mm assistant port, and a laparoscopic grasper is then used to deliver the string of the endocatch bag containing the specimen through the midline camera port. It is then secured outside of the body with a Kelly clamp later for specimen extraction.

Removal of all ports is always performed in a sequential manner under direct visualization. We prefer to use the robotic fourth-arm port for placement of the Jackson–Pratt (JP) drain and this port is typically removed first. Care is taken to remove this port with a "one-to-one" motion so as not to disrupt the position of the JP drain. If the drain is accidentally moved, a laparoscopic instrument may be inserted through one of the indwelling robotic ports (close to reposition the drain to the desired location. Each port site is directly visualized on removal to ensure that there is no bleeding internally so as to prevent port site hematomas which can be severe enough to warrant re-exploration. The camera port is the last to be removed as this is our extraction site for the surgical specimen.

Using cautery, we cut down on the skin and fascia over the port enough to insert an index finger into the defect. The external portion of the string on the endocatch bag (Covidien) is held in the non-dominant hand after the port is removed and using the dominant hand a gentle sweep with the index finger is performed to ensure that there is no bowel or omentum directly under the fascia. The fascia and skin are then incised down onto the index finger with cautery to a minimum estimated length necessary for specimen removal. After the specimen has been extracted and all port sites inspected externally for hemostasis, we close the extraction site with a single fascial layer using the necessary number of figure-of-eight 0-Vicryl suture to ensure complete closure of the defect. The skin layer of the extraction and all other port sites are then closed with subcutaneous 4–0 Biosyn suture and skin adhesive (Dermabond; Ethicon), or alternatively dressed with Steri-Strips, gauze, and an occlusive biomembrane dressing (Tegaderm; 3 M Corporation).

Robotic-Assisted Laparoscopic Cystectomy (RALC) and Urinary Diversion

The patient is positioned and padded in an identical manner as that described for RALP (lithotomy position with steep Trendelenburg). Port placement for RALP is very similar to that of RALC, with some modification, and the reader should, therefore, refer to that section for details on how to properly place these ports. Particularly important during RALC is the ability to perform extended pelvic lymphadenectomy and mobilization of the ureters along with transferring the left ureter to the right under the sigmoid mesentery [5]. For intracorporeal diversion, there are several different schemas for port placement depending on the type of urinary diversion. This chapter will focus on the basic port placement for robotic cystectomy.

The first port to be placed is that of the robotic camera. Pneumoperitoneum is established using the Veress technique and the 12-mm camera port is the first to be placed, and is slight to the left of

the umbilicus. Under direct visualization, the robotic and assistant ports are then placed as outlined in Fig. 3.5. The assistant is positioned to the right of the patient, and the first assistant port (12 mm) is placed approximately 2 to 3 finger breadths above the ASIS and 1–2 cm medial to the mid-axillary line using the Veress technique with a radially dilating STEP trocar. The next port to be placed is the 8-mm right-sided robotic camera port which is positioned approximately 2–3 cm below the level of the umbilicus and slightly lateral to the right rectus muscle. Attention is then turned to the 10-mm assistant port for suctioning, which is placed slightly cephalad and halfway between the camera and the right-sided robotic port. We prefer to use a 10-mm versus a 5-mm assistant port as the larger size permits easier passage of clips and energy devices for control of the vascular pedicles when needed. For the da Vinci fourth arm, an 8-mm robotic port is placed at a position two to three finger breadths above the left ASIS and one to two cm medial to the mid-axillary line. The final 8-mm robotic port is placed on the left side, in a mirror image to the right-sided 8-mm robotic port (2–3 cm below the umbilicus, lateral to the edge of the left rectus muscle). The robot is then docked as previously described.

At our institution, we prefer to perform intracorporeal urinary diversion. We prefer to use a gel port for the camera site, this way we can remove the specimen before the urinary diversion. If performing intracorporeal diversion, the 5-mm suction port should be changed to a 12-mm suction port, so

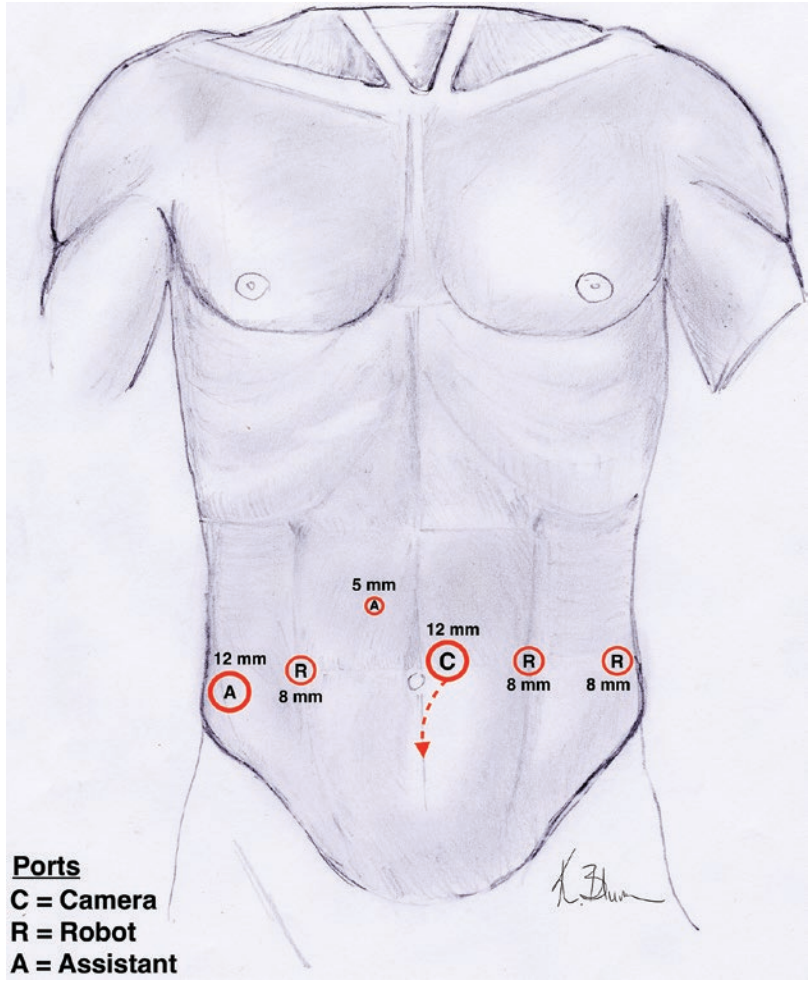

Fig. 3.5 Port placement for robotic-assisted radical cystectomy and urinary diversion. A 4- to 6-cm periumbilical incision is made going toward the symphysis pubis for the extracorporeal creation of the conduit or the neobladder. We routinely place the stoma in the right lower quadrant through the rectus muscle but, in select cases, we may utilize the 10-mm assistant port site for the stoma to improve cosmesis. (Illustration by Kyle A. Blum)

there is easier access for the stapling device at various angles. For ileal conduit diversions, our stoma site is typically the RLQ through the rectus muscle or, in select cases, we may expand the 10-mm assistant port site for the location of the stoma.

For orthotopic neobladder diversion, a hybrid approach may be used. The ports remain in place, and the segment of intestine is delivered via gel port for the creation of the reservoir extracorporeally. The neobladder is then placed back into the pelvis, the midline incision is closed, and the robotic system is re-docked in order to perform the urethroneovesicostomy and ileal-ureter anastomosis [6]. It is sometimes beneficial to preplace anastomotic sutures robotically in the urethra before creation of the neobladder. Intra-abdominal robotic urinary diversion has been described using a slightly different template for port placement [7]. Beecken et al. [7] utilize an initial three-port placement, using the standard da Vinci system, with the 12-mm paraumbilical camera port (via Hasson technique) and two 8-mm robotic arms placed lateral to the right and left rectus and slightly inferior to the umbilicus. Additionally, 10-mm assistant trocars are placed lateral to the robotic ports and above the ASIS [7]. These are used for passage of graspers, suctioning, clip appliers, and bowel stapler.

Robotic-Assisted Renal Procedures

Robotic-Assisted Laparoscopic Radical Nephrectomy (RALN) and Partial Nephrectomy (RALPN)

The port placement for robotic-assisted laparoscopic renal procedures can be challenging due to the laterality of the surgery and the positioning of the patient. Enough space must be given between each port to permit freedom of movement for all arms while creating a working space for the bedside assistant. The operating room table orientation will need to be re-configured to accommodate the robot which is docked facing the dorsal aspect of the patient (in lateral decubitus position) and at an angle to the location of the renal hilum, particularly for partial nephrectomy [8]. The monitors, insufflation tower, and electrocautery stand are set up on the same side of the room as the robot and directly facing the bedside assistant (Fig. 3.6).

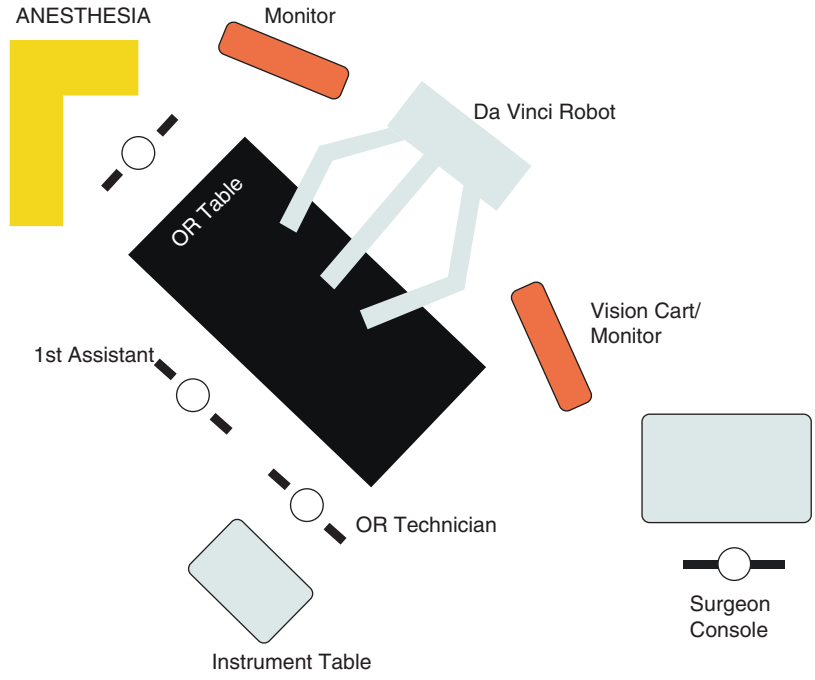

Fig. 3.6 Operating room setup and orientation for robotic renal procedures. The OR table is typically placed at an angle which allows the robot to approach the dorsal aspect of the patient (in lateral decubitus position) when being docked. The first assistant is then facing directly opposite to the robot and vision cart/monitors

The patient is placed in the full flank position, and the bed is flexed slightly to expose the space between the costal margin and the ASIS. Additionally, this lowers the hip to allow space for the 4th arm. After the patient is prepped and draped, pneumoperitoneum is established by placing the Veress needle in a region slightly inferior to the ipsilateral subcostal margin and superior to the umbilicus.

The following anatomical landmarks are then identified: ASIS, subcostal margin, anterior axillary line, mid-clavicular line, and posterior axillary line (Figs. 3.7 and 3.8). The 12-mm camera port is placed at the mid-clavicular line 2–3 finger breadths cephalad to the umbilicus. The 0° lens is used for the placement of the remaining ports under direct visualization. For the robotic arms, one is placed 8–10 mm away from the camera at the costal margin; the other is placed half distance between ASIS and camera port. Finally, the 4th arm is placed low and medial. Ideally, this port is midline, as low on the abdomen as feasible, however, based on body habitus, attempt to place it as low and medial as possible (Fig. 3.9).

With robotic partial nephrectomy, the positioning of the robotic ports can be adjusted depending on the location of the tumor. For upper pole tumors (and patients with a large body habi-

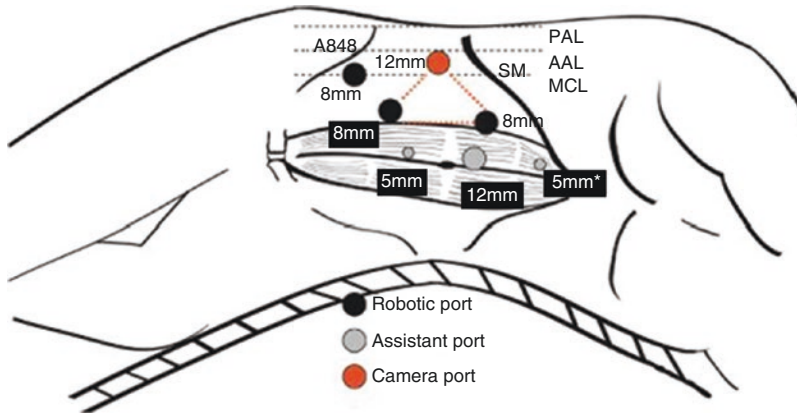

Fig. 3.7 Port placement for right-sided robotic radical nephrectomy. The 12-mm camera port and the 8-mm robot arm ports are triangulated toward the renal hilum. *A subxiphoid 5-mm port may be added for liver retraction during *right-sided* renal procedures. *ASIS* anterior superior iliac spine, *SM* subcostal margin, *AAL* anterior axillary line, *MCL* mid-clavicular line, *PAL* posterior axillary line

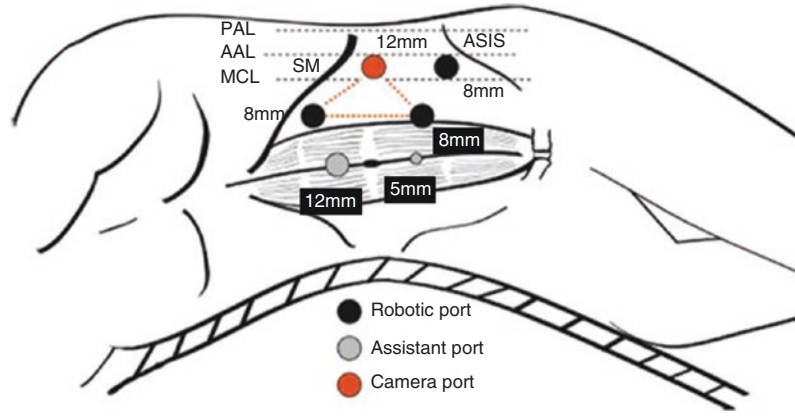

Fig. 3.8 Port placement for left-sided robotic radical nephrectomy. The 12-mm camera port and the 8-mm robot arm ports are triangulated toward the renal hilum. *ASIS* anterior superior iliac spine, *SM* subcostal margin, *AAL* anterior axillary line, *MCL* mid-clavicular line, *PAL* posterior axillary line

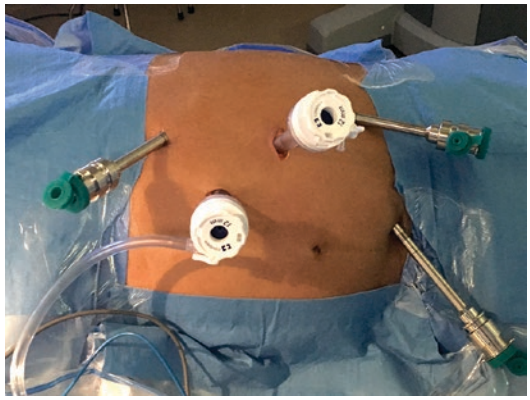

Fig. 3.9 Final port placement for a left-sided, robotic-assisted radical nephrectomy. *AAL* anterior axillary line, *MCL* midclavicular line, *ASIS* anterior superior iliac spine, *LRB* lateral rectus border, *SM* subcostal margin

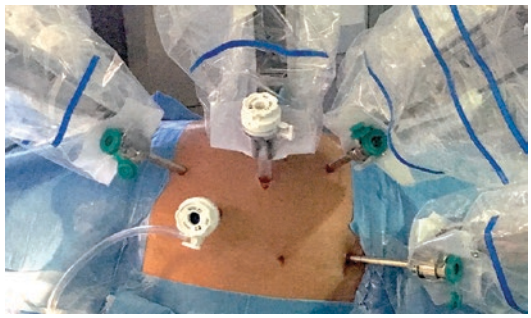

Fig. 3.10 Docking of the robot for *left-sided*, robotic-assisted radical nephrectomy. The patient is positioned in the right lateral decubitus position, and the robot is docked facing the dorsal aspect of the patient

tus), the ports may be shifted laterally and superiorly [9]. Use of the fourth arm is optional and may be used for retraction. Our port schema is designed for the daVinci Si model. If using the daVinci Xi model, little to no adjustment for tumor location is required. Use of a longer robotic cannula allows for the use of the fourth arm without collision with the other robotic arms and the assistant port.

The role of the bedside assistant is crucial to the success of robotic partial nephrectomy. The assistant can be responsible for clamping and unclamping the artery and vein to during warm ischemia as well as for passing the sutures needed for obtaining hemostasis in the surgical site. In addition, they may be required to retract the colon during dissection, and for the right-sided position, liver retraction is important as well [10]. One or two assistant ports may be used. These are typically placed in the periumbilical midline, adjusting laterally if the patient is obese. The 12-mm port is placed approximately 2 cm cephalad to the umbilicus and the optional 5-mm port is placed 2 cm caudal to the umbilicus, and the robot is then docked facing the dorsal aspect of the patient (Figs. 3.9 and 3.10).

Robotic-Assisted Laparoscopic Pyeloplasty and Pyelolithotomy

For most robotic-assisted renal procedures the positioning of the patient is fairly similar. As previously described for robotic-assisted radical and partial nephrectomy, the operating room table orientation will need to be re-configured to accommodate the robot which is docked facing the dorsal aspect of the patient. The patient is positioned in a full flank position with mild flex. The robot, tower with monitors, insufflation, and electrocautery are all positioned on the same side of the room so that they are directly facing the bedside assistant (see Fig. 3.6).

Our landmarks for port placement in the lateral decubitus position are the ASIS, ipsilateral subcostal margin, anterior axillary line, and midclavicular line (see Figs. 3.7 and 3.8). Pneumoperitoneum is established with the Veress needle in a region slightly inferior to the ipsilateral subcostal margin and lateral to the umbilicus. The port placement for upper urinary tract reconstruction is exactly the same as for RAPN (see section on RAPN and RARN). For pyeloplasty, we prefer a total of four ports: one camera, two robot, and one assistant. For liver retraction, an additional 5-mm port can be placed in the midline, subxiphoid area for a self-retaining retractor [11, 12].

Robotic-Assisted Laparoscopic Sacrocolpopexy (RALSC)

The open transabdominal approach for sacrocolpopexy has achieved high success rates for most patients; however, the morbidity of the operation and the length of post-operative stay are limiting factors [13]. The transvaginal approach is another option that is less invasive but has not demonstrated as uniformly successful outcomes as the transabdominal approach [14]. Surgeons, therefore, developed laparoscopic sacrocolpopexy in an effort to strike a balance between providing good outcomes with a minimally invasive approach. Unfortunately, the laparoscopic technique is challenging and operative times are significantly longer than the transvaginal approach, and its widespread use has been limited [15]. Recently, surgeons have turned to the da Vinci robot to perform robotic-assisted laparoscopic sacrocolpopexy (RALSC) so as to maximize the benefits of laparoscopy while decreasing the technical challenges of a straight laparoscopic approach using the improved visualization and increased range of motion of the robotic system [16, 17].

For this procedure, the patient is placed in Trendelenburg and dorsal lithotomy position with the arms tucked on both sides. After she is prepped and draped, a Foley catheter is inserted to decompress the bladder. A standard periumbilical incision can be made for placement of the 12-mm camera port, but occasionally we may place the camera port supraumbilically as an alternate site. We use a Veress technique for insufflation followed by a 12-mm cutting trocar for insertion of the camera port once pneumoperitoneum has been established. The robotic camera is then used to inspect the abdominal viscera to ensure no injuries have been made and the intra-abdominal site for the first assistant port, on the patient's right side, is identified. This site is approximately 2 to 3 fingerbreadths above the ASIS and slightly lateral to the midclavicular line. Using the Veress technique and a radially dilating STEP trocar, a 12-mm port is then placed under direct visualization. This port is used for passage of sutures and synthetic mesh material.

Attention is then turned to the first 8-mm robotic port which is placed lateral to the right rectus muscle and in line with the umbilicus. It should be noted that our positioning of the robotic ports for RALSC is similar to that for RALP; however, they must be placed slightly more cephalad to allow for maximal access to the sacral promontory while still being able to reach the pelvis during sacrocolpopexy. Another 5-mm assistant port is placed midway between the right-sided robotic assistant port and the camera port and is used for suctioning and retraction. The second 8-mm robotic port is then placed on the left side, lateral to the rectus muscle and again in line with the umbilicus. The final configuration is shown in Fig. 3.11. We routinely employ the fourth arm,

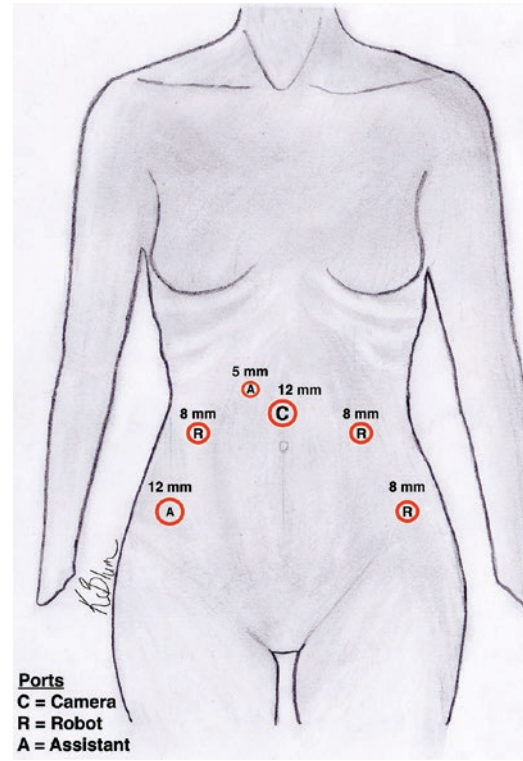

Fig. 3.11 Port placement for robotic-assisted laparoscopic sacrocolpopexy. The camera port may be placed supraumbilically as shown. In addition, the 8-mm robot arm ports are placed slightly more cephalad compared to those in a prostatectomy to allow better access to the sacral promontory. (Illustration by Kyle A. Blum)

placed approximately three fingerbreadths cephalad to the iliac crest on the left lateral sidewall.

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4 Anesthetic Considerations for Robotic Urologic Surgery

Michael A. Olympio

Abstract

The proper management of anesthesia for robotic-assisted laparoscopic urologic surgery (RALUS) must focus on the complex physiology and implications of Pneumoperitoneum (PPT) and the Trendelenburg position (TP) which challenge the neurologic, ocular, pulmonary, cardiovascular, and renal systems. The type of inflation gas and degree of abdominal and hydrostatic pressure proportionally affect these systems, while restricted access to the limbs hinders routine monitoring, interpretation, venous access, and safety. The cardiovascular effects are profound, but generally well tolerated and hidden, whereas the management of ventilation becomes far more difficult. Special techniques for monitoring neuromuscular blockade (NMB), blood pressure (BP), and central venous pressure (CVP) are indicated. Pre-anesthetic evaluation, surgical positioning, drug effects, airway and fluid management, and recognition of common complications ought to inform the specific conduct of anesthesia, while the experience of the surgeon may have the most profound influence over the course of anesthesia.

Keywords

Anesthesia · Considerations · Robotic · Intra-abdominal pressure · Intraocular pressure · Cardiovascular · Ventilation · Prostate · Laparoscopic · Urologic

Abbreviations

AICD	Automated implantable cardiac defibrillator
AION	Anterior ischemic optic neuropathy
APSF	Anesthesia Patient Safety Foundation
ASA	American Society of Anesthesiologists
BP	Blood pressure
CBF	Cerebral blood flow
CC	Closing capacity
CO	Cardiac output
COPD	Chronic obstructive pulmonary disease
CPAP	Continuous positive airway pressure
CPP	Cerebral perfusion pressure
CPT	Capnoperitoneum
CSF	Cerebrospinal fluid
CVP	Central venous pressure
EA	Epidural analgesia
EAES	European Association of Endoscopic Surgery

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EDV	End-diastolic volume
ETT	Endotracheal tube
FRC	Functional residual capacity
GA	General anesthesia
GFR	Glomerular filtration rate
HR	Heart rate
IAP	Intra-abdominal pressure
ICP	Intracranial pressure
IOP	Intraocular pressure
IPSC	Intermittent pneumatic sequential compression
LA	Local anesthetics
LMWH	Low molecular weight heparin
MAP	Mean arterial pressure
MPAP	Mean pulmonary artery pressure
NMB	Neuromuscular blockade
NMDA	N-methyl-D-aspartate
NSAIDs	Non-steroidal anti-inflammatory drugs
OSA	Obstructive sleep apnea
PAOP	Pulmonary artery occlusion pressure
PAP	Pulmonary artery pressure
PCA	Patient-controlled analgesia
PCEA	Patient-controlled epidural analgesia
PCV	Pressure-controlled ventilation
PCWP	Pulmonary capillary wedge pressure
PE	Pulmonary embolism
PION	Posterior ischemic optic neuropathy
PMMA	Pharmacologic multimodal analgesia
POI	Postoperative ileus
POVL	Postoperative vision loss
PPT	Pneumoperitoneum
PVR	Pulmonary vascular resistance
RALRP	Robotic-assisted laparoscopic radical prostatectomy
RALS	Robotic-assisted laparoscopic surgery
RALUS	Robotic-assisted laparoscopic urologic surgery
RBF	Renal blood flow
SAB	Subarachnoid block
SV	Stroke volume
SVR	Systemic vascular resistance
TAP	Transversus abdominis plane
TEA	Thoracic epidural analgesia
TIVA	Total intravenous anesthesia
TLC	Total long capacity
TP	Trendelenburg position
UOP	Urine output
VCV	Volume-controlled ventilation
VILI	Ventilator-induced lung injury

The Physiological Effects of Pneumoperitoneum, Position, and Trendelenburg

Degree of Intra-abdominal Pressure (IAP)

Higher degrees of IAP may cause proportionally adverse effects (Table 4.1) [1], while the European Association for Endoscopic Surgery (EAES) recommends, "… to use the lowest IAP allowing adequate exposure (5–12 mmHg) … and to avoid an IAP of more than 12 mmHg combined with TP because it reduces pulmonary compliance … [2]." Despite their conclusion that the hemodynamic effects of pneumoperitoneum (PPT) are without consequences, the anesthesiologist will struggle against IAP to achieve respiratory stability and to prevent other complications.

Cerebral Effects

High IAP will increase intracranial pressure (ICP) (which may occur early), and these effects

Table 4.1 Adverse effects of higher intra-abdominal pressure (12–15 mmHg vs. 5–7 mmHg)

Increased	Decreased
Shoulder-tip pain	Venous return
Heart rate	Preload
Mean arterial pressure	Cardiac output
Pulmonary vascular resistance	Pulmonary compliance
Systemic vascular resistance	Renal blood flow
Renin–aldosterone	Urine production
Angiotensin	Hepatoportal circulation
Vasopressin	Splanchnic microcirculation
Airway resistance	Gastric mucosal pH
pCO_2	
Liver enzymes	
Central venous pressure	
Shunt	
Intraocular pressure	
Intracranial pressure	

Derived from Catheline [1]
Abbreviations: *pH* partial pressure hydrogen ion, pCO_2 partial pressure carbon dioxide

are mediated through compression of the inferior vena cava, increased CVP, impaired venous drainage of the lumbar venous plexus, and subsequently impaired cerebrospinal fluid (CSF) resorption [3, 4]. Pre-emptive hyperventilation does not significantly decrease ICP. Postoperative headache, nausea, and vomiting are attributed to this ICP, and not to hypercarbia [5]. Compensatory mean arterial pressure (MAP) elevations may be caused primarily by the release of vasopressin which may also be the mediator of reduced splanchnic blood flow [6]. Despite these concerns, there has been a documented preservation of cerebral oxygenation in RALUS patients [7]. Whereas it was previously impossible to measure ICP in RALUS patients, a new ultrasonic method of correlating optic nerve sheath diameter with ICP has now been reported [8], and shows an increase to values above 20 mmHg.

Ocular Effects

At least three to six devastating complications of postoperative visual loss (POVL) have occurred in the RALUS population, attributed to posterior ischemic optic neuropathy (PION) [9, 10]. POVL after any procedure is extremely rare (0.02–0.1%) but previously well described in major prone spine surgery [10]. Although many authors focus on the potentially detrimental effects of intraocular pressure (IOP) [11, 12], the Anesthesia Patient Safety Foundation (APSF) expert consensus conference in 2013 described the presumed mechanism of injury for PION, which is a documented swelling of the optic nerve [8] or compartment syndrome behind the globe causing impairment of pial, and perhaps central retinal arterial blood flow into a watershed zone of the optic nerve [13]. Most if not all cases of POVL after RALUS are thought to be from PION [10]. The documented swelling is presumed to occur through Starling forces, and might be attenuated through reductions in capillary osmotic and/or increases in oncotic pressure [13]. Similar to the American Society of Anesthesiologists (ASA) recommendations to prevent POVL in the prone spine surgery patient, they recommend minimizing (1) otherwise steep TP, (2) IAP, (3) duration of those factors, (4) crystalloid to colloid ratio, and (5) blood loss [13]. These mechanisms for PION are postulated to be independent of otherwise known increases in IOP, or central retinal artery occlusion, or even cortical blindness. Any of those mechanisms might have been a factor in three other cases of anterior ischemic optic neuropathy (AION) and POVL after *open* radical prostatectomy [10]. Therefore, the ASA recommends informed discussion of this rare but catastrophic risk with the patient *prior to* the day of surgery [13]. PPT and TP will similarly increase hydrostatic pressure in the face and sclera, leading to edema or plethora, and may cause edema of the glottis and vocal cords affecting the course of extubation.

Cardiovascular Effects and Valvular Considerations

Table 4.2 summarizes the hemodynamic effects of capnoperitoneum (CPT) in TP in predominantly healthy patients [14–21]. Hemodynamic derangements upon the establishment or release of PPT arise from a complex interaction of painful trocar puncture, direct IAP, posture, intravascular volume, vagal activity, and neurohumoral effects [2, 22, 23], all of which dictate a deliberate anesthetic approach. The most immediate, vagal hypotension and/or bradycardia may be treated with slower inflation, temporary deflation, or anticholinergics. Despite this transient effect, IAP in combination with TP consistently causes increases in CVP, MAP and systemic vascular resistance (SVR), without decreases in myocardial contractility, cardiac output (CO), or heart rate (HR) which is typically maintained or increased as a result of CO_2 absorption and catecholamine release [24, 25]. Mean pulmonary artery pressure (MPAP) and pulmonary capillary wedge pressure (PCWP) typically increase. SVR is highest during initial TP and then tapers back towards baseline with time, and dramatically falls upon exsufflation [20], potentially causing cardiac arrest [26]. End diastolic volume (EDV) may be elevated in TP [16, 19], but in some patients, new data indicate the potential for

Table 4.2 Hemodynamic effects of capnoperitoneum in the Trendelenburg position

References	Author-Year	Surg	IAP	Monitor	MAP	CO	SVR	CVP	PCWP	HR	MPAP
[14]	Odeburg 1994	Chole	12	PA	↑	↔	↔	↑↑	↑↑	↔	↑↑
[15]	Hirvonen 1995	Hyst	14	PA	↑	↓	↔	↑	↑	↔	↑
[16]	Gannedahl 1996	Chole	12	PA-TEE	↑	↔	↑	↑↑	↑↑	↓	↑
[17]	Falabella 2007	RALRP	15	TEE	↑		↑				
[18]	Meininger 2008	RALRP	12	TDCI	↑	↔	↔	↑		↔	
[19]	Harris 1996	Colec	15	PA-TEE	↑	↔	↔	↑↑	↑↑	↔	↑↑
[20]	Rosendal 2014	RALRP	15	PA, PC	↑	↓↑	↑	↑↑		↑	
[21]	Lestar 2011	RALRP	12	PA, TEE	↑	↔	↔	↑↑	↑↑	↔	↑↑

Abbreviations: *IAP* intra-abdominal pressure, *MAP* mean arterial pressure, *CO* cardiac output, *HR* heart rate, *SVR* systemic vascular resistance, *MPAP* mean pulmonary artery pressure, *CVP* central venous pressure, *PCWP* pulmonary artery wedge pressure, *Chole* cholecystectomy, *PA* pulmonary artery catheter, *PC* pulse contour, *TEE* transesophageal echocardiography, *Hyst* hysterectomy, *RALRP* robotic-assisted laparoscopic radical prostatectomy, *TDCI* transthoracic doppler cardiac index, *Colec* colectomy

diastolic dysfunction causing a decrease in EDV and decrease in stoke volume (SV) [23]. All the above data suggest that volume loading may not be indicated or appropriate before assuming TP.

SVR consistently increases (but moderates over time [20]) because of resistance to aortic outflow across the diaphragm, and/or from immediate increases in vasopressin and/or nor-epinephrine [24]. Myocardial wall stress of both ventricles can thus increase, and presumably, may have caused initial decreases in CO after insufflation [20]. Such effects lead to concerns about increased oxygen demand, compromised intra-myocardial coronary blood flow, and ischemia in susceptible patients. Catecholamine secretion explains the maintenance of CO when it might otherwise be expected to fall. An increase in volatile anesthesia or beta blockade to counteract increased MAP may be deleterious by virtue of their myocardial depressant effects [19]. Alternatively, increased filling, wall stress, and SVR might better be counteracted with vasodilators (e.g., nicardipine) and/or modulation of sympathetic activity through alpha-2 receptor agonists (e.g., clonidine, dexmedetomidine) [24, 27].

Renal Function

Renin-angiotensin is stimulated through reductions in renal blood flow (RBF) and glomerular filtration rate (GFR) and is correlated with r-TP, duration of PPT, and higher IAP as well as preoperative decreased renal function, or lower levels of hydration [28]. RBF and function typically return to normal after exsufflation. Intraoperative attenuation of renal hypoperfusion has been accomplished with nitroglycerine, clonidine [24], dexmedetomidine [27], dopamine, and epidural anesthesia. In addition to the effects of IAP, the anesthesiologist should also be prepared to induce hypotension during partial nephrectomy, as opposed to warm ischemia by renal artery cross-clamping, as this technique is shown to preserve postoperative renal function [29].

Pulmonary Effects and Ventilation Strategies

PPT and TP will significantly reduce total lung capacity (TLC) and total lung compliance [30], and increase airway resistance. The diaphragm is shifted cephalad, and functional residual capacity (FRC) is reduced >50%, while the volume of the lung may reach its closing capacity (CC) [31]. This causes atelectasis and shunt leading to oxygen desaturation and is overcome through the application of optimal positive end-expiratory pressure (PEEP) [32], identified through spirometry and illustrated in Fig. 4.1. Clinically, one may be able to increase compliance from 15 mL/cmH_2O to as much as 40 mL/cmH_2O through such maneuvers. PEEP is not devoid of detrimental effects, however, and might reduce venous return and cause hypotension.

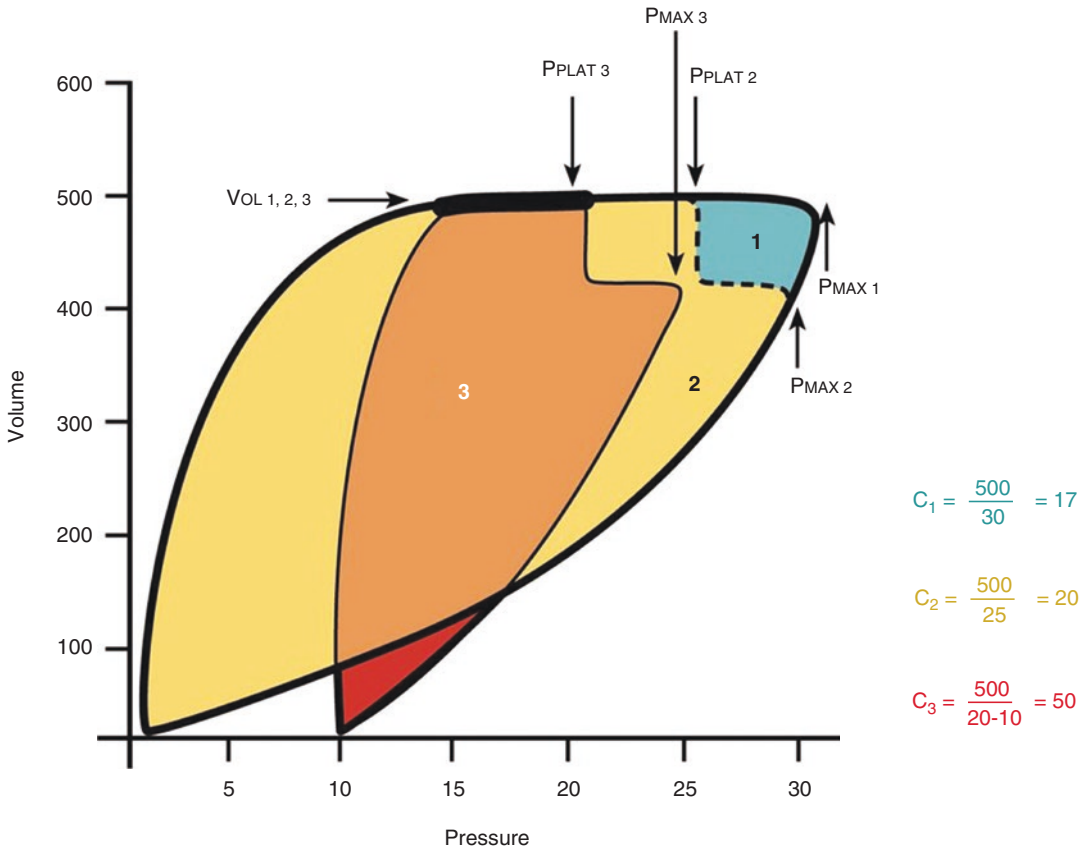

Fig. 4.1 Spirometry pressure-volume loops indicating no positive end-expiratory pressure and no inspiratory pause in loop 1 (*blue*) with a resultant (dynamic) compliance of 17 mL per cm H_2O. The addition of an inspiratory pause may lead to a greater distribution of gas and a lower inspiratory plateau pressure (plateau pressure 2 of 25 cm H_2O), without the contribution of resistance to airflow. An improvement in (static) compliance to 20 mL per cm H_2O (loop 2, *orange*) is evident. If positive end-expiratory pressure is added in loop 3 (*red*), the compliance might dramatically improve as the curve is shifted to the *right*, with lesser change in pressure (plateau pressure 3—positive end-expiratory pressure), thus improving compliance to 50 mL per cm H_2O. P_{PLAT} plateau pressure, *C* compliance, P_{MAX} peak inspiratory pressure, V_{OL} tidal volume

With CO_2 being the most common insufflation gas, it may compel the anesthesiologist to increase ventilation in compliance-reduced lungs. Hypercarbia is generally well tolerated [33], but extreme hypercarbia may occur in patients with poor CO, lung disease, obesity, or impaired ventilation, necessitating postoperative ventilation, or it might worsen a metabolic acidemia leading to myocardial depression and systemic vasodilation, or cause direct sympathetic stimulation [34]. End-tidal CO_2 ($EtCO_2$) increases over 8–10 min from the onset and reaches a plateau over the next 15–20 min; whereas retroperitoneal insufflation will further increase CO_2 absorption from higher vascularity and spread to other spaces. CPT lowers intraperitoneal pH causing abdominal or shoulder tip pain [35]. Isothermic (37° vs. 21°) CO_2 will improve pulmonary function and perhaps urine output (UOP) in the postoperative period [36].

Hypercarbia from CPT is generally overcome by increasing minute ventilation, but complications of pneumothorax, pneumomediastinum, pneumopericardium, and subcutaneous emphysema have all occurred [37]. Sudden or even gradual deterioration in oxygen saturation, peak inspiratory pressure, or development of hypercarbia must not be confused with the possibility

of endobronchial intubation as the abdomen is inflated. Although PPT typically leads to atelectasis and shunt with hypoxemia [31, 37], there is evidence that pO_2 may steadily increase over time [38] through recruitment of vascular perfusion to ventilated areas of the lung or reduction in flow (via compression) to previously atelectatic areas. The optimal type of ventilation for PPT with TP has not been determined [39], although recent multicenter randomized trials (PROVHILO [40]) continue to support the use of small tidal volumes (8 ml/kg) to prevent ventilator-induced lung injury (VILI). Current evidence [41, 42] suggests that shear injury may occur at low lung volumes if the alveoli are constantly closing then re-opening, particularly with inhomogeneous lungs. This can be partially or fully prevented with PEEP, to prevent such "atelectrauma." On the other hand, overdistention may lead to structural and biological changes that cause capillary leak and pulmonary edema. The PROVHILO study, however, included only open-abdomen surgeries with excellent pulmonary compliance (34–45 ml/cmH_2O), thus arguing the provision of PEEP may have been irrelevant and/or unnecessary to prevent atelectasis. Similarly, patients in the IMPROVE study [43] had high compliance in both experimental and control groups (46–55 ml/cmH_2O), but included PEEP of 7 in those ventilated with low tidal volume (7 ml/kg). Outcomes were improved in that group, leading many to adopt these low volumes with PEEP strategies. This author similarly uses low tidal volume (5–8 ml/kg) with higher PEEP (7–12) and longer inspiratory/expiratory time [44], with higher rates, to optimize compliance and enhance volume distribution. Permissive hypercapnia has repeatedly been shown not to impair outcome, nor to be harmful in routine patients [33]. Adjustment of the I:E ratio should be made to effect the greatest volume for the least amount of pressure, without creating auto-PEEP. Multiple authors have shown that pressure controlled ventilation (PCV) will improve compliance compared to volume controlled ventilation (VCV), while also decreasing *peak* at the expense of increasing *mean* airway pressure [39, 45]. The retroperitoneal surgical approach causes less peak inspiratory and plateau pressure and higher compliance than does the transperitoneal approach.

Lower Limb Circulation

PPT will enhance venous stasis and vascular resistance in the lower extremities in proportion to the IAP [46], with evidence of an ischemia-reperfusion syndrome derived from elevations in plasma oxidative stress markers and reductions in total antioxidant status [47]. These effects are posture dependent occurring in r-TP, but not in TP. Nevertheless, massive pulmonary embolism (PE) has occurred during laparoscopic hysterectomy in TP [48]. Intermittent pneumatic sequential compression (IPSC) devices reverse some of the physiological causes of ischemia/reperfusion [49]. If the pressure gradient from peritoneum to lower extremities (in r-TP) is neutralized, there is normalization of otherwise elevated SVR, associated with significant increases in CO [50], but that study did not include a subgroup of TP patients. EAES clinical practice guidelines [2] recommend the IPSC device on all prolonged laparoscopic procedures and in combination with low molecular weight heparin (LMWH). Hydrostatic effects causing relative hypotension to the calves may be implicated in TP-dependent calf compartment syndrome and rhabdomyolysis after prolonged robotic cystoprostatectomy [51]. Other risk factors may include constant compression stockings, use of vasoactive drugs, hypovolemia, and hypertrophied calf muscles.

Monitoring Issues

Routine Monitoring

Routine monitoring includes a recent mandate for audible alarms for pulse oximetry and capnography so that a misconnection, hypoventilation, or oxygen desaturation would be more readily detectable [52].

Peripheral Nerve Stimulation

The arms and legs in robotic-assisted laparoscopic radical prostatectomy (RALRP) are inaccessible for monitoring the degree NMB. Understanding the facial twitch is imperative to avoid direct muscle stimulation and subsequent overdosing of agents. Robust stimulation of the muscle innervated by cranial nerves V and VII can be obtained by placing the positive lead over the styloid process and negative lead anterior to the ear canal. Alternatively, new devices can directly measure train-of-four ratios through electromyography, without the clinician feeling or observing the twitch. The consequence of residual NMB in these patients is significant [53].

Hydrostatic Gradients, Blood Pressure, and CVP

For those robotic patients placed in extremes of positioning, the measuring device must be at or referenced to heart level. For example, the "beach-chair" position for orthopedic shoulder surgery has been of significant concern to anesthesiologists after several cases of catastrophic neurological outcomes occurred. In response, the APSF published serial discussions on measurement and management of cerebral blood flow (CBF) and cerebral perfusion pressure (CPP) in extreme positions [54]. Essentially, the complexities of "syphon" versus "waterfall" effects are not completely understood. Figure 4.2 emphasizes these postural hydrostatic effects. Understanding the difference between "referencing" a cuff or a transducer and "zeroing" a transducer is critical to having a sensible discussion on this issue. When monitoring BP, CVP, pulmonary artery occlusion pressure (PAOP), or pulmonary artery pressure (PAP) with an arterial line in patients positioned in steep TP for RALUS, the transducer must be zeroed at the stopcock that is referenced horizontally to the right atrium (5 cm below the sternum at the forth intercostal space). One must then account for any negative hydrostatic gradients to the calf or positive gradients to the cranium. Similarly, a BP cuff should be close

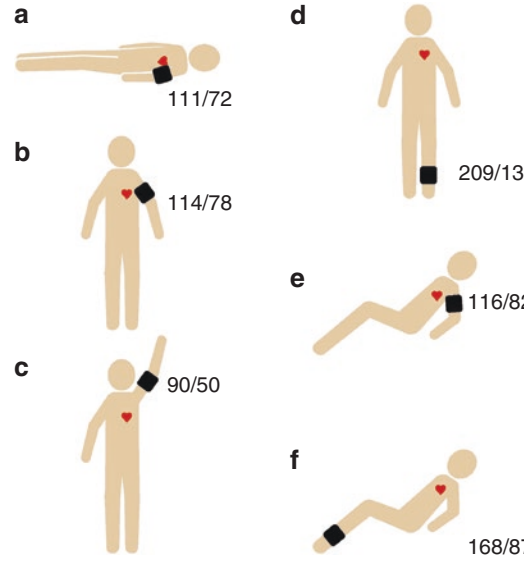

Fig. 4.2 Actual blood pressure readings of the author, taken in triplicate in various locations and body positions. Note similar readings in **a**, **b**, and **e** when the cuff is near heart level, despite posture, and note the decrease in pressure reading when the measurement site is above the heart in **c**. This reading is lower because of a negative hydrostatic gradient. Alternatively, when the pressure is measured below the heart in **d** and **f**, the reading may be dramatically higher, depending on the depth of the hydrostatic gradient. See text for details

to the heart level, on the biceps, and certainly not on the elevated calf or ankle. Experts suggest that the pressure reading be adjusted for the hydrostatic gradient, according to the organ at greatest risk of hypoperfusion [54] (Fig. 4.3).

Pulse Oximetry

The continual measurement of oxygen saturation via pulse oximetry (SpO_2) is a standard of care [52]. The typical placement of a digital probe is not accessible after positioning. Probes placed on the earlobe may read unreliably low, while relatively new forehead reflectance pulse oximetry probes have also been contraindicated by the manufacturer for patients in TP (OxiMax MAX FAST, Nellcor/Tyco Healthcare). Although readings may well be obtained, they are more variable than concurrent finger recordings, and they read lower saturations [55]. A recommendation must

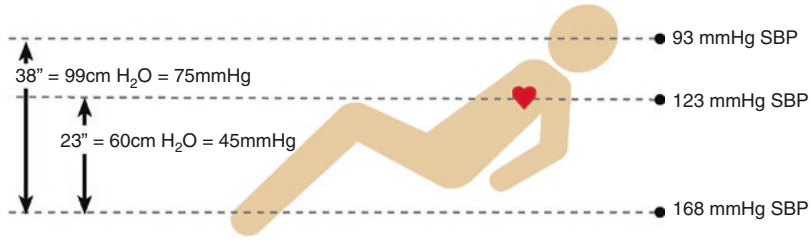

Fig. 4.3 Mathematical corrections of a systolic pressure of 123 mmHg measured at heart level. Since the brain is 15 in. above the heart (= 39 cm H_2O = 30 mmHg), the pressure is reduced to 93 mmHg. Similarly, the ankle reading is 23 in. below the heart and the pressure is increased by 45 mmHg to 168 mmHg. Generally, 1 vertical inch converts to 2 mmHg change. Similarly 4 vertical centimeters converts to 3 mmHg. *mmHg* millimeters of mercury pressure, *cm* H_2O centimeters water pressure, *SBP* systolic blood pressure, ″ inches

be made for using conventional digit sensors in patients placed in TP with PPT.

Capnography and Pulmonary Function

The capnogram yields very useful information about resistance to exhalation from alterations in pulmonary mechanics, or from obstructive lung disease or bronchospasm during PPT. With expectations of particularly difficult ventilation, arterial cannulation should be considered for blood gas sampling. Caution is advised in the use of capnography to predict pCO_2 in the elderly patient and those with cardiopulmonary disease, since there is an increase in the $P(a\text{-}Et)CO_2$ difference in patients under PPT for Lap-C [56] secondary to an increase in dead space ventilation (increased V/Q) and/or a decrease in CO.

Pre-anesthesia Assessment

The pre-anesthetic evaluation of the laparoscopic [34] and RALUS [57] patient specifically addresses potential problems with ICP, IOP, hemodynamics, ventilation, volume loading, and positioning. Since postoperative edema of the face, eyes, and larynx might delay extubation, necessitate re-intubation, or require insertion of oral or nasal airways, any known or suspected preoperative airway challenges will be magnified in the postoperative period. Compression of nerves is not always directly responsible for postoperative deficits, as preexisting susceptibilities have been described particularly for ulnar neuropathy. Anesthesiologists should document these preexisting susceptibilities. Since IOP will rise during PPT and TP, glaucoma may be a significant concern. Cervical spine disease and limited range of motion may be a factor if the patient is in the lateral position with flexion, causing lateral displacement of the cervical spine with the potential stretch of the brachial plexus or exacerbation of spinal stenosis. Lateral flexion of the lumbar spine might exacerbate foraminal stenosis, back pain, or radiculopathy. Any calf pain, myopathies, or use of statin drugs should be considered whenever the legs are elevated and compressed in leg holders.

Cardiac issues are common in the elderly urological patient. Those with new or unstable exertional angina or dyspnea should be evaluated with stress echocardiography to stratify risk and to optimize management with beta-blockers, nitrates, and/or aspirin preoperatively. Echo or stress testing in compromised patients [58] detects abnormalities in up to 71% and would lead the anesthesiologist to select optimal drug combinations in light of the SVR and pulmonary vascular resistance (PVR) effects of PPT and TP. Those with drug-eluting coronary stents may need several days to discontinue thienopyridines [59] and should continue 81 mg aspirin according to a recent ASA practice alert [60]. The thienopyridine should be reinstituted as soon as possible after surgery. Murmurs require echocardiographic diagnosis since valvular dysfunction may profoundly alter hemodynamics under PPT

and TP. Modern pacemakers or automatic implantable cardioverter-defibrillators (AICDs) are complex and require specific interrogation of the battery, rate-responsive mode functions, and magnet effects [61]. The AICD function must be reactivated postoperatively.

Patients with severe chronic obstructive pulmonary disease (COPD) and/or reactive airways, and especially symptomatic obstructive sleep apnea (OSA) must be assessed for risk and counseled for postoperative recovery, continuous positive airway pressure (CPAP), or ICU ventilation. OSA is predominantly associated with obesity and is caused by a decrease in pharyngeal muscle tone with soft tissue obstruction under sedation or during sleep. The syndrome leads to hypopnea, apnea, hypoxia, and hypercarbia with sympathetic activation, leading to hypertension, tachycardia, cardiac dysrhythmias, and congestive failure [62]. Preoperative bronchodilator therapy may be indicated in those with COPD or reactive airways, and incentive spirometry could be helpful in these impairments to prevent postoperative atelectasis that might occur with splinting after renal procedures. Bowel preparations include magnesium citrate which will promote loss of intravascular/interstitial volume, causing hypovolemia in addition to NPO status, or previous intravenous dye studies that might further cause an osmotic diuresis.

Anesthesia Intraoperative Concerns

Airway Management

Although several studies describe the use of various laryngeal mask airway devices for spontaneous ventilation during laparoscopic surgery, these have typically been performed in short duration, outpatient surgery and/or cholecystectomy with the patient in r-TP. Endotracheal intubation is considered standard management for RALUS.

Neuromuscular Blockade

Most clinicians assume that deep NMB will soften the abdominal wall and increase intraperitoneal compliance, or increase pulmonary compliance. There is evidence to the contrary, and the use of 1 MAC isoflurane/fentanyl without *any* NMB provided adequate surgical conditions in two-thirds of patients undergoing open radical prostatectomy [63]. Nevertheless, the use of NMB during robotic surgery would be considered routine, as the risk of movement or coughing during robotic surgery could cause injury.

Anesthetic Maintenance Drugs

Historically, numerous combinations of volatile and intravenous anesthesia have been described for laparoscopic surgery, with general emphasis upon the rate of emergence, the incidence of nausea and vomiting, the hemodynamic profiles, emergence delirium, postoperative pain, and the patient's satisfaction. It is difficult to prove significant clinical differences in outcome, with so many possible combinations of drugs. Choice of anesthetic agents is based upon preference, experience, hemodynamic and side-effect profiles, but specific adjuvants are discussed elsewhere in this chapter. Total intravenous anesthesia (TIVA) without volatile agents is one option and might include propofol, midazolam, ketamine, and remifentanil administered as infusions. The use of N_2O is controversial since it can diffuse into bowel with solubility much greater than nitrogen and also diffuses into a CPT, but there seems to be no conclusive evidence against its use in laparoscopic surgery [64].

Fluid Management

The perioperative inflammatory response and its effects upon the plasma-interstitial oncotic barrier may well be disrupted by indiscriminate amounts and types of intravenous fluid [65]. Hypervolemia increases perioperative risks of bowel dysfunction, anastomotic leakage, pulmonary edema, wound infection, and cardiovascular complications [66, 67] in major abdominal surgery. Documented reductions in UOP with colloid fluid restriction do not cause acute renal

failure [67]. Chappell et al. [65] emphasizes the use of crystalloid to replace urine output, actual deficits, and minimal insensible losses only and not presumed NPO deficits or ongoing third-space losses. Judicious colloid use is recommended to replace intravascular blood loss (Table 4.3). Hypervolemic crystalloid therapy may worsen a shift (as much as 80%) into the interstitium that otherwise might be limited and caused by the surgical inflammation itself. Furthermore, 60% of colloid may also shift outward if given in excess of normovolemia and may trigger the release of atrial natriuretic peptide, a substance known to injure the endothelial glycocalyx causing a further cascade of immunological injury [65]. Intravenous fluids may need to be increased in TP patients prior to exsufflation and leveling the operating table, as sympathetic tone is removed. A reduction in volatile anesthetic and treatment with a pressor may concurrently serve to restore the intravascular volume. Surgeons may request an induced diuresis in particular types of procedures.

Table 4.3 A rational approach to perioperative fluid management

Current physiological insights into fluid management
• Blood volume after fasting is normal
• The extracellular deficit after usual fasting is low
• Insensible fluid loss is negligible
• A primarily fluid-consuming third space does not exist
• Crystalloid overload can induce fluid and protein shifts to the interstitium
• Crystalloids load the interstitial space 4:1
• Colloidal overload deteriorates the vascular barrier
• The endothelial glycocalyx is diminished by hypervolemia
Recommendations for fluid management
• *Optimizing* does not mean *maximizing* blood volume
• Maintain adequate circulation and oxygen delivery to tissues
• Abolish preoperative volume loading in normovolemic patients
• Abolish routine replacement of high insensible and third-space losses
• Replace urine output and insensible (0.5–1.0 mL/kg/h) losses with isotonic crystalloid
• Replace actual blood loss (and protein-rich fluid shifts, if any) with iso-oncotic colloid
• Replace all fluids in a timely, "as-needed" manner
• Use specific goal-directed therapy, not *restrictive* therapy

Derived from Chappell [65]
Abbreviations: *mL/kg/h* milliliters per kilogram per hour, *iso-* isosmotic

Complications

The anesthesia provider may encounter several intraoperative complications that may be reduced, attenuated, or eliminated through proper preparation, monitoring, or intervention [37]. These include peripheral nerve injury, gas embolism, subcutaneous emphysema, peripheral and pulmonary edema, hypertension, sudden cardiovascular collapse, pneumothorax, and endobronchial intubation. A host of surgical complications are beyond the scope of this chapter. Subcutaneous emphysema is normally self-limited but may require deflation of the abdomen and subsequently lower IAP should the gas traverse into the thorax, mediastinum, and cervical regions. Sudden cardiovascular collapse may occur as the abdomen is inflated, induced by vagal stimulation [68], but may also be caused by primary dysrhythmia, myocardial infarction, tension pneumothorax, severe respiratory acidosis, cardiac tamponade, anaphylaxis, or gas embolism [37, 69]. The embolism of CO_2 gas is physically different from nitrogen, due to its higher solubility and easy elimination through ventilation, but cardiovascular collapse from sudden and massive CO_2 embolism would require similar aggressive intervention [69], and the $EtCO_2$ initially increases before decreasing [37]. Oxygen desaturation may be caused by the cephalad migration of the diaphragm causing endobronchial intubation. Peripheral nerve injuries include the peroneal, femoral, and ulnar nerves. The former risk might be attenuated by carefully positioning the legs in stirrups and avoiding direct pressure on the common peroneal nerve, or avoiding tape compression across the thighs. Brachial plexus injuries might be caused by shoulder braces pushing down the shoulders, and this method of securing the patient might be avoided by using foam, bean, or gel mattresses.

Blood loss is consistently minimal (mean 109–191 mL) for RALRP [70], but may be far greater for radical cystectomy and nephrectomy depending upon the degree of anatomic abnormality, disruption by tumor, and/or vascular invasion.

The Specific Conduct of Anesthesia

Reported Methods

Multiple reviews on RALUS anesthetic considerations have now been published [57, 71–79]. Some recommended additional large-bore IV access, although this seems less relevant today; silicone gel pads; and awake tucking of the arms to ensure comfort.

Costello and Webb [73] described their management of 40 patients for RALRP: the use of fractionated heparin (enoxaparin) administered the evening before, and the evening of the surgery; intra-arterial cannulation of the radial artery; pulse oximeter probe on the earlobe (see previous concerns); general anesthesia with midazolam/propofol induction, remifentanil/sevoflurane maintenance, and intravenous morphine for postoperative analgesia; combination lumbar epidural analgesia with oral clonidine to augment analgesia to provide better hemodynamic stability, to modulate the acute tolerance effects of remifentanil, and to lower IOP; dosing of the epidural at the end of the case with only local anesthesia, followed by catheter removal; a minimum 2 L of crystalloid and 1 L of colloid; and caution with the use of non-steroidal anti-inflammatory drugs (NSAIDs).

Conacher et al. [57] minimize IAP to reduce its effect upon RBF, GFR, and UOP, and used mannitol and/or furosemide to lower ICP and IOP or to induce diuresis to flush the kidney in certain pyeloplasty procedures; concomitantly they routinely volume pre-loaded their patients to counteract the immediate effects of IAP but reduced fluid administration for those patients placed in TP; NSAIDs were avoided in patients with borderline renal function; maintenance anesthesia included remifentanil, and they placed CVP lines but minimized use of arterial lines; analgesics included low-dose ketorolac and diamorphine, narcotics and only occasional patient-controlled analgesia (PCA) morphine, since it increased postoperative ileus (POI), nausea, and time to discharge; epidural analgesic techniques were discounted as unnecessary, except perhaps for cystectomy and ileal conduit, where the sympathetic blockade was observed to increase bowel activity thereby easing surgical manipulation and reducing POI.

Phong and Koh [72] described post-extubation respiratory distress secondary to laryngeal edema from prolonged TP and IAP, in association with high endotracheal tube (ETT) cuff pressure. They recommended the cuff leak test as a pre-extubation indicator of edema. They also described transient C5/6 brachial plexus neuropraxia with weakness only, ascribed to pressure from the shoulder brace.

Gerges et al. [74] described the pharmacology of their multimodal techniques, incorporating oral and/or intravenous NSAIDs, acetaminophen, *N*-methyl-D-aspartate (NMDA) antagonists (ketamine), and alpha-2 agonists (clonidine and dexmedetomidine), added to short-acting volatile agents/narcotics (sevoflurane, desflurane, remifentanil), or weak narcotics such as tramadol, to facilitate rapid emergence from anesthesia.

Lew and Sullivan [75] prefer arterial line BP monitoring and recommend isovolemic fluid management, describing the methods and limitations of determining that value, and recognizing that RALUS patients require less fluid than patients for open surgery. They use a non-slip foam egg crate mattress taped to the OR table, and without a sheet between the patient and egg crate. Padded sleds secure the adducted arms to the body.

Awad et al. [76] provide an extensive review of the literature similarly outlining the cardiovascular, intracranial, renal, intraocular, pre- and intraoperative concerns described above. They reference a significant incidence of peripheral nerve injuries and describe their method of securing the patient with a body-fitting bean bag and interspaced gel pad while taping the bean bag to the table, and padding the shoulders and arms within the bag.

Gupta et al. [77], describing gynecologic robotic-assisted laparoscopic surgery (RALS), secure their patients by using foam pads on the chest strapped in an X-like pattern, to prevent sliding. They also insert two peripheral intravenous lines, as a precaution against rapid bleeding, and they prefer a standard mixture of propofol induction, atracurium relaxation, ondansetron anti-emesis, isoflurane, fentanyl, midazolam, and glycopyrrolate, and they uniquely describe the use of hydrocortisone to prevent laryngeal and ocular edema. They prefer PCV with low tidal volumes (6–8 ml/kg) using moderate PEEP (4–7 cmH_2O). They limit IV fluid until the release of the PPT.

Berger et al. [78] reviewed a host of unique complications in RALUS patients, additionally including: higher conversion rates to open surgery in the morbidly obese, hypovolemia from fasting and bowel preparations, reflux, impaired visualization and communication in crowded operating rooms, alopecia from prolonged scalp pressure, endoscopic light burns, surgical bleeding requiring transfusion in 0.8–2%, and non-recoverable robot failure in 0.4%.

Most recently, Lee [79] reports a plateau in the rate of robotic approach to prostatectomy, now at 80% in the USA. He concludes that RALUS reduces hospital stay, blood loss, postoperative pain, and provides a more rapid return of urinary function and higher rate of potency than traditional open surgery. RALUS is documented to have a 6.6% incidence of positioning injuries. He similarly prefers PCV with tidal volume 6–8 ml/kg and PEEP of 4–7 cmH_2O, or the alternative inverse ratio ventilation with 2:1 or 1:1 I:E ratios, to increase mean airway pressure. Similar to this author's concerns, he recognizes that a cross pattern of taping the chest could reduce lung compliance, and he states that increased SVR may lead to a reduction in stroke volume and increased myocardial wall stress and oxygen demand. He does not suggest the use of a vasodilator, however, as does this author.

Local Anesthetics and Nerve Blocks

Pain related to RALUS may be visceral or somatic, secondary to the organ dissection, the trocar insertion sites, diaphragm stretch from PPT, and/or insufflant chemical irritation. A review of 24 studies of intraperitoneal local anesthesia showed only a mild indication of benefit when using 20 mL of 0.25 or 0.75% ropivacaine, each given twice during surgery [80]. Alternatively, the transversus abdominis plane (TAP) block is a peripheral nerve technique that is gaining popularity for many laparoscopic abdominal surgeries, but may need further randomized trials to declare its benefit, despite the ease of insertion and feasibility even in obese patients [81].

Epidural Supplementation

Epidural analgesia (EA) with local anesthetics (LA) provides superior postoperative analgesia compared to systemic opioids, particularly with patient ambulation [82], less impairment of postoperative renal function after RALUS oncosurgery [81], the promise of less tumor progression in patients undergoing open radical prostatectomy [83], superior suppression of the sympathetic nervous system and oxidative stress [84] and improved postoperative diaphragmatic function [85]. Systemic opioids were shown to have the highest risk of nausea and sedation, while EA had the highest risk of pruritus, urinary retention, and motor block. However, motor block and nausea were reduced with patient control of the EA (PCEA). Specifically, thoracic (as opposed to lumbar) epidural analgesia (TEA) is considered to be the most effective neuraxial technique for improving outcomes in pain, kidney function, POI, stress response, catabolism, hypercoagulability, immune suppression, and cardiopulmonary complications [82]. Furthermore, thoracic location eliminates motor blockade, decreases dose requirements, and causes less urinary retention [82]. A Cochrane review demonstrated that TEA with LA alone shortens POI from 37 to 24 h compared to the use of IV or neuraxial narcotic agents [86]. TEA may also have beneficial effects on ventilation, demonstrating significantly lower peak inspiratory pressure and higher dynamic compliance

with larger expiratory tidal volume when compared to general anesthesia (GA) alone [26]. Although these benefits are real, they may not apply to patients with ever-shorter hospital stays.

Subarachnoid Supplementation

Our practice has considered the use of adjunctive subarachnoid block (SAB) in combination with GA, for the conduct of RALUS. In particular, we have utilized SAB, instead of TEA, out of convenience, the expedition of care, and presumed benefits that would be analogous to TEA (no data to support this notion). The SAB is established prior to GA, for the primary purpose of providing a sympathectomy to overcome the physiological effects of elevated SVR while in TP with PPT. A secondary purpose is to provide a multimodal, narcotic-sparing anesthetic to reduce POI. Isobaric tetracaine with intrathecal fentanyl may be used for longer duration surgeries, but we have used hyperbaric bupivacaine/epinephrine without narcotics in the shortest (RALRP) cases, administered in the sitting position. The literature supports the anti-inflammatory effects and metabolic stress reduction of neuraxial blockade, as a means to improve surgical recovery [87]. One study demonstrated significantly lower pain and analgesic use in gynecologic robotic patients receiving combined spinal narcotic with general compared to GA alone [88]. Surprisingly, they did not incorporate local anesthetics. Therefore, an outcome study in RALUS patients ought to test the effectiveness of this combined technique on hemodynamics, bowel function, and quality of recovery.

Pharmacologic Multimodal Analgesia

Pharmacologic multimodal analgesia (PMMA) has been evaluated as a discreet concept for >20 years, and it serves to minimize the use of narcotic analgesics to avoid their complications of sedation, respiratory depression, nausea, vomiting, pruritus, POI, and urinary retention. PMMA refers to the adjunctive and continuous perioperative use of NSAIDS (e.g., ketorolac, ibuprofen, naproxen, diclofenac), selective cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib, valdecoxib), and dexamethasone, ketamine, tramadol, dexmedetomidine, clonidine, acetaminophen, gabapentin, and pregabalin in various combinations. Neuraxial and local analgesia is also part of the PMMA concept but is separately considered above. The benefits of PMMA (only 30% reduction in postoperative narcotic requirement) are challenging to ascertain given various types of surgery and potentially adverse effects on coagulation, renal function, stroke, or coronary events [89, 90]. However, White et al. [91] emphasize that most PMMA studies have compared only a single adjuvant in combination with morphine, and they found little to no data justifying specific treatments of post-RALUS pain.

Following a meta-analysis of NSAIDs, COX-2 inhibitors, and acetaminophen, Elia [90] determined that only NSAIDs resulted in a significantly combined reduction in pain scores, nausea/vomiting, and sedation. He also determined an association with new renal impairment in 1.7% of those on COX-2 inhibitors and an increase in surgical bleeding from 0.2 to 1.7% in those taking NSAIDs. Others have shown no significant increase in renal impairment from COX-2 inhibitors or NSAIDS [92].

Ketamine (NMDA receptor antagonist) has shown similar reductions in morphine requirement but no reduction in the incidence of nausea and vomiting and questionably improved functional outcome [82, 93]. Gabapentin showed no clinically significant reduction in pain score or PONV, and it increased the risk of sedation [94]. Liu [82] confirmed that only NSAIDs and ketamine demonstrated statistically significant reductions in pain scores, while only NSAIDs reduced the risk of opioid-related side effects (nausea, vomiting, and sedation). Future outcome research must focus on patient satisfaction, with pain being only one part of that outcome.

Acetazolamide has been shown to reduce the postoperative referred pain of laparoscopy secondary to the presumed actions of carbon dioxide in the acidification of the peritoneum [95]. Dexmedetomidine, like clonidine, is a specific

alpha-2 adrenergic agonist that inhibits sympathetic activity and provides antinociceptive and sedative activity in animals [24]. In humans, it is administered intravenously for sedation but may not alone provide significant amounts of analgesia without heavy sedative or even general anesthetic effects, and it is more effective for pain when given neuraxially. We use low-dose dexmedetomidine to attenuate the sympathetic response to PPT and TP in RALRP, but the cardiovascular and sympathetic effects of the drug are complicated and cause bradycardia or even cardiac arrest when other vagotonic drugs are administered [96].

Promotility and Antiemesis

POI is a multifactorial problem and may be attributed to anastomotic leakage, pelvic hematoma, urine, bowel wall edema or narcotics, leading to prolonged recovery [97, 98]: (1) metoclopramide has no advantage for motility, since it has no effect on the colon and may cause sedation; (2) propranolol may help through inhibition of catecholamines; (3) neostigmine, despite its muscarinic effects, is ineffective; (4) NSAIDs and narcotic-sparing techniques are advantageous; (5) methylnaltrexone and alvimopan [98] may be effective; and (6) lidocaine by infusion is recently advocated in laparoscopic colectomy. Effective antiemetic routines have been extensively reviewed [99], but the incidence remains high at up to 30%.

Author's Preferences for Anesthetic Management

A second IV is typically placed in the external jugular for three reasons: to provide immediate access, blood sampling capability, and avoidance of unrecognized infiltration of the arm. We do not routinely place intra-arterial catheters, except for longer duration radical cystectomy in which there is no intraoperative access to the radial artery, but this may depend upon the skill of the surgeon. Depth of NMB is measured through stimulation of cranial nerves V and VII at the styloid process. Hydrostatic issues for ICP and IOP are worrisome, but we do not administer mannitol or furosemide, and recent evidence suggests that CBF and CPP increases more than ICP in TP [100]. We flex the neck while in TP, thus elevating the eyes about 5–10 in., reducing the hydrostatic pressure by about 10–20 mmHg. We secure the patient primarily with dense "memory foam" padding and cross-taping, and use shoulder braces only as a precaution against sliding, but not with pressure against the shoulders. The arms are padded and tucked with the palms against the thigh, thumbs anterior, to minimize pressure on the ulnar groove. We routinely use IPSC devices. The depth of the ETT is minimized to avoid endobronchial migration. Our group has combined single-dose tetracaine spinal anesthesia with general anesthesia in a variety of RALUS procedures, but not routinely. Reduction of perioperative opioids and volatile agent (isoflurane) is accomplished through the use of vasodilators instead, to control the PPT-induced hypertension. We do not typically use N_2O or remifentanil, and desire low intraoperative fluid administration (<1000 mL crystalloid) during PPT in TP for RALRP (without neuraxial blockade), recognizing the expected decline in UOP until the abdomen is deflated and table leveled, at which time an additional fluid bolus of approximately 1 L is administered. The patient is induced with 1–2 mcg/kg fentanyl, propofol, and rocuronium with isoflurane. We have selectively used multimodal adjuncts and eliminated all narcotics in some cases, using acetaminophen or celecoxib premedicants with intravenous clonidine (or occasionally dexmedetomidine infusion), ketorolac (if no celecoxib), and ketamine. Hemodynamic stability is achieved with the alpha-2 agonists or if additional control is needed after insufflation, nicardipine infusion (5–10 mg/h) provides highly effective and controllable attenuation of high SVR. Patients are routinely extubated at the conclusion of RALRP and nephrectomy but may require a short period of postoperative intubation in the upright position for laryngeal edema after prolonged cystectomy in TP. Finally, the external jugular line provides an excellent surrogate of

CVP with a typically robust waveform, due to the venous distention in steep TP posture.

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5 Robotic Urologic Surgery: How to Make an Effective Robotic Program

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Abstract

Robotic urology is here to stay and the its acceptability is increasing by each passing day. The hospitals are keen to initiate the program but as this is a huge undertaking and involves major financial investment along with the need for appropriate infrastructure and medical team. This chapter aims at guiding the institutions in identifying the thrust areas that need to be addressed to ensure the establishment of a successful robotic program.

Keywords

Robotic surgery · Urology · Hospital · Surgery

Introduction

The technical improvement is an integral part of surgical evolution. Surgeons are always striving to make their procedures more effective and less invasive. This has led to the introduction of minimally invasive surgery with the objective of replicating the open procedure using minimal access, and minimal incisions. Despite the initial resistance, laparoscopic surgery soon became the standard approach for numerous procedures. This kind of surgery has been shown to offer many advantages, such as less pain, better cosmetics, early recovery, and early discharge [1, 2]. However, it also suffers from several limitations, such as 2-D vision, counter-intuitive motions, poor ergonomics, rigid instruments, and steep learning curves [3]. There was a need for a technology that could overcome the shortcomings of laparoscopic surgery. In this context, the introduction of robotic surgery was a breakthrough, as it revolutionized the field of minimal access surgery. The improved vision, dexterity, ergonomics, ability to overcome the anatomical challenges in pelvic surgery, movement scaling, high precision, intuitive movements all contributed to the increased acceptability and diffusion of this technique [4]. Today, robotic-assisted surgery has replaced open surgery for many procedures, especially in the urological field. It has been estimated that there are more than 1400 robots in the United States alone [5].

Robotic-assisted radical prostatectomy has been the torchbearer for this robotic revolution. The major credit goes to Menon and his Henry Ford Hospital team, who demonstrated the feasibility and safety of the robotic prostatectomy and almost single-handedly led to its wide acceptability in the United States, and worldwide [1, 6, 7].

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The robotic platform has now percolated across various surgical disciplines like gynecology, general surgery, cardiac surgery, and pediatric surgery.

While it offers many advantages, adopting a robotic surgery program comes with many challenges. Among other things, such a program involves a substantial financial investment, as well as provision of space, renovations, procurement of a well-trained surgical team, and the recurring cost of disposables. The goal of this chapter is to highlight the requirements to start an effective robotic urology program, which can ensure a long-term success.

The Formation of an Institutional Policy

The Need for a Plan of Action

The first step towards establishing a robotic program is to have a planning committee in place, which should include hospital administrators, surgeons, anesthetists, human resource managers, technicians, nursing administrators, and financial advisors. The inclusion of the specialists from various divisions helps in proper brainstorming and redressal of the concerns and interests of all the involved parties. This committee has the task of assessing the need and viability of a robotic program in a particular institution. The short term and long term goals should also be established at the outset in order to have a baseline that can be used to measure outcomes in future. The team should determine if a robotic program is required at the specific institution, and if it will serve its best interests. This can be performed by assessing several factors, such as patients' demand, the level of competition with other hospitals, and loss of patients to referral due to the lack of robotic facility at the institution. It is also advisable to evaluate data from other hospitals who have recently started a robotic program and assess the changes in their patient volumes, economic effects, and overall outcomes. Another issue is the availability of an adequate infrastructure, which is essential for establishing a new robotic program. The planning committee should also identify the surgical services, which are most suited and ready for an upfront implementation of the robotic program. This is an extremely important step as the results of this will actually determine the viability of the robotic program for that specific institution and an erroneous choice can curb the aspirations of the institution to continue the program. As it may not be viable to procure a robot just for one surgical discipline, it may be necessary to have a plan of action ready for the development of other departments. The availability of surgeons who are already trained in the robotic surgery is mandatory and should be looked in to. The Institute may need to hire a specialist to start the program, which might add to the economic burden. Surgeons that are already working with the Institute may need further training and mentorship to overcome their learning curve. Such trainings require a monetary investment, and the logistics of this should be worked out. As with any new technology, the institute should be ready to accept the fact that the financial benefits will be delayed and they should be ready to bear the additional financial burden till the program is successful. For all these reasons, an institute should be realistic in its assessment of the outcomes of a new robotic program, especially during the learning curve period of the surgical team. Likewise, all efforts should be made to mitigate any harm to patients during the implementation period, and thereafter.

Administrative Coordination and Marketing

It is advisable to have a robotic program coordinator who acts as a bridge between the operating team and the administration. The Coordinator is the primary person who is responsible for overseeing the development of the robotic program and can coordinate with the technical team, administration and the surgical team on a regular basis.

The need to have a marketing team in place is also essential to make a new robotic program

successful. The team may help in the initial assessment of the patient pool and identification of best avenues for the growth of the program. The team should work out to "sell" the program to the patient population by highlighting the achievements and the results of the institution using robotic technology. They can also collaborate with the surgical team in order to publish patient information brochures, which can be disseminated to the referring physicians as well as to the masses. It is also helpful to have a website in place which can provide information regarding the technology, the literature, advantages and the results of the program at the institution. The use of billboards, print as well as digital media can be of help in marketing.

Cost Benefit Analysis

As the costs of starting a new robotic program include the cost of robot, cost of instruments and disposables, training of the team, maintenance and repairs of the equipment, development of the infrastructure, it should be understood that it will take time to come at par with the cost incurred, and the benefits will be delayed.

Bolenz et al. compared the cost of robotic-assisted radical prostatectomy (RARP) with open radical prostatectomy (ORP) and laparoscopic radical prostatectomy (LRP) in 643 patients. They found that although the mean length of hospital stay for RARP was lower than that of ORP, the median cost was higher (RARP: $6752; LRP: $5687; ORP: $4437; $p < 0.001$). The main contributor to the cost in RARP was the surgical supply cost (RARP: $2015; LRP: $725; ORP: $185) and operating room cost (RARP: $2798; LRP: $2453; ORP: $1611; $p < 0.001$). They concluded that if the purchase and maintenance costs were also included, the expenses incurred would increase by $2698 per patient [8]. Kim et al. also reported similar findings in a cohort of 29,837 patients who had an RARP or ORP. Patients who had an RARP had lesser complications and earlier discharge as compared to ORP. However, they still had higher hospitalization costs ($10,409 vs. $8862; $p < 0.001$) [9].

Steinberg et al. specifically evaluated the effect of the learning curve on the cost incurred. They found that the learning curves varied from 24 cases to 360 cases and the cost incurred to overcome it varied from $95,000 to $1.3 million. The average learning curve was of 77 cases and the cost incurred was $217,034 [10]. It has also been shown that once the learning curve has been overcome, the costs decrease substantially [11].

Alemozaffar et al. compared the cost of robotic partial nephrectomy (RPN) with open (OPN) and laparoscopic partial nephrectomy (LPN) and found that the overall costs were similar for RPN, LPN, and OPN ($6375 vs. $6075 vs. $5774, $P = 0.117$, respectively). The cost of disposables was higher in RPN and LPN than OPN ($2179 vs. $1987 vs. $181, $P < 0.001$, respectively). The prolonged stay in ORP led to higher costs compared with LPN and RPN ($2418 vs. $1305 vs. $1274, $P < 0.001$, respectively) [12]. Hyams et al. compared the cost of RPN with LPN and found that RPN had a higher cost premium ($1066/case) [13].

There is controversy regarding the cost comparison between open, laparoscopic and robotic cystectomy. The length of stay is less with robotic cystectomy which may ultimately decrease the overall cost. Lee et al. compared the costs of robotic radical cystectomy vs. open radical cystectomy and found that cost of robotic radical cystectomy with ileal conduit was $20,659 compared to $25,505 for their open counterparts [14]. On the contrary, Leow et al. found that robotic radical cystectomy had a higher cost than open mainly due to the cost of disposables [15].

Thus it can be understood that a higher expenditure is inevitable with the use of the robotic platform. It should also be considered that there is no direct financial incentive for performing a robotic surgery, as the third party reimbursement rates are not higher than those of open or laparoscopic surgery [3]. As such, this financial burden is mainly borne by the institution. However, once the institution becomes a high volume robotic center, surgeons might be able to maximize their efficiency, output, productivity and patient care pathway, which might in turn greatly mitigate the expenditure, and make it comparable to open surgery [16].

Establishment of the Facility

Operating Room Requirements

A well-planned operating room is essential for safety of the equipment and streamlining of the surgery. It is ideal to have a dedicated operating room for robotic surgery, which is large enough to accommodate the operating console, patient cart, monitors, surgical table, anesthesia equipment, additional screens, recording devices, and nursing trollies. It should also allow an effective navigation in the room if required. There should be an allowance of ample space for the movement of assistants, technicians, and staff. A dedicated operating room also excludes the need for shifting the robot from one room to another, which minimize the chances of damage to the equipment during transportation. A room containing accessory instruments, backup, and troubleshooting equipment should also be available, and easily accessible from the operating room. The inputs from the surgical team, as well as the engineers or sales representatives of the manufacturers can be extremely valuable in optimizing robot operating room planning.

Establishing a Robotic Team

It is imperative that a committed and competent team is mandatory to make the robotic surgery program a success. The team carries the responsibility for patient care and safety along with ensuring the best surgical outcomes.

The operating/console surgeon is the main person who determines the outcomes and should ideally be having large experience in open and laparoscopic surgery, a comprehensive knowledge of the pelvic and the retroperitoneal anatomy and the desired set of surgical skills required for the robotic intervention.

Given that operating (robotic) surgeon is physically away from the patient, the role of the bedside assistant is extremely important during the surgery. Indeed, bedside assistant provides active support during surgery by providing traction, counter traction, suction, irrigation, clipping, etc. Bedside assistant should also be well versed with the docking of the cart, handling of the equipment, and troubleshooting in order to ensure a smooth flow of the operation. The assistant also plays a pivotal role in preparing and training new residents and fellows, who would eventually acquire the role of bedside assistant and operating surgeon in the future.

The availability of competent and trained nursing and technical staff is also essential. The surgical nurse has the responsibilities of ensuring a smooth flow of surgery, and to protect the patient throughout the course of surgery. The robotic team should have an optimal understanding of the robotic system, and they should be able to provide assistance in draping the robot, calibrating the robot, supplying necessary instruments, help in troubleshooting, and overall preparation of the operating room. They should also be ready in case of conversion of the procedure to laparoscopy or open surgery.

The role of anesthetists is also extremely important especially during the learning curve of robotic surgery. The initial procedures, during the learning curve, may run for long durations. Patient positioning during pelvic surgery, prolonged pneumoperitoneum, restricted lung expansion (especially in elderly patients) may pose a significant challenge to the anesthesia team. A competent team, which is well versed with the robotic procedures has the potential to improve the outcomes.

Training Programs

Surgeons should avail all the available opportunities to gain familiarity with the robotic platform. Robotic surgeons are required to have the theoretical, as well as the practical knowledge of working with this highly technological modality. They should be familiar with all the standard operating protocols, as well as have the ability to deal with demanding situations like removing the patient cart rapidly during an emergency, what to do when the system stalls, and basic troubleshooting in order to make the surgery safe for patients. The FDA recommends that manufacturing companies

should provide basic training. As such, Intuitive Surgical provides a basic training, which spans over 2 days [17]. The first day is dedicated to familiarizing the surgeons with the various parts of the console, robot cart, and the equipment. The second day is dedicated to animal model-based training for new robotic surgeons. It has also been recommended that before performing the first individual case, a surgeon should observe at least three cases performed by an expert in the field, and should get himself/herself familiar with the procedure by watching surgical videos. [3] The American Urological Association recommends supervision by a proctor in the initial part of the learning curve of a new robotic surgeon. The proctor should have performed at least 50 robotic cases, with at least 20 cases that are similar to the one being performed. It is usually recommended to have a proctor for at least the first three cases, but the actual required number may depend upon the hospital recommendations [18].

Robotic surgery training has now been included in the American Urological Association's (AUA) core curriculum for residents (www.auanet.org/common/pdf/about/SOP-Urologic-Robotic-Surgery.pdf). The AUA recommends that the program director should make sure that the residents/fellows have adequate training and have performed a minimum of 20 cases before finishing their training. The AUA also recommends that a trainee should have received training on the console for at least ten cases, especially during the key steps of the surgical procedure, before having the privileges to perform robotic surgery. Virtual reality simulators have also been widely recommended for the training purpose [19]. Fellowship programs in robotic urology can add a lot to the newly graduated residents, and have been shown to significantly improve surgery outcomes [20].

Evaluation and Analysis of Outcomes

As with any other branch of surgery, a continuous evaluation and assessment of outcomes is essential for the establishment of a successful surgical program. Regular meetings between the surgical team and the anesthesia team are useful to discuss the expectations and the anticipated difficulties during surgery. This should help in understanding and overcoming the difficulties faced during the procedure. Tools such as Shewhart charts and cumulative summation (CUSUM) control charts can be used for a continuous assessment of skills and patient safety. These methods allow the assessment of the mentorship duration required for a certain procedure and also help in the timely identification of adverse events. New procedures can be considered to be "learnt", when their outcomes match to those of the established surgical technique ("golden standard"). This methodology ensures that patient safety is not compromised during the learning curve of new surgeons [21].

Periodic morbidity and mortality meetings are also essential to assess the growth curve of the robotic program, understand the obstacles, compare the results with those in the literature and plan for measures to improve the overall outcomes. Likewise, outcome research analysis should be conducted by reported periodically, as this allows surgeons to evaluate their outcomes objectively. The results of this analysis can also be disseminated in the public domain, which might help in adding credibility to the surgical team, as well as the hospital. Ideally, endeavors should be made to have a protected database, which contains all the necessary information about patients' profile, procedures, complications, postoperative course and follow up. Such database allows continuous and updated analyses of the trends and outcomes, which might, in turn, allows timely interventions with the aim of improving the quality and growth of the program.

On the administrative level, apart from the evaluation of the outcomes, there should be a time-based evaluation of the available infrastructure, economical parameters (e.g. cost-benefit analysis), economic sustainability, and proper utilization of the available resources. Such assessment can allow prompt adjustments that might be necessary to optimize the benefits of the program. These analyses can also be used to

judge the sustainability of a robotic program in a specific institution.

Conclusion

Robotic surgery is here to stay and has the potential to significantly affect how the surgeries will be performed in the future. It is imperative that with increasing research and development, robotic surgery will continuously evolve and its utilization will expand. More and more institutions will be considering the establishment of a robotic program, which increases the importance of pre-emptive planning in order to achieve the best results.

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6 Laparoscopy Versus Robotics: Ergonomics—Does It Matter?

Theodoros Tokas, Ali Serdar Gözen, Jan Klein, Alexandra Tschada, Thomas Frede, Dogu Teber, and Jens Rassweiler

Abstract

Laparoscopy offers significant benefits to the patients, mainly due to its minimally invasive nature. Nevertheless, it is also characterized by significant ergonomic limitations which make it tedious for the surgeon. Robotic surgery seems to offer a valid solution to this problem but is also accompanied by several important ergonomic handicaps. In this chapter, we want to focus on the ergonomic problems of laparoscopy, in comparison to the da Vinci system, based on the current literature and personal long-term experience with both techniques. Additionally, we present different solutions to the ergonomic predicaments that one may encounter during a complex procedure, and future perspectives that could aid in the creation of ergonomically designed operating theatres for minimally invasive procedures.

Keywords

Laparoscopy · Ergonomics · Robotic surgery · da Vinci · Surgeon posture · Laparoscopic instruments

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Introduction

Laparoscopy has brought many benefits to patients mainly by reducing the peri-operative morbidity. On the other hand, its distribution is handicapped by the difficulty of the procedures due to some significant ergonomic limitations. Even more, it has been recognized, that laparoscopic surgery can also harm laparoscopic surgeons and this phenomenon is now under worldwide investigation [1, 2].

The disadvantages of laparoscopic procedures are mainly due to the nonergonomic design of surgical instruments and the outdated environment of the operating theatre, but also due to the

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lack of proper education of laparoscopists worldwide [3]. As laparoscopic surgery became more advanced and complex, the duration of the procedures expanded and, in proportion, so did the levels of mental and physical stress imposed to the surgical team [4]. Yet so far, only minor changes have been made to the operating room, which was originally designed for conventional operations, and also recently proposed designs by the manufacturers (i.e. OREST - Dornier; OR-1 -Karl Storz) are not based on ergonomic studies [5].

Ergonomics, a relatively new science, gained wide popularity in the field of industrial engineering. Experts began to notice, that when workers do their jobs under nonergonomical circumstances they become stressed and fatigued, resulting in a drop of quality and quantity of production. As the advertising industry began to tout the "ergonomic design" of various cars and household utensils, ergonomics was respected as a serious factor influencing the sales of such products. Today, enormous sums are earmarked for ergonomical research into industrial design. In turn, new software tools have been developed to assess the ergonomic feature of new products. These tools are designed to measure the posture and movement of the human body very accurately, without using any markers.

Unfortunately, medicine did not get in on the ground floor of these ergonomic developments, because in this area productivity and quality cannot be connected as directly to ergonomics as in industry, and the profit gained from ergonomic reorganization is difficult to quantify in financial terms [6]. Thus, the main reason for choosing a particular instrument represents its cost-quality ratio and not its ergonomic design.

However, based on recent efforts from general surgeons and urologists, the assessment of laparoscopic surgery is now under way (Table 6.1). We have already many objective data on the problems that arise in the course of everyday practice, and some attempts have been made to alter the operating environment accordingly [7, 8].

Table 6.1 Components of ergonomics (modified from Stone and McCloy, ref. 6)

To optimise system performance while maximising human wellbeing and operational effectiveness, ergonomics embraces a range of human centred issues:
– Body size (anthropometry), motion, and strength capabilities (biomechanics)
– Sensory-motor capabilities—vision, hearing, haptics (force and touch), dexterity
– Cognitive processes and memory (including situational awareness)
– Training and current knowledge relating to equipment, systems, practices, and medical conditions (including emergencies)
– Expectations and cultural stereotypes related to operations and equipment
– General health, age, motivation, stress levels, and mental fatigue

During laparoscopic operations, surgeons suffer from high levels of mental and physical stress. After a certain time (i.e. 4–5 h) the so-called *fatigue syndrome* sets in characterized by mental exhaustion, reduced dexterity, and a reduced capacity for good judgement [9]. On the other hand, the recently introduced da Vinci robot offers significantly improved ergonomics, by providing a confortable sitting position in a console with arm support. Additionally, a camera offering 3D-vision, as well as a stable robotically controlled instrumentation with 7 degrees of freedom and foot pedals, are provided by the robotic system. However, the device has also some limitations, compared to open surgery and even laparoscopy, such as the complete loss of the tactile sense [10–17].

Mental Stress

Mental stress is caused by numerous factors [18]. The view of the operative situation is displayed on a monitor widely separated from the field of action, so the surgeon has to overcome the natural instinct to direct the eyes to the activity of the hands. Moreover, he cannot reach the operative field directly with his hands. The

two-dimensional viewing of a three-dimensional field has to be interpreted and synchronized to instrument movement by use of only 4 degrees of freedom. In addition to performing the operation, the surgeon has to monitor constantly the different devices used during the procedure (i.e. insufflator, gas-connection, suction device). In case of an inexperienced anaesthetist further factors may aggravate the situation (i.e. degree of relaxation, excessive fluid administration, etc.).

Although it is not easy to measure mental stress, there are early reports using physiologic measurement, such as skin conductance level or electro-occulography. Van der Schatte et al. [19] introduced the following three cardiologic stress parameters:

- The mean square of successive differences between consecutive heart beats (MSSD).
- The pre-injection period (PEP) corresponding to the time of isovolumetric contraction.
- The average heart rate (HRA) recorded by an ambulatory monitoring system.

The MSSD reflects the beat-to-beat variability of the heart rate and is highly linked to respiratory sinus arrhythmia (RSA). Changes in RSA can display changes in vagal activity. If vagal activity decreases, RSA and MSSD will also be reduced because fewer oscillatory changes in heart rate occur. An increased stress level will therefore lead to a decrease in MSSD. In conclusion, high MSSD values reflect low stress level.

The PEP is the interval between the onset of ventricular depolarization and the opening of the semilunar valves. Changes in PEP correspond to changes in ß-adrenergic inotropic drive to the left ventricle. The ß-adrenergic tone can be manipulated by epinephrine infusion, adrenoreceptor blockade, exercise, and emotional stress.

It has been shown, that mental stress can be compensated for with mental effort, but such efforts surely lead to earlier fatigue.

Physical Stress

Standing in a fixed position, determined by the placement of trocars and the site of the screen, causes static strain to the eyes, head, neck, spine, and the joints of the knee and foot, which translates into eyestrain, neck and shoulder pain or stiffness. This phenomenon is accentuated during major pelvic procedures, in which the surgeon has to operate in a parallel axis to the patient. This type of stress can be measured by duration of the stressful postures and the degree of rotation of the joints respectively, and declination of the spine as compared to a comfortable position [20–24]. Further measurements include force plate measurements of the feet and motion analysis. Lee et al. could demonstrate that also the assistant has to face a high-risk ergonomic situation, being created by the assistant's left or caudal leg, bearing 70–80% of body weight over time [25].

In order to pivot the instruments around the trocars, which are fixed to the abdominal wall, increased muscle activity and awkward movements of the upper limb are necessary. The force to control laparoscopic instruments can be six times greater than that needed for open surgery, and the problem is magnified further by the nonergonomic design of the handle. Badly designed hand instruments can even lead to damage of the nerves of the thumb and thenar, causing the so-called laparoscopist's thumb [26].

To measure physical strain precisely, a wide array of sophisticated devices has to be used. The investigative tools for such cinematic studies are based on cinematography, video recording, optoelectronic systems, goniometers, and systems combining photocells, light beams, and timers. The movements (i.e. the posture) of the surgeon are recorded on standard or special (infrared) video cameras for evaluation [27]. In most cases, the individual being measured has to wear a special outfit with reflective markers, motion sensors, electrodes, etc, which is not easily accomplished during clinical cases. Markers attached to the surgeon may drift, and the view of the marker is often obscured during manipulation. It is also uncertain to what degree the wires and attached

sensors may influence the surgeon's movement. For this reason, ergonomic studies are mainly done during laboratory experiments.

The Role of Questionnaires

Beside the objective evaluation of mental and physical stress during laparoscopic or robotic surgery, the analysis of the subjective assessment of ergonomic problems is important [3, 28]. This is mainly based on questionnaires. Such studies have been able to provide information on prevalence, significance, and awareness associated with the different techniques. Hemal et al. [2] found that surgeons performing laparoscopy have indeed significant ergonomic problems resulting in frequent neck pain, shoulder stiffness, finger thumbness, and eye-strain in 13–22.4%. This was significantly more frequent compared a control group of open surgeons who reported such problems only in 6–10.2%.

Ergonomic Limitations of Laparoscopy (Tables 6.2 and 6.3)

Surgeon Posture

Basic studies defined the ergonomic ideal position for the laparoscopic surgeon as follows [26, 29]:

- 20° abduction of the forearms with 40° internal rotation and 10° retroversion
- 90–120° flexion of the elbow
- No rotation of the surgeon

The arm is slightly abducted, retroverted, and rotated inward at the shoulder level. The elbow is bent at about 90–120°, and the hand grasps the instrument in the basic position, with the wrist slightly extended; the metacarpophalangeal and the proximal interphalangeal joints are flexed at 30–50°; and the distal interphalageal joints are almost extended. Fingers 2–5 are abducted by about 5–10°, and the thumb is opposed to the

Table 6.2 The ergonomic problems of laparoscopic surgery

Problem	*Description*
Incorrect surgeon posture	Results mainly in physical stress
Static stress from maintained suboptimal position, no body supports	Musculoskeletal problems (shoulder pain, gonarthrosis) due to rotated and bent position
Joint (spine, shoulder, elbow, wrist, knee) angulation	Musculoskeletal problems (shoulder pain, gonarthrosis)
Paralel axis between surgeon and patient (torero position)	Musculoskeletal problems (shoulder pain, arthrosis)
Weight distribution	Musculoskeletal problems (knee, foot pain, gonarthrosis)
Visual problems	Result mainly in mental stress
Alignment between eyes, monitor and operative field	The view of the operative field is displayed on a monitor widely separated from the field of action. The surgeon has to overcome the natural instinct to direct the eyes to the activity of the hands.
Visual perception—Misalignment in eye-hand-target	Misorientation between real and visible movements on the screen Impaired hand-eye coordination Absence of shadows
2-dimensional vision	2-dimentional viewing of a 3-dimentional field No stereovision (3D-camera and display)
Problems with instrumentation	Result in mental and physical stress
Trocar position—triangulation	Reduction of the range of motion Reduced access to the operating field Conflict between instruments
Instrument articulation—range of motion	Only four degrees of freedom (instead of 6)
Tremor due to fulcrum effect	Inversion of instrument's motion with a varying scaling effect
Reduced haptic sense	Only minimal tactile feedback
Discomfort due to instruments, non-ergonomic handles	Surgeon's thumb, wrist pain

index finger. Maintaining an incorrect surgeon or assistant position can lead to increased static stress, which results in musculoskeletal and joint discomfort or even pain.

The correct adjustment of the table height, respectively the use of stands to avoid the raising of shoulder during laparoscopic surgery, is very important. In the survey of Wauben et al. [3] the chosen table height varied between 45 and 55 cm, with 60% of the surgeons preferring the table at pubic height. The lowering of the patient towards the surgeon may also compensate for insufficient lowering of the table and provide a better angle to the working field (Fig. 6.1a, b).

Especially during a laparoscopic prostatectomy, the surgeon has to operate in a parallel axis to the patient, having to maintain the so-called *torero position* (Fig. 6.2). As the ports are placed bilaterally to the midline, the surgeon reaches over the patient and across the midline during the whole procedure, suffering from chronic shoulder injury. Furthermore, such a position results in an uneven weight distribution (Fig. 6.3a–c) and, as a consequence, in chronic knee, ankle, and foot pain.

Table 6.3 The ergonomic problems of robotic surgery

Problem	*Description*
No tactile feedback	Haptic sense has to be compensated by vision
Minimal control of grasping force	Force has to be adapted by experience (i.e. risk of suture rupture)
No direct access to assistant port	The surgeon is completely dependent on assistant (i.e. suction, clipping, suture insertion)
No direct communication with assistant	Only from Console to OR-table
Assistant limited by arms	Disturbed access, same problems of laparoscopy
Only 2D-vision for assistant	View of surgeon may differ from the view of screen of assistant
Some physical discomfort	Musculoskeletal problems at the neck and shoulder due to the anteflexed position and mental stress

Visual Problems

A major problem is the *two-dimensional view of the telescope*. The absence of shadows, stereovision and movement parallax, in particular, make it difficult for a surgeon to accurately determine spatial distance and movements,

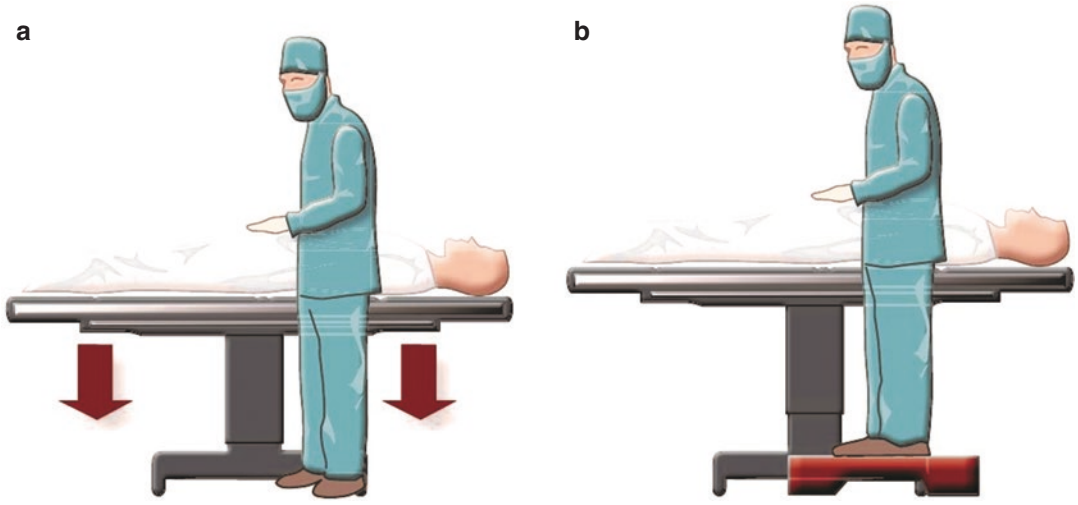

Fig. 6.1 Adjustment of table height in order to maintain optimal elbow (90° to 120°) and shoulder (not raised) position. (**a**) The table should be lowered to 70–80% of the elbow's height. (**b**) In case of non-adjustable table height or shorter surgeon, the use of stands proves to be beneficial

Fig. 6.2 Torero position. The surgeon has to work in a parallel axis to the patient. The medial shoulder remains elevated, causing shoulder sicomfort, and the medial elbow doesn't maintain the optimal angle

thus impairing his eye-hand coordination (Fig. 6.4a). The latter may be compensated by the experience of the surgeon, particularly if the working field is small and the camera can be put close to the object, however especially in case of reconstructive surgery (pyeloplasty, urethro-vesical anastomosis) it may become a crucial handicap [30].

Moreover, during pelvic procedures, the display monitor is positioned toward the patient's lower extremities, requiring a secondary neck strain to maintain it into the optic field and to achieve an eye-monitor-instrument alignment (Fig. 6.4b). Musculoskeletal complaints could result in chronic problems and loss of quality of care, quality of urologists' life, and even to absence from work. Several studies have suggested an optimal monitor position, ideally in front of the surgeon, at a level below to the head and close to the hands. The ideal view angle is 15° below the horizontal line of sight (Fig. 6.5) [18, 31, 32].

In the laparoscopic literature, a number of aids have been described to improve the surgeon's depth perception [33]. Shadows can be

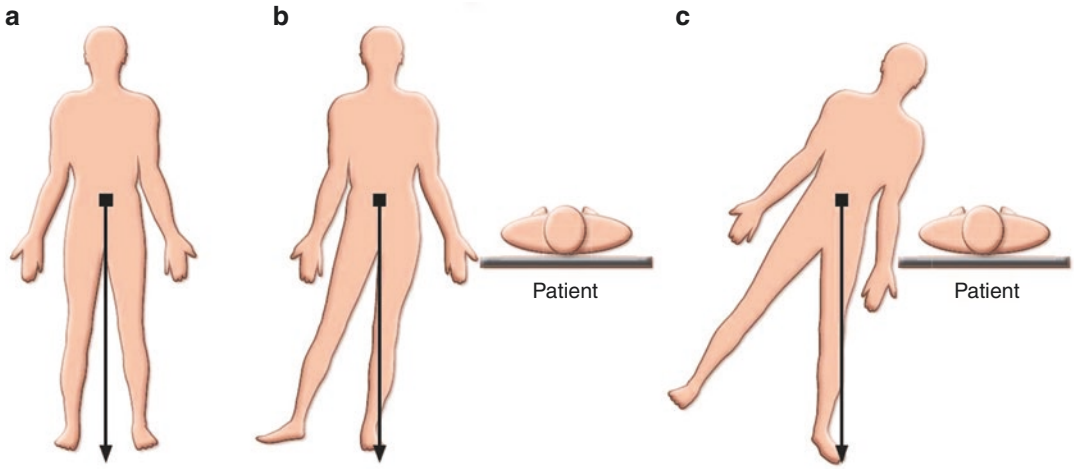

Fig. 6.3 Surgeon weight distribution during laparoscopy. (**a**) The optimal position, maintained in kidney procedures, in which the surgeon doesn't work in a parallel axis to the patient. The weight is equally distributed in the center and between the legs. (**b**) The torero position in pelvic procedures. The surgeon has to bend towards the patient in order to access the instruments in the working trocars. The weight is unevenly distributed to the medial foot, ankle and knee resulting in chronic stress of these joints. (**c**) Extreme case in which the surgeon has to maintain an extended bending position. In this case the contralateral leg has to be continuously raised, resulting in additional stress to the contralateral hip joint and back muscles

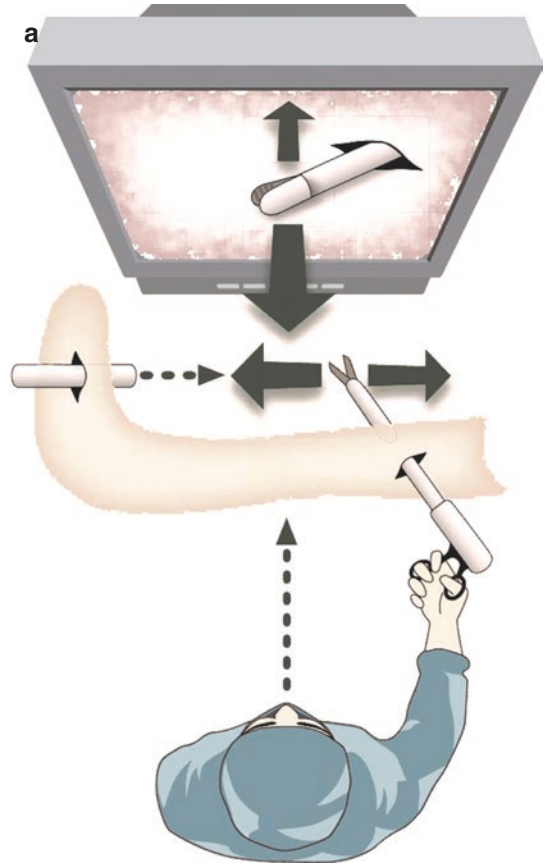

Fig. 6.4 The problem of impaired eye-hand coordination. (**a**) Movement on screen may differ from the axis of the instruments. (**b**) Dissociation of eye-target-axis

Fig. 6.5 The ideal view angle: 15° below the horizontal line of sight

introduced by using illumination cannulae. Stereovision can be introduced by using a stereo-endoscopic system [23]. Comparisons between mono- and stereo-endoscopes, however, have demonstrated that, with current technology, three-dimensional systems show no advantages for the experienced surgeon [34, 35]. Another possibility would be the use of rotatable endoscopes and instruments [33]. However, the recent introduction of *HDTV-technology* has significantly improved the depth perception, mainly due to the better resolution of the image.

In the review of Wauben et al. [3] carried out in the year 2004, only 19% used a flat screen. 71% of the monitors were placed on a tower without height adjustment, and 10% on a movable arm without height adjustment. Even, if the placement of the monitor below the eye-level has been recommended in the ergonomic guidelines based on several randomized studies [28, 36], 77% of the respondents were not hindered by the actual monitor position, and 64% were even satisfied. This correlates with the personal experience of the authors.

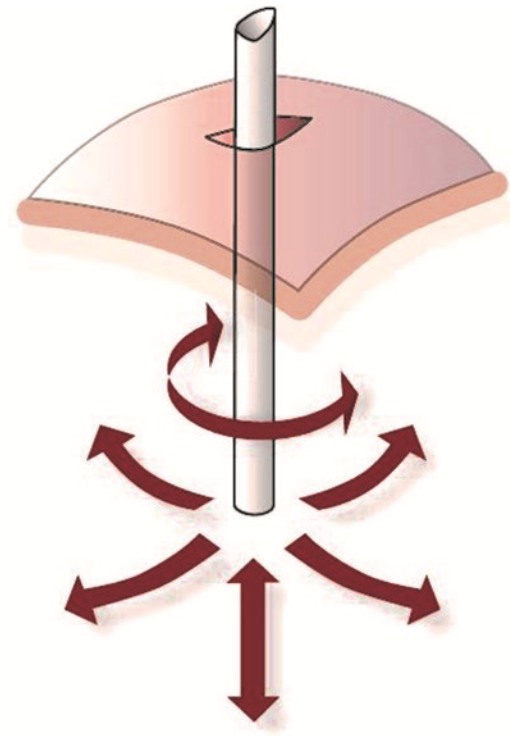

Fig. 6.6 The degrees of freedom (DOF) are limited to four by the incision point that acts like a spherical joint

Instrumentation

Laparoscopic surgery in general is handicapped by the *reduction of the range of motion,* because of the fixed trocar position determining the angle of the respective instrument to the working field [21, 22]. The incision point acts like a spherical joint that *limits the degrees of freedom (DOF)* of the instrument from six to only four (Fig. 6.6): jaw, pitch, rotation, insertion, plus the actuation of instrument. This applies also to the endoscope, making it impossible to observe anatomic structures from different sides while keeping the viewpoint in focus.

An ideal grip for manipulation of the functional elements and holding the laparoscopic instrument is a mixture of three different grips:

– The contact grip characterized by touching an object with parts of the hand;
– The seizing grip carried out by the thumb and one or all fingers;
– The encircling grip employing two or more fingers mainly to perform strenuous work.

The *contact grip* is used for activation of HF-current, suction/irrigation buttons or cogwheels for rotation of the instrument; *seizing grip* for open/closing the effector; and *encircling grip* for holding the instrument. To support this, the instrument's handle must contact the hand at its most sensitive zones: the fingertips and the area between the thenar of the thumb and the inner surface of the hand. The instrument's shaft must represent an extension of the lower arm so as to transfer the turning movement directly to the effector.

Mattern and Waller [26] focused on the requirements of an *ideal handle for laparoscopy*. Mostly in use are two types of handles: ring handle (like scissors) and shank handle, both with an in-line and angled version. Some needle holders have palm-handles (i.e. in-line shank handles), and recently pistol handles have been introduced. Because of their symmetrical form, ring and shank handles can be used equally well by both right and left hands. They can be produced economically and are easy to clean. Ring and shank handles are suitable for one-handed manipulation of two instrument functions (i.e. opening/closing of the effector and rotation; dissector, scissors, etc.). Elements for further functions such as suctioning, cutting with coagulation have no place on these two-dimensional flat handles. For this reason foot pedals have to be used.

Utilizing foot pedals or hand-controlled devices could prove to be an important factor for improving instrumentation. It has been reported that 87% of the laparoscopic surgeons use a foot pedal to control diathermic or ultrasonic equipment [3]. Only a few (17%) use a hand-controlled device. The use of the foot pedals was found to be uncomfortable by more than a half of the respondents (53%). This concerned the lack of visual control, unbalanced

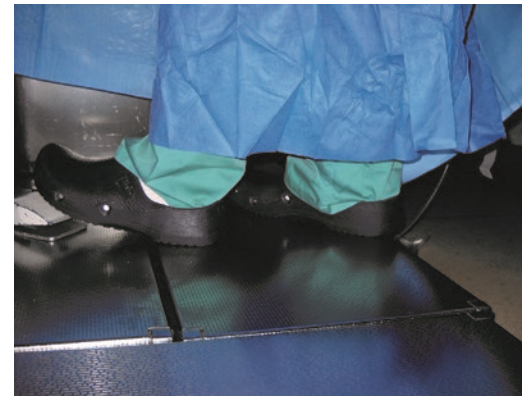

Fig. 6.7 Control of foot-pedal during laparoscopic surgery with the right leg bearing 70–80% of body weight, and 20° anteflexion of left foot

position of the surgeon, and the use of too many pedals during laparoscopic surgery. On the other side, only 5% fully agreed that pedals cause discomfort in the legs and the foot. However, there is no doubt that the surgeon has to flex the foot to control a foot pedal, which requires to balance the body weight on the contralateral leg (Fig. 6.7).

Multifunctional instruments may reduce time-consuming instrument changes. Applying such functions (i.e. coagulation, irrigation/suction) requires special handles. Three-dimensional pistol handles allow the integration of several different elements because of the handle volume. Also motorized 6-DOF-instruments use such handles (Fig. 6.8a–c). However, there have been further modifications of ergonomic multifunctional handles, which can be found in the literature [7, 26, 37]. Unfortunately, most of them remain experimental.

With increasing training and analysis of the important geometrical factors, laparoscopic surgeons were able to deal with some of these problems, even in case of endoscopic suturing [38, 39]. In principle, this means that the angle between the instruments should not be less than 25° and not more than 45°; the angle between the operating field and the horizontal line should not exceed 55°. Moreover, the choreography of endo-

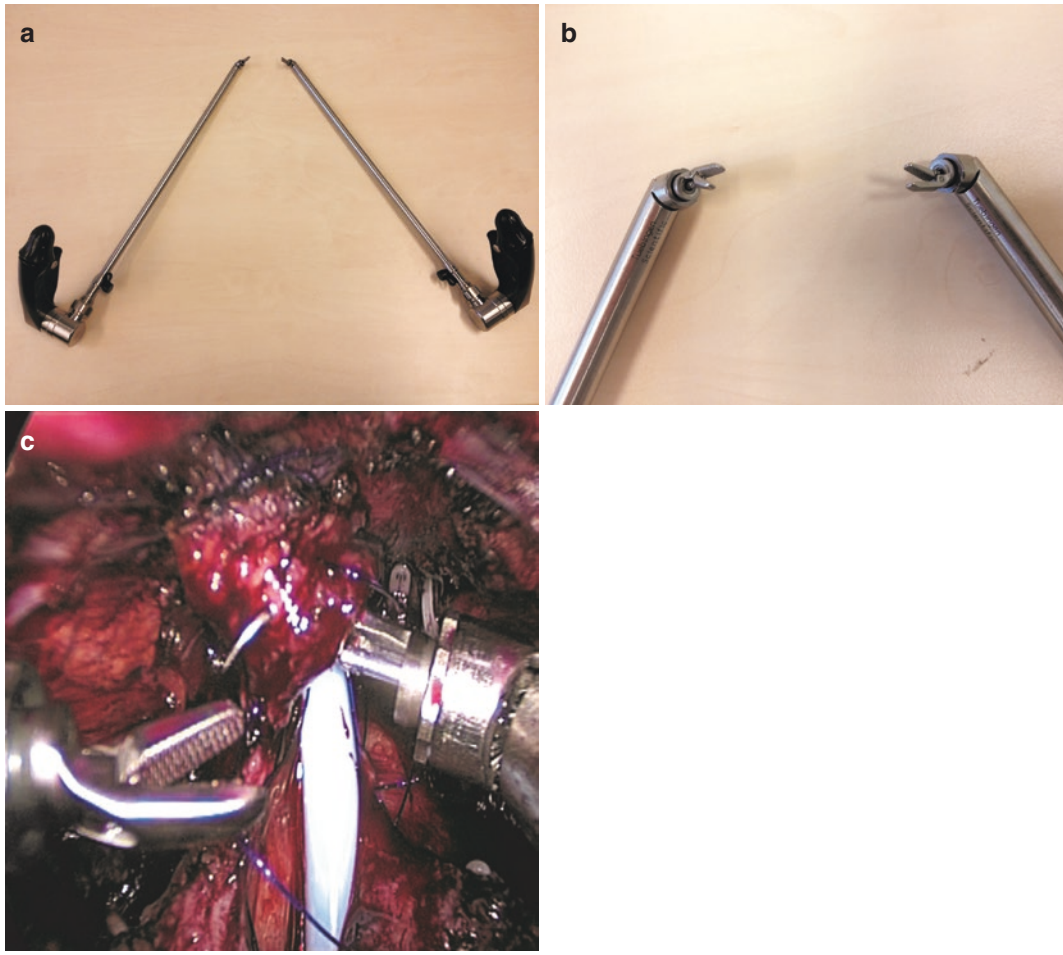

Fig. 6.8 The Radius surgical system (RSS). (**a**) Ergonomic handles providing a comfortable and multifunctional grip. (**b**) The articulated tips offering 6 DOFs. (**c**) Urethrovesical anastomosis using the RSS

scopic suturing tries to overcome the limitations: by use of the almost perpendicular angle between the needle-holders to adjust the position of the needle, respectively by use of the non-dominant hand for passing the needle (Fig. 6.9a–c).

However, there is no doupt that, even the experienced laparoscopic surgeon is still limited in his movements, if compared to open surgery. This becomes most evident when performing a complex procedure such as laparoscopic radical prostatectomy. There are several important steps during this operation which are significantly more difficult to carry out in comparison to open surgery, i.e. the control of the dorsal vein complex, the dissection of the lateral pedicles, the preservation of the neurovascular bundles and, most importantly, the urethrovesical anastomosis.

Ergonomic Platforms

An ergonomic platform is a complex device, able to improve more than one ergonomic parameters (Table 6.2). Already in 1999, Schurr et al. [40] proposed a special chair (i.e. cockpit design) with pedal switches to improve the ergonomy of laparoscopic procedures. The use of a surgical support, during laparoscopic radical prostatectomy (Fig. 6.10a, b), helps to reduce the stress on the knee joints suffering from arthoscopically proven

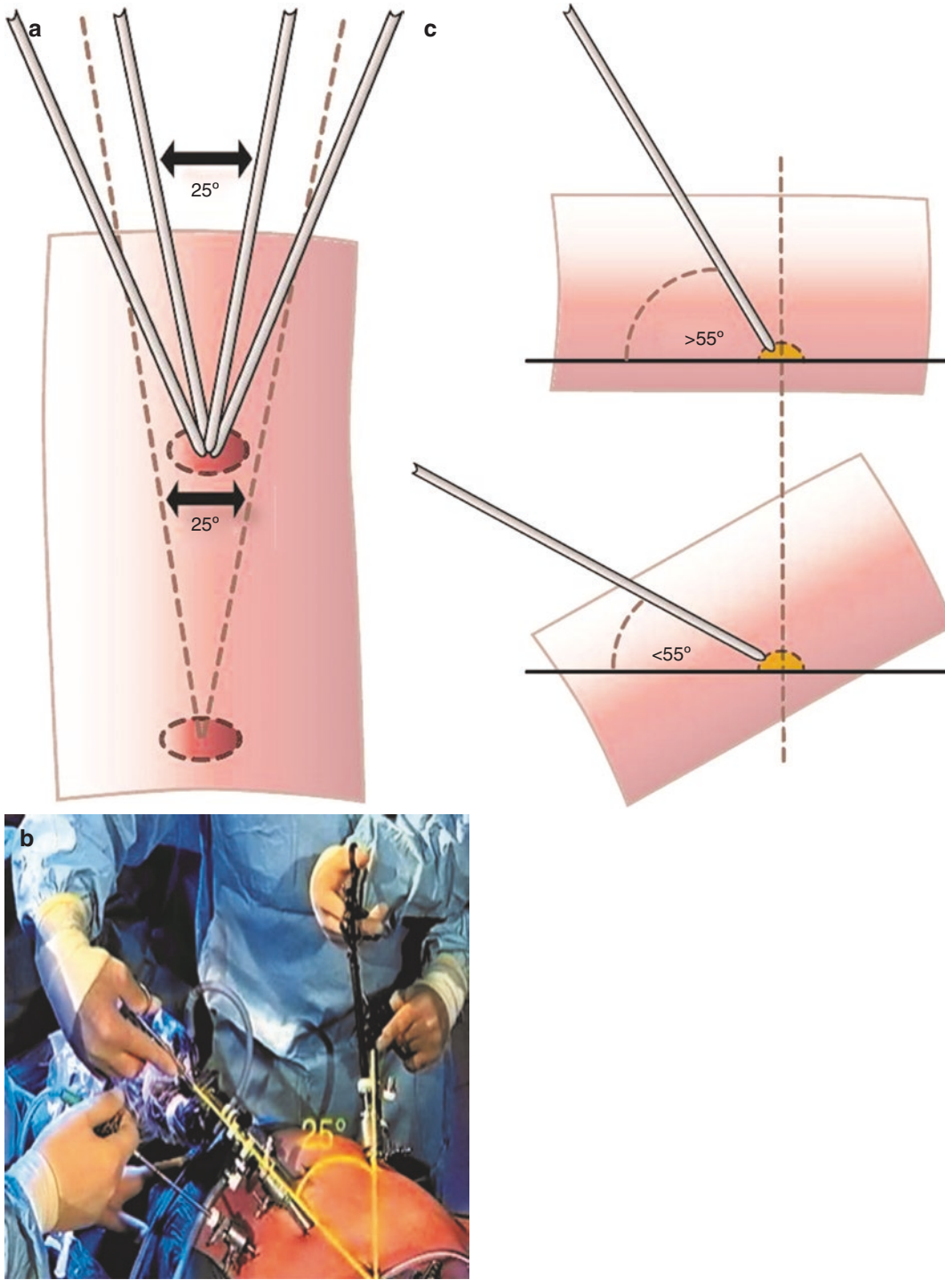

Fig. 6.9 Geometry of laparoscopic suturing. (**a**) Angle between the instruments (scheme) should be not less than 25° and not more than 45° (scheme). (**b**) Use of port beyond mid-line for suturing. (**c**) Angle between the operating field and the horizontal line should not exceed 55° (scheme)

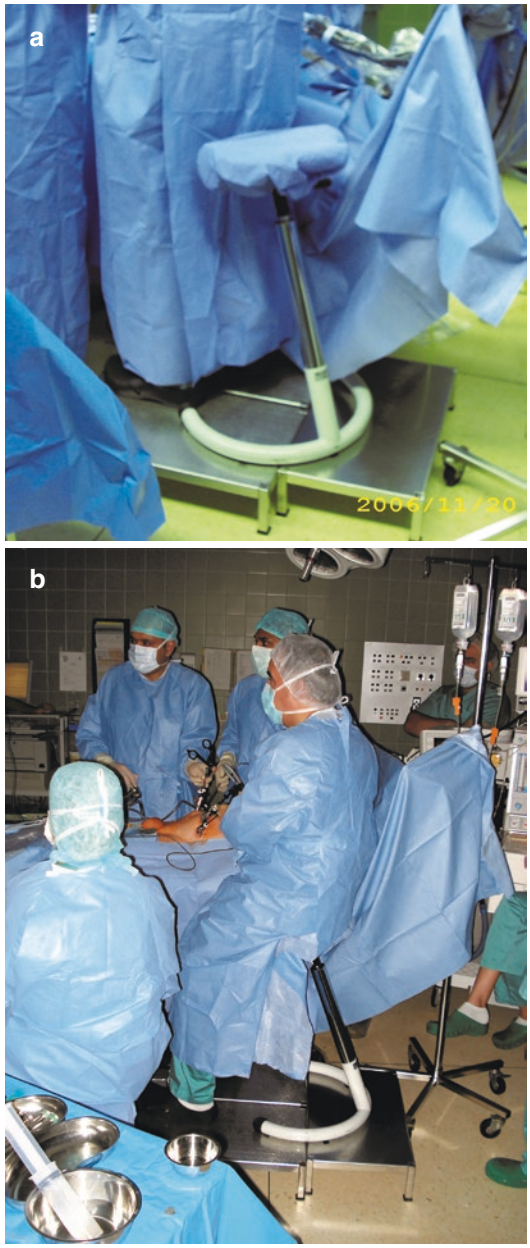

Fig. 6.10 The use of a chair/support (**a**) during laparoscopic radical prostatectomy (**b**)

gonarthrosis. This chair can be only used when the surgeon works with the ipsilateral trocars.

Albayrak et al. [41] presented a specially designed ergonomic body support consisting of a platform with foot pedal, a semi-standing support, a remote control, and a chest support. EMG results showed an average reduction of 44% of the erector spinae muscle, 20% for the semitendinosus muscle, and 74% for the gastrocnemious muscle contraction, when using the chest support. The average muscle contraction reduction using the semistanding support was 5%, 12%, and 50% respectively.

The most extensively studied ergonomic platform is the ETHOS chair. This surgical chair (ETHOS^{Tm}-platform, ETHOS-Surgical, Portland, USA) consists of a saddle-like seat, a chest-support, two armrests, and footrests (Fig. 6.11a). All accessories are individually adjustable. The height of the seat is adjusted by a motor-lift, remotely controlled, in a range of 89–122 cm. The distance between the footrests is 89 cm. The open straddle reaches a 53 cm of length and fits to most operating tables. The surgeon "rides" over the patient's head, once under anesthesia, during pelvic procedures. The prototype has been already evaluated in a clinical setting [42] and the 2nd generation model has been tested only in an experimental setting [43] demonstrating significant improvements in times and ergonomic scores. As a tool, it is able to improve the surgeon posture by providing a pleasant sitting position and supporting all parts of the body during the whole procedure. It also improves visual alignment as the surgeon maintains an ideal angle, looking directly to the monitor and, hence, making the straight, and relatively extended back and neck posture unnecessary. Foot pedals can also be fixed on the footrests, making them easy to use without having a visual contact (Fig. 6.11b).

Ergonomic Systems in Laparoscopy

A laparoscopic ergonomic system is a combination of different ergonomic instruments or devices that help to improve multiple ergonomic drawbacks of laparoscopy (Table 6.2). The system aims to create an optimal ergonomic environment that is, by definition, adjusted to the needs of the surgeon. During the last year, we have been using a combination of ETHOS™, the 3D laparoscope, and the Radius needleholders with 6 degrees of freedom (Fig. 6.12). This combination proves to be much faster than conventional laparoscopy and as fast as robotic surgery. At the same time, the

Fig. 6.11 The ETHOS™ ergonomic platform (**a**) offers body support and ideal joint angulation, abolishes the torero position, and provides an optimal view angle (**b**)

surgeon mentions significantly less discomfort, of all muscle groups, in comparison to conventional laparoscopy, and comparable discomfort with robotic surgery [44]. Undeniably, the future research in ergonomics for laparoscopy aims in this direction.

Telemanipulators

A more conceptional approach to these problems represents the development of computer-enhanced telemanipulators. The concept of intelligent steerable surgical instrument system

Fig. 6.12 Combining the ETHOS™ ergonomic platform with the 3D camera and the RSS needleholders in an experimental pelvitrainer radical prostatectomy setting

Fig. 6.13 The da Vinci surgical system

has been described by various authors, and finally formed the basis for the industry to develop a marketable product, providing six (seven) DOF: the da Vinci system [10–15].

Telepresence Surgery

The da Vinci system is the first surgical system that addresses most of these problems sufficiently:

- The problem of surgeon posture
- The problem of depth perception
- The problem of eye-hand coordination
- The problem of non ergonomic instrumentation and
- The problem of limited range of motion (i.e. DOF)

For this purpose, a computerized robotic system has been designed, offering a stereo-endoscopic system, a computer controlled mechanical wrist providing six DOF (plus actuation of the instrument), used from a console with handles that can be utilized always in an ergonomic working position (Fig. 6.13).

The Surgeon's Console

The surgeon performs the procedure seated at the console and holding specially designed instruments (Fig. 6.14a). Highly specialized computer software and mechanics transfer the surgeon's hand movements exactly to the microsurgical movements of the manipulators at the operative site. The video image gathered from inside the abdomen provided by two parallely arranged 3-chip-cameras is projected so that it coincides with the workspace of the master manipulators.

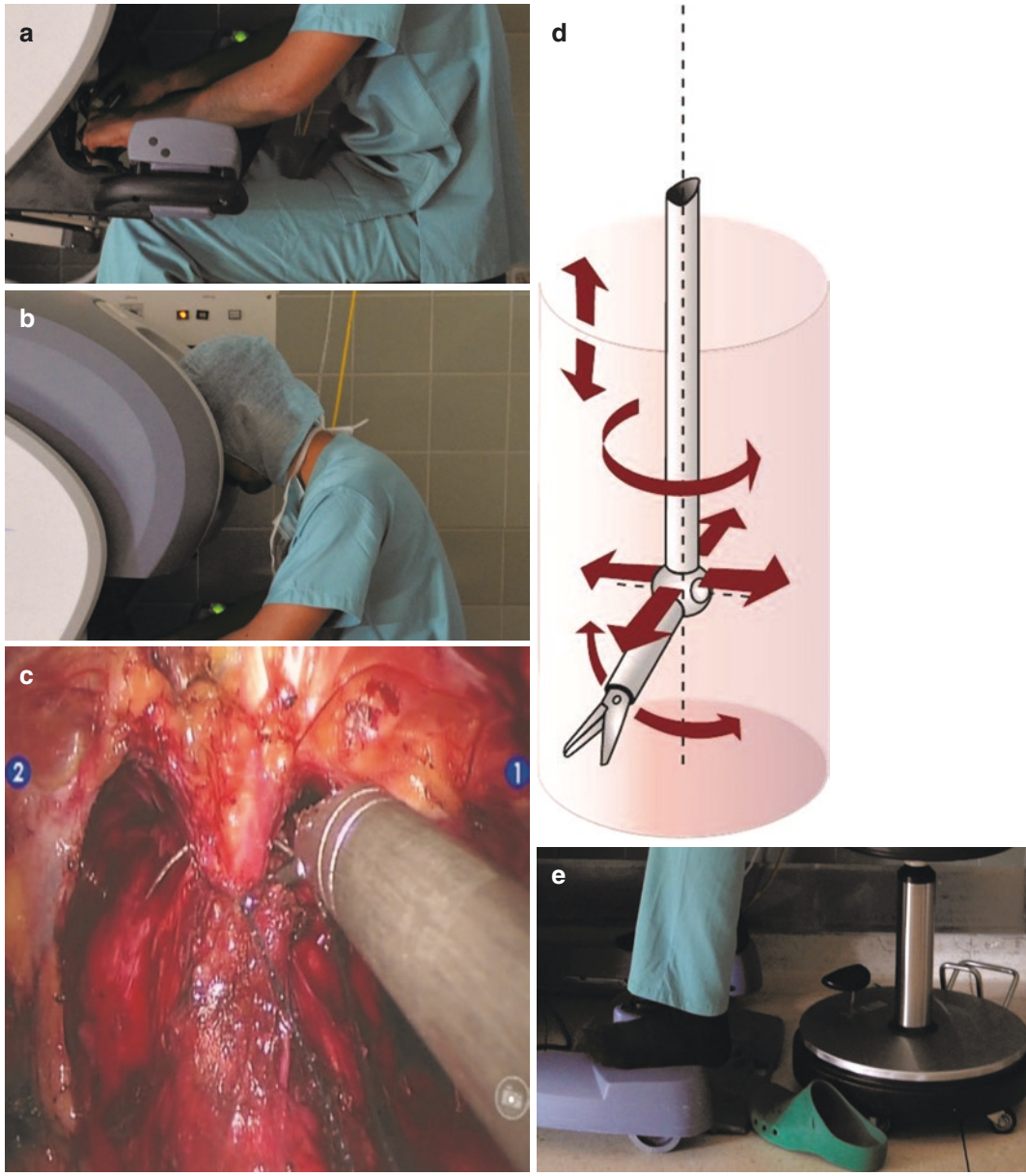

Fig. 6.14 The ergonomic advantages of the da Vinci robotic system. (**a**) Comfortable sitting position with an arm support. (**b**) Ideal view angle (15° below the horisontal line of sight). (**c**) 3D camera. (**d**) Instrumentation offering 6–7 degrees of freedom. (**e**) Foot control of five pedals

This overlap creates the visual illusion for the surgeon that his hands are holding onto tool tips inside the body (Surgical Immersion^{R} Technology). As a result, the surgeon manipulates the tools as if he is holding on to the instruments directly.

The 3D-Imaging System (Fig. 6.14b, c)

The high-resolution 3D endoscope consists of two–three-chip charge coupled device cameras (InSite^{R}) with two high-intensity illuminators to ensure a bright image of the operative field. 0° as well as 30° lenses can be used, the 30° lenses can be additionally mounted looking either down- or upwards. The video image enables an up to tenfold magnification according to the distance of the endoscope to the operative field. The endoscope—once inserted—is moved by the surgeon: Camera control is achieved by pressing the footswitch that locks the slave-tool manipulators in place and gives the operator control of the camera through the master manipulators. The endoscope is then manipulated according to simultaneous movement of the two handles at the console. Another foot pedal can be also used for re-focussing the image.

The Surgical Arm Unit

Every motion of the handles is sensed by high-resolution motion-sensors, processed and transferred to the two surgical manipulators. These slave manipulators (surgical arms) provide three degrees of freedom (pitch, jaw, insertion). The last elements are the surgical instruments (i.e. end-effector): At the tip of the instruments, a cable driven mechanical wrist (Endo-wrist^{R}-technology) adds three more DOF (including rotation) and one motion for tool actuation (i.e. grip) (Fig. 6.14d). The grip torque of the end-effector (i.e. needle-holder, forceps) was programmed to 1.0 Newton. Monopolar and bipolar electrocautery can be applied to one of the end-effectors by using one of the 5 foot-switches at the console, if the respective instrument has been introduced. In order to enhance precision, the system allows for scaling of the master-slave motion relation. Accordingly, a motion scale of 3:1 will move the tool 1 mm inside the abdomen for every 3 mm of motion at the master console. Usually, a motion scaling of 2:1 is used. In addition, the system filters unintended movements (i.e. by tremor) by applying a 6 Hz motion filter. Finally, it is possible to temporarily disconnect the end-effectors from the master handles within its working space, while the position of the instruments remains unchanged (clutch-function controlled by foot-pedal; Fig. 6.14e).

Ergonomical Advantages of the da Vinci System

The main ergonomical advantage represents the introduction of a console (Table 6.4):

- The surgeon works in a seated position
- With a virtual 3D-in line view to the operating field
- The elbows are supported by an arm rest
- The surgeon has five different foot pedals to activate
- The clutch-function allows the surgeon always to work with his arms / hands in an ergonomical position
- The surgeon moves the camera with automatic correction of the adequate position of the instruments
- The surgeon has two ergonomic handles (i.e. two loops) that transfer the activation of the 7 DOF-instruments, independent of the type of the instrument (i.e. forceps, needle-holder).

Table 6.4 Comparison of ergonomic advantages of laparoscopic versus robotic surgery

Laparoscopy	Robotic surgery
Use of all trocars	Excellent working ergonomy at console
Use of all instruments	Tremor filter, Working scaling
HDTV-technology for all	3D-Vision for surgeon
Six- to eightfold magnification	In-line view to (virtual) operative field 6 degree of freedom instruments Tenfold magnification

The *seated position of the surgeon,* with a virtual in-line view to the working field, represents an innovation for surgical procedures, which has been only realized during microsurgery using an operative microscope (Fig. 6.14a, b). However, there is no need for the surgeon to exchange the instruments under the view of the operating field. He is able to activate different exchangeable instruments. As we know from penile surgery (i.e. hypospadia repair), the sitting position minimizes the physical stress of the surgeon and allows easy use of the foot-pedals in contrast to the standing position of the surgeon during laparoscopy.

The *camera-control by the surgeon* requires a certain learning curve, but after this it offers a stable and adequate view of the working field with automatic adaptation of the instruments. Moreover, the clutch-function enables to work always in a centralized—per se most ergonomical—position at the console, independent from the situation at the operating field. This represents a significant advantage over laparoscopy, where some steps of the operation may require an awkward position of the surgeon due to the fixed trocar arrangement.

The fact that the surgeon does not need to adapt to the handle (i.e. scissors-like, palm-type) of the respective instrument (i.e. forceps, needle-holder) represents another advantage over laparoscopy (and open surgery).

Ergonomic Disadvantages

The main disadvantage for the surgeon at the console represents the complete lack of haptic sense (i.e. tactile feedback). This has to be compensated by visual senses. Moreover, the surgeon depends completely on adequate assistance (i.e. suction, clipping) of the surgeon at the OR-table. He can only demonstrate and communicate, where a clip should be placed.

The surgeon posture during da Vinci procedures is similar to the position maintained during microscopy. The surgeon console allows a comfortable posture for surgeons with height between 64 and 73 in. (163–185 cm). However, as the angle of back flexion increases to 30°, shorter individuals will be challenged to reach the eyepiece. As a result, heels are unable to rest on the floor despite the console being as low as possible, and the upper arms are unable to remain perpendicular to the floor while arms on the armrest. With the chair lowered so that the feet can reach the pedal, the surgeon is then unable to see into the screen. Furthermore, when in neutral upright seated position, the surgeon suffers a neck and back hyperextention. Similarly, tall surgeons will have to bend over greater than 30° for viewing. This results to a kyphotic-seated posture [17]. Finally, disadvantages of the motion scaling (2:1), represent the fact that the surgeon may need to move long distances with his arms at the console for certain manoeuvres (i.e. pulling on a suture/thread during continuous suturing), which can be easily performed with the laparoscopic techniques.

According to Lux et al. [17], in order to correct the few ergonomic drawbacks of da Vinci surgery, the following should be noticed:

- The chair should be on lockable castors for improving mobility near the console workstation.
- The chair should have a readily adjustable height, lumbar support, and a tiltable seat angle, though generally parallel to the floor.
- The seat depth should be adjustable as, aiding in lumbar support.
- Chair and console height should be adjusted so that the view screens are at a comfortable position for viewing when the feet are resting on the ground in front of the pedals with knees at a 90° angle or greater.
- Elbows should remain tucked close to the body and not flared.
- The position should be attained at the onset of the case, with periodic revaluation if discomfort occurs later.
- Avoid firmly pressing into the headrest, as this can result in undue forehead pain and neck strain.

The ergonomics of the assisting surgeon are limited even more, compared to standard laparoscopy [14]. This is due to the interference of the

Fig. 6.15 Working at the OR-table surrounded by the robot-arms interfering with the actions of the assistant

robotic arms, which may significantly reduce the dexterity of the assistant (Fig. 6.15). Moreover, the surgeon cannot use the trocars of his assistant (i.e. to demonstrate correct use of the suction device; correction of a retracting instrument). With the use of a 4-arm system the surgeon can control most of the functions attributed to the assistant (i.e. use of the telescope, retraction). Moreover, the surgeon has no easy access to parameters of auxiliary devices for laparoscopy (i.e. insufflator flow, pressure of pneumoperitoneum, setting of the HF-generator) and the communication to the staff at the OR-table might be disabled (i.e. noise of insufflator, respiratory device, patient warmer) causing significant mental stress.

Comparative Studies on Ergonomics of Laparoscopy and Robotics

There are several studies comparing the ergonomics of both techniques. Berguer and Smith [45] were the first to compare the laparoscopic and robotic ergonomics in a sophisticated experimental study with novices and experienced laparosopic surgeons. Overall, there was a **lower stress level with the robot, however it did not reach statistical significance.** Additionally, they used the ZEUS-robot, which provides only 4 DOF. Interestingly, the seated position alone did represent an advantage. Due to the inferior ergonomy of the device, the authors measured a significantly higher arm abduction angle with the ZEUS-system, compared to the laparoscopic technique despite the seated position. Since this finding was not accompanied by a higher deltoid muscle activation, the authors concluded that it resulted from the placement of surgeon's arms on the padded armrest of the ZEUS-system.

Similarly, Lee et al. [46] did not find any advantage of the ZEUS-system over manual laparoscopy in their simulation study. In contrast, the time to completion was longer for the telerobotic technique with the ZEUS-device. However, based on the Rapid Upper Limb Assessment (RULA) score, and the Job Stain Index (JSI), they found that **telerobotic surgery provides a more comfortable environment for the surgeon without any additional mental stress**.

Van der Schatte et al. [19] presented a very interesting experimental trial in a surgically inexperienced population. They had to perform three different tasks (rope passing, needle copping, bend dropping) using either laparoscopy or the three-armed da Vinci robot. Based on the introduction of objective parameters to measure mental discomfort (MSSD, PEP), they could clearly demonstrate the **superiority of the robot-assisted group in terms of lower stress load**

and increased work efficiency. The authors could demonstrate that the implementation of a robotic system for execution of laparoscopic tasks enhances performance and reduces cognitive stress levels as well as physical discomfort.

Bagrodia and Raman [47] presented a survey based on a questionnaire sent out via the Endourology Society and Society of Urologic Oncology to surgeons performing open, pure laparoscopic, or robot-assisted prostatectomy. Neck and/or back pain were experienced in 50%, 56%, and 23% of surgeons after open, laparoscopic, and robot-assisted prostatectomy. **In the robotic group, neck pain was overwhelmingly more common than back pain** (21% vs 1%). This is due to the sitting position at the console. However, certain tasks are associated with more arm abduction but not concomitant increases in deltoid muscle activity, because the operators' arms are supported by padded arm-rests. The high frequency of neck pain during robot-assisted surgery likely comes from straining to optimally visualize the high resolution display, similar to what is experienced when reading a book on a table or working on a computer for long times.

Chandra et al. [48] recruited nine laparoscopic experts with substantial laparoscopic and robotic experience and 20 laparoscopic trainees without any robotic experience, who performed sequentially ten trials of a suturing task using either robotic or standard laparoscopic instrumentation, fitted to the ProMIS™ surgical simulator. They proved that, **by performing complex tasks such as knot tying, surgical robotics is most useful for inexperienced laparoscopists** who experience an early and persistent enabling effect. **For experts, robotics proved to be most useful for improving economy of motion**, which may have implications for the highly complex procedures in limited workspaces (eg, prostatectomy).

Only recently, two studies assessing surgeon discomfort by utilizing electromyography could demonstrate interesting results. Hubert et al. [49], utilizing skin electrodes of the trapezius, extensor digitorum and erector spinae muscles, in a well-organized study with live porcine models, demonstrated that **physical workload and perception of the effort invested was significantly greater during standard laparoscopy than da Vinci surgery**. Nevertheless, they found **no significant difference in mental stress between the two modalities**. A greater physical activity for trapezius and dorso-lumbar muscles, and significant appearance of fatigue of the trapezius muscles was recorded during laparoscopic procedures. Finally, **heart rate during standard laparoscopy was significantly increased**, confirming greater physical expenditure. Lee et al. [50] recruited three groups of surgeons, namely, laparoscopy experts with no robotic experience, novices with no or little robotic experience, and robotic experts, who performed six surgical training tasks. They used surface electromyography from eight muscles (biceps, triceps, deltoid, trapezius, flexor carpi ulnaris, extensor digitorum, thenar compartment, and erector spinae). Mental workload assessment was conducted using the NASA-TLX. The **cumulative muscular workload from the biceps and the flexor carpi ulnaris with da Vinci was significantly lower than with laparoscopy**. Interestingly, **the cumulative muscular workload from the trapezius was significantly higher with robotic surgery than with laparoscopy**, but this difference was only observed in laparoscopic experts and robotic surgery novices. NASA-TLX analysis showed that both robotic surgery novices and experts expressed lower global workloads with robotic surgery than with laparoscopy, whereas laparoscopy experts showed higher global workload with robotic surgery. Robotic surgery experts and novices had significantly higher performance scores with robotic surgery than with laparoscopy. The authors concluded that **robotic experts could benefit the most from the ergonomic advantages of robotic surgery**.

The Impact of the Type of Procedure

The advantage of robotic-assisted surgery significantly depends on the type of the procedure. Back pain represents the most common pain location after laparoscopic radical prostatectomy (28%). However, in studies following laparoscopic cholecystectomy or splenectomy, back

pain was not one of the most cited problems [3]. With appropriate patient positioning, most of these procedures can be performed with all trocar sites placed to one side of the midline, similar to transperitoneal or retroperitoneal laparoscopic renal surgery. Such a configuration permits the surgeon to stand orthogonally to the patient, minimizing torque on the back. Consequently, the majority of surgeon strain is transmitted to the neck, which is hyperextended to look at the video display while working at a lower-than optimal height on tables that were initially designed for open procedures [36].

Laparoscopic radical prostatectomy, however, is quite different, because it requires the surgeon to operate in a craniocaudal (or parallel) axis to the patient. Thus, ports are placed on both sides of the midline and operative work may necessitate reaching over the patient and across the midline (i.e. during urethrovesical anastomosis). Furthermore, the monitor is not located across the patient but towards the lower extremities, requiring secondary neck strain while the back and torso are already torqued toward the pelvis (Torero position). Collectively, such positioning variable may be reflected in a higher rate of back discomfort in the reviewed literature [2, 23, 51].

Indeed, the relevance of the ergonomic advantages of the robot, have to be balanced against the ease of performing the respective procedure by pure laparoscopy (Tables 6.4 and 6.5).

Table 6.5 Steps to compensate for ergonomic limitations of laparoscopy and robotic surgery

Laparoscopy
Adjustment of table height to guarantee relaxed working (i.e. right angle of elbow)
Support for the surgeon enabling to operate temporarily in a seated position
Design of special chairs that incorporate pedal switches and body support (i.e. cockpit type) to reduce fatigue
Adjustment of the height of the monitor to avoid "chin-up"-position
Placement of trocars (i.e semilunar arrangement) to provide an adequate angle of the instruments (i.e. by changing their use)
Use of a motorized camera-holder (ie AESOP) to improve the stability of the image
Insertion of instruments by the OR-nurse enabling the surgeon to keep his eye on the monitor
Follow a trunk endurance training program
Robotics
Intensive training and standardization of the camera position, use of clutch function, position of fourth arm to reduce the mental stress (i.e. minimize the use of the foot pedals)
Use of the flexed position of the instrument (i.e. forceps) to apply it similar to a right-angle dissector
Standardization of the trocar position to minimize collision of the arms and disturbance of the assistant

Discussion

Most of the laparoscopic procedures in Urology are technically challenging. The experience in the United States has clearly demonstrated that the da Vinci-system may significantly shorten the learning curve of these operations [13]. In Germany, however, based on a different reimbursement system, the device has not yet the same successful user rates (<10% vs 80%). As a consequence, the rate of laparoscopic procedures (i.e. radical prostatectomy) is about 30%. It has to be emphasized that, until now, there is no prospective randomized study comparing both techniques, neither clinically nor technically [16, 52].

Therefore, a more practice-oriented approach is used to evaluate the impact of the robot on the ergonomics.

At the beginning, some specific difficulties of the da Vinci system have been encountered [11]:

- Interpretation of magnified anatomy
- Lack of tactile feedback
- Coordinated interaction between surgeon and assistants
- Need of specific instruments for urological procedures

Interpretation of Magnified Anatomy

The first problem for a laparocsopic surgeon represents the interpretation of the respective anatomical structures (i.e. the dorsal vein complex, bladder neck, vas deferens) seen under stereoscopic vision with a tenfold magnification.

It proved to be difficult to adjust the new image to the known two-dimensional picture one has been used to over the last decade. The same applies to identify small vessels.

Lack of Tactile Feedback

The lack of haptic sense aggravates the dissection technique in this novel situation. Even if "standard" laparoscopy does only provide a minimal amount of tactile sensation, the effect of training and experience finally enabled the surgeon to have a certain haptic sensation, i.e. to assess the shape of the prostate, the severity of adhesions, the strength of a suture or knot. The da Vinci-system, actually, does not provide any tactile feedback. To avoid the injury to instruments, needles and tissue, the device has a programmable grip torque that differs for the various end-effectors (grasper, fine needle holder, etc.). Usually, a grip torque of 1 N is recommended for all instruments. Moreover, some force feedback is provided, so that tissue contact (i.e. bony resistance), as well as external forces (collision of slaves), is reflected at the master.

Nevertheless, the surgeon has to compensate the missing tactile feedback by the improved stereoscopic vision (i.e. observing the deformation of tissue and the increasing tension on the suture). Indeed, with increasing experience, one is able to estimate the applied strength on the suture when performing a knot. It proved to be only difficult, if some tension has to be applied to the suture (i.e. to control the DVC). Nevertheless, working remotely without tactile feedback requires new surgical skills, solely based on visual inputs. This of course increases the mental stress during surgery.

Coordinated Interaction Between Surgeon and Assistants

The complexity of the operation itself requires proper assistance and instrumentation. In contrast to a laparoscopic nephrectomy or adrenalectomy, a robotic radical prostatectomy cannot be performed as solo-surgery. There is a need of retraction of the gland or adjacent structures. For vascular control, clips have to be placed, and sometimes suction is required to clear the operating field. All this has to be carried out by the assistant working under a deteriorated ergonomic situation (Fig. 6.15).

Prerequisites for a Successful Operation

Based on a correct indication, the success of any operation is based on the following factors:

- The expertise of the surgeon
- The expertise of the assistant
- The interaction between surgeon and assistant
- The working ergonomy
- A proper instrumentarium

There is a general consensus, that the *expertise of the surgeon* represents the key-factor of the success of the operation, independent of the technique (i.e. open vs laparoscopic vs robotic) [53]. However, beside the expertise of the assistant, the interaction between both, as well as an ideal working ergonomy, may play an important role.

In *laparoscopy*, an experienced surgeon has accomplished facilities to overcome the drawbacks of the technique. Even more, he is able to compensate for some deficiencies of his assistant by taking over his part / port respectively adjusting the camera. This is based on the direct and uncomplicated interaction between surgeon and assistant. A significant advantage of laparoscopy represents the fact that the surgeon is able to apply every instrument (i.e. clips, staplers), and is not utilizing only monopolar scissors, bipolar forceps, and needle-drivers. However, even based on a large experience, there are steps during the operation which still induce significant physical stress (i.e. suturing of the urethrovesical anastomosis in a deep pelvis with a prominent pubic bone). Moreover, in the standing position there is usually a slight rotation of the torso together with significant force on the

standing leg (i.e. during bipolar coagulation using the foot pedal; Fig. 6.7).

In *robotic surgery*, the working ergonomy for the surgeon is optimized due to the seated position, the clutch-function, the tremor filter, and the in-line 3D-vision. It is important to note, that the sitting position alone does not improve the performance as shown by Berguer and Smith with the ZEUS-device lacking the 7-DOF [45]. Moreover, using the da Vinci robot the surgeon himself controls the camera. On the other hand, there is no tactile feedback, and the surgeon is very much dependent on optimal assistance (i.e. placement of clips). The working ergonomy for certain steps of the procedure can be even worse than during standard laparoscopy, because of the robotic arms interfering with the manipulations of the assistant. The introduction of the fourth arm has improved this with respect to proper tissue retraction and exposure of the working field, but the situation for the assistant remains unchanged. Moreover, the mental stress of the surgeon at the console, controlling five foot pedals and two arm handles (plus the fourth arm) should not be underestimated.

In conclusion, based on similar levels of expertise, laparoscopy has the advantage that the surgeon is able to use all instruments via all trocars. He can even use different instruments, which are not available for the surgeon at the console, such as peanuts, right-angle dissector, Ligasure. On the other hand, robotic surgery offers the optimal seated working position and ergonomy, but the lack of tactile feedback and a handicapped access for the assistant.

Perspectives

Evidently, manufacturers yet have insufficiently taken into consideration most of the aspects of ergonomics with respect to laparoscopy. In contrast to the enormous improvement of the video- and camera-systems (i.e. from 1-chip, 3-chip to 3D-HDTV-technology), we are still using the same scissors, dissectors, and needle-holders. Patents of ergonomic instrument design have been bought by the companies, but not yet brought to clinical use [29]. Automated camera-holders like the AESOP have been withdrawn from the market. The only significant improvement of the instruments represented their ability to be cleaned for easy sterilization. Some ideas were realized to improve the control of the auxiliary devices (i.e. insufflator, HF-generator) directly by the surgeon with the OREST-system (Dornier) or even the OR-1 (Karl Storz). However, all these improvements have no impact on the ergonomics of the procedure.

What is important for laparoscopy? Does the robot represent the final solution? Even if the da Vinci device has optimized the ergonomics of laparoscopic surgery, it has also some limitations and is not cost-effective. Therefore, we still believe, that a significant effort should be invested to improve the ergonomics of pure laparoscopy. The geometry for a successful performance of the procedure has been analyzed sufficiently) [29, 38, 39, 54]: This concerns the angle between both instruments (25°to 45°), the angle between the instruments and the working field (<55°), and the angle of the elbows (90–120°). The position of the table, the patient and the surgeon (i.e. using a stand) has to accomplish this. However, the placement of the trocars may not be always adequate (i.e. due to the anatomy of the patient, intra-abdominal adhesions, etc.). Intraoperative navigation using the preoperative data of a CT-scan may be helpful to determine the optimal position of the trocars (Fig. 6.16) [55].

Some authors have focused on the adequate placement of the video monitor to avoid the "chin-up" position, e.g. below the eye level of the surgeon [20]. Even guidelines for ergonomics of laparoscopy have been formulated, but most of the laparoscopic surgeons are not aware of them [3, 36]. The assisting nurse has to stabilize the position of the trocar during exchange of the instruments to allow the surgeon to keep his eyes on the monitor (Fig. 6.2).

On the other hand, particularly in case of long-lasting procedures, a sitting position may be very helpful (Fig. 6.10). During laparoscopic radical

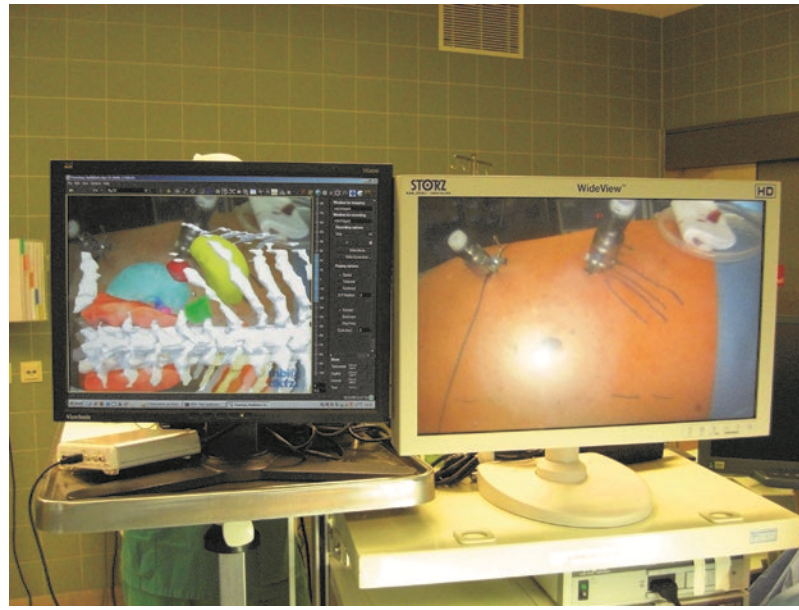

Fig. 6.16 Preoperative determination of optimal trocar placement based on segmented CT-scan images

prostatectomy, this is only feasible during some steps of the procedure, when only the ipsilateral ports are used (i.e. apical dissection, dissection at bladder neck). For suturing, the surgeon should still stand up. Some authors have proposed to place the surgeon or camera-assistant in the midline close to the head. This might be inconvenient for the anaesthetist and difficult in case of large or obese patients [21, 56, 57]. Others have proposed a specific OR-chair with arm-rests and a foot bank for the pedals [40, 41]. This seems to be a very interesting idea, however, such a chair would also require a change of the configuration of the OR-table. Nevertheless, the recently introduced ETHOS ergonomic platform could overcome these problems by allowing the surgeon to ride over the patient, avoiding the torero position and maintaining a comfortable sitting position with a continuous optimal joint angulation, arm and foot support, optimal weight distribution, direct monitor contact and pedal utilization (Fig. 6.11) [42, 43].

There is consensus, that future operating theatres should be equipped with OR-tables specifically designed for laparoscopic surgery. Such an ergonomic operating platform should be accompanied by a seated position of the surgeon, but also minimize any friction between the surgeon leg and the table when using trocars beyond the midline, respectively minimize the need of rotation (i.e. torque).

Finally, the ergonomy of the handles, minimizing the applied force and maximizing the tactile ability has to be improved [26]. Needleholders with an integrated spring-loaded mechanism to open the branches, which require significant force to stabilize the instrument, should be withdrawn from the market. The software to test newly designed instruments is available.

Recently, Tse et al. [51] could show, that trunks muscle training significantly improved the discomfort and failure rate of laparoscopic surgery when randomizing medical students. Indeed, daily laparoscopic surgery may represent such a continuous training and contribute to the learning curve of the experts.

In case of robotic surgery, further improvement should mainly aim at the development of devices offering haptic sense for the surgeon [58]. Furthermore, adjustable parts should be added in order to offer a comfortable posture for surgeons with height lower than 64 and higher than 73 in.

Conclusions

There is a need to improve the ergonomics of laparoscopic surgery. The design of the da Vinci robot offers a variety of ergonomic advantages compared to pure laparoscopy. However, there are also some disadvantages, such as the lack of tactile feedback, and restricted ergonomics for the assistant. The impact of these advantages depends also on the type of the procedure. On the other hand, efforts should be undertaken by all manufacturers being involved in the design of the operating theatre to focus on the improvement of ergonomics according to the existing guidelines. This concerns the design of armamentarium and instruments, but also the OR-table, platforms, OR-chairs, arrangement of lines and cables. The combination of different ergonomic instruments and platforms to form ergonomic systems, and improve many different ergonomic parameters, could be the future in creating an ideal ergonomic environment in minimally invasive surgery.

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The Robotic Patient-Side Assistant

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Abstract

A team-based approach in the robotic operating room is critical for success and the patient-side first assistant is central to this team. A well-trained assistant is necessary to maximize efficiency and minimize complications. The assistant needs to understand and manage a multitude of issues including the plethora of equipment, safe patient positioning, gaining safe access into the abdomen, optimal port placement, efficient robot docking, managing insufflation and optimizing the robotic performance during the case. The assistant needs to be facile, ambidextrous laparoscopist and an effective communicator with the console surgeon and the rest of the team. An assistant who can troubleshoot effectively and quickly respond to problems and complications can make a major difference in the outcome of the operation. We review all salient aspects of the role and considerations of an effective and experienced patient-side assistant. Although the job is often thankless and underappreciated, the patient-side assistant is a key member of the robotics team and crucial for successful outcomes.

Keywords

Robotic · Assistant · Troubleshooting · Bedside · Table side · Patient-side

Introduction

A dedicated team-based approach is paramount for consistent success in the robotic operating room. Although often overlooked, the patient-side first assistant is central to this team. A well-trained assistant is necessary to maximize efficiency and minimize complications.

Importance of the Assistant

There is much truth to the statement "The console surgeon is only as good as the assistant." As the only surgeon scrubbed during the procedure, the patient-side assistant is in large part responsible for the efficient and safe progression of the surgical procedure. It requires extensive knowledge of the robot, robotic instruments and a plethora of laparoscopic equipment. The assistant must be familiar with the robot's limitations and con-

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stantly monitor the environment to prevent potential problems and delays. They must be able to quickly identify and troubleshoot any problems. An inexperienced or poorly trained assistant can severely disrupt the flow of the operation and potentially cause a major complication.

A firm understanding of the first assistant's role is a necessary step to gaining proficiency as a robotic console surgeon [1]. The ability to direct where and what the assistant should be doing at all times throughout a case is an essential part of learning how to perform the operation. Simply learning to perform only the console portion of the case is shortsighted and slows the console surgeon's progression on the learning curve. Therefore programs dedicated to training robotic surgeons should incorporate intensive first assistant experience as a cornerstone of the surgical training [2–6].

Requirements of the Assistant

In addition to a keen knowledge of the robot, the patient-side first assistant must be skilled in safely positioning the patient, properly inserting trocars, judging the optimal port placement locations, efficiently docking and managing the robot throughout the operation. Since robotic surgery is an extension of laparoscopic surgery, it requires a basic knowledge of laparoscopic surgical principles. A thorough understanding of general safety issues and emergency scenarios should be mandated as part of the initial training protocol [7]. An excellent assistant should be familiar with an almost endless list of constantly changing laparoscopic tools. The job demands nimble two-handed assistance, keen eye-hand coordination and expects one to manage multiple variables at once. Despite the industrious nature of the job, much of the effort goes unseen and can often seem thankless.

Patient Positioning, Gaining Access and Port Placement

The patient-side assistant must understand the critical nature of proper patient positioning, port placement, and docking. The assistant must understand optimal positioning concepts and provide sufficient padding and support for the patient. Improper positioning and padding can limit surgical access and hinder case progression. The association between inadequate padding, poor positioning, and neuromuscular-skeletal complications is well established [8].

While the flank position is often used in open and robotic surgery, the steep Trendelenburg position is unique to many laparoscopic and robotic pelvic-based operations. It is used for a number of urologic, gynecologic and colorectal procedures to gain access to the deep pelvic organs. During steep Trendelenburg, a cephalad slide of the patient on the operating room table can occur. This can lead to serious injuries such as incisional tears, postoperative hernias, nerve injury and pain due to stretching of the anterior abdominal wall [9]. Techniques to prevent the patient from sliding include the use of shoulder blocks, shoulder restraints (Badillo strap), gel pads, foam padding (Pink Pad® or egg crate), vacuum beanbags or tape across the chest [10].

The patient side assistant is also often tasked with gaining access to the abdomen and port placement. Access and trocar related injuries can often be avoided with proper technique and training [11]. There are a number of techniques used to gain abdominal access for laparoscopy; however, a recent Cochrane review found no single optimal approach [12].

The two most common methods of establishing access are the Veress needle and Hasson port entry. The main advantages of the Veress needle are ease of use and quick access. In experienced hands, it is a safe and extremely reliable technique. However, due to the blind nature of its insertion, there is a small risk of inadvertent bowel or vascular injury [13, 14]. The safest and most reliable point of entry for the Veress needle is at the left subcostal location (Palmer's Point), but the umbilical entry site is another reliable site and most often chosen. The surgeon must develop a feel for the needle as it passes through the fascia and recognize the characteristic "pop" of the needle as it passes into the peritoneal cavity. Manually lifting up on the external abdominal wall during Veress needle placement can help with Veress needle access as it increases tension on the abdominal fascial layers as well as

increasing intraperitoneal negative pressures. After a satisfactory "water drop test", the gas should be attached and turned on at its highest flow, while keeping the needle completely steady. At this point, attention is focused on the initial pressures registered within the abdomen at the tip of the Veress needle. Initial pressures should register at or below 9 mmHg. Intraperitoneal pressure should increase steadily and slowly, with flow rates through the Veress needle registering between 1.0–1.5 L/min. A high pressure or low flow is often an indicator that the needle tip is inserted into a structure or not optimally in the correct cavity. The "initial opening pressure" test is the most reliable test to confirm proper needle placement; however, the "drop test", aspiration, injection, and recovery can all be used to avoid iatrogenic injury [15].

If the surgeon is unsuccessful in placing the Veress needle or is uncomfortable with the method, the Hasson technique can be employed [16]. With the Hasson technique, direct access is gained into the peritoneal cavity using a small incision. Advantages of the Hasson technique include direct visualization and may be preferable when attempting to access a hostile abdomen. Disadvantages of Hasson access include lengthier time for access and a greater chance of air leak issues once pneumoperitoneum is established [17, 18].

A recent Cochrane Review of 46 randomized control trials examined 13 laparoscopic entry techniques [12]. Overall, there was no evidence that any single technique was superior at preventing major vascular or visceral complications. The Hasson technique was more successful than the Veress needle at gaining access, but did not reduce the risk of organ injury compared to direct trocar entry. Optical trocars also did not appear to reduce the risk of injury versus the Veress needle.

Insufflation Pressure

Once access to the peritoneum is gained, and the camera port is placed, careful inspection of the Veress site and camera port site must be done to ensure no iatrogenic injuries. The room lights should be lowered during port placement. Transillumination of the abdominal wall can help to avoid injuring superficial and large blood vessels that would not be otherwise seen. Ports should be strategically placed and spaced apart to minimize intra and extra-corporeal interference and clashing. Poor choice in port site selection and/or suboptimal techniques can severely impede the operation. If the surgeon is unsure of an optimal port template, technique related articles with illustrations regarding the proposed procedure should be referenced. After all the ports are placed, the insufflation pressure should be lowered to 15 mmHg or less as desired by the surgeon.

Principles of Docking, Sweet Spot, and Burping

Proper docking of the robot is an essential step in the operation. Improperly docked arms can result in limitations in robotic instrument movement and even rarely patient injury.

Docking for the da Vinci® Si™ version of the robotic system requires more attention than the da Vinci® xi™. It is important to position and park the Si robot at an optimal distance and angle from the ports. This optimal distance is called the "sweet spot". The blue line and arrow on the camera arm can help judge how close to park the robot to the patient and stay within the "sweet spot".

Docking the robot is usually a coordinated effort between the patient side assistant and the person driving the robot in. Since the individual driving the robot often cannot see exactly where the robot needs to dock, it is the role of the scrubbed assistant to guide them into the optimal approach angle and park location. Clear orientation as to which way to turn and how sharp to turn should be established prior to moving the robot. Consistent directions from the assistant and practice as the driver also aid in creating a smoother and easier docking experience as well as avoiding collisions into non-sterile obstacles in the room.

Once the robot is parked in the proper position and the arms are docked to the ports, it is essential to ensure the robotic ports are inserted to the proper recommended depth. The abdominal fascia should be lined up with the wide black marking on the metallic robotic ports. Failure to do so

may result in ports pulling out inadvertently, especially when abdominal pressures run low. Once docked, the arms must be checked for possible areas of conflict. If the arms appear to have external collision points, the robotic arm should be re-optimized while carefully stabilizing the port with one hand to prevent inadvertent port pullout during the process. Potential places where the robot can lean on the patient should be identified and adjusted before starting the case. As the camera and instruments are inserted, and arms are directed towards the working area, the ports should be "burped" to minimize fascial torque on the robotic arms. "Burping" is achieved by grasping/stabilizing the port in one hand while clutching the robotic arm with the other and essentially pulling up the arm up towards the ceiling in order to minimize the pressures at the port insertion site. By minimizing the fascial torque applied to the port, burping minimizes arm movement restrictions and abnormal feedback that the console surgeon may experience. Burping also may minimize the potential for fascial tears that can result in air leaks, hernias, and additional post-operative pain.

Docking the Robot: Differences Between Si and Xi Platforms

The da Vinci® Si™ system was designed using a similar mechanical platform to the da Vinci® S™. The major modifications of the Si platform were primarily related to an improved camera system (improved resolution, near infra-red imaging capability), upgraded console/control options (improved cautery options, re-assignable foot pedal controls), advanced instrumentation (vessel sealer, stapler, and suction) and customizable, upgradable software. The basic mechanics and frame of the robot itself remained relatively unchanged. Similar to the prior platforms, the Si requires close attention to docking angle to optimize robotic arm motion and minimize collisions. Optimal robotic docking usually requires an approach angle perpendicular to the axis of the robotic ports, parked to the correct "sweet spot" distance and centered on the camera port. For deep pelvis operations (prostatectomy, cystectomy), the robot is optimally parked between the legs with the patient in Trendelenburg position. Setting up the proximal robotic arm joints at right angles enables the instrument and camera arms to have the widest available range of motion. If access to the groin is needed during the robotic procedure (vaginal manipulator or cystoscopy), the robot can be alternatively angle docked, and the arms tweaked to compensate for the different approach. Although angled docking can result in a diminished range of motion, experienced users can still maintain reasonable access to the deep pelvis.

The da Vinci® Xi™ system has many advances over the Si. Many of these changes have improved the ease of docking and automated positioning the robot for a smooth procedure. The Xi system has been designed with four robotic arms that are attached to a deployable boom. The boom can be lowered/raised, swing side-to-side, and extend/retract so that the robot can be docked from many different approach angles. The boom is equipped with laser targeting, allowing the team to quickly center the robot approach angle and more easily park within the sweet spot. Once the laser crosshairs are in line with the camera port, the camera arm is docked. The camera is attached and pointed at the target anatomy. This targeting then automatically adjusts the boom location in order to optimize its position for fewer instruments clashing and better working space. Although these features are generally not necessary for an experienced team, they can be very helpful to the novice surgeon and inexperienced team.

The robotic instruments on the Xi are longer, and the robotic arms have been redesigned to have a wider range of motion and less external collisions due to a sleeker design with the addition of an additional, rotating joint. While a minimum of 8 cm distance between ports is recommended for the Si, the Xi can tolerate port-to-port distances of 6 cm. Since the camera on the Xi system docks to a standard Xi port and not a 12 mm port, the camera is not restricted to one port site can move from one port to another. All of these improvements in Xi system design have resulted in a more flexible and forgiving platform and enables a wider range of indications and procedures to be done compared to the Si platform.

An additional option on the Xi system is a feature called Integrated Table Motion. The Trumpf

Medical TruSystem® 7000dV OR Table wirelessly connects to the Xi system and enables the table to be safely adjusted without undocking and redocking the robot. Any manual table adjustments are simultaneously coordinated with all of the Xi's boom and robotic arms while the robot is still docked to the patient.

Without this system, any inadvertent movement of the operating table without undocking all robotic ports can result in serious injury to the patient.

Specifics on docking techniques can be further referenced in the daVinci® manual or online resources.

Being Comfortable

At this point, the patient side assistant is left alone as the console surgeon will begin the robotic portion of the procedure. To provide precise and high-quality table-side assistance for a prolonged period of time, the assistant must be comfortable. An ergonomically supportive chair with adjustable seat height, armrests, and back support is recommended. This chair can be draped to help maintain sterility. Prior to docking the robot, the operating table should be lowered to the lowest setting so that the assistant's arms are situated in a comfortable posture throughout the case. A dedicated monitor for the assistant should be placed in a comfortable location, so that neck strain is minimized. The assistant should also have a clear line of sight to the insufflation pressure values since air leaks and oversuctioning need to be readily identified. A Mayo stand to hold equipment that the assistant will need should be within arm's length of the assistant. Drapes that have a built-in or makeshift pouch can help the assistant keep instruments nearby without having them fall on the floor. The assistant should also be aware of the position of each robotic arm and avoid contact or contamination of them. Wearing adequate eye/facial protection is extremely important since body fluids can often spray from pneumo-insufflation. Remaining comfortable throughout the case is key to the success of the patient side assistant, and its importance should not be overlooked.

Basic Rules and Principles During the Operation

During the course of the operation, the patient side assistant is the eyes and ears of the console surgeon. There should be constant back and forth communication between the console surgeon and the first assistant, as the first assistant can add valuable input to the console surgeon's decision tree throughout the case. Moreover, the patient-side assistant should be encouraged to speak up and voice tableside concerns, providing valuable real-time feedback to the otherwise unaware console surgeon. For example, information that two robotic arms are externally clashing with each other would be very helpful to the console surgeon who may be struggling with movement limitations and unaware of this problem. Simple responses from the assistant, such as "needle out of the body" or "change to zero degree on console", keep the console surgeon and OR staff abreast of the current tableside events and should be mandated as protocol. Using call-outs, cross-check, and check-backs should be incorporated during surgery to avoid technical errors or removing the wrong instrument during critical portions of the procedure.

To be maximally efficient, the assistant should always be actively involved in the operation, maximizing exposure and retraction. The assistant should become comfortable using two-handed retraction whenever two assistant ports are available. Dynamic two-handed triangulation of tissues to provide maximal tissue retraction is a key concept that is difficult to master but critical to maximizing efficiency. It involves creating a 3-dimensional field of view for the console surgeon by providing two opposite points of retraction at the surgical site. This frees up both console surgeon's arms to freely dissect instead of employing one robotic arm for broad retraction. This is one major conceptual difference between conventional laparoscopic and robotic techniques.

Fixed retraction can also be employed to free up an assistant hand. This can be done with the fourth robotic arm or with a passive retraction suture such as an externally passed Keith needle. A Keith needle can be introduced percutaneously

through the abdominal wall, attached to tissue that requires retraction, percutaneously brought out again and secured to the abdominal wall. Another method to provide hands-free retraction is the NovaGrasp™ (NovaTract Surgical, LLC). It is a hand free retraction device that can provide repetitive fixed retraction from various directions without the addition of another port.

One of the most important roles of the assistant during the operation is providing a clear visual field for the console surgeon primarily with suction and retraction. As stated above, two-handed triangulation of tissues provides maximal tissue retraction and a three-dimensional surgical field for the operating surgeon. The second method of providing an adequate visual field is suction. Clearing the field of excess blood, evacuating smoke from within the abdominal cavity and revealing the source of small bleeders is an essential role of the assistant. Unlike open surgery, the use of suction must be in small bursts. Continuous suction can result in loss of pneumoperitoneum, increased bleeding and pulling out of ports.

One possible solution to the problems associated with loss of pneumoperitoneum is the AirSeal® system (ConMed, Utica NY). The AirSeal® is an advanced laparoscopic insufflation system that can rapidly maintain pneumoperitoneum changes despite continuous suction [19]. This novel system uses a clever valve-less ports design and creates a horizontal pressure barrier by using re-circulated intra-abdominal CO_2. It may be useful during procedures with the potential for major blood loss (e.g., partial nephrectomy), but it may provide additionally benefits such as decreased intra-abdominal pressure settings and reduced fogging and smoke within a laparoscopic field. Disadvantages to this system are increased cost, increased background noise and stiffer/thicker gas tubing that may slightly impede the movement of the slightly larger port.

Laparoscopic suction devices usually have an irrigation function that can aid in visualization. Irrigating large blood clots can help break them up and allow for easier removal, while small amounts of irrigation can help clear an actively bleeding field without compromising intraabdominal pressures. However, over irrigation may result in excess edema and fluid retention postoperatively. The da Vinci system has an available robotically controlled suction instrument that enables the console surgeon to control the suction irrigator but requires the use of one robotic arm.

During the case, constant attention must be paid when inserting an instrument through any port. The Si and Xi system have "memory" when changing or re-inserting an instrument. After initially placing an instrument, any re-insertion of the same or new instrument will return the instrument to the last known position. Although this is a very helpful feature in most instances, careless re-insertion and lack of appropriate training can still result in inadvertent tissue trauma and catastrophic consequences. After the initial instrument placement, further instruments changes are often inserted through the ports blindly, and the assistant must pay careful attention to the changing dynamics of the surgical field and use extreme care to gently deliver the instrument in a safe angle while remaining attentive to tissue resistance. When placing an instrument through a port that is adjacent to the bowel, it is best to angle the instrument away from the bowel and visualize entry of instruments when necessary. Sharp instruments, such as scissors, should ideally be inserted through medially placed ports that are not adjacent to the bowel. If there is any uncertainty during instrument insertion or if resistant is met, the console surgeon must visualize the problem and watch the instrument in under direct vision. If the bowel is punctured by an instrument and removed without visualization, it is easy to miss the injury and miss the opportunity to address the problem immediately. One should have a low threshold to stop the procedure and inspect the field for inadvertent bowel or other injuries.

Once the assistant understands the surgical steps and the console surgeon's needs, a flow of the case can be established. Movements become anticipated, and optimal suction and retraction are provided. Instruments required for the next step in the operation will be prepped earlier and times waiting for instruments or instrument changes will be reduced. Failure to continuously utilize the assistant and to challenge the assistant to anticipate future steps can result in suboptimal exposure and slow surgical progression.

Urgent and Emergent Scenarios

The patient side assistant should always be prepared for a crisis. It is recommended that the surgeon discusses these potential situations with the team in advance and have a formal plan of action prior to the procedure. Having the needed equipment and supplies available in the room along with drilling for these unfortunate situations will most likely result in faster response times and improved performance. Vascular repair "rescue sutures", clip applicators and lap sponges to apply compression are items that should always be readily available during surgery. Specifically, ligation devices such as laparoscopic Hem-o-Lok® clips and applicators (Teleflex, Morrisville, NC), titanium clip applicators and vascular load staplers are commonly used in these scenarios. The assistant surgeon should be very familiar with their use. A 4-in. long 4-0 monofilament suture on a small tapered needle (or something equivalent) should always be on the field preloaded on a laparoscopic needle driver in case a vascular repair is necessary. Alternatively, a braided "rescue needle" with a pre-placed clip at the end can be very useful to control major bleeding laparoscopically.

Additional ports can sometimes be placed in an urgent situation to enable the assistant to provide additional help. The assistant should also mentally drill emergency maneuvers and techniques to minimize hesitation if an unfortunate situation unfolds. Preparation, quick action and calm thinking are keys to success in minimizing disasters.

If a non-emergent vascular injury occurs or continuous bleeding is encountered, the first step should be to temporarily raise the intra-abdominal pressure. In some cases, bleeding from major venous injuries can be slowed with this maneuver, giving the console surgeon the opportunity to repair the injury. There should be a low threshold for the addition of additional laparoscopic ports to provide additional retraction or suction if needed.

If these initial steps are not successful, compression of the area for 5–10 min with a robotic instrument or the assistant will give the surgical team time to prepare for the next steps. The introduction of a compressive sponge such as a 4 × 18 in. or 4 × 9 in. laparotomy sponge (Medical Action Industries, Arden, NC) through a 12-mm port can quickly stabilize rapid bleeding and buy time to recover and prepare for a coordinated attempt at repair. If the bleeding is serious, anesthesia should be alerted as soon as possible to manage any hypotension and blood loss. While the bleeding is controlled with compression, there is an opportunity to order blood products, secure additional vascular access, start pharmacologic pressors, get necessary instrument trays and call for a vascular surgeon or backup team.

When faced with brisk bleeding, an expeditiously placed non-traumatic grasper on a bleeding vessel is the simplest and most obvious maneuver that an assistant or console surgeon can do. In some cases, a hand port can be placed to provide direct manual pressure to salvage a laparoscopic procedure or provide compression during conversion to an open operation. If the abdomen needs to be opened quickly, the assistant, if possible, should try to laparoscopically hold point pressure on the bleeding source while the robot is quickly undocked and backed away. A cut-down incision can be made along the shaft of a port to rapidly enter the abdomen and avoid other injuries; however, caution must be made that once the intra-abdominal pressure is normalized to atmospheric pressure a lacerated vessel can transform into a rapid bleeder. Although it is always preferable to fix the problem with a closed abdomen, a timely decision to convert to an open operation may be crucial in preventing additional morbidity or mortality.

Troubleshooting

In addition to providing assistance to the surgeon, the patient side assistant main role is to troubleshoot and adapt to the operation constantly. As the only scrubbed surgeon, the patient side assistant can provide immediate relief to common problems. Table 7.1 provides a list of common problems encountered during robotic surgeries and possible solutions. As more experience is gained, the assistant will develop a quick algorithm in diagnosing and fixing many of these commonly faced issues.

Table 7.1 Troubleshooting: a diagnostic table of potential problems and solutions for the patient-side assistant

Problem	Possible causes	Solutions
Loss of pneumoperitoneum	**Inflow problem**	
	Insufflation tube unplugged or not screwed on tight	Plug in or tighten insufflation tube
	Out of CO_2	Replace CO_2 contained
	Line is kinked	Unwind tubing
	Port inflow valve closed	Open port inflow valve
	Insufflation tube leak	Replace main line
	Leak or Outflow problems—(Listen for leaks)	
	Port valve leak	Make sure all port valves closed
	Port site incision leak	Stitch port site or use towel clip
	Robotic port green seal leak (Si)	1. Plug seal with finger to confirm seal leak location 2. Replace green seal
	Non-robotic port seal leak	1. Plug seal with finger to confirm seal leak location 2. Replace reducer cap or port
	Suction issues	1. Avoid over-suctioning by keeping an eye on insufflation pressure. 2. Make sure suction button not jammed on "on" position 3. Consider AirSeal®
Loss of suction	Suction tubing unplugged	Plug in suction tubing
	Suction motor/ mechanism off	Turn on suction motor
	Suction tip clogged	Flush or replace suction tip
	Suction controller/ tubing cracked	Replace component
	Vacuum generator failure or leak	Replace vacuum generator
	Charcoal filter clogged (Neptune type device-if applicable)	Replace Neptune filter (if applicable)
Port pullout	Camera Port Pullout	For Si system: (1) Use translucent camera port to set proper shaft depth (fascia should be within ribbed area of port" (2) Use ribbed ports, not smooth ports (3) Can switch to balloon port (4) Avoid complete loss of pneumoperitoneum (5) Check for leaks or inflow issues For Xi system (1) Ensure port at proper depth (Thick black line)
	Robotic Port Pullout	(1) Set to proper depth on robotic ports (thick dark line on the port) (2) Avoid complete loss of pneumoperitoneum (3) Check for leaks or inflow issues
Unclear image	Dirty Camera Lens	Remove camera lens and clean (Cleaning the inside of camera port may also be needed)

Table 7.1 (continued)

Problem	Possible causes	Solutions
	Camera Fogging	1. Clean and warm lens with warm water 2. Clean and apply Antifogging solution or Betadine to lens 3. Keep unused lenses in warm water bath (Si system only; Xi system digital chip can be damaged by this solution) 4. Open Camera port valve to allow air leak through port with camera in place (speeds warming) 5. Wait until lens warm up in patient 6. Warm CO_2
	Splattering or Steaming of Xi Lens	Change electrocautery energy box Consider AirSeal®
Robotic arm limitations (Range of motion limited or "arm feels funny")	Robot parked too far/ too close	1. Park robot within sweet spot for Si 2. Ensure camera port at laser crosshairs for Xi
	Robot arms not set properly	Set robotic working arm elbows at 90 degrees
	Robot arm-arm conflicts	Optimize robotic arm angles (Use Patient clearance buttons on arms for Xi)
	Robotic arm bumping assistant, patient, equipment, table	Reset arm or move obstruction (Use Patient clearance buttons on arms for Xi)
	Robotic arm not burped	Burp arm
	Robotic arm drape fasteners too snug	Loosen up arm drape
Instrument failure	Instrument not recognized	1. Remove and re-insert instrument 2. Replace instrument 3. Ensure arm drape correctly applied or replace drape
	Instrument Expired	Replaced Instrument
	Trouble Grasping or Closing	1. Spin instrument 2. Remove and re-install instrument 3. Inspect instrument for cable breaks and replace if needed
	No Energy Source	1. Ensure electrocautery wires connected 2. Ensure electrocautery turned on 3. Ensure patient grounded 4. Ensure proper electrocautery settings 5. Ensure connect to console controls
Fault code encounter	**Recoverable Faults**	1. Clear with fault override 2. Ensure Ethernet cord connected (Xi) 3. Contact Customer service
	Non Recoverable Faults	1. Undock Robot 2. Turn off System and Re-boot 3. Contact Customer Service with fault code
Incorrect needle count	Needle lost in abdomen	1. Scan field immediately with minimal movement of field (more movement could hide the needle) 2. Obtain intraoperative KUB to confirm location in abdomen 3. Use C-Arm to help locate needle
Excess bleeding/Loss surgical field (non-emergency)	Suction Clogged	1. Flush or replace suction tip 2. Refer to *Loss of suction* checklist above 3. Consider 10 mm suction tip

(continued)

Table 7.1 (continued)

Problem	Possible causes	Solutions
	Low insufflation pressures	1. Check for leaks 2. Refer to *Loss of pneumoperitoneum* checklist above 3. Compress/Pack bleeder and allow pressures to recover 4. Increase insufflation pressure setting to 20 mmHg 5. Consider AirSeal® (maintains pneumoperitoneum despite suction)
Emergency situation	Emergency Bleeding	1. Attempt to grasp/compress vessel 2. Sponge via assistant port for compression and hold 5–10 min 3. Change arm to needle drivers and repair with 4-0 monofilament suture 4. Consider stapler, clip applicator, or flowable hemostatic agent 5. Consider open, or hand assist conversion with rapid entry by cutting down directly on port (expect increased bleeding once exposed to atmospheric pressure)
	Crashing patient	(1) Desufflate and undock immediately (2) Take out of Trendelenburg if air embolus (Mill-Wheel Murmur)
	Air Embolus (Mill-Wheel Murmur)	(1) Turn to Left Lateral Decubitus/Trendelenburg (2) Aspirate central line

Summary

As the only surgeon scrubbed during most of the case, the patient side assistant is responsible for the efficient and rapid progression of the procedure as well as the care and safety of the patient. In addition to assisting the console surgeon, the assistant must constantly identify and troubleshoot problems with the robot, equipment, and patient. They are the first to respond to emergencies and must be able to quickly diagnosis and manage each event. The patient-side surgeon is truly the unsung hero of robotic surgery, sometimes spending hours in a darken room, beaten up by a robotic arm in a small space, constantly cajoled by the console surgeon, who may not fully understand the conditions they are working in. The patient side surgeons are rarely if ever, congratulated with the type of respect or admiration the console surgeon receives. However, the assistant must remember that without them the case cannot be completed in an efficient and often safe manner.

Although the assistant is often overlooked, they command one of the most important jobs within the operating room.

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8 Training of Operating Room Technician and Nurses in Robotic Surgery

Stacey Dusik-Fenton and James O. Peabody

Abstract

Over the last several decades, there has been much technological advancement in the operating room. Laparoscopic surgery or minimally invasive surgery (MIS) was introduced over 20 years ago as an alternative to open surgery, and many surgical procedures can now be performed this way. However, some procedures have proven to be difficult to do in a pure laparoscopic environment.

Keywords

Operating Room · Team Member · Robotic System · Robotic Surgery · Minimally Invasive Surgery

Introduction

Over the last several decades, there has been much technological advancement in the operating room. Laparoscopic surgery or minimally invasive surgery (MIS) was introduced over 20 years ago as an alternative to open surgery, and many surgical procedures can now be performed this way. However, some procedures have proven to be difficult to do in a pure laparoscopic environment. A new and increasingly common technological device is the master–slave robotic system. With a master–slave robot system, the surgeon controls the main operating instruments and the camera (operating the robot) from a remote console or workstation.[1] The most commonly used robotic system is the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA). This robotic system provides the surgical team advantages such as 3D vision, magnification, wristed instrumentation, and tremor filtration for the robotic surgeon.[2] These advancements with the robotic system can overcome some of the drawbacks of laparoscopic surgery, in particular those related to suturing and working at difficult angles in smaller spaces. As the utilization of robots continues to evolve in the operating room and medical field, so will the role of the nurse and scrub technician.

During minimally invasive procedures, nurses must provide an increased amount and complexity of technical support. Nurses and technicians must seek opportunities to educate themselves about the technology, assess its impact, and determine how to best care for their patients with it.[3] While this increased knowledge is required for both laparoscopic and robotic surgeries, the complexity and novelty of the da Vinci system

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require a special educational effort. This knowledge will allow for educational and professional growth for the perioperative nurse and technician. A main role for nurses in the operating room is that of a patient advocate, and nurses must use this new technological knowledge and apply it to the overall care of their patient.

As of March 2009, there were 1,171 da Vinci robotic systems worldwide with 863 systems in the United States (Intuitive Surgical, Sunnyvale, CA). Over 140 hospitals own more than one da Vinci robotic systems, and one facility has five systems. Multiple robotic systems in a facility can increase the challenges and complexity of care for the perioperative nurse and technician. Multiple systems in an institution can increase the challenges because of a variety of instruments being used, different equipment, surgery services, and surgeons using the device. Nurses throughout the world are faced with the challenges, anxiety, and excitement of MIS, both laparoscopic and robotic, in the operating room.

Role of the Nurse and Technician

The primary role of the surgical nurse is to manage the environment in the operating room and to protect the patient within that environment.4 A thorough understanding of the da Vinci system is critical for the perioperative nurse when caring for their patient. The nurse and technician must be able to prepare the robot, provide optimal patient care, and set up necessary instruments and supplies for every robot procedure. As well as preparing for successful robotic cases, the nurse and technician must be ready to troubleshoot any potential electrical or mechanical malfunctions with the robot. The team must also ready for potential conversions to laparoscopic or open cases. The perioperative nurse must function in a variety of roles ranging from patient advocate, educator, team leader, coordinator, and problem solver. With the help of an organized robotic team, the nurse and technician will develop individual roles yet continue to work together for a positive outcome for each patient undergoing a robotic-assisted laparoscopic procedure.

The perioperative nurse must function as an educator for both themselves and other team members. The lead nurse should keep aware of the new software installations and new hardware developed for the robot. The surgical team should communicate any problems with the function of the robot such as difficulty with the 3D vision or problems with the functioning of an instrument or robotic arm so that the field engineer can be promptly notified. Open communication with the company's field engineers enables the nurse and team members to be aware of these developments and help to troubleshoot any problems. Once nurses are confident in their knowledge base, they can begin to teach other team members and new team members so that all are aware of the robotic developments and new procedures. Nurses must seek opportunities to learn and educate others regarding new developments in the robotic field. These educational opportunities and resources may be found through the robotic company online, robotic courses, conferences for nurses and surgeons, journal articles, robotic texts, and via other robotic centers.

Team leader and coordinator are important aspects of the perioperative nurse's role. The nurse must work with the surgeon to coordinate and advocate for their patients. The perioperative nurse is the leader in the room. With this important role, the team will be coordinated, and all equipment and supplies will be readily available. All robotic procedures have the potential of conversion to laparoscopic or open surgery. As the coordinator, the nurse is aware and prepared for all emergencies. The nurse should have equipment and instruments available if any conversion is necessary. There are several emergency "backups" that are built into the robot. As the team leader, one must ensure that the robot is always plugged into an electrical outlet, both the surgeon console and the patient-side cart. There is approximately 15 min of battery backup if there is a power failure in the medical facility. This backup allows the team enough time to safely remove the instruments and undock the robot. If the robot has been left unplugged, and the battery is empty, the robot will not function for the procedure to begin. It is important for the nurse to ensure and

coordinate that the robot is always plugged into an electrical outlet, especially if the system has been moved around the operating room or from one room to another.

The da Vinci robot consists of three main components. These include the vision cart, patient-side cart, and the surgeon console (Fig. 8.1). The nurse and all team members in the operating room must be familiar with all three components. Preparation of the camera and scope, which is housed on the vision cart and draping of the robotic arms of the patient-side cart, must be completed for each robotic case. The operating room team must know how to connect, calibrate, and set up the three components of the robotic system.3 There are potential mechanical and electrical malfunctions for each of the three components. Therefore, the nurse and operating team must be familiar with the system to properly troubleshoot all potential malfunctions. The operating team must also be familiar with the emergency procedures to remove the patient-side cart or robotic instruments from the patient.

Troubleshooting and problem-solving skills are important for the perioperative robotic nurse. Device failure with the robot may be mechanical or electrical. The nurse and team members must be able to identify the issue with the robot and try to correct the problem. The correction phase will help avoid potential laparoscopic or open surgery conversions. The operating room should be equipped with sterilely packed scopes, extra light cables, camera, drapes, sterile adapters, light bulbs, and instruments for immediate use if there is a malfunction. Having these items set aside and ready can save valuable time during the procedure. Once the mechanical or electrical failure has been identified, the team members may correct the issue. Telephone communication with the field engineer of the company can also be of assistance during both the identification and the correction of the problem. Some problems can be corrected easily, occasionally by simply rebooting the system. According to *AORN*, "to prevent user error and rapidly recognize device failure, all healthcare team members must thoroughly understand robotic surgery and their role in the procedure."5 Each team member must know their role for the team to function and avoidance of potential failures.

The role of the technician is that of an instrument engineer. With the assistance of the perioperative nurse, the technician coordinates the supplies and equipment necessary for the robotic surgery. The instruments, draping, calibration, and overall room preparation are completed in coordination between the technician and the nurse. The technician must also be aware of the differences in instrument use between the robotic surgeons, the differences between the three generations of da Vinci robots if they are all available in the same institution, and the variances between the instruments and the equipment. Educating other team members, troubleshooting and problem solving can be an important role of the technician. As a member of the dedicated team, the technician has an important role of the MIS team.

Fig. 8.1 Three components of the da Vinci robot – surgeon console, patient-side cart, and vision tower

The Dedicated Operating Room Team

The hospital and health system must invest time and money into developing a successful robotic program. Initial setup costs for the hospital include the purchase of the robotic system, identifying and developing a lead surgeon and assistant surgeon, and purchase of instruments and supplies. A dedicated, committed, and a highly trained operating room team are also necessary for the program to be a success.

The costs for training operating room personal must be considered. The new team should attend the training sessions, preferably with the rest of the surgical team so that the group can begin to work together. The team must practice to learn how to drape, calibrate, and troubleshoot the system as well as learning the basic functions of the robot for things like optimal positioning of the robotic arms, instrument changes, and lens changes. If there is any confusion for the team members, this can lead to inefficient handling of the equipment, instruments, and supplies.[5] An inefficient team and robotic system use will increase operative time and decrease cost-efficiency while increasing inventory and maintenance costs.[5] Creating a dedicated operating room team may help to overcome these inefficiencies.

Together as a dedicated team, they will learn and understand the complexity of the robotic system as well as the robotic surgeon and the robotic procedures. Open communication and dedication among the members including the surgeon are vital for the team to be successful. This communication is not only among hospital team members but also with the company's field service engineer and customer service representative. The involvement of the service engineer and service representative will aid in the training and education of the team members. These individuals can provide information regarding the robotic system and assist in the troubleshooting process. As stated by Leach et al., the

> …extent to which team members share the same understanding of operation, the major steps in the operation, and the critical points that might lead to surgical difficulties – and the OR environment – maintenance of a calm, positive working environment with expectations for respectful and supportive behaviors where "everyone matters" – influence surgical outcomes…[4]

A dedicated team that is training and communicating together and is working in a supportive environment facilitates in the establishment of a successful robotic program. The nurse and technician develop confidence in their roles and thus aid in the overall operating room efficiency. The efficiency is evident in room turnovers, room preparation, troubleshooting, patient care, and overall care of the complex robotic equipment. With an efficient and dedicated operating room team, the surgeons, hospital administration, management team, and patients will all benefit and notice a positive outcome. Positive patient results, decrease in operating room time, increase in productivity, and increase in staff satisfaction will be identified by all.

Robotic Room Preparation

When a hospital system makes the decision to purchase a robotic system, there are many factors that the administration, management, surgeon, and operating room team must appreciate and address. To begin, the type of robotic system and the generation of robotic system must be decided. Should the system be the high definition model, will there be 3D imaging system in the room for the assistants, what is the size and layout of the room, or are there other screens for assistant and visitors to view are a few other important questions that need to be addressed. The location of the system in the room and if the electrical outlets in the room can handle to voltage of the system are a few factors that must be thought through prior to the purchase of the system. Will the robotic system have a permanent "home" or will the system be moved throughout the operating room?

Once the type of system has been determined, it is beneficial for the hospital and operating room to have a permanent and stable room that will house the robot. If the robotic system must be moved from operating suites, there is a potential for damage to the system as well as injury to team members. The da Vinci robot consists of three components. These include the surgeon console, patient-side cart, and the vision tower. Each of these components requires its own electrical circuit and must be plugged in to maintain a constant charge on the battery. The battery backup is for emergency power failure and enables the surgeon to complete a portion of the surgery and the assistant to de-dock the robotic arms from the trocars. The system will not work

if there is not sufficient life on the battery and may take up to 24 h for the battery to properly recharge. Failure to maintain the battery can cause surgery cancellations or require conversions to laparoscopic or open surgery. Due to a set length of the cables connecting the three components of the robotic system, the three components must be kept in close proximity to each other. This requires adequate planning and developing of an organized robotic suite.

The assistant's ability to view either a 2D or a 3D screen is yet another factor to consider while preparing the robotic suite. Will the assistant be sitting or standing, will they be on the right side or the left side of the patient, will the assistant be able to communicate with the console surgeon, and where is the position of the patient in relation to the anaesthesia team. Once all components have been determined, the robotic room can be arranged and organized for a variety of robotic surgeries. The operating room's final arrangement must be beneficial for all those team members involved in the procedure, including the patient.

Once the room layout has been determined, the patient positioning equipment must be determined. There will be slight variances with patient positioning. This is related to the surgeon's preference and the type of surgery that will be performed. For the transperitoneal robotic-assisted prostatectomy, the patient is in a lithotomy position with extreme Trendelenburg position. The lithotomy position requires stirrups that will provide maximum support for the patient and adequate room for the robot. Due to the Trendelenburg position, the team must ensure that the patient is secured on the operating room table to prevent shift of position relative to the fixed robot during the procedure. The arms are tucked at the patient's side with ulnar nerve protectors around the hand and under the ulnar nerve (Fig. 8.2). The ulnar nerve protectors are taped and secured in an X configuration across the chest and taped to the operating room table. Safety straps are secured over the tape for an extra layer of security (Fig. 8.3). For robotic cystectomies or other pelvic robotic cases, the positioning is the same as the prostate. Robotic kidney cases have noticeable differences with positioning (Fig. 8.4). The patients are in a lateral decubitus position with operative side facing upward. An axillary roll is placed as well as a gel roll behind the patient to avoid potential rolling. The arm is placed in a Kranske arm holder, or pillows are placed

Fig. 8.2 Patient positioning of arms with ulnar nerve protectors for a robotic prostatectomy

Fig. 8.3 Patient in lithotomy with *yellow* finn stirrups, secured with tape and safety straps and Trendelenburg position

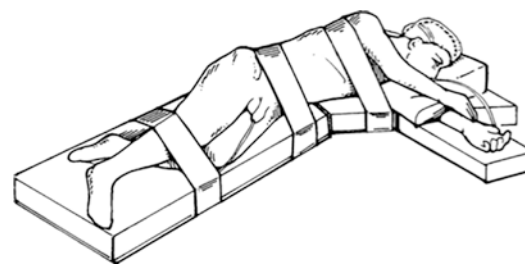

Fig. 8.4 Lateral robotic kidney position

between the two arms and secured with tape and rolled gauze dressing. The lower leg is flexed while upper leg is extended, with pillows between the two legs. Foam donuts are placed at the knee and ankle to protect from pressure points on the bed. The chest and legs are secured with tape and ulnar nerve protectors to secure patient to the bed. Once again, there are minor changes with surgeon preferences. Some surgeons prefer to use bean bags or gel pads between the patient and the bed. The ultimate goal for all the surgeries is to provide adequate security and protection for the patient while allowing access for the surgeon and the robot to perform the desired surgery.

For the operating room team, instrument trays and disposable products should be assessed, evaluated, and kept to a minimum for overall efficiency. The trays may be organized and based on laparoscopic instruments, robotic instruments, and open instruments. Each tray should have the minimum number of instruments that will be adequate to perform the surgery. If the tray has too many instruments, it will increase the turnover time for both central processing and room preparation. Similar to positioning, the trays will once again have slight variance depending on the robotic surgeon and surgery.

Efficiency in the operating room has a vested interest for all members of the operating room team as well as the surgeon, management, and hospital administration. Turnover time can be defined as "wheels out" to "wheels in." This definition is the time from when anaesthesia leaves the operating room with a patient until the time anaesthesia arrives at the room with the next patient. There are many factors that may affect the efficiency in the operating room, including instrument availability, operating room team, anaesthesia team, and team experience. Operating room efficiency improves with a dedicated team and with team experience.

Robotic Assistants

For the first time in the history of surgery the primary surgeon is not required to be by the bedside performing and assisting the surgery. This aspect puts phenomenal responsibility on the shoulders of the assistant in robotic surgery. The assistant surgeon may be a physician, a surgical assistant, or a registered nurse first assistant (RNFA). For robotic surgery with the da Vinci robotic system, the surgeon is operating from the console and the assistant is at the bedside. The surgeon then must rely on the assistant to provide direct hands on care to the patient. Communication among the members of the team is critical. The room should be arranged in such a way that it is easy for the team members to hear each other. During robotic surgery, the bedside assistant has a vital role in the overall care for the patient during the procedure.

The da Vinci robotic system used one robotic arm for the camera and may be equipped with two or three instrument arms. With three instrument arms (four-arm system), there is need for only one bedside assistant. Other surgeons may have the system with two instrument arms and may utilize either one or two bedside assistants. The main bedside assistant may assist from either the right side or the left side of the patient. This is dependent on a variety of factors. Factors include the surgeon training, experience and preference, assistant preference, the type of robotic surgery, and the operating room setup. For example, an assistant that is left handed may prefer to assist from the left side or visualization for the assistant might be optimal when the assistant is on the right side of the patient. It is beneficial for the console surgeon, bedside assistant, and the operating room team to identify these factors prior to the commencement of the robotic surgery.

The bedside assistant has a variety of roles and responsibilities. As mentioned before, the surgeon is at the robotic console and "unscrubbed" away from the patient's bedside. The assistant is the one at the bedside and must be prepared for potential emergencies such as conversions to laparoscopic or open surgery. The assistant should possess and develop expertise in laparoscopic skills such as gently grasping tissue to provide exposure, suctioning smoke, blood and other fluids, applying clips, and suture manipulation. As the laparoscopic skills and knowledge of the

operative steps improve, the assistant is able to move in a coordinated fashion ("dance") with the robotic console surgeon. The assistant is able to anticipate the surgeon's next move and is prepared for each of the subsequent steps during the surgery. Robotic skills also are necessary for the bedside assistant to develop. The assistant aids in the placement of the ports, docking of the robotic arms, placement of the robotic instruments, and scope changes and maintenance. The console surgeon may assist in the port placement and wound closure, but the surgeon is dependent on the bedside assistant for all other manipulations of the robot.

A well-trained primary assistant may become an educator for others who are in training to become bedside assistants. The primary assistant must educate others and help train them with both their laparoscopic and robotic skill base. Teaching is a key role for the primary bedside assistant. Depending on the hospital setting, there are a variety of team members that may become the primary bedside assistant. Some hospital settings use other surgeons or retired surgeons as the assistant. In teaching facilities, residents and fellows are used as the primary assistant who then develop the skill base to become expert console surgeons. Other facilities utilize ancillary staff team members such as physician's assistants (PA), registered nurse first assistants (RNFA), or surgical technician first assistants. There are many benefits in the utilization of ancillary staff as the primary bedside assistants. These assistants are long-term staff members and do not rotate through the operating room in the manner that residents and fellows do. The ancillary staff may become part of the dedicated robotic team and aid in the development of OR efficiency and overall patient care.

Conclusions

A successful robotic surgery program is dependent on a well-trained, motivated, and involved team of perioperative nurses and technicians. Their strong involvement in the program will help the surgeons who are perfecting procedures and developing new ones. The team will do so by keeping the robotic equipment functioning at its capacity, by helping the flow of the operation through having the necessary instrumentation ready and available, by efficiently turning the room over between cases, by providing assistance at the patient side when called on to do so, and by serving in their role as patient advocate to make sure that the operating room environment is as safe as possible for their patient.

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9 Robotic Urologic Surgery: How to Make an Effective Robotic Program—A European Perspective

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Abstract

Over the last decade the introduction of novel technologies substantially changed our approach to patients with urologic pathologies. Worldwide the number of robotic procedures performed per year is rapidly increasing. In current literature the relevance of robotic surgical training is progressively increasing although it is not easy to define and validate standardized paths for surgeons that are approaching for the first time to robotic surgery. In this context, the European Association of Urology Robotic Urology Section (ERUS) made several efforts in order to develop and validate an educational program for surgeons starting their robotic career.

Keywords

Robotic surgery · Robotic curriculum · Training · Robot-assisted radical prostatectomy

Introduction

The continuous and incessant implementation of technological updates revolutionized the practice in the field of most medical and surgical specialties. In particular, the introduction of novel technologies substantially changed our approach to patients with urologic pathologies over the last decade, where profound changes in the management of individuals with prostate, kidney, and bladder diseases were observed. For example, when considering the case of prostate cancer, available data suggest that robot-assisted radical prostatectomy (RARP) is able to provide substantial benefits in terms of perioperative outcomes as compared to open radical prostatectomy (ORP) without compromising oncologic control [1–3]. Moreover, retrospective analyses demonstrated that RARP might be associated with significant benefits in terms of perioperative results and functional outcomes such as continence preservation and potency recovery compared to the open and

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laparoscopic approaches [4–7]. As a consequence, the majority (80%) of radical prostatectomies are currently performed robotically in United States alone [8]. Similarly, the number of robotic procedures performed per year is rapidly increasing also in Europe. On the other hand, it should be highlighted that these benefits are evident in particular in the hands of experienced surgeons in high-volume centers. This is mainly related to the "learning curve" phenomenon typical of the introduction of a novel technology, which might still limit the benefits associated with the use of minimally invasive techniques such as robotic surgery on a large scale. Thomson and colleagues demonstrated that, also for a highly experienced surgeon, RARP has a relatively long "learning curve" period. In particular, the authors were able to demonstrate that the outcomes of the minimally invasive approach in the first cases were worse as compared to what observed in patients treated with open surgery by the same high-volume surgeon. However, the results of RARP improved progressively and surpassed the ones of ORP in terms of quality of life and positive surgical margins after a certain number of procedures [9]. This applies also to other procedures, where a higher number of cases done by a single surgeon or by an institution might be associated with improved results in patients treated with robot-assisted surgery. Various training methods aiming at reducing the learning curve phase and, therefore, at improving surgical outcomes in a rapid fashion have been developed in different countries and healthcare systems [10–14]. Nonetheless, it is not easy to define and validate standardized paths for surgeons that are approaching for the first time to robotic surgery, where the lack of long-term results and validation studies often precluded the diffusion of these initiatives [15].

In this context, the European Association of Urology Robotic Urology Section (ERUS) made several efforts in order to develop and validate an educational program for surgeons starting their robotic career. This resulted into the implementation of a novel educational program dedicated to urologists at the beginning of their career with robotic surgery that includes a basic training, a 6-month fellowship period, and a final evaluation done by experts. Of note, this represents nowadays the only validated training for robotic surgeons. This chapter will review the basic principles of the establishment of a robotic training program and will describe the strengths of the ERUS robotic curriculum for RARP.

The Importance of a Robotic Program

To start with a successful and self-sustaining robotic program, a well-structured plan is required. First, an accurate market analysis that should include the estimated surgical volume and competing entities equipped with robots in the surrounding area is mandatory to understand if a single institution can support and maintain a robotic program. For example, it has been demonstrated that, in order to be cost-effective, a single hospital should perform approximately more than 300 cases per year [16]. Subsequently the planning of a proper robotic team with multiple members with specific roles is required to familiarize with the technology itself. This could be conducted trough a multidisciplinary panel including members of different groups (e.g., hospital administrators, anesthesiologists, nurse coordinators, and obviously surgeons). A well-trained surgeon able to perform the procedure and keep the robotic program afloat is mandatory otherwise an expert surgeon should be enrolled to ensure the safe introduction of this technology.

The next step should be focused on maintenance and growth initiatives to maximize the benefits of the robotic program. For example, it is very important to prospectively collect data in order to track the outcomes and to implement measures aimed at further improving your own results. Indeed, continuous monitoring of the results of the procedures performed, interaction with colleagues, and a regular update with new technologies are essential measures to maintain and ameliorating the quality of care at your own institution. Finally, recent studies have shown that patients' interest in robotic surgery is rapidly growing [17]. For this reason, the impact of a robotic program at your institution could be improved with initiatives aimed at improving patient awareness regarding the potential

benefits associated with the robotic technology in different settings.

Training: Worldwide Situation

Nowadays, the main available curricula for robotic surgeons are the FRS (Fundamentals of Robotic Surgery) in the US, the FSRS (Fundamental Skills of Robotic Surgery) in the US, the BSTC (basic skills training curriculum) in Canada and the ERUS initiative in Europe. They are at various stages of validation and offer different combination of theoretical and practical training, using various simulators and models. It should be stressed that validation studies are mandatory to obtain a gold standard curriculum that possibly would have also a cross application and multispecialty features [15]. As already happened in the field of laparoscopy with the FLS (Foundamentals of Laparoscopic Surgery), it is expected that one of these may become the model for further surgical training in order to standardize training nationally and even internationally. This step would also allow for certifying surgeons as being able to safely and efficiently perform specific robotic procedures at a national or international level [18]. It is therefore important at this time that surgical educational figures worldwide would work together to promote the development and finalization of initiatives aimed at surgical education in the setting of robotic approaches.

The Erus Proposal: A "Structured Curriculum"

Prevalently, there are two main types of learning scenarios in surgery where the patient is at an increased risk for adverse outcomes. The former is when a novice surgeon is learning a specific procedure or when an experienced surgeon is performing novel approaches for the first time. The latter is when a pioneering surgeon seeks to innovate or develop a new technique [14]. Of note, the former is a common situation that could be prevented by introducing an adequate procedure-specific training program. Recently, it has been shown that surgeons adopting robotic surgery have a substantial learning phase that varies according to the task being learnt [19]. There is also growing evidence that non-technical skills (NTS) that affect patient safety and outcomes are related to surgical experience [20]. Therefore, there is a need for integration of these components within one structured curriculum. Since a few years the ERUS educational working group is developing a structured training curriculum in Urology focused on surgeons with limited robotic experience that are willing to perform RARP at their institutions [21]. The concept of a structured training program means that it is composed of different steps and tasks that the participant has to accomplish in a given sequence. This approach leads to a more progressive and exhaustive training that could be applicable to surgeons with different surgical experience, eventually resulting into excellent outcomes. In fact, this method includes all the available simulation training modalities as the e-learning, virtual reality, laboratory training with various models ranging from synthetic, animal and cadaveric models and finally the supervised modular console training. It is also the first structured training program on RARP to incorporate the use of cadaveric models, "in vivo" lab activities, and a non-technical skills module [15]. Of note everything is included into a fellowship-style training program of the length of 6 months, which provide the most comprehensive training that couldn't be attained with other modalities such as short-term courses, mini-fellowships, and mentored skill courses [14]. This training has proven to be a valid, acceptable and effective tool able to shorten the trainee learning curve and improve patient safety with promising results [10].

Validation: Pilot Study

The first validation study of the ERUS robotic curriculum included ten participants coming from different institutions undergoing a 12-week training program that included e-learning, operating room observation, bedside assistance, and double-console observation, an advanced robotic skills course, and modular robotic training with the aim of being able to complete a full procedure autonomously at the end of the training period.

Most of the participants had minimal experience with robotic surgery with a median time of involvement as a console surgeon of only 4 months. At the end of the training, approximately 80% of them were judged to be able to perform a RARP independently and safety. The two participants who did not achieve the minimum average score were residents and it was hypothesized that they were not able to perform a sufficient number of cases during the training period. Therefore, the length of the fellowship has been increased to 6 months to allow the trainee to be exposed to an adequate number of cases, as detailed in the following section on the current version of the ERUS Curriculum.

All participants were asked to fill a questionnaire. They found all the parts of the training to be useful. More than 70% of them considered the advanced part of the course including dry and wet lab extremely important and more than 90% of them would recommend this fellowship to other colleagues. Thanks to these encouraging results, ERUS group is working to endorse more training programs with the aim to certify surgeons for urologic procedures [10].

Erus Curriculum Today

The idea of the ERUS educational group starts from the concept that the human being is not the ideal training module. This is particularly true in the setting of robotic skills development. Nowadays, several alternative training models exist and it is of extreme importance to optimize their use for educational purposes. The ERUS curriculum has the aim to develop both theoretical and technical knowledge, improving performance, shortening the learning curve, and achieving proficiency in the use the robotic system ameliorating patient safety and outcomes. Under this light, it should be stressed that the total duration of the curriculum was extended to 6 months to expose the trainees to an adequate number of cases during the modular training. Moreover, only high-volume centers that fulfill selected criteria and would be able to provide a sufficient number of cases and qualitative mentoring of the fellow during the modular training are considered as host centers. Table 9.1 lists the requirements to be fulfilled in order to be eligible as host center for the ERUS curriculum program (Table 9.1). Of note, the curriculum is not restricted on the basis of previous experience with open surgery because both novice and experienced open surgeons require mentoring during the initial phases of robotic surgery skill acquisition [14].

Erus Curriculum Structure

The ERUS robotic curriculum lasts 6 months and is structured in four main parts (Fig. 9.1). The first is the theoretical part, which can be performed independently by the participant also at their host institution and consists of theoretical training and e-learning. The second part consists of a 4-week period of live case observation and tableside assistance at the host center. The third part represents a very important step forward for the trainee because he will participate to a 5-day intensive advanced skill course at a dedicated training center where could also interact with his peers participating to the ERUS curriculum in other host centers. The last part of the curriculum is the most durable and important step that include up to 5 months of modular robot-assisted prostatectomy console training at the host center. The ERUS robotic curriculum is then concluded after the trainee performs a full-procedure autonomously at his host center. This procedure will be

Table 9.1 Host center criteria to be eligible as host center for the ERUS curriculum program

Two or more robotic surgeons with extended experience (>250 robot-assisted radical prostatectomies performed in total and > 100 cases in the host center during the past 12 months)
Five or more peer-reviewed publications in the past 5 years from the center
Commitment to train properly and allow the trainee access to the robot
Availability of simulators and/or dry lab for training

Abbreviation: *ERUS* European Association of Urology Robotic Urology Section

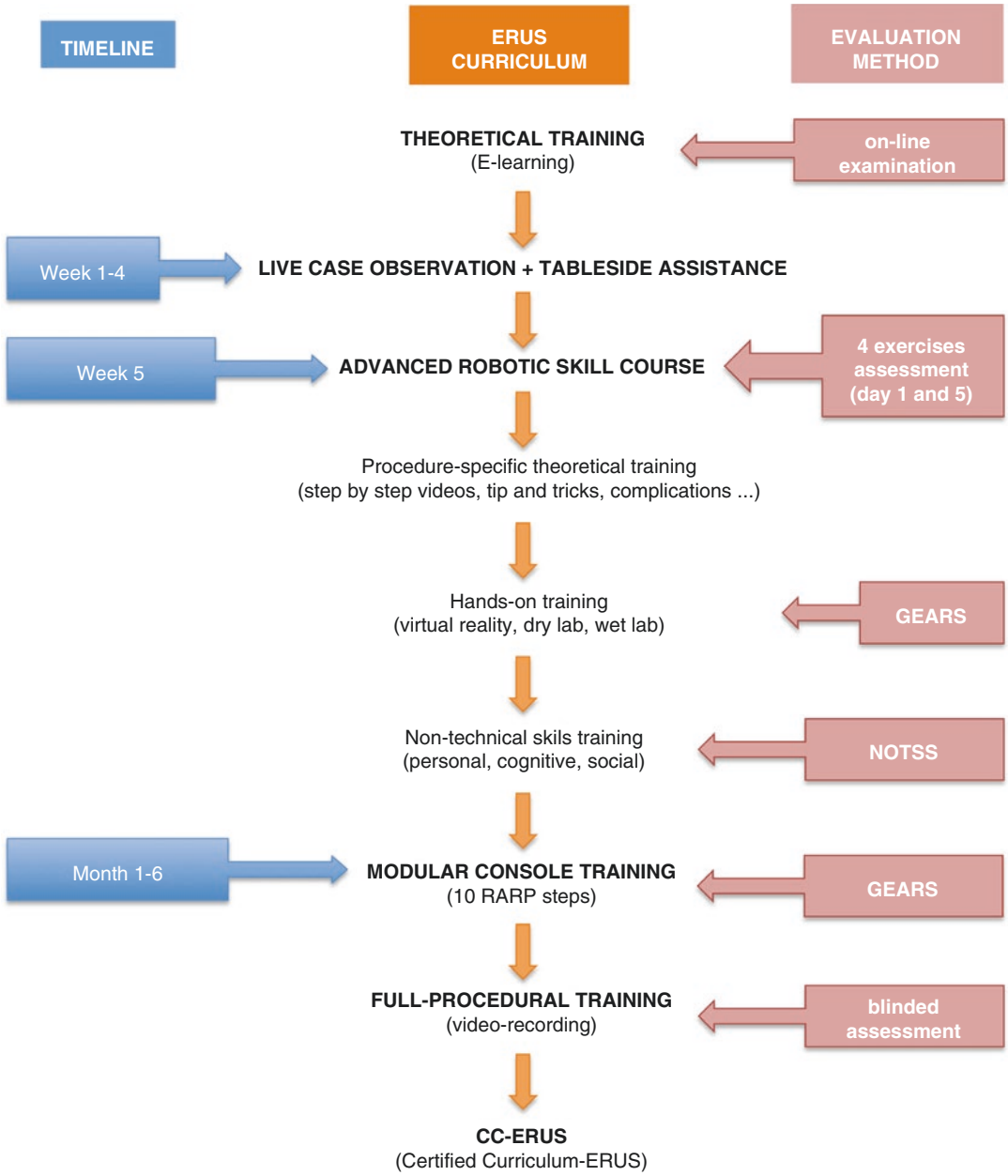

Fig. 9.1 Structure of the ERUS curriculum with evaluation method used in each phase. *ERUS* European Association of Urology Robotic Urology Section, *GEARS* Global Evaluative Assessment of Robotic Skills, *NOTSS* Non-technical skills for surgeons, *CC-ERUS* ERUS certified curriculum

then evaluated by a specific committee of independent blind reviewers, who will assign a score to each step of the surgery. A minimum score is necessary in order to be considered able to safely and efficiently perform a RARP and, therefore, to successfully accomplish the training.

Theoretical Training

For a successful performance of any surgical task the participant needs to know what to do (domain knowledge) and how to do it (technical knowledge) [22]. For this reason, the theoretical

training is of extreme importance. We choose the e-learning modality because of its practicality. It comprises notions regarding components and main features of the robotic system, basic principles of endoscopic surgery, surgical anatomy and surgical procedures. Of note, this step is concluded by an examination via multiple-choice questions that the participant must pass to get the access to hands-on and modular training.

Live Case Observation and Tableside Assistance

Live case observation allows for the participant to better understand what learned during the theoretical course. There is the possibility to directly interact with mentors/trainers with specific questions and discussions. At the same time, the participant is continuously stimulated to pay attention to important details that must be acquired. 3D screens and double consol facilities could improve capturing information during live case observation allowing the same vision as the surgeon (Fig. 9.2a, b). It is also demonstrated that tableside assistance might be beneficial for console surgeons [14]. For example, Thiel and colleagues reported that assistants substantially improve their intra-abdominal spatial orientation after a three-phase specific training including the basics of robot functionality, a step-by-step video of the procedure, and a hands-on practice session [23].

Advanced Robotic Skill Course

The advanced robotic skill course is an intensive 5-day course performed at a certified center able to offer to the participant all the technology and technical facilities needed. Indeed, the ERUS robotic curriculum contemplates virtual reality simulation, dry lab, and web lab sessions during this phase. The first day of the course include a half-day **introductive course** given by a technician who will explain all the main features of the robotic system in order to familiarize with the equipment and face troubleshooting.

During all the week there are sessions dedicated to **procedure specific theoretical training** where trainers show specific procedural step-by-step videos, explain main tips and tricks, and alert on possible complications and their management.

Hands-on training represents the core of the advanced robotic skill course. The first step is virtual reality simulation, which has been demonstrated to improve surgical performances [10, 12, 24–26] (Fig. 9.3). It is particularly useful to familiarize with the console, three-dimensional vision, and wristed instruments. All the participants are assessed on day 1 before starting hands-on training and on the last day. During the ERUS validation study the scores on four different simulator exercises significantly increased after 5 days of training particularly in trainees with low baseline robotic skills [10]. Virtual reality simulation is able to substantially improve performances on dry and wet lab exercises, which are

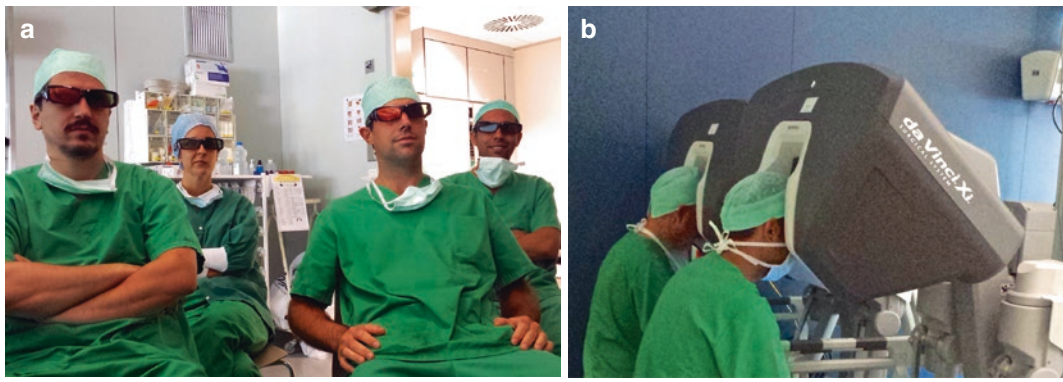

Fig. 9.2 (**a**) Live case observation with 3D screen and glasses. (**b**) Double consol live case observation

Fig. 9.3 Virtual reality; trainees using daVinci simulator

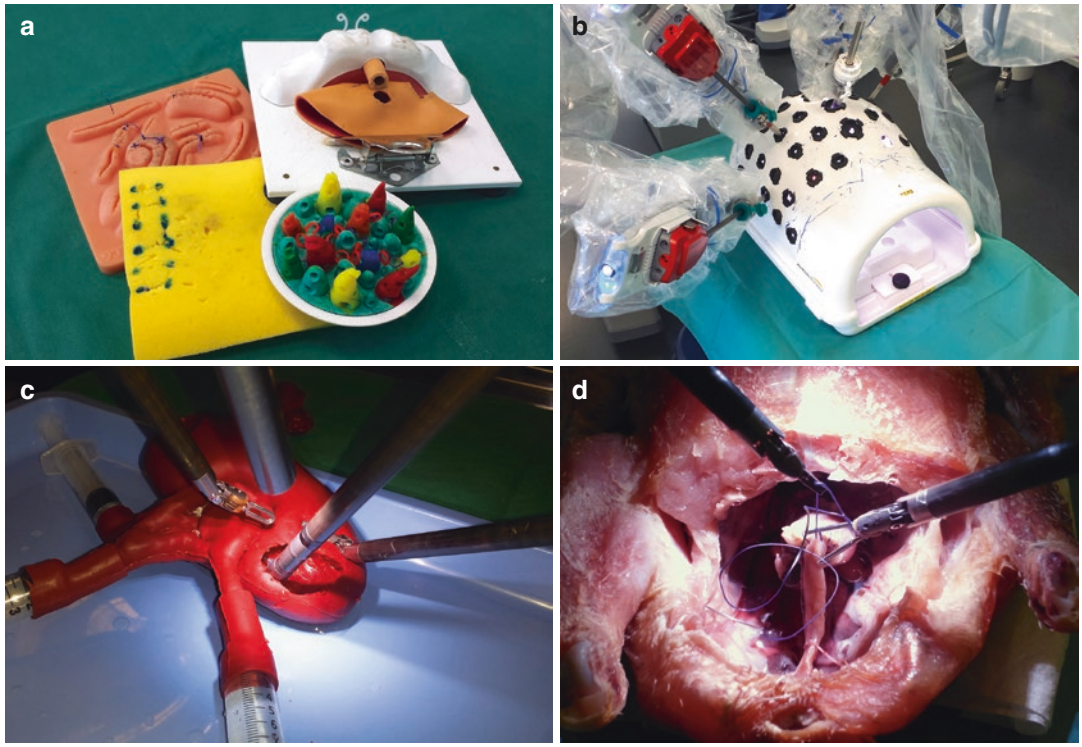

Fig. 9.4 (**a**) Exercises used during dry lab hands-on training (peg transfer, suturing and anastomosis model). (**b**) Dry lab hands-on training box. (**c**) Dry lab kidney training model for partial nephrectomy practice. (**d**) Dry lab chicken model; for anastomosis practice

the next hands-on training model proposed [25]. Therefore, it is mandatory to accomplish this step before moving forward to more complex exercises in the dry and wet lab.

Various dry lab synthetic and animal models are available (Fig. 9.4a–d). Dry lab exercises as peg transfer, vertical and horizontal suturing and anastomosis models are widely used with partic-

ular attention of the mentor to explain technical issues to the participant. Is essential to start with a simple model and to change it with a more demanding one only when the trainee is able to perform it in a technically correct way and with an appropriate timing. Regarding animal models, the Venezuelan chicken is a very useful and cheap model for the uretro-vescical anastomosis that mimics the "in vivo" procedure and allow for several consecutive surgical simulations [27]. Conversely, the dog cadaver model is very useful particularly for urologist because of the similarity of the dog prostate to the humans. This, in particular, allows participants to train also very demanding steps of the radical prostatectomy such as the bladder neck and apical dissection, the nerve-sparing dissection and the uretro-vescical anastomosis. As such, the wet lab represent the most sublime, but also the most expensive model that permit to practice complex exercises in a realistic setting due to the similar anatomy of some organs between animals and humans [11, 12, 28, 29] (Fig. 9.5). All participants are assessed continuously during dry and wet lab exercises. Differently from the virtual reality simulation, dry and wet labs lack objective assessment tools. However, validated non-objective tools as the GEARS (Global Evaluative Assessment of Robotic Skills) have been proven to reliably differentiate between different robotic skill levels [30]. Recently a study demonstrated that skills developed during lab training would directly improve performance during live human surgery. In this study a group of gynecologic surgeons naive to robotics practiced at simulators until reaching the expert's benchmarks. Before performing their first-ever human robotic surgery hysterectomy they completed also robotic pig laboratory training. The comparison of perioperative outcomes as operative time, blood loss and blinded assessments of surgical skill between experts and non-experts yielded similar results [31]. These findings are encouraging, even if further studies are needed to strengthen this evidence also in the context of urologic procedures.

Non-technical Skills

Most of the existing training programs, such as the FSRS and the FRS, lacks a non-technical component. On the other hand, one of the main advantages of the ERUS robotic curriculum compared to other available training paths is the inclusion of a non-technical skill theoretical course that is incorporated in the theoretical training and a non-technical course, which is planned during the advanced robotic skill course.

Non-technical skills could be divided in three distinct categories. The first one is cognitive skills that include the decision-making process

Fig. 9.5 Wet lab pig training model that permits to practice complex exercises in a realistic setting

and situation awareness, the second one is social skills that incorporate communication, teamwork and leadership abilities and the last one is personal resource factor including individual's ability to cope with stress and fatigue.

Two principal modalities are used to deliver non-technical skills, the former is classroom teaching and the latter is simulation-based training. For example, live observation of own practice videos and mistakes represents an excellent teaching method. Debriefing after critical incidents is useful to consolidate non-technical skills. During classroom teaching the participant is continuously assessed using specific rating systems. For example, the NOTSS (Non-Technical Skills for Surgeons) is a rating system used to assess the cognitive and social skills in the workplace; it follows the same hierarchical structure of categories, elements and behaviors as systems used in other professions such as anesthetists (ANTS) and aviators/aircraft pilots (NOTECHS) [32].

Non-technical skills should be integrated in previously validated simulation-based curriculums in order to develop skillsets in a structured and safe environment.

Modular Training in Robot-Assisted Radical Prostatectomy

In 2006, Stolzenburg and colleagues proposed the concept of modular training for laparoscopic radical prostatectomy with the aim to establish a teaching program that would ascertain the safe and efficacious training for residents with no previous experience with open pelvic surgery. The procedure was divided in 12 steps with different levels of difficulty and the trainee starts gradually from the simplest. The modular training allows fellows to perform surgical steps of the procedure with increasing level of complexity in a progressive, supervised and proficiency-based way.

In the ERUS robotic curriculum the robot-assisted extraperitoneal radical prostatectomy was similarly divided into individual steps listed here:

1. Bladder detachment
2. Endopelvic fascia incision
3. Ligation of dorsal vein complex
4. Bladder neck incision
5. Dissection of the vasa and seminal vesicles
6. Preparation and section of prostatic pedicle
7. Dissection of neurovascular bundles
8. Apical dissection
9. Urethrovescical anastomosis

The fellow starts performing the step corresponding to his skill level and the mentor should complete the remaining part of the procedure (Fig. 9.6). With this approach the fellow progressively improves and acquires the capability to pass to a more complex module. Once he is able to perform independently and safety all the steps, the aim is to allow the fellow to perform the entire procedure by himself. At the end of 6 months participants are required to video-record a full-length procedure and to send it to experts for a blind evaluation. The mentor would give the accreditation to the fellow only if the quality of the recorded case is considered satisfactory according to predefined criteria.

The availability of a dual console facility represents a further modality to intensify the education, because it allows direct proctoring during the procedure. Under this light, Morgan and colleagues compared the outcomes of RARP using dual-console versus single-consol and demonstrated that in a resident training program using intra-, peri- and postoperative measures dual-console may represent a safer and more efficient modality for robotic surgical education [33].

Once the ERUS robotic curriculum is successfully completed and the video is judged to be satisfactory according to the objective scores of the independent blind reviewers, the fellow would receive a certification for the specific procedure.

Credentialing

Currently there is no consensus on a robotic surgery credentialing process. Credentialing is important to certificate the trainee to overcome the technical learning curve so can deliver safe

Fig. 9.6 Modular training; the trainee has the access to a specific web platform in order to fill each performed procedural step

and effective care to the patients. This should be the result of a standardized, competency-based process regulated by robotic surgery experts. However, nowadays the risk is that credentialing would represent only an industrially driven process that is neither standardized nor competency based. At present there are no healthcare regulation entities that deal with credentialing

guidelines for robotic surgery. Of note, the aim of credentialing shouldn't be to single out expert surgeons from the group, but to provide a certification confirming that the surgeon is able to deliver a safe and effective care to his patients. To do this, there are a lot of delicate issues to be clarified. For example, it is still unclear how to determine the minimum number of cases per each procedure to consider a trainee ready to start safely and efficaciously. Indeed, the literature reveals a wide range of minimum recommended number of cases required to overstep the learning curve of RARP ranging from 8–12 to 800 [34, 35]. Another problem is the definition of the learning curve. For example, there is a huge difference between the concept of technical learning curve that can be overcame during a defined training interval and the concept of outcome learning curve which is a process that could even last years [36]. Furthermore, important inter-individual differences exist such as surgeon's innate skill level, case density during the initial learning curve and the presence or absence of peer collaborative learning. In order to obtain a consensus for the right credentialing of robotic surgeons, standardization is needed and this could be obtained only trough well structured validation processes.

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My Prostate Cancer: Patient's Perspective

10

John M. Barry

Abstract

On March 6, 2007, I had a robotic-assisted radical prostatectomy and pelvic lymph node dissection for a pT2C, N0, M0, Gleason 3 + 4 adenocarcinoma of the prostate. At my 11-year follow-up, I was disease-free, continent of urine, and as potent as I wanted to be. This is my story.

Keywords

Prostate cancer · Personal · Incontinence · Erectile dysfunction

Diagnosis and Treatment Plan

My serum prostate-specific antigen (PSA) level was elevated to 6.81 ng/mL on October 9, 2006. I was 66 years old. My prostate was normal on digital rectal examination. All of my previous PSA determinations had been normal, and I didn't have time to deal with the issue. There were two meetings coming up, the Western Section of the American Urological Association (AUA) and the Northwest Urological Society (NWUS), and I wanted to spend Christmas with my mother who was dying in a nursing home in Winona, MN, 2000 miles away. At the section meeting, I was nominated to be the President of the AUA. After the NWUS meeting in early December, I spent Christmas with my mother, and then returned to Portland for a determination of my total and free PSA. On December 27, 2006, they were 6.7 ng/mL and 10%, respectively.

I plotted my data on two nomograms and determined that the probability of a positive biopsy was about 0.85.

I stopped taking a baby aspirin a day, which I had been doing for no good reason, calculated my International Prostate Symptom Score (IPSS) and Sexual Health in Men (SHIM) score (they were 7 and 21, respectively). Then I made two telephone calls: one to Dr. Mark Garzotto, one of our three urologic oncologists, and one to Karen Gates, RN who had been in our urology clinic nurse for over two decades. After my lower colon prep and an oral dose of a fluoroquinolone, the three of us met in the procedure room of our urology clinic at 7:00 AM, Wednesday, January 3, 2007, where Mark did a digital rectal exam to be certain there was no stool, a transrectal ultrasound (TRUS)-guided prostatic local anesthetic block, and ten needle core biopsies. I developed a vasovagal reaction with the first biopsy, spent a few minutes in the head-down position until my blood pressure and pulse returned to normal, and nine more samples were taken. My prostatic apex was not numb.

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Table 10.1 Prostate biopsy results

Site	Right	(% of core)	Left	(% of core)
Base	3 + 3	<5	PIN	
Upper mid	3 + 4	10	3 + 4	10
Lower mid	3 + 3	20	3 + 3	5
Apex	3 + 3	20	Benign	
Transition zone			PIN	3 + 3

At 8:00 AM, right after the biopsies, I did my morning general urology clinic, finished it shortly after noon, and then took the tram up the hill to the other campus to do the kidney transplant candidate clinic with the transplant nephrology staff and residents.

Dr. Chris Corless, genitourinary pathologist, read the slides later that day, and Mark Garzotto called and said that he and I needed to discuss the results. We met at the conclusion of the afternoon renal transplant candidate clinic and reviewed the results (Table 10.1). We agreed on the necessity for treatment of this intermediate risk prostate cancer and reviewed the options of surgery, radiation, cryosurgery, and high-intensity focused ultrasound (HIFU). We decided that the best therapy for this curable lesion was a radical prostatectomy, probably unilateral nerve sparing on the left. The questions were, “Where and by whom?” I started my Kegel’s exercises.

After input from many sources, including three of my friends who were experienced open prostatectomy surgeons and had become robotic prostatectomy surgeons, I decided to have a robotic-assisted laparoscopic radical prostatectomy by my friend of 25 years, Dr. Mani Menon, at the Vattikuti Urologic Institute of the Henry Ford Health System (HFHS) in Detroit. As he and I chatted on the telephone, I felt my anxieties melt away, and I knew the decision was correct.

Recovery from the Biopsies

Initial gross hematuria started the day after the biopsies and resolved, for the first time, 4 days later, just before my wife, Toni, and I went to the Oregon Governor’s Inaugural Ball at the Convention Center. Hematuria returned on Monday, January 8, 2007, right after the resident, Dr. Lisa Bland, and I finished bilateral nephrectomies and a kidney transplant. It resolved 11 days after the biopsies.

The prostatic soreness required regular dosing with acetaminophen for 4 days. It recurred from time to time after that, and it always responded to acetaminophen.

The lower urinary tract symptoms (LUTS) initially resolved 4 days after the biopsies, only to recur at decreasing intervals. By January 17, two weeks after the biopsy, the LUTS were gone.

A sleep disturbance began the day of the biopsies and required some help from my primary care physician, Dr. Donald Girard. He prescribed a short-acting hypnotic (zaleplon), which I took when I was awakened by thoughts about prostate cancer between 1:00 AM and 3:00 AM each night. The night of January 13, ten days after the biopsies, sleep was finally undisturbed by my ruminations about prostate cancer.

My first ejaculate, a week after the biopsies, was like crankcase oil (or hot fudge sauce, depending on one’s frame of reference). A week later, it had changed to the color of caramel sauce, and then finally became clear.

January 11–26 was spent surfing, first in The Cove on Maui, and then at Pua’ena Point on the North Shore of Oahu.

On January 13, ten days after the biopsies, my thoughts changed from, "I'm going to miss my prostate" to “I want it out.”

Detroit

Toni and I flew coach class on Northwest Airlines from Portland, OR, to Detroit on Sunday, March 4. We were met in the baggage claim area by a driver with a Lincoln Town Car and taken to the Ritz-Carlton Hotel in Dearborn. We arrived at the hotel at about 7:00 PM. We stayed in a suite with

Club Floor privileges and the Vattikuti Comfort and Care Package.

We were driven in a Town Car to the HFHS campus for our visit with Dr. Mani Menon's team and the Department of Anesthesiology on Monday, March 5. That evening, it was a soft diet and a bisacodyl suppository. Shameem, Mani's wife, called to see how I was doing, and I told her that I hadn't quite started bouncing off the walls, but I was close to doing so. My daughter, Dr. Michelle Barry, checked into the adjacent room very late that night.

Radical Robotic Prostatectomy + Bilateral Pelvic Lymphadenectomies

The three of us were up at 3:30 AM to get ready to take a Town Car back to the Henry Ford Hospital and its preoperative area. After I stripped and got into a hospital gown, Nurse Christine started an IV in my right hand, gave me heparin 5000 subcutaneously, and hung the IV antibiotic, a cephalosporin. Pam, a big black woman, came in and shaved my anterior thighs and ticklish abdomen. Dan Eun, one of the urology residents (now a professor at Temple University School of Medicine in Philadelphia), introduced himself, and Mani came by to say, "Hello." My anxiety level peaked. I started thinking about Saddam Hussein's execution and criminals who were getting prepared for lethal injection. Then I was wheeled out of the preoperative area, down the hall, and into the operating room (OR). The anesthesiologist met me at the doorway, and in we went. It was the same room where I'd watched Mani do a robotic prostatectomy 17 months earlier when I was a Vattikuti Visiting Professor. I transferred to the OR table, and that's the last thing I remembered until we were on our way from the recovery room to my private room, 21A, on B-3. Michelle and Toni were with me. My calf squeezers were working, ketorolac was given IV every 6 h, and I was getting heparin 5000 units subcutaneously every 8 h. The 20 Fr. 5 cc Bard 0165v20s Silastic-coated Foley catheter with 20 cc in the balloon was taped to my left thigh and drained into a bag off the left side of the bed.

I was euphoric! The prostate was out, and I was alive.

The evening of surgery, I was up, walking in the hall, and chatting with patients and their families. I even invited the wife and daughter of the man across the hall to come over and chat. He had undergone his radical prostatectomy that same day. I called my wife at the hotel and asked her to bring my laptop computer and thumb drives so I could give a talk at Urology Grand Rounds the next morning.

The next morning, it was a liquid diet, an inspection of the six port sites, the left periumbilical one of which was the extraction site, and off to give my 7:00 AM Urology Grand Rounds talk, "Time Management for Urologists," in my purple Vattikuti Institute robe and hooked to my Jackson-Pratt drain, IV, and urine drainage bag. This was followed by a short case presentation of a woman with end-stage renal disease, chronic pyelonephritis, and an ileal conduit. I gave a Society for the Prevention of Cruelty to the Prostate (SPCP) necktie to each of the three residents, Michael Fumo, Daniel Eun, and James Lewis, who had participated in my surgery. Then I returned to my room to wait for the discharge/outpatient care class. The nurse suggested that I take a couple of acetaminophen + codeine tablets to deal with any discomfort during the class. This turned out to be the only narcotic I took in the entire postoperative period. Brad Baize, a nurse with an injured hand, gave an excellent presentation about the expected postoperative course and how to manage the bladder drainage catheter and deal with potential problems. I was disappointed that many of the patients said that their urologists at home refused to provide follow-up care unless the procedure had been done by them or in their medical community. When I returned to my hospital room, I received my last dose of ketorolac, my last dose of heparin, my drain was removed, my IV was pulled, and the catheter tape was removed and replaced with an elastic Velcro strap. I changed the overnight bag for a leg bag, got dressed in my navy-blue suit, white shirt, and a necktie. We called for a Town Car, and the three of us returned to the Ritz-Carlton.

Post-op Days 1–6

The afternoon of postoperative day 1, we walked from the hotel to the mall, which was about a quarter of a mile away, and back, and spent about an hour in the club on the 10th floor. That evening, I took a bisacodyl suppository and had a loose, incomplete bowel movement. That night, I streaked the sheets with a small amount of stool. After that, I used a pad on the sheets every night until we left the hotel. Fortunately, I never needed one after that first night. The next day, we walked to the mall and spent some time with Michelle who left for Albuquerque in the early afternoon.

Friday, we saw the movie, "300," by mistake. It was good.

Saturday, I had a normal bowel movement, and we went to see the movie, "Dreamgirls." It was good.

Sunday, we visited the mall and relaxed. That evening, Mani and Shameem picked us up, and we went to dinner at an excellent Lebanese restaurant, Le Sheesh. I came to the conclusion that the back seat of a Lincoln Town Car was much more comfortable than the back seat of a sport-utility vehicle (SUV).

Monday, we went to the Henry Ford Museum, and I revised the VIP discharge patient instructions. I went by Town Car to the Henry Ford Hospital (HFH) where I was assigned an office next to Mani's. I saw two pre-op patients to whom I described my experience. I illustrated my leg bag to the second one. Afterward, I met with the residents and some of the staff for a presentation of the day's inpatients. Then we made hospital rounds. I was pleased to be the "Poster Boy" for the VIP program. After a return to the hotel, I started trimethoprim/sulfa (TMP/S) in preparation for a cystogram and, hopefully, catheter removal the next day.

One-Week Follow-up

Tuesday, 1 week after surgery, we loaded the carryon bag with urinary incontinence supplies, books, and two daily newspapers. We were driven to HFH for our 10:50 AM appointment. The cystogram was negative for a leak, and the physician assistant, Folusho Ogunfiditimi, removed the catheter a few minutes later. Mani, Folusho, Toni, and I reviewed the pathology reports for both the intraoperative frozen sections and the surgical specimen permanent sections. The specimen weighed 38.3 g. The intraoperative frozen section margins were negative for tumor. The final stage was pT2C, N0, M0. The final Gleason grade was 3 + 4. We discussed penile rehabilitation with a 5-phosphodiesterase inhibitor and injections of Bimix, a combination of papaverine and phentolamine. I signed up. One-half hour later, I felt the urge to void, and went into the restroom where I voided clear urine with a good stream. There was a twinge of perineal pain at the very end of the void, and I had difficulty shutting it off. Thirty minutes later, I went again and noticed that my pad and briefs were wet. I had brought extra pads but had forgotten to bring an extra pair of briefs. So, it was back to the hotel and a call to Mani's office to cancel my participation in the VIP website revision, case reviews with the residents, and rounds on the robotic prostatectomy patients done that day.

Wednesday morning, it was up at 6:30 AM, a Town Car ride to the HFH where I gave Urology Grand Rounds on "The Urinary Tract in Renal Transplantation." After that, I made rounds with the residents and Mani, revised the Vattikuti website with a webmeister, Pam Landis, went to the off-site clinic to see patients with Mani, and talked on the telephone with a mutual friend who, unfortunately, had a recurrence of his leukemia. I saw pre-prostatectomy patients until about 2 PM. Then I returned to the hotel by Town Car and took a nap. That evening, we had dinner with Mani and Shameem in the restaurant at the Ritz-Carlton.

Thursday morning, we had breakfast on the club floor and took the hotel's courtesy SUV to the Greenfield Village, which, unfortunately, was closed. So, we did a second visit to the Henry Ford Museum. The pads and I were becoming well acquainted. I found that if I folded a towel from a towel dispenser in a men's room, it would fit inside a pad and soak up a few milliliter of urine so I could just toss or replace the paper towel and not have to change the pad.

Friday morning, after breakfast on the club floor, we walked over to the mall and saw a bad movie, "Wild Hogs." That evening, we returned to the mall and went to a sports bar called "Strikers." Toni had a giant salad topped with chicken, and I had 1/2 rack of St. Louis-style baby back ribs with mashed potatoes and a beer. Ah, real food.

On the 11th post-operative day, we went to the Club Floor for our last breakfast and packed for the long trip home. Our hotel bill for the 13 days was about $6700. It was worth every penny. We were driven by Town Car to the airport; checked our bags; and ate a great lunch of shrimp, bean soup, and tuna sashimi at the restaurant in the Airport Westin Hotel. Then we flew home First Class on Northwest Airlines with a change of planes in Minneapolis. Toni's parents and Cody, our dog, met us at the airport. We were home in bed by 10 PM.

The First 3 Months

Sunday, March 18, was grocery shopping, pad shopping, and relaxation by reading the Sunday Oregonian and watching some of the NCAA men's basketball tournament games on TV. That evening, we took chicken soup and cocktail fixings to Duane and Christie's house where we had dinner and played with the dogs.

On post-operative day 13, Toni went back to work, and I went into the urology office at the Oregon Health Sciences University (OHSU) Center for Health and Healing (CHH) to pick up some files. Then I visited the laundry, picked up the mail, talked to the Lake Winona Manor health-care team about my mother's deteriorating health, chatted with Jim, my brother, on the telephone, and made a list of things-to-do for the first part of the week. Things were getting back to normal.

On postoperative day #16, I did office work that included revision of our Urology website and the chairing the Renal Transplant Selection Conference.

Friday, I gave myself the first of the bi-weekly injections of Bimix (papaverine and phentolamine). It resulted in a three of five erection.

Saturday, we went to the beach for a 24-h stay that included two long walks. The urinary control was slowly getting better. Pads + toilet paper or another paper liner were still required, and I was down from three or four pads a day to one or two.

Sunday was shopping for the week, paying bills, Kegel's exercises, and resting at home.

Monday, March 26, postoperative day #20 was to be another short day in the office. I met with the Portland Veterans Affairs Medical Center Renal Transplant Program Administrator and transplant nephrologists in the morning and gave a medical student lecture at 4 PM on male external genitalia. In between, I met with the nurse coordinators who gave me a "Welcome Home" basket full of goodies.

Tuesday, March 27, three weeks after prostatectomy, a pleasant orgasm without ejaculation was induced.

Wednesday, I worked in the office from 7:00 AM until 12:30 PM.

Thursday, I worked in the office from 7:45 AM until 5:00 PM. The Vattikuti website editing was completed and mailed to Pam.

Friday was a day off, the first dose of tadalafil, the second postoperative orgasm, a movie ("The Shooter") with one of my daughters, Wendy, and a visit to the gym with care not to lift more than the prescribed 20 pounds. The pad count was three for 24 h because of the exercise routine.

Saturday was an early visit to the gym, breakfast with Toni's family, and completion of the tax preparation packet for our accountant, Maurice Williams. Tadalafil 10 mg caused a stomach cramp that lasted for 2 days.

Sunday evening my painful perineum, blood-tinged urine, and relatively poor urine control reminded me that I had done too much at the gym Friday, Saturday, and Sunday.

The week of April 2 was my first full week back at work. Monday was 7:00 AM–4:00 PM. Tuesday was 7:00 AM–12:30 PM, Wednesday was 7:00 AM–4:30 PM and Thursday was 6:30 AM–7:00 PM, a day that was too long. Urinary continence was good until about 12:30 PM each day. Walking and running for the tram resulted in pelvic pain and initial hematuria. I had to take ibuprofen Thursday night for the first time since

post-op day 10. Friday, April 6, was the 1-month anniversary of the robotic prostatectomy and my first living donor renal transplant since surgery. It went well. I was continent for the $4^1/_2$ h it took, but initial hematuria began to plague me. Friday night I had pelvic discomfort. Saturday morning we had breakfast with Toni's sister and her husband at a local café. Part of Saturday was cleaning house and shopping in preparation for cocktails at 5:00 PM with Dr. Ja-Hong Kim, a urology chief resident from the Cleveland Clinic, her husband, and a woman friend of hers. Saturday night was spent forcing oral fluids, passing clots at the beginning of each void, and taking acetaminophen for pelvic soreness. The initial hematuria had cleared by dawn. I had done too much. Urinary continence was best when I wasn't very active, and Sunday was a one-pad day.

Monday, April 9, was to be a usual full day. Monday included the residents' conference at CHH, the VA for a renal transplant meeting, and back to CHH where I had the first postoperative PSA blood draw. The result was a very reassuring 0.05 ng/mL. Tuesday was a very light day. Wednesday was the usual 6:45 AM–5:30 PM. After work, Dr. Susan Orloff, a liver transplant surgeon, and I shared a bottle of wine with some cheese and bread while we discussed the future of transplantation at OHSU. My urine control faded as the day progressed. Thursday was the usual 6:45 AM–7:00 PM. Friday was two cases in the OR, the second of which was a living, genetically related donor renal transplant. Bloody spotting of my pads was apparent at the end of the case, and there was a little gross hematuria. Perineal discomfort was present while I made rounds at University Hospital, the Veterans Affairs Hospital, and Doenbecher's Children's Hospital before I headed back to the tram for the ride to the office to finish the workday. Friday night, I passed two eraser-sized dark clots. Saturday morning was breakfast with Toni's family and some light shopping. That evening, while Toni was at her dental school class reunion, I had an enjoyable dinner at Jake's with Nadir Monis, a former Afghani, who has returned to work for Novartis. Sunday was without incident, and I started practicing my pop-ups on the bedroom floor that morning in anticipation of a return to surfing.

Monday, April 16, I drove to the clinic, parked my car, and took a streetcar to the Governor Hotel where I was one of the faculty members for the Liver and Renal Transplant Seminar. I was dry all day. Tuesday was the 6-week mark, and I was dry nearly all day. I've continued with the 5-PDE inhibitor pills and the Bimix penile injection protocol. There was a persistent area of numbness on my upper, inner left thigh in the distribution of a branch of the genitofemoral nerve. I suspect the nerve was cut, burned, or stretched during the pelvic lymphadenectomy. Tuesday was spent in the office, making resident rounds and preparing for adoption of the electronic medical record system to the inpatient services. Wednesday, Toni and I flew by Southwest Airlines to Phoenix to attend the American Association of Genitourinary Surgeons meeting. Although there was no more hematuria, urinary leakage would occur late in the day and with sudden increases in abdominal pressure. It was a good meeting. I went swimming for the first time since the surgery, and met with friends, including Mani Menon, my surgeon. I sat next to a friend from the Cleveland Clinic at the banquet, and we revisited our radical prostatectomy experiences. Toni and I returned home Saturday evening.

The week of April 23 was a full-time work week. The surgeries were two cases of bilateral nephrectomies for polycystic kidney disease with renal transplantation, and one kidney transplant into a morbidly obese diabetic man. Saturday, I tried a penile injection 20 μg of prostaglandin E1. It resulted in a 10 of 10 painful erection. The erection lasted for about 30 min. The pain lasted for about 2 h. Urinary continence continued to improve slowly. A pad was still necessary. I didn't leak during the hours of surgery, but I took a bladder break every 2–3 h and I had a spot of blood on the pad liner after standing at the operating room table for several hours. Sunday, I returned to the gym and did two sets of three upper body exercises and three popups with leg flexion

exercises. There was no hematuria afterward and no incontinence during the workout.

The weeks of April 30 and May 7 were both full work weeks. I was totally continent of urine until mid-afternoon, and then minimal to mild stress incontinence appeared. I wore a pad all day. The triangular pads were more comfortable than the uniform width pads. I was hoping that erections without chemical enhancement would arrive one of these months. The left upper inner thigh numbness persisted.

Saturday, May 19, Room 6323 at the Disney Grand Californian Hotel during the AUA Annual Meeting was our first attempt at intercourse since the prostatectomy. It was successful in the sense that the 10 μg PGE1-enhanced erection was adequate for penetration, and the orgasm was as pleasant as before. Instead of ejaculate, however, there was urine even though I'd emptied my bladder just before bed. The PGE1 erection lasted for about 30 more minutes, and the penile pain lasted for another 3 h. The minor perirectal pain persisted for a few hours and responded to 1 g of acetaminophen. Urinary continence continued to improve slowly. The left upper inner thigh numbness was replaced at times by an inappropriate sensation of coldness. Monday night, masturbation produced no urine leakage.

June 1 was another long case of bilateral nephrectomies and a renal transplant. I was totally dry during a long case, but still wore a pad for security. I tended to leak a bit late in the day. That weekend, I started practicing my long board pop-ups in the swimming pool.

Three Months

The pelvic soreness with exercise and bowel movements resolved. The hematuria had resolved several weeks ago. Erections were not present without chemical enhancement. The orgasm was accompanied by ejaculation of clear urine. This could be reduced with an empty bladder, controlled with a conscious effort to contract the external sphincter at the time of orgasm or by using a condom, and eliminated if the orgasm took place when supine. The combination of papaverine and phentolamine worked, prostaglandin E1 in lidocaine worked very well, but was painful, and the combination of a vacuum erection device and penile injection worked well. Oral tadalafil 10 mg didn't work, and I quit using it. A "Pocket Rocket" vibrator was a good addition to the penile rehabilitation program.

I wore one pad per 24 h for occasional urinary leakage. Leakage would occur late in the day when I was tired, broke wind, or laughed with a full bladder. The left femoral branch of the genitofemoral sensory neuropathy was slowly improving.

It wasn't unusual to go for 48 h without a bowel movement, and glycerin suppositories were helpful.

The serum PSA on July 2 was <0.05 ng/mL.

August 9–12. I returned to surfing for the first time since the surgery. I was a little rusty, but Toni and I caught several waves at San Onofre, Cardiff Beach, and Cardiff Reef in Southern California.

Six Months

My IPSS was 4 (low) with a bother, or quality of life, score of 2. In retrospect, I had urinary urgency before the radical prostatectomy, and that had completely resolved. The SHIM score without treatment was 5 (severe impotence). With treatment, specifically penile injection with a vasodilating agent, the SHIM score was 27.

September 19, 2007, Toni and I traveled to Chicago where we spent two and a half days with three members of the AUA staff doing a site visit for the 2009 AUA Annual Meeting. I was dry but wore a panty liner for security.

The PSA on October 2 was <0.05 ng/mL. I let Drs. Menon and Garzotto know the good news.

Nine Months

December 6 found us on our way to the Northwest Urological Society where I read the paper, "Ten things your urologist may not have told you about your radical prostatectomy." The paper was well

received, and we had a good time at the meeting. I still wore a panty liner a day for security. I went to Minnesota, spent Christmas with my dying mother, made her funeral arrangements, returned to Portland, and waited for the death call. It came at 6:30 AM, 16 days later. Toni and I met my brother and his wife, Kay, in Minnesota, and with family and friends, put my mother to rest beside our dad at Hillside Cemetery in St. Charles, MN on January 14, 2008.

One Year

I was cancer free by PSA determinations, continent of urine, but wore a panty liner for security at work or when I wore light-colored slacks; erections were adequate with penile injection of PGE1, papaverine, and phentolamine or Triple P, and the left inner thigh numbness and dysesthesia were hardly noticeable.

On May 23, 2008, we had just returned from the AUA Annual Meeting in Orlando. I was now President of the AUA. I didn't have to wear a pad at any time. The left anterior thigh numbness and dysesthesia continued to resolve slowly. Every now and then, there was about a 2.5 of 5 spontaneous erection that was not quite "stuffable."

June 6, 2008, I was dry. ED required treatment. The left genitofemoral neuropathy was ~95% resolved, scrotal muscle tone was returning to normal, and the scars were almost unnoticeable.

June 28, 2008, was my real return to surfing. We were at Short Sands Beach on the Oregon coast about 2 h from home. With a hood, 4/3 wetsuit, gloves, booties, a 12-foot long board, and perfect swells on a high tide, I had eight rides, one after the other. It was perfect. In August, we surfed at Turtles in Southern California.

Dr. Menon received the B. C. Roy Medical award from the President of India.

Eighteen Months

On October 8, 2008, my PSA was 0.01 ng/mL.

Two Years

My PSA was <0.05 ng/mL, I had pad-free urinary continence, no bowel dysfunction, and I was as potent as I wanted to be with intracavernous injections. The left genitofemoral nerve numbness had resolved.

Five Years

My PSA level continued to document "cure."

Dr. Menon received the Lifetime Achievement Award from Intuitive Surgical, the developer of the da Vinci Surgical Robot.

Six Years

Dr. Menon received the Most Distinguished Physician Award from the American Association of Physicians of Indian Origin.

Seven Years

Dr. Menon received the Hugh Hampton Young Award from the American Urological Association. I'm at the banquet.

Nine Years

On March 11, 2016 my PSA was 0.01 ng/mL, and my urinary control, bowel function and erectile function were unchanged from the 2-year follow-up.

Dr. Menon received the Keyes Medal from the American Association of Genitourinary Surgeons. I'm seated with him, Shameem, their daughter and son-in-law at the banquet.

Afterthought

Would I do it again? Yes, in a heartbeat.

11 Treater to Target: A Urologist's Personal Experience with Prostate Cancer

Paul F. Schellhammer

Abstract

A urologist's personal experience with multiple surgical, hormonal, and radio/immunotherapeutic options for the treatment of advancing prostate cancer.

Keywords

Biochemical failure · Stereotactic radiation · Immunotherapy · Clinical trials

Words matter. Webster's dictionary defines a survivor as, *"one who lives through affliction, one who outlives another.*" Survivor is the most common identifier for any individual who carries the diagnosis of a particular disease and is still alive. It is specifically applied to the cancer community to imply a victory over the declared enemy—the cancer cell. It also implies a certain degree of rigor and determination that a particular individual demonstrates in the cancer battle, and, consciously or subconsciously might suggest that the nonsurvivors, the patients who have succumbed to their disease process, perhaps did not fight hard or long enough. Is the survivor a more positive thinker, a more active seeker of care, or imbued with whatever number of attributes that resulted in apparent victory? I use the word "apparent because, for the physician community, survivorship is time limited and measured in increments, whether 2, 3, 5, 10 years or beyond. For the patient community, it frequently is optimistically equated with cure or permanent freedom from disease. As our understanding about cancer niches and dormancy increase, the state of true freedom from cancer becomes less secure.

Therefore, I prefer the term "participant" over "survivor." It implies an ongoing process whereby patients participate with their physicians in deciding treatment options, addressing the need for repeated therapies and participating in an ongoing physician-patient partnership to better health.

The word cure is a hallmark term in the vocabulary of cancer. It is interesting here to recall the derivations of the word cure from the Latin word *curare* which is translated "to care." Because of the increasing success of medical interventions, caring for the patient has translated to curing the patient or stated otherwise as fixing the problem and relegating it to an unpleasant and forgotten memory in history. However, a disease is a process and caring for the patient with the disease is also a process and the first priority of a physician, we ought not to condense all that this involves into the single endpoint—"the cure"—and thereby run the risk of minimizing "the caring."

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The war word conjures up a powerful image for the patient with cancer. An individual at war must exercise hypervigilance and attention to the enemy. This constant state of readiness can be exhausting and energy depleting. It tends to consume all of one's attention and adversely impact the quality of life and forfeit the opportunity to learn to live well with cancer. This scenario is magnified in the case of prostate cancer, where very long life expectancy measured in years and even decades after diagnosis can be expected. As a participant in the process of discussing and choosing avenues of therapy with the caring physician, the patient will enjoy a more productive experience and outcome than that described by a combatant in constant survivorship mode. Participation encourages an attitude of living well with cancer which, in my opinion, is an important objective. To paraphrase a statement to make this point—the patients who do best are those who dance with rather than battle their disease.

The mantra of today's medicine is to follow evidence-based principles which are based on well-conducted randomized controlled trials. In the case of prostate cancer, few such trials exist to guide evidence-based decision making. Therefore we rely on retrospective reviews, observational series, and case reports which have a much lower pedigree of evidence. But a great deal can be learned from case series and case reports. Furthermore, a case report can imprint in our memories a story which is more easily recalled than a series of summaries or reviews. By telling my story, I find myself formulating anew the discussions I have had with prostate cancer patients. In fact, every clinic is an exercise in my thinking about the subject—from my personal perspective and from the perspective of the patient that I am counseling.

For the rest of this chapter I will discuss the treatment decisions and steps in which I have participated, my approach to these decision points, and, where available, provide references to studies that supported the decision. I trust the story, although officially only a Level 4 case report, is informative.

Diagnosis

PSA was first approved in 1986 as a marker to monitor for disease recurrence after radical prostatectomy and subsequently in 1996 as a diagnostic or screening marker. Intrigued by the possibility of PSA as a test for early detection, I became an early adopter. In 1990, at age 50, I began personal annual PSA testing. My first PSA was 2.4 ng/mL. I was quite content as this represented a result well below the accepted norm at that time of 4.0 ng/mL and implied good prostate health. Annual PSA's through 1998 remained stable. In 1995, Gann was the first to point out that absolute cutpoints were perhaps inappropriate and that PSA levels should be assessed as a continuous variable with increasing levels between 0 and 4 ng/mL, predicting an increased risk of prostate cancer [1]. His data showed that a PSA level of 2–3 ng/mL represented a threefold risk for cancer when compared to a PSA of less than 1.0 ng/mL. More recently Vickers and Lilja have established the normal median PSA of a 40–50 year-old as 0.68 ng/mL. They also suggested that approximately 50% of cancers that will be lethal arise from the cohort of men whose PSA is >1.6 ng/mL at age 45–49, or >2.4 at age 51–55, the upper ten percentile of PSA for each age group [2]. In 1998, my monitoring was discontinued for 2 years. When it was resumed in 2000 the level had risen to 6.5 ng/mL confirmed on several determinations. TRUS-guided biopsies revealed Gleason 4 + 3 adenocarcinoma. The hiatus between 1998 and 2000 for PSA determination is explained by the fact that I suffered a myocardial infarction in 1998. Although there existed a strong family history of heart disease, my lipid profile was in the low-risk category. Furthermore, I had never had any symptoms, and I had passed all the stress testing without incident. With this event, PSA concerns were put very much to the side as I engaged in cardiac rehabilitation. However, I think it is worth noting that the visceral reaction to my cardiac event versus that experienced with the cancer diagnosis was remarkably different. After the cardiac event, I worked to partner with my heart in an exercise

and dietary regimen and move forward toward better health and an optimistic future. The diagnosis of cancer filled me with a sense of dread and betrayal. Destruction of the alien by whatever means was my urgent focus. This was in spite of my knowledge that the greatest threat to my quality of life and longevity was heart disease and not prostate cancer. Emotions constitute a powerful driving force which often overrides reason and measured deliberations. Physicians are frequently asked by patients when they are confronted with a diagnosis, "Doc, what would you do?", "What would you advise your father or brother to do?" It is important to remember that however long and diligently we have weighed the question in our hypothetical situation, these hypothetical decisions do not include the emotional overlay of reality testing. The practice field differs from the playing field, and we cannot assume that our measured assessments of pros and cons, risks and benefits would necessarily play out in similar fashion when personally faced with the unwelcome cancer diagnosis. This reminds us that the cancer word is jarring and disorientating however well-informed or well-educated the patient may be.

The year was 2000—The available treatments for localized prostate cancer at that time were surgery, external beam radiation, or brachytherapy. Minimally invasive laparoscopic and robotic-assisted approaches had not yet been introduced in the USA. As a surgeon, I favored surgery with its removal of billions of cancer cells in a 2–3-h procedure and the information of pathologic staging that might direct further therapy. For node-positive pathology, an ECOG trial [3] has been published demonstrating a survival benefit for adjuvant androgen deprivation. Recent observational studies also support the addition of adjuvant pelvic radiation for a enhance survival benefit [4]. For node-negative disease, adjuvant radiation had been tested in three randomized trials studying patients with unfavorable pathology [5–7]. The SWOG trial demonstrated an overall survival benefit to adjuvant radiation therapy [5]. The German [6] and EORTC [7] trials demonstrated a biochemical failure free benefit [6, 7].

When patients ask me, "What is the best treatment currently available for localized prostate cancer," I discuss surgery, radiation for intermediate and high disease and active surveillance for low risk, and on occasion for favorable, intermediate risk disease. In the future, discussion of focal therapy will enter this conversation. An agency for health care and research assessment of treatment modalities for localized prostate cancer catalogs the risks and benefits of all therapies and emphasizes the importance of a well-informed patient [8]. After patients consider and research all options, I discuss my rationale for choosing surgery but that I can well understand and support another choice.

The firm advice I can give with confidence is that time is on the side of the patient to review information, seek other opinions, and evaluate the risk and benefit ratio of treatment options. Often the most dissatisfied patients are those that propel themselves to urgent action without having given the time to assess the quality of life implications of therapy. Before leaving the discussion of diagnosis, I will comment on the subject of screening and chemoprevention.

The urology community has digested and reexamined the multiple publications emanating from the PSA screening studies conducted in the USA (PLCO) and Europe (ERSPC) [9, 10]. The United States Preventive Task Force has concluded that the risks of screening outweigh any benefits and consequently recommended categorically against PSA screening, i.e. a class D recommendation. This decision has been criticized and likened to "throwing out the baby with the bathwater." This controversial decision has been the subject of many debates and pro/con panels. A rational argument for risk-stratified screening or "smart screening" together with the more liberal recommendation of the active surveillance option has been suggested in a number of publications. I reference one here [11].

In addition to negating the prostate screening and early detection pathway, regulatory bodies have also advised against efforts at prostate cancer chemoprevention. While well-conducted randomized phase 3 trials addressing chemoprevention

were completed {PCPT [12] and REDUCE [13]} demonstrating that five alpha reductase inhibitors reduced the incidence of prostate cancer diagnosis, an FDA panel voted against their use for prostate cancer chemoprevention. This was based on a possible signal of increased incidence of high-risk disease for which there were a number of very strong explanations other than causal. In my opinion, a rational risk-benefit deliberation would not disqualify five alpha reductase inhibitors as a prostate cancer chemoprevention strategy.

Life After Radical Prostatectomy

My immediate postoperative course was uneventful. However, 6 weeks postoperatively, I developed fatigue, leg and abdominal pain, followed by fever and chills. A CT scan revealed a psoas abscess which was promptly drained percutaneously with eventual recovery. No surgical procedure is complication free and that 30-day morbidity and mortality figures don't reveal the full range of possible postoperative complications.

My prostate pathology was favorable reporting pT2, margin negative, N0, but Gleason 4 + 4 with a tertiary pattern of 5 (more about pathology reports later). Postoperative PSA's were undetectable at less than 0.1 ng/mL at 6 weeks and 6 months. Recovery of urinary continence and sexual function was satisfactory. However, I believe it is accurate and appropriate to advise patients that it is highly unlikely that sexual function will recover to match preoperative baseline, and that even urinary function; in the best of circumstances may have occasional lapses. At 1 year, my PSA was less than 0.1 mL. Several months later it climbed to 0.2, and then to 0.35 ng/mL. I could see nothing but a continued upward trend and that I would take action sooner or later. The question was, should it be sooner? At the time there were data from salvage radiation series that men whose PSA's were less than 1 ng/mL [14] had better outcomes than those whose PSA's were greater than 1 ng/mL. The larger multi-institutional cohort reported by Stephenson showing a clear correlation of post-salvage radiation PSA recurrence-free survival to pre-salvage PSA level had not yet been reported [15]. Some series advocated androgen deprivation together with salvage radiation for patients with high-risk features [16]. A Phase III trial comparing salvage radiation with or without Casodex 150 ng for 2 years (RTOG 9601) has been completed and was presented at the 2016 ASCO—GU conference [17]. In this trial, the addition of anti-androgen monotherapy to adjuvant radiation therapy provided biochemical, metastases free, and overall survival benefit, but this information was unavailable in 2001. I conferred with several "experts." Most advised against immediate therapy and specifically against radiation. This is in keeping with the general urologic practice as reported by an AUA survey in 1996 whereby only 13% of urologists stated that they employed salvage radiation therapy. Almost 10 years later in 2004, the CAPSure database assessment noted an increase to 20% [18]. Salvage radiation is delivered on the assumption that failure after radical prostatectomy is local in the area of the prostate bed. But is PSA recurrence after radical prostatectomy due to a local failure or distant failure, or both? My bone and CT scans were normal, as is usually the case, and were not helpful in making this determination. I made the decision to receive 6 months of androgen deprivation along with prostate bed radiation. The bone mineral density preserving effects of zoledronic acid had just been reported, and I opted to receive zoledronic acid pre-androgen deprivation and at its completion in 6 months.

How can "early" salvage radiation plus androgen deprivation be supported? The evidence for local failure after radical prostatectomy has been documented with prostate bed biopsy studies showing cancer in up to 40% of PSA failure cases [19, 20]. The 10-year clinical local failure rate in the SPG4 trial and the control arm of SWOG 8794 approached 20%, a rate higher than the distant failure rate [21, 22]. However, studies using MRI have shown a much higher incidence of bone metastatic disease than would be found by the traditional bone scan [23], and disseminated tumor cells are present in the bone marrow in men with PSA failure with unexpected frequency [24]. These findings also support the distant failure

component of PSA recurrence. Observational studies from Stanford demonstrated a benefit using androgen deprivation and whole pelvic radiation versus prostate bed radiation alone [16]. Fortunately, six trials are in process that will resolve uncertainties concerning combination adjuvant/salvage therapy combined with androgen deprivation as well as the benefit of extended field radiation. RTOG trial 0534 (ClinicalTrials.gov identifier NCT00567580) is a three-arm trial testing prostate bed radiation only versus prostate bed radiation plus androgen deprivation versus whole pelvic radiation plus prostate bed radiation plus androgen deprivation. The UKNCI Canada RADICALS trial (ClinicalTrials.gov identifier NCT00541047) will test adjuvant versus salvage radiation each with no, short-, or long-term androgen deprivation. The Stampede trial is a multi-armed sequential trial that is testing a number of combination therapies, i.e. androgen deprivation, docetaxel, zoledronic acid, Celebrex with a recent abstract reported at GU ASCO 2016 [25]. It is encouraging that Level 1 evidence will be available in the future upon which to base decisions. Currently, Level 4 evidence from a large cohort gathered from a cancer centers reports that salvage radiation initiated when the PSA level is <0.5 ng/mL provides an encouraging 48% PSA progression-free response at 6-year follow-up [15]. When administered at even lower levels of detectable PSA, more favorable biochemical failure free outcomes can be expected. A word of caution in analyzing adjuvant and salvage studies. A bright line distinguishing adjuvant from salvage radiation does not exist and what might be identified as an adjuvant in some cases is more appropriately classified as salvage. Radiation is classified as salvage when given for a PSA rising above an identified undetectable cutpoint. This undetectable cutpoint is a moving target. On their review of the literature, the prostate cancer guidelines committee identified 54 cutpoints used to identify PSA failure after radical prostatectomy [26]. For uniformity of reporting, they established ≤0.2 ng/mL as an undetectable PSA. Others have supported a higher level of ≤0.4 ng/mL [27]. Patients receiving radiation identified as "adjuvant" within the first 4–6 months after radical prostatectomy when their PSA is undetectable by these definitions would be receiving radiation identified as salvage when lower PSA failure cutpoints are utilized, i.e. the RADICALS trial uses <0.1 ng/mL. In the SWOG 8794 adjuvant trials 30% of patients had detectable PSAs and, therefore, by definition, were, in reality, receiving salvage radiation.

For accuracy of reporting and analysis, post-radical prostatectomy radiation might be better calibrated to a PSA trigger and time boundary after surgery (less than 6 months for adjuvant), than to the terms "adjuvant" or "salvage." And I believe that urologists who would prefer to use salvage radiation should consider using reliable ultra-sensitive PSA assays. The success of salvage radiation is PSA sensitive and is most successful when delivered at lower absolute PSA levels [28]. The initiation of post-radical prostatectomy radiation at the earliest indication of a PSA rise might narrow any gap of benefit that separates "adjuvant" from "salvage" therapy.

Postradiation and Androgen Deprivation

I received radiation in a traditional four-field box technique to a dose of 64 Gy. The urinary and rectal irritated symptoms I experienced have resolved with time. Androgen deprivation was quite tolerable. Hot flashes were tolerable, but the dramatic suppression of libido and function brought me to the powerful recognition, beyond any text description, of the power of the steroid molecules to imprint and drive behavior. I was delighted to discontinue androgen deprivation after 6 months of therapy at which time my PSA had fallen to less than 0.02 ng/mL. This level was maintained over the next 3 years. Serum testosterone recovered, and I truly felt that the clock had been reset and that my quality of life had been restored to the pre-hypogonadal state. Equipoise had been re-established, and life was good. That is not to say that life had been previously bad. I only use this well-understood colloquialism to express my renewed state of well-being. However, 36 months after initiation of androgen deprivation and 33 months

after completion of salvage radiation, the PSA began another series of rises. It is worth reflecting on the emotional impact of the first rise after radical prostatectomy and this second and subsequent rises. The first PSA rise after surgery brought home the fact that surgery had failed to remove all cancer and that "cure" (yes, I was in this thought mode) had not been achieved. There was significant anxiety and disappointment that actually exceeded the negative visceral response at diagnosis. I was entering the universe of the ticking PSA clock. The second PSA failure confirmed that I was in the story for the long haul. The alien remained in residence. Resolve replaced anxiety and disappointment. I was going to become a greater participant in the process and would need to turn my strategy from cancer elimination to delaying progression and living well with the situation. And it was now necessary to start thinking about the next step. I obtained serial PSA's over the next 6 months with a progression to a PSA of 7 ng/mL (calculated doubling time of approximately 4 months). During this time I scanned for the possibilities of a clinical trial in place of androgen deprivation. Androgen deprivation was certainly going to play a role in the future, but other clinical trial possibilities might be of benefit, and androgen deprivation would disqualify entry in these trials. Throughout the years I had encouraged patients to enter clinical trials and supervised many such patients on a number of a wide variety of Phase II and Phase III trials. Now it was my turn to practice what I had preached.

Search for Clinical Trial

In 2004, there was a paucity of clinical trials for a rising PSA in the hormone naïve population (since androgen deprivation was 3 years previous and my testosterone was normal, I was still in the naïve clinical state). One was a vaccine immunotherapy trial (PROSTA-VAC) under the auspices of CALGB and the other a tyrosine kinase inhibitor trial under ECOG. Geography determined the trial in which I would enroll because the ECOG site was a short Southwest Airlines flight away permitting 1-day travel to and return. I was most satisfied with the clinical care, but personal experience with this and a subsequent trial substantiated firsthand that clinical trial entry and participation are every time intense and resource consumptive effort. In the absence of my position as a physician, whereby I could determine blood draws and scan schedules, it would have been quite difficult to adhere to trial requirements without sacrificing professional responsibilities. Clearly, a more friendly clinical trial process is necessary for the patient and physician. Clinical trialists have written convincingly in this regard. Streamlining will be necessary if the 2–3% enrollment is to be improved upon and if Level 1 evidence is to become available [28]. Clinical trials are a team effort. The term team implies an equal opportunity for all members—especially and specifically the patient.

While the experimental agent I received, a dual tyrosine kinase inhibitor (since approved for the use in recurrent breast cancer), slowed the rate of PSA rise, it nevertheless continued to progress to a level of 4 ng/mL. At this time I felt it was appropriate to pull the androgen deprivation trigger once again.

An interesting observation as a result of this trial process was the review of pathology as part of eligibility. Both the initial pathology and the trial review of pathology were reported by expert genitourinary pathologists. There was a significant discrepancy in both the pathologic staging (PT 2, margin negative became PT 3A margin positive) and Gleason grade (4 + 4 with a tertiary pattern of 5 became 3 + 4). I believe this degree of separation is unusual. I could never get both readers to the same microscope and H&E section for discussion. However, comparing results of one institutional series to another is problematic due to the subjective nature of pathology examination and variability of institutional definitions. And add to this the variables with specimen processing.

The Rest of the Story

Faced once again with a rising PSA, I made the decision to begin combined "triple" androgen blockade, a combination of Lh/Rh agonists,

anti-androgen, and 5-alpha reductase inhibitor. While the PSA fell, it did so somewhat sluggishly, and after reaching a PSA nadir of 0.2 ng/mL began rising at 9 months post-initiation of therapy. Anti-androgens were withdrawn without response. There is ample data that a PSA nadir is a prognostic factor with regard to the subsequent outcome [29] and further data suggests that PSA lower than 0.2 ng/mL, and into the ultrasensitive undetectable level of less than 0.05 ng/mL, is desirable. I had entered the castration resistant disease state. The term "castration resistant," I believe, will need further refinement. Ample evidence now exists that the androgen receptor continues to drive prostate cellular proliferation and pharmaceuticals to block AR activity provide effective treatment and survival prolongation. The term "castration-recurrent" may better describe this disease state.

In 2008 with a testosterone level in the castrate range, and with a PSA on the rise after trial of bicalutamide withdrawal, I was searching for other options. There was no Level 1 evidence to support any pharmaceutical therapy at that time, and unfortunately, that remains true to this day. I initiated a trial of ketoconazole and hydrocortisone and a course of GM-CSF [30, 31]. There was no PSA response. I was advised with regard to transdermal estradiol patch which I began and have continued to the present [32]. Estradiol slowed my PSA doubling time but of equal importance improve my sense of well-being. A few observations about estrogen therapy are pertinent. Recall that the Veterans Association Urologic Research Group studies demonstrated that oral diethylstilbestrol (DES) was associated with a cancer survival superior to orchiectomy. The cardiovascular morbidity associated oral estrogen, however, overwhelmed the cancer specific benefits resulting in an inferior overall survival outcome. David Byar, the lead statistician for the veteran studies concluded that DES, in addition to lowering testosterone, exerted a direct cytotoxic effect on the prostate cancer cell [33]. Currently estradiol delivery via a transdermal patch bypasses the first pass through the liver which is responsible for the metabolic changes predisposing to cardiovascular mortality and thereby dramatically reduces this concern. Estrogen is barely mentioned in the guidelines of the major oncology societies. It is essentially overlooked and very much underappreciated. Traditional ADT deprives the male of both testosterone and estrogen thereby compounding adverse events. In addition to its cytotoxic toxic effects, estrogen reduces/eliminates hot flashes, preserves bone health, and is now recognized to support sexual function [34–36]. The Patch trial (ClinicalTrials.gov NCT00303784), a large RCT being conducted in the United Kingdom, is currently randomizing men to traditional LHRH analogues (control arm) or transdermal estrogen patches with the primary endpoint of overall survival and a number of secondary endpoints which include PSA response, quality of life and bone health. Hopefully, the Patch trial will substantiate the benefits of estrogen therapy and bring it back into the mainstream of prostate cancer therapy.

The global effects of medical or surgical castration are currently more widely recognized along with the need for better counseling for the patient and significant other. An excellent resource for informing and guiding both physician and patient in this arena is a recently published manual titled "Androgen DeprivationTherapy, An Essential Guide for Prostate Cancer Patients and Their Loved Ones." [37] As I commented in my review of this publication, "It was only when I began my personal journey with androgen deprivation therapy (ADT) that I was able to appreciate the profound impact this treatment has on daily life. Even with my real-life experience with ADT, accumulated over a decade, I know I cannot, within limits of one or even several office visits, begin to prepare and educate patients about their new reality. I could not even do that for myself! If only a complete, user-friendly manual existed. Now it does."

In 2012, my PSA had gradually risen to10 ng/mL and a technetium bone scan which I was receiving annually revealed a solitary metastatic site in the third lumbar vertebrae. I was asymptomatic. In view of the evidence of progression on imaging, now with M1b CRPC, I was eligible for a Phase 2 clinical trial combining 2 "hormonal" agents each of which had individually

proved effective in extending survival in Phase 3 RCT's for patients with M+ CRPC [38, 39]. Abiraterone acetate is characterized as an androgen synthesis blocker as it interfered with the C-17 hydroxylase, C20, 21 lyase enzymes on the pathways converting precursor steroid molecules to androgens. Enzalutamide was characterized as an androgen receptor blocker as it displaces androgens from binding to the AR by preferentially occupying the receptor niche. With different mechanisms of action to interfere with androgen receptor activity, there was the potential for inducing as complete an androgen blockade environment—as with all trials, LHRH agonist therapy continued—as was currently possible. Furthermore there appeared to be no indication for overlapping toxicity other than that associated with further depletion of testosterone activity. The trial protocol required pre-entry bone biopsy which was accomplished under CT guidance without difficulty. The vertebral biopsy analysis seemed ideal for this drug combination. The specimen stained strongly positive for the androgen receptor. There was no evidence of neuroendocrine dedifferentiation, no AR V7 detectable and SRC, a proliferation driver, was negative. All factors lined up for an excellent response. Nevertheless during the 6 months on trial, my PSA doubled from a level of 10–20 ng/mL. There was no good explanation. Was prednisone given with abiraterone, perhaps, a culprit via a "glucocorticoid hijacking mechanism"? Furthermore, two side effects were problematic. Fatigue was not disabling but was a daily drag, and my usually normotensive blood pressure rose steadily requiring antihypertensives.

The concept of targeted medicine is very attractive but also, as illustrated by the above, can be very complicated as we begin to scratch the surface of personalized medicine.

It was time for a new start. Our department at Eastern Virginia Medical School had been involved with the earliest sipuleucel-T trials [40, 41]. The final analysis of the Phase 3 IMPACT trial led to FDA approval in 2010 [42].

The IMPACT trial had randomized men with asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer to a cellular based immunotherapy treatment arm versus a control arm and demonstrated a statistically significant survival benefit for the patient receiving immunotherapy. FDA approval was a breakthrough decision which brought the first immunotherapy for any cancer to the clinic. Since then there has been an explosion of interest in immunotherapy with a number of dramatic successes in its use in the treatment for other malignancies. Immunotherapy can be characterized as flexible, durable, targeted, and adaptable attributes that are admirably suited for addressing the same characteristics associated with tumor cell survival. There was no hesitation on my part to move forward with Provenge immunotherapy. There was also developing evidence that radiotherapy might potentiate immunotherapy. Some of the beneficial effects of radiotherapy might be attributed to the to the abscopal effect. Cellular death caused by radiation, specifically high dose radiation producing double strand breaks and mitotic death, releases a host of antigens which provide a broad repertoire of targets for immunotherapeutic activity [43]. Concurrently the observation that local control of metastatic sites could be accomplished by stereotactic radiation was leading to trials of radiation for men with oligometastatic (defined as one to three, or perhaps up to five metastatic sites) disease [44, 45]. The double benefit of local control and the priming by antigen spreading or antigen cascade for subsequent immunotherapy was very attractive. In 2013 when my PSA had risen to 20 ng/mL, I received stereotactic radiation (9 Gy/day × 3) to the isolated L3 vertebrae followed by Provenge therapy. My PSA gradually fell. A follow-up sodium fluoride PET/CT scan revealed an additional L1 metastasis which was also treated with stereotactic radiation. PSA levels gradually declined over 30 months less than 1 ng /mL. Obviously, I am very much appreciative of this good fortune, and it has influenced my thinking and management of patients with good performance status and oligometastatic disease.

The future is bright with a wealth of developing treatment possibilities on the horizon. Radium 223 (xofigo) [46] will be an option for control of osseous metastases with a survival benefit.

Immunotherapies with checkpoint inhibitors are promising. PARP inhibitors have demonstrated remarkable responses in patients with BRACA1/2 and AMT genetic defects [47]. Perhaps the most remarkable trials are those studying the cyclical delivery of super-physiological doses of testosterone [48]. This concept is counterintuitive. However, a very provocative editorial appearing several years ago was entitled "The two faces of Janus. Steroid molecules are responsible for both cellular death and cellular proliferation" [49]. The challenge will be directing these pathways for an appropriate response. However, if high dose testosterone does enter into the clinic, it perhaps will be the only treatment for an advanced cancer that both controls disease while simultaneously allowing the patient to feel stronger and better! An ultimate win/win! And some "old-timers" in the pharmaceutical lexicon as ASA, NSAIDS, statins, metformin, vitamin D are finding a new role in the treatment of prostate cancer.

In conclusion, prostate cancer is often not cured or completely eradicated but can be reduced to a chronic disease which may be controlled for a prolonged period of time. Philosophically it can be said to mimic life by its slow pace of attrition. Patients can be considered participants and partners in the process of the therapeutic efforts to slow attrition. Finally, I paraphrase a physician author Wendy Harpham who described her reaction to the news that her hematologic malignancy had returned after a period of remission. She wrote as follows—"My cancer didn't make life uncertain but exposed me to the uncertainties of life. In losing my sense of tomorrow, its concerns, its uncertainties, I began to appreciate the time I had—and in a way never before possible—I found today. So I continue to participate, and life is good."

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Part II

Training, Credentialing and Research

Training in Robotic Urologic Surgery

12

Michael D. Weintraub, Steven V. Kheyfets, and Chandru P. Sundaram

Abstract

Multiple modalities exist for training urologic surgeons in robotic surgery. These include dry and wet lab exercises, virtual reality and augmented reality simulators and animal and cadaver models. The learning curve associated with various robotic surgical procedures is variable, and training curricula aim to help novice surgeons most effectively overcome the steep part of the curve. While a standardized training protocol or credentialing process does not currently exist, multiple innovative training curricula have been developed with the intent of creating a comprehensive and effective learning environment in which to master the skills necessary for performing robotic procedures, and are explored in this chapter.

Keywords

Robotic · Training · Simulators · Virtual reality · Augmented reality · Curricula

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Introduction

Since approval of the daVinci Surgical System (DVSS) by the United States Food and Drug Administration in 2000 and the performance of the first robotic prostatectomy in 2001 [1], robotic surgery has grown exponentially. The expanding and evolving use of robotic surgery in the field of urology has led to the development of new training paradigms specific to this modality. As robotic surgery itself is driven by advances in technology, so the types of tools available to train the next generation of robotic surgeons are expanding and take advantage of the opportunities offered by the internet and virtual reality. While standardized training curricula and credentialing processes exist in many other surgical domains, these are still under development for robotic surgical training. This chapter provides an overview of some of the trends in training paradigms and innovations in curricular development for robotic surgery.

Learning Curve

The learning curve generally refers to the period of time or number of cases that a surgeon must perform in order to become proficient in a particular procedure. Various measures have been studied in order to determine learning curves, in particular, patient outcomes and operative time.

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Once the operative time and patient complication rates approach those of an experienced surgeon, a trainee may be deemed to be on the plateau of the curve, which represents the portion of the curve at which proficiency has been achieved. The development of training models in robotic surgery aims at shortening the steep part of the learning curve, during which the surgeon's skills are evolving, and proficiency has not yet been achieved while concomitantly ensuring patient safety while the trainee remains on this part of the learning curve.

Since the inception of robotic surgery, multiple studies have looked at the learning curve associated with various types of surgical procedures. These studies have recently been reviewed [2]. In an early study of the learning curve for robot-assisted radical prostatectomy (RALP), in which RALP was performed by a single surgeon with >2500-case experience in radical retropubic prostatectomy (RRP), the learning curve required for comparable outcomes was about 150 cases, while a comparable comfort level was achieved at about 250 cases [3]. A contemporary retrospective study of RALP performed by three surgeons at three different academic centers actually found that 1600 cases were required to achieve a positive surgical margin rate of <10%, while about 750 cases were needed to reach a plateau in operative time [4]. For robot-assisted radical cystectomy (RARC), 30 cases were required to achieve a positive surgical margin rate of <5% [5].

Validation of Training Models

Models for training and the tests implemented to ensure proficiency must be validated in order to be deemed effective tools that enhance the training process and accurately reflect the trainee's abilities. Validity may be tested on a number of levels: Face validity refers to the extent to which the tool being used corresponds to the real life experience. Content validity is a measure of how accurately a given test is able to verify proficiency in the skill under scrutiny. Construct validity refers to the ability of a test to differentiate between various levels of expertise [6]. Training programs in robotic surgery are tested for face, content, and construct validity to ensure that they meet their intended purpose.

Surgical simulation has emerged as an attractive option for skills acquisition in robotic surgery. Benefits of simulation include the ability of trainees to practice on their own time, the ability to repeat the same exercise multiple times (in some cases as many times as desired), and the absence of induction of potential harm to a patient. Simulators can broadly be divided into physical and virtual reality (VR) simulators. Physical simulators include cadaveric, animal and bench ("dry lab") simulators. VR simulators use software that creates an artificial environment which closely mimics the surgical experience and guides trainees through the performance of procedure-specific tasks.

Each type of simulation has its benefits and disadvantages. Cadaveric and animal simulation, while arguably having the highest fidelity to a live patient, are expensive and provide trainees with a limited number of uses. Moreover, cadaveric tissue texture is different from that of live patients. Live porcine models, while having better tissue fidelity than cadaveric models, do not completely mimic normal human anatomy either [7].

Dry Lab Curricula

A number of dry lab models have been validated as effective teaching tools in robotic surgery. The group from the Univesity of Southern California has developed the Fundamental Inanimate Robotic Skills Tasks (FIRST) curriculum. This curriculum comprises a set of four exercises performed on the DVSS: a horizontal mattress stitch through a Penrose drain, clover pattern cutting through gauze, a peg transfer exercise using a dome-shaped pegboard, and a circular needle target exercise (Fig. 12.1). The FIRST curriculum was validated for face, content and construct in a multi-institutional study involving 96 trainees and attending physicians in

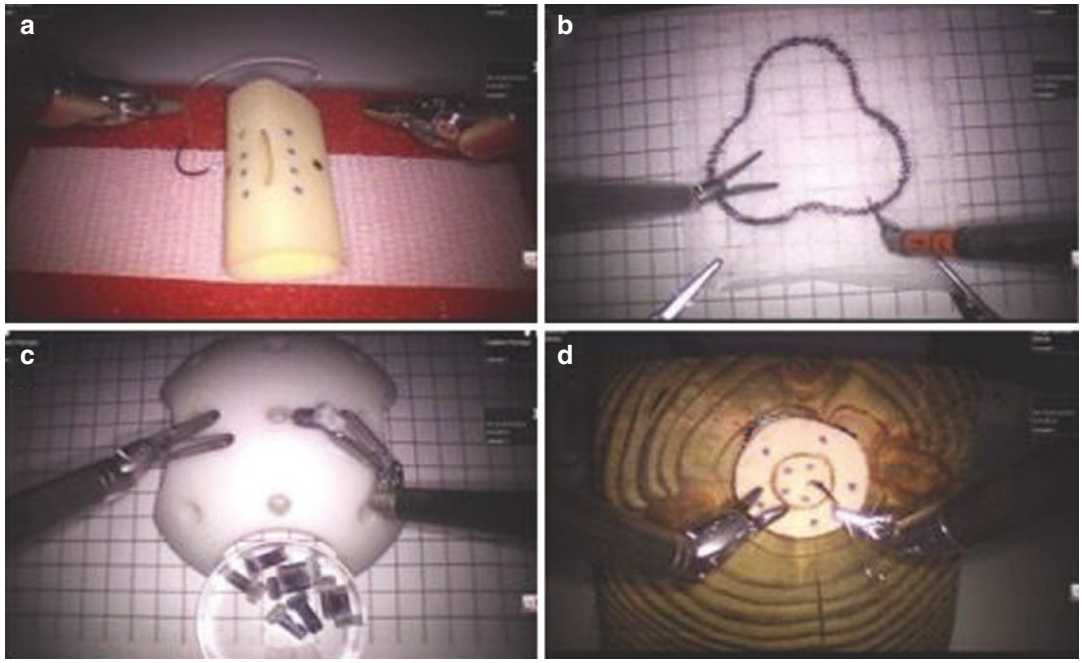

Fig. 12.1 FIRST curriculum. (**a**) Horizontal mattress. (**b**) Clover pattern cut. (**c**) Dome and peg. (**d**) Circular needle target. Reprinted from The Journal of Urology, 6(6), Alvin C. Goh, Monty A. Aghazadeh, Miguel A. Mercado, Andrew J. Hung, Michael M. Pan, Mihir M. Desai, et al. Multi-Institutional Validation of Fundamental Inanimate Robotic Skills Tasks, 1751–1756, Copyright 2015, with permission from Elsevier

urology and general surgery [8]. Construct validity in this study was demonstrated not only between experts and trainees but between trainees at different stages of training (novice versus intermediate). Cutoff scores for each exercise were generated based on average scores of the 23 experts in the cohort, to define "proficiency" in each exercise. However, the authors convey that a limitation of this curriculum thus far is an absence of correlation between proficiency in the inanimate tasks and performance in the operating room.

A similar curriculum of dry lab exercises has been developed at Indiana University. This curriculum includes a similar set of exercises, including pegboard transfer, pattern cutting, placement of letters on a letterboard, and suture handling and knot tying exercises. More advanced exercises are provided for senior residents [9]. These exercises were performed during multiple, short weekend sessions, and were supplemented by the online daVinci modules and practice during actual cases. Notably, these sessions were easy to implement and, based on surveys conducted following the sessions, were shown to have a positive effect on residents' subjective assessment of their improvement and interest in robotic surgery.

Intuitive Surgical Inc., the manufacturer of the DVSS, has recently validated another set of 9 dry lab exercises to develop proficiency in using the robotic system (Fig. 12.2). The first four exercises, termed "Ring Roller Coaster," require passage of a ring over a wire. Each exercise employs a wire of slightly different shape and orientation, making ring passage progressively more difficult. The next set of exercises involves needle driving in various orientations using a foam pad, and the last set of exercises tests suturing and knot tying on a soft hollow tube called a "lumen model," similar to a Penrose drain. While the model used in these exercises was specially fabricated for the company, the study's authors stress that the objects needed to create these tasks may be purchased at any crafts store and, therefore, analogous models may be easily

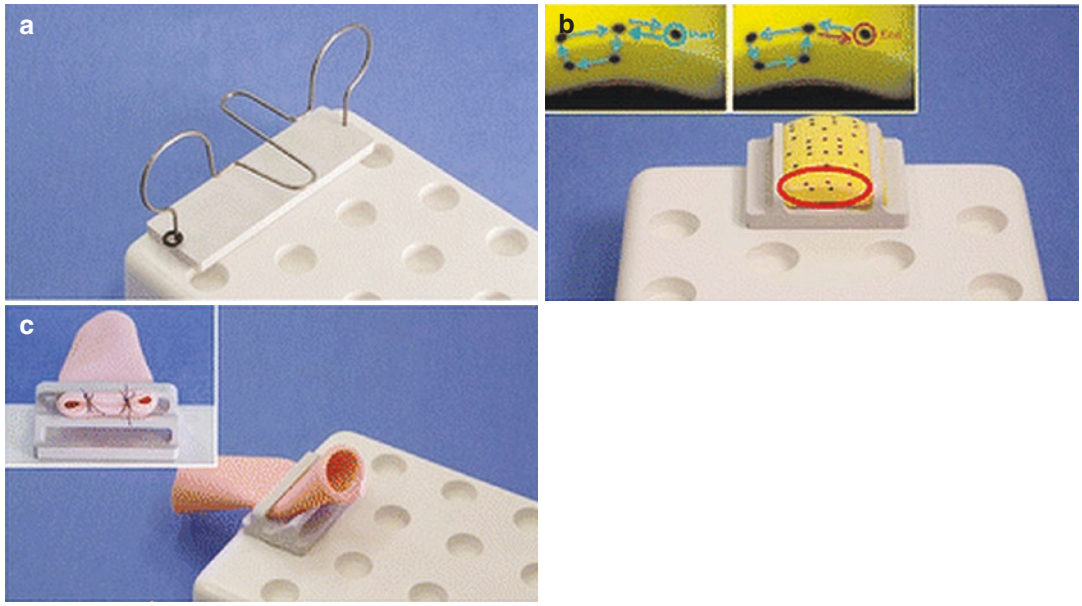

Fig. 12.2 Intuitive dry lab exercises. (**a**) "Ring Roller Coaster." (**b**) Foam pad. (**c**) Lumen model. Reprinted from Surgical Endoscopy, Construct validity of nine new inanimate exercises for robotic surgeon training using a standardized setup, 28(2), 2014, 648–56, Jarc AM, Curet M. With permission of Springer

implemented at any institution and may be a cost-effective means of training on the robotic platform. Construct validity was demonstrated for this set of exercises in a company-sponsored study [10]. The same authors subsequently developed four analogous exercises specifically for use with daVinci Single-Site instrumentation and validated their face, content and construct validity [11].

Virtual Reality Simulators

The first validated VR simulator was the Mimic daVinci-Trainer (DVT), developed by Mimic Technologies, Inc. (Seattle, WA) (Fig. 12.3a). This was validated in 2009 in multiple studies for face, content, and construct [12, 13]. The da Vinci Surgical Skills Simulator (DVSSS) was the next generation simulator, using the Mimic software (Fig. 12.3b). Unlike the DVT, which is a standalone device separate from the actual daVinci console, the DVSSS provides software to use with an add-on pack that attaches directly to the robotic console and integrates with the daVinci® Si™, Si-e™, and Xi™ robotic platforms. The DVT and the DVSSS were compared side by side for face and content validity with the conclusion that both systems had an equivalent benefit for robotic surgical training [14].

Two other platforms have been developed for use with the DVSS, namely the SimSurgery Education Platform (SEP, SimSurgery, Oslo, Norway, see Fig. 12.3c) and the Robotic Surgical Simulator (RoSS, Simulated Surgicals, see Fig. 12.3d). TheRoSS II™ is a second-generation platform with improved graphics and visualization. The RoSS platform has been validated for face and content validity [15, 16] and has been used as the primary platform in the development of several surgical skills curricula.

Mimic, Inc., introduced the daVinci Xperience Team Trainer in 2014 as an optional hardware add-on for the DVT. The Team Trainer allows for coordinated training of bedside and console surgeons through 13 skill exercises emphasizing effective object transfers, assistance with retraction and clip application. The MScore is a scoring

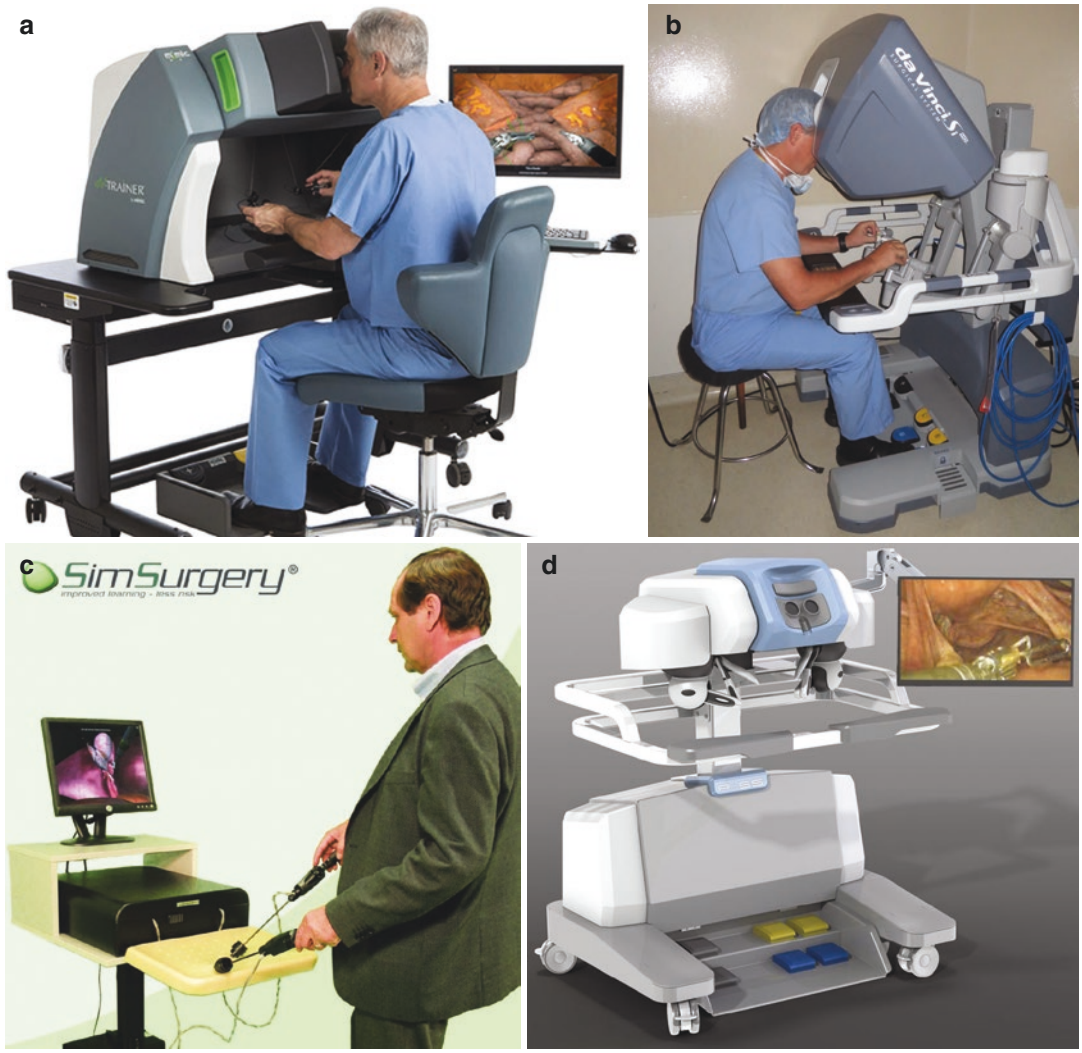

Fig. 12.3 Surgical simulation platforms. (**a**) Mimic DVT. Courtesy of Mimic Technologies, Inc. (**b**) Intuitive DVSSS. Courtesy of Simulated Surgicals. (**c**) SimSurgery SEP. Courtesy of Simulated Surgicals. (**d**) Simulated SurgicalsRoSS. Courtesy of Simulated Surgicals

system developed to evaluate the performance of each surgeon (primary and assistant), both separately or as a team.

Modular Training

Modular training curricula have been established in order to address the issue of the learning curve in robotic surgery. In this scheme, the operation being taught is divided into modules, or steps, of varying complexity, and the trainee systematically progresses through the modules. A modular training pathway was initially established for laparoscopic extra peritoneal radical prostatectomy [17]. Here, the surgery was divided into 12 steps, and each step was rated according to the level of difficulty, with the assigned difficulty level termed a "module." Trainees had to complete a certain number of cases for each module and had to demonstrate proficiency in a given module prior to graduating to the subsequent

module. Completion of all modules was an indicator that the trainee had reached the plateau on the learning curve and had demonstrated competence in the procedure.

A modular training pathway was subsequently validated for RARP [18]. Similar to the first study discussed, the procedural steps of RARP were broken down into modules. Proficiency in each module was graded by a panel of experts and learning curve was assessed based on a mean performance in a given module by the experts. The study showed that the RARP assessment score was beneficial in rating proficiency in various steps of the procedure, with a trend toward significance with respect to construct validity, that is—having the ability to differentiate between novice and expert surgeons. A unique value of this study is that it assigned a learning curve to each step of the procedure, reflecting the differential difficulty of the various steps and the different amount of practice necessary to gain proficiency in each of these.

Existing Curricula in Robotic Surgery

A standardized training program, the Fundamentals of Laparoscopic Surgery (FLS), exists for training in laparoscopy. The FLS curriculum was developed in 1997 by the Society of Gastrointestinal and Endoscopic Surgeons (SAGES) and is widely used in assessing proficiency in laparoscopy skills. Successful completion of FLS is mandated for certification by the American Board of Surgery. Currently, there is no standardized training program in place for robotic surgery. The American Urological Association (AUA) has developed an online urologic robotic surgery course, which is a video-based instructional course and consists of nine online modules ranging from fundamentals of robotic surgery to advanced techniques specific to particular procedures. Intuitive Surgical has developed online robotic video modules which are available on its da Vinci Community website, aimed to serve as supplemental resources for training on the robotic console.

A curriculum based on the RoSS platform was developed out of Roswell Park Cancer Institute in Buffalo, NY. This is a simulation-based training curriculum called the Fundamentals Skills of Robotic Surgery (FSRS). This curriculum includes four modules consisting of a total of 16 tasks, with each task having three levels of difficulty. A prospective study randomized participants with various skills levels at three academic centers to an experimental group (who participated in the FSRS) and a control group to compare their performance on inanimate exercises using the DVSS [19]. Improved metrics were noted in the experimental group compared to the control group in most of the exercises. Moreover, after being graded on their performance on the inanimate tasks, some of the participants in the control group crossed over to the FSRS curriculum, and were then re-tested, revealing improved metrics in the crossover group compared to the control group.

The Fundamentals of Robotic Surgery (FRS) curriculum was developed by a multidisciplinary and multi-institutional panel which met in a series of conferences dedicated to developing a standardized curriculum for robotic surgery. Participants in these conferences were members of a wide spectrum of organizations, including the American College of Surgeons (ACS), American Council for Graduate Medical Education (ACGME), European Urologic Association (EUA), and the Department of Defense. The representatives of these associations provided their recommendations on a structured robotic training program, and a consensus was reached after several rounds based on a modified Delphi method of decision-making [20]. The first conference was dedicated to developing a set of 25 pre-, peri-, and post-operative goals. These goals were ranked by experienced surgeons and then subjected to a vote by the committee. The second and third conferences were devoted to generating a curriculum to meet these goals. One innovation of this curriculum is the develop-

ment of a single VR device, termed the "FRS dome," on which all of the psychomotor training tasks of the curriculum were to be performed (Fig. 12.4). Another is the integration of team training and communication training into the curriculum. Significantly, the goal of this curriculum was to create a modular, stepwise training approach which is not dependent on the time constraints inherent in a multi-day course and can be replicated at any training institution and across multiple surgical specialties. The curriculum developed as a result of these deliberations is set to undergo prospective validation.

The European Association of Urology's (EAU) Robotic Urologic Section (ERUS) also developed a structured training curriculum based on the performance of robot-assisted radical prostatectomy (RARP) [21]. The curriculum was developed as the result of discussions over the course of three separate meetings. Goals or themes discussed at the first two meetings (ERUS-2012 and EAU-2013) were used to generate a curriculum proposal, and a curriculum was developed based on a questionnaire circulated to experts present at the third meeting (ERUS-2013). The goals of the curriculum included sequential mastering of the technical aspects of the procedure, as well as a number of "non-technical" skills including troubleshooting of the robot and effective communication of the operating room team. The curriculum that was developed consisted of an initial week-long course of didactics and practice in a dry and wet lab, followed by a 6-month fellowship. During the fellowship, the trainees progressed from observation to bedside assisting to modular training in each of the steps involved in the operation. The curriculum was recently validated in a multi-institutional pilot study [22].

Fig. 12.4 FRS dome. Photograph courtesy of Florida Hospital Nicholson Center

A robotic training curriculum was also recently developed at the University of Texas Southwestern [23]. This curriculum included completion of the daVinci Community online tutorial, a half-day proctored hands-on tutorial with practice in docking and port placement, and self-practice on nine inanimate exercises. A trainee's initial performance on each task was rated by a proctor to establish a baseline. Subsequently, a proficiency cutoff score was established, and a trainee was deemed proficient in a given task after achieving two consecutive performances above this cutoff score. The authors validated this curriculum in a group of 55 trainees over multiple surgical specialties.

Tools for Assessment

Validated tools have been developed both for global assessment of proficiency and for procedure-specific assessment. The Global Evaluative Assessment of Robotic Skills (GEARS) was the first standardized and validated assessment tool specific to robotic surgery [24]. This was developed by separately assessing six domains of robotic procedures, namely depth perception, bimanual dexterity, efficiency, autonomy, force sensitivity, and robotic control. The seminal vesicle dissection of robot-assisted laparoscopic prostatectomy (RALP) was chosen as the index procedure to validate the assessment capability of GEARS. Since the initial single-institution study, GEARS has been validated as a useful tool for assessment of intraoperative proficiency in robotic procedures [25] and is frequently employed as a reference in other studies of assessment models.

While GEARS is a global assessment tool designed to evaluate competence in any robotic procedure, procedure-specific assessment tools are also in development. The Robotic Assessment Competence Evaluation (RACE) was developed to assess competency in the performance of the urethrovesical anastomosis (UVA) during RALP [26]. This step of the procedure was chosen as the basis for assessment due to its difficulty and the potential for development of complications. The UVA was deconstructed into six domains so that a separate grade could be assigned for each domain. In a prospective multi-institutional trial involving 28 surgeons divided into three groups (novice, advance beginner, expert), RACE was shown to have construct validity, inter-rater reliability, as well as concurrent validity when compared to assessment using GEARS.

Augmented Reality Training

A recent innovation in robotic training has been the development of "augmented reality" (AR) training, which offers a potentially more "true to nature" view of the operative field during simulation, enhancing the face validity of virtual reality training. With this end in mind, a Hand-on Surgical Training (HoST) technology was developed by the Roswell Park Cancer Institute and State University of New York at Buffalo. Based on analysis of prior procedures performed by expert surgeons, this program augments the learning environment with audio and visual cues and real-time explanations during the performance of virtual reality tasks, using the RoSS platform and following the FSRS curriculum.

A prospective multi-institutional trial randomized robot-naïve participants or those with minimal console experience (<25 h) to training using the HoST environment or to the standard FSRS curriculum [27]. Following completion of the training, participants performed a urethrovesical anastomosis as part of RALP on an inanimate model, and their performance was recorded for expert grading. A crossover group included participants who initially underwent the standard FSRS training, then were offered the opportunity to undergo HoST training. The HoST and crossover groups were found to outperform the control group in most of the skills assessed. Additionally, these two groups were found to have lower levels of mental fatigue and lower scores for temporal demand and effort when using the National Aeronautics and Space Administration task load index (NASA TLX) questionnaire. AR is a promising new avenue in robotic training, but has yet to be brought into mainstream practice.

Another AR platform was recently developed by the group from the University of Southern California. This was developed by a collaborative effort between surgeons, software engineers, and graphic designers. Footage of robotic partial nephrectomy performed by an expert surgeon underwent 3D editing and was enhanced with commentary and audiovisual cues to create a series of technical and cognitive exercises using the Mimic DVT. The initial platform includes five modules comprising the steps of the procedure. An internal study involving novice, intermediate and expert surgeons showed demonstrated promising results for face, content, construct, and concurrent validity [28]. A porcine robotic partial nephrectomy model was used as the gold standard for high-fidelity training in this study, and continuing refinement of this platform is underway to increase its utility as a comprehensive training tool.

Mimic has developed the Maestro AR training curricula, using the DVT platform. Currently, curricula are available for a number of urologic procedures, including partial nephrectomy and RALP, with separate curricula for the DV Si and Xi models. These curricula integrate 3D video footage of a surgery performed by an expert in the field with interactive exercises performed by the trainee. Each curriculum includes virtual exercises designed to teach key steps in the procedure.

Credentialing and Assessment

There is currently no standardized credentialing or certification process for robotic surgery. Recommendations have been made by various

organizations, including the American Urologic Association (AUA). The Society of Urologic Robotic Surgeons has published on specific recommendations regarding credentialing [29]. These include participation in a multifaceted training curriculum with sufficient amount of practice both in live cases and simulation. The recommendations stress the importance of both mentoring of surgeons in training by more experienced peers, as well as subsequent proctoring as the trainee becomes more proficient and independent on the console. Multiple experts in the field have provided similar recommendations that emphasize the formulation of a structured training and mentoring approach [30]. Currently, though, credentialing remains institution-dependent.

The technological innovations that have led to the development of VR and AR in training have also fostered novel methods of assessment. Telementoring has emerged as a way for expert surgeons to provide feedback to more novice colleagues irrespective of geographic location. A recent study evaluated a second generation telementoring interface developed by Intuitive Surgical for use with the da Vinci platform, termed Connect [31]. The program allows for the real-time merging of the mentor's "telestrations" with the real-time view of the surgical field through the console, in addition to live audio feedback. In this study, robot-assisted prostate and kidney surgeries were prospectively randomized to telementoring either remotely or with the presence of both trainee and mentor in the operating room. Trainees were mid-level residents at a single academic institution, who had previously completed a robotic training course. Mentors were fellows or attending physicians with at least 150 cases completed as primary surgeon. No difference was noted in objective intraoperative parameters such as EBL, surgical time, and complication rate between the two groups. Assessment of the trainees' performance using a validated survey also did not significantly differ. This study, while limited in scope, demonstrated the safety and feasibility of remote telementoring, which may have a role in training and real-time guidance of less experienced surgeons who, due to geographic location or hazardous conditions, do not have access to face-to-face expert mentoring or may require urgent remote intraoperative consultation. This study did also demonstrate that implementation of a successful telementoring program may be limited by the quality of internet connectivity, a not inconsequential factor considering the potential application of telementoring to remote areas.

Another interesting concept which has emerged for the assessment of surgical performance is the crowd-sourced review ("crowdsourcing"). In a comparative assessment, laypeople (crowdworkers) assessed surgical skill based on on-line review and using both a global assessment survey (GEARS) and a survey specific to the performance of an isolated step of a particular surgery, notably the urethrovesical anastomosis (RACE) [32]. These reviews were compared to the reviews by expert surgeons (peers). A significant correlation between peer and crowdworker review was found. The study notably emphasizes that crowdsourcing was accurately able to identify those surgeons with the lowest performance scores as assessed by their peers. Thus, the potential application of this methodology is as a less expensive and more time-efficient method for the assessment of deficiencies in surgeons in the training phase of their career. However, wide applicability of crowdsourcing remains to be seen, and assessment by expert surgeons in the field remains the gold standard in the evaluation of trainees.

Conclusions

With the expanding use of robotics in genitourinary surgery, much has been done to create standardized curricula for training surgeons in order to most efficiently overcome the learning curve associated with robotic surgical procedures, while minimizing patient harm. Technological innovations have permitted the creation of multi-dimensional curricula integrating dry lab and wet lab practice along with virtual and augmented reality teaching. While no single standardized curriculum exists currently, multiple promising programs have been developed to achieve the goals of training.

At the same time, supplementary teaching resources including use of online training modules and videos as well as the newly evolving concept of telementoring, are providing additional avenues for learning and mastery of skills in this rapidly evolving field. Various innovative tools in the assessment of progress, including surveys specifically geared toward assessment of global robotic skills or specific steps of a robotic procedure, as well as crowd-sourcing, are being validated in order to facilitate trainees' progress along the learning curve and provide surgeons with accurate and objective feedback regarding their performance and goals for improvement. The development of a standardized curriculum will likely entail development of a credentialing process to ensure that all robotic surgeons have met minimal training criteria to be considered proficient in the surgeries they perform. The results of these efforts will be important in the coming years as robotic surgery becomes incorporated into the armamentarium of more urologic surgeons.

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13 Animal Laboratory Training: Current Status and How Essential Is It?

Spencer Craven and Alvin C. Goh

Abstract

In recent years, the emphasis of robotic training has moved outside of the operating room and into simulated environments. Three methods of robotic training have been utilized including inanimate, virtual reality, and animal models. Animal models provide the most high fidelity and complex training, but they are also expensive, may be inconsistent, and can require additional support such as veterinary staff and lab facilities. At present, no standardized or validated robotic training program exists and efficacy data on the various training methods is evolving. Animal model training appears to have utility in a comprehensive robotic training program with a defined role in higher-level procedure-based training.

Keywords

Robotic · Training · Simulation · Animal model · Animate · da Vinci · Inanimate · Virtual reality

Since the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA) was first introduced in 1998, urologists have been on the forefront of utilizing robot-assisted laparoscopic surgery (RAS). A rapid and widespread adoption of the system has led to an exponential rise in the number of RAS cases over the past decade [1]. In 2014, over 91,000 robot-assisted urology procedures were performed, and this number is only expected to increase in the coming years [2].

As the percentage of robotic cases increases, RAS has also become an important part of resident training. Minimally invasive surgery is no longer the domain of fellowship trainees, but is expected in every residency program. Recent studies have shown that both US and Canadian urology trainees are dissatisfied with their exposure and training in RAS during residency [3, 4]. Indeed, changes to resident work hours may further reduce the number of cases that residents are exposed to, and, with an increased emphasis on patient safety, a traditional apprenticeship model for surgical skills training may no longer be sufficient [5, 6].

While traditional training according to the Halsted model has been the mainstay of surgical training for the past century, the robotic surgical platform introduces new challenges in surgical education. The traditional model is based on the belief that trainees must acquire skills in patient management and technical operations with increasing responsibility with each advancing

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year [7]. Attending surgeons lead the trainee through the operation side-by-side. However, this model must be adapted when teaching RAS as the robotic interface precludes hands-on teaching and is generally operated by a single surgeon at a time.

In addition, surgical training on actual patients has financial and medicolegal implications [8]. Indeed, the surgeon's technical skills have been directly linked to patient outcomes [9]. In prostatectomy, it has been shown that adequacy can be achieved after 20–25 cases [10], but that improvement can be seen even beyond the 100th case [11]. It is therefore necessary to devise a new way of training surgeons in RAS such that surgical skills can be acquired while minimizing the impact on patients.

Robotic surgery also presents a unique set of skills that are different from open or laparoscopic surgery and include camera control, clutching, lack of tactile or force feedback, and 3D vision. Recently, new methods for robotic skills assessment and training have been explored. There is a growing emphasis on basic skill acquisition to take place prior to entry to the operating room. Additional benefits of a regimented training program with deliberate practice in which discrete training goals are emphasized in a setting separate from the clinical environment include the long-term development of expertise, decreased fatigue, enhanced skill retention, and flexibility in scheduling [12–14]. Recommendations from the Minimally Invasive Robotic Association (MIRA) and the Society of Gastrointestinal Surgeons (SAGES) in 2007 encouraged the rapid development and implementation of a training program unique to robotic surgery. At present, no such standardized or validated program exists [15].

Other societies outside of urology have already recognized the need for and developed a specialized training program in relation to laparoscopic surgery. Since 2009, The American College of Surgeons (ACS) and SAGES have required all residents to obtain Fundamentals of Laparoscopic Surgery certification (FLS) as a license for laparoscopic surgery. The FLS is a set of standardized exercises performed on standardized training equipment with accepted standards for proficiency. The FLS program was developed over a period of 7 years [16–18] during which it underwent extensive study to determine whether it met the requirements of large-scale assessments [19]: ease of use, low cost, reliability, accuracy, validity of skills assessment, and correlation with future surgical performance [20]. A training program in RAS with basic robotic exercises for training and establishing competency would need to undergo similar study and validation, but also presents its own unique challenges.

In recent years, the emphasis of robotic training has moved outside of the operating room and into simulated environments. Three methods of robotic training have been utilized including inanimate, virtual reality, and animal models. With the various environments for simulation, the question becomes which method is best or whether there is an ideal combination which best supports robotic training. Our group has extensively developed, validated, and implemented robotic training skills tasks across different training environments.

Simulation environments are designed to emulate the different facets of robotic surgery. Each training environment has its own advantages and limitations (Fig. 13.1). Inanimate models are inexpensive, simple, and reproducible; however, they tend to be labor intensive for assessments and most lack any form of automation, requiring an external proctor for training. The cost associated with designating a robot for training purposes can also be prohibitive, while utilizing clinically-used robots for training can limit accessibility and may not provide adequate support for a training program. Some exercises are also not reusable, incurring more cost and labor to training.

Virtual reality is reproducible, reusable, and automated. The platforms have the advantage of being able to be used by trainees alone at any time, which is important given resident schedules. However, the platforms tend to be expensive and complex interactions such as tissue handling and suturing have been difficult to reproduce reliably. An area where virtual reality excels is in providing familiarity with the mechanics of robotic controls and handling of robotic instruments.

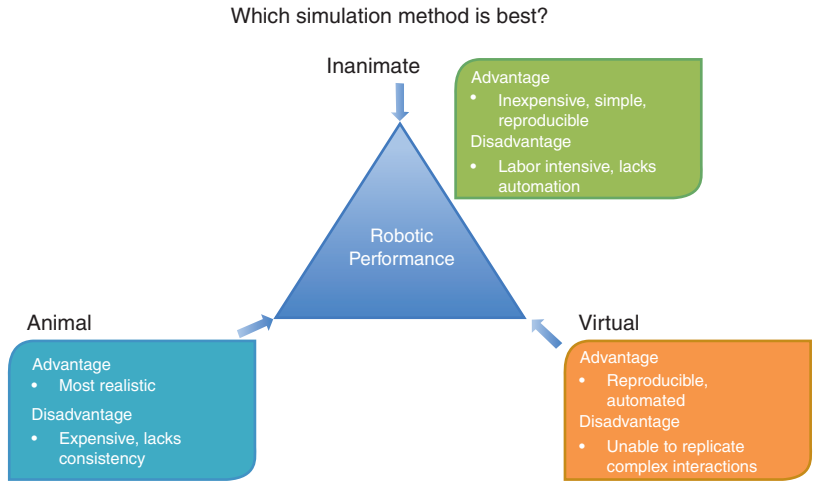

Fig. 13.1 Comparison of simulation methods

Animate or tissue models, such as animal-based training, tend to provide the most high-fidelity and complex training, but they are also expensive, may be inconsistent, and can require additional support such as veterinary staff and lab facilities. Inanimate and virtual reality training are discussed in detail in other chapters. We will focus on animal model training here, but as no training method exists in isolation, a brief overview of different methods is provided to illustrate the groundwork necessary for a comprehensive robotic surgery training program.

The simplest RAS training utilizes a working DaVinci robot to accomplish a set of tasks on inanimate objects. The Fundamental Inanimate Robotic Skills Tasks (FIRST) were designed for inanimate skills training [21]. The authors deconstructed the robotic prostatectomy into basic cognitive and motor skill requirements and developed inanimate tasks to teach and assess these skills utilizing common materials and 3-D printed objects. Face, content, and construct validity were then also established in a multi-institutional external validation study [22]. Expert performance was used to establish proficiency targets for training and has been used to incorporate FIRST into a comprehensive, proficiency based robotic training curriculum. Additional dry lab exercises based on virtual reality exercises have also been developed and tested for validity [23]. Although the setup and materials needed for these training tasks are simple, the program still requires the use of a robot as well as proctors which can limit access.

Virtual reality is a developing method for robotic training. The cost associated with acquiring and using a fully functional robot for training has stimulated the commercial creation of robotic simulators that can be used for training both basic robotic skills and robotic procedures. There are currently five virtual reality simulator systems for robotic training: the Surgical Education Platform (SEP; SimSurgery, Oslo, Norway), the Robotic Surgical System (RoSS; Simulated Surgical Systems, San Jose, CA, USA), the dV-Trainer (Mimic, Seattle, WA, USA), the da Vinci Skills Simulator (dVSS; Intuitive Surgical), and the RobotiX Mentor (3D Systems, Simbionix Products, Cleveland OH, USA). The majority of the literature has focused on these virtual reality platforms and the exercises they provide. However, there is still not conclusive evidence that skills gained on these simulators can transfer to the proficiency level required for safe RAS [24].

Animal model training has been the longest utilized training method, but is also the least studied. Weekend robotic training courses utilizing animate models were used to teach the first robotic procedures and are still used today to

train physicians new to robotic surgery. It would appear logical that utilizing the actual robotic platform to operate on real tissue gives an authentic training experience that should translate to the operating room. However, there is no validated study to date that connects robotic performance in an animal model to clinical robotic performance. Although no studies have investigated such a correlation, animal models have also been used as a proxy for in vivo robotic experience in many inanimate and virtual training validation studies [25–28].

A fundamental step in connecting training performance to in vivo robotic surgical performance is the development of a standardized tool to measure robotic performance. The Global Evaluative Assessment of Robotic Skills (GEARS) was developed to measure robotic surgical skills and to monitor robotic skills acquisition [29] (Fig. 13.2). This tool relies on global rating scales to measure performance. GEARS is composed of six procedure-independent domains: depth perception, bimanual dexterity, autonomy, efficiency, force sensitivity, and robotic control. Each of these domains is assessed along a 5-point anchored Likert scale. The GEARS assessment tool has been extensively validated in a multi-institutional setting confirming construct validity, reliability, and utility in its ability to differentiate between different robotic skill levels [30]. GEARS is the

Depth perception

1	2	3	4	5
Constantly overshoots target, wide swings, slow to correct		Some overshooting or missing of target, but quick to correct		Accurately directs instruments in the correct plane to target

Bimanual dexterity

1	2	3	4	5
Uses only one hand, ignores nondominant hand, poor coordination		User both hands, but does not optimize interaction between hands		Expertly uses both hands in a complementary way to provide best exposure

Efficiency

1	2	3	4	5
Inefficient efforts; many uncertain movements; constantly changing focus or persisting without progress		Slow, but planned movements are reasonably organized		Confident, efficient and safe conduct, maintains focus on task, fluld progression

Force sensitivity

1	2	3	4	5
Rough moves, tears tissue, injures nearby structures, poor control, frequent suture breakage		Handies tissues reasonably well, minor trauma to adjacent tissue, rare suture breakage		Applies appropriate tension, negligible injury to adjacent structures, no suture breakage

Autonomy

1	2	3	4	5
Unable to complete entire task, even with verbal guidance		Able to complete task safely with moderate guidance		Able to complete task independently without prompting

Robotic control

1	2	3	4	5
Consistently does not optimize view, hand position, or repeated collisions even with guidance		View is sometimes not optimal. Occasionally needs to relocate arms. Occasional collisions and obstruction of assistant.		Controls camera and hand position optimally and independently, Minimal collisions or obstruction of assistant

Fig. 13.2 Global evaluative assessment of robotic skills (GEARS)

only validated tool for intraoperative robotic skills assessment and is now widely used for surgical evaluation and training. By utilizing the GEARS assessment in animal model training, trainees can be provided with formative feedback on performance and identify specific areas of weakness for further training. The authors have also used this standardized assessment to measure and track the impact of training on clinical robotic performance.

A standardized robotic skills assessment tool, such as GEARS, is necessary to correlate animal training performance to in vivo robotic surgical performance. Validated skills evaluation is critical to determining the impact of animal model training sessions on robotic skills acquisition. To date, animal laboratory training for robotic skills has lacked any objective assessment of performance. In order to justify the costs associated with animal-based model training, objective metrics for performance and standardized feedback are essential.

Animal model training presents additional challenges. The largest barrier to the widespread use of animal models for robotic training is cost. Live animal labs require a specialized facility, a robotic platform dedicated to animal use, robotic equipment, animals, and support staff such as veterinarians and technicians.

The significant cost in animal model training is associated with obtaining a daVinci robot for this use. A new daVinci robot with a single console can cost $1,750,000. Thus, obtaining a console for training alone can be cost prohibitive. However, if the hospital's robot is used, thereby avoiding the capital investment in a new robot, this also presents an opportunity cost to the hospital. In a study of a large training center, it was determined that trainees utilized 361 h of training time for robotic surgery over the course of a year [31]. The average length of a prostatectomy was 296 minutes at the same facility, meaning the training time equated to 73 potential prostatectomies that were not performed. Based on the potential hospital revenue of 73 robotic cases and hospital stays, the training program resulted in a potential loss of $622,784.90 in net patient revenue or $1725 for every hour of training [31]. Any institution interested in making animal training a large part of its training program must take these costs into account.

An animal training program also incurs additional costs for every training session associated with the animals and robotic instruments. The direct costs of porcine labs at this same institution, without accounting for veterinarians, technicians, or other staff, was determined to be $1093.40 for approximately 5 h of lab time or about $79,000 for the year of training [31]. A validation study for the dVSS trainer found that working with anatomical samples, animal models, or inanimate models is costly in terms of equipment and mobilizing the robot (estimated cost: $500/h) [32]. Other studies have identified the high cost of robotic instruments as a barrier to inanimate or animal model training noting that, even using training instruments that allow for more uses, the instrument costs are $8325 for a single set [33].

Animal model training requires specialized facilities that are equipped to handle live animals and can provide staff such as veterinarians and technicians to support the lab. Building and maintaining an animal facility requires significant funding support. Many training programs do not have access to such facilities and thus cannot practice on-site animal model training. Even when the facilities are present, the additional costs of animal model training can be a barrier to its use in RAS training. A study comparing virtual reality training courses and animal training courses demonstrated a cost ratio of 0.74 in favor of virtual reality laboratory training over animal training [34].

Training on animal models can also bring up ethical questions. Some labs can be performed on animal cadavers or simple animal tissue such as turkey legs, while other more complex labs and procedure simulations are best in live animal models. Surgical training on these animals would be classified as non-survival surgery. In non-survival surgery, the animal is euthanized before recovery from anesthesia. There are laws and regulations in place for the humane treatment of animals used for non-survival surgeries. Although facilities follow strict guidelines in the manage-

ment of their animal subjects, there is ongoing controversy whether this use is ethical or even necessary now that there are alternative methods for RAS training.

Robotic training, regardless of the method, holds the potential for cost benefits in the operating room. A study on laparoscopic training showed that virtual reality training resulted in quicker completion times, reduced errors, instructor time savings, and avoidance of equipment spoilage costs. All of these led to a cost savings in excess of $160,000 in a year [35]. Another study showed that robot-assisted radical prostatectomy operative costs are directly related to length of the learning curve which ranges from $49,613 to $554,694 for curves of 13 to 200 cases respectively. The average learning curve costs $217,000 worth of operative time. Training, whether it is virtual, inanimate, or animal, can shorten this curve and reduce its cost. The question is which type of training is optimal or whether a combination offers training with the best quality and efficiency.

In 2013, a study was published comparing the relative merits of three standardized robotic training methods, inanimate, virtual reality, and an in vivo porcine model, to address this very question [36]. The authors observed that overall performance on inanimate tasks significantly correlated with virtual reality robotic performance and in vivo robotic performance based on standardized metrics of performance. Virtual reality performance and in vivo animal performance were also strongly correlated. However, certain aspects of inanimate task training showed stronger correlation with animate robotic performance highlighting some of the current limitations of virtual reality simulation. The authors suggest that given the current limitations of each form of simulation, a combination of training environments would appear ideal for skill acquisition.

It is important to note that although performance on animal models is often used as a substitute for intraoperative performance, this has also not been studied directly in the literature [25–28]. Once validated inanimate and virtual tasks are available along with a validated method to measure robotic surgical performance, the important remaining question is whether performance on these simulated tasks actually correlates with intraoperative robotic surgical performance. This connection between simulated performance and clinical performance is known as concurrent validity. This important association was established for the first time in a recent study [37]. In this study, 21 surgeons (17 novices and 4 experts) were evaluated on 8 virtual reality exercises on the dVSS simulator and 4 inanimate exercises (FIRST tasks) [37]. Their simulator-based performance was then compared to robotic performance of the endopelvic dissection during a robotic prostatectomy as assessed by GEARS. There was a strong positive correlation between virtual reality performance, inanimate performance, and clinical robotic performance. Specifically, inanimate skills performance and robotic clinical performance showed a stronger association compared with virtual reality performance, supporting previous observations in an animal model [21, 37]. Although animal model training was not directly correlated with clinical performance in this study, the correlation between the two provides the basis for further investigation in the use of animal model training as a surrogate for robotic skills acquisition.

In an ideal evaluation of RAS training methods, there would be conclusive data on the efficacy of each simulation environment. Although the tools for such a study have now been developed, this data is not yet available with the current state of RAS training literature [24]. Animal model training is currently held as the gold standard of robotic training. It is used for robotic training courses, many hospitals require it for credentialing, and multiple studies use animal models as substitutes for in vivo surgical performance despite the lack of empiric evidence. With rising costs and a lack of evidence regarding efficacy, the defined role of animal model training in a comprehensive robotic training program is yet to be determined. The emergence of validated inanimate and virtual reality training methods may reduce the need for animal training. Alternatives to live tissue are being developed that may provide sufficient fidelity to obviate the use of animal training in the future.

A comprehensive robotic training program will likely consist of a combination of different methods of simulation. Animal training, with its high cost, requirements, and complexity, is not ideal for basic skills acquisition. Standardized, validated inanimate and virtual reality training may serve this purpose. However, these methods are not able to simulate complex tasks or tissue interactions that are required for advanced training. Animal model training may ultimately find its defined role in higher-level procedure-based training. It is likely high-fidelity animal model training will become centralized to specialized centers trained and equipped to handle this form of simulation. The American College of Surgeons has led the way in developing and accrediting educational institutes. In a similar model, geographically focused training facilities could be credentialed for animal model-based advanced robotic training. These centers could serve as sites for procedure-specific training as well as surgeon credentialing. Future work is needed to establish valid animal model training requirements and optimize use of animal models in robotic surgical training.

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Impact of Virtual Reality Simulator in Training of Robotic Surgery

14

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Abstract

Virtual reality simulation is a cost-effective training tool for robotic surgery. With available platforms, users can develop basic, intermediate, and advanced surgical skills. Simulators provide users with objective scoring feedback to improve operating performance. Although there is no present gold standard curriculum for simulator training, we review available exercises and metrics suitable for curriculum design.

Keywords

Simulation · Training · Robotic surgery · Virtual reality

Background

The first simulation training tool for robotic surgery became available in 2007 [1]. Robotic surgical simulators pose many advantages for institutions with robotic surgery trainees because these are both safe and cost-effective tools for robotic surgical training.

Simulation provides a safer environment for trainees to practice basic technical skills [1]. The learning curve associated with robotic surgery can be dangerous if practiced during live clinical cases. Additionally, these training tools provide users with an objective evaluation to longitudinally track performance and skill progression [2]. Each individual can tailor his or her practice to target weak skills and improve scores for difficult exercises [3]. Instructors and institutions can then use this data to analyze the surgical proficiency of each trainee [4].

Virtual reality simulators are also more cost effective training tools [5]. Purchasing a da Vinci robot solely for training purposes is prohibitively expensive at most centers. Additionally, if the robot is being utilized for both training purposes and clinical cases, depending on case volume, trainees may have limited access to practice [1]. Also, use of the console for simulation purposes adds mileage to the console and can later increase cost of repairs and maintenance [4]. Adding to the cost, clinically utilized robotic instruments have a fixed number of usages before they are no longer viable [1]. This would lead to additional instrument expenses. As a result, simulators provide a more cost effective alternative for trainees to practice surgical skills.

Available Platforms

Currently, there are four major platforms of virtual reality simulators available on the market.

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Fig. 14.1 Mimic dV-Trainer and exercises. (**a**) dV-Trainer console. (**b**) Suturing exercise. (**c**) Maestro Augmented Reality. (**d**) Example score report. (Used with permission from Mimic Technologies, Inc.)

The first simulator released for da Vinci robotic surgery was the dV-Trainer by Mimic Technologies Inc. in Seattle, Washington, USA [5]. This device has 65 unique exercises ranging from basic to advanced [1]. The stand alone simulator is portable and sits on a tabletop as shown in Fig. 14.1a [1]. User's hand and wrist movements are tracked with three cables [1]. These cables make the dV-Trainer master controllers arguably less fluid as compared to those of the actual surgeon console [1]. The Xperience Team Trainer (XTT) is a simulation tool for surgical assistants. It is developed by Mimic as an accessory to the dV-Trainer designed for concurrent team training.

The da Vinci Skills Simulator (dVSS) is the only simulator that utilizes the actual da Vinci surgeon console as seen in Fig. 14.2 [1]. This simulator provides trainees with the opportunity to familiarize themselves with the console they will use during live operations. This allows for a higher degree of transferability of skills from the simulator to the operating room [6]. The software on this simulator is a combination of content provided by Mimic, 3D Systems, and Intuitive Surgical.

The Robotic Surgical System (RoSS, Simulated Surgical Systems, San Jose, CA, USA) has been available since 2009 [5]. This device is a portable, stand-alone unit shown in Fig. 14.3. Currently there are 52 available exercises [1]. These exercises are divided into five categories: orientation module, basic surgical skills, motor skills, intermediate surgical skills, and hands-on surgical training [1]. However, compared to the da Vinci surgeon console, the RoSS has a smaller range of motion, less field of depth, and increased need for instrument clutching [4].

The RobotiX Mentor Robotic Surgery Simulator (RMRSS, 3D Systems, Israel) is the newest simulator to become available and is shown in Fig. 14.4a [5]. It aims to replicate a more realistic training system than those previously available [7]. The exercises focus on procedure-based simulation with various types of procedures [7].

Fig. 14.2 DVSS Console. (Used with permission from Intuitive Surgical, Inc.)

Features

Virtual reality simulators provide a broad range of exercises focusing on different robotic skills. These exercises range from basic to advanced. Basic skills include EndoWrist manipulation, instrument and camera control, needle control, and suturing. These are designed to assist beginners

Fig. 14.3 ROSS Surgical Simulator. (Used with permission from ROSS Systems)

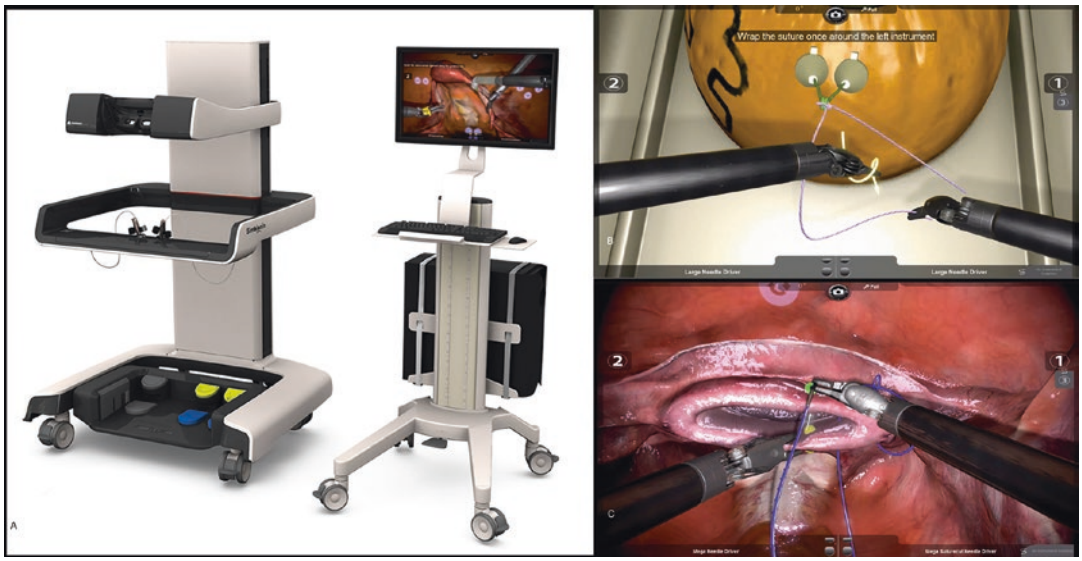

Fig. 14.4 RobotiX Mentor Robotic Surgery Simulator console and exercises. (**a**) RobotiX Mentor Robotic Surgery Simulator Console. (**b**) Fourth arm cutting exercise. (**c**) Procedure-based simulation exercise. (Used with permission from 3D Systems. Copyright 3D Systems, Simbionix RobotiX Mentor)

with important robotic maneuvers. Exercises that are procedure-specific guide the users through various steps of the operation.

Since each simulator hosts unique software, the available exercises vary. The RMRSS by 3D Systems hosts its own version of augmented reality, shown in Fig. 14.4c, allowing the user to perform critical steps for procedure simulated cases. Not only do trainees observe the various steps, but also they can practice performing the necessary techniques [7]. Available cases include prostatectomy, hysterectomy, vaginal cuff closure, inguinal hernia repair, and lobectomy [7]. Additionally, the RMRSS allows for simulation of possible errors during the procedure [7]. It also allows users to practice trocar placement [7].

Mimic's dV-Trainer offers more than 60 exercises, the most of any robotic simulator. It includes four major categories of exercises, which are da Vinci overview and basic skills training, advanced surgical skills training, procedure-specific content, team training. For da Vinci overview and basic skills training, the exercises are surgeon console overview, EndoWrist manipulation, camera and clutching. For advanced surgical skills training, there are needle control and needle driving, suturing—shown in Fig. 14.1b—and knot tying, energy and dissection. For procedure-specific content, Maestro AR provides virtual instruments augmented onto 3D case videos to advance clinical decision-making and procedural knowledge; refine surgical skills specific to the procedure. An example is shown in Fig. 14.1c. For team training, XTT enables the robotic surgeon and first assistant to train together with this optional component for the dV-Trainer. Augmented reality exercises through the dV-Trainer's Maestro AR series allow the user to improve upon intermediate to advanced skills; these exercises take users through real cases allowing the trainees to become more familiar with steps of the operation [8]. Procedures currently available for augmented reality include partial nephrectomy, prostatectomy, and hernia repair [8]. For the dVSS, key exercises are developed collaboration with Mimic Technologies, so the exercises are the same as dV-Trainer. In addition to that, dVSS also has suturing exercises developed by 3D Systems (formerly known as Simbionix).

The RoSS divides its unique exercises into three tiers of difficulty [4]. This includes its own augmented reality feature called Hands-on Surgical Training (HoST), integrating surgical videos with specific actions and icons [4]. Cases include radical prostatectomy, hysterectomy, and cystectomy [4]. This is paired with a feature entitled "Omni Phantom" which provides haptic feedback and can control movements during augmented reality exercises [8].

Scoring

All simulators provide users with objective scoring criteria after completion of an exercise. All exercises have a threshold for passing or failing in a given exercise. On all platforms, users can visualize their exercise proficiency based on green, yellow, or red coloring to indicate their performance level [4]. Users are provided with an overall proficiency score based on individual scoring criteria specific to each machine [4].

Scoring criteria on the dVSS applicable to all exercises include: overall score, time to complete, economy of motion, instrument collisions, excessive instrument force, instrument out of view, master workspace range, and drops. Additional criteria are used for specific exercises that test different skills [4]. On the dVSS the passing threshold can not be changed by the institution owning the simulator; it is set by the manufacturer [4]. Both the dVSS and the dV-Trainer use the "Mscore" portal for trainees to track their progress over time. An example score report is shown in Fig. 14.1d. Trainees are able to see their performances and compare them to the national and institutional averages. Additionally, institutions can use this portal to track trainee progress and exercise proficiency.

Unlike the dVSS, the dV-Trainer allows the institution to choose the threshold for passing [4]. Additionally, the dV-Trainer hosts two versions of software: the original "1.0" version and the new "2.0" version [4]. The new version scores exercises based on proficiency. The suggested

threshold for proficiency is determined by expert surgeon performance. The metrics for both versions are the same; the original version utilized percentages to score exercises; whereas, the new version uses a point system [4]. Individual institutions can decide which version they would like to use on their dV-Trainer [4].

The RoSS simulator utilizes a unique scoring system and display. At the end of the exercise, trainees see sideways performance bars [4]. These bars fill up based on the user's performance [4]. A full bar indicates that the trainee performed the exercise perfectly. This is meant to illustrate how much the trainee's performance deviates from a pre-determined "optimal" performance. The RoSS scoring criteria includes overall score, camera usage, left tool grasp, left tool out of view, number of errors (collisions or drops), right tool grasp, right tool out of view, time, tissue damage, and tool-tool collisions [4].

Each simulator utilizes similar criteria to objectively score user performance. The proficiency threshold and display vary between software.

Validation

Several of the simulation platforms have undergone extensive validation studies.

Face Validation

Face validation studies use questionnaires to assess simulator realism [9]. No uniform questionnaire was designed to access face validity. Commonly used questionnaires among these studies were five points or six points Likert scale or visual analog scale (VAS). Questionnaires evaluating overall realism were used in most studies. Across simulation platforms, realism in these studies was generally rated "high" [10–14]. Specified questionnaires accessing a wide array of parameters were also used. These parameters include ease of use, realism of exercises, graphic realism, hardware realism, realistic instrument movement, movement precision, depth perception, and interaction with objects (Table 14.1).

Table 14.1 Face validity studies

	dV Trainer	dVSS		RMRSS
Questions	5-item Likert scale (1 = very unrealistic… 0.5 = very realistic)	5-item Likert scale (1 = very unrealistic… 5 = very realistic)	10 points visual analog scales, Median (range)	5-item Likert scale (1 = very unrealistic… 5 = very realistic)
How easy to use, general realism?	3.9 [15], 4.4 [17]	4.1 by novices, 4.3 by experts [22]	8 (5–10) [16], 8 [19, 20]	3.7 [23]
How realistic were the exercises?	3.9 [15], 3.9 [17]			
How would you rate the visual realism?	4.1 [15], 3.6 [17], 4.3 ± 0.8 [18]		9 (6–10) [16], 8 [19]	3.5 [23]
How would you rate the realism of the hardware (grippers, foot pedals, stereoscope)?	3.8 [15], 4.0 [17], 4.1 ± 0.7 [18]			4.2 [23]
How would you rate the realism of movement simulated?	3.8 [15], 3.9 [17], 4.1 ± 0.8 [18]	4.4 [21]	9 (8–10) [16], 8 [19]	
How would you rate the precision of movement?	3.1 [15], 3.7 [17]		9 (6–10) [16]	
What do you think of the realism of depth perception	4.0 ± 1.1 [18]			
What do you think of the realism of interaction with objects	4.2 ± 0.8 [18]			

For all these parameters, realism was rated moderate to high, varied among individual studies [15–23]. One study compared the dVSS and dV-Trainer. The dVSS was judged more realistic and with better hardware (foot control, 3D view, movement of masters) than the dV-Trainer ($p < 0.001$) [13]. In one case series on the RoSS, 52% of participants rated the simulator somewhat close and 45% very close overall to the da Vinci robot console [24].

Content Validation

Content validity access the training value of the simulator from the perspective of expert surgeons [9].

Questionnaires concerning the usefulness of simulators for training purpose and their integration in residency curriculums were used for evaluation. These questionnaires were also designed as Likert scale or VAS [10].

General usefulness was evaluated with the following questions [13]:

- Do you think simulators would be useful in training people to use a da Vinci robot?
- Do you think simulators should be implemented in residency training?
- Do you think simulators should be used for qualification testing in robotic surgery?

Training values regarding different aspects were evaluated separately [25]:

- Effective training tool for teaching anatomy?
- Effective training tool for teaching technical skills?
- Effective training tool for teaching surgical steps?

The training values for trainees with different robotic surgical experience, subdivided as surgical residents, surgical fellows and experienced robotic surgeons were also evaluated, respectively [16].

Expert robotic surgeons rated the dVSS and dV-Trainer as very useful training system for residents (8/10 and 10/10, respectively) [16, 22]. Among 31 experts participating in a survey, 94% found the RoSS useful for training residents or medical students [26]. The XTT was considered useful for bed assistant (85.7%) and robotic surgical teamwork (100%) training [27]. All nine studied tasks of RMRSS were scored between 4.3 and 4.6 out of 5, demonstrating these tasks as important for robotic training [23]. In one study, dV-Trainer was considered very useful for training surgical residents and surgical fellows (10/10, 9/10, respectively), however, less so for training experienced robotic surgeons (6/10) [16].

Construct Validation

Construct validity measures the ability of a simulator to differentiate performance between experts and novices on given tasks [19].

In construct validation studies, participants were divided into different groups based on their robotic surgery experiences. Each participant was then assigned to a series of exercises on the simulator. The simulator recorded participant's performance based on specific metrics, an overall score was also calculated at the completion of each exercise that was a weighted average of the individual metrics measured in the given exercise.

Twenty-four cohort studies were on construct validity [3, 10, 12–16, 18–21, 23, 25, 27–37]. Each exercises were executed once in 17 studies [3, 10, 13, 14, 19–21, 23, 25, 28–32, 34, 35, 37], twice in one [18], three times in five [12, 15, 16, 27, 33] (In one study, each exercise was repeated thrice, with the first attempt for familiarization and the last two attempts averaged as the performance [27]), and at least twice in one study [36], as summarized in Table 14.2.

Of the studies that comprised two study groups (experts and novices) each, among which five were on dV-Trainer [10, 12, 15, 28, 29], three were on dVSS [3, 33, 37], two were on RoSS [34, 35], all showed that experts significantly outperformed novices ($p < 0.05$) in overall score and most of the metrics. For studies with three study groups (experts, intermediates and novices) each,

Table 14.2 Construct validity studies

Study	Simulator	Participants		Exercises	Assessment	Results
		n	groups			
Hung et al. [3]	dVSS	49	38 novices (residents <30 cases, range 0–20); 11 experts (>30 cases, range 30–2000)	4 tasks (PB2, RR2, SS3, T)	Overall score (unpublished data)	Experts had significantly better overall scores than novices ($p < 0.001$) for all tasks
Kenney et al. [10]	dV-Trainer	26	19 novices (students, residents, and consultant surgeons, 1.3 2.2 h); 7 experts (mean 140 cases, range 30–320)	4 tasks (DN, SP, PP, PB1)	Overall score (pooled data) and 9 metrics: total task time, maximal force, total motion, instrument collisions, time out of view, time out of center, dropped targets, successful targets, unattempted targets (pooled data)	Experts performed significantly better than novices ($p < 0.05$) on overall score for all tasks and metrics except maximal force
Lee et al. [12]	dV-Trainer	20	13 novices (residents, fellows, and surgeons <50 h); 7 experts (>50 h)	4 tasks (PB2, MB1, RR1, TR) 3 times	2 metrics: time to complete, number of errors (each task)	Experts performed better than novices in all tasks, with significant difference ($p < 0.05$) for error in three tasks (PB2, MB1, RR1) and for completion time in TR
Liss et al. [13]	dV-Trainer vs dVSS	32	7 medical students (0 h), 7 attending urologists (0 h), 7 junior residents (<5 h), 6 senior residents (5–50 h); 6 fellowship- trained urologists (>50 h)	1 task (T) first on dVSS then on dV-Trainer	Overall score and the same 7 metrics (economy of motion, time to completion, excessive instrument force, instrument collisions, instruments out of view, master workspace range, and drops) for dVSS and dV-Trainer (unpublished data)	Both simulators were able to differentiate experience levels among the groups (overall score, $p < 0.05$); significant difference on metrics ($p < 0.05$): dV-Trainer among the 5 groups on critical errors, economy of motion, and missed targets, for dVSS on completion time, economy of motion, and instrument collisions
Perrenot et al. [14]	dV-Trainer	75	19 nurses and students; 37 surgeons and residents; 8 novices (0 cases); 6 intermediates (surgeons 21 ± 12 cases); 5 experts (surgeons 264 ± 164 cases)	5 tasks (PP, PB1, CT1, MB1, RR1)	Overall score (pooled data) and 7 metrics (economy of motion, time to completion, excessive instrument force, instrument collisions, instruments out of view, master workspace range, and drops) (unpublished data)	Robotic surgeons (experts and intermediates) outperformed all other subjects without experience; significant difference ($p < 0.05$) for all metrics on all tasks except time of excessive force and instruments out of view
Sethi et al. [15]	dV-Trainer	20	15 novices (medical students and residents >1 interaction with robot); 5 experts (surgeons >50 cases)	3 tasks (RC, SW, LB) three times	2 metrics: time to complete, time of instrument out of view (each task)	Experts performed significantly better than novices ($p < 0.05$) only on SW task (completion time and instruments out of view)

(continued)

Table 14.2 (continued)

Study	Simulator	Participants		Exercises	Assessment	Results
Hung et al. [16]	dV-Trainer	63	16 novices (medical students, 0 cases); 32 intermediates (residents, fellows and surgeons, 0–50 cases); 15 experts (mean 315 cases, range 0–800)	10 tasks (PB2, CT2, RW2, MB2, RR2, ED1, NT, SS3, DN1, T) three times	Overall score (pooled data and each task) and 11 metrics: number of object drops, motion economy, excessive instrument force, number of instrument collisions, instrument out of view, master controller range, number of missed targets, time to complete, misapplied energy time, number of broken vessels, blood loss (pooled data)	Statistically significant difference ($p < 0.05$) across all three groups for all tasks on overall score and five metrics (completion time, economy of motion, excessive instrument force, instrument collisions, and number of missed targets)
Schreuder et al. [18]	dV-Trainer	42	15 novices (9 students, 3 residents, 3 specialists; 0 cases); 14 intermediates (2 residents and 12 surgeons; 24 cases, range 6–50); 13 experts (>240 cases, range 70–1200)	3 tasks (PB2, CT2, TR), 2 times	8 metrics (economy of motion, time to completion, excessive instrument force, instrument collisions, instruments out of view, master workspace range, number of errors and drops) (each task)	Significant difference ($p < 0.05$) during the second attempt: intermediates vs novices (PB2, completion time; CT2, economy of motion and errors; TR, completion time, economy of motion, number of instrument collisions, and errors); experts vs intermediates (PB2 and CT2, completion time and economy of motion); experts vs novices (PB2, completion time, economy of motion, and number of drops; CT2, completion time, economy of motion, master workspace range, instrument collisions, and number of drops; TR, completion time, economy of motion, number of instrument collisions, and errors)
Alzahrani et al. [19]	dVSS	48	30 novices (1 attending, 1 fellow, 13 residents, 13 students, 2 research assistants, 0 cases); 12 intermediates (4 attending, 3 fellows, 5 residents, mean 9 cases, range 20–45); 6 experts (mean 250 cases, range 5–390)	9 tasks (PB2, RW3, MB2, RR2, ED1, NT, SS2, DN1, T)	Overall score (each task) and 11 metrics (completion time, economy of motion, time of excessive force, number of instrument collisions, number of missed targets, master workspace range, drop, instrument out of view, misapplied energy time, broken vessels, blood loss) (pooled data)	Overall score: intermediates significantly better than novices ($p < 0.05$) in all tasks except RW3 and ED1; experts significantly better than intermediates in all tasks except MB2 and ED1; experts significantly better than novices in all 9 tasks. Metrics: significant difference ($p < 0.05$) for intermediates vs novices for completion time, economy of motion, time of excessive force, number of instrument collisions, number of missed targets; for experts vs intermediates for master workspace range; for experts vs novices for completion time, economy of motion, excessive force time, number of instrument collisions, master workspace range, and missed targets

Kelly et al. [20]	dVSS	38	19 novices (1 resident and 18 students, 0 cases); 9 intermediates (6 residents, 1 fellow, 2 faculty member, mean 29.2 cases); 10 experts (2 residents, 1 fellow, 7 faculty members, mean 233.4 cases)	5 tasks (CT1, RR1, ES1, TR, DN1)	Overall score (each task)	Experts scored better than novices (overall score for all tasks except CT1), intermediates better than novices (overall score only for RR1, TR, and DN1, $p < 0.05$); experts scored better than intermediates (all tasks except CT1) but the difference was not significant
Lyons et al. [21]	dVSS	46	25 novices (residents <10 cases, range 0–10); 8 intermediates (surgeons, mean 38 cases, range 12–50); 13 experts (mean 150 cases, range 60–1400)	8 tasks (PB1, PB2, RW3, MB3, RR2, ES1, SS3, T)	Overall score (each task) and up to 10 metrics (completion time, economy of motion, time of excessive force, number of instrument collisions, number of missed targets, master workspace range, critical errors, instrument out of view, drop, missapplied energy time) (each task)	Overall score: intermediates significantly better than novices ($p < 0.05$) for all tasks except PB1 and MB3; experts significantly better than novices for all tasks; experts better than intermediates for PB1, MB3, RW3, SS3, ES1, but the differences were not significantSignificant difference ($p < 0.05$) in metrics: novices vs intermediates for economy of motion for PB1, PB2, MB3, RR2, SS3, and T; completion time for PB2, MB3, RR2, ES1, SS3, and T; excessive force time for MB3, RR2, RW3, and SS3; novices vs experts for completion time and economy of motion in all 8 tasks; master workspace range in all tasks except RW3; number of instrument collisions in all tasks except MB3 and ES1; critical errors in all tasks except PB1 and ES1); intermediates vs experts for number of instrument collisions in PB1 and SS3
Whittaker et al. [23]	RMRSS	46	20 novices (students, 0cases); 15 intermediates (consultant surgeons and senior residents 4–680 cases); 11 experts (mean 271 cases, range 70–1160)	9 tasks (KT, RS, 4 AC, PPD, VED, VDS, HDS, CS, IS)	Time to complete, total errors, instrument collisions, instruments out of view, clutch usage, distance by camera, number of movements, path length, inaccurate punctures, inaccurate targeting, precision, cuts outside marked line, cuts >2 mm deep, unnecessary piercings, average distance from target, suture breakage, needle drops, knot tail length deviation, correct suturing angle, needle passage accuracy, suture overstretch, new suture requests	Experts significantly outperformed novices in 17/25 of metrics ($P < 0.005$), experts outperformed intermediates in 7/25 metrics ($P < 0.005$), significant differences between intermediates and novices in 11/25 of metrics ($P < 0.005$)

(continued)

Table 14.2 (continued)

Study	Simulator	Participants		Exercises	Assessment	Results
Hung et al. [25]	dV-Trainer	42	15 novices (medical students, 0 cases); 13 intermediates (surgeons <100 cases); 14 experts (>100 cases)	1 procedure (RPN)	10 metrics (anatomy, technical, steps, questions, depth perception, dexterity, efficiency, force sensitivity, autonomy, robotic control)	Intermediates outperformed novices for all metrics (significant difference at $p < 0.05$ except for pierce distance error and time instruments out of view); experts scored better than intermediates for all metrics with no significant difference; experts outperformed novices for all metrics (significant difference at $p < 0.05$ except for pierce distance error and time instruments out of view)
Xu et al. [27]	XTT	27	11 with robotic bed-assistance experience, 7 with laparoscopic surgical experience, 9 without bed-assistance or laparoscopic experience	3 tasks (MB1, RWR, CRW) three times, first attempt for familiarization and the last two attempts averaged as the performance	Overall score (each task) and 7 metrics (task duration, instrument motion, instrument collision, excessive force, out of view, clipping distance, incorrect clips) (each task)	Both the groups RA and LS performed better than the control group; a slight superiority of performance of the group RA over LS was observed in nearly all metrics, but statistical significance was only achieved in the excessive instrument force ($p < 0.05$)
Lendvay et al. [28]	dV-Trainer	15	11 novices (residents, 0 cases); 4 experts (surgeons: 2 < 10 cases/year, 1 10–25 cases/year, 1 > 25 cases/year)	1 task (PB1)	6 metrics (task time, economy of motion, peak ring strain, number of instrument collisions, time instrument out of view, time master control out of center)	Experts performed significantly better than novices ($p < 0.05$) for completion time, economy of motion and master control out of center
Kang et al. [29]	dV-Trainer	20	10 novices (residents, 0 cases); 10 experts (10–313 cases)	1 task (T3)	Overall score and 7 metrics (economy of motion, time to completion, excessive instrument force, instrument collisions, instruments out of view, master workspace range, and missed targets)	Experts performed significantly better than novices in overall score and all metrics ($p < 0.05$)
Van Der Meijden et al. [30]	SEP	16	9 novices (surgeons <50 cases); 7 experts (surgeons >50 robotic surgery and laparoscopy cases)	1 task (suture)	2 metrics (tool tip trajectory, completion time)	Experts scored significantly better than novices ($p < 0.05$) for tool tip trajectory, but not for completion time

Gavazzi et al. [31]	SEP	30	18 novices (students, 0 cases); 12 experts (surgeons, mean 148 cases, range 30–500)	2 tasks (AM and SK)	time to complete, lost arrows, tool collision, close entry for AM; time to complete, max tightening stretch, equipment dropped, max winding stretch, collision for SK	Experts significantly outperformed novices ($p < 0.05$) in both tasks on completion time, lost arrows, tool collision sum, and close entry sum
Finnegan et al. [32]	dVSS	39	18 novices (residents, fellows, and surgeons, 0–20 cases); 8 intermediates (surgeons 21–150 cases); 13 experts (>150 cases)	24 tasks (all basic tasks except ED2 and SS3)	Overall score (pooled data) and 1 metric (time to complete) (unpublished data)	Significant difference ($p < 0.05$) on overall score in the following: intermediates vs novices, all tasks except PP, CT1, SC, ES1, ED1, SS2, and DN2; experts vs intermediates, ES1, ED1, TR, SS2, DN2, and T Significant difference ($p < 0.05$) on completion time: novices vs intermediates, PB1, PB2, RW1, RW2, RW3, MB1, RR1, RR2, ED2, NT, SS1, and DN1; intermediates vs experts, all tasks except PP, PB1, PB2, RW1, RW3, RR1, SS1, and DN1
Connolly et al. [33]	dVSS	24	20 novices (medical students, 0 cases); 4 experts (>20 cases)	5 tasks (PP, PB2, CT2, MB2, SS3), 3 times	Overall score (each task) and 1 metric (time to complete) (each task)	Experts significantly outperformed novices ($p < 0.05$) on overall score and time in all tasks
Chowriappa et al. [34]	RoSS	27	15 novices (surgeons, 0 cases); 12 experts (>150 cases)	4 tasks (BP, CTC, FAM, and NHE)	Overall score (each task) and 5 metrics (safety in operative field, critical errors, bimanual dexterity task time, economy) (each task)	Experts significantly outperformed novices ($p < 0.05$) in overall score and the following metrics: all except critical errors for FAM; all except economy for CTC; all except bimanual dexterity and task time for BP; bimanual dexterity and task time for FAM; all except critical errors for NHE
Raza et al. [35]	RoSS	61	49 novices (medical students, residents, surgeons, 0 cases); 12 experts (>150 cases)	4 tasks (BP, CTC, FAM, NHE)	10 metrics (task time, distance by left hand, distance by right hand, left tool out of view, right tool out of view, tool-tool collision, tissue damage, distance by camera, number of errors, clutch usage) (each task)	Experts significantly outperformed novices ($p < 0.05$) for all metrics for BP; all except right tool out of view for CTC; all except left tool out of view, right tool out of view, tissue damage, and distance by camera for FAM; all except left tool out of view, right tool out of view, tool-tool collision, and number of errors for NHE
Balasundaram et al. [36]	SEP	12	10 novices (residents, 0 cases); 2 experts (>50 cases)	5 tasks (NM, ST, SWT, ASK, IS), 10 times by residents, 2 times by experts	3 metrics (completion time, path length, number of errors) (each task)	Experts significantly outperformed novices ($p < 0.05$) during second attempts in all tasks for completion time, but not path length

(continued)

Table 14.2 (continued)

Study	Simulator	Participants		Exercises	Assessment	Results
Foell et al. [37]	dVSS	53	48 novice (residents, <10 cases; 5 experts (surgeons, >20 cases)	7 tasks (CT1, PB1, MB1, TR, SS1, RW2, PB2)	Overall score (each task)	Experts performed significantly better than novices on five out of the seven dVSS exercises: CT1, PB1, MB1, TR, and SS1, $p < 0.05$). Only the RW2 and PB2 did not demonstrate evidence of construct validity

- The 26 basic exercises on the dV-Trainer and dVSS are as follows: *PP* pick and place, *PB1* peg board 1, *PB2* peg board 2, *CT1* camera targeting 1; *CT2* camera targeting 2, *SC* scaling, *RW1* ring walk 1, *RW2* ring walk 2, *RW3* ring walk 3, *MB1* match board 1, *MB2* match board 2, *MB3* match board 3, *RR1* ring and rail 1, *RR2* ring and rail 2, *ES1* energy switching 1, *ES2* energy switching 2, *ED1* energy dissection 1, *ED2* energy dissection 2, *NT* needle targeting, *TR* thread the rings, *SP1* suture sponge 1, *SP2* suture sponge 2, *SP3* suture sponge 3, *DN1* dots and needles 1, *DN2* dots and needles 2, *T* tubes. The other dV-Trainer basic exercises are *PP_O* pick and place old, *PB3* peg board 3, *T2* tubes 2, *T3* tubes 3
- Basic dV-Trainer exercises available only for the early releases are *SW* string walk, *LB* letter board, *RC* ring cone, *Sp* suture sponge, *DN* dots and numbers
- Basic RoSS exercises: *PP* pick and place, *BP* ball placement, *BD* ball drop, *SC* spatial control, *CTC* coordinated tool control, *FAM* fourth arm manipulation, *NHE* needle handling and exchange, *CC* clutch control, *NR* needle removal, *FAR* fourth arm removal, *TR* tissue retraction, *KT* knot tying
- Basic SEP exercises: *AM* arrow manipulation, *NM* needle manipulation, *ST* suturing without traction, *SWT* suturing with traction, *IS* interrupted suture, *ASK* abstract square knot, *SK* surgeon's knot
- Basic XTT exercises: *MB1* match board 1, *RWR* ring walk retraction, *CRW* clipping ring walk
- Basic RMRSS exercises: *KT* knot tying, *RS* railroad suturing, *4 AC* 4th arm cutting, *PPD* puzzle piece dissection, *VED* vessel energy dissection, *VDS* vertical defect suturing, *HDS* horizontal defect suturing, *CS* continuous suturing, *IS* interrupted suturing

one study on dV-Trainer [16] and one study on RMRSS [23] showed statistically significant difference in performance ($p < 0.05$) across all three groups. One study on dV-Trainer [25] and three studies on dVSS [19–21] showed both experts and intermediates significantly outperformed novices, experts performed better than intermediates but no statistically significant difference were seen.

There are several shortcomings in these construct validity study design. Most of these studies comprised small cohort of participants, ranging from 12 to 61. Also there was no agreed standard on novices. Some studies enrolled subjects without any robotic surgery experience as novices [13, 14, 16, 18–20, 23, 25, 27, 28, 31, 33–36]. Some studies enrolled individuals with limited robotic surgery experience as novices [3, 10, 12, 15, 21, 30, 32, 39]. There was no agreed definition on experts. Some studies rated experts according to the mean number of robotic cases performed, which ranged from 140 to 315 [10, 14, 16, 19–21, 23, 31]. In some studies, expert rating was based on the minimum number of cases performed, with a wide range from 10 to 240 [3, 15, 18, 25, 29–37]. Lastly, performance assessment methods varied among these studies. In some studies, performance assessment was on pooled data for overall score or metrics, which could not give an accurately estimate the difference between levels of experience, since it inevitably introduced bias by mixing results for tasks of different levels of difficulty. Only six studies evaluated each task on both overall score and metrics [21, 23, 27, 29, 33, 34].

Concurrent Validation

Concurrent validity of a robotic simulator reflects how the participant's performance on the simulator correlated to the performance on the gold standard, namely – live da Vinci Surgical System [9]. Participant's performance on simulator is compared to performance on da Vinci Surgical System either on dry laboratory or on wet laboratory.

Concurrent validity was reported in eight studies (one dVSS RCT, four dV-Trainer, two dVSS cohort study, one XTT) [6, 12, 14, 17, 22, 25, 27, 37] (Table 14.3). Comparison between the simulator and live robot for the same tasks in six studies [12, 14, 17, 22, 27, 37]. Comparison between simulated tasks and in vivo robotic partial nephrectomy in one study [25]. Comparison between simulated tasks and ex vivo animal tissue exercises in one study [6].

Of the six studies that compared the same tasks on both simulators and the actual da Vinci console, three studies on dV-Trainer showed high correlation regarding overall scores of the exercises or metrics of the pool data. However, as for individual tasks, not so much of a correlation was seen either in overall score or different metrics [12, 14, 17]. For the two studies, one on dV-Trainer [25] and one on dVSS [6] that compared the performance on simulators and the performance on robotic wet laboratories, high overall scores correlation were observed.

There are several shortcomings in concurrent validity study design. Assessment methods for concurrent validity in simulators and da Vinci Surgical System console were different. Performances on the simulator were recorded by the simulator intrinsic system. Performance of the wet or dry laboratories were graded by experts based on Global Evaluative Assessment of Robotic Surgery (GEARS) [22, 25], or Global Operative Assessment of Laparoscopic Skills (GOALS) [6, 27]. These grading systems have been previously validated and published, demonstrating high correlation and repetition with the simulators' intrinsic grading systems [3, 22, 38].

Predictive Validation

Predictive validity is ability to select those who will not be able to perform surgical operations well, despite training, and the reverse, those who will excel [3]. Participant's performances on simulators are compared to performance on da Vinci Surgical System console over a period of simulator training.

Only one RCT is on the dVSS predictive validation study [6]. There was high correlation ($r = 0.7$, $p < 0.0001$) between the overall score

Table 14.3 Concurrent validity studies

Study	Simulator	Participants		Simulator exercises	da Vinci Surgical System console exercises	Assessment	Results
		n	Groups				
Hung et al. [6]	dVSS	24	2 medical students, 14 residents, 5 fellows, 1 intern, and 2 staff members with 0 cases (range 0–10)	17 tasks (all basic tasks except PP, PB1, CT1, RW1, MB1, RR1, ES2, SS1, SS2)	Participants performed 3 ex vivo tasks with da Vinci robot on animal tissue (bowel resection, cystotomy and repair, and partial nephrectomy)	Overall score and up to 11metrics (depending on task) on dVSS. 3 metrics: time to complete, the number of dropped needles and instrument collisions, and GOALS for ex vivo animal tissue exercise	High correlation on overall score between baseline on simulator and initial animal exercises ($r = 0.7$, $p < 0.0001$)High correlation between economy of motion and efficiency ($r = -0.5$), depth perception ($r = -0.6$), and bimanual dexterity ($r = -0.7$, $p < 0.01$), and between time of excessive force and tissue handling ($r = -0.7$, $p = 0.0002$) Moderate correlation between simulator and robot for number of instrument collisions ($r = 0.5$, $p = 0.01$). Completion time on simulator moderately correlated with time to complete animal tissue tasks ($r = 0.4$, $p = 0.06$) and autonomy ($r = -0.6$, $p = 0.004$)
Lee et al. [12]	dV-Trainer	20	13 novices (residents, fellows, surgeons <50 h); 7 experts (surgeons >50 h)	PB2, MB1, TR, RR	Dry lab: PB2, MB1, TR, RR	Overall score and 2 metrics: time to complete, numbers of errors	No correlation on individual 4 tasks between dV-Trainer and da Vinci robot; correlation only for pooled data for 4 tasks for time ($r = 0.55$, $p = 0.026$) and errors ($r = 0.62$, $p = 0.011$).
Perrenot et al. [14]	dV-Trainer	75	5 experts (surgeons: 264 ± 164 cases)	PP, PB1, RR1, MB1, CT1	Dry lab: PP, PB1, RR1, MB1, CT1	Overall score and 7 metrics: time, economy of motion, excessive instrument force, drops, collisions, instrument out of view, master workspace	The overall scores on the robot were strongly correlated dV-Trainer ($r = 0.822$). For individual tasks, only PP & RR showed correlation ($r = 0.661$, $r = 0.62$)
Egi et al. [17]	dV-Trainer	12	9 intermediates and 3 experts (>50 laparoscopic procedures)	PP, PB1, TR, SS1	Dry lab: PP, PB1, TR, SS1	1 metric: time, and OSATS	Correlation between tasks on dV-Trainer and da Vinci robot on time ($r = 0.60$–0.62 depending on task, $p = 0.030$–0.041) and between overall OSATS score and SS1 task ($r = 0.58$, $p = 0.046$)

Ramos et al. [22]	dVSS	36	24 novices (0 cases); 12 experts (200 cases, range 30–2015)	PP, PB2, MB1	Dry lab: PP, PB2, MB1	Overall score and 7 metrics: number of objects dropped, economy of motion, excessive instrument force, number of instrument collisions, instruments out of view master controller range, time to complete for dVSS. 3 metrics: number of instrument collisions, number of drops and time to complete and GEARS for da Vinci robot	Moderate correlation ($r = 0.54$, $p < 0.001$) between overall score for dVSS and total GEARS score for da Vinci robot. High correlation between time to complete on simulator and GEARS time ($r = 0.87$) and efficiency ($r = -0.79$, $p < 0.001$). Economy of motion: moderate to high correlation with efficiency ($r = 0.64$), depth perception ($r = 0.75$), and bimanual dexterity ($r = 0.63$, $p < 0.001$); moderate correlation for number of instrument collisions ($r = -0.48$, $p = 0.002$) and master workspace range ($r = 0.48$, $p = 0.001$)
Hung et al. [25]	dV-Trainer	42	13 intermediates (surgeons <100 cases); 14 experts (surgeons >100 cases)	VR mobile sponge exercise	In vivo wet lab: porcine robotic partial nephrectomy	GEARS for videos of simulated task and in vivo porcine RPN with da Vinci robot	High correlation ($r = 0.8$, $p < 0.0001$) on overall score (GEARS) between simulated renorrhaphy and in vivo RPN
Xu et al. [27]	XTT	27	11 with robotic bed-assistance experience, 7 with laparoscopic surgical experience, 9 without bed-assistance or laparoscopic experience	MB1, RWR, CRW	Dry lab: MB1, RWR, CRW	Overall score and 5 metrics: tasks completion time, instrument motion, instrument collisions, excessive instrument force, instrument out of view for XTT. GOALS for da Vinci robot	Each exercise demonstrated correlation with at least one metrics ($p < 0.05$). For separate exercises, a strongest correlation was in MB1, followed by CRW. The correlation was poor in RWR
Foell et al. [37]	dVSS	53	48 novice (residents, <10 cases; 5 experts (surgeons, >20 cases)	CT1, PB1, PB2, RW2, MB1, TR, SS1	Dry lab: RT, NP (needle passing)	Overall score of each task on dVSS; 2 tasks (RT and NP), 2 metrics (time to complete, number of errors) on da Vinci robot	Overall score on all but one (PB2) of the seven exercises correlated with time to completion on both RT and NP tasks ($p < 0.05$). None of the seven different overall scores, however, correlated with number of errors for both RT and NP tasks

- Basic exercises on the dV-Trainer and dVSS are as follows: *PP* pick and place, *PB1* peg board 1, *PB2* peg board 2, *CT1* camera targeting 1, *CT2* camera targeting 2, *SC* scaling, *RW1* ring walk 1, *RW2* ring walk 2, *RW3* ring walk 3, *MB1* match board 1, *MB2* match board 2, *MB3* match board 3, *RR1* ring and rail 1, *RR2* ring and rail 2, *ES1* energy switching 1, *ES2* energy switching 2, *ED1* energy dissection 1, *ED2* energy dissection 2, *NT* needle targeting, *TR* thread the rings, *SP1* suture sponge 1, *SP2* suture sponge 2, *SP3* suture sponge 3, *DN1* dots and needles 1, *DN2* dots and needles 2, *T* tubes. The other dV-Trainer basic exercises are *PP_O* pick and place old, *PB3* peg board 3, *T2* tubes 2, *T3* tubes 3
- Basic dV-Trainer exercises available only for the early releases are *SW* string walk, *LB* letter board, *RC* ring cone, *Sp* suture sponge, *DN* dots and numbers
- Basic XTT exercises: *MB1* match board 1, *RWR* ring walk retraction, *CRW* clipping ring walk
- Dry lab: *RT* ring transfer, *NP* needle passing

during the initial test on the dVSS and the final test on a da Vinci robot ex vivo animal tissue exercises according to GOALS [6].

Limitations

Currently, simulators have shown to effectively improve basic skills [37]. This is due to the large availability of exercises targeting basic robotic skills. As a result, simulation use has been shown to be effective for beginner learning curves [2]. However, simulator usage has shown little benefit for advanced skills [2]. A dearth of advanced skill exercises renders the simulator less useful for surgeons that have mastered the basic robotic skills. For example, there are no exercises that effectively simulate tissue dissection. Future simulator software necessitates more specialized exercises based on specialty and type of procedure [37]. This will allow trainees to target steps of operations they will be performing in the operating room. Since only one user is in control during simulation exercises, there is limited opportunity for mentor guidance [3]. If simulator use occurs before hands-on training, trainees could miss many teaching benefits from expert surgeons [3]. Finally, simulator use has shown to result in a higher frustration than live robotic console use [39]. Although passing or failing metrics are useful they most likely contribute to this increased frustration. Trainees practicing on a robotic console on an animal model showed less mental workload [39]. This high mental workload could decrease user compliance and diminish effects of simulator ownership.

Curriculum

Currently, no gold standard for a robotic simulation curriculum exists. Many institutions have created their own curricula to train physicians and test proficiency. However, these curricula are varied and are up to the discretion of the institution and software available. The phases of robotic training can be broken down into three general stages [40]. The first is the preclinical phase. Here, the trainee learns basic skills with a simulator. In the second phase, the trainee acts as a bedside assistant. He or she learns trocar and robot placement, instrumentation, and troubleshooting during procedures. Concurrent in the first two phases, the trainee learns the procedural steps of the relevant operations. The final stage is the operative console phase. During this stage the trainee begins to operate with the expert surgeon and becomes increasingly autonomous.

Many of the current simulation training curricula available are based on overall proficiency. This allows the trainee to have clear goals and end points [41]. That way he or she has an effective and efficient path to master skills. Without such end points it has been found that trainees were less likely to practice on the simulator and did not accomplish the same goals as they would with set targets [41]. A proficiency-based curriculum allows the user to master skills in an efficient manner with long-term retention [41]. One point of debate is what the threshold for proficiency is and what metrics most accurately determine if someone is proficient. The globally accepted and validated GEARS scoring metric does not apply for simulation since there is no tissue handling involved [42], although it has been utilized successfully in the validation of a procedure-specific VR simulation module [3]. Most curricula set an arbitrary composite score, such as 91%, that the trainee must obtain before moving to the next exercise [42]. This composite score can be based on time, economy of motion, number of instrument collisions, excessive instrument force time, instruments out of view time, master workspace range, number of drops, misapplied energy time, blood loss volume, and number of broken vessels [42]. Some of these metrics do not apply to each exercise and are subsequently removed. Institutions that have utilized a proficiency based curriculum were interested in finding a curriculum involving the minimum necessary training time for a surgeon to be competent enough to perform live cases [42]. Although all trainees were able to achieve competency, the amount of time for each trainee to become proficient varied greatly [42]. This suggests that a standard curriculum based on simulator use

duration or number of exercise attempts would not be effective for all trainees. This indicates that evaluation based on reaching competency is adequate without "time to competency" restrictions. Interestingly, those who took longer to become proficient on the simulator showed a faster skills decline [42]. These individuals needed more frequent training to remain proficiency. Whereas, those who became proficient quickly remained proficient for longer period despite a lack of simulator usage [42].

When analyzing time to perform on par with expert surgeons it took an average of six attempts for novice users [43]. This number varied based on different metrics. Some metrics were learned quickly and the learning curve plateaued. However, for most metrics, the learning curve was steep from one to four attempts and then plateaued at six [43]. This suggests six attempts could be a minimum threshold for standard time to proficiency. However, some curricula are based on proficiency with a maximum number of attempts [44]. The user must qualify as proficient in under a set number of attempts or else they must retest. This would be most effective for testing or credentialing to allow institutions to determine if the individual is competent on the robot.

On the simulator overall score was shown to correlate best with prior robotic experience [33]. The definition of an expert surgeon ranges from 20 or more cases to over 100. Novices are generally medical students with no prior experiences or less than 10 cases [37]. Therefore, in order to create a curriculum, expert surgeons select exercises involving variety of skills with a broad range of difficulty [33]. The most reliable metrics showing the highest construct validity were time, economy of motion, and errors [37]. This indicates that the creation of a gold standard curriculum must include expert surgeon feedback to select exercises and indicate the threshold for proficiency. Any curriculum needs a broad range of exercises that allow the trainee to develop all necessary skills prior to live cases. It also indicates that overall score is best calculated using time, economy of motion, and errors.

Other institutions have based their curricula on time to complete. Time was the largest factor determining if a user was "proficient" in an exercise. The user must complete an exercise in a certain amount of time three consecutive times [41]. The results showed that time to complete was the single metric that correlated best with experience [41]. Time also showed steady improvement during the learning curve phase [45]. One study showed that it took trainees on average 10 repetitions to acquire basic skills with a proficiency of 90% [45]. If institutions can create a curriculum relative to expert, they can use this method to determine if a trainee is proficient on the robot and is qualified to be an autonomous surgeon. However, speed alone should not be the end goal of training. Too much focus on time to completion could lead to the user making dangerous errors and a failure to develop critical skills.

Although the curricula previously mentioned analyzed proficiency based on overall score, it is also important to analyze specific metrics. Overall score is convenient and comprehensive, but a user must ensure that a high score in one metric does not compensate for lower scores in other skills [45]. The goal is to ensure acquisition of all robotic skills. Instrument collision is another metric that shows steady improvement with training [45]. Similarly, critical errors showed a steady improvement and was the most useful metric to ensure safety of a surgeon [45]. Critical errors should be weighed heavily in creation of metrics for an overall composite score to ensure safety in conjunction with accuracy and efficiency [45].

Although no gold standard exists, it is important to develop a standard curriculum as robotic assisted surgeries become more prevalent. The adherence to a curriculum has been proven to improve basic, fundamental skills [46]. This is important for beginners, but shows little benefit for experienced surgeons [2]. However, the evaluation criteria remain up to debate. One study indicated that trainees did not even need to pass an exercise to acquire the necessary basic skills [46]. Additionally, this curriculum must also maximize learning while minimizing fatigue. Users show highest rates of compliance when simulator training is divided into to smaller and more frequent sessions compared to long spo-

radic sessions. Evaluation criteria and thresholds to proficiency remain the largest obstacles to creating a standard curriculum and as more curricula are created, knowledge of scoring methods and learning curves make this goal more obtainable.

Future Directions of VR Simulation

Simulation has advanced significantly since the introduction of the dV-Trainer in 2007. There are still many frontiers left to cross. As software advances there is a need for increased procedure specific training [1]. This will allow trainees to build skills directly related to a specific procedure. Users can target difficult steps to improve overall operation proficiency. Augmented reality will continue to expand case types and user interaction will increase. Another promising feature would be patient specific simulation. Future simulators would allow surgeons to practice difficult operations prior to the live case. The simulator would generate an interactive exercise based on patient CT or MR reconstructions. Then he or she could practice different scenarios to ensure positive patient outcomes.

With regards to curricula, there is much hope for what a standardized curriculum can provide outside of a training tool. A curriculum could allow physicians to "warm up" prior to surgery [1]. It has been shown that surgeons that spent time on the simulator immediately prior to a case performed better than those that did not [47]. A basic "warm up" curriculum could help surgeons practice and ensure better surgical performance and patient outcomes. A "remediation" curriculum could benefit trainees that are struggling on specific steps or skills in the operating room. This curriculum would be designed to target difficult skills or procedures to build upon weaker skills. There is already a correlation between simulation usage and performance in the OR. With a specifically tailored remediation curriculum, institutions could ensure trainees had an effective method to improve difficult skills. Finally, a curriculum would be useful for re-credentialing purposes [1]. An institution could ensure that all surgeons operating robotically met minimum requirements for safety and competency both in the simulated and live environment.

With current controversy and lawsuits regarding robotic surgeons without adequate training, it is more important now than ever to devise a gold standard to ensure baseline safety in robotic surgery [41].

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15 Credentialing and Hospital Privileging for Robotic Urological Surgery

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Abstract

Robotic assisted surgery offers many benefits to the surgeon, hospital, and patient alike. As a result, there has been a rapidly growing demand for surgeons capable of performing robotic procedures such as Robotic assisted laparoscopic prostatectomy. However, there is a noted learning curve associated with achieving surgical proficiency, which makes it imperative to implement training and credentialing practices to ensure surgeons are properly equipped with the necessary prerequisite skills essential to conducting the procedure. Currently, there are no standardized guidelines for the training or credentialing of physicians. This chapter will describe current training and credentialing practices, including proctorship and preceptorship, and discuss the need for standard competency-based credentialing guidelines.

Keywords

Robot Assisted Laparoscopic Prostatectomy (RALP) · Credentialing · Learning curve · Proctoring · Preceptoring · Surgical simulation · Training · Standardized credentialing · Safety · Urology

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Introduction

With the widespread and swiftly growing popularity of robotic surgery, we find ourselves in need of guidelines by which to assess and credential surgeons to perform these technologically advanced minimally invasive surgical procedures. Despite the growing field of robotics, there is still no standard operating procedure (SOP) to define how to train and credential surgeons making the transition from general or minimally invasive surgery to robotic surgery. There have been plenty of protocols put in place for individual practices, universities and hospital systems, but no general set of rules put in place by governing bodies. A few of these examples will be outlined later in the chapter in Table 15.2. There is controversy surrounding the conversation of the utility of a standardized set of credentialing practices. Some would argue that it should remain at the institutional level and not be regulated by outside review boards. Throughout this chapter, we will touch on some of the points made by both sides of this argument.

The machine that has made this drastic advancement in surgery possible is the da Vinci surgical system produced by Intuitive Surgical (Sunnyvale, CA). Urology has been at the top of the ladder when it comes to utilization of robotic assisted procedures. At the top of this list is the Robotic Assisted Laparoscopic Prostatectomy (RALP), however, it can be found in other

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procedures such as nephrectomy and cystectomy. These technique have rendered many of the former gold standards obsolete, making the training completed by many physicians currently in practice out of date. The skills acquired during surgical residencies and advanced training are still very much relevant, however, the skills needed to operate the da Vinci system were not covered in their surgical residencies. A disconnect between practicing physicians and up and coming urological surgeons has now been created. This reinforces the importance of training and credentialing for robotic surgeons at all points in their career. Throughout this chapter, we will focus on current common standards in credentialing, models of SOPs being utilized, things to consider when putting a credentialing program in place and also propose how to standardize the credentialing process to insure all surgeons are properly trained prior to using the da Vinci surgical system in live cases.

Implications of Robotic Surgery: Bridging the Gap Between Laparoscopic Urological Surgeons and Robotic Urological Surgeons

Robotic surgery has quickly made its way into the mainstream of urologic surgery in the United States—spanning from hospital systems to universities and even some private institutions. It has proven itself to be a better successor, in some respects, over its older sibling laparoscopy. There are several aspects of the daVinci surgical system that lend themselves to this.

Robotic assisted laparoscopy has a few key features that when in the hands of an experienced and highly trained surgeon can prove to be very beneficial for patients and surgeons alike. It allows the surgeon to view his movements and surroundings on a full HD screen with 3-dimensional visualization and zooming capabilities—correcting a major deficit of laparoscopic surgery (the loss of natural hand-eye coordination and intuitive movement experienced by the physician). The DaVinci software provides a solution to this issue by aligning the motion of the surgical tools with the physician's frame of reference and positioning the image of the surgical site atop the physician's hands, which provides both spatial and visual alignment [1].

The system also utilizes a motion scaling technology that filters out small, unintentional and uncontrollable movements in the surgeon's hand, providing a steadier, more deliberate approach to surgical processes. This allows the surgeon to achieve a level of manual dexterity that would otherwise be unobtainable. Another, potentially overlooked benefit is that the surgeon is able to sit at the surgical console controlling the robot in a more ergonomical position, leading to a lower incidence of fatigue during procedures.

The leading use of robotics in urologic surgery is for RALP, and as such there is a plethora of data surrounding oncologic, surgical, and functional outcomes from these procedures. The rate of biochemical reoccurrence following RALP is similar to both open and laparoscopic prostatectomy [2–4]. Additionally, RALP is associated with similar rates of positive surgical margins (PSM) when compared to both alternate modalities [3–5]. Furthermore, data on functional outcomes and complication rates is similar between the three methods with RALP having a positive impact on hospital stay, blood loss, and transfusion requirements [3, 5]. RALP has also been associated with better post-surgical continence rates and has been shown to have some advantages in recovery of potency [6].

Defining the Learning Curve

The benefit of robotic surgery is clear, however, as with any new surgical technique, dedicated training and acquisition of a unique set of cognitive and technical skills are necessary to achieve competence. This is evidenced by the learning curve (LC) associated with robotic assisted surgeries (RAS). The LC refers to the period of time in which a novice robotic surgeon finds the procedure more difficult, has longer operative times, higher complication rates, and poorer outcomes [7]. The effects of the LC have wide reaching implications on operative time, surgical out-

comes, and complication rates, and as such is of concern for patients and institutions alike. This becomes obvious when examining the effect a physician's LC has on complicated procedures such as RALP, for which the LC affects all aspects of surgical outcomes.

The rate of positive surgical margins following RALP is a telling marker for surgical and post-operative success. A prospective study involving 100 consecutive RALPs performed by the same surgical team found the rate of positive surgical margins to be reduced from 45.4% in the first 33 cases to 11.7% in the final 34 cases [8]. Additionally, greater surgical experience has been shown to improve outcomes and reduce the rate of biochemical recurrence in prostatectomy patients across all preoperative risk categories [9]. Surgical experience has also been shown to be inversely correlated with complication and blood transfusion rates during minimally invasive robotic prostatectomy [10]. While it should not be surprising that RALP is invariably effected by surgical experience, it is noteworthy that this LC is also experienced by more veteran surgeons with significant prior experience using non-robotic laparoscopic methods. A study examining the first 60 RALP cases and last 60 laparoscopic prostatectomy cases of three surgeons, each with over 200 prior laparoscopic cases, found the operating time and blood loss to be greater for the RALPs (236 versus 153 min, $p < 0.001$ and 245.6 versus 202 ml $p < 0.001$) [11].

The effect of the LC for RALP is also seen when analyzing operating time. A 2008 study by Steinberg and colleagues has estimated the improvement to be as extreme as 1–21 min per case [12]. One of the direct benefits of lower operating times is a higher surgical volume. Annual surgical volume has been shown to be a primary factor in patient hospitalization period following minimally invasive (MI) prostatectomy [13]. Higher annual surgical volumes has also been associated with lower patient morbidity and mortality [14]. In addition to patient outcomes, lower operating time and higher surgical volume provide hospitals with a significant monetary benefit. The effect of the LC on operating time (OT) has been estimated to cost between $95,000 and $1,365,000 in operating and anesthesia services [12].

Evidence of an experienced based learning curve for RAS exists for other urologic procedures as well. Nephron-sparing surgery has become the standard treatment for small renal masses, and the technical advantages provided by the daVinci system allow for increased precision in the excision of difficult to reach renal masses. As a result, an increasing number of institutions are reporting the use of the daVinci system in robotic assisted partial nephrectomy with evidence of comparable functional and oncologic outcomes to established techniques [15, 16]. Studies assessing the LC of robotic partial nephrectomy using OT, warm ischemia time and PSM rate as endpoints, have estimated proficiency can be achieved in 20–30 cases [16, 17]. The use of the daVinci for Robotic Assisted Radical Cystectomy has also begun to evolve as an alternative option to open radical cystectomy for patients with muscle invasive bladder cancer. The International Robotic Cystectomy Consortium investigated the LC by describing the number of procedures required to achieve adequate operative time (21), lymph node yield (30), and margin positivity <5% (30) [18].

Similar studies assessing the LC for other robotic assisted urologic surgeries have attempted to define the LC as the number of cases required to achieve operative times and outcomes similar to that of open procedures. For surgeons experienced in open upper tract procedures, the operative time for robotic pediatric pyeloplasty decreased with successive cases and became similar to that of open pyeloplasty following 15–20 procedures [19]. For robot-assisted adrenalectomy, surgeons experienced with laparoscopy had similar outcomes to those patients undergoing a lateral transperitonel laparoscopic approach following 20 cases [20].

The wide reaching effect of the LC demonstrates the need for a strong emphasis to be placed on proper training and credentialing of robotic surgeons of all backgrounds in order to ensure a high quality of patient care. Even with the extensive literature describing the influence of surgical

experience and volume on the LC of RALP, there is no consensus on the length of the learning curve or the end criteria by which to define proficiency. Furthermore, the variability in the LC observed in different procedures illustrates the need for credentialing systems to be based on procedure specific competency and proficiency. Attempting to define the learning curve for RAS should be considered an important exercise moving forward, because it can help direct the improvement of both training and credentialing systems.

Training

The success of robotic urologic surgeons has been accompanied by an increasing demand for robotic surgeons by both hospitals and their patients. This trend will likely continue in the coming decade. As a result, there is a need for increased access to quality training modalities for aspiring urologic surgeons.

Residency

Current training programs and residencies have shown the promising benefits that a formal education in robotic surgery can have for physicians. Shroeck and colleagues have described one such training program proven to be effective for RALP. This involves progressing trainees from bedside assistance to the robotic console, where they are exposed to increasingly complex portions of the procedure [21]. Following in-depth lecture and video exposure, trainees were initially familiarized with the basic functionality of the robot through training from an Intuitive Surgical, Inc. (Sunnyvale, CA) representative. In the operating room, trainees would then assist their surgical mentors at the bedside before assisting with portions of the procedure behind the console. The sequence of procedural involvement began with bladder dissection, incision of the endopelvic fascia, and control of the dorsal venous plexus; followed by suturing and testing the vesicourethral anastomosis; and finally ending with the most complex portions: bladder neck incision, posterior dissection of the prostate, nerve sparing, transaction of the dorsal venous complex and urethra, and pelvic lymphadenectomy [21]. This progression was gradual and trainees only advanced through the series of task after they had proven an adequate level of proficiency in the previous task. This program was largely a success, as trainees experienced a decrease in operating time throughout their training and even achieved times comparable to their mentors by the end of their training period [21]. Additionally, there was no evidence to suggest that the trainee involvement altered or compromised the care of the patient, as the estimated blood loss and rates of positive surgical margins were comparable between trainee assisted cases and those performed by their mentors alone [21]. While the successes of programs such as this provide promise for the future of RUS training, there is still a need for improvement.

For a program to be successful such as this, it requires a high surgical volume and a large number of cases on which residents can train. Common patient features including obesity, prior hormone therapy, high risk pathology, and complex anatomical differences between patients would likely limit the number of cases on which a trainee could participate [22]. As a result, this level of training and can only be achieved at larger facilities dedicated to teaching. Smaller facilities would likely only be able to provide training to a limited number of aspiring robotic surgeons and the number and complexity of the available cases could limit their training. In light of the impending need for an increased number of surgeons competent in robotic techniques, alternative training options need to be created.

Fellowship and Mini-fellowship

While the increasing quality and number of residency programs offering training in robotics continues to increase, the demand for robotic procedures by patients and hospitals alike will require practicing surgeons to learn and utilize robotic techniques. Long-term two year fellow-

ship programs in robotics do exist and their training schematics as well as their success in teaching required skills to trainees can mirror that of residency programs [23]. However, programs such as this are not feasible for the practicing urologic surgeon who cannot afford the commitment of time. One training method that has been increasingly utilized by experienced physicians naïve in robotics is the "mini-residency".

Mini-residency, or mini-fellowships, (MR) are short intensive training programs, which allow surgeons with previous laparoscopic training the opportunity to develop and improve their aptitude for robotics. One such program developed by McDougall and colleagues at the University of California, Irvine displayed the success of a 5-day MR focusing on RALP in encouraging post-graduate urologists experienced in laparoscopy to successfully incorporate the use of robotics into their practice [24]. The MR program included dry lab model skills training, wet lab skills training with animal and cadaveric models, and operating room observation experience. Twenty-one robotic naïve urologists were trained over the 5-day period, all having preformed 20–60 laparoscopic procedures before attending the program, and all were offered proctoring experience at their respective institutions following the program. Fourteen months following the program, 95% of the attending urologists were successfully performing RALP at their home institutions [24].A comparable program has reported the long-term impact of a 5-day RALP intensive MR program for 47 participating urologists through 1-, 2-, and 3-year follow-up questionnaires [25]. After 1, 2, and 3 years following the program, 78% (33 of 42), 78% (25 of 32) and 86% (18 of 21) of responding surgeons were actively performing RALP, respectively [25]. Partnered attendees were more likely than solo attendees to perform RALP following the program. Furthermore, of attendees performing RALP after the program, the number of yearly cases preformed increased from year to year. A similar MR program focusing on robotic kidney surgery was conducted at the International Symposium on Robotic Kidney and Adrenal Surgery held at the Cleveland Clinic in October, 2009. Twelve of the 27 participating urologists returned a 3-month follow-up questionnaire, and all 12 indicated they had performed robotic surgical procedures following completion of the course [26]. Overall, the number of robotic procedures performed by the participants increased by 56% following the course [26].

The success of these programs in helping urologists to successfully implement robotic programs at their home institutions is promising. However, developing these programs is a challenging task for an institution, and as a result, there are currently a limited number of available programs. Successfully implementing such a program requires dedicated and experienced instructors as well as a venue and resources to conduct both dry-lab and animal/cadaveric laboratory training. In addition to the logistical challenges, these programs are financially demanding, having been estimated to cost upwards of $10,000 per attendee [25]. Furthermore, as evidenced by the learning curve, robotic naïve surgeons trained in this method will require further training via proctoring and preceptoring to achieve competency. Overcoming these barriers and implementing similar programs is an important step for the robotic community, as it would allow for experts to efficiently and effectively transfer of skills to less experienced surgeons.

Robotic Surgery Simulation

As a result of the growing acceptance of the robotic platform as the gold standard for many minimally invasive (MI) urologic procedures, there is heightened demand for effective training outlets, which cannot be met by the existing formal training programs. Furthermore, the growing concern that resident and trainee involvement in procedures may lead to worse patient outcomes and the associated medico-legal risks has lessened the accessibility and effectiveness of formal training in some cases [27–31]. In light of this, the proper use and implementation of surgical simulation as an adjunct in robotic surgical training has potential value by allowing for repetition based learning in a low-risk environment.

While the use of simulation contrasts the motto 'see one, do one, teach one' familiar in surgical training, it is a commonly employed training method in highly technical and skill based professions in which the cost of error is high. One such example is the use of flight simulators in aviation training, which has been mandatory in the United States aviation industry since 1955 [32]. From the success of simulation based training in other professions, it is clear that for a simulation to be useful it must be a repeatable self-driven exercise that provides quantitative feedback, so to enable a trainee to not only hone specific skills and track their progress, but also to allow differentiation between users of different skill levels [27, 33]. Despite its relatively short history in medicine, the use of surgical simulation as a means to augment the training of surgeons has been a noted success. The use of simulators allows surgeons-in-training to overcome certain elements of the learning curve outside of the operating suite. This not only leads to better technical skills, which further promotes patient safety and quality outcomes, but also saves valuable time and resources [33]. This is especially relevant in the case of robotic surgery, due to the complexity of MI robotic surgery, and the extended learning curve associated with the technical nature of the daVinci robot.

Currently many forms of surgical simulators exist, ranging from low-tech and low-fidelity box trainers designed to improve hand eye coordination, to realistic high-fidelity simulation using animal and cadaveric models as well as Virtual Reality (VR) simulators that make use of state of the art technology. While there are many generic skill simulators for both laparoscopic and robotic surgery, access to procedure specific models realistic enough to provide external validity in measuring competence has been lacking. In the past, a commonly used model for robotic urologic procedures have been live animals such as swine. While, this form of simulation is proven to be effective in shortening the learning curve, and lower operating time, it requires access to a daVinci console, which creates expense and limits access to smaller and non-educational institutions [29]. An alternative high-fidelity simulation option is the use of VR simulators, in which tasks are performed on a computer-based platform and the visual environment is virtually generated. Historically there has been hesitance to incorporate VR-Simulation into training programs due to technological shortcomings and a lack of evidence supporting their validity as a training modality. However, recent studies have demonstrated the efficacy of urologic surgery training with VR systems and have provided promising evidence for the future of simulation training.

In December of 2011, Intuitive Surgical Inc. (Sunnyvale, CA) released The da Vinci® Si Skills Simulator (this is an attachment to the da Vinci robot itself). Compatible with any da Vinci® Si model, this additional software employs three-dimensional simulation visuals to provide the user with numerous skills exercises in virtual environments and task specific metrics of varying difficulty. This technology allows residents and surgeons to learn and practice the use of the robotic device in a non-operative fashion as well as track their acquired proficiency. With a focus on the basic use of the system and its features, the Skills Simulator lets trainees accustom themselves to the interface through manipulation of the actual surgeon console controls. By providing its users the ability to train on the gold standard robot itself, the Skills Simulator allows trainees to gain unparalleled hands-on practice and an unmatchable level of comfort with the robotic platform prior to participating on any patient-based surgery. As a result the Skills simulator has been shown by several studies to have superior face, content, and construct validity to other simulators that merely imitate the console [34]. In addition to promoting safe training practice, having both the operative and training modules combined into a single device would prevent institutions from having to make separate expensive purchases. Surgeons-in-training would be able to observe procedures completed by their mentors, and then practice with the simulating software between cases and whenever the operating room is vacant. However, this could lead to accessibility issues in institutions with high demands for robotic procedures, as it would limit the available time to use the robot for training.

This could be especially relevant at institutions without a heavy focus on education as well as those with fewer consoles, high surgical volumes, and many robotic surgeons.

VR simulation is also available in standalone consoles that do not require use of the daVinci Robot itself. Currently four such systems exist, the Mimic® dV-Trainer™ (Mimic Technologies, Seattle, WA, USA), the Robotic Surgery Simulator (RoSS, Simulated Surgical Systems, Williamsville, NY, USA), the ProMIS (Haptica, Ireland), and the SEP robot simulator (SimSurgery, Oslo, Norway). An advantage of standalone consoles is that access for trainees would not be limited by surgical case volume as in the case of the Skills Simulator. VR simulators can also be leased, which makes simulators more accessible to smaller and traditionally non-teaching institution that may not wish to make a permanent and expensive investment. As an imitation of the robotic console, an obvious concern with these consoles is the validity of the system, and whether or not skills and aptitudes displayed on these consoles are transferable to the daVinci robot.

Of these simulators, Mimic®'s dV-Trainer™ (MdVT), developed by Mimic technologies in collaboration with Intuitive Surgical Inc. (Sunnyvale, CA) is by far the most globally validated and widely used. The console itself is a tabletop unit with foot pedals mimicking the real robotic console. Studies have shown there to be correlation between performance on the MdVT and the gold standard robot itself providing strong evidence for concurrent validity of the system [35, 36]. Construct validity has also been demonstrated by a study on the effectiveness of simulation training on the dV-Trainer versus repeated exercises on the actual da Vinci® system. This study found that each practice approach yielded similar improvements in the timing and accuracy of some drills [34]. Additionally, in a prospective randomized trial, Whitehurst and colleagues found that robotic naïve surgeons trained with Mimic®'s dV-Trainer™ performed equally in post training procedures to those trained with traditional fundamental laparoscopic surgery dry lab tasks using the da Vinci [37]. Furthermore, a 2016 study showed VR systems to be effective in measuring relevant competency metrics in urology postgraduate trainees during objective structured clinical examinations (OSCEs) [38]. Currently, there is far less literature examining the validity of other simulation options in training.

The proven ability of these simulators to both build and accurately assess technical skills provides promising evidence for their continued and increased use in robotic surgical training. Furthermore, the ability of VR simulators to provide real time feedback and standardized measurements of proficiency in important technical aspects of RAS allow the progression of a given trainee to be tracked and compared with that of more experienced physicians. The AUA currently recommends that exercises with virtual reality simulators be implemented in to the curriculum of robotic surgical residency and training programs [39]. Best practice recommendations also recognize the value of VR simulation in progressing through the technical learning curve associated with robotic surgery in a low stress and low risk environment [31]. More recent technological advances in VR allow for simulation of full-length procedures in an "augmented reality" setting that provides 3D virtual instruments for interaction with anatomy in a 3D video environment. One such simulation technology is MIMIC's Maestro AR, which provides simulation of full-length partial nephrectomy, hysterectomy, and prostatectomy. The potential application of this technology suggests that VR simulators may be the solution to the reduction of training opportunities faced by current surgical trainees [40]. However, there is still a need to prove the predictive validity of these simulated "procedures" before their use can serve as anything more than a supplement to more proven modalities.

As robotic surgery continues to gain popularity among patients, surgeons, and residents, the need for an affordable and accepted robotic training device will persist. There is still ample room for technological innovation within the realm of robotic surgical training beyond the recent efforts. Advances in this area will hopefully

enhance the convenience and quality of education for students of robotics and further promote the safe integration of patient surgery into the experiences of the novice surgeon.

Proctoring and Preceptorship

Proctors and preceptors play a crucial role in the process by which an aspiring robotic surgeons transition their skills from training into competency. As such they are an important part of the privileging and credentialing process at any institution. A proctor is a more experienced and practiced surgeon that observes a surgeon learner operate in the beginning portion of their learning curve (usually their first several robotic cases). The proctoring physician is not to provide assistance or guidance to the operating surgeon, his role is strictly to assess the surgeon's knowledge, skill, and overall competence. While a proctor may intervene in an emergent situation when deemed necessary, the surgeon learner remains responsible for the patient, and as such a proctor is not liable for any action or in-action [30]. Following a procedure, the proctor submits a report to the department head or medical staff of the surgeon's home institution, which includes a recommendation as to whether the surgeon requires proctoring for future cases. In the end, the decision to grant surgical privileges remains the responsibility of the institution, and they may act on the proctor's recommendation as they see fit. As such the number of proctored cases a surgeon must perform prior to gaining privileges is at the discretion of the relevant governing body of their institution, and the specific guidelines they have in place.

The crucial role of a proctor in assessing and certifying competency demands a high level of experience and skill in urologic robotic surgery, especially regarding the procedures they observe. Currently, there is no consensus definition of a proctor, and while the American Urological Association (AUA) guidelines recommend for a proctor to have completed a minimum of 50 urologic surgical procedures, with at least 20 cases similar to that which is being proctored, the requisite standards vary by institution as displayed in Table 15.1 [39]. As a result there will without a doubt be inconsistencies in the level of experience and thus expertise between proctors. Additionally, as evidenced by the variability of the learning curve, the level of expertise gained by a given surgeon at 20 cases could potentially be inadequate for them to serve as a proctor. With this in mind, there seems to be reason for a more valid, accurate, and quantifiable measure of expertise to be used for screening proctors.

The term preceptor is often used interchangeably with that of a proctor, however there are some notable differences in both the role and responsibility of a preceptor in the operating room. In contrast to the strictly observational role of a proctor, a preceptor takes a more active and advisory role in the operating room. In an effort to teach and transfer skills to the surgical learner, the preceptor will provide direct live feedback and guidance to the trainee, when necessary. This is a valuable learning tool in the early stages of

Table 15.1 Standard operating practice for proctors during robotic surgery[a]

A. Proctors should have completed at least 50 robotic surgical cases overall with at least 20 cases similar to the one that is being proctored.
B. Informed consent must be obtained from the patient, about the presence and responsibility of the proctor.
C. Granting temporary privileges to the proctor to assist during surgery should that be required, may be considered.
D. The role and responsibility of the proctor should be clearly defined including his/her responsibility in the event of a complication.
E. The proctor should be present in the operating room for the entire surgery.
F. Legal liability of the proctor should be minimized after consulting with the local legal counsel and the institution must indemnify the proctor against possible legal action.

[a]Acknowledgement: This table represents the current AUA recommendations for proctorship during robotic surgery. It was originally adapted from the Recommendations of the Society of Urologic Robotic Surgeons (SURS). Training, credentialing, proctoring and medicolegal risks of robotic urological surgery: recommendations of the society of urologic robotic surgeons. Zorn KC, Gautam G, Shalhav AL, et al, J Urol. 2009;182(3):1126–32.

the learning curve. A preceptor also remains primarily responsible for the care and well-being of the patient, and may assist or even directly participate in the operation. Thus, preceptorship is essential early in the learning curve to transfer learned abilities to the operating room and establishing the necessary operative skills, while also prioritizing patient safety [41]. Preceptorship can occur at the home institution of either surgeon, or even within structured weekend courses, fellowships, and residencies [42].

Current Credentialing Models

Currently there is no accepted national or international consensus surrounding credentialing and privileging for robotic urologic surgery, despite many attempts to address the issue [30, 31]. As a result, although some institutions have taken steps towards implementing a standardized credentialing system, the system varies among hospitals, and the requirements for obtaining credentials are not always based on competency. While the American Urologic Association (AUA) currently provides a standard operating procedure for those seeking credentials in robotic surgery, they do not outline requirements for granting privileges for specific procedures [39]. Instead they simply describe the responsibilities of credentialing parties and outline the minimum experience requirements for the practice of urological robotic surgery. The AUA maintains that credentialing physicians for operative procedures is the responsibility of each institution, and that qualified committees or individuals at each site may formulate their own requirements for approving a surgeon's practice of robotic surgery. The credentialing protocols for several such institutions are displayed in Table 15.2.

Considerations When Implementing Credentialing Programs

The increasing awareness of these demands have led to the development of best practice guidelines, which promote the need to establish competency based guidelines for credentialing and privileging surgeons in order to ensure a higher standard of care is provided to patients [31]. Historically, this has been accomplished through the review of case logs and based primarily on the number of cases performed by a given trainee. This is often accomplished formally through a proctoring system, in which an expert surgeon observes a trainee and assesses their proficiency with robotic skills through a set number of cases. However, due to the variability of the learning curve associated with RAS, there is no consensus on the requisite number of proctored cases necessary for a trainee to become proficient. As such, credentialing should be based of the demonstration of proficient and safe application of basic robotic skills and procedural tasks, rather than the completion of a set number of surgical cases [31]. While the use of proctored cases can serve to monitor the proficiency and competence of a surgeon in this manner, it is important that the way in which competency is assessed is consistent. As displayed in Table 15.2 this is not the case for current credentialing systems, in which the number of required proctored cases varies by institution.

The lack of guidelines surrounding credentialing as a whole is likely due in part to the outside pressures on surgical facilities to implement robotic programs. The growing popularity and success of robotic surgery has led to an increased patient awareness of surgical benefits and a subsequent migration towards the technology. Patients are made aware the option of robotic surgery not only through clinical counseling and word of mouth, but through advertisements by Intuitive Surgical, Inc. (Sunnyvale, CA). As a result, patients are seeking out facilities and surgeons known to operate robotically over their counterparts. This creates a pressure for surgeons and hospitals to adopt the practice of robotic surgery or risk losing business. While embracing the use of robotics can be of value to hospitals, physicians, and patients alike, the associated benefits are dependent on the proper implementation of a robotics program. As discussed, there is a clear learning curve associated with robotic surgery and while short-term training courses are of value, undue pressure to implement

Table 15.2 Institutional guidelines for robotic credentialing

Institution	UPSTATE University Hospital, Syracuse, NY	CROUSE Hospital, Syracuse, NY
Date of implementation/ revision	April, 2015	July 6th, 2015
Proctor definition	A Surgeon May serve as a proctor after having performed at least twenty (20) robotic assisted cases previously. The robotic committee must approve the physician as being a proctor and noted in the practitioner's credentialing file.	
Credentialing guidelines for robotic certification		
No prior robotic experience	1. Must preform 3 proctored cases with daVinci certified proctor. 2. The daVinci proctor must sign off on the competency of the surgeon to proceed with independent use of the daVinci. 3. Surgeon is then granted provisional privileges for proceeding with the next 7 cases. 4. Following these 10 cases, (3 proctored and 7 independent) intra- operative and peri-operative outcomes are reviewed by the Robotic committee.	1. Must show evidence of observing one robotic case prior to specialized training. (May be done at another institution) 2. Applicant must complete daVinci training course within 7 days of their first proctored case. 3. Must be proctored for five robotic cases. (a) Evidence of proctored cases at other institutions are eligible provided the same model console was used. 4. Must complete robotic training, proctoring, and privilege application process within 6 months.
Prior robotic experience at other institutions	1. Documentation demonstrating privileges at other hospitals may be accepted in place of proctored cases, upon review by the Robotic Committee. 2. Surgeon is given provisional privileges for 10 cases. 3. Intra- operative and peri- operative outcomes are reviewed	1. Must submit evidence current robotic privileges and competency at other institutions. 2. Must submit proof of successful completion of daVinci training course. 3. Provide evidence of successful completion of at least 12 cases within the past 5 months of 25 annual cases using robotic privileges. (a) In the case of insufficient volume, consideration may be given to an applicant provided they are proctored for an additional 5 robotic cases.
Robotic experience through residency or fellowship	1. Letter of recommendation from either a residency or fellowship program indicating proficiency with the daVinci platform may be accepted in place of proctored cases. 2. Surgeon is given provisional privileges for 10 cases. 3. Intra- operative and peri-operative outcomes are reviewed.	1. New graduate applicants with residency or fellowship robotic training must provide evidence of robotic training and provide a log of at least 25 at-the-console cases. 2. Must subsequently be proctored for a minimum of 2 cases.

such a practice quickly can compromise patient care [43]. To avoid undue influence in the operating room, credentialing should not be an industry driven process. The general consensus of expert groups such as the Society of Urologic Robotic Surgeons is that the credentialing process should

be self-regulated by robotic surgery experts in a consistent, competency based, and standardized manner [30, 31, 44].

The Need for Standardized Credentialing

Creating a standardized system for training and credentialing robotic surgeons would guarantee that a certain level of competence is achieved and maintained and subsequently ensure a certain level of results and safety for patients. This would establish future guidelines, which would set the precedence for patient safety and outcomes for years to come. This has been displayed in the case of laparoscopic surgery after the American Board of Surgery began requiring completion of Fundamentals of Laparoscopic Surgery in 2009 [45]. The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has created the FLS curriculum, which serves as a set of guidelines for laparoscopic surgery training and credentialing. After having been validated as a means of training and credentialing trainees, the FLS curriculum is now endorsed by the American College of Surgeons. All general surgery certification candidates are required to have successfully completed the FLS training curriculum before being eligible for the American Board of Surgery certification. At this point in time, there is no such curriculum in place for robotic surgery, however, the AUA has recently set forth loosely based standard operating procedures for institutions to follow in order to help with credentialing robotic surgeons internally. The purpose of this is to generate uniform standards which may be applied to all medical staff requesting privileges to perform procedures utilizing the robot and also to decrease the heterogeneity of concepts and to generate criteria universally applicable to all those wishing to obtain privileges.

Standardized training and credentialing, if mirrored to the FLS training curriculum, can improve surgical outcomes and patient safety, specifically in urologic surgery. The requirement for acquiring credentials varies among hospitals. There is no standardized method, and more importantly, most of these requirements are not competency-based but rather require a number of proctored cases. Robotic surgery credentialing should be the result of a standardized, competency-based peer evaluation system. It is important that this process be self-regulated by robotic surgery experts in a clear, comprehensive, and reproducible manner. It may be logical to follow the example set by laparoscopic surgeons and the Fundamentals of Laparoscopic Surgery (FLS) curriculum. This has been demonstrated in the case of laparoscopic surgery after the American Board of Surgery began requiring completion of Fundamentals of Laparoscopic Surgery in 2009 [45].

Moving Forward

Suggested Recommendations for the Safe Implementation and Credentialing of RARP at an Institution—Society of Urologic Robotic Surgeons [29, 39]

1. The establishment of a national/international, centralized, certification authority which would institute and uphold standards for safe introduction of RARP in an institutional credentialing committee setup.
2. Credentialing of institutions and individuals to be based on these standard guidelines. The guidelines need to cover basic requirements with regards to training, certification courses, departmental staffing and infrastructure.
3. Until residency programs provide an abundance of skilled robotic urologists (5–10 years), we recommend an increased number of regional centers to assist with preceptoring through mini-residency programs.
4. The central certification authority, rather than the robotic industry, should assume responsibility for identifying and promoting expert robotic surgeons.

   Only such designated experts, based on peer-support, submitted videos and case logs, should be permitted to serve as a proctor.

5. The central certification authority will need to develop a standardized report for proctors to complete for each RARP, which will need to be submitted to the institutional robotic committee for review.
6. The first few (3–5) cases of the novice urologist will need to be proctored by an approved proctor, preferably by the same proctor for all cases. Individualized requirements may be necessary for those with laparoscopic vs open radical prostatectomy experience and background. The proctor's report will then collectively be reviewed by the institutional departmental staff/credentialing committee prior to granting unrestricted robotic privileges.
7. Legal liability of the proctor/preceptor to be minimized by including the institutional legal counsel in the credentialing committee of the institution. He/she should be actively involved in the formulation of guidelines and their implementation.
8. The institution should indemnify the proctor against any possible legal implications while performing proctoring services for RARP.
9. Informed consent must be obtained from the patient with regards to the role of the proctor during the surgery and thereafter.
10. The role of the proctor should be clearly defined by the institutional credentialing committee. Whether or not the proctor is expected to intervene in case of a possible intraoperative necessity should be clearly established and documented beforehand.
11. A system of periodic review by the institutional robotic committee of the performance of the surgeon including case selection, surgical competence, management of complications and postoperative outcomes should be set in place. Continuance of robotic privileges should be subject to consistent performance in all of these criteria. Failure to perform adequately should result in a recommendation for a refresher training or additional preceptoring prior to continuity of these privileges.

Conclusion

Robotic surgery has made a significant impact on urological procedures throughout the world. However, there is still no uniformity in how to train and credential surgeons using this technology. This chapter has discussed the gaps that exist between laparoscopic and robotic surgery and discussed in detail the learning curve associated with this technology. Training programs, simulation technology, and proctors/preceptors will help reduce this learning curse so robotics may be adapted into many urological procedures. Credentialing models were discussed and the need for standardization has become apparent. Only after the development of proper credentialing criteria will urologic surgeons be able to perform robotic surgery in a safe and efficient manner.

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16 Innovation in Surgery: Idea, Development, Assessment, Exploration, and Long-Term Monitoring (IDEAL) Guidelines

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Abstract

The evidentiary standards to support the regulatory approval and dissemination of surgical innovation have historically been low. The IDEAL Collaboration has developed a framework and specific recommendations how to improve the development of surgical innovation that is finding increase recognition by researchers, editors, funders and regulators worldwide. In this chapter, we describe the IDEAL recommendations as they apply to robotic-assisted surgery in urology.

Keywords

Surgical innovation · Drug approval · Device approval · Robotic surgery · Randomized controlled trials · Food and Drug Administration · Premarket approval · Safety · Registries

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Introduction

The development of robotics in urology has transformed our specialty at a rapid pace, ever since the first robot-assisted laparoscopic prostatectomy (RALP) was performed in Frankfurt, Germany in 2000 [1]. The versatility of robotics and computer-assisted surgery has led to its expanded use beyond the prostate, including in treatment of benign lesions of the kidney, bladder, and testis, as well as in subspecialty fields such as female urology, infertility, and reconstructive urology. The combined market for surgical navigation and robotic systems is estimated to be more than $1.6 billion in 2013, over 90% of which was held by Intuitive Surgical and the *da Vinci* surgical system [2]. Growth in this market is expected to reach $3 billion by 2020.

The regulatory approval process for devices is different from those of pharmaceuticals, and notably the evidentiary standards tend to be lower. If a device manufacturer can claim that a similarly, already approved device is on the market, a premarket notification pathway can be used to fast-track approval [3]. This currently accounts for 98% of all device approvals in the United States. The *da Vinci* robotic device (Intuitive Surgical, Sunnyvale, CA, USA) was approved initially based on an approval pathway that compared the device to standard laparoscopic surgery, specifi-

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cally looking at outcomes from the device when used to treat gallbladder disease or gastroesophageal reflux disease [4]. The device was quickly adopted in urology to perform robotic-assisted laparoscopic prostatectomies for clinically localized prostate cancer. Perhaps because of the low standard of the premarket approval process, no randomized controlled trial (RCT) has compared robot-assisted laparoscopic prostatectomy head-to-head with traditional, open approaches. Surgical research is inherently challenged with regards to equipoise and willingness to randomize, blinding of patients and study personnel, learning curve issues and expertise bias. However, the increased and rapid application of robotics to newer indications, including pediatrics, warrants careful and well-designed safety to maximize patient benefit and diminish inadvertent harms.

The IDEAL Collaboration was formed as an international non-profit group of surgeons and methodologists to attempt to reform the way surgical research is performed. The group initially met at the Balliol College in Oxford and henceforth published an initial 3 article series in The Lancet [5–7]. The developmental pathway for surgical techniques differs from pharmaceutical development in oftentimes-incremental iterations that evolve over time. The IDEAL framework seeks to establish an evidence-based evaluative approach for surgical interventions that derives from the recognition of this distinct developmental pathway and proposes five fundamental stages: Idea, Development, Exploration, Assessment, and Long term follow-up [5]. In this chapter, we review these five stages of surgical innovation in greater detail with specific reference to robotic-assisted surgery in urology in the hopes that future investigators may follow this framework and in turn, improve the body of evidence used to support clinical use of these advancements.

Stage 1: Idea

Innovations in surgery can arise from serendipity, from out-of-the-box thinking arising from emergencies, as well as through careful planning and laboratory studies. As such, advancements in surgery can be both planned and unplanned. Historically, surgical innovation has followed incremental improvements, whereby a new procedure is a small change from a previously established technique. Often, these types of innovation occur simultaneously by happenstance as individual surgeons modify their procedures based on experience and anecdotal observations of patient outcomes. As such, surgical innovation can be either unrecognized or poorly evaluated until a surgeon retrospectively considers a series of cases, and this by nature allows for only lower quality evidence.

In order to successfully implement a developmental framework that lends itself higher quality evaluation, surgeons who believe that they have invented a new technique should be deliberate in reporting of the novelty and active in pursuing subsequent evaluation. It is accepted that "first-in-man" studies by design deal with either single or a small number of cases. The basic principles of medical ethics, including utility, beneficence, and non-maleficence, should be used to guide and promote reporting. Surgeons should report new experiences and give others opportunities to learn from the utility of new techniques, as well as any unexpected outcomes or benefits that have been observed to date. This allows for other surgeons to reproduce the successes while avoiding

Table 16.1 Example of study at idea stage 1

Clinical background
– Flexible ureteroscopy represents a challenging technique to master and robot-assistance may improve ergonomics and procedure outcomes.
Design
– A robotic console and manipulator for a flexible ureteroscope was developed. Preclinical studies were described, explicit data collection protocols were written in advance and submitted for ethical review. Patients were provided with a detailed informed consent process and oversight was described.
Findings
– Robotic flexible ureteroscopy was performed with a prototype and complete stone removal was achieved in first few cases, establishing proof of concept.

Based on source: Saglam et al. A New Robot for Flexible Ureteroscopy: Development and Early Clinical Results (IDEAL Stage 1-2b), *Eur Urol* 204, 66:1092–1100 [8]

failures. Table 16.1 provides an example, based on innovative s work studying robot-assisted ureteroscopy [8].

The IDEAL framework promotes the use of open access registries to record key details of new innovations, which can then be used by peers to facilitate information searches prior to embarking upon modifications of or development of future techniques [9]. Ideally, the registry should be used to record all first-in-man procedures, including those that may have led to "near misses" or patient harms. Anonymous reporting has been suggested as a way to encourage such reporting to mitigate the fear of legal or regulatory repercussions, although in practice there would likely need to be formal legal protections to promote complete transparency. To date, we are not aware that any such first-in-man registry is in use yet, underscoring the underlying challenges. There have been initiatives in developing reporting standards for surgical case reports [10]. Hospitals and local municipalities should also seek to promote reporting in such registries and informed patient consent should, as always, remain paramount in the development of novel therapies by innovative surgeons.

Stage 2a: Development

The development stage of surgical innovation is the stage that is most disparate from pharmaceutical development, and the stage in which there remains arguably the most urgent need for transparent, uniform reporting [11]. Once an idea has been conceived and a surgeon has been using the new technique or device, innovation is particularly fluid and experience drives rapid iterative changes. Unfortunately, although the small modifications may hold valuable information for peer surgeons and innovators, this information is often poorly reported for a variety of reasons. First, surgeons may be hesitant to report on harms and setbacks based on only a few cases perhaps because of the belief that doing so may stifle continued advancement of their technique or device and potentially cast a negative light on their own abilities. There may also be concerns about whether there is value in reporting such failures with only a few case events, particularly if the setbacks are perceived as insignificant. Frequently, surgeons wait until the development stage has concluded before reporting the final version of a technique, as if it had been used in all cases [11]. This is unfortunately seen in many of the retrospective surgical case series, and it is easy to see how the practice can lead to deceiving conclusions. Complications or limitations reported in such case series may not necessarily apply to the final technique and lack of iterative reporting allows for only limited understanding of what can go wrong and why. Unlike pharmaceutical development, where patient eligibility for a novel medication is by nature limited to certain subjects at the study onset, surgical development naturally lends itself to selection bias and modified eligibility as a surgical technique becomes more refined or the surgeon gains experience. Whether or not a novel device or innovation is deemed successful may be based on short-term outcome measures that may not represent the true benefit or harms of the procedure. However, this does not diminish the value of reporting of short-term outcomes in order to promote continued refinements and evaluation.

The IDEAL recommendations recognize that randomized trials during the developmental stage of a device or new surgical innovation are often undesirable and of limited use because of the procedural modifications and varying eligibility of the patients. As such, the IDEAL framework emphasizes transparent, thorough reporting of all developmental milestones, and supports prospective (rather than retrospective) studies at this stage [11]. All cases should be reported without omissions and differences in technique, patient factors, and outcomes should be reported, including when and how technique, design, or indications were changed. This type of reporting represents a new type of observational study, key elements of which include a prior protocol, clearly defined outcomes, and transparent sequential reporting of cases. An additional area of improvement in reporting involves standardizations in terminology, particularly with respect to the grading of patient risk factors and comor-

bidities, as well as grading of outcomes such as pre-operative and post-operative functional performance and the severity of complications. Some efforts have already been made in standardization of the latter, with the use of classification systems such as Clavien-Dindo for complications [12].

Stage 2b: Exploration

The exploration stage can be viewed as the "tipping point" for a surgical innovation. Once an innovation reaches the exploration stage, the technique or device may begin to be applied to patients with broader indications for use. This stage allows for the production of higher quality evidence in a more representative patient population than can be generated in the previous development stage. Although development itself can and is expected to continue, widespread use of the technique or device allows for valuation of previously unforeseen complications or outcomes. Another specific challenge to surgical innovation is that of the surgical learning curve, something that gains importance once a procedure has sufficiently matured in its development to find wider dissemination. Studies have suggested widely varied learning curves for proficiency, from greater than 100 robot-assisted laparoscopic prostatectomy cases [13] to just 30 robot-assisted radical cystectomy cases [14]. Much of the criticism wielded against the rapid and unstructured dissemination of robotic surgery to treat localized prostate cancer relates to the lack of a more rigorous approach to the training of hundreds of urologists in both academic and community setting that embarked on the adoption of the robotic approach [4]. Seminal work by Andrew Vickers focused on open radical prostatectomy has illustrated the profound of the learning curve on surgical outcomes [15]. One of the objectives of IDEAL stage 2b is therefore to identify potential learning curve issues as well as to identify and minimize variation of surgical performance that could impact outcomes. Stage 2b provides valuable information and consensus building in preparation for IDEAL stage 3. For example, complexity and steepness of the learning curve combined with patient and physician preferences, may affect exploration and adoption. Table 16.2 provides an example [16].

More definitive evaluation to permit regulatory body approvals (for example, by the US Food and Drug Administration) may be possible in Stage 2b. Prospective observational studies are the most likely study design in the exploration stage. In order to maximize the value of such studies, the IDEAL collaboration makes several recommendations [11]. First, data should be collected for consecutive patients from multiple surgeons who are undertaking the new intervention. Doing so can lead to the identification of important patient characteristics (which patients would be best suited for the new intervention), technical intervention variables (what to expect and how to manage unexpected outcomes, including co-

Table 16.2 Example of study at development/exploration stage 2

Clinical background
– Robotic assisted kidney transplantation has been described, however information regarding perioperative management techniques are lacking.
Design
– Observational study of 67 consecutive patients who underwent live-donor robotic kidney transplant.
– Single institution with 6 month follow-up of 54 patients.
Findings
– All patients underwent robotic kidney transplant with regional hypothermia.
– No conversion to open surgery.
– Mean console time was 130.8 min
– Mean warm ischemia time was 2.3 min
– Mean rewarming time was 42.9 min
– Three patients developed head-neck edema. No delay in graft function. No graft thrombosis/stenosis/leaks.
– Mean 6-month serum creatinine 1.2 mg/dL.
– Patient survival was 96.3%, death-censored graft survival was 100% at 13.4 months mean follow-up time.

Based on source: Sood, Akshay, et al. "Minimally Invasive Kidney Transplantation: Perioperative Considerations and Key 6-Month Outcomes." *Transplantation* 99.2 (2015): 316–23 [16]

interventions) and clinical outcomes of interest (indications for the technique or device). Next, data should be collected for a range of outcomes and both benefits and harms should be assessed. Standardized frameworks and terminology should be used. Study design should also include reporting of surgical variation and learning curves whenever possible, and should specifically report variables that are known to affect skill and learning, including surgeon/center volume, operating times, and training techniques. While the reporting of these studies should be thorough and transparent, they should also have a secondary aim of planning for a more definitive future study, ideally a randomized controlled trial. The collaboration of multiple surgeons and centers during this stage can naturally lend itself to such RCT development.

Stage 3: Assessment

The assessment stage of the IDEAL framework requires the most definitive forms of evaluation, preferably a randomized controlled trial. Although there are certainly occasions where RCTs may be deemed unnecessary, for example when earlier observational studies have demonstrated very large effect sizes [17], however it is anticipated that few new interventions can achieve such results. There may also be impracticalities to completing an RCT that are often inherent to surgical development; for example, it may be difficult to recruit patients to a study that randomizes them to a surgical intervention, there may be concerns about technology becoming outdated by the completion of a trial, or conducting the RCT may be prohibitively expensive. In that case, a less rigorous study than a RCT that is feasible to complete, can be given preference. Ideally, however, randomized controlled trials represent the "gold standard" for comparisons of efficacy and effectiveness, particularly when performed in multiple centers with large numbers of patients. Table 16.3 provides an example from the urological literature [18]. There are ongoing efforts to provide guidance on how randomized controlled trials of surgical interventions should best be designed and executed [19]. In situations where RCTs are deemed unnecessary or impractical, the assessment stage mandates that observational studies published in their stead should have prospective designs, predefined research protocols with eligibility criteria and built-in quality control measures, and as many positive design features of an RCT as possible [20]. As a prior methodological study has suggested, many observational studies in urology lack most of these defining characteristics [21].

There are several experimental designs that may serve as alternative to an RCT, most notably non-randomized controlled trials and interrupted time series. In the former, a cohort of patients

Table 16.3 Example of study at assessment stage 3

Clinical background
– Open radical cystectomy (ORC) in patients with bladder cancer is associated with significant perioperative complication risk.
– Minimally invasive techniques have developed to minimize perioperative complications and recovery time.
– There is increased interest in robotic assisted radical cystectomy (RARC) however the majority of data is retrospective.
Design
– Randomized, expertise-based controlled trial, 58 patients underwent ORC, 60 patients underwent RARC.
– Primary endpoint: rate of grade 2–5 complications
– Secondary endpoint: number of grade 2–5 complications, rate and number of grade 3–5 complications, surgical time, intraoperative blood loss, pelvic lymph node yield, rates of positive margins, length of stay, 3 and 6 month patient reported quality of life outcomes, total surgical and admission costs by surgery type.
Findings
– There was no statistical difference in the rate of grade 2–5 complications between the two groups
– Estimated blood loss was less in the RARC, operative time was less in the ORC group. There were no differences in quality of life measures at 3 or 6 months between the groups. Average operative cost was higher in RARC group.

Based on source: Bochner, Bernard H., et al. "Comparing Open Radical Cystectomy and Robot-Assisted Laparoscopic Radical Cystectomy: A Randomized Clinical Trial." *European Urology* 67.6 (2015): 1042–50. Reference [18]

undergoing the novel surgical innovation is compared to a concurrent control group undergoing standard treatment. As many elements of an RCT as possible are included, including prospective design and standardized data collection. The main elements that are missing are randomization, allocation concealment and blinding of patients and personnel. To minimize selection bias, known risk factors are prospectively identified and collected and subsequently controlled for in the analysis. Propensity scoring and other advanced statistical techniques can be used where possible to adjust or match for known prognostic factors. Investigators would also seek to minimize performance bias by treating patients in the intervention and control equally and accounting for any variations of care that may be considered co-interventions. Meanwhile, detection bias can usually be controlled for even in observational studies by blinding outcome assessors. In interrupted time series studies, a temporal rather than concurrent control group is used. In these studies, outcomes of interest are measured during a period of time prior to introduction of a novel innovation or device, and then measured again during a sequential period after the intervention is introduced. Risk of bias remains high in these studies, particularly when there may be systematic, unrelated changes to clinical care at the institution where the study is taking place. The advantage of the interrupted time series, however, is its ability to isolate the effects of a new surgical intervention as it relates to quality measures and associated healthcare costs, by tracking the onset of factors other than the surgical intervention itself.

Stage 4: Long-Term Study

The final stage of the IDEAL framework involves long-term evaluation and surveillance. The goal for this stage is for discovering late or rare problems as well as reporting changes in use of a technology or device over time. Similar to Phase IV post-marketing surveillance in pharmaceutical clinical research, this stage typically involves evaluation of procedures through well-designed, large, prospective observational studies. They are usually performed based on clinical registries or databases, and can be used to provide outcomes data for subgroups of interest as well as rare endpoints in surgery. Prospective registries formed for this application should monitor both indications and outcomes. Such long-term observational studies can provide information that may previously be unseen, including variations in and insights into practice patterns (i.e. which patients are selected to undergo a procedure or technical variations in approach based on surgeon preference) [20].

However, the value of long-term studies is highly dependent on the quality and nature of data collection; of particular importance is complete and accurate data entry. Standardizations in coding terminology can allow for improved data capture and it is hoped that improvements to electronic medical record meaningful use guidelines can also drive advancements in these areas. Limitations to database and registry-guided observational studies include that key data are often not routinely collected, making true intention-to-treat analyses often not possible. Furthermore, patients who have multiple procedures can have eventual successful outcomes that may be misattributed to the initial procedure. Differences between time-of-data-entry versus actual date of procedure can lead to time biases during analysis that can also confound the results.

An additional source of long-term study is device surveillance data submitted by manufacturers to regulatory bodies, such as to the Food and Drug Administration (FDA). Device manufacturers are required to report device related deaths, serious injuries, and malfunctions to such regulatory bodies and providers and consumers can voluntarily submit similar data themselves. This data, although useful, must be approached with caution given the inherent selection biases in reporting and incompleteness of data. Events may be underreported and as such make determination of incidence or prevalence challenging. There is clearly room for improvement in device surveillance and a role for routine data collection and monitoring of devices for purposes of improvement [20]. The high initial investment

Table 16.4 Example of study at long-term study stage 4

Clinical background
– Robotic assisted laparoscopic prostatectomy has been rapidly adopted despite limited data on outcomes and costs compared to open retropubic radical prostatectomy
Design
– Population based observational cohort study utilizing US Surveillance, Epidemiology, and End results Medicare linked data.
– Outcomes: morbidity/mortality, length of stay, anastomotic strictures, incontinence, erectile dysfunction and additional cancer therapy.
Findings
– 8337 men identified that underwent RALP or open RRP. Use of RALP increased from 9.2% (2003) to 43.2% (2006–2007).
– Death during study period and overall postoperative complications were not significantly different between two groups, however patients undergoing RALP experienced fewer anastomotic stricture was less likely with RALP, Erectile dysfunction and incontinence were more likely with RALP.

Based on source: Hu, Jim C., et al. "Comparative Effectiveness of Minimally Invasive Vs Open Radical Prostatectomy." *JAMA: The Journal of the American Medical Association* 302.14 (2009): 1557–64. *MEDLINE.* Web [22]

and maintenance costs of the robot and its instruments also mandate careful and well-designed economic studies, particularly in an age of increasing scrutiny in resource utilization. To date, no "true" prospective registry for the use of robotic devices exists, although for some indications, high volume centers have committed to share and pool their outcomes. For now, the closest that comes to meeting IDEAL stage 4 requirements are analyses based on administrative databases such as SEER-Medicare. Table 16.4 provides an example [22].

Conclusions

The versatility of robot-assisted surgery and the continued rapidly evolving applications of computer-assisted surgery will no doubt continue to transform how we care for our patients in the operating room. The IDEAL framework for evaluation of surgical innovation is intended to promote a shift away from the traditional, uncontrolled retrospective case series that compose the bulk of surgical research yet leave many questions unanswered to prospective studies governed by an a priori protocol.

The IDEAL recommendations serve as a practical framework through which surgical innovation can occur. Knowledge and endorsement of the IDEAL principles can give urologists the competitive advantage needed to remain at the cutting edge of innovation, while simultaneously generating high quality data that promotes the adoption of new techniques by our peers, can withstand the scrutiny of regulatory and cost-analysis agencies, and reaffirms the safety profiles required and owed to our patients.

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Collaborative Quality Initiatives

17

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Abstract

Quality improvement collaboratives were developed in many medical and surgical disciplines with the goal of measuring and improving the quality of care provided to patients. In urology, there are several such groups, including the Michigan Urological Surgery Improvement Collaborative (MUSIC), the Pennsylvania Urologic Regional Collaborative (PURC) and the International Robotic Cystectomy Consortium (IRCC). In this chapter we will discuss the historic background, rationale and goals of these collaboratives, with a focus on efforts aimed at improving patient selection, intraoperative skills and techniques, and postoperative outcomes following robotic surgery.

Keywords

Quality improvement · Collaboratives · Robotic prostatectomy · Robotic cystectomy · Robotic nephrectomy

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Background

Quality improvement collaboratives have been established in multiple medical and surgical disciplines. The common goal of such collaboratives is to measure and improve the quality of patient care. The operational strategies used by these collaboratives involve several consistent principles. First, they collect high-quality data using standardized definitions and methodologies. Second, the data are analyzed and used to provide performance feedback to individual physicians and practices. Third, collaboratives participants work together to identify and implement processes of care, procedures, and/or techniques that yield the best patient outcomes. Finally, results of these interventions are shared across the entire collaborative in order to improve patient care at a population-level (Fig. 17.1) [1].

One pioneering quality improvement collaborative was the Northern New England (NNE) Cardiovascular Disease Study Group, a voluntary consortium composed of 23 cardiothoracic surgeons and hospital administrators from five hospitals in Maine, New Hampshire and Vermont hospitals that perform Coronary Artery Bypass Grafting (CABG) surgery. The NNE collaborative created a registry and commenced data collection in 1987. After reviewing data collected by the collaborative, it was clear that there were differences in mortality across the institutions as a result of different aspects of patient care. As a

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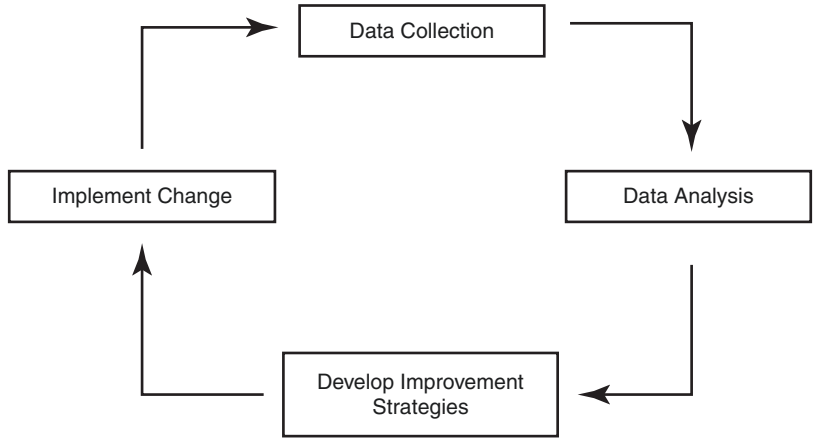

Fig. 17.1 Schematic representation of quality improvement collaboratives. First collaborative wide data is collected. It is analyzed, and areas of variation and potential areas for improvement are identified. Collaborative wide improvement strategies are developed, and change is subsequently implemented

consequence, three steps were performed in an attempt to reduce mortality associated with CABG surgery [2]. First, each surgeon was provided with outcomes data including personal, hospital-level, and collaborative-wide results. Next, training sessions were conducted to identify and discuss techniques that may improve outcomes. Finally, site visits were performed to assess the similarities and differences between each CABG surgery. Following the intervention, the collaborative found an overall 24-percent reduction in mortality, with all but one practice achieving better outcomes [2].

After the success achieved with the Northern New England Cardiovascular Disease Study Group, in 2004, Blue Cross Blue Shield of Michigan (BCBSM) started a regional collaborative improvement program with physicians and hospitals from across the state of Michigan. The Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) was established in 1997 with aims to develop a statewide registry of percutaneous coronary interventions, and to improve quality of care and patient outcomes [3]. Shortly after the development of BMC2 BCBSM developed Value Partnerships in which BCBSM works closely with hospitals and physicians to improve patient care and reduce cost. The goals of the Value Partnerships are to reward improvement, refine clinical processes and protocols, encourage collaboration, and focus on population-based cost. One component of the Value Partnerships is Collaborative Quality Initiatives (CQI). Five of the oldest CQIs in Michigan have saved an estimated 793-million-dollars state wide [4].

The first surgical collaborative in Michigan, the Michigan Surgical Quality Collaborative (MSQC), was developed in 2005. There are now 73 hospitals participating in the MSQC. The collaborative was designed to target common surgical conditions and procedures, and to improve both long- and short-term morbidity and mortality with each diagnosis or intervention [5, 6]. Hospital-wide and collaborative-wide data are provided to participating hospitals every three months. Leaders of the group meet quarterly to discuss best practices, and these personal interactions and connections allow for more rapid quality improvement [5]. Over the first four years of the collaborative the hospitals participating were found to have significantly greater improvements in morbidity compared to hospitals not participating in the collaborative. In addition, the annual savings as a result of this collaborative was estimated to be approximately $20 million dollars [6].

Collaboratives in Urology

Currently, there are several on-going data sharing collaboratives that aim to improve outcomes for urologic patients. The Urological Surgery

Quality Collaborative (USQC) was founded in 2009 as one of the initial collaboratives in the field. The USQC focused on improving the quality of care provided to non-muscle invasive bladder cancer patients [7]. Shortly after the establishment of the USQC, the Michigan Urological Surgery Improvement Collaborative (MUSIC) was founded in 2011. MUSIC is a physician-led quality improvement collaborative that includes 85 percent of urologists in the state of Michigan. MUSIC's mission is to make Michigan the best place in the world for prostate cancer care. Like its predecessors, MUSIC seeks to achieve this goal by collecting clinically credible data and sharing these data with urologists in order to identify and disseminate specific processes of care that improve patient outcomes. The strategies utilized by high performing centers provide a framework for providing the best care to all patients [1].

There were four initial goals for prostate cancer care in MUSIC including the following: 1. encouraging appropriate imaging, 2. improving the safety of transrectal prostate biopsy, 3. improving post-prostatectomy outcomes with surgeon video review, and 4. optimizing treatment decision-making for patients with newly-diagnosed prostate cancer [8].

In keeping with these goals, one of the early successes in MUSIC was reducing hospitalizations following prostate biopsy across the state of Michigan. Through data obtained from the MUSIC registry, a statewide baseline hospitalization rate was determined, and it was noted that there was wide variation across practices. Data from the collaborative quickly clarified that the primary reason for hospitalization following prostate biopsy was infection with fluoroquinolone-resistant bacteria. In response to this analysis, MUSIC developed statewide antibiotic pathways consisting of either tailored antibiotics based on the results of a pre-procedure rectal swab, or an augmented pathway consisting of fluroquinolone plus an addition (often parenteral) antibiotic administered at the time of biopsy. Selection of the second agent varied by practice and is based on local antibiotic resistance patterns. Implementation of these pathways at practices across the state led to 50-percent reduction in the frequency of hospitalizations following prostate biopsies [9].

A second collaborative in urology is the more recently-established Pennsylvania Urologic Regional Collaborative (PURC). Similar to MUSIC, PURC group focuses on improving prostate cancer care for patients across the state of Pennsylvania, and is funded by contributions from local health systems and a local payer. There are a total of six participating practices (Einstein Health Care Network, Fox Chase Cancer Center, Hospital of the University of Pennsylvania, Jefferson Urology Associates, Temple University and Urology Health Specialists) in southeastern Pennsylvania. Currently over 2900 patients are in the PURC database. The goals of their collaborative are: 1. Provide reliable platform for data collection, 2. Reduce variation in prostate cancer care, 3. Evaluate outcomes following prostate biopsy, radical prostatectomy, 4. Improve patient-centered decision making for patients with prostate cancer. In 2016, PURC hopes to expand their collaborative to other practices throughout the state of Pennsylvania and contiguous regions [10].

An additional collaborative with a focus on robotic cystectomy is the International Robotic Cystectomy Consortium (IRCC) that was founded in 2006 to help provide data regarding oncologic outcomes and safety of robotic cystectomy [11]. IRCC members aim to develop a broader, more rapid understanding of intraoperative factors and outcomes for robotic-assisted cystectomies. There are a total of 14 centers worldwide and 21 surgeons involved in the IRCC [11].

Robotic Surgery and Improving Surgical Outcomes

As quality improvement collaboratives have emerged their missions have evolved, but the overall goal remains to improve patient outcomes and provide cost effective care. In order to continue improving patient outcomes, collaboratives have begun to further explore specifics of surgical technique. These consortiums have delved deeper into preoperative decision making (i.e., patient

Table 17.1 Current urology collaboratives and their ongoing work for optimizing preoperative planning, intraoperative skill assessment and improvement and postoperative outcomes in robotic urologic surgery

Robotic urologic procedure	Preoperative planning	Intraoperative improvement	Postoperative outcomes
Robot-assisted radical prostatectomy – MUSIC	Appropriateness criteria	Peer and crowd-based video review	Notable Outcomes and Trackable Events (NOTES)
			Patient reported outcomes (MUSIC-PRO)
Robotic cystectomy – IRCC		Evaluating robotic proficiency	Analysis of complications and outcomes
Robotic partial nephrectomy – Multi-institutional robotic partial nephrectomy group – Vattikuti Global Quality Initiative in Robotic Urologic Surgery		Intraoperative hemorrhage surgical checklist	Analysis of complications and outcomes
			Analysis of complications and outcomes

Abbreviations: *MUSIC* Michigan Urological Surgery Improvement Collaborative, *IRRC* International Robotic Cystectomy Consortium

selection), evaluation and identification of key technical aspects of the surgery, and postoperative outcomes (Table 17.1).

Patient Selection and Surgical Preparation

One of the most important aspects of robotic surgery is selecting the patients who are appropriate for surgery and for robotic surgery. With nearly 50% of patients now choosing initial active surveillance over local treatment, optimal patient selection is paramount [12]. In this area, MUSIC has developed appropriateness criteria for management of prostate cancer. The criteria, constructed using the RAND/UCLA Appropriateness Methodology, take into account the patient's comorbidities, age, life expectancy, Gleason score, volume of disease, and PSA density. Based on this information over 160 clinical scenarios were evaluated, and said to be "highly appropriate, appropriate, uncertain, inappropriate or highly inappropriate" for initiating active surveillance. The goal of these criteria is to make sure that optimal treatment strategies are being selected for patients, and to allow for improved patient counseling prior to initiating prostate cancer treatment [13].

Another group optimizing preoperative preparation for robotic prostatectomy is the Quality Assurance Program (QAP), started by the London Cancer group [14]. QAP had multiple interventions, the first intervention aimed improving preoperative preparation prior to robotic prostatectomy. All preoperative MRIs were reviewed prior to the surgery with a uroradiologist and urologist who performed radical prostatectomies. At this conference, group members review the tumor location and establish an operative plan to maximize cancer excision and nerve sparing [14]. In addition, the group rated the surgical procedure based on difficulty, which was then used to emphasize potential training opportunities for training surgeons. A number of other practices were implemented by the QAP, and will be discussed later in this chapter.

Surgical Skill And Technique

The IRCC has evaluated a variety of intraoperative factors during robotic cystectomy including: intraoperative surgical time, margin status, estimated blood loss and lymph node removal. In 2010, the consortium determined that proficiency during robotic cystectomy is achieved by the thirtieth performed robotic assisted cystectomy [15]. They defined proficiency by positive margin status, operative time and EBL. In addition, the group further evaluated whether robotic prostatectomy experience impacted robotic cystectomy surgeons' operative time, EBL, margin status and lymph node removal. They found that surgeons

who had performed 51 to 100 robotic prostatectomies were 60 percent less likely to have EBL greater than 300, and were 75% less likely to have an operative time lasting longer than 6 h when they performed robotic cystectomies [16]. These findings of the IRCC demonstrate that there is a learning curve to robotic-assisted cystectomy, and providers who have more robotic experience are likely to have lower intraoperative times and EBL.

Although there are no formal collaboratives currently focusing on robotic partial nephrectomy, a group of five premier U.S. institutions (Cleveland Clinic Foundation, Henry Ford Hospital, Johns Hopkins University, New York University, Washington University in St. Louis) participate in a data sharing initiative to improve outcomes for robotic partial nephrectomy (RPN). Notably, the group developed a treatment safety checklist to manage hemorrhage during RPN. Their steps include: careful review of preoperative imaging, careful dissection of the hilum with potential use of laparoscopic Doppler ultrasound probe, clamping of the renal artery prior to branch points, determining whether intraoperative hemorrhage is secondary to arterial versus venous bleeding. Based on the physician's assessment of whether the bleeding is arterial or venous, a strategic checklist for managing the bleeding was developed and implemented across the five institutions [17].

Aside from experience and surgical checklists, there is a void that needs to be filled in order to continue to improve robotic training and provide continuous improvement. One strategy to improve intraoperative surgical skills is to develop methods for surgical review. The Michigan Bariatric Surgery Collaborative (MSBC), a collaborative of 38 bariatric surgery programs across the state of Michigan, is one of the leaders in developing intraoperative review strategies. MBSC performed an analysis of surgical video review and subsequent post-operative complication rates [18]. In this landmark study, twenty surgeons from across MBSC submitted a videotape of a laparoscopic gastric bypass procedure, which were rated for skill in a blinded manner by surgeons within their collaborative. The relationship between surgeon skill and complication rates was analyzed. The group found that there was a wide variation in surgical skill, and those with lower skill ratings had significantly higher rates of complications. Based on these results the MBSC began utilizing site visits, made online video of collaborative surgeons available for analysis, and perhaps most importantly, began providing anonymous constructive feedback by their peer physicians to help improve their technique [18].

This work from MBSC was instrumental in inspiring leaders across the field of urology to develop similar strategies for improving surgical skill [19]. In 2015, MUSIC sought to evaluate whether both peer and crowd-sourced reviewers were able to evaluate the technical skill of surgeons performing robotic prostatectomy. Peer review is optimal, but oftentimes may be limited by time and cost. As a result, MUSIC sought to determine if lay reviewers were able to accurately assess surgical skill. Both peer and lay crowd reviewers were asked to evaluate four key portions of robotic prostatectomy: bladder neck dissection, apical dissection, nerve sparing and the anastomosis. Global robotic skills were assessed using the Global Evaluative Assessment of Robotic Skills (GEARS) while the anastomosis was also assessed using the validated Robotic Anastomosis and Competency Evaluation (RACE) instrument [20, 21]. Twelve MUSIC surgeons submitted individual videos for review by 25 peer surgeons in MUSIC, and 680 crowd reviewers from the Amazon.com Mechanical Turk platform. There was a strong correlation between peer and crowd-sourced reviewers, and both sets of reviewers agreed on the ranking of the lower scoring surgeons [22].

This study was important for future collaborative initiatives in robotics for a number of reasons. First, the videos were distributed via a secure internet-based tool, which increases the feasibility of using this system at a broad level. Another important result from this study was ability for the crowd to review the film and have similar results when compared with peer-based assessments. This demonstrates the intriguing potential of using lay-person review to identify surgeons with opportunities for improved

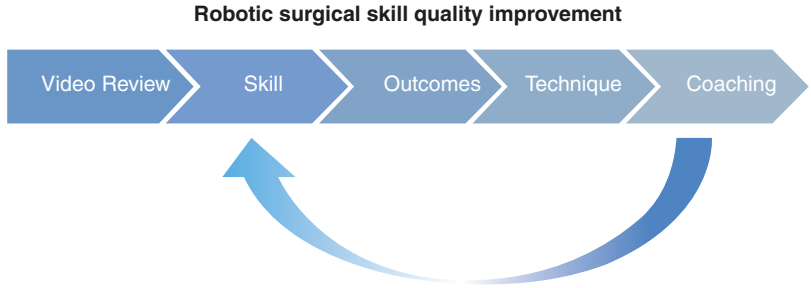

Fig. 17.2 Improving patient outcomes for patients undergoing robotic surgery in a collaborative structure: The role of video review to understand the role of surgeon skill and technique. Implementation of surgical coaching strategies that utilize best practices for technique and skill identified by video review has the potential to improve the skill of surgeons within the collaborative with the aim of improving patient outcomes

performance. This is less costly and less time consuming compared to peer review. Once the crowd-review has identified a lower performing surgeon, the surgeon could then undergo video review by a peer, with goals for the peer to provide coaching and constructive feedback to help improve the surgeons' technique [22]. This review system will allow for constructive criticism and training to be provided by fellow surgeons to their peers, and may be important for reducing complications and improving outcomes for robotic surgery.

Similar to MUSIC and MBSC, the members of the QAP video recorded and stored all robotic prostatectomies performed at their institutions. Each month the surgeons' outcomes were reviewed, including margin status, complications, 3-month continence and 12-month potency. The video recordings for both the highest quality and lowest quality surgical practice were reviewed monthly with all surgeons involved in the group. For example, the group reviewed the video for the surgeon with the highest 3-month continence rates, and also reviewed videos involving any complications. Outcomes were assessed using the International Consultation on Incontinence Questionnaire (ICIQ), International Index of Erectile Function (IIEF) and postoperative complications.

Using video review, surgeons were able to alter their surgical technique based upon the continence and potency outcomes of high-performing surgeons, and subsequently improve their 3-month continence rates and potency rates [14]. After implementation of their preoperative planning and postoperative video review they found that the complication rate was reduced by 50%. Three-month urinary continence was increased by 10 percent, and 12-month potency was increased by 40 percent [14].

The work done by MBSC, MUSIC and QAP demonstrated that video-review may play an important role in training and improving robotic surgeons. Expansion of video-libraries and secure web-based systems for video-review can help expand the availability of peer-review to larger numbers of providers. Collaboratives allow for feedback and coaching across large populations, and may help improve patient outcomes and delivery of optimal robotic care (Fig. 17.2).

Patient Outcomes and Postoperative Factors

A final area of focus for urologic collaboratives is postoperative outcomes. Urologists in MUSIC defined an uncomplicated recovery pathway following robot-assisted radical prostatectomy, and then identified specific deviations from the expected recovery including: rectal injury, high volume blood loss, extended length of stay, drain use, catheter replacement, hospital readmission or mortality. Collectively, these events are called Notable Outcomes and Trackable Events after Surgery (NOTES). MUSIC abstractors reviewed data for over 100 surgeons, and if any deviation from expected recovery occurred the events

leading up to the deviation were analyzed. The project demonstrated that 50.2% of deviations in care occurred as a result of an anastomotic or gastrointestinal event [23]. A reporting system like NOTES provides objective measures of complications for individual surgeons. In addition, it provides individual surgeons with feedback on their performance, and subsequently gives them opportunities to reflect, and work towards improving their patients' short-term post-operative recovery.

A more recent priority in MUSIC is to improve patient-reported outcomes (PRO) following radical prostatectomy. Radical prostatectomy remains a common treatment modality for prostate cancer; however, it can be associated with significant morbidity, including urinary incontinence and erectile dysfunction. With the goal of improving these outcomes MUSIC created a statewide, electronic program called MUSIC-PRO that allows prospective measurement of urinary and sexual function outcomes across diverse academic and community practices. MUSIC-PRO now has 17 participating practices and has collected data on nearly 2000 patients. Patients are provided with an on-line questionnaire or paper form regarding urinary function and erectile function at 3, 6, 12 and 24 months following radical prostatectomy [1]. The results of the survey are delivered to surgeons from across the state. In addition, surgeons receive summary data providing them with comparisons between patients in their practice versus patients at all sites. Initial data demonstrate variation in recovery of urinary function [1]. Using information from the top surgeon performers, MUSIC-PRO may aid in the development of strategies to improve outcomes for patients across the State. In addition, the information from the MUSIC-PRO initiative can be used to guide pre-operative counseling for patients with similar baseline characteristics and clinicopathologic data.

Likewise, the IRCC maintains a significant focus on postoperative outcomes and complications as well. In 2013 the group evaluated over 900 patients who had undergone robotic cystectomy. They analyzed and graded all complications. They found that gastrointestinal, infectious and genitourinary complications were most common, and that the majority of complications were found to be low grade [24]. This information is important as it allows for comparison to open cystectomy, and can provide patients with important information during pre- and postoperative counseling.

Similarly, the multi-institution group focused on understanding and improving RPN has evaluated outcomes and complications. The group recently compared surgical outcomes for robotic versus laparoscopic partial nephrectomy and found that patients in the RPN group had lower warm ischemia times, complication and positive surgical margin rates [25]. In addition, they evaluated the incidence and risk factors for urine leak following RPN. The group found that tumor size, a tumor located in the hilar region, longer operative time, longer warm ischemia time and patient's receiving a pelvicalcyceal repair were at increased risk of developing a urinary fistula [26]. This is important information to have preoperatively and may help guide preoperative and postoperative counseling for patients undergoing RPN.

More recently, an additional collaborative in urology, the Vattikuti Global Quality Initiative in Robotic Urologic Surgery has been developed. The group consists of 10 centers worldwide with a standardized data collection system for RPN. Initial work from this group analyzed outcomes of RPN for cystic tumors. In their analysis, they found that RPN for cystic masses has similar perioperative and pathologic outcomes compared to solid renal masses [27]. Again, this information can guide clinical decision making and patient counseling.

Conclusion

There are a number of quality improvement collaboratives in urology that have a central database, provide feedback to surgeons about their performance and implement strategies to improve patient care and outcomes. Recently, there has been an international movement to improve outcomes for patients undergoing robotic surgery. The groups discussed in this chapter have been instrumental in developing

strategies for video review and skill-based feedback for robotic surgeons. Moving forward this video-review and peer-based feedback is critical for continuous improvement in robotic surgery.

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Health Services Research and Robotic Surgery

18

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Abstract

There is increasing awareness that surgeons must become experts on the systems necessary to achieve reliable, safe and high-quality surgical care and authorities on the "value" of different interventions for patients. The study of these issues—termed *Health Services Research*—is particularly relevant for robotic surgeons.

Robotic surgery was rapidly adopted in urology, despite little prospective data showing a benefit over open surgery. Thus, interpreting data on the benefits of robotic surgery often requires an understanding of observational outcomes research as well as advanced analytic techniques. What's more, the diffusion of robotic surgery has occurred in a way that differs from many prior surgical innovations: who gets surgery, where they get surgery and when they get surgery have all been impacted by unique aspects of robotic surgery. As we look to the future of payment reform, novel payment schemes like bundled payments and accountable care organizations will play a dramatic role in shaping patterns of surgical care and surgical systems. In aggregate, these changes will no doubt impact robotic surgery as well.

While the entirety of this field is too broad to be covered in a single chapter, the above key issues are felt to be of particular interest to the urologic surgeon. In the following chapter we will systematically survey these key issues related to the study of health systems, outcomes and their relation to robotic surgery.

Keywords

Outcomes assessment · Patterns of care · Cost measurement · Value · Bundled payments · Accountable care organizations · Technology dissemination

Outcomes Assessment in Robotic Surgery

Over the past 15 years, new robotic surgical techniques have seen widespread adoption. Perhaps nowhere is this more obvious than in the case of robot-assisted radical prostatectomy (RARP) for prostate cancer. First described in a case report by Abbou [1], Menon's standardization [2–6] of RARP has resulted in dissemination of robotics in the United States and throughout the developed world where the majority of radical prostatectomies (RP's) are now done robotically [7–9].

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Robot-assisted surgery offers many hypothetical benefits such as stereoscopic vision, enhanced visual magnification, and more degrees of freedom compared to traditional minimally invasive surgery. As such, many authors hypothesized that this surgical approach would lead to lower rates of short- and long-term side effects, including urinary incontinence and erectile dysfunction, relative to the conventional open radical prostatectomy (ORP) [10–13]. Perhaps more importantly, it was hoped these technical advantages could result in better oncologic outcomes. For example, several investigators postulated that the adoption of minimally invasive approaches would result in fewer positive surgical margins and lower rates of additional cancer therapies after surgery [11, 14–16].

Despite considerable interest in testing these hypotheses, the dissemination of RARP took place largely absent high-level evidence supporting its superiority. Instead, researchers have had to develop models to retrospectively compare the effectiveness of RARP vs. ORP. Understanding these approaches is obligatory for those hoping to correctly assess the benefits of robotic surgery, deciding on whether to invest in a surgical robot and counseling patients and colleagues about these approaches.

Defining the Outcomes

There is tremendous variation in the reporting of postoperative complications, functional outcomes, and oncologic results in urologic oncology, regardless of the surgical approach [17–20]. Several efforts have been undertaken to standardize the definition of endpoints.

Perioperative Outcomes

The manner in which perioperative outcomes or complications are reported is a significant confounder when trying to assess differences in complications between RARP vs. ORP [21]. Such confusion has led to efforts to standardize the reporting of complications following surgery. Martin et al. [22] developed 10 criteria for the evaluation of studies reporting postoperative complications. (Table 18.1) These include methods of data accrual, definition of complications, outpatient information, severity grading, procedure-specific complications, length of stay, mortality rates and cause of death, duration of follow-up, and data on preoperative risk factors [22]. These criteria were subsequently modified and adapted for urologic surgery by Donat [23]. While many notable studies [24–26] have adopted the Martin-Donat criteria for standardized reporting of complications, these criteria are not routinely applied in most settings. For example, a recently published systematic review comparing the perioperative outcomes of RARP vs. ORP identified only one publication

Table 18.1 Martin criteria for the evaluation of article reporting complications after surgery

Criteria	Requirement
Method of accruing data defined	Prospective or retrospective accrual of data are indicated
Duration of follow-up indicated	Report clarifies the time period of postoperative accrual of complications such as 30 days or same hospitalization
Outpatient information included	Study indicates that complications first identified following discharge are included in the analysis
Definitions of complications provided	Article defines at least one complication with specific inclusion criteria
Mortality rate and causes of death listed	The number of patients who died in the postoperative period of study are recorded together with cause of death
Morbidity rate and total complications indicated	The number of patients with any complication and the total number of complications are recorded
Procedure-specific complications included	Radical prostatectomy: anastomotic leak, lymphocele, urinary retention, obturator nerve injury, …
Severity grade utilized	Any grading system designed to clarify severity of complications including “major and minor” is reported (e.g., Clavien and Dindo grading system)

that fulfilled all 10 of the Martin criteria [11, 27]. Comparative assessments ought to fulfill these criteria to be considered valid and relevant [11, 28].

The cornerstone of the Martin-Donat criteria is a standardized grading system for complications [22]. The most commonly used grading system is based on the work by Clavien et al. [29]. In their pioneering investigation, the authors systemically categorized postoperative complications into four grades according to their severity. In 2004, this grading system was updated by Dindo et al. [30], who modified the criteria to improve their accuracy and applicability (Table 18.2).

The Dindo classification system records any deviation from the regular postoperative course as a complication [21, 29–31]. This grading system is easily applicable and reproducible in patients treated with RP [21, 28, 31].

Of note, many comparative assessments do not consider blood transfusions as complications but as separate endpoints. Consequently, many have argued that if blood transfusions were considered complications, most if not all evidence would show lower complications with RARP compared to ORP. The adoption of these standardized evaluation tools in more recent publications facilitates the comparison of short-term outcomes of RARP vs. ORP. For example, Agarwal et al. [24] demonstrated the safety of robotic surgery in a large cohort of patients with clinically localized PCa treated at a single referral tertiary center; this report represents one of the first efforts to use the standardized Martin-Donat criteria to examine morbidity and mortality after RARP.

Table 18.2 Dindo grading system

Dindo Classification of post-operative complications:
– Grade 0: absence of any complications;
– Grade 1: presence of any deviation from the normal postoperative course;
– Grade 2: management that includes not more than intravenous blood transfusion;
– Grade 3: complications that require surgical, endoscopic, or radiologic intervention;
– Grade 4: life-threatening complications requiring intensive care management;
– Grade 5: complications that cause the death of the patient.

Functional Outcomes

The use of clear definitions for potency and continence recovery is essential for comparing functional outcomes between patients treated with RARP and ORP. For one, the adoption of validated questionnaires, such as the International Index of Erectile Function (IIEF), has been widely advocated for the assessment of erectile function after surgery [12, 20, 32]. Briganti et al. [20] showed that an Erectile Function domain of the IIEF $\geq$22 represents a reliable score for defining a satisfactory erectile function after radical prostatectomy. Therefore, such a definition should be applied when assessing the rates of erectile function recovery after ORP and RARP [20].

Similarly, when evaluating postoperative urinary continence, previous studies have demonstrated that the definition of incontinence substantially affected the rates of continence recovery [33–35]. In an effort to define more stringent criteria for satisfactory continence, Liss et al. [35] recently observed that patients reporting the use of one pad or more per day had a significant decrease in postoperative quality of life compared to their counterparts using no pad. Consequently, many have advocated that urinary continence recovery after surgery should be strictly defined as the use of no pad [35]. Given that improvements in urinary continence and erectile function recovery after 36 months of follow-up are trifling, a median follow-up of at least 3 years should be considered compulsory when comparing functional outcomes between open and minimally invasive surgery.

Oncologic Outcomes

When evaluating oncologic outcomes, the short follow-up in series of patients treated with RARP prevents investigators from comprehensively comparing cancer-specific mortality rates between the two surgical approaches [11, 17]. Indeed, given the indolent natural history of clinically localized PCa, a long follow-up is needed to assess important postoperative oncologic outcomes such as

metastasis-free survival and cancer-related mortality. Given that robotic surgery has only been widely adopted in the past decade, secondary endpoints have been used.

Biochemical recurrence (BCR) is one of the most frequently reported surrogate endpoints. However, the rates of BCR are dependent on several confounders, such as preoperative and pathologic characteristics, length of follow-up, and use of adjuvant hormonal or radiation therapies [36–39]. A pioneering study by Menon et al. [40] was the first to report the 5-year BCR-free survival rates in a large cohort of patients treated with RARP alone (without adjuvant therapies), supporting the safety of this approach.

The presence of positive surgical margins at final pathology has also been proposed as a proxy for cancer control [11, 14, 15, 41–43]. Again, caution should be used. The impact of positive margins on the long-term risk of BCR and cancer-specific mortality remains controversial and is dependent on the presence of other adverse pathologic features at RP, as well as patient life expectancy [44–49]. Additionally, the rates of positive margins may depend more on surgical expertise [49] and/or surgical technique (i.e., aggressiveness of nerve-sparing), rather than RARP vs. ORP. Of note, the learning-curve phenomenon may play a more significant role in patients treated with minimally invasive surgery, given the recent introduction of the robotic technique and the relatively low cumulative case volume of early adopters [7]. Many men with outcomes in the range of 10+ years post operatively had their surgery in a time when the operation was not yet common. Patients with the longest follow up by definition have less experienced surgeons. Consequently, this endpoint may not be mature enough to comprehensively assess the oncologic safety of robot-assisted vs. open surgery [48, 50].

Similar limitations apply when comparing postoperative therapies [13, 14, 50, 51]. For example, administration of adjuvant radiotherapy and hormonal therapy depends on disease characteristics at final pathology [50, 52]. For example, evidence from randomized trials support the use of adjuvant androgen deprivation therapy following RP in patients with node-positive Pca [38, 53]. Similarly, the likelihood of lymph node invasion at RP depends on the extent of the pelvic lymph node dissection performed [53–55]. Since patients treated with RARP are less likely to receive a lymph node dissection at RP [56], the use of postoperative cancer therapies may be higher in ORP patients when it really reflects more precise nodal staging. Moreover, given the lack of consensus on the benefits of adjuvant radiotherapy following RP, the selection of patients for adjuvant therapies relies immensely on patient-physician perceptions and preferences [52, 57, 58]. Such considerations may limit the validity of this endpoint as a proxy of cancer control after RP [50].

Costs and Expenditures

In an era of heightened scrutiny for spending and resource allocation, treatment-associated expenditures represent an important endpoint [14, 59, 60]. One of the purported disadvantages related to the adoption of minimally invasive surgery is the substantially higher costs associated with the purchase of robotic equipment and the use of disposables [61, 62]. Some observational data supports this [63]. On the other hand, several authors have postulated that shorter length of stay and lower rates of transfusions could result in lower costs of RARP compared to ORP in the early postoperative setting [60]. However, the absence of prospective studies comparing the costs and expenditures associated with RARP and ORP limits our ability to fully test these interesting hypotheses [59, 60, 62]. Moreover, much proposed savings from a shortened length of hospitalization and lower transfusion rates rely on health care provider reimbursement policies, which may vary from one country to another [60, 64]. The potential benefits of RARP with regard to lower rates of positive surgical margins and use of additional cancer therapies could also result in substantial savings for the health care system in the long term [14].

A retrospective study of a large hospital database employing direct line-item costs

found that robotic prostatectomy did incur slightly higher costs but tended to result in lower morbidity profile (lower rates of any complications, blood transfusion and prolonged length of stay) compared with open prostatectomy [63]. Another study using the same database found that even among just robotic surgeons there was a striking disparity in 90-day hospital costs following RARP [65]. Even after excluding physician fees, for RARP surgeons in the top and bottom decile of costs there was a nearly ten-fold variation in mean costs of performing this operation. Taken together, these results suggest that despite the apparent higher cost of RARP, there may be substantial opportunity to dramatically increase the value proposition of RARP by reducing unwarranted variation in processes of care and by reducing costs associated with morbidities, complications and length of stay. Cost-reductions associated with improved quality of life and oncologic outcomes may require more time to accrue but could be significant.

Observational Studies

Retrospective Studies from Tertiary Referral Centers

A number of retrospective studies from high-volume tertiary referral centers showing better short-term postoperative outcomes for patients undergoing RARP fueled the initial enthusiasm for minimally invasive approaches for PCa surgery [2, 40, 41, 66, 67]. However, these data should be interpreted with caution.

First, results obtained from high-volume referral hospitals and surgeons may not be applicable to the broader general population. From a population-based perspective, most patients are treated at community hospitals [68]. Second, the introduction of a robotics training program at high volume centers is associated with more stringent patient selection with regard to preoperative disease and patient characteristics [69, 70]. Specifically, patients with more favorable disease and health are more likely to be selected to the novel approach, herein minimally invasive surgery [69]. Such selection bias may result in better short- and long-term outcomes for patients treated with minimally invasive approaches compared to their open counterparts. Some of these selection biases are often unrecorded in retrospective studies, potentially limiting the external validity of such studies to an extent that any statistical adjustment would not appropriately mitigate [71].

Several systematic reviews and meta-analyses based on retrospective data from high-volume centers showed significant benefits for RARP with regard to perioperative outcomes, functional results, and oncologic endpoints [11, 12, 72–74]. Unfortunately, the aforementioned limitations also apply to these investigations, in addition to the usual publication bias for positive studies [75]. Consequently, despite the high number of patients evaluated, these meta-analyses do not provide a definitive answer to the question: Which surgical approach is best for the treatment of patients with clinically localized PCa? If one assumes that adjustment for case-mix is appropriately performed (which is not a given), the best interpretation of these data may be that the outcomes of the best RARP series (or surgeons) are better than those of the best ORP series (or surgeons).

Population-Based Studies

As previously discussed, data from high-volume referral centers may not be generalizable to the overall population. In the absence of randomized controlled trials, several authors give credence to population-based analyses evaluating the effectiveness of RARP vs. ORP in large contemporary cohorts of patients with clinically localized Pca [14, 76–79]. Such studies allow for comparison of competing therapies across a broad range of health care settings [76].

Interestingly, results obtained from these data somewhat differ from those originating from high-volume centers [13, 51, 76, 77]. In their assessment of a large population-based cohort of patients within the Nationwide Inpatient Sample, Trinh et al. [79] were able to demonstrate

superiority of RARP over ORP for virtually all perioperative outcomes. However, in a landmark investigation by Hu et al. [76], no differences were observed between ORP and RARP with regard to perioperative outcomes and long-term functional results when evaluating a population aged 65 years or older enrolled in Medicare. Gandaglia et al. [13] examined postoperative complications and use of additional cancer treatments in a more contemporary cohort of Medicare beneficiaries and corroborated the results of the Hu et al. study.

Barry et al. [77] compared the odds of problems with continence and sexual function following RARP and ORP in Medicare beneficiaries treated between 2008 and 2009 using rigorous survey instruments and validated questionnaires. They observed that robotic surgery was associated with a non-significant trend toward greater problems with urinary continence. Further, the adoption of RARP was not associated with better erectile function recovery rates at a median follow-up of 14 months [77]. One key drawback of these large studies is that many originate from Medicare enrollees, who are by definition older than 65 years of age. As screening decreases in these populations as a result of more stringent PSA guidelines, these results may become less generalizable for men who actually receive radical prostatectomy [80].

Statistical Methodology Applied in Retrospective Studies Comparing the Two Techniques

Several efforts have been made to limit the effect of selection bias in retrospective observational studies using advanced statistical tools [81]. For example, propensity score matching represents a commonly used approach. This method allows the selection of control subjects matched with treated subjects for readily available covariates, which, if unaccounted for, would lead to biased estimates of treatment effects [82]. When matching is performed, the covariates in the control and treatment groups are balanced following the matching process [82]. Thus, analyses performed on the post-propensity score matched population should lead to theoretically unbiased comparisons between postoperative outcomes of the two surgical techniques. However, many investigators feel that although the effect of measured confounders is minimized with advanced statistical techniques, the effect of unmeasured confounders may be amplified [83, 84].

Another statistical method gaining traction in urologic outcomes research is the instrumental variable analysis. This approach claims to perform "pseudo-randomization" by accounting for both measured and unmeasured confounders [85]. By definition, an instrumental variable should be associated with the odds of receiving the treatment of interest (e.g., RARP) but should not be associated with the analyzed endpoint (e.g., cancer-specific survival) except through the choice of treatment. Examples of instrumental variables that could be used to compare RARP vs. ORP are the density of RARP cases performed in a given area, the distance to the closest hospital performing RARP, or even physician-level preference for RARP. These instruments are conceptually sound, however the quality of the instrument must always be verified using statistical calculations such as the F-statistic [86, 87]. For example, one would expect the density of RARPs performed in a given area to influence the choice of treatment; however, we do not expect that variable to affect the endpoint (for example, postoperative complications) except through the choice of treatment (herein RARP vs. ORP). The instrumental variable is subsequently used for pseudorandomization, thereby allowing estimation of the effect of a certain treatment on the "marginal" population, e.g. individuals for whom the likelihood of undergoing the treatment is based on the instrumental variable [88].

Prospective Randomized Trials

At the time of writing, two randomized trials have been accruing patients and results are expected in the short-term [89, 90]. Gardiner et al. [89] are recruiting 200 patients per treat-

ment arm (RARP vs. ORP) at a major public hospital clinic in Queensland, Australia with results expected to be forthcoming [91].

In this study, one surgeon is performing all RARPs while another surgeon is performing all ORPs. The endpoints considered are oncologic (positive surgical margins, BCR, and need for further treatments) and non-oncologic (pain, physical and mental functioning, fatigue, urinary continence, erectile function recovery, quality of life). Cost modeling for each approach, as well as a full economic appraisal, will also be performed [89]. The second trial is currently recruiting participants at the Mayo Clinic, and the preliminary results are expected by May 2016 [90]. The primary endpoint is trifecta status, i.e. free of biochemical recurrence, potency, and continence, at two-year follow-up.

Results from two randomized controlled trials comparing RARP vs. pure laparoscopic RP have been published [92, 93]. Asimakopoulos et al. [92] randomized 128 patients with clinically localized prostate cancer in two groups: RARP vs. laparoscopic RP. The primary endpoints were erectile function and urinary continence recovery, postoperative complications, and pathologic results [92]. The study showed that patients treated with RARP had higher erectile function recovery rates compared to their laparoscopic counterparts. However, no differences were found between the two surgical approaches when evaluating the other endpoints. Recently, Porpiglia et al. [93] presented the results of their prospective randomized trial comparing RARP and laparoscopic RP. The authors included 120 patients with clinically localized PCa, who were randomly assigned to RARP or laparoscopic RP. The same surgeon performed all cases.

The authors did not find any differences between the two surgical approaches with regard to postoperative complications and pathologic results; however, RARP provided better recovery of functional outcomes (i.e., urinary continence and erectile function) at 12-month follow-up [93]. The relatively small number of patients included limits the generalizability of these prospective trials. Additionally, given the relative rarity of traditional laparoscopic prostatectomy, the relevance of these results is likely limited.

Another recent high-profile surgical trial was recently performed at Memorial Sloan Kettering, which compared open versus robotic cystectomy [94]. This is one of the few true randomized clinical trials comparing open robotic genitourinary surgery and provides a valuable contribution to the literature. There are obvious methodological issues with the study such as the fact that the urinary diversion (the source of most of the complications) was performed in an open fashion in both arms. Also, like many of the above studies, this was performed at a large center where aspects of the patient population and surgeon experience may differ from the general practice patterns in the community [94–96]. Finally, there is the critically important question of surgical skill. Ultimately, any clinical trial of surgery is open to the critique that the most it can ever say is that surgeons A, B and C are better at technique 1, than surgeons X, Y and Z are at technique 2. In contrast, what most patients and doctors want to know is if one technique is *generally better than another*.

Thus, it is our view that high quality analytic techniques, population based studies and standardized endpoints must supplement single and multi-center trials for comparing these two techniques. The level of evidence supporting the superiority of one approach over the other (RARP vs. ORP) depends on the type of study design, and ultimately the study designed should be tailored to the specific hypothesis at stake.

Dissemination

As robotic surgery has seen widespread adoption in the developed world, we have been privy to a "natural experiment" about the ways that high tech treatment modalities are disseminated into practice. Unique incentives related to the specialized equipment, high barriers of equipment and

training, and competition for patients all have influenced the dissemination of the surgical robot.

Early Adopters and the Surgical Learning Curve

No discussion of the dissemination of the surgical robot is complete without discussion of the costs required to adopt robotic surgery. Initial financial outlays required to develop a robotic surgery program are considerable. The fixed, variable and opportunity costs for robotic surgery suites are all high. A new surgery system employing a surgical robot may cost between $1 million and $2.5 million per unit, surgeons must perform between 150 and 250 procedures in order to become proficient, and the robotic systems also frequently require expensive maintenance contracts and costly disposable equipment [97]. As a result, a hospital deciding to start a robotic surgery program must weigh costs that are not present with traditional surgical techniques. It is not surprising that many of the earliest adopters of robotic surgery were academic centers and hospitals with >300 beds and high surgical volume [98, 99].

Given the popularity of robotic surgery as well as its disproportionate use at large academic centers, many hypothesized a resultant shift in surgical volume *away* from small community centers and towards large academic centers. There is considerable observational data that this has occurred. One study of robotic surgery adoption in Wisconsin showed that the presence of a surgical robot was associated with both high-volume and with a greater percentage increase in surgical volume compared with non robot-owning centers [100]. A similar study off all prostatectomies in the states of New York, Pennsylvania and New Jersey showed that increases in prostatectomy volume from 2000 to 2009 occurred almost entirely at very high-volume centers (>109) annually, while there was a decrease in the *number* of hospitals performing the surgery and a nearly doubling in proportion of patients travelling more than 15 miles for surgery [101].

In terms of centralization of RARP for individual surgeons, a similar trend has been inferred. A 2012 study by Lowrance et al., relying on surgeon-reported case logs, suggested that practice patterns are moving towards centralization at the level of the individual surgeon [8]. In their study, they found that the median number of annual surgeries for robotic surgeons was 26 compared with only 8 for exclusively open prostate surgeons—the obvious implication being that robotic surgery has led to the concentration of this procedure in the hands of a comparatively small number of higher volume surgeons.

Given the well-known volume-outcomes effect in prostate surgery [102], it is hoped that quality improvements will be seen as a result of centralization. Case mix and referral patterns may also have a significant impact on the perceived benefit of large institutions [103]. If so, then the potential benefits of centralization due to dissemination of the surgical robot may be more modest. The aspects of care that are responsible for the volume-outcomes effect in surgery generally are subject to an ongoing study [104]. Assessing for any shift in outcomes as a result of robotic-induced centralization of prostatectomy is a key area for ongoing study.

Additionally, there may be some unforeseen downstream effects of robot-induced centralization–such as financial hardship for small but important rural hospitals and loss of surgical skills at such institutions. If oncologic surgeries become the sole purview of the high-volume, urban robotic surgeon, then this may have substantial implications for access to care and maintenance of surgical skill for rural patients and practitioners, respectively [105].

There is no doubt that the purchase and maintenance of a surgical robot cannot be maintained purely on the basis of a small handful of RARPs. Surgeons and hospitals with such small volumes therefore are unlikely to find the procedure financially feasible. It could be argued that such surgeons may not be the best to be performing such operations; however, community urologists play a key role. Both the maintenance of surgical skill and the financial viability of community urologic practices depend on maintenance of

adequate surgical volume. If opportunities for these operations become rare outside of major centers, fewer new urologists may choose to practice in small rural hospitals. A SEER-Medicare study from 2000 to 2003 found that the median number of men treated by a minimally invasive RP surgeon was less than five Medicare operations annually [106]. Given that some economic analyses require hospitals to perform nearly 200 robotic operations annually to justify the purchase of a robot [107], such low-volume prostate surgeons may soon become a much smaller minority.

Competitive Pressures and Adoption of Expensive Technologies

Expensive technologies are widely recognized as a key driver of health care costs, especially in the United States [108]. Given the high priority placed on controlling costs, the process of robotic surgery diffusion can provide a model of how high-tech and expensive treatment modalities are disseminated as well as their impact on overall spending. In addition to direct insights on robotic surgery itself, we can also view its dissemination as a model for how other expensive treatments such as proton beam therapy and high-intensity focused ultrasound are seeing growing adoption and face many of the same controversies. Like robotic surgery, many of these new technologies come with considerable costs, despite unproven superiority [64].

Given the high costs of starting a robotic surgery program, there is concern that perverse incentives within a fee-for-service system may spur increased utilization [109]. This phenomenon of "supply-induced demand" can be illustrated in robotic surgery. Having paid for an extremely costly robotic surgical system, a hospital must somehow recover the costs of purchasing and maintaining the surgical robot. Given that robotic surgery is not generally reimbursed at a substantially higher rate than open surgery in a fee-for-service system such as the US—there may be considerable pressure to increase surgical volume in order to recoup spending. The volume required to recoup the costs of a surgical robot has been estimated to be around 15 RARPs weekly provided that the length of stay after robotic surgery stays below 1.5 days [107]. Given these economic factors, there is a clear incentive to expand surgical volume. In an era where many advocate conservative management of low-risk conditions like prostate cancer, there is clearly a conflict of interest.

There is some data to suggest that market competition between hospitals and patient demands in response to aggressive marketing strategies were the main drivers of its adoption [78]. Having acquired a surgical robot and potentially facing substantial competitive pressure for patients, hospitals and doctors must aggressively compete to sustain the fairly high volumes required to break even for this new technology. Frequent, oftentimes non-evidence based claims on hospital websites were found to repeatedly tout the benefits of robotic surgery [110]. Given the perfect storm of factors potentially driving up robotic surgical costs, and the key role for fee-for-service care, novel payment schemes have been proposed. If it is possible to reduce the "fee-for-service" incentives, which may drive up utilization, then some of the impetus to disseminate surgical robots may be reduced.

As described above, there is good evidence that adoption of a surgical robot is associated with high surgical volume [111]. Some have asked whether this trend is primarily a *migration* of treatment away from open surgeries or an *expansion* of treatment. There is evidence from other disease states where treatment *expansion* has occurred following the adoption of new technologies—e.g., minimally invasive vascular and endoscopic gastroenterologic procedures [112–116]. A recent article showed that ownership of IMRT machines by urology practices may be associated with increased odds of recommending this therapy [117]. While this was not specifically shown with robotic surgical approaches, similar financial incentives may well be present. Given that many cases of prostate cancer have a relatively indolent course and may not require aggressive treatment—many fear that the above fee-for-services incentives in robotic surgery

may lead to an expansion of surgery for men who might otherwise be deemed non-surgical candidates either due to advanced age, comorbidities or low risk prostate cancer.

Some have attempted to assess this by measuring the change in disease characteristics seen following the adoption of robotic surgery. If the pressures of purchasing and maintaining a surgical robot *expand* rather than migrate surgical volume, then this may be accompanied with a loosening of indications for surgery—e.g., operations on men with shorter life expectancies, more comorbidities, or lower risk cancer. Some single institution studies have published series assessing changes in stage and grade for prostatectomy following the adoption of the surgical robot. One series from Italy in fact showed an *inverse* stage migration after robotic surgical adoption [118]. A series from Memorial Sloan Kettering in New York shows a similar shift [119]. Others have shown more mixed results. For example, a single institution study by Briganti et al. showed that men receiving RARP tended to be younger, and healthier (such men are probably more ideal surgical candidates suggesting a higher bar for operative management) but also with lower risk disease (suggesting the opposite, a potential loosening of indications for surgery) [69].

One difficulty in assessing these changes in case mix is that there are substantial confounders related to the disproportionate location of robots at large urban centers (where men may be younger, wealthier and more likely to be screened with greater likelihood of early-stage cancer). Perhaps more importantly, adoption of robotic surgery coincided with two significant epidemiologic trends in the surveillance and management of prostate cancer. First, there is a continuing rise in incidence coincident with early detection. Also, the decade from 2000 to 2010 saw vast increases in the utilization of active surveillance—which would be expected to actually raise the threshold for surgery [120]. However, given the hypothetical net opposite of these two forces, definitive inferences between the epidemiology of the "threshold" for performing surgery and the dissemination of the surgical robot is less clear. No studies to date have shown a definitive population based shift in the loosening of indications for surgery as a result of robotic surgery.

Novel Payment Schemes in Robotic Surgery

Given the high cost of robotic surgery, as well as the controversies regarding its potential therapeutic benefits, initiatives to contain health care costs and ensure value will likely impact practice patterns for robotic surgeons in the years to come. While no specific financial rewards or penalties are currently tied to robotic surgical approaches, new legislation aimed at controlling medical costs are likely to impact surgical practice patterns in the near future.

The Patient Protection and Affordable Care Act, commonly referred to as the Affordable Care Act (ACA), was introduced in 2010 as a concerted means to address the rising tide of United States health care spending, improve access and increase value [121]. An additional goal of the ACA is to improve the quality of health care delivered within the United States through novel incentive schemes. More specifically, section 3022 of the ACA empowered the Centers for Medicare and Medicaid Services (CMS) to investigate novel reimbursement mechanisms aimed at improving communication and coordination between healthcare providers, with the goal of eliminating redundant health care expenditures [122]. Accountable Care Organizations (ACOs) represent the first iteration of these novel care delivery models aimed at facilitating high-value health care delivery through shared cost-savings programs such as the Medicare Shared Savings Program (MSSP) [123]. Under this program, participating health care provider organizations are entitled to a portion of any accrued health care cost savings if certain performance standards are met. Although the initial versions of these programs carried no financial penalty, beginning in 2019, health care provider organizations participating in the MSSP will be subject to "two-sided risk," whereby they

would be responsible for any costs in excess of the bundled payment negotiated with CMS for predefined episodes of care.

More recently, the United States Congress passed the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which aims to standardize care delivered at the individual provider level by introducing a merit-based incentive payment system (MIPS). Whereas ACO's incentives are tied to large organizations, these incentives are at the level of individual providers. More specifically, MIPS and MSSP aim to facilitate high-value care by maximizing health care quality, safety, appropriate resource use, and patient satisfaction. Under the provisions of MACRA, high-performing providers may receive payment adjustments from CMS up to +27 percent, whereas the poorest performing providers will be penalized up to −9 percent [124].

Owing to the significant cost associated with episodes of surgical care in the United States (by some estimates over $400 billion per year) [125], commonly performed procedures such as joint replacement, colorectal diversions, and cardiovascular procedures have been the target of early alternative payment models (APMs). Launched in 2013, the Bundled Payments for Care Improvement initiative (BPCI) offers providers a variety of bundled payment options ranging from the index surgery admission alone to bundles for the index hospitalization, readmissions, and all other post acute care [126]. Given the rapidly growing Medicare-eligible population [127] and their accompanying urologic conditions [128], it is reasonable to infer that urologists will not be immune to the aforementioned payment reforms. More specifically, the equivocal perioperative benefits associated with robot-assisted vs. open surgery for various urologic conditions are likely to come under scrutiny [76, 79, 94]. Consequently, there will be a growing need for robust cost-effectiveness analyses evaluating the role of robotics in urologic surgery, and subsequently determining appropriate payment bundles for such episodes of care. Several organizations are currently developing bundled payment schemes for genitourinary surgery.

Alternative Payment Models: Bundled Payments and Surgery

The precise impact of the alternative payment models (APMs) proposed within the ACA and MACRA on surgical care remains unclear, although early results suggest that health care providers and hospitals alike will need to adjust in order to maintain financial viability. While ACOs commonly target large provider organizations and seek to improve preventative care and coordination, bundled payments may ultimately be more relevant for surgeons. More specifically, future reimbursement models similar to the BPCI are likely to target the significant cost variation noted among commonly performed surgical procedures such as joint replacement and colectomy, and prostatectomy, penalizing high cost outliers and rewarding cost-saving surgeons [65, 129]. For example, preliminary results from the BPCI for total joint replacements suggest that significant cost savings can be accrued through greater care coordination. More specifically, Lorio and colleagues found that implementation of the BPCI resulted in decreases in average length of stay (4.27 days to 3.58 days) and discharges to inpatient facilities (from 71% to 44%), which resulted in an approximately 10% reduction in overall costs to Medicare. Of note, readmission rates were essentially constant [130].

However, some of this cost variation may be beyond the control of the surgeon, instead representing inherent patient characteristics that predispose these individuals to more protracted—and therefore costly—episodes of care. Consequently, surgeons may be unfairly punished for operating on patients with poor baseline performance status and/or a greater number of medical comorbidities. For example, Gani et al. found that the number of patients undergoing elective colectomy who contributed to a net negative hospital margin increased from 33.7% under the traditional fee-for-service model to more than 40% under the bundled payment model. Unanticipated postoperative complications were at least partially responsible for these loses, as evidenced by the fact that median costs were higher among patients

who developed a postoperative complication ($42,537 vs. $22,829, $P < 0.001$) and among patients with an observed to expected length of stay greater than 1 ($36,826 vs. $16,197, $P < 0.001$) [131].

Health Care Reform and Robotic Surgery

The specific impact of APMs on the field of urology is even less clear. In a retrospective analysis by Hawken and colleagues evaluating the role of urologists in MSSP ACOs, it was determined that only 10% of eligible urologists were MSSP ACO participants between 2012 and 2013. At an organizational level, only 50% of the initial MSSP ACOs included at least one urologist [132]. Of note, the current iteration of MSSP ACO regulations does not require specialist participation, and it is reasonable to infer that urologist participation is likely to increase in the coming years. Another possibility would be dual systems whereby ACO-type incentives are predominantly present on the level of primary care practices (in order to emphasize coordination, prevention and reduction in low value care), whereas procedural work is paid under a bundled payment model in order to address unwarranted variation in costs and practice variations.

While the precise role of practicing urologists within the ACO and bundled payments models remains to be seen, robotic surgery is already being scrutinized given its rapid adoption, high cost, and uncertain value proposition [8]. Furthermore, as described above, the preponderance of literature suggests that the use of robotic surgery, at least in the immediate perioperative period is associated with significant added cost. In a recent meta-analysis by Bolenz and colleagues, costs associated with minimally invasive radical prostatectomy techniques ranged from $5058 to $11,806 compared to $4075 to $6296 (United States dollars) for open technique. Robotic procedures were associated with the highest direct costs [60]. Leow et al. showed a similar increased cost for the robotic version of cystectomy [63].

In theory, movement towards regional high-volume centers, which have been shown to have superior perioperative outcomes [133]—may partially address cost-effectiveness concerns surrounding robotic applications within urologic surgery [134]. Decreased length of stay, reduced complications and improved quality of life could all theoretically attenuate the financial costs of robotic surgery, but this has never been definitively shown. Some have attempted to assess how this could occur: Scales and colleagues conducted a sensitivity analysis comparing costs of open versus robot-assisted radical prostatectomy, concluding that cost equivalence could be achieved if 10 to 15 robotic cases using the same robot were performed per week [107]. However, complicating this picture are the results of a 2012 study by McWilliams et al. evaluating the implications of variations in health care spending growth on ACOs. More specifically, they found that ACO spending targets were highly unfavorable for high growth hospital referral regions, regardless of baseline spending levels [135]. If high volume ACOs provide costlier care, then the centralization due to robotic surgery may exacerbate the financial costs due to dissemination of robotic surgery.

Future Perspectives

As evidenced by the recent Supreme Court ruling in King v. Burwell [123], the ACA is likely here for the foreseeable future. A critical component of the ACA are its provisions aimed at improving the value of health care delivered within the US. Central to these provisions are various APMs that will fundamentally change how health care provider organizations are reimbursed for episodes of care. More specifically, bundled payments will emphasize high value health care delivery by eliminating waste and rewarding coordinated, high-quality care. Given the high cost of surgical care in the US, perioperative episodes of care are in the crosshairs of the aforementioned payment reforms. Robotic surgery is of particular interest given the high fixed costs associated with these procedures.

Many insurance companies do not currently reimburse at higher rates for robotic procedures, requiring health care organizations to distribute the added fixed costs associated with robotic acquisition and maintenance across other services [136]. As APMs such as bundled payments become more ubiquitous, the aforementioned cost deferral strategies will no longer be viable. Consequently, health care provider organizations will be required to either significantly reduce variable costs associated with robotic procedures (e.g., reduce perioperative inpatient costs) or abandon the technology entirely. Consequently, it is incumbent on the current generation of robotic urologic surgeons to conceive of strategies by which to improve the value of robotic surgery. Health services research will play a central role in evaluating the cost-effectiveness of robotic surgery at the population level, developing hospital-level strategies to streamline care, as well as to analyze our outcomes to assess their true value.

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Part III

Prostate

19 Development of the Vattikuti Institute Prostatectomy: Historical Perspective and Technical Nuances

Firas Abdollah, Deepansh Dalela, and Mani Menon

Abstract

Robot-assisted radical prostatectomy for patients with prostate cancer (PCa) was pioneered at the Vattikuti Urology Institute, and came to be eponymously titled as Vattikuti Institute Prostatectomy (VIP). Driven by the benefits of a minimally invasive approach, Menon and colleagues improvised upon their technique of VIP over the last fifteen years. A number of technical maneuvers were adopted to improve the trifecta outcomes for patients: cancer control, continence and recovery of sexual function. These include the Veil of Aphrodite approach to improve functional outcomes, bimanual palpation of the excised prostate specimen to decrease positive surgical margin rates, and adoption of a Retzius-sparing approach to RP, amongst other important modifications. In this chapter, we briefly discuss the key steps in the evolution of the VIP procedure, and relevant outcomes.

Keywords

Prostate cancer · Robotic-assisted radical prostatectomy · Oncological outcomes · Functional outcomes · Nerve-sparing surgery

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Brief Historical Introduction

Radical prostatectomy (RP) is the standard treatment modality for the surgical extirpation of prostate cancer (PCa). While the basic principles of technique were described in the early twentieth century by Proust, Young and Millin, open RP (ORP) continued to be a significantly morbid procedure, with the attendant risks of post-operative bleeding, incontinence, and impotence. It was not until the 1980s when Walsh, Donker and Lepor described the anatomical approach for open retropubic prostatectomy [1, 2], which allowed decreased intraoperative blood loss and greater likelihood of return to potency (secondary to preservation of the neurovascular bundle posterolateral to the prostate). This new RP technique became the gold standard for surgical treatment of localized PCa in patients seeking surgery.

Although the first laparoscopic RP (LRP) was performed nearly a decade later in 1997 by

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Scheussler and colleagues [3], the initial results were rather disappointing: it was not until the French surgeons Bertrand Guillonneau and Guy Vallancien described their 'Montsouris' technique in 2000 [4] that urologists started considering minimally invasive approach for RP. Driven by the perioperative safety, lower morbidity and the potential for better functional outcomes, Mani Menon and the surgeons at the Vattikuti Urology Institute started the world's first structured robotic surgery program in early 2001 [5], and the technique of robot-assisted radical prostatectomy (the "Vattikuti Institute Prostatectomy" [VIP]) was developed, the evolution of which has continued in the last one and half decade.

The details of the VIP procedure, from its evolution to the current approach, has been described in detail elsewhere [5–11]. For purposes of this chapter, we will briefly highlight the salient points in the evolution of the VIP. Accordingly, we divided the chapter into two headings:

(a) Why did we start a robotics program?
(b) What is the VUI experience with robotic prostatectomy?

Why Did We Start a Robotics Program?

With the description of the modern technique for ORP in the 1980s, the performance of this procedure increased sharply. In the early 2000s, a number of high volume centers published their perioperative and functional outcomes following ORP [12–14]. While the average blood loss was around 1000 mL, the transfusion rates varied between 10 and 30% and overall complication between 6.5 and 20%. Using data from SEER-Medicare, Begg and colleagues noted an overall complication rate of 30%, urinary incontinence in 20% and anastomotic stricture in 15% of patients at a nationwide level [15].

Minimally invasive surgery, in theory, had the potential to decrease the peri- and post-operative morbidity. With this thought in mind, Menon invited the French surgeons Bertrand Guillonneau and Guy Vallancien to help start a minimally invasive program. Comparison of outcomes of the 40 initial LRP indeed showed a better perioperative safety profile compared to ORP: while the mean operative time was longer for LRP vs ORP (~4.3 vs. 2.3 h), blood loss, transfusion rates, mean length of stay and overall complication rates were significantly lower for LRP (unpublished data)**.** However, LRP was limited by two-dimensional images, counterintuitive movements, rigid instruments, limited degrees of motion and ergonomic difficulties, and intrinsically presented technical challenges in patients with higher body mass index (BMI). Menon, who had extensive training in ORP (>1000 cases) with Walsh, felt that the technique and outcomes of LRP may not be always easily reproducible. He had already seen the da Vinci robot while visiting Montsouris Institute in Paris, and hypothesized that with the magnified view, 3-D vision and wristed movements, the robot can deliver the benefits of minimally invasive surgery more reliably and reproducibly than a pure laparoscopic approach. Somewhat serendipitously, in November 2000, the FDA approved the use of the da Vinci robot surgical system for abdominal surgery. With the financial assistance of the Vattikuti foundation, the da Vinci robot was leased and integrated into the minimally invasive program at Henry Ford Hospital, and the first robotic prostatectomy was performed on November 29, 2000.

What is the VUI Experience with Robotic Prostatectomy?

Initial Results and Comparison with Open and Laparoscopic Radical Prostatectomy

The initial results of the robotic approach were compared with the LRP and ORP (the "gold standard") in a prospective fashion. Despite an equal distribution of baseline characterisitcs such as age, BMI and tumor aggressiveness [5, 16], estimated blood loss, transfusion rates, postoperative pain score and post-operative length of stay were significantly lower with the robotic compared to the open approach (although the operative time was still longer with VIP [mean 4.8 vs. 2.3 h with ORP]). Likewise, when compared to LRP

Table 19.1 Odds ratio for important outcomes for laparoscopic, robotic and open radical prostatectomies performed at the Vattikuti Urology Institute in 2004

Variables	Open radical prostatectomy (reference values)	Laparoscopic radical prostatectomy (odds ratio)	Robotic prostatectomy (odds ratio)
Operating room time	163 min	1.51[a]	0.91[b]
Estimated blood loss	910 mL	0.42[a]	0.10[a]
Positive margins	23%	1	1
Complications	15%	0.67[a]	0.33[a,b]
Catheterization time	15.8 d	0.50[a]	0.44[a]
Hospital stay >24 h	100%	0.35[a]	0.07[a,b]
Postoperative pain score (0–10)	7	0.45[a]	0.45[a]
Median time to continence	160 days	1	0.28[a,b]
Median time to erection	440 days	NA[c]	0.4[a]
Median time to intercourse	>700 days	NA[c]	0.5[a]
Detectable prostate-specific antigen	15%	1	0.5

The reference values were those from open radical prostatectomy performed at our institution; odds ratio was the ratio of the observed to the reference value. Abbreviations: NA, not available

[a]$p < 0.05$ compared to open radical prostatectomy

[b]$p < 0.05$ compared to laparoscopic radical prostatectomy

[c]Most patients undergoing laparoscopic radical prostatectomy were not sexually active at baseline

performed by the French surgeons at Detroit, equipoise in terms of perioperative outcomes was quickly achieved (~20 cases) between VIP and LRP. The feasibility of establishing a minimally invasive training program, using a structured mentoring approach, was thus demonstrated, enhancing the ability of trained "open" surgeons to replicate the outcomes of experts in laparoscopic radical prostatectomy.

By the time nearly 1110 VIPs were performed, the robotic console time was 90–100 min, blood loss 50–250 mL and the majority (92%) of patients were discharged within 24 h. Importantly, by 6 months after surgery, ~85% of patients undergoing VIP were continent, compared to 60% after open RP, and >60% of men were able to have sexual intercourse (compared to ~30% with open RP) one year after surgery. Table 19.1 further highlights the comparative outcomes.

Technical Modifications in VIP: Raising the Bar

The widespread dissemination of prostate specific antigen (PSA) screening brought about a demographic shift in diagnosis of PCa: men were being diagnosed with less aggressive PCa and at an earlier age than before. While this translated into excellent oncological outcomes for men opting to undergo surgery, the importance of achieving optimal functional outcomes (urinary continence and erectile function) in young and healthy men became more pronounced. The technique for VIP evolved keeping the aim of "trifecta" in mind (i.e., maximizing continence, erectile function recovery and cancer control outcomes) [5–11]. As stated earlier, the technical details for each modification will not be discussed in this chapter; we will, however, present a synoptic report.

Cancer Control Outcomes

Robotic Prostatectomy: Exploring the Long Term Efficacy

When we started the robotics program, long-term RP series from high volume centers (such as Johns Hopkins and Washington University) had reported 10-year biochemical recurrence-free survival (BCRFS), metastases-free survival (MFS) and cancer-specific survival (CSS) of 68–74%, ~90% and 96–97%, respectively [17,

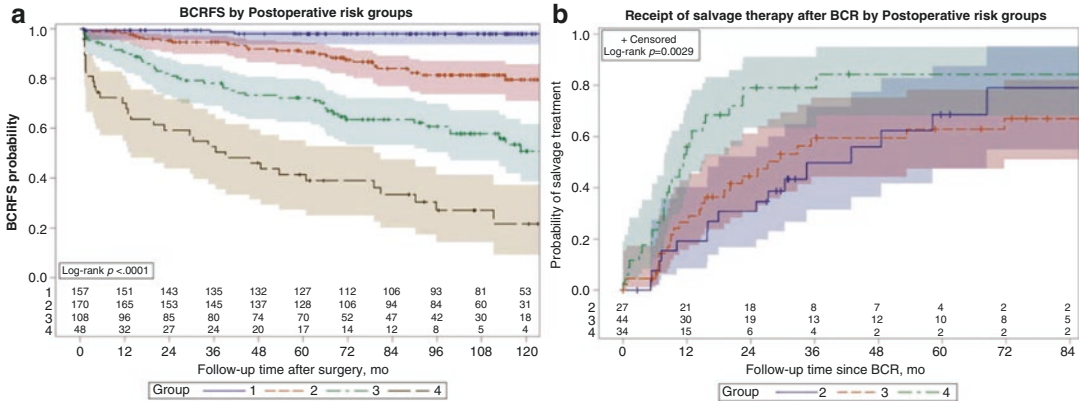


Fig. 19.1 Probability of biochemical recurrence free survival (BCRFS) (**a**) and receipt of salvage therapy (**b**) stratified by post-operative risk groups amongst 483 patients undergoing Vattikuti Institute Prostatectomy between 2003 and 2005 at Vattikuti Urology Institute. The lowest risk group corresponds to patients with pT2, Gleason 3 + 3, and negative margins ($n = 157$). Risk group 2 ($n = 170$) combines patients with pT2, Gleason 7, and also negative margins or pT2, Gleason 6, and positive margins. Risk group 3 ($n = 108$) combines (1) patients with pT2, Gleason >8, and negative margins; (2) patients also with pT2 but Gleason 3 + 4 and positive margins; and (3) patients with pT3–pT4, Gleason 3 + 4, independent of margin status. All patients in risk group 4 ($n = 48$) have primary Gleason >4. In addition, they present pT2 with positive margins or pT3–pT4. Reprinted from European Urology, 58(6), Menon M, Bhandari M, Gupta N, Lane Z, Peabody JO, Rogers CG, et al., Biochemical recurrence following robot-assisted radical prostatectomy: analysis of 1384 patients with a median 5-year follow-up, pp. 838–846, Copyright 2010, with permission from Elsevier

18]. Importantly, these results represented outcomes for men diagnosed predominantly in the pre-PSA screening era, and as such, included a greater proportion of men with more advanced disease compared to contemporary men diagnosed with PCa. For our first 1384 patients with median 5-year follow-up, the actuarial BCRFS was noted to be 86.6% and 81% at 5 and 7-year respectively, with a median time to BCR of 20.4 months [19]. Of note, this cohort of patients had moderately aggressive PCa: while 49.0% were D'Amico intermediate or high risk on biopsy, 60.9% had Gleason 7–10 disease, and 25.5% had >pT3 disease on final pathology. In 2014, we reported the outcomes of 483 men who underwent VIP between 2001 and 2003 and had at least 10-year follow-up [20]. Actuarial BCRFS, MFS, and CSS rates at 10 years were 73.1%, 97.5%, and 98.8%, respectively, which were comparable to outcomes from ORP [17, 18] and LRP series [21, 22]**.** D'Amico risk stratification [23] and pathological Gleason score, pathological stage and positive surgical margins were independent pre- and postoperative predictors of BCRFS, respectively. Importantly, to aid patient counseling, guide postoperative surveillance regimens and allow prognostication of oncological outcomes, we identified 4 novel postoperative risk groups, stratified by the likelihood of BCRFS and receipt of salvage therapy (Fig. 19.1a, b).

Isolated Internal Iliac Lymph Node Dissection for Low Risk Prostate Cancer

The extent and template of pelvic lymph node dissection (PLND) in patients with low risk PCa has been a matter of much debate [24]. In 2008, Schumacher and colleagues [25] showed that in 122 patients undergoing ORP with extended PLND and harboring node positive disease, 70% of all node positive patients had positive internal iliac nodes (either alone [21%] or in combination with other lymph nodes (LN) [49%]), while 4% of patients had only external iliac and obturator node involvement (which was the commonly proposed template of limited PLND [when performed] in patients with low risk PCa) (Fig. 19.2). We hypothesized that in patients with low risk

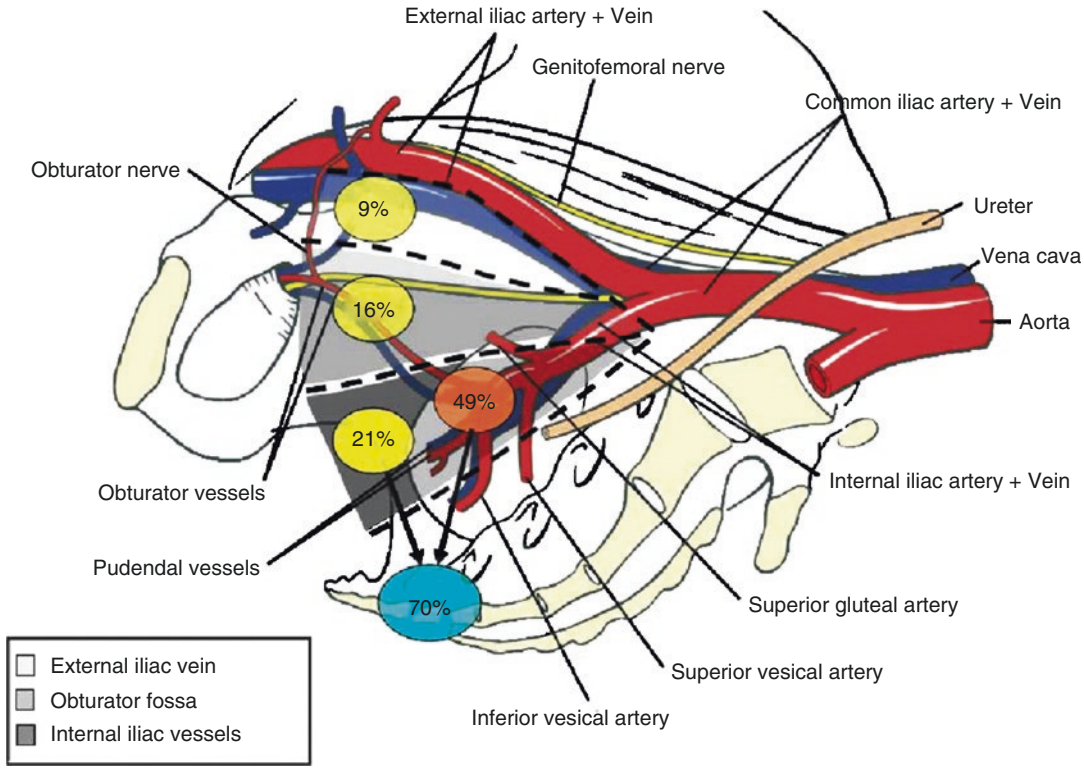
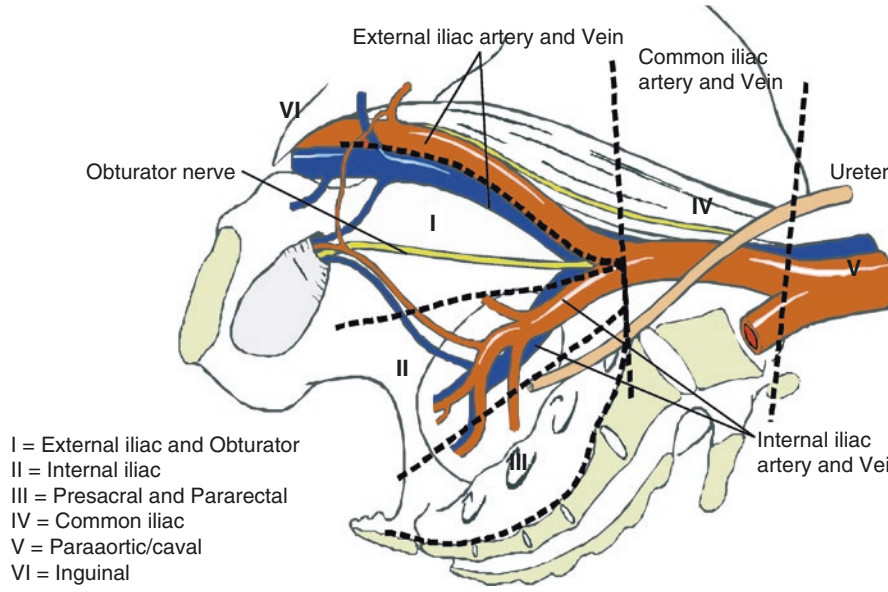


Fig. 19.2 Percentage of lymph node positivity in the external iliac, obturator and internal iliac regions of 122 pN1 patients undergoing extended pelvic lymph node dissection in the study by Schumacher et al. [25]. Reprinted from European Urology, 54, Schumacher MC, Burkhard FC, Thalmann GN, Fleischmann A, Studer UE, Good outcome for patients with few lymph node metastases after radical retropubic prostatectomy, pp. 344–52, Copyright 2008, with permission from Elsevier

disease (i.e., primary Gleason 3 on biopsy, PSA < 10 ng/mL and 0–1% Partin predicted probability of LN metastases [26]), performing limited internal iliac LN dissection (instead of limited external iliac/obturator LN dissection) would increase the likelihood of positive nodal yield. Based on the PLND template of Mattei et al. [27] (Fig. 19.3), outcomes of 1006 patients that underwent limited zone 1 dissection (external iliac and obturator regions), 90 undergoing limited zone 2 dissection (internal iliac), and 55 undergoing extended PLND (zone 1 and 2; external iliac, obturator and internal iliac) were compared [9]. Node positivity was significantly higher in patients with zone 2 vs zone 1 dissection (6.7% vs. 0.5%); further, in patients who underwent combined zone 1 and 2 dissection (with a node positivity rate 10.9%), 5 out of 6 patients had positive LN only in zone 2 (internal iliac region). Accordingly, from 2008 onwards, we modified our template of PLND for patients with low risk prostate cancer and 0–1% Partin-predicted probability of nodal disease from zone 1 to zone 2 dissection. On the other hand, patients with high risk/aggressive prostate cancer with Partin probability of LN involvement >5% still get an extended PLND [zone 1 and 2].

MORE: Modified Organ Retrieval and Examination

One of the major criticisms of the robotic approach (compared to open) has been the lack of tactile feedback for the operating surgeon. This is especially important in patients with high likelihood of harboring extra-prostatic disease: indeed, a systematic review [28] showed higher odds of



Boundaries of pelvic lymph node dissection (PLND) subdivided into different regions. "Limited" PLND removes tissue along the external iliac vein and from the obturator fossa corresponding to region I. "Extended" template PLND removes tissue along the major pelvic vessels (external iliac vein, obturator fossa and internal iliac artery and vein) corresponding to regions I and II.

Fig. 19.3 Zones of pelvic lymph node dissection (PLND) as suggested by Mattei et al. [27]. Traditional "limited" PLND included dissection of LN in external iliac and obturator regions (zone 1); the Menon-modified approach of limited PLND includes internal iliac bed (zone 2) only [9]. Extended PLND refers to removal of LNs along the external iliac, obturator and internal iliac regions (i.e., zones 1 and 2). Reprinted from European Urology, 53, Mattei A, Fuechsel FG, Bhatta Dhar N, Warncke SH, Thalmann GN, Krause T, et al., The template of the primary lymphatic landing sites of the prostate should be revisited: results of a multimodality mapping study, pp. 118–25, Copyright 2008, with permission from Elsevier

positive surgical margin (PSM) in patients with pT3a disease undergoing robot-assisted radical prostatectomy (RARP) compared to ORP. In 2012, utilizing the GelPOINT system (Applied Medical, Rancho Santa Margarita, CA, USA), we developed a technique for extraction of the resected prostate specimen for intraoperative examination (MORE, **M**odified **O**rgan **R**etrieval for **E**xamination)**.** MORE consists of a GelPOINT device inserted periumbilically. Following prostate excision, it is retrieved through the GelPOINT without undocking the robot, and examined bimanually on-table by the surgeon [29]. Lesions suspicious for PSM are sent for frozen-section analysis. Lymphadenectomy is performed while the biopsy specimens are assessed; if positive, more tissue may be removed from the pelvic bed to achieve negative margins. We prospectively compared 103 patients with pT3a disease who underwent MORE approach to a control group of 74 consecutive patients with pT3a after conventional VIP [30]. The PSM rate in the MORE group was 17.5% (18/103) compared to 36.5% (27/74) in the control group ($p = 0.004$); the odds ratio was 0.37 (CI: 0.18–0.74; $p = 0.005$). Out of 79 cases selected for targeted frozen section analyses, the site selected for frozen section biopsy matched the site of extra-prostatic extension at final pathology in 73.4% cases. There were no significant differences in operative times between the MORE and the control group (182.5 vs. 175.9 minutes, $p = 0.6$). While initially we performed MORE only in patients with a Partin table predicted probability of extracapsular extension >25%, we are offering it now to all our patients.

High Risk Prostate Cancer: Recent Insights from our Center

With the United States Preventive Services Task Force (USPSTF) 2012 guidelines recommending

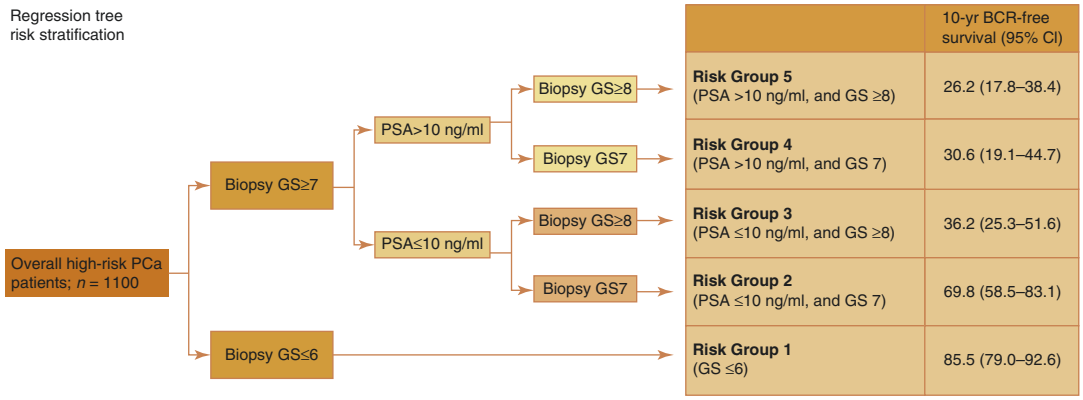


Fig. 19.4 A novel biochemical recurrence risk stratification regression tree, based on the data of 1100 D'Amico high-risk prostate cancer patients treated with robot-assisted radical prostatectomy (with and without lymph node dissection) between 2002 and 2013 at three tertiary care centers. *BCR* biochemical recurrence, *CI* confidence interval, *GS* Gleason score, *PCa* prostate cancer, *PSA* prostate-specific antigen. Reprinted from European Urology, 68, Abdollah F, Sood A, Sammon JD, Hsu L, Beyer B, Moschini M, et al., Long-term cancer control outcomes in patients with clinically high-risk prostate cancer treated with robot-assisted radical prostatectomy: results from a multi-institutional study of 1100 patients, pp. 497–505, Copyright 2015, with permission from Elsevier

against PSA screening [31], and increasing utilization of active surveillance in patients with clinically low risk disease [32], urologists are more likely to operate on patients presenting with clinically high risk PCa, alone or as a part of multimodality approach (combining radiation therapy and hormone therapy along with surgery). The D'Amico classification [23], one of the most commonly used preoperative tumor risk stratification systems, defines high risk disease as clinical stage T2c or higher, or PSA >20 ng/mL, or biopsy Gleason 8–10, potentially lumping a heterogeneous cohort of patients into one prognostic sub-group. Using multi-institutional data from our center (along with San Raffaele Hospital in Italy and Martini Clinic in Germany), Abdollah et al. [33] recently assessed long-term cancer control outcomes for 1100 clinically high-risk PCa patients undergoing RARP. BCR at 1-year, 5-years, and 10-years was 19.2%, 37.7%, and 49.6%, respectively. Furthermore, the authors utilized a regression-tree approach to stratify patients into five novel risk groups (based on patients' biopsy Gleason score and serum PSA levels), depending on the aggressiveness of the disease (Fig. 19.4). While the 10-year BCRFS and CRFS were 85.5% and 99.0% in risk group 1 (Gleason score ≤6), they were 26.2% and 55.0% in risk group 5 (PSA >10 ng/mL and Gleason score ≥8) (both $p < 0.001$). In a separate study, Abdollah et al. [34] developed a novel nomogram to predict favorable pathological outcomes (i.e., specimen-confined disease, pT2-T3a, node negative, and negative surgical margins) in clinically high-risk PCa patients undergoing RARP and identified PSA level, clinical stage, primary/secondary Gleason scores, and maximum percentage tumor quartiles as independent predictors. Both the nomogram [34] and the aforementioned novel risk groups [33] can be of great utility in preoperative counseling of patients with clinically high risk PCa, and in predicting their pathological outcomes and recurrence-free survival respectively. This can be of great aid in decision making for multimodality treatment.

Erectile Function Outcomes

Leveraging the Robot: Initial Attempts to Maximize Nerve Sparing

The male pelvis has a complex neuroanatomical structure, with the pelvic plexus supplying the parasympathetic and sympathetic fibers to the corpora cavernosa of the penis and mediating

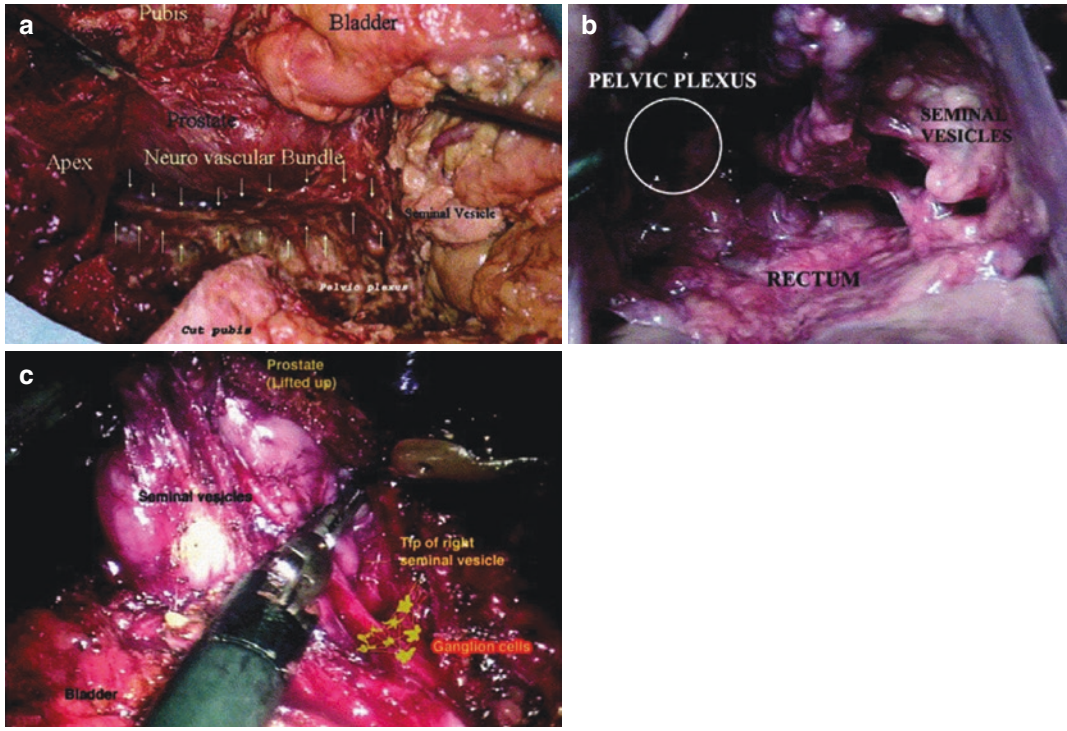


Fig. 19.5 (**a**) Anatomic dissection showing exact course of neurovascular bundles, pelvic plexus and its relation with seminal vesicles and prostate. The neurovascular bundle is clearly visible once the periprostatic fascia is removed. (**b**) Anatomic dissection from the posterior view (looking through pouch of Douglas) showing location of the seminal vesicles, pelvic plexus and rectum. (**c**) Intraoperative picture showing location of the ganglions in relation to the seminal vesicles. Reprinted from European Urology, 43, Tewari A, Peabody JO, Fischer M, Sarle R, Vallancien G, Delmas V, et al., pp. 444–54, Copyright 2003, with permission from Elsevier

penile erection. Walsh and Donker had elucidated the neuroanatomical correlations in their seminal studies nearly two decades earlier. In an effort to further trace the neural connections from the pelvis to the penis using the excellent visualization with the robotic approach, Tewari and members of the VIP team [6] undertook detailed cadaveric dissections using a combination of laparoscopic equipment, robotic magnification and open surgical dissection (Figs. 19.5 and 19.6). Based on the knowledge obtained from these dissections, a series of important maneuvers were described to maximize nerve sparing at each step of the surgery (summarized in Table 19.2).

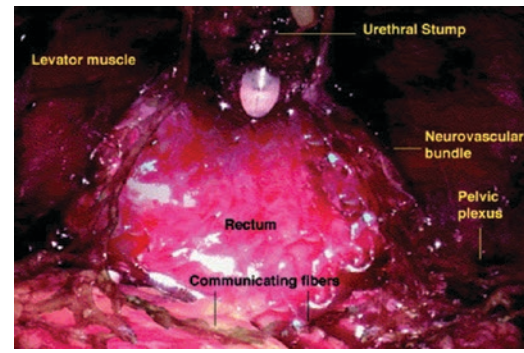


Fig. 19.6 Computer enhanced location of the neurovascular bundles following radical prostatectomy. Reprinted from European Urology, 43, Tewari A, Peabody JO, Fischer M, Sarle R, Vallancien G, Delmas V, et al., pp. 444–54, Copyright 2003, with permission from Elsevier

Table 19.2 Key steps: neurovascular structures at risk and critical maneuvers to maximize nerve sparing during radical prostatectomy[a]

Step of operation	Neurovascular structure at risk	Critical maneuvers
Retrovesical dissection	Pelvic vesical and prostatic plexus	No dissection lateral to the seminal vesicles, and no excessive use of cautery or clips.
Anterior dissection	If the dissection is carried too far laterally, the nerves may be injured	Avoid dissecting too deep in the groove between prostate and rectum.
Control of dorsal venous complex	Autonomic nerve fibers may lie in close proximity of the apex.	This is an important step due to its effect on hemostasis and visualization. Poor visualization is detrimental for nerve sparing.
Anterior bladder neck transection	None	None.
Posterior bladder neck transection	Laterally pelvic, vesical and prostatic plexus are located deep to the bladder neck	Dissection under vision and with meticulous hemostasis. Avoid excessive incision lateral to the bladder neck.
Seminal vesicle dissection	Pelvic, vesical and prostatic plexus	No dissection lateral to the seminal vesicles, and no excessive use of monopolar cautery. Use accurate control (clips or bipolar cautery).
Control of pedicles	Vesical and prostatic plexus and proximal part of neurovascular bundles	Meticulous dissection to expose the blood supply and individually control them using clips applied or bipolar current close to the prostate. Avoid monopolar cautery.
Lateral dissection	Neurovascular bundles	Approach through the triangle and leave a thick sheath of lateral pelvic fascia
Urethral transection	Neurovascular bundles	Transection under vision.
Anastomosis	Neurovascular bundles	Anastomosis should be performed under vision without any pool of blood. Be careful for the posterior stitches, particularly at 5 and 7 o'clock.

[a]Adapted from European Urology, 43, Tewari A, Peabody JO, Fischer M, Sarle R, Vallancien G, Delmas V, et al., pp. 444–54, Copyright 2003, with permission from Elsevier

Veil of Aphrodite

While these technical modifications allowed us to enhance the standard nerve sparing approach (as described by Walsh and Lepor [2]), around the same time, a number of researchers postulated that the nerve fibers supplying the corpora cavernosa do not always lie in the traditionally described posterolateral neurovascular bundle: Kiyoshima, Takenaka and Lunacek [35–37] suggested that instead 'periprostatic' nerve fibers are distributed over the surface of the prostate, anterolaterally as well as posterolaterally. Costello et al. [38] performed immunohistochemical staining of periprostatic nerve fibers and observed that while the relative proportion of parasympathetic nerve fibers on the anterior and anterolateral surface of the prostate was 14.3%, it changed to 23.1% at the level of the prostatic apex, suggesting the possibility that some of the parasympathetic fibers 'swung' anteriorly along their cephalo-caudal course over the surface of the prostate. Additionally, Kiyoshima [35] noted that varying amounts of adipose tissue was interposed between the prostatic capsule and prostatic fascia in nearly half (48%) of the cases. In our own anatomic study [6], we observed the existence of the multilayered periprostatic fascia, the most prominent of which were the prostatic fascia medially and the lateral pelvic fascia laterally. While the main neuro-vascular bundle was located posterolateral to the prostate (enclosed in

the triangular space formed by these two layers and the Denonvilliers' fascia), multiple smaller nerves ramify within the layers of periprostatic fascia along the lateral surface of the prostate (Fig. 19.7). Intrigued by all these findings, we hypothesized [39] that 'high anterior release' (HAR) of the prostatic fascia off the prostatic capsule and carrying out an intrafascial (i.e., below the plane of prostatic fascia [Fig. 19.8]) dissection would allow preservation of these smaller periprostatic fibers (in addition to the traditional neurovascular bundles). The preserved fascial layers, along with the interspersed nerve fibers, was eponymously termed "Veil of Aphrodite" (Fig. 19.9). On histological examination of prostate specimens after standard and Veil nerve sparing surgeries [40], a rim of lateral prostatic fascia was present in all patients undergoing standard approach, with a mean margin clearance of 1.4 mm and mean nerve bundle count of 10 in the lateral prostatic fascia. In contradistinction, the mean margin clearance and nerve bundle count in the Veil group was 0.3 mm and 2, respectively (both $p < 0.001$) (Fig. 19.10). When we compared the outcomes of Veil nerve sparing to the standard nerve sparing surgery in preoperatively potent men (Sexual Health Inventory for Men [SHIM] score >21), 97% (34/35) patients in the Veil group were able to have erection sufficient for intercourse at 12 months, compared to 74% (17/23) patients in the standard group [41]. Subsequently, Myers [42] and later Walsh himself [43] reported potency rates of 67–70% (defined as return to baseline Sexual Health Inventory for Men [SHIM] score >22) at one year with the HAR of levator fascia, without compromising the surgical margins of the resected tumor (although in contrast to Menon et al. [39, 41], the plane of dissection adopted by these authors was between the prostatic and levator ani fascia).

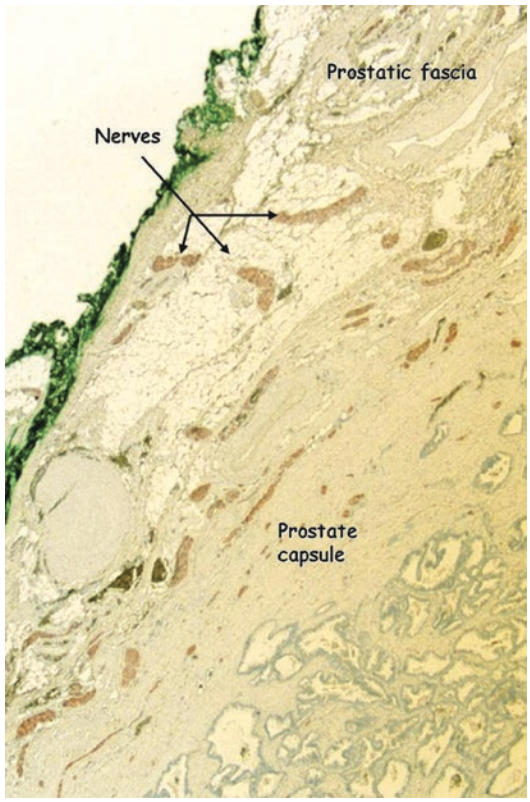


Fig. 19.7 Photomicrograph showing prostatic fascia and nerve elements. Nerves stained with S-100 nerve stain. Reprinted from Urology, 66, Kaul S, Bhandari A, Hemal A, Savera A, Shrivastava A, Menon M, Robotic radical prostatectomy with preservation of the prostatic fascia: a feasibility study, pp 1261–5, Copyright 2005, with permission from Elsevier

The benefit of Veil nerve sparing consistently seen over the years and after performing nearly 2600 VIPs: rates of erection sufficient for intercourse in preoperatively potent men undergoing bilateral veil nerve sparing were 70% and 100% at 12 and 48-month follow-up, respectively (with or without use of medications or erectile aids) [10]. Amongst all-comers (regardless of preoperative potency status), patients undergoing Veil-nerve sparing surgery had superior erectile function outcomes compared to patients undergoing standard nerve sparing surgery (Fig. 19.11).

The "Super Veil" Preservation

While the recovery of potency after Veil nerve sparing was encouraging, nonetheless, we felt there was still scope for further improving outcomes. Eichelberg et al. [44] performed permanent sections of 31 prostate specimens (in patients undergoing non-nerve sparing RP) at the level of apex, mid and base, and observed that 21.5–28.5% of nerve fibers were dispersed

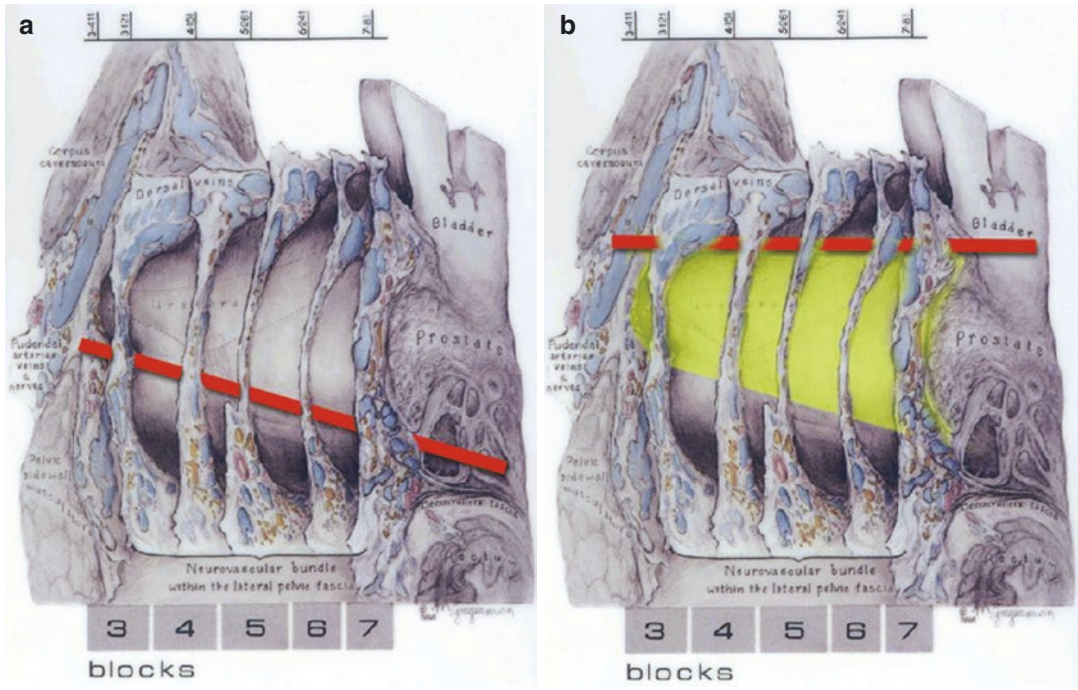


Fig. 19.8 (**a**) Plane of dissection for standard nerve sparing. (**b**) Plane of dissection for "veil of Aphrodite." Yellow area depicts prostatic fascia, which is preserved. Reprinted from Urology, 66, Kaul S, Bhandari A, Hemal A, Savera A, Shrivastava A, Menon M, Robotic radical prostatectomy with preservation of the prostatic fascia: a feasibility study, pp 1261–5, Copyright 2005, with permission from Elsevier

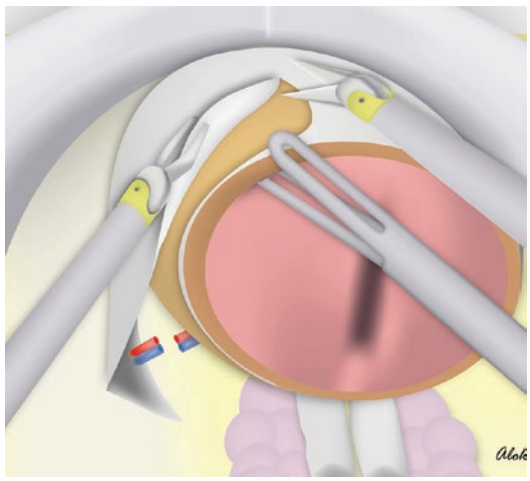


Fig. 19.9 Plane of incision and dissection for Veil of Aphrodite preserving surgery. Reprinted from European Urology, 51, Menon M, Shrivastava A, Kaul S, Badani KK, Fumo M, Bhandari M, et al., Vattikuti Institute prostatectomy: contemporary technique and analysis of results, pp. 648–57, Copyright 2007, with permission from Elsevier

over the anterolateral surface of the prostate, with about 10% lying between the 11 o' clock and 1 o' clock positions. We hypothesized that preservation of these additional fibers (the "Super-Veil" nerve sparing) [9] may further aid in recovery of potency. However, this plane of dissection was challenging: the tissue in the anterior region of the prostate tends to be more fibromuscular than the lateral prostate, and the prostatic fascia becomes adherent to the puboprostatic ligaments anteriorly, which overlies the dorsal venous complex (DVC). To minimize the risk of inadvertent PSM and bleeding from the DVC, we restricted the performance of Super Veil sparing in appropriately selected candidates (preoperative SHIM score >17, focal Gleason 6 disease and PSA < 4 ng/mL) who opted for surgery and maximal nerve preservation. At a median follow-up of 2 years, 92% of patients undergoing Super Veil approach were able to have erections sufficient for intercourse at a median follow-up of

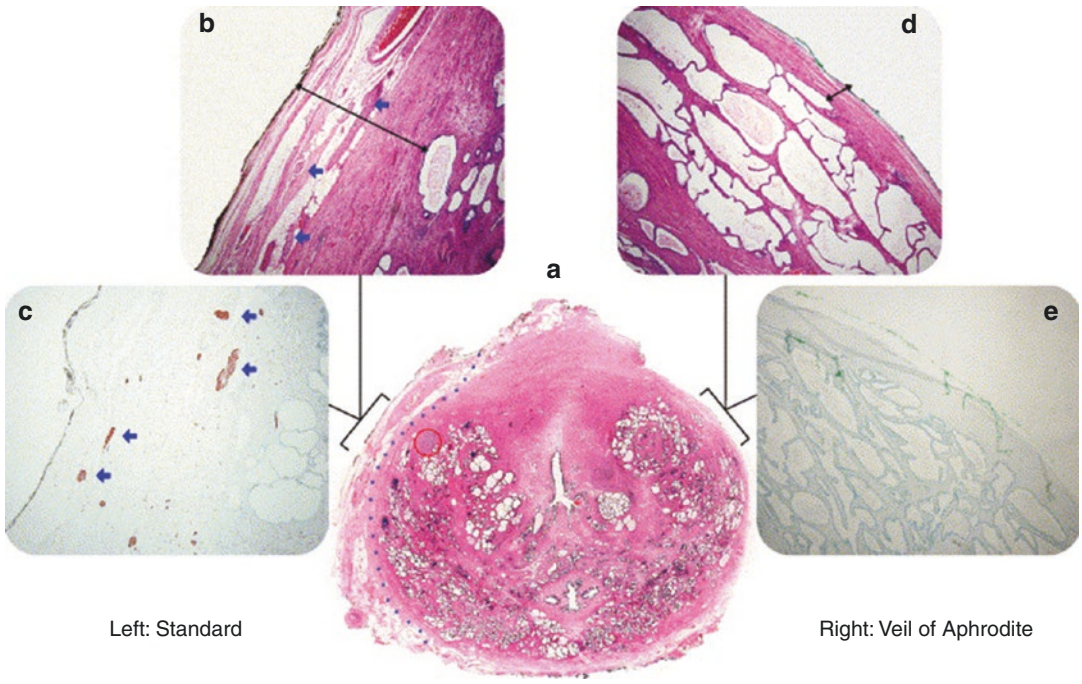


Fig. 19.10 Whole-mount section of prostate with standard technique (ST) on the left and Veil of Aphrodite technique (VT) on the right. (**a**) Entire whole-mount, hematoxylin and eosin (H&E). Note the tumor (red circle), presence of lateral prostatic fascia (LPF) on the left, and its absence on the right. For comparison, blue dotted line represents the plane of excision for VT, as has been done on the right. (**b**, H&E; **c**, S100; ×40). Matching area of left AL zone. Note the LPF with nerve bundles (blue arrows). Margin clearance (black arrow line) is 1.6 mm. (**d**, H&E; **e**, S100; ×40). Matching area of right AL zone. Note the absence of LPF and periprostatic nerve bundles. Margin clearance (black arrow line) is 0.3 mm. Reprinted from European Urology, 49, Savera AT, Kaul S, Badani K, Stark AT, Shah NL, Menon M, Robotic radical prostatectomy with the "Veil of Aphrodite" technique: histologic evidence of enhanced nerve sparing, 1065–73, Copyright 2006, with permission from Elsevier

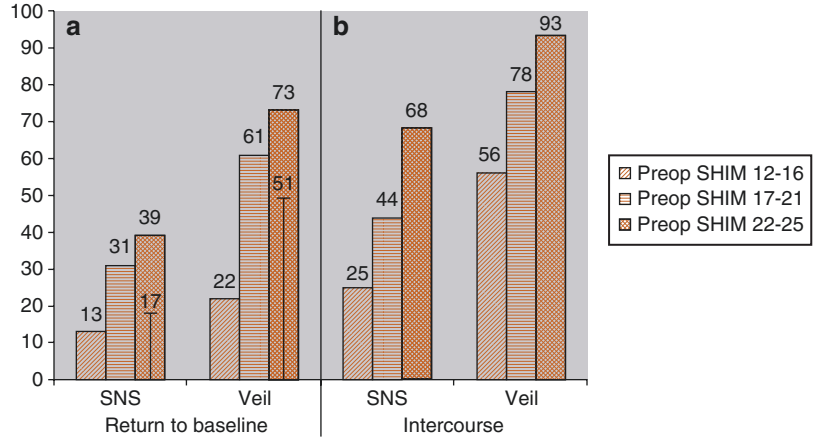


Fig. 19.11 Postoperative return to (**a**) baseline Sexual Health Inventory for Men (SHIM) score and (**b**) erection sufficient for penetrative intercourse in patients with various levels of preoperative erectile dysfunction (the line inside the bars represents the percentage of patients not receiving postoperative phosphodiesterase 5 inhibitors). Reprinted from European Urology, 51, Menon M, Shrivastava A, Kaul S, Badani KK, Fumo M, Bhandari M, et al., Vattikuti Institute prostatectomy: contemporary technique and analysis of results, pp. 648–57, Copyright 2007, with permission from Elsevier

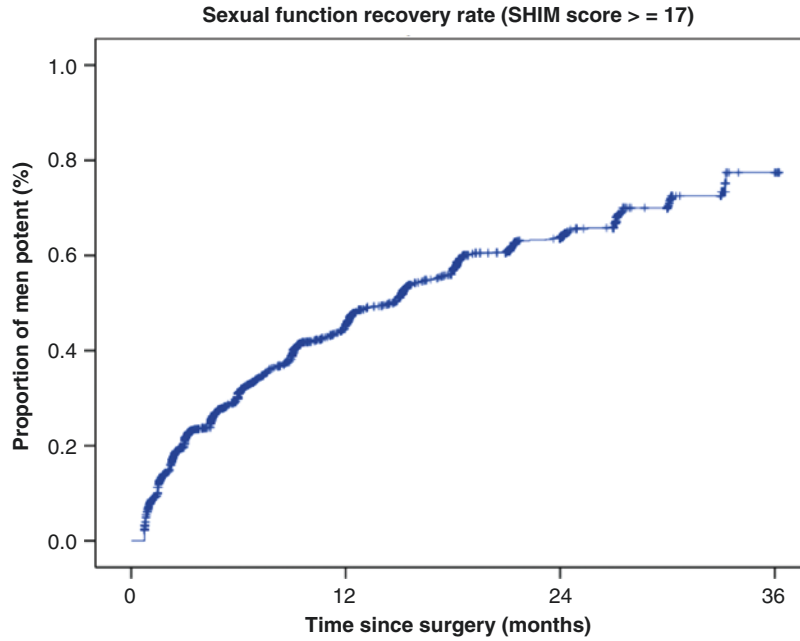


Fig. 19.12 Postoperative erectile function recovery (defined as Sexual Health Inventory for Men [SHIM] score of 17 or above) over a 3-year follow-up period amongst 3458 preoperatively potent (defined as preoperative SHIM score of 17 or higher) patients undergoing unilateral or bilateral nerve sparing VIP at our center between 2001 and 2012

2 years; 45% of patients had a SHIM of 18–25 [9]. This benefit was however, minimal, compared to our historic rates of potency recovery with the Veil approach, but patients undergoing Super Veil were able to have intercourse earlier than Veil patients (possibly owing to the minimal neuropraxic and thermal damage as the dissection is performed further away from the primary neurovascular bundle than the Veil procedure).

Overall, the sexual function recovery rate for 3458 preoperatively potent (SHIM score >=17) patients undergoing unilateral or bilateral nerve sparing VIP at our center between 2001 and 2012 are presented in Fig. 19.12, with nearly 80% of patients recovering their preoperative sexual function.

Improving Erectile Function: What Didn't Work?

Over the course of evolution of the VIP procedure, we tried a number of different interventions/technical modifications to enhance the recovery of postoperative erectile dysfunction, and Table 19.3 summarizes these approaches. Unfortunately, none of them showed a consistent and reproducible impact on hastening return to normal erectile function.

Urinary Continence

One of the most important determinants of successful functional recovery post RP is recovery of urinary continence. Prevalence of significant urinary incontinence (symptomatic or requiring a surgical procedure for correction) post ORP was variable, with rates up to 20% being reported using nationwide SEER-Medicare data [15]. Using the robotic approach, we managed to improve upon that substantially: amongst our first 2600 patients undergoing VIP [10], the rate of social continence (defined as need for no pads or one safety liner per day) was 95.2% at 12-month follow-up, and 84% of patients had regained total urinary control (no urinary leakage). The median time to recovery of total continence was 4 weeks, significantly shorter than what had been reported from centers of excellence for ORP [45, 46].

Table 19.3 Brief overview of attempted technical modifications aimed at expediting return of erectile function, over a fifteen-year period (2001–2015) at our center

Year	Technique	Intent
2002–05	Athermal technique	No decrease in ED
2004	Oral rhokinase inhibitors (Fasudil)	Decreased inflammatory edema: faster recovery of potency after RP.
2005–06	Remote ischemic preconditioning	Decreased ischemic damage to penile NVB: better potency after RP.
2008	Intra-pelvic ketorolac	Decreased inflammatory edema: faster recovery of potency after RP.
2008	EndoPat testing	Assess endothelial dysfunction and potential recovery of potency
2011–12	Pelvic hypothermia	Cooling the nerves: decreased ischemic /inflammatory damage
2012–14	Intraoperative ICI	Presence of response: objective proof of nerve sparing: better potency after RP?
2012–14	Intraoperative Doppler of NVB	Presence of flow: objective proof of NVB preservation: better potency after RP?

Abbreviations: *ED* erectile dysfunction, *RP* radical prostatectomy, *NVB* neurovascular bundle, *ICI* intracavernosal injection

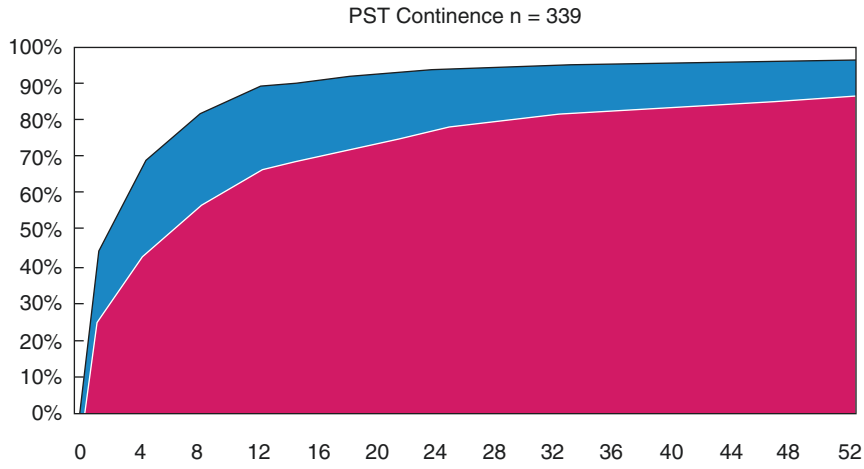
Placement of Percutaneous Suprapubic Tube

A urethral catheter is associated with significant post-operative morbidity after RP: in a study by Lepor et al. [47], 45% of men reported moderate to severe bother with an indwelling urethral catheter. In 2008, we objectively assessed patient discomfort in 202 men undergoing VIP followed by a percutaneous suprapubic tube (PST) placed robotically, to that of 50 patients with urethral catheter. The details of PST placement have been described elsewhere [48, 49]; briefly, after confirming the integrity of urethro-vesical anastomosis, a 14 Fr PST is placed through the anterior abdominal wall, anchored into the bladder through the limbs of a horizontal mattress suture (which passes through the full thickness of the bladder well and the anterior abdominal wall), and finally the external suture is tied to the skin over a sterile plastic button to cinch the bladder to the anterior abdominal wall. Patients in the PST group had significantly decreased catheter-related discomfort (as measured on the Faces Pain Score-Revised scale) than their urethral catheter counterparts on post-operative days 2 and 6 (median score 2 vs. 4, and 0 vs. 2 respectively, both $p < 0.001$). One patient in the PST group needed anticholinergic medication, compared to 4 in the urethral catheter group ($p < 0.001$).

On long-term follow-up of 339 patients undergoing drainage with PST [49], an encouraging rate of recovery of urinary continence was observed (Fig. 19.13): 293 patients (86.4%) had total urinary control and only nine (2.7%) required >1 pad/day over a mean follow-up of 1-year. The median time to 0–1 pad/day was 2 weeks (interquartile range [IQR] 0–6); median time to total control was 6 weeks (IQR 1–22). 15 patients (4.4%) had a procedure-specific complication, of which 13 were minor (Clavien Class I/II 3.8%); one patient had a bladder neck contracture.

Retzius-Sparing Robotic Prostatectomy

Galfano et al... [50] demonstrated the feasibility of a 'posterior' approach to robotic prostatectomy: incising the peritoneal cul-de-sac and accessing the prostate via the rectovesical pouch allowed the preservation of all the anterior structures in the space of Retizus (like puboprostatic/pubourethral ligaments) and the bladder neck, both of which may play a key role in recovery of urinary continence. In an updated report, Galfano and Bocciardi [51] indeed showed excellent continence outcomes in Italian patients undergoing robotic prostatectomy: nearly 90% of patients were continent (0–1 pad/day) one week after



	0	1	4	8	12	24	32	52
0-1 pad/day, %	0	44.2	68.7	82.6	90.0	93.8	95.6	97.3
Total Urinary Control, %	0	25.4	43.1	57.2	67.0	77.9	82.0	86.4

Weeks

Fig. 19.13 Recovery of urinary continence at 1-year follow-up in 339 patients undergoing VIP with placement of percutaneous suprapubic tube (PST). Reprinted from Sammon JD, Trinh QD, Sukumar S, Diaz M, Simone A, Kaul S, et al. Long-term follow-up of patients undergoing percutaneous suprapubic tube drainage after robot-assisted radical prostatectomy (RARP). BJU Int. 2012;110:580–5. With permission from John Wiley and Sons

catheter removal (or two weeks after surgery), without adversely affecting the surgical margin or potency rates. Rha et al [52] noted similar continence rates 4 weeks after Retzius sparing robotic prostatectomy in 50 Korean patients. None of the previous reports on functional outcomes of RP had described such a high rate of continence recovery. In an effort to confirm these findings in American patients, we performed a prospective non-randomized study [53]: between July 2014 and December 2014, 40 patients underwent Retzius sparing prostatectomy (RSP), while 41 underwent traditional Vattikuti Institute Prostatectomy (VIP). Key differences in the two cohorts are highlighted in Table 19.4.

Post-operatively, 95% patients undergoing RSP were continent (defined as 0–1 pad/day) by 4 weeks, compared to 61% undergoing VIP; the median time to continence recovery was 12 days vs. 15 days respectively (log rank p value<0.001). Median pad weights (as measured by 24-h pad test) were 0 gm vs. ~60 gm at 2 weeks postoperatively, and 0 gm vs. 15 gm at 4 weeks, in RSP vs. VIP groups, respectively (both $p < 0.001$). Retzius sparing approach was a significant predictor of continence recovery, after controlling for the relevant preoperative covariates and degree of nerve sparing [53]. There were no significant differences in perioperative complications, surgical margins or recovery of potency between the two groups. We have recently concluded the recruitment of patient in a randomized controlled trial comparing the two techniques, the results of which shall further elucidate our findings and help to explore the beneficial impact of RSP on continence recovery.

Perioperative Safety

Keeping in mind the primacy of the principle of *primum non-nocere* (first do no harm), we maintained special focus on ensuring the safety of

Table 19.4 Key preoperative and perioperative differences in 81 patients undergoing Vattikuti Institute prostatectomy (VIP) or Retzius sparing prostatectomy (RSP) between July and December 2014 at Vattikuti Urology Institute

Characteristic	Overall (n = 81)	VIP (n = 40)	RSP (n = 41)	p-value
Age (years); median (IQR)	64 (58–59)	66.5 (59.3–71.0)	62.0 (54.5–67.0)	**0.03**
BMI (kg/m^2); median (IQR)	28.9 (25.3–31.3)	29.2 (27.1–33.2)	28.0 (24.7–31.0)	**0.049**
ASA; n (%)				
2	49 (60.5)	20 (50.0)	29 (70.7)	0.06
3	32 (39.5)	20 (50.0)	12 (29.3)	
D'Amico risk group; n (%)				
Low	16 (19.8)	4 (10)	12 (29.3)	**0.01**
Intermediate	51 (63.0)	25 (62.5)	26 (63.4)	
High	14 (17.3)	11 (27.5)	3 (7.3)	
Pelvic lymph node dissection (PLND); n (%)				
No PLND	10 (12.3)	1 (2.5)	9 (22.0)	0.025
Limited PLND	55 (67.9)	29 (72.5)	26 (63.4)	
Extended PLND	16 (19.8)	10 (25)	6 (14.6)	
Nerve sparing; n (%)				
Veil	56 (69.1)	17 (42.5)	39 (97.5)	<0.001
Standard excision	20 (24.7)	20 (50.0)	0 (0)	
Wide excision	4 (4.9)	3 (7.5)	1 (2.5)	

Abbreviations: *IQR* interquartile range

our patients undergoing VIP since the inception of the robotics program at VUI. Using a strict application of standardized reporting criteria [54–56], we analyzed peri- and postoperative complications (over a median follow-up of 2 years) in 3317 patients undergoing VIP between 2005 and 2009 from an intensive review of multiple datasets (including our prospective prostate cancer database, claims data, and electronic medical and institutional morbidity and mortality records) [57]. The overall complication rate was 9.8% (medical 2.4%; surgical 8.7%). Minor (Clavien 1–2) and major (Clavien 3–5) complications were 7.3 and 3.8% respectively. Majority (81.3%) of complications occurred within 30 days of surgery, and nearly 70% of them were treated conservatively (including in-office dilatation). The most common medical complications were ileus (n = 20, 0.6%), while the most common surgical complications were lymphovascular (n = 77, 2.3%) and urine leak/urinoma (n = 34, 1%). There were a total of 68 (2%) reoperations (most commonly post-discharge, for bladder neck contracture), 115 (3.5%) readmissions (most commonly for lymphocele or urine leak/urinoma) and 60 (1.8%) emergency room visits not requiring readmissions (most commonly due to tube malfunction). Importantly, we adhered to all the 10 Martin Donat criteria [55, 56] in identifying complications; only two prior reports on RP [58, 59] (one of which was on robot-assisted RP [58]) had examined complications with such rigor. Rabbani et al. [59] examined 3458 patients undergoing ORP and noted a much higher rate of overall complications (27.5%) over a median follow-up of 3 years. As such, we can safely conclude that in our hands, robotic prostatectomy continues to be a safe procedure.

Conclusion

A brief tabular description of salient changes in technique are highlighted in the Table 19.5 [60]. As of 2016, surgeons at VUI have a combined experience of performing >10,000 robotic urologic surgeries, the majority of which have been robotic prostatectomies. Over the course of last 15 years, the technique and approach for Vattikuti Institute Prostatectomy has undergone many modifications, each of which were aimed at improving the outcomes of our patients.

Table 19.5 Technical changes in Vattikuti Institute Prostatectomy over the years[a]

Year	Technique	Benefit
2001	Initial approach to bladder neck	Decrease operating time
2002	Running anastomosis	Decrease leak, and stricture
2002	Avoid monopolar cautery after seminal vesicle transection	Not evident
2003	"Veil" nerve-sparing	Improve post-operative erectile function
2004	Anterior traction on the bladder to identify bladder neck	Easier transference of skill
2004	Delayed ligation of the dorsal venous complex	More precise urethral transection, decrease positive apical margins
2004	Not opening the endopelvic fascia	Earlier recovery of urinary continence
2007	Double-layer anastomosis (Posterior reconstruction of the rhabdosphincter: "Rocco" stitch)	Unchanged continence, decrease urinary leak
2008	Use of percutaneous suprapubic tube instead of urinary catheter	Decrease patient discomfort, and earlier recovery of urinary continence
2008	Primary hypogastric node dissection for low-intermediate risk disease	Increased node positivity
2010	Barbed anastomotic suture	Decrease anastomotic time
2012	Modified Organ Retrieval for Examination (MORE) using GelPoint access	Bimanual palpation and frozen section biopsies to assess surgical margins
2015	Retzius sparing prostatectomy with bladder neck preservation	Faster recovery of urinary continence

[a]Adapted from Development of the Vattikuti Institute Prostatectomy: Historical Perspective and Technical Nuances, 2011, Piyush K. Agarwal. With permission of Springer

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20

Nerve Sparing Robot-Assisted Radical Prostatectomy: Assessment of Clinical and Technical Factors Impacting Recovery of Sexual Function

Kamaljot S. Kaler, Simone Vernez, Douglas Skarecky, and Thomas E. Ahlering

Abstract

In this chapter we discuss cavernous neuroanatomy, pathophysiological mechanisms of nerve injury, and strategies to minimize damage. We summarize our surgical technique for cautery-free robotic prostatectomy with an emphasis on minimally invasive traction neurovascular bundle dissection and report on potency outcomes.

Keywords

RARP · Robotic prostatectomy · Prostate cancer · Nerve sparing · Sexual function

Introduction

The anatomical technique for nerve-sparing radical retropubic prostatectomy and post-operative effect on erectile function were first described by Lepor and Walsh in 1983 [1]. Nearly two decades later technology introduced the possibility of a relatively bloodless surgical field and dramatically improved visualization via laparoscopic radical prostatectomy popularized by Guilloneau, Vallencien, and Abbou and subsequently robotic-assisted radical prostatectomy (RARP) popularized by Menon and indeed many of the authors of this book [2, 3]. While early emphasis was placed on proper anatomic dissection of the neurovascular bundle (NVB), more recently, the avoidance of "trauma" to the NVB has surfaced as an important factor. Evidence suggests that trauma to the NVB is as problematic as preservation [4, 5]. Some degree of injury to the NVB occurs in essentially all cases requiring weeks to months to years for recovery. The delay happens as a consequence of surgeon skill and patient resistance/recovery to injury due to baseline health status and age. In this chapter we will examine anatomic principles of cavernous nerve preservation, pathophysiology of nerve injury, athermal and minimal traction techniques for nerve preservation during RARP, and potency outcomes.

Cavernous Neuroanatomy

Walsh and Donker [6] described the tortuous path of the parasympathetic nerves that run from the pelvic plexus past the seminal vesicles and then along the posterolateral aspect of the prostate between the true capsule and the lateral prostatic

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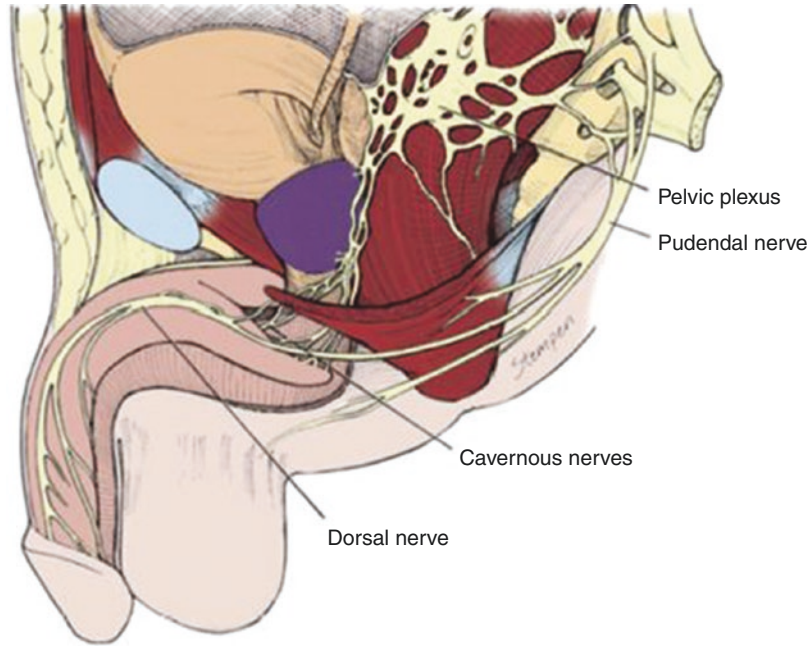

Fig. 20.1 Supralevator and infra-levator neural pathways of the cavernous nerves. This figure was published in Campbell-Walsh Urology, 9th ed., Walsh PC, Partin AW, Anatomic radical retropubic prostatectomy, Copyright Elsevier 2007

fascia (the supra-levator pathway); the nerves continue on just posterior and lateral to the urethra where they pierce the urogenital diaphragm and continue on below the pubic bone (the so-called "infra-levator" pathway) where there are delicate neural interconnections at the penile hilum between the cavernous and dorsal nerves (Fig. 20.1) [7, 8].

Recently, attention has been given to the network of ganglia and pre and post-ganglionic nerves coursing along with the CN surrounding the rectum, prostate and seminal vesicles.

If one considers the typical course of recovery of erectile function following RP, the two years typically required for recovery is consistent with long established neuroanatomical teachings. The parasympathetic nervous system and specifically the parasympathetic cavernous nerve is characterized by a long pre-ganglionic nerve that is always myelinated and leaves the spinal cord (S2–S4) and travels to the penis where it enters a 2nd ganglion in the wall of corporal bodies and then short (2–3 mms in length) post ganglionic nerves that complete the innervation (Fig. 20.2) [9]. Hence, if during the dissection of the NVB along the edge of the prostate a recoverable injury such as traction or stretch occurs, the nerve should undergo Wallerian degeneration and then regeneration and recovery. Recently some findings have suggested a link to recovery of sexual function to the number of ganglion along the wall of the rectum or SVs in opposition to classical neuroanatomic and physiologic teachings [10–12].

Along classical teachings, in 2005, Costello and associates reported a detailed description of the plexus of nerves running within the NVB based upon a series of elegant micro-dissections in human cadavers [13]. They found multiple nerve branches (6–16 in number) that emanated from the pelvic plexus and spread significantly, with up to 3 cm separating the anterior and posterior nerve fibers, much like the findings of Takenaka and colleagues [14]. Importantly, they found in all 24 dissections, the NVB ran 0.5–2 cm inferior to the tip of the seminal vesicle. Similar to Menon, Costello noted that the NVB courses along the posterolateral border of the prostate within the bounds of lateral pelvic fascia, the pararectal fascia, and Denonvilliers' fascia (Fig. 20.3) [13]. However, in distinction to Menon and associates, they feel that the nerves located within the Veil of Aphrodite innervate the prostate only. They also noted branches to the levator ani and anterior rectum. Similar to Takenaka, Costello found that the nerves converge at the mid-prostate, forming a more condensed bundle, and

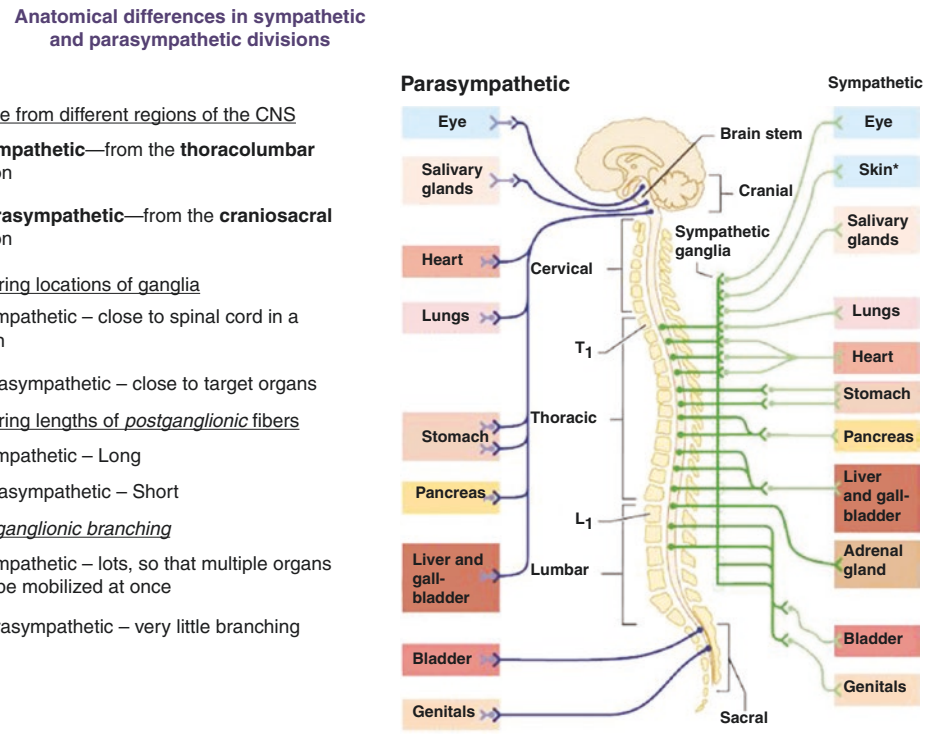

Fig. 20.2 Anatomical differences between parasympathetic and sympathetic divisions. This figure was published in Campbell-Walsh Urology, 9th ed., Walsh PC, Partin AW, Anatomic radical retropubic prostatectomy, Copyright Elsevier 2007

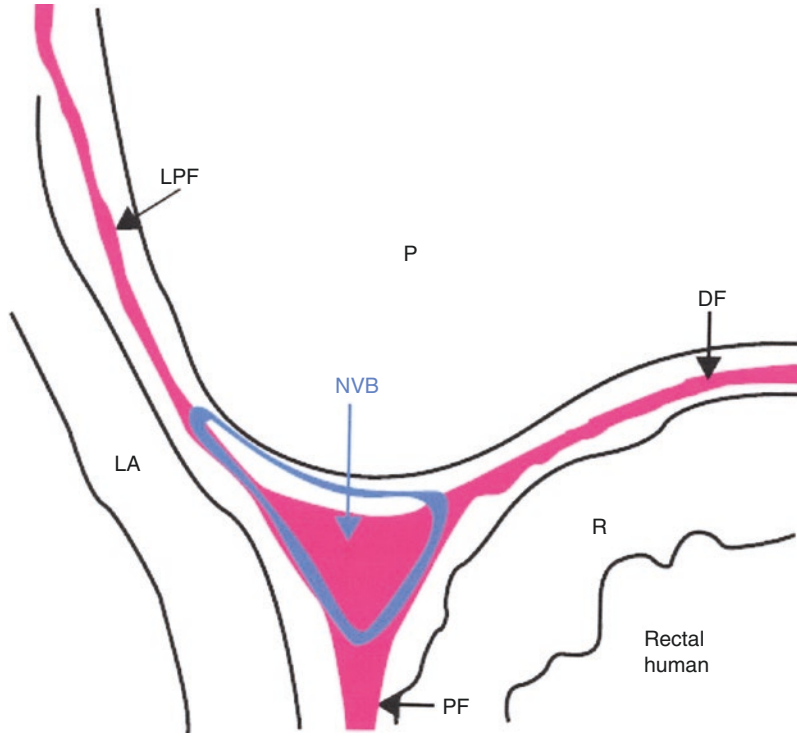

Fig. 20.3 Position of the NVB and its relationship to the prostate (P), rectum (R), and fascial layers. The widening Denonvilliers' fascia (DF) laterally fuses with the lateral pelvic fascia (LPF) and pararectal fascia (PF). The posterior and lateral divisions of the NVB run within these fibrous leaves. Reprinted from Costello AJ, Brooks M, Cole OJ. Anatomical studies of the neurovascular bundle and cavernosal nerves. BJU Int 2004;94:1071. With permission from John Wiley and Sons

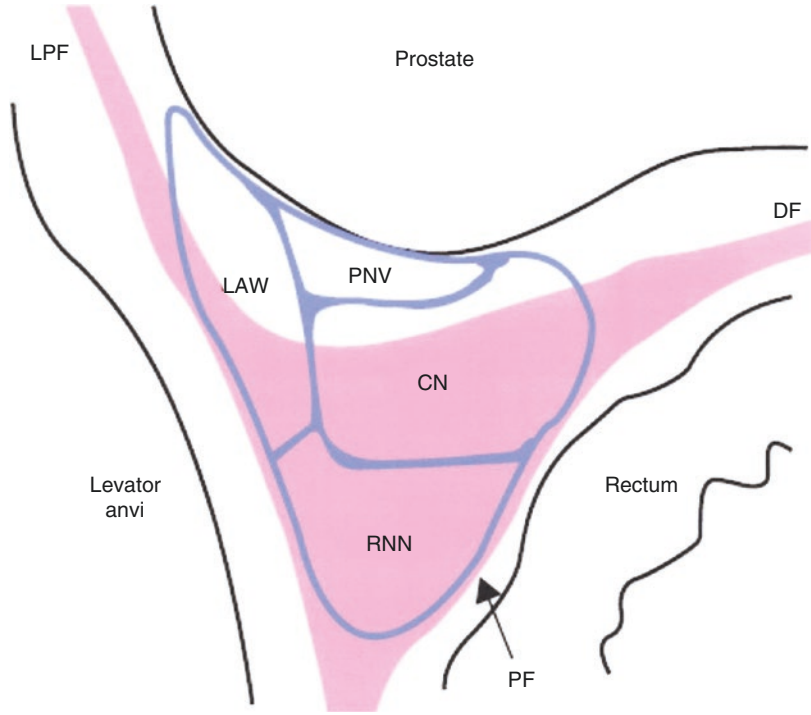

Fig. 20.4 Functional organization of the NVB: RNV, neurovascular supply to the rectum; DF, Denonvilliers' fascia; PF, pararectal fascia; LPF, lateral pelvic fascia; LANV, neurovascular supply to levator ani; PNV, neurovascular supply to the prostate; CN, cavernosal nerves. Reprinted from Costello AJ, Brooks M, Cole OJ. Anatomical studies of the neurovascular bundle and cavernosal nerves. BJU Int 2004;94:1071. With permission from John Wiley and Sons

then diverge again when approaching the prostatic apex, where they divide into numerous small branches that descend along the posterolateral aspect of the membranous urethra before penetrating the corpora cavernosa. Figure 20.4 demonstrates the functional organization of the NVB according to their findings. Menon contends that additional nerves important for sexual function may exist within the periprostatic fascia that covers the lateral and anterior surface of the prostate (aptly named the Veil of Aphrodite; see Section 20.9) [15]. The authors acknowledge they have not traced these nerves to the corpora cavernosa. They also hypothesize that because the plane of dissection is away from the cavernosal nerves, other factors such as decreased traction, avoidance of thermal injury, and preservation of extra blood supply may also play a role in preservation of nerve function.

Pathophysiology and Classification of Cavernosal Nerve Injury

Peripheral nerve injuries (as opposed to central or spinal cord injuries) were initially classified by Sir Herbert Seddon in 1943 (Fig. 20.5) [16]. In this classification, three categories of injury occur: (1) *Neurapraxia*: a mild compression, blunt impact, or stretch injury to the nerve with no structural damage. A concussion-like state results in a transient conduction block from which full recovery is likely to occur; recuperation may take hours to weeks; (2) *Axonotmesis*: a moderately severe injury, which results in axonal disruption and Wallerian degeneration; the nerve can regenerate or regrow from the point of injury to the end organ at approximately 2.54 cm/month—recovery takes 8–24 months; (3) *Neurotmesis*: occurs after severe injury or laceration that transects the nerve completely with no capacity for regrowth. Further, a neuroma or scar may form resulting in a permanent injury with a potential for only partial recovery. During radical prostatectomy, injury to the pelvic nerves and neurovascular bundles occurs along this spectrum of nerve injury. The application of Seddon's principles to the injury and recovery of function of the cavernosal nerves (CN) was only introduced in 2008 [4]. Basic neurosurgical concepts such as "dissecting the organ off of the nerve as opposed to dissecting the nerve off of the organ" originated from Seddon's works and are now applied to RARP.

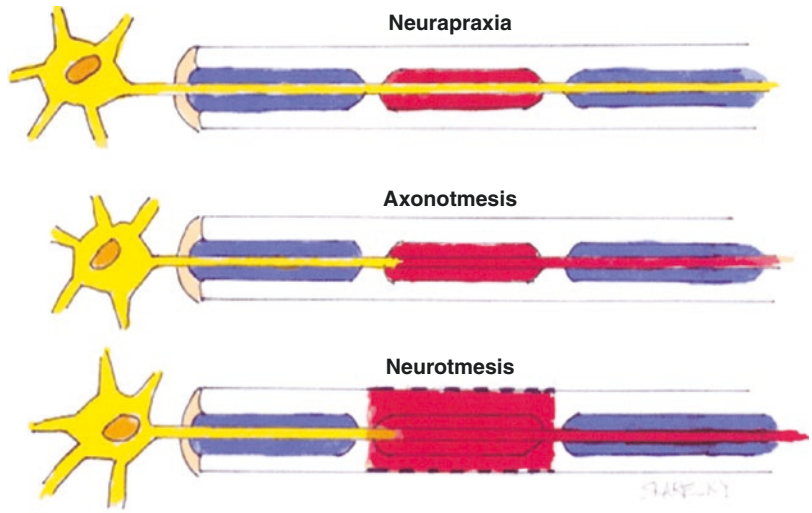

Fig. 20.5 Classification of nerve injury according to Seddon [16]. (Illustration by Douglas Skarecky)

Thermal Injury

The use of "typical" thermal energy on the prostatic pedicle where bipolar cautery is applied to seal arteries promotes desiccation and augments thermal dissemination leading to CN injury. An increase in temperature from just 39 °C–41 °C can produce neural injury [17–19]. At 45–55 °C, coagulation occurs [20]. As temperatures continue to rise beyond that point, cell death occurs, with denaturation occurring at 57–60 °C and protein coagulation at 65 °C [21]. Donzelli and associates have shown that both monopolar and bipolar cautery cause thermal injury to nearby neural tissue [22].

Early in our experience, we reported the adoption of an athermal technique to control the prostatic vascular pedicle (PVP) using temporary occlusion of the PVP with bulldog clamps followed by suture ligation [23]. By simply avoiding cautery, potency at 3 months increased from 8 to 38% [23, 24]. However, in the Cautery group, remarkably about 70% of patients had steady recovery of potency [25]. The best explanation for this delay was that although injury to the NVB occurred, the injury was not permanent and the CN could regenerate.

The recommendation to avoid thermal injury during RARP has been well documented. In fact, in 2012 a consensus RARP group recommended that the simplest solution to avoid thermal injury is to not use thermal energy altogether near the NVB [26]. Although complete avoidance of cautery has its stated advantages this method necessitates the use of clips which requires traction. How then does one avoid traction when controlling the PVP? Further investigations into the thermodynamics of cautery by Mandhani, Tewari and colleagues (2008) showed that during RARP both mono and bipolar electrocautery raise temperatures to an equivalent degree but mono-polar cautery appeared to coagulate more efficiently and hence shorter periods of application reduced thermal spread compared to bipolar cautery [27]. Khan, Ahlering and associates demonstrated the thermodynamic impact of heat sink effect by adjacent arteries and veins. They demonstrated in a porcine model that blood flow, though the inferior epigastric vessels, markedly reduced thermal spread [28]. Zorn and colleagues also demonstrated that the pathological findings thermal spread to adjacent tissues can be measurably reduced by using cold irrigation concomitantly with cautery [29]. The use of judicious spot monopolar cautery can control bleeders and minimize traction. When cautery is used we generally use short bursts of intermediate (35 w) monopolar cautery performed in a pinpoint fashion. The addition of cooled saline irrigation may further limit the spread of heat from surgery [29]. We find that point cautery using a single blade of the monopolar scissors is most efficient and precise.

Traction Reduction and Neurovascular Bundle Dissection

As discussed previously, a major mechanism of neuropathic injury is traction. In this regard, there are two primary schools of thought existing with regard to the direction of NVB dissection and minimization of nerve traction. The technique originally described by Walsh is considered retrograde as the prostate is initially freed at the apex and carried back toward the bladder. Walsh notes that if unilateral wide excision is planned, the contralateral NVB should be freed from the prostate at the apex to avoid traction injury [30]. The counter-school favors antegrade dissection of the NVB initially described during laparoscopic RP. Some believe the latter approach has several advantages. First, geometrically speaking, the use of long straight instruments makes the antegrade approach more practical because it is easier to see (especially with a 30° lens). This technique also allows for dissection in an intuitive, straightforward direction toward the penis, as compared to trying to see around the prostate and dissect back toward the bladder. In addition, this dissection may be accomplished with less traction on the NVBs. When contemplating forces associated with traction during the antegrade approach, neurosurgeons dictate there is less risk of traction injury when the prostate is dissected off of the NVB rather than dissecting the NVB off of the prostate.

Patel combines an antegrade and retrograde approach. Before controlling the pedicles with clips, he initiates the separation of the nerve in the mid-prostate and dissects antegrade to the apex and retrograde to the PVP. Patel developed this hybrid technique to more clearly separate the NVB from the PVP. He notes this separation permits precise clipping of the PVP without concern for inadvertent injury to the NVB, which he believes is not necessarily the case with a pure antegrade approach [31].

The principles of "traction and countertraction" are important in terms of surgical exposure and performing an anatomically correct dissection. On the other hand, these principles are in direct opposition to the neurosurgical premise of "dissecting the tumor off of the nerve". This basic premise of neurosurgery has been known and taught for decades to avoid undue nerve injuries during procedures across all surgical disciplines. Excessive traction on the neurovascular bundle has profound unintended consequences as the NVB is fragile [5]. Traction injury occurs by direct stretching of the arterionervosa causing bleeding in the perinerium leading to secondary inflammation and compression of the axon. When the injury is severe enough to injure the axon, (called axonotmesis) the axon will go through Wallerian degeneration and subsequent regeneration which typically takes 9–15 months. The goal of reducing traction injury is to reduce axonotmesis and hence increase neurapraxia. Neurapraxia is the lowest level of nerve injury similar to a concussion and the nerve regains function within days to weeks. Similar to other specialties in which "dissecting the tumor off of the nerve" is instilled from day 1, we as robotic surgeons must turn our concentration toward minimizing traction during ligation of the PVP and dissection of the NVB especially at the apex. The hallmark of successful reduction in axonotmesis is an obvious increase the percent of men who report erections within the first three months of surgery. This remains a particularly challenging goal for the experienced surgeon and a formidable obstacle for the novice.

Our technique begins with division of the PVP. The transition between the PVP and NVB is reliably identified when after transecting the last vessels in the PVP the prostate typically springs or releases forward. On the right side, we use the fourth arm to gently hold up on the prostate. An inter-fascial dissection is done in antegrade fashion sharply with scissors. As the dissection is carried toward the urethra, the prostate is continually re-grasped with the left hand to "see around the corner" and follow the contour of the prostate. The assistant never uses the suction irrigator to traction the NVB. Bleeders encountered are left alone or sutured. On the left side, the assistant holds the prostate with a grasper just superior-lateral to the seminal vesicle and gently pulls the prostate out of the pelvis toward the camera and

medially. The antegrade approach also facilitates the difficult task of separating the NVB at the apex. Near the left apex, a maneuver which can facilitate release of the NVB is to switch the scissors to the left hand for dissection of the left NVB (or to the right for left-handed surgeons). This allows the surgeon to avoid crossing instruments. It is our opinion that inadvertent permanent transection injury occurs most frequently at the left apex due to "crossing" of the hands. Of note transection of the tissues anterior to the urethra (dorsal venous complex and puboprostatic ligaments) has no evident risk of NVB injury.

Inflammatory Damage

Following primary injury either mechanical (dissection, traction) and/or thermal to the NVB there is undoubtedly a secondary wave of inflammatory damage that ensues possibly leading to additional delays in recovery. The inflammatory cascade includes activation of coagulation factors, pro-inflammatory cytokine formation, hypoxia, microcirculatory impairment from endothelial damage, acidosis, free radical production, and apoptosis [32]. Neutrophil and macrophage infiltration with subsequent release of proteolytic enzymes further contribute to tissue destruction [33, 34].

Hypothermia and Reduction of Inflammation

Theoretically, this inflammatory cascade might be blocked or mitigated with the use of local tissue hypothermia. Application of hypothermia pre-emptively (before dissection starts) should prepare tissues for imminent damage by lowering their metabolic rate and oxygen demands. With sufficient temperature reduction, the cell enters into a quiescent state of low energy utilization. When injury ensues, energy reserves are available for repair without going into anaerobic metabolism. As a result, less lactate formation occurs, protein synthesis is preserved, and most importantly, the inflammatory cascade is blunted. With less pro-inflammatory molecules and free radical species generated, the risk of apoptotic cell death is reduced. Tissue damage from leukocyte infiltration is further reduced because cooling also blocks adhesion molecule transcription and inhibits neutrophil adherence [35].

The use of local tissue hypothermia for injury is well established. Everyone is familiar with applying an ice pack to an injured extremity. Icing is well known to greatly reduce pain and edema after closed soft tissue injury [36, 37]. There is objective proof of this therapeutic effect; Schaser and coworkers quantified this effect by assessing microvascular permeability after controlled striated muscle injury in rats with or without superficial cold therapy for 20 min [38]. The cold-therapy group was found to have significantly decreased interstitial fluorescent-labeled albumin levels compared to sham animals. In addition, cold therapy was found to preserve microcapillary density and reduce leukocyte adhesion, chemotaxis, and myonecrosis. Kelly and colleagues showed that regional hypothermia to 4 °C protected against ischemic peripheral nerve injury after prolonged application of a tourniquet to the hind limb in rats [39].

We previously implemented a strategy for local hypothermia using a cooling balloon in the rectum designed to cool the NVBs and urethra. The basic hypothesis was that the most important factor for improving outcomes in experienced surgeons centered on reducing patient related inflammation as opposed to surgeon skill/technique. Our preliminary findings suggested we were able to reduce inflammation and improve continence [40]. However, our recently completed randomized control trial (RCT) failed to show clinical improvement in continence or sexual function in five high-volume surgeons [41]. In the RCT high volume surgeons (500–3500 case experiences) were selected in order to minimize differences in surgeon experience and skill. In the end, it appears that surgeon skill/technique, but not necessarily experience, far outweighed patient related inflammation issues. Recently evidence for alternative anti-inflammatory approaches to reduce the time of nerve recovery has been advocated by Patel et al. [42] and Lee

et al. [43] using tissue biografts and an anti-adhesion shield, respectively. Although both approaches have been promising in single surgeon experiences, multi-centered RCTs are necessary to weigh the impact of multiple surgeons and their skill versus patient related inflammatory injury factors.

Preoperative Assessment and Planning and Potency Outcomes

The most important step in counseling patients regarding recovery of sexual function is baseline documentation of their potency. We recommend a minimum of obtaining a International Index of Erectile Function (IIEF-5) also known as SHIM (Sexual Health Inventory for Men), age, medical issues such as hypertension, diabetes, cardiac disease and testosterone levels (free and total). To this end, rigorous data collection and reviewing of personal and expert video recordings facilitates a firm understanding of one's own experience and outcomes.

A preoperative IIEF-5 score of 22–25 is highly predictive of recovering normal sexual function [44]. However, defining sexual recovery still remains a challenge. We suggest utilizing both a quantitative (EPIC, yes/yes) and qualitative assessment (IIEF-5 score) to clarify sexual function outcomes. The two most important questions in this regard are from the EPIC questionnaire: 1) are your erections adequate for intercourse and 2) are your erections satisfactory [45]? A subjective patient self-assessment comparing erectile firmness as a percentage of pre-operative firmness is also useful in assessing recovery at three months postoperatively [46]. In our experience, we have not had a single recovery following radical prostatectomy in patients with a baseline IIEF-5 below 14. Further, in patients already taking a PDE-5 inhibitor, we recommend subtracting 7 from their baseline IIEF-5 score to obtain a truer assessment of preoperative sexual function.

Lastly, an oncological plan is of utmost importance when counseling the patient. The decision to perform bilateral, unilateral, or wide excision nerve sparing is based on T stage, Gleason score, site and percent involvement of biopsy cores. Some surgeons also assess for extra prostatic extension on magnetic resonance imaging to further guide operative planning [47, 48]. We recommend ipsilateral wide excision with obvious abnormal digital rectal findings and/or higher volume disease (i.e., multiple cores with 50–75%) or high-grade disease (Gleason 4 + 3 or higher).

High Anterior Release and the Veil of Aphrodite

Menon's technique emphasizes the presence of accessory nerves located in the anterior prostatic fascia which may be important for potency. In this approach, the lateral prostatic fascia is incised anteriorly – the so-called high anterior release (HAR) or Veil of Aphrodite. In 2005, Kaul et al. reported on outcomes with this technique. A total of 154 consecutive men underwent RARP with antegrade NVB preservation and Veil of Aphrodite modification [49]. The dissection for the Veil of Aphrodite begins by entering the intrafascial plane between the prostatic fascia and the capsule, starting infero-laterally near the PVP and carried up to the apex. The authors note that at the conclusion of the dissection, an intact "Veil" of periprostatic tissue should extend from the pubo-urethral ligament to the bladder neck. Among men with an average age of 57.4 and preoperative SHIM of >21, at 12 months 96% were having intercourse (defined as an answer of ≥3 to question 2 of the SHIM), 69% had "normal erections," and 20.6% achieved a median post-operative SHIM of 22. Of note, oncologic efficacy was not compromised with this technique—positive surgical margin rates among patients with pT2 disease was 5%, mostly at the apex, but none within the region of the Veil of Aphrodite.

Walsh's group has also described a modification to their interfascial NVB dissection technique which includes a release of the levator fascia much higher on the prostate (more medial and anterior at the apex) than they previously did [50]. In this report, the authors compared outcomes of 93 pre-potent men (IIEF-5 22–25) who

underwent bilateral nerve sparing with HAR and 74 patients who underwent standard nerve-sparing radical prostatectomy. Post-operative potency was defined, with or without PDE5 inhibitors, as a IIEF-5 of ≥16 and/or a response of "most times or almost always" to the question "In the last 4 weeks, when you attempted sexual intercourse, how often was it satisfactory to you?" Return to baseline was defined as an IIEF-5 of ≥22. Of note, overall median age was 53 (range 49–57). Patients who underwent unilateral or bilateral nerve sparing with HAR achieved a 90.9% potency rate compared with 76.8% for patients who did not ($p = 0.03$); 69.7% of men in this HAR group returned to baseline potency status, compared with 54% ($p = 0.07$). The authors suggest that improved potency with this technique occurs due to decreased traction injury as there was no apparent improvement in outcomes when the HAR was unilateral or bilateral.

Anatomically, there is little evidence to support the notion that HAR release preserves more autonomic nerve fibers important for erections. Using intraoperative electrical stimulation nerve mapping during radical prostatectomy, Takenaka and colleagues found that stimulation at the base of the putative NVB (where the more anterior fibers would be running) increased intraurethral pressures rather than intracavernous pressures [42]. Nerve stimulation at the rectal wall 1 cm posterolateral to the putative NVB resulted in increased intracavernous pressure. This finding was substantiated clinically by the previously described study by Kaul et al. who found improved continence rates with the Veil of Aphrodite technique (97% required no pads at 12 months) [49].

Effect of Unilateral Wide Excision on Potency

Excision of one of the NVBs may be necessary in efforts to control cancer. Walsh et al. [51] and Kundu et al. [52] both reported their experience with unilateral nerve-sparing (UNS) surgery. In 1987, Walsh et al. reported that 69% of men potent before RP who had unilateral wide excision were potent after RP, compared to 85% who had bilateral NS (BNS). Kundu et al. reported a similar trend in overall potency rates at 18 months, of 53 and 76% after UNS and BNS RP, respectively. A unifying theme among these reports is that reducing the volume of nerve tissue by 50% only reduced potency rates only by about 15–20%. In 2009 we similarly reported the impact on potency and time to recovery of potency in men undergoing either unilateral versus bilateral nerve preservation [53]. We defined wide excision as all tissue from the midline of the rectum from the bladder neck to the urogenital diaphragm. We analyzed a highly select group aged ≤65 years with normal IIEF-5 scores (22–25) to insulate the analysis from confounding patient-related variables.

The 2-year potency (yes/yes) outcomes in men undergoing BNS was 92% and in men undergoing wide excision of one nerve was 80%. About a 15% reduction in potency outcomes after a 50% reduction in nerve volume speaks to significant redundancy. Further qualitatively speaking the average IIEF-5 in men undergoing successful BNS versus successful UNS was 22.0 (20.2–23.8) versus 21.0 (19.8–22.1), respectively ($P = 0.37$). Another qualitative assessment, patient-reported "fullness of erections", showed similar findings to the IIEF-5 scores. Hence the redundancy is remarkable as the quality of erections was similar in men with one versus two nerves spared. The time-line to recovery with UNS and BNS were parallel suggesting cross-over rather than compensation as accounting for the mechanism of redundancy. Similar findings with open and laparoscopic techniques have been reported by others; with ratios of 1.1–1.43 [53–56]. This information implies that there is significant nerve redundancy and questions the logic of intra-fascial nerve sparing and the risk of a positive surgical margin.

Testosterone and Recovery

Symptoms of hypogonadism include erectile dysfunction, low libido, fatigue, mood changes, decreased bone mineral density, increased body fat and associated co-morbid conditions such as

cardiovascular disease, neurovascular disease, diabetes and metabolic syndrome [57]. Hypogonadism is defined in males by the combination of specific symptoms and testosterone levels below 350 ng/dl or 230 ng/dl [58]. In the setting of prostate cancer, calculated free testosterone (FT) appears to be more clinically significant [59]. The FT level has two implications: higher free testosterone levels appear to favorably predict low grade Gleason score and faster recovery of sexual function. Thus, it is important to obtain both pre-and postoperative testosterone and free testosterone levels. Further, in patients who are hypogonadal post-surgery, it is reasonable to consider testosterone replacement therapy in carefully selected men who are compliant with follow-up. Evidence shows that testosterone therapy can be safe in the post-prostatectomy setting. While PSA levels may rise in association with testosterone therapy, prostate cancer recurrence rates are not effected [60].

Postoperative Prophylaxis for Erectile Dysfunction

Radical prostatectomy has significant effects on the vasculature to the corpora cavernosum. Approximately half of patients experience venous insufficiency and 50% of patients experience arterial insufficiency, leading to fibrosis and loss of smooth muscle [61]. Rat models have shown endothelial cell apoptosis, decreased nitric oxide levels, and hypoxia contribute to fibrosis [62].

Several studies have explored methods to prevent fibrotic changes and promote sexual recovery. Montorsi and associates reported that 6 months following surgery spontaneous erection occurred in 67% of patients who performed self injection with PGE-1 compared to 20% in patients that did not use injection therapy. Moreover, only 17% of patients who injected PGE-1 developed venous leak by doppler ultrasound criteria versus 53% of patients who did not [63]. Studies examining vacuum erection devices (VED) have shown similar results [64]. Finally, Padma-Nathan et al. showed that nightly sildenafil following radical retropubic prostatectomy resulted in higher rates of recovery of full potency (27% vs. 4%) in a randomized trial [65, 66]. Schwartz and colleagues performed a histological study to examine the effects of sildenafil, finding that higher doses (100 mg vs. 50 mg every other night) results in greater volume of cavernosal smooth muscle fibers in post-operative biopsies [67]. In a 2014 randomized trial, Montorsi and colleagues that showed tadalafil hastened recovery [68].

Still existing studies are limited and lack sufficient numbers. As a result, at this time, there is no clear consensus. Our current regimen is 5 mg of tadalafil nightly starting on postoperative day 1. For those patients who are highly motivated, PGE-1 self-injection three times per week is also offered. Alternatively, adding an VED to a daily tadalafil can be initiated to prevent issues with penile girth and length in motivated patients; we recommend 10 min a day without a constriction band [69].

Conclusion

With increased understanding of the neuroanatomy of the male pelvis efforts to preserve the cavernosal nerves during radical prostatectomy have been met with increased success. Extraordinary care should be taken to avoid electrocautery, excessive heat application, and traction in the vicinity of the cavernous nerves. Our results using a cautery-free minimal traction technique seem to promote the return of erectile function. These efforts can be enhanced with prophylactic medications.

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21 Extraperitoneal Robot-Assisted Radical Prostatectomy: Simulating the Gold Standard

Ahmed Ghazi and Jean Joseph

Abstract

For almost two decades, robot assisted radical prostatectomy (RARP) has been the preferred method at many institutions to remove a cancerous prostate. The shorter learning curve associated with RARP, when compared to laparoscopic radical prostatectomy, has facilitated its adoption in both academic and community settings. The extraperitoneal approach, which is common to open prostatectomists, is often abandoned as they transitioned to a robotic approach, due to difficutly developing the extraperitoneal space, and identifying extraperitoneal anatomical landmarks laparoscopically. The extraperitoneal route furthers the quest of minimal invasiveness, as it maintains the integrity of the abdominal cavity, and avoids potential lysis of adhesions in patients with prior abdominal surgeries. In this chapter, we provide a detailed review, which should prove useful to both expert and novice robotic prostatectomists, seeking to add the extraperitoneal approach to their surgical armamentarium.

Keywords

Extraperitoneal radical prostatectomy · Extraperitoneal access

Introduction

Radical retropubic prostatectomy, long referred to as the gold standard for the surgical management of prostate cancer, is performed in the extraperitoneal space, without entry into the abdominal cavity. However, most minimally invasive techniques, robot assisted radical prostatectomy (RARP), and laparoscopic radical prostatectomy (LRP) are performed transperitoneally. RARP has fast become the most common form of prostate cancer surgical management at many institutions. It is usually performed by entering the abdominal cavity, with an initial bladder "take-down" step. The familiar laparoscopic transperitoneal anatomy and larger working space have made the transperitoneal route a preferred approach for the majority of surgeons performing prostatectomies laparoscopically or using robot assistance. Both transperitoneal and extraperitoneal approaches are routinely used at our institution. Herein the procedure and the

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arguments for the extraperitoneal robot-assisted radical prostatectomy technique, which has been my preferred approach in over 2000 cases, are presented.

Robot-Assisted Radical Prostatectomy Procedure

Access

Extraperitoneal access is the first step in all procedures. The initial access is obtained via a 2–3 cm periumbilical incision to expose the posterior rectus sheath. A 1 cm incision is made in the anterior sheath, bringing the rectus muscle fibers into view. This incision should be very superficial to avoid bleeding which may result from incising the muscle fibers. Using a small clamp, the muscle fibers are retracted laterally allowing visualization of the posterior sheath. Once the latter is visualized, a balloon dilator is inserted over the posterior sheath, down to the retropubic space of Retzius. With the scope inserted through the balloon, the retroperitoneal space is created under direct vision (Fig. 21.1). The epigastric vessels can be visualized, with care taken not to dissect them off of the lower aspect of the rectus muscle belly. This can lead to bleeding compromising visualization. The external iliac vessels can be easily visualized and care taken not to compress them or tearing the epigastric vessels from their take-off point. Once the space has been created the balloon dilator is removed. If more space is needed a long beveled trocar can be used to bluntly push the peritoneum cephalad. A fan retractor or laparoscopic clamp can be used to push the peritoneum off the anterior abdominal wall. This step is necessary to facilitate placement of the assistant trocars. Extreme caution is advised at this stage to avoid entering the peritoneal cavity. This can be a significant challenge in patients with prior lower abdominal surgeries, such as a herniorrhaphy or appendectomy. Entering the peritoneal cavity decreases the extraperitoneal space due to bulging of the peritoneum. The procedure can still be carried out extraperitoneally as discussed below.

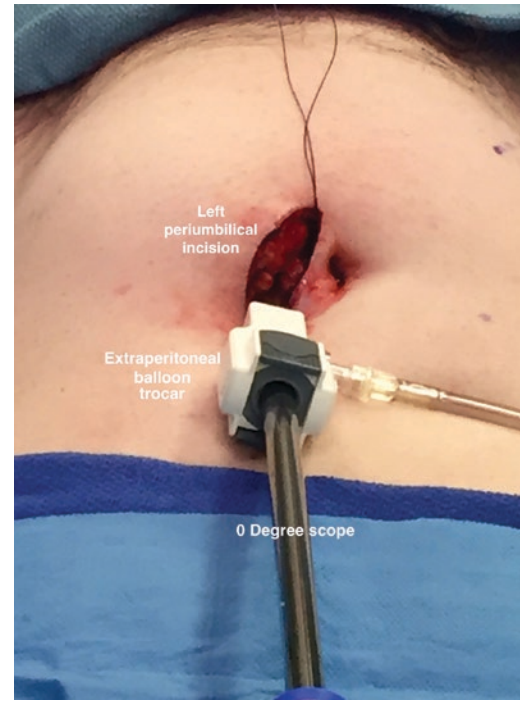

Fig. 21.1 View of abdomen with balloon dilator inflated

Port Placement

Four to five additional ports are placed under direct vision, with enough space left between the robotic trocars, to avoid instrument collision. Care should be taken not to place the assistant ports too lateral. This can lead to decreased ability to reach the pelvis, or work area, due to restriction from the pelvic brim. Both a 3-arm and a 4-arm robot can be used with this approach, with enough space available for one or two assistant ports. With the previous robotic systems (Standard, "S", and "Si), the robotic arm used for the camera is attached to the 12 mm port. The newer Xi robot requires exchange of this periumbilical trocar, for a12 mm daVinci trocar, to help lessen gas leakage. A Vaseline impregnated gauze wrapped around the trocar is also helpful in reducing gas

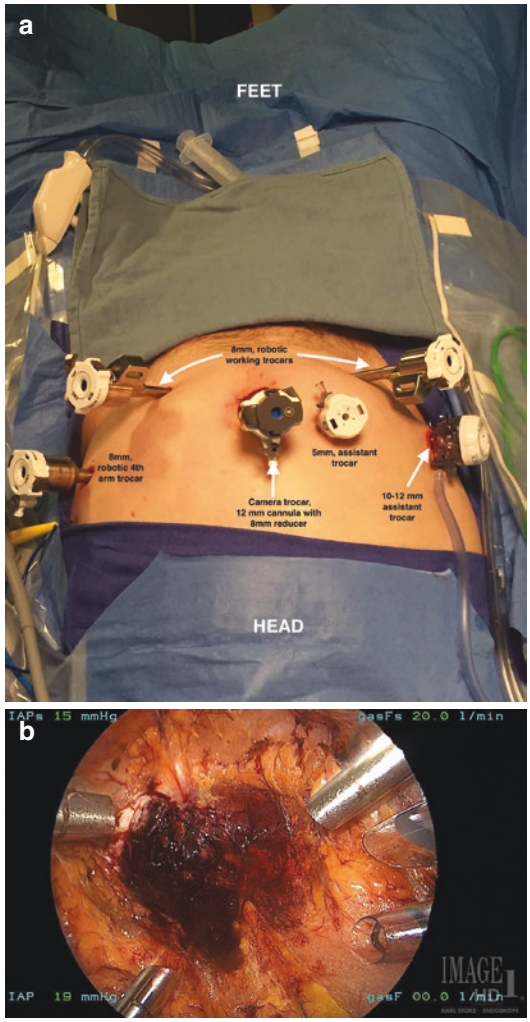

Fig. 21.2 (**a**) Extenal view of trocars. (**b**) View of EP space with trocar in place

leakage. An 8 mm reducer is placed through that trocar, before inserting the 8-mm daVinci camera (Fig. 21.2a).

Endopelvic Fascia

Once the extraperitoneal space is developed, access to the endopelvic fascia is immediate (Fig. 21.2b). The bladder dissection or "take-down" step is eliminated with the extraperitoneal approach. The endopelvic fascia is incised freeing the prostate from its lateral attachments. Accessory vessels, if present, are identified and preserved. Puboprostatic ligaments are trimmed to further facilitate mobilization of the prostatic apex.

Dorsal Vein Ligation

The groove between the urethra and dorsal vein can often be identified with lateral retraction of the prostate apex. A 2-0 vicryl suture ligature is used to ligate the dorsal vein. We do not routinely ligate the branches of Santorini's plexus, but this can be done to help minimize bleeding during the bladder neck dissection.

Bladder Neck Dissection

Using a Prograsp in the 4th arm, or a fan retractor if a 3-arm unit is used, tension is placed on the bladder to help visualize the bladder neck. Blunt dissection and cautery are used to facilitate visualization of the bladder neck fibers. These are pushed cephalad, with care taken not to enter the prostate capsule. Once the longitudinal urethral fibers are identified, the bladder neck is transected sharply. Cautery is used selectively to control bleeding from the bladder neck. Upon entering the anterior aspect of the bladder, the trigonal ridge is identified, prior to transecting the posterior bladder neck.

Seminal Vesicle Dissection

Following the bladder neck transection, the longitudinal muscular fibers overlying the seminal vesicles can be visualized. They are incised transversely in the midline bringing the ampullae into view (Fig. 21.3). The ampullae are clipped and retracted anteriorly using the 4th arm, or a grasper, to assist in visualizing the seminal vesicles. The artery to the vas can be seen coursing between the seminal vesicles and ampullae. The ampullae and artery to the vas are clipped en bloc.

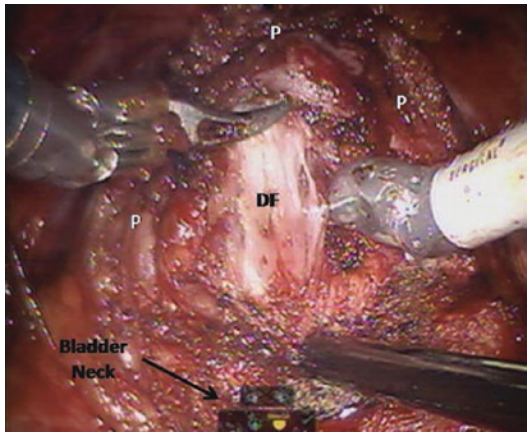

Fig. 21.3 Division of the posterior Denonvilliers' fascia (seminal vesicle fascia) for identification of the vasa deferens and seminal vesicles; DF, Denonvilliers' fascia

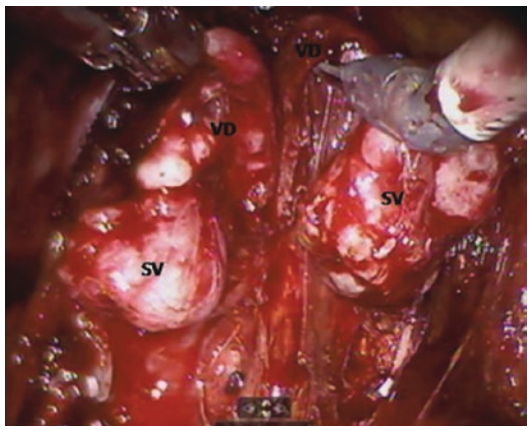

Fig. 21.4 Complete dissection of both seminal vesicles and vas deferens

Posterior Prostate Dissection

Retracting the ampullae anteriorly allows visualization of Denonvilliers' fascia (Fig. 21.4). The latter is incised exposing the perirectal fat. Using blunt dissection, the prostate is freed from the anterior rectal wall. Care should be taken to avoid injuring the rectum, particularly in patients with conditions causing significant periprostatic inflammation, where the rectal wall is adherent to the posterior prostate. An assistant's finger or a rectal bougie can be helpful in delineating the tissue planes and avoid a rectal injury. The rectal wall should be inspected immediately if an injury is suspected.

Neurovascular Bundle Dissection

We perform a cautery-free technique using clips to control all vessels entering the prostate. The ampulla from the contralateral side being dissected is used to place traction on the prostate. The prostate capsule is exposed bluntly. Vessels and surrounding neural tissues coursing behind the prostate are pushed posteriorly. Once the main neurovascular trunks are identified, vessels entering the prostate are clipped (Fig. 21.5). We perform an interfascial dissection in nerve-sparing cases. Once the main vessels entering the base of the prostate are controlled, the remainder of the dissection is carried out bluntly, pushing the neurovascular bundle posteriorly. In non-nervesparing cases, the pelvic fascia is incised next to levator ani. The bundles and investing fascia are left attached to the prostate when a wide resection is performed. Fig. 21.6a demonstrates a completely resected bundle on the right side, versus the left where the bundle has been preserved. A bilateral neurovascular bundle preservation is shown in Fig. 21.6b. We do not perform or recommend an intrafascial dissection due to the increased risk of positive surgical margin.

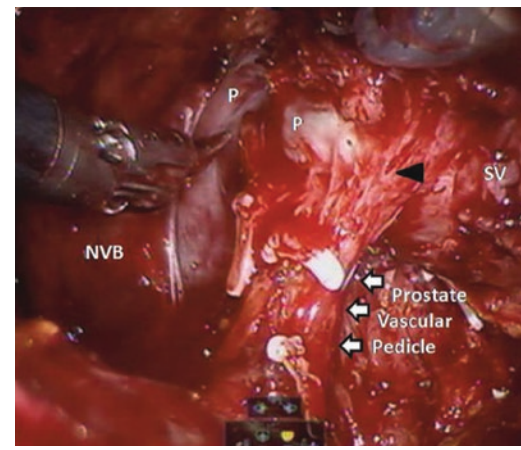

Fig. 21.5 Plane for nerve-sparing dissection along the lateral border of the prostate (indicated by the *black arrow-head*); P, prostate; SV, seminal vesicle; NVB, neurovascular bundle

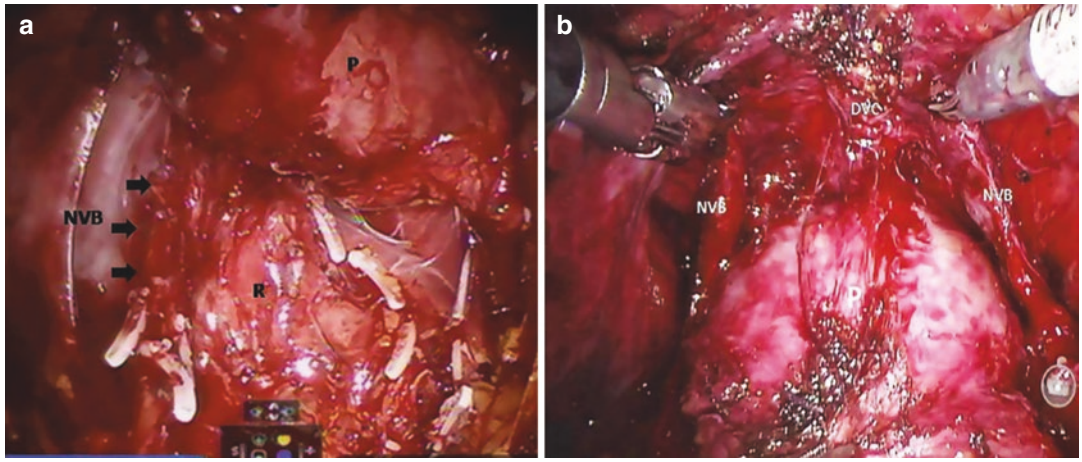

Fig. 21.6 Operative view of a bilateral and unilateral nerve-preserving dissection prior to apical dissection. (**a**) Unilateral nerve-sparing dissection (left nerve-preserving technique and right non-nerve-preserving technique). (**b**) Bilateral nerve-sparing dissection. Note the use of fewer clips during preservation of the nerve; NVB, neurovascular bundle; R, rectum; P, prostate; DVC, dorsal venous complex

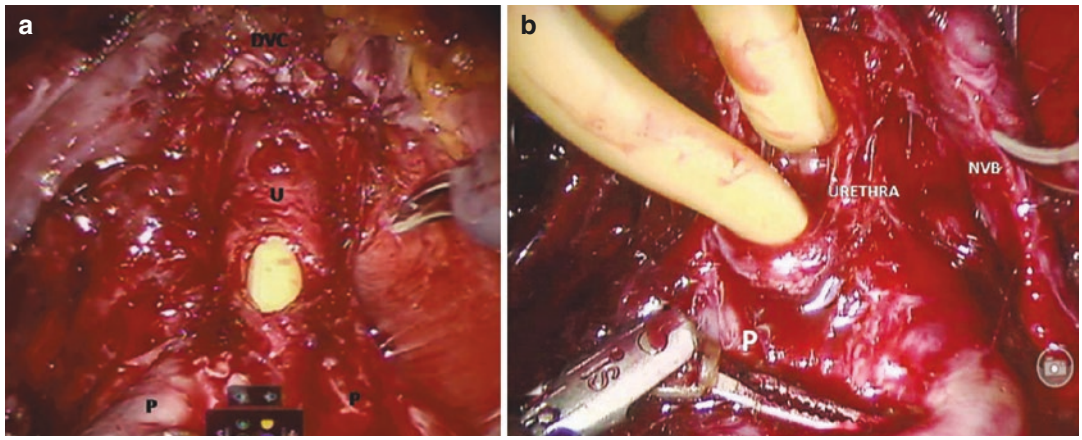

Fig. 21.7 Division of the urethra following dissection and ligation of the dorsal venous complex. (**a**) Division of the anterior lip of the urethra, revealing the Foley catheter. (**b**) Division of the posterior lip of the urethra; NVB, neurovascular bundle; U, urethra; P, prostate; DVC, dorsal venous complex

Apical Dissection

The previously ligated dorsal vein is transected, identifying the urethra (Fig. 21.7a). When a very broad dorsal vein is present, it can also be transected with subsequent oversewing using a 2-0 vicryl on an SH or RB needle. The previously placed suture can at times become loose during the apical dissection, due to traction on the prostate. Increasing the intra-abdominal pressure to 20 mmHg helps achieve hemostasis before the vein stump is oversewn. The contour of the prostate should be followed during this step, to avoid transecting the prostate apex. This dissection is carried out in a caudal direction, to limit this risk.

The Foley catheter is inserted through the prostate to allow visualization of the anterior urethra. We prefer transecting this sharply to avoid ischemic mucosal trauma to the urethra (Fig. 21.7b). This also helps prevent cautery damage to the adjacent neurovascular bundles.

Once the prostate is freed, it is placed in an endocatch bag and pulled near the tip of one of the assistant's trocar.

Posteroir Reconstruction and Vesicourethral Anastomosis

Prior to starting the anastomosis, Denonvilliers' fascia is sewn to the posterior urethra and bladder neck (Figs 21.8 and 21.9a). This step helps approximate the bladder neck to the urethra, in preparation for the vesicourethral anastomosis. We use two covidien V-loc™ sutures, with care taken not to incorporate the neurovascular bundles if they have been spared. These sutures start in the midline and end laterally. With the comple-

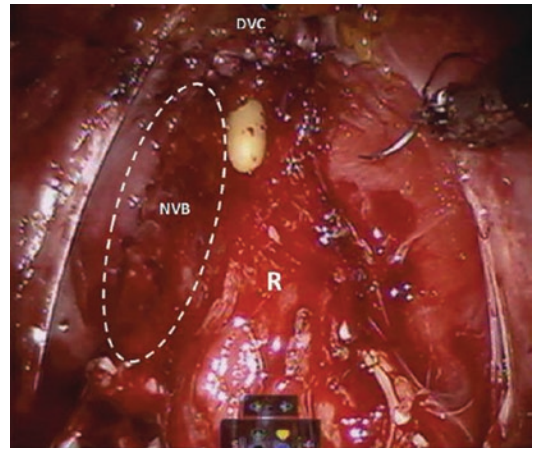

Fig. 21.8 Operative view following removal of the prostate with preservation of the left neurovascular bundle. *Dotted circle* delineating the preserved bundle; R, rectum; NVB, neurovascular bundle; DVC, dorsal venous complex

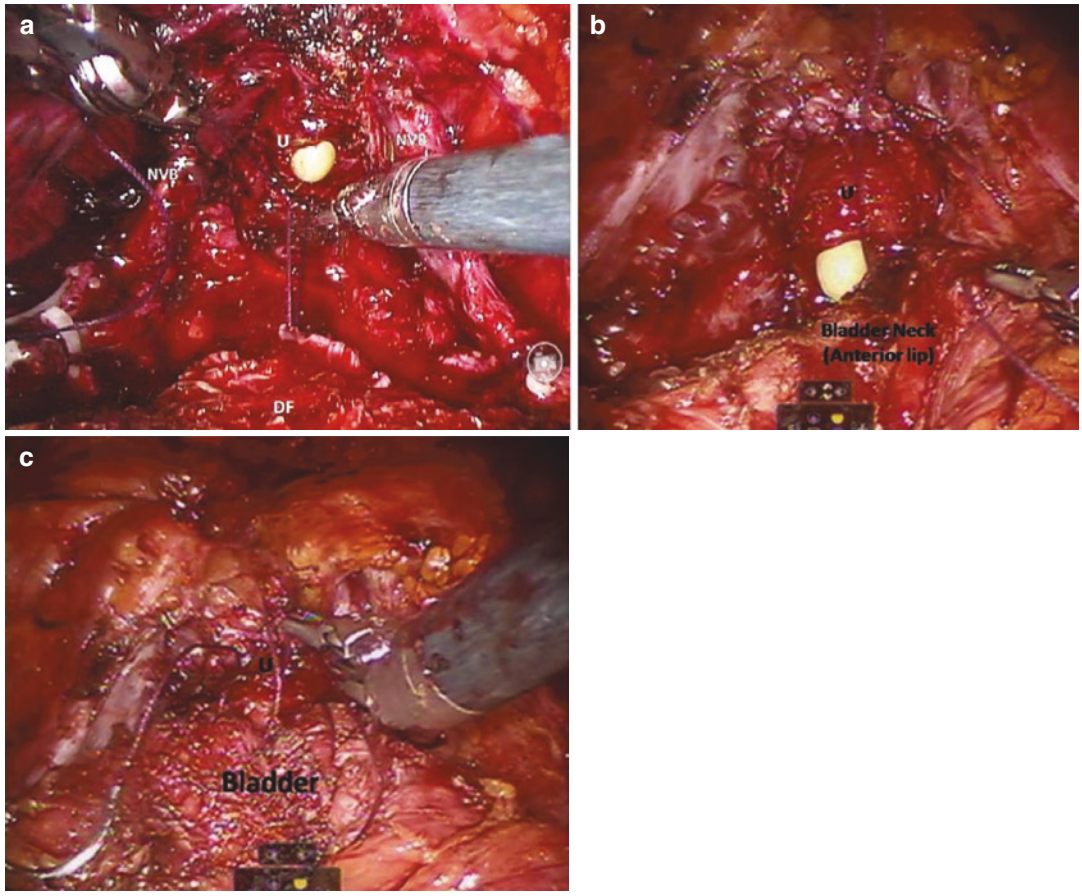

Fig. 21.9 Urethro-vesical anastomosis. (**a**) Dorsal suture, approximating severed ends of the Denonvilliers' fascia at the posterior bladder neck and urethral stump. (**b**) Completing the dorsal aspect of the anastomosis. (**c**) Approximation of the ventral aspect of the anastomosis before applying tension on the running suture

tion of the anastomosis described below, these sutures are anchored to the pubic symphysis, anteriorly suspending the bladder neck.

The anastomosis is completed using two separate (2-0 vicryl, RB 1 needle) sutures. The first suture is placed at the 5 o'clock position in the urethra and anastomosed to its corresponding position at the bladder neck (Fig. 21.9b). This is carried out in a counterclock-wise direction to the 11 o'clock position. The second suture is done in the opposite direction from the 5 to 11 o'clock (Fig. 21.9c). The Foley catheter is used to help identify the urethral lumen. We routinely decrease the pressure in the retroperitoneal space to 8–10 mmHg to facilitate approximation between the bladder and urethra. A 20 Fr 30 cc Foley catheter is placed into the bladder, prior to tying the anterior anastomotic suture.

Specimen Retrieval and Closure

Once the robot is disconnected from the patient, the specimen bag is passed through the midline trocar. A 19 Fr Blake drain is placed in the space of Retzius (Fig. 21.10). The working and assistant trocars are removed under direct vision, ensuring hemostasis from these sites. The anterior rectus sheath is incised according to specimen size and subsequently closed. No other fascial closure is necessary using the extraperitoneal approach. When trapped intra-abdominal air is suspected, a small opening in the posterior rectus sheath and peritoneum is recommended to evacuate the air, for improved patient comfort postoperatively.

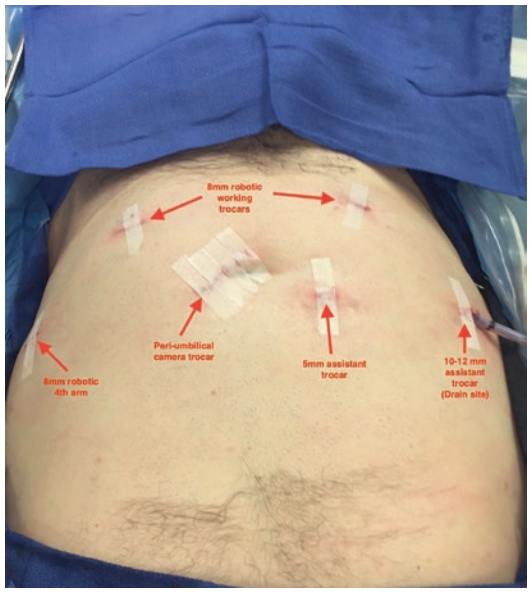

Fig. 21.10 Post-op view of abdomen with drain in place

Postoperative Care

Patients are generally discharged home on postoperative day 1 or when they tolerate oral nutrition and do not require intravenous analgesia. A Jackson–Pratt drain placed after surgery is removed prior to discharge if output is less than 30 cc in an 8-h period. The drain is otherwise removed as an outpatient when the output meets such criteria. Foley catheter removal is done 7–10 days postoperatively as an outpatient.

Comparing to the Gold Standard

Unlike open prostatectomy which is generally performed by accessing the space of Retzius, in a completely extraperitoneal fashion, to date there is no uniform way of performing a laparoscopic or robot-assisted radical prostatectomy. Most of these procedures are performed transperitoneally, connecting the abdominal cavity with the space of Retzius. In the extraperitoneal approach, the peritoneum serves as a natural retractor keeping the bowel away from the operative field. In transperitoneal procedures, a steep Trendelenburg position may be required to achieve this task. This can lead to ventilation difficulties and anesthetic complications in patients with compromised respiratory function.

A number of advantages and disadvantages to these two approaches have been described in the literature [1, 2]. Several studies have compared the transperitoneal and extraperitoneal laparoscopic/robotic approaches [3]. Patients with prior abdominal surgeries were found to be best suited for the extraperitoneal approach to avoid potential lysis of adhesions and associated bowel complications.

With the transperitoneal approach, the removal of the natural peritoneal barrier places blood

from the operative site and potential urine leak from the vesicourethral anastomosis in direct contact with the bowel which can lead to postoperative ileus. The dissipation of blood into the abdominal cavity does not allow small bleeders to potentially tamponade. Access to the intraabdominal cavity is useful in the setting of lymphatic fluid leakage. The peritoneal surface allows prompt resorption of lymphatic fluid. With meticulous clipping, such lymphatic fluid leak can be avoided. This step is generally fast, since the pelvic vessels are often already exposed with the balloon dilation step.

As with pure laparoscopic prostatectomy, increased experience with robotic procedures has led many centers to adopt an extraperitoneal approach. Following the description of the extraperitoneal approach by Raboy et al. [4] and Bollens et al. [5] who presented the first case report and the first case series of extraperitoneal radical prostatectomy, a number of centers have performed these procedures with several having experience well above a thousand [6]. Gettman and Abbou reported their first four cases with this approach using robotic assistance [7]. In 2006, we published one of the larger robotic series using the extraperitoneal approach [8]. Whether a pure laparoscopic or robot assistance is used, the rationale for the extraperitoneal approach has been the avoidance of the peritoneal cavity and potential complications, similar to the well-accepted open radical prostatectomy technique.

The False Arguments Against the Extraperitoneal Approach

The Anastomosis

Critics of the extraperitoneal approach often cite tension on the vesicourethral anastomosis, due to the bladder or urachal attachments to the abdominal wall. We have found no difficulty approximating the bladder to the urethra. Our recommendation is to decrease the pneumopreperitoneum insufflation pressure to 8–10 mm Hg and to have the assistant suction to collapse the space. This allows the bladder to easily approximate to the urethra with the first knot, which is the most difficult. Subsequent suture placement approximating the bladder neck to the urethra is generally easier. It is not recommended to move the patient, or change the incline of the table, while the robot is docked. This is not a concern with the new Xi robot, if using a paired Table. A more commonly used alternative is the application of perineal pressure, which leads to protrusion of the urethral stump, facilitating suture placement in difficult cases. As for open radical retropubic prostatectomy, once the gas is evacuated from the retroperitoneal space, or the retractors are removed, the bladder neck remains approximated to the urethra with no undue tension.

The Working Space

The extraperitoneal approach has been reported to be more difficult due to a smaller working space. When properly developed, with no peritoneal rent, the space is quite large and non-limiting. A peritoneal rent, however, can significantly collapse the space making visualization difficult. In such setting a fan retractor can be used to retract the bladder cephalad. A steeper Trendelenburg may be required to keep the intra-abdominal contents and peritoneum cephalad. A 5-mm trocar can also be placed in the peritoneal cavity to help evacuate trapped intraperitoneal air. These steps eliminate the need to convert to a transperitoneal laparoscopic procedure.

Faster port placement following intra-abdominal insufflation has been reported with the transperitoneal approach. In the setting of prior abdominal surgery, however, longer operative time may be associated with lysis of adhesions, while the extraperitoneal approach would allow expeditious access to the space of Retzius. The extraperitoneal method is most advantageous in patients with prior abdominal operations. Over a third of my patients have had prior abdominal surgeries, including bowel resection, liver transplant, and others. In my experience with both approaches, I have had faster surgery time due to a shorter time interval between skin

incision and endopelvic fascia incision. Intra-abdominal dissection or bladder takedown steps are not necessary.

Besides rapid access to the target organ, another advantage worth mentioning is the rapid completion of wound closure. With the posterior rectus sheath, and peritoneum intact, this approach eliminates the need for fascia closure. Only the fascial opening for retrieval of the specimen requires closure. In my series of extraperitoneal cases, I have not experienced either bowel or omental adhesions when the procedure is completed extraperitoneally. Entering the abdominal cavity requires meticulous fascial closure to eliminate such risks.

Unifying the peritoneal cavity with the space of Retzius can lead to bowel adhesions to the operative site. Not only can this potentially complicate subsequent laparoscopic or open intra-abdominal interventions, it potentially places the bowel in the path of radiation should adjuvant radiation become necessary.

Developing the working space is nearly impossible in patients with prior laparoscopic extraperitoneal mesh hernia repair. This is the main indication that I use to perform a transperitoneal procedure. Besides the previous dissection of the extraperitoneal space, the mesh causes significant inflammatory reaction obliterating the space, causing troublesome peritoneal rents. In such settings it is best to proceed immediately to a transperitoneal route.

The Extended Node Dissection

Open prostatectomists with decades of experience and large series of open radical prostatectomists have yet to show conclusive evidence that an extended lymph node dissection provides therapeutic benefit. This argument persists for both laparoscopic and robotic surgeons. Critics of the extraperitoneal approach have cited the inability to perform an extended lymph node dissection. Proper retraction and a downward angled scope can easily permit cephalad dissection up the common iliac node chain (Fig. 21.11a) and further to allow a thorough and extended node dissection. Similar to open retropubic radical prostatectomy, an extended lymph node dissection can be performed using an extraperitoneal approach (Fig. 21.11b). As mentioned above, the absence of the resorptive peritoneal surface is associated with a higher risk of lymphocele, which is not a trivial drawback. Meticulous clipping of all lymphatic channels is necessary to mitigate such risks. A lymphocele collection is possible in both approaches, but it is much less

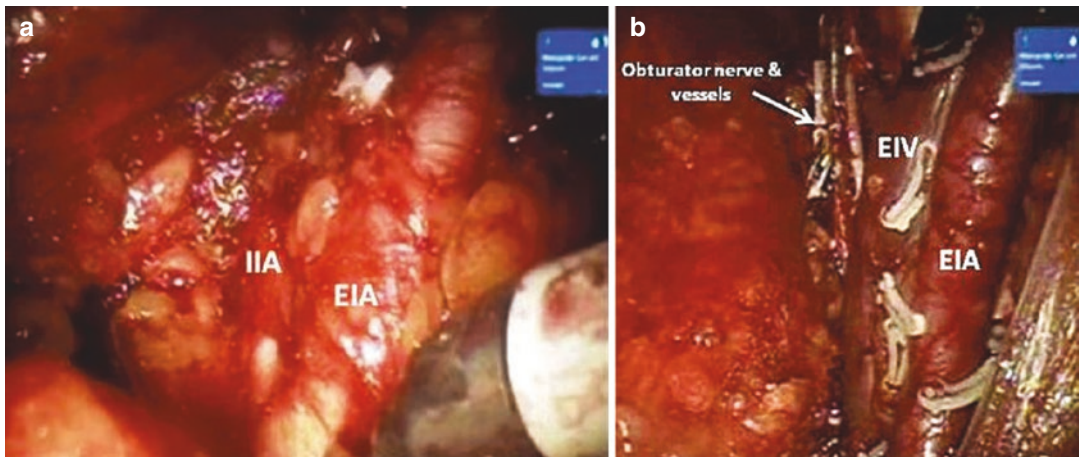

Fig. 21.11 (**a**) Cephalad limit of an extended lymph node dissection at the bifurcation of the iliac arteries, using a downward angled scope. EIA, external iliac artery; IIA, internal iliac artery. (**b**) An extended lymph node dissection performed using an extraperitoneal approach. EIA, external iliac artery; EIV, external iliac vein

likely during intraperitoneal surgery. For patients undergoing an extended lymph node dissection, a transperitoneal route helps minimize the risk of lymphocele.

Conclusions

The extraperitoneal approach is increasingly preferred at a number of centers, once they have overcome the perceived limitations discussed above. Avoiding the abdominal cavity furthers the goals of minimal invasiveness and best duplicates the gold standard open radical retropubic prostatectomy. Minimal modifications are necessary when using the Xi robot. Perhaps with upcoming robots, particularly the daVinci Sp single port surgical system, the extraperitoneal space will gain more popularity. Creation of space laterally to avoid arm collision, and to place the assistant trocars will not be necessary. The space created by the balloon dilator alone will be sufficient to accommodate the single port system. The longer learning curve associated with extraperitoneal space creation has been a limiting factor in the adoption of the extraperitoneal approach. The arrival of the SP robotic system is likely a game changer.

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Retzius-Sparing Approach for Robot-Assisted Laparoscopic Radical Prostatectomy

22

Antonio Galfano, Silvia Secco, Dario Di Trapani, Giovanni Petralia, Elena Strada, and Aldo Massimo Bocciardi

Abstract

Robot-assisted laparoscopic radical prostatectomy (RARP) is currently the standard surgical treatment for localized prostate cancer. Since 2010, Dr. Aldo Bocciardi has developed a new anatomical approach through the rectovesical pouch at Niguarda Hospital in Milan.

The technique has been fully standardized and described for all stages of prostate cancer with surgical indication; obviously, the larger is the anatomical damage, the worse will be the functional results.

Sparing all the Retzius space structures, this approach allows an earlier and improved continence recovery, without compromising the oncological outcomes.

Keywords

Prostate cancer · Radical prostatectomy Robot-assisted laparoscopy · Robotic surgery · Da Vinci · Retzius-sparing RARP · Bocciardi approach

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The Idea

In the early 2000s, radical prostatectomy had a quick evolution and revolution thanks to the advent of robotic surgery. Deriving from the first pioneeristic laparoscopic experiences, in that period the two most popular approaches were those proposed by the Montsouris Institute of Paris and the Vattikuti Institute Prostatectomy (VIP) developed in Detroit [1, 2].

Starting from our proctor attitudes, we began our robotic experience with the Montsouris approach, which provided for a preliminary incision in the rectovesical pouch in order to release the seminal vesicles and then continued with a standard Retzius space dissection. The rationale for this approach was to avoid traction on the neurovascular bundles and improve the functional efficiency of the nerve-sparing procedures.

In order to minimize the anatomical damage and using the proficiency of the surgical Da Vinci device, we developed the original idea to perform the whole radical prostatectomy through the Douglas space using only the Montsouris incision.

The very first case of Retzius-Sparing prostatectomy (RSP) was performed in January 2010, after 2 unsuccessful tries (in both cases because of fear of damages due to inexperience) that were converted to the standard approach through the Retzius space [3].

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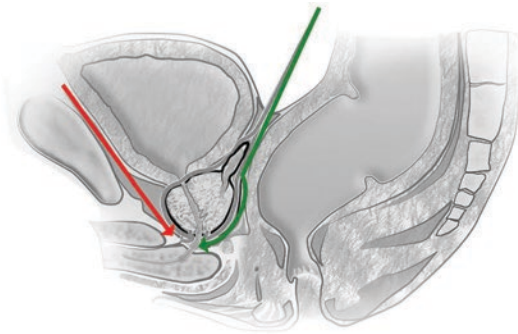

Fig. 22.1 Sagittal anatomical view highlighting the different approaches. Red arrow: standard approach for RARP; green arrow: Retzius-sparing Bocciardi approach

Rationale

The anatomical rationale for this kind of approach is very strong. The classical anatomical studies by Patrick Walsh [4] report and demonstrate the incontrovertible role of the neurovascular bundle in maintaining the post-prostatectomy erectile function; nevertheless, in the following years, several other structures have been advocated to play a role in continence and potency preservation; as they lay in the Retzius-space and need to be crossed to reach the prostate (Fig. 22.1), sparing the Retzius-space could be the best way to obtain good functional results.

Endopelvic Fascia

The first anatomical structure met during radical prostatectomy is the endopelvic fascia, that covers the prostate like a light blanket. Several evidences report that sparing the endopelvic fascia could result in a quicker recovery of urinary continence, but data are controversial [5]. Moreover, the endopelvic fascia is a perfect anatomic landmark to correctly identify the neurovascular bundles [6].

Santorini Plexus and Puboprostatic Ligaments

The standard RARP technique includes Santorini plexus section (and potential hemostatic suture) and dissection of the pubo-prostatic ligaments. More than assuring a lower blood loss (in RARP blood loss is almost constantly low), leaving intact those structures, it allows the preservation of the anatomical support to the bladder and of the small arteries running through the plexus. The role of these arteries is currently unknown, but a possible role in the accessorial blood supply of the striated sphincter or of the corpora cavernosa cannot be excluded [7].

Puboprostatic ligaments are important fixity means of the urinary continence system. A huge number of studies confirmed that puboprostatic ligaments preservation improves the time of urinary continence recovery [8].

Prostatic Fascias

Several reports show that the prostate is surrounded by vascular and nervous fibers in its whole circumference. Studies conducted on fetal and adult cadavers not only confirmed this data, but also analysed the territory innervated by those nerves, showing that they run straight towards the urethral sphincter and the corpora cavernosa [9].

Accessory Pudendal Arteries

The presence of accessory pudendal arteries varies from 4 to 75% [10, 11]. The role of these arteries is to provide a supplementary penile blood supply, but their effective importance in erectile function maintenance is currently debated [12, 13].

Technique

A standard 3-arm Da Vinci robot (Intuitive Surgical, Sunnyvale, California, USA) was used in the first 30 cases, while a 4-arm Si system was used subsequently. Several experiences are available with the new Xi System, that can be used for this approach without modifications of the technique. Up-to-date, more than 1000 cases have been operated in our institution, and several

improvements have been introduced. Currently, the technique for RSP is structured as follows:

- The patient is put in the standard 30° Trendelenburg position, with the arms fixed along the body. Legs are spread and the Da Vinci robot is front-docked, but in special cases with the Si or in case of Xi Da Vinci system, it can be side-docked. Several devices can be used in order to avoid slipping of the patient and traction of the brachial plexus.
- Usually, in non-operated patients, a Veress needle is inserted to induce the pneumoperitoneum; a standard Hasson technique is used in patients with suspect of adhesions. Six laparoscopic trocars are inserted. We use to have the table-side assistant on the right and the fourth arm on the left; the main operative arms have the monopolar scissors on the right and the bipolar Maryland on the left. The grasper (usually a Cadiere forceps) is kept in the medial left arm, while the Maryland is in the lateral arm. Figure 22.2 shows the standard disposition of the arms: 1 and 3 are quite symmetrical, while 2 is the grasper, making mostly upwards and downwards tractions.
- The initial set up is with a 30° lens-down during seminal vesicles isolation, while the lens is turned up during all the following steps. About 90% of patients have an adhesion of sigma and left colon that reduces the space in the rectovesical pouch; freeing this adhesion is fundamental to have enough operative space; if the field is still occupied by the colon, it can be useful to put a stay suture with a Ethilon 2–0 straight needle coming from the 5 mm assistant port and stretching the epiploic appendixes surrounding the colon backwards; this step comes from an original idea of Prof. Vito Pansadoro (Fig. 22.3).
- The grasper lifts up the peritoneum covering the bladder. The parietal peritoneum is then incised for 5–7 cm about 1 cm over the reflection of the Douglas space. Seminal vesicles and deferens vasa are isolated and incised, possibly with small clips and avoiding cautery, especially at the tip of the vesicles (Fig. 22.4). Hem-o-loks in this step can be used, but they occupy a too large room for the small surgical field. As such, currently we pre-

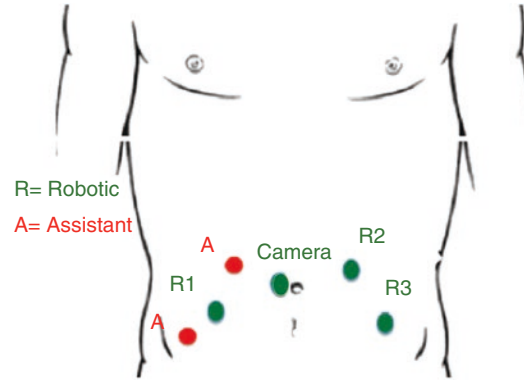

Fig. 22.2 Standard trocar positioning for Retzius-sparing Prostatectomy with the Da Vinci Si system. The grasper is usually put on the arm 2, while the Maryland on the arm 3 (*A* assistant, *R* robotic arm)

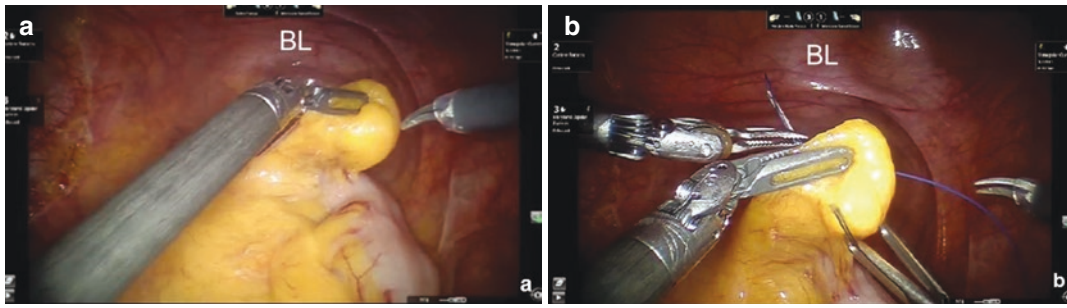

Fig. 22.3 "Pansadoro stitch": the epiploic appendixes surrounding the colon are suspended (**a**) and fixed with a Ethilon stitch with a straight needle (**b**) coming from the 5 mm assistant port in order to improve the space in the rectovesical pouch (*BL* bladder)

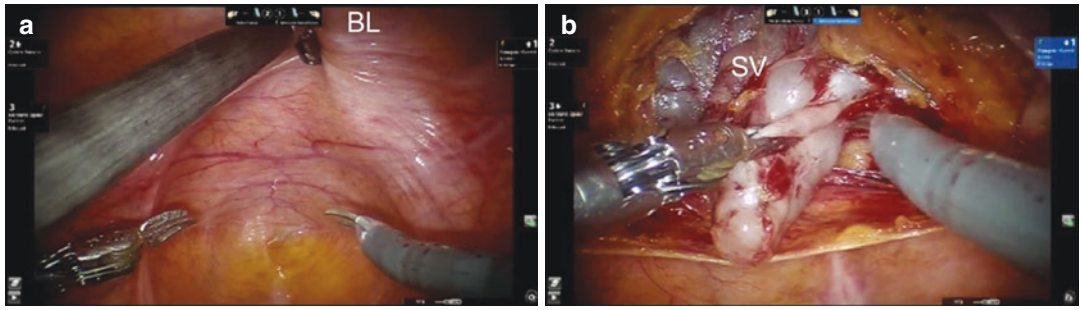

Fig. 22.4 Douglas space incision and Seminal Vesicles isolation (*BL* bladder, *SV* seminal vesicle). (**a**) the Cadiere grasp suspends the peritoneum covering the bladder; (**b**) the right seminal vesicle is dissected up to its base

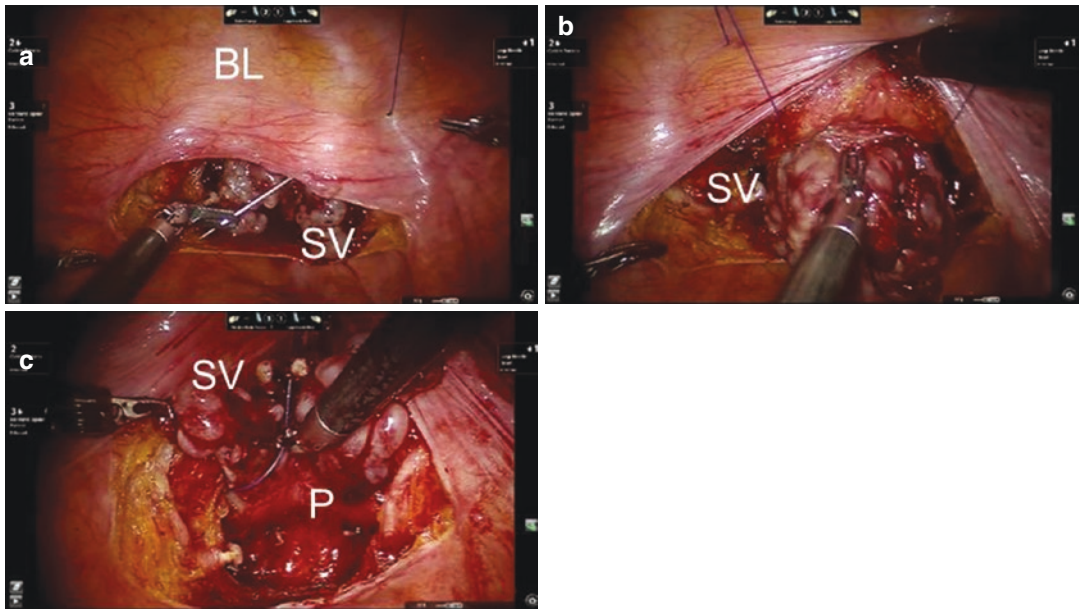

Fig. 22.5 Transabdominal stitches: the stitches are passed 1 cm above the pubis in order to suspend the bladder and gain space (**a**); the Cadiere is used to retract upwards the seminal vesicles (**b**), that are hooked to the stitch (**c**) (*BL* bladder, *SV* seminal vesicle, *P* prostate)

fer to use Aesculap BBraun DS clips, which have a quite good strength in a small space.

– Two transabdominal prepubic Ethilon 2–0 stitches are positioned laterally at the level of the deferens incision in order to stably lift the bladder and improve the space in the surgical field (Fig. 22.5).
– The prostate is lifted upwards by the Cadiere grasper, and the Denonvillier's fascia is separated by the postero-lateral surface of the prostate in an antegrade direction, reaching the prostatic apex, maintaining an intra-, inter- or extrafascial plane according to the oncological situation. In case of adherences, palpable disease or doubts the surgeon chooses to follow wider dissection planes (Fig. 22.6).
– The lateral pedicles are isolated, clipped and sectioned, and the neurovascular bundles are completely, partially spared or dissected according to the oncological situation (Fig. 22.7).
– The grasper traction is moved towards left or right in order to improve lateral exposition and to allow blunt dissection of the lateral aspects of the prostate (Fig. 22.8).
– The prostate is pushed downwards by the grasper and the vesicoprostatic junction is

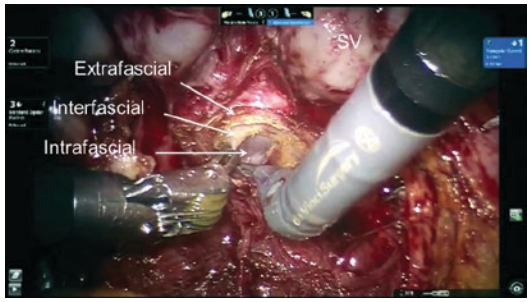

Fig. 22.6 Choosing the plane: Extra-, inter-, intrafascial dissection on the posterior surface of the prostate (*SV* seminal vesicle)

identified, isolated and sectioned, sparing the bladder neck. Usually, the tip of the Maryland is used as blunt dissector to pass behind the anterior part of the bladder neck and facilitate isolation. Moreover, in order to facilitate the identification of the bladder neck orifice during the initial steps of the anastomosis, 2 short quickly absorbable 3–0 stay stitches are positioned at 6 and 12 o'clock (Fig. 22.9).

– The anterior surface of the prostate is bluntly isolated from the Santorini plexus without any incision. In case of extrafascial dissections, it

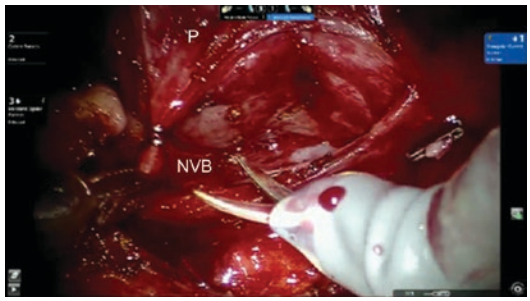

Fig. 22.7 Pedicles and neurovascular bundles isolation. The left pedicle has been clipped and the bundle is visible (*P* prostate, *NVB* neurovascular bundle)

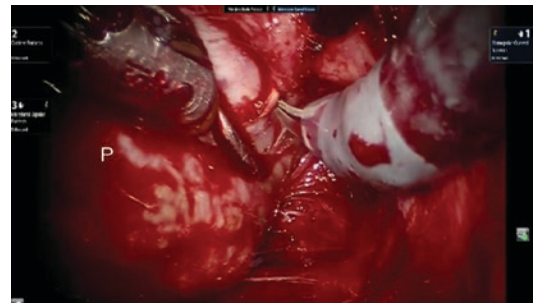

Fig. 22.8 Lateral dissection: the right lobe of the prostate is being separated from the surrounding fascias. A small artery entering the prostate is clearly visible, even though it is not the zone of the pedicle (*P* prostate)

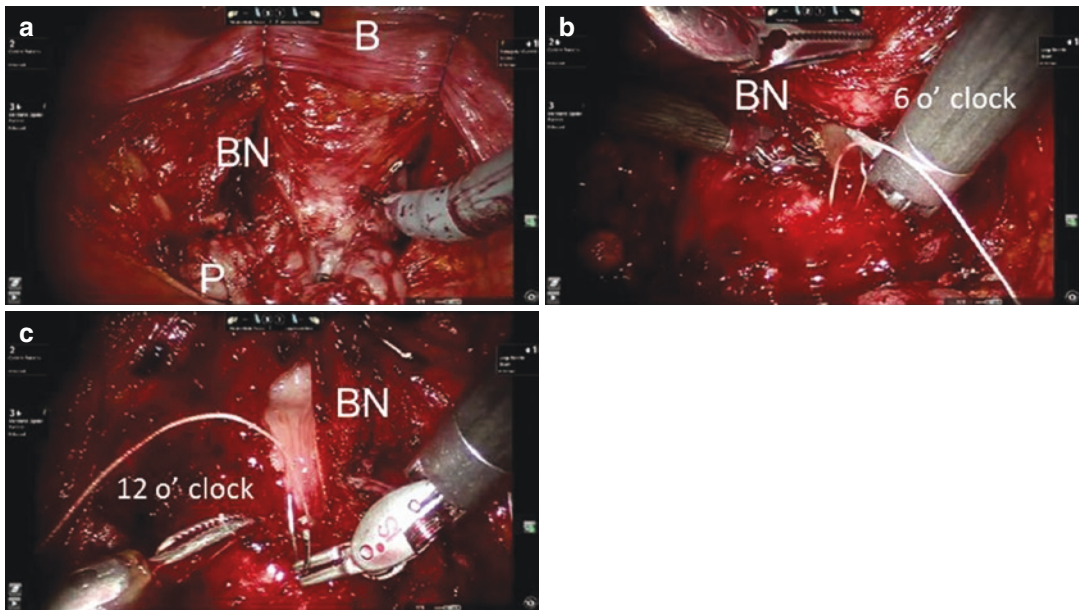

Fig. 22.9 Bladder neck isolation (**a**). After surrounding the bladder neck with the Maryland, it is opened and two stay sutures are positioned in order to facilitate the anastomosis. The first one at 6 o'clock (**b**), the second one at 12 o'clock (**c**)

is frequent to open some venous vessels. In this cases, suction should be avoided and irrigation with saline water or with glycine solution allows improved vision. Glycine allows also to continue coagulation without any problem. In case of locally advanced anterior prostate cancer, the Santorini plexus can be partially or completely resected (Fig. 22.10).

– The apex is finally isolated and the urethra is incised. The prostate is positioned into an endobag (Fig. 22.11).
– Hemostatic control is performed, using small clips, monopolar or bipolar cautery or other hemostatic agents (Floseal, Surgiflo or others). The surgical field is reduced to the stamp of the prostate, especially in the full (360°) intrafascial dissections. In the correctly selected cases, this approach allows to have a really full intrafascial nerve-sparing dissection (Fig. 22.12).
– The anastomosis is performed using a modified Van Velthoven suture. We use two 3–0 barbed sutures (V-Loc, Covidien), starting the anastomosis from the 12 o'clock position up to the left anterior lateral quarter. If the bladder neck has been spared, 3 passages are enough to reach the 9 o'clock position; the right half circle of the suture is then performed up to 6 o'clock; finally, the last posterior left quarter from 9 to 6 o'clock is completed.

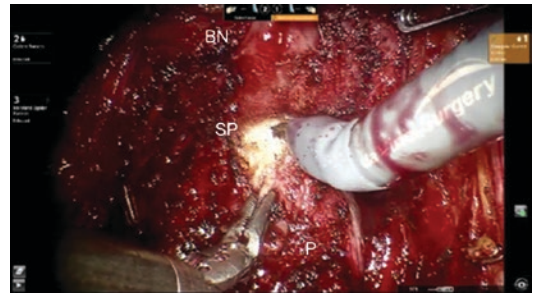

Fig. 22.10 The Santorini plexus is spared, being isolated and separated form the prostate, without the need of formal sutures (*SP* Santorini plexus, *BN* bladder neck, *P* prostate)

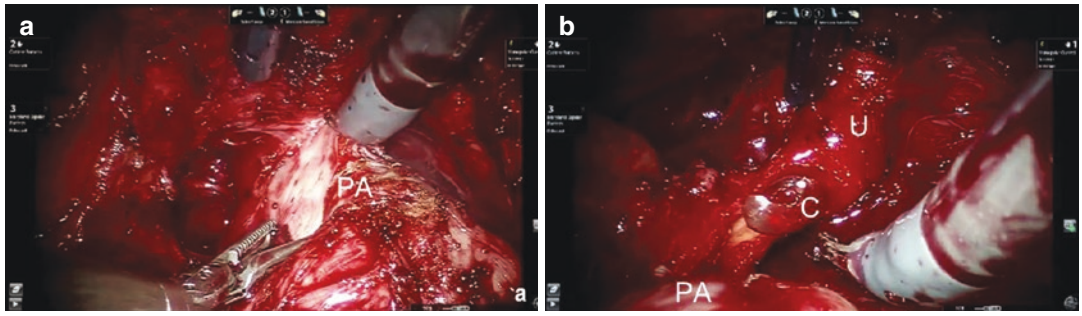

Fig. 22.11 The Prostatic Apex (PA) is isolated (**a**) and the Urethra (U) is sectioned (**b**) (*C* catheter)

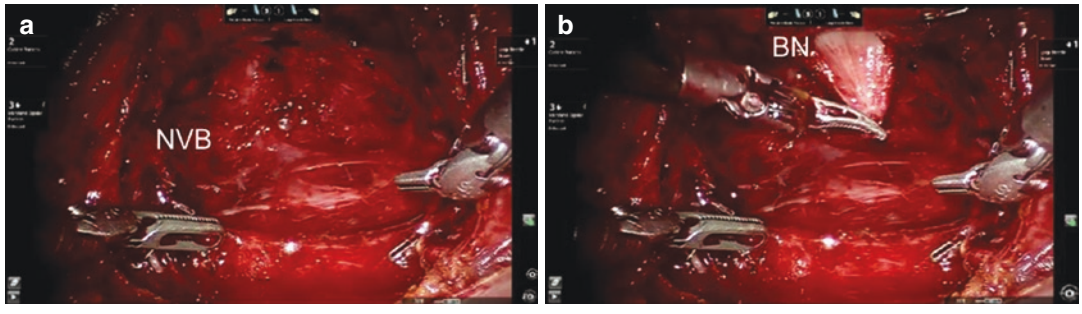

Fig. 22.12 Prostatic fossa: the negative stamp of the prostate is visible, with a 360° intrafascial dissection and the neurovascular bundle (NVB) visible (**a**). The 12 o'clock stitch is retraced downwards to open the bladder neck (BN) and begin the anastomosis (**b**)

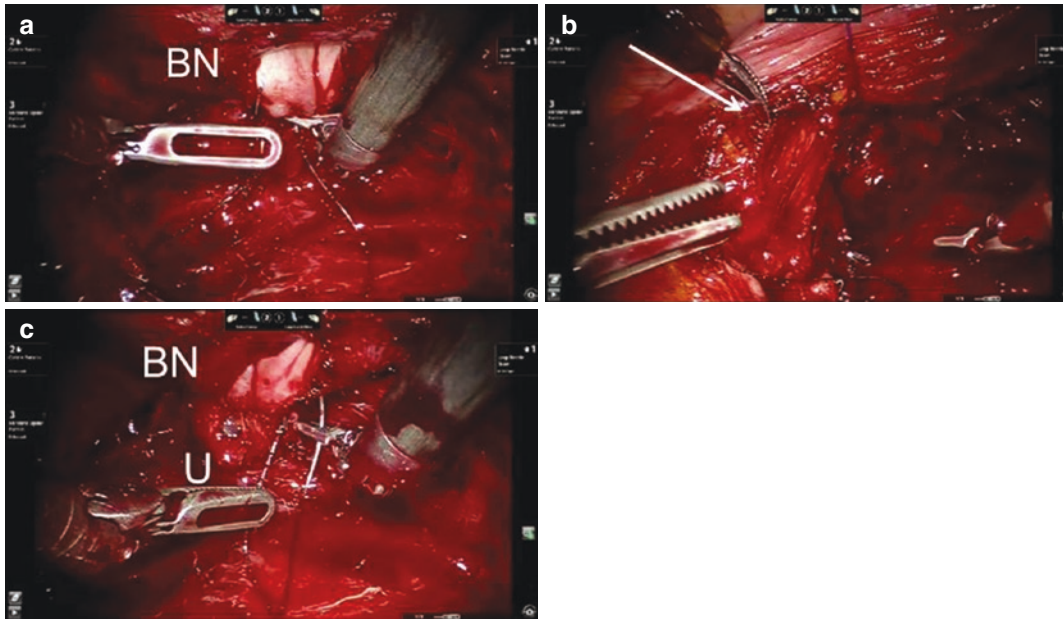

Fig. 22.13 The Anastomosis begins with the anterior left quarter (**a**); the Maryland is used to keep the left suture away from the field while completing the right side (**b**); the right half of the suture is then performed (**c**) (*BN* bladder neck, *U* urethra)

We suggest not to complete immediately the left lateral half-circle, because the surgical field becomes too closed and giving the first right half-circle stitches it can result very difficult. The Maryland is used to hold the left suture away, while the right side of the anastomosis is completed (Fig. 22.13).

Suprapubic Tube

Starting from 2012, after having completed 200 RSPs, we began to use a suprapubic tube (SPT) as urinary drainage instead of the urethral catheter in all cases with no major contraindications (bladder cancer history, non-watertight anastomosis). The rationale to use this kind of drainage is to foster early discharge, as the SPT is better tolerated by patients than the urethral catheter (UC); moreover, involuntary traction of the catheter against the anastomosis at home can results in damage to the anastomosis and consequent urethral stenosis, while traction on the SPT does not result in any damage. Usually we fill the bladder with 300 cc saline at the end of the anastomosis; if it comes out to be watertight, we insert a 14 Ch 2-way balloon Foley SPT (Fig. 22.14). We recommend not to use smaller SPTs or non-balloon single way catheters, as in case of bleeding from the bladder wall it is enough to gently retract the balloon against the wall to solve the problem.

At the beginning of our experience, we compared the discomfort of the two different drainages, confirming that the SPT is better tolerated than the UC, without differences in complications (Fig. 22.15) [14].

Moreover, a further advantage of the SPT is the postoperative management: in case of urinary retention it is sufficient to open the SPT again, without the need of any kind of urethral or anastomotic instrumentation (e.g., removing catheter and inserting it again).

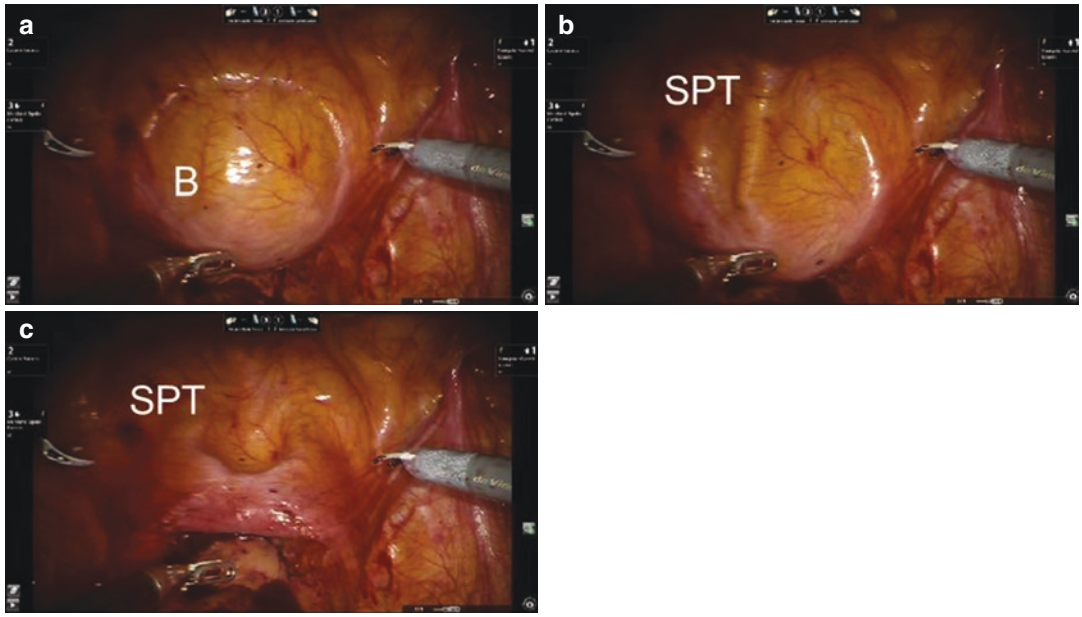

Fig. 22.14 Suprapubic Tube (SPT) positioning: the bladder (B) is filled with 300 cc of saline solution (**a**); the SPT is inserted and the bladder emptied (**b**); the Foley 14 Ch balloon is inflated with 10 cc (**c**)

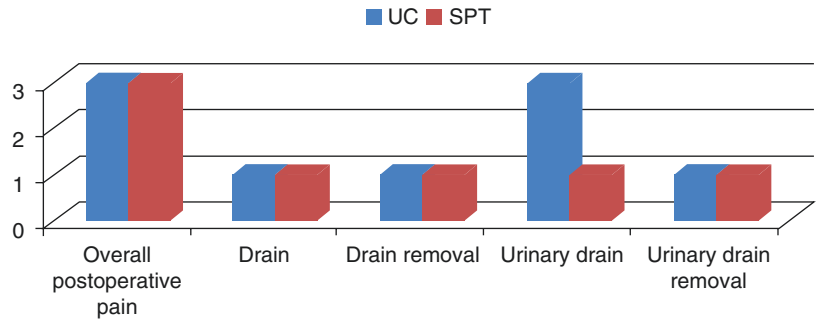

Fig. 22.15 SupraPubic Tube (SPT) versus Urethral Catheter (UC) discomfort. Visual Analogue Scale results

Pelvic Lymph Node Dissection

In case of intermediate or high risk prostate cancer cases, according to the EAU or AUA guidelines [15, 16], an external and internal iliac and obturator lymph node dissection (LND) can be performed. No additional difficulties are met during LND, and it is usually performed after radical prostatectomy. In order to reduce the risk of lyhmpocele, our current practice is to fix the peritoneum open with some clips that have the effect of a peritoneal fenestration (Fig. 22.16).

Results

Perioperative Outcomes

After the first cases, in which the technique was not standardized, a progressive improvement of the perioperative, functional and oncological results was noticed.

Currently, in our institution the RSP is performed by 6 different surgeons and more than 1000 cases have been operated on. Generally, RSP is quite a quick surgery, as no Retzius-space

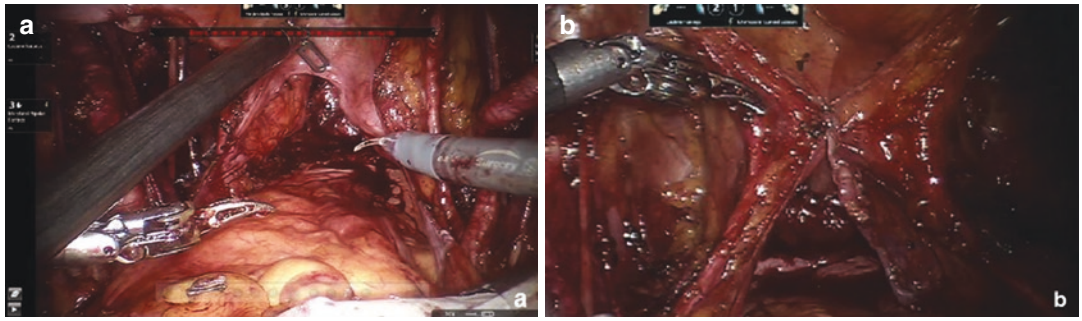

Fig. 22.16 Panoramic view after pelvic lymph node dissection (**a**); metallic clips fenestrating the peritoneum in order to reduce the probabilities of lymphocele formation (**b**)

dissection and no deep venous complex isolation and control are needed.

Beyond the first 100 cases, median console time was 120 min in our early experience; in the second generation learning curves, it took less than 30 cases to reach 120 min.

In the first 1000 patients, we rarely experienced major intraoperative complications: most of them occurred during lymph node dissection (1 ureteral lesion, 1 obturator nerve lesion, 3 hypogastric branch lesions that required intraoperative transfusions). No intraoperative complication was directly imputable to the technique (in particular, no rectal lesions occurred up-to-date).

At the beginning of our experience, we kept the patients as in-patient until the catheter was removed; gaining confidence, we began discharging patients in the second/third postoperative day (POD); selected patients who did not need pelvic lymph node dissection have been discharged in POD1, but we are not continuing this practice because of public Italian reimbursement problems (Italian national health system rules cut the reimbursement up to 70% if the patient is discharged before POD2). Up-to-date, median discharge day is POD3 (IQR 2–3).

Up to case 1000, we elected to perform cystogram in all patients; currently, we are changing our practice and have began performing cystogram only in patients who have a UC and not a SPT. In fact, SPT is currently our guarantee that the anastomosis has been checked as waterproof with 300 cc of saline solution. In those cases, in our experience, only 1 patient out of more than 400 had a contrast leakage.

Median catheter removal is POD 7 both for SPT (IQR 7–8) and UC (IQR 7–10) patients, with an acute urinary retention rate of 4% for SPT and 2.5% for UC (p = NS).

In mid-2016, we began a new study (currently ongoing): according to this approach, our equip closes the SPT in selected patients with a perfectly spared bladder neck and a satisfying surgeon-judged anastomosis and the patient tries to void in POD3 before discharge. If the voiding is successful, the SPT is removed and the patient discharged. We estimate that even if about 1 patient out of 4 could not be able to urinate properly, early catheter removal could be useful for the majority of patients; moreover, as it is sufficient to open the SPT without any instrumental maneuver, we think it would not have an impact on catheter management and postoperative course of most patients.

Postoperative complications were graded according to Clavien-Dindo classification [17]. Table 22.1 depicts the complications reported in our series.

Oncological Results

Stratifying our series according to the EAU oncological risk classification [15], we operated only low risk patients in the first 50 cases; afterwards, we extended the indication also to intermediate and high risk patients. In the first 1000 patients, we operated 41.2% of low risk, 43.4% of intermediate and 16.4% of high-risk patients.

Table 22.1 Postoperative complications according to Clavien-Dindo classification in the first 400 patients (minimum 1-year follow-up)

Clavien-Dindo Grade	Rate
Overall	91 complications in 76 pts (19%)
I-II	3% AUR 4.2% Bleeding w/ transfusions 1.2% Fever 3% Lymphorrhea 0.2% Urosepsis 2.8% DVT 0.2% Temporary neurological deficiency of the peroneal nerve (due to surgical position)
IIIa	8.6% Percutaneous drainage of lymphocele 0.6% Embolization of bleeding vessels
IIIb	1.8% Surgical correction of laparocele 0.4% Small bowel resection for perforation 0.2% Reoperation for retained drain 0.4% Reoperation for bleeding w/ hematoma
IV-V	0%

After the first 100 cases, where the standardization of the procedure was paid in terms of a high positive surgical margin (PSM) rate (21% in pT2 cases), our PSM rate was quite similar to the standard RARP.

Our overall PSMs are 26%. Differentiating the results per pathological stage, we had positive surgical margins in 10.3% of pT2 patients (8% of focal, 2.3% non-focal ones), 35% of pT3 ones. Most of the PSMs were located at the prostate apex (46%) and posterolateral region (bundle region 32%) and came from more aggressive disease (Gleason >6 in 68% of cases).

At a median follow-up of 30 months on the first 400 patients (including all risks and the learning curve), radiotherapy was performed in an adjuvant setting in 10.2% of patients (for adverse pathological features: pT2 with extended PSM, pT3a with PSM, all pT3b) and as a salvage treatment in 4.4% of patients.

Biochemical disease-free survival (bDFS) was 81%. Figure 22.17 shows the BDFs Kaplan-Meier survival curve for the whole series and according to pT stage.

Two patients had a clinical progression with hormone-resistant metastatic disease and died after chemotherapy at a follow-up of 36 and 60 months, respectively.

Functional Results

Functional results are clearly dependent on the oncological feasibility of an anatomically conservative surgery; we will follow the recommendations of the Pasadena Consensus Conference [18] in defining full-, partial-, and non-nerve-sparing procedures.

Within 7 days after catheter removal, 90% of patients were continent using no pad or one 24 h dry safety pad. At a median follow-up of 30 months, 96% of patients are continent (no pad) in the complete series; we observed no continence improvements after the first 12 months.

Up-to-date, 1 anastomotic stricture occurred, in a patient who had an accidental UC self-extraction with the balloon fully inflated on POD6.

Subdividing our patients according to the anatomical damage during surgery (fully, partial and non-nerve-sparing approach), we can recognize different continence recovery patterns (Fig. 22.18).

Considering our whole series, at a median follow-up of 30 months, 48% of patients are potent.

Selecting the preoperatively potent patients <65 years old undergoing fully intrafascial nerve-sparing surgery, 38% reported to have had the first sexual intercourse within one month from surgery. This figure rose up to 65% at 3 months, and 77% at 6 months, 81% at 12 months, with a median time to erectile function recovery of 48 days (Fig. 22.19).

Finally, we achieved the trifecta outcome (continence, potency and 1-year free from biochemical relapse) in 45% of cases; considering

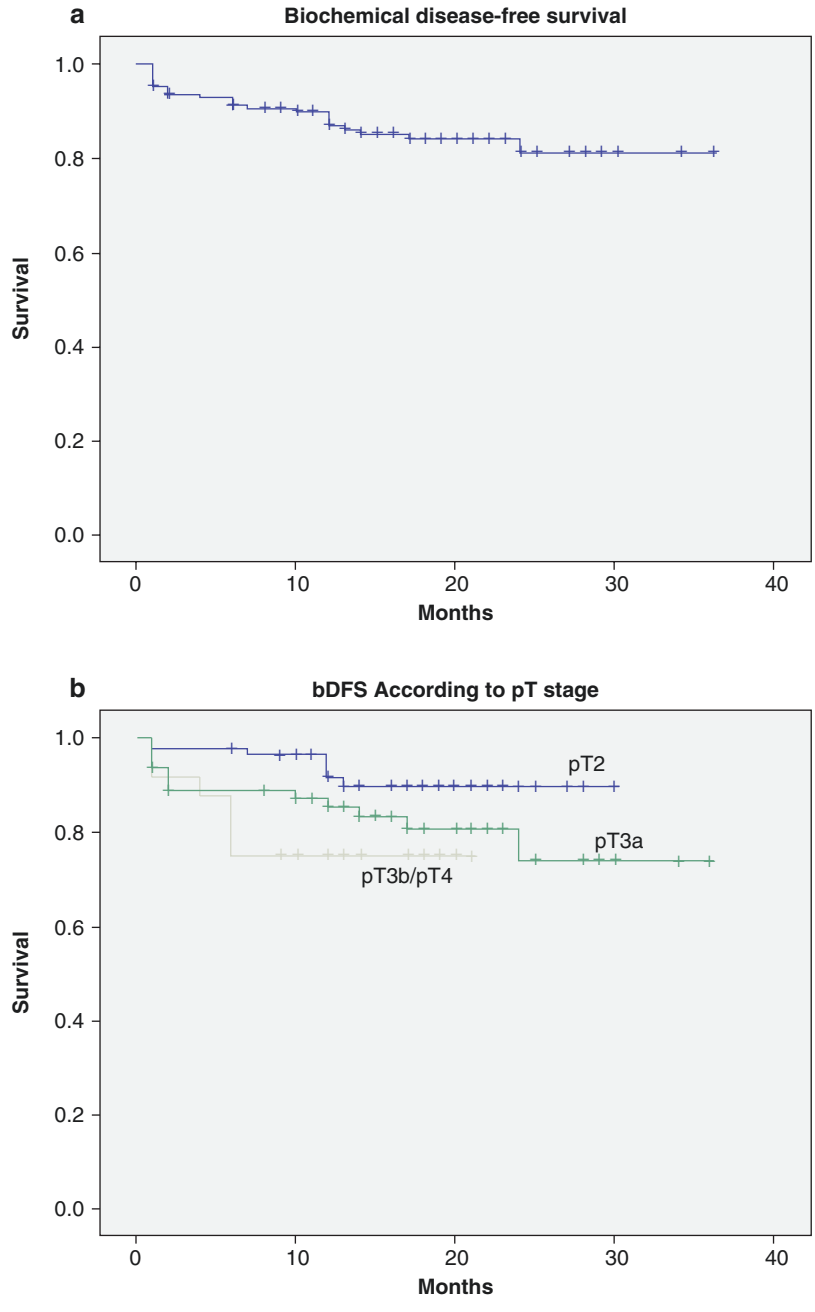

Fig. 22.17 Kaplan-Meier curves for biochemical disease-free survival for the whole series (**a**) and stratified for pathological T stage (**b**)

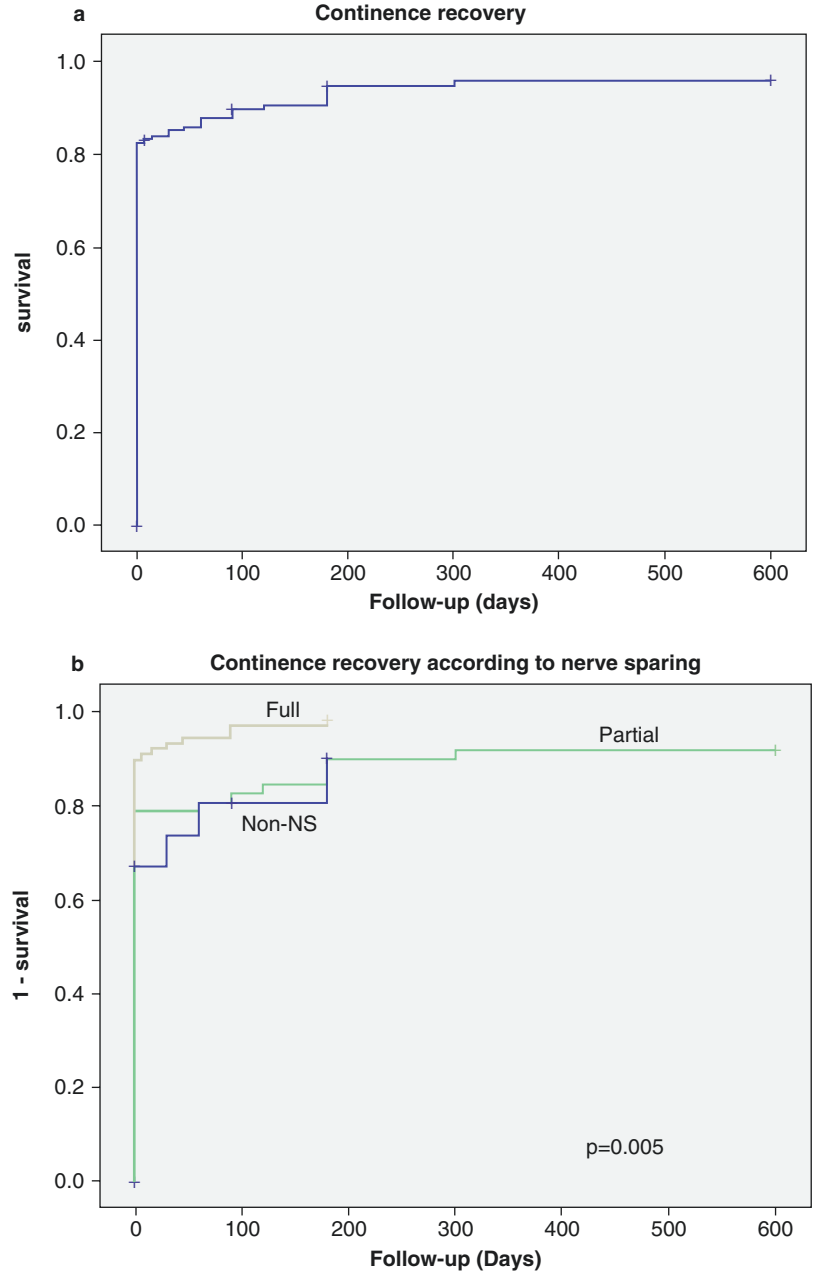

Fig. 22.18 Kaplan-Meier curves estimating continence recovery for the whole series (**a**) and stratified for nerve-sparing approach (full, partial or non nerve-sparing) (**b**)

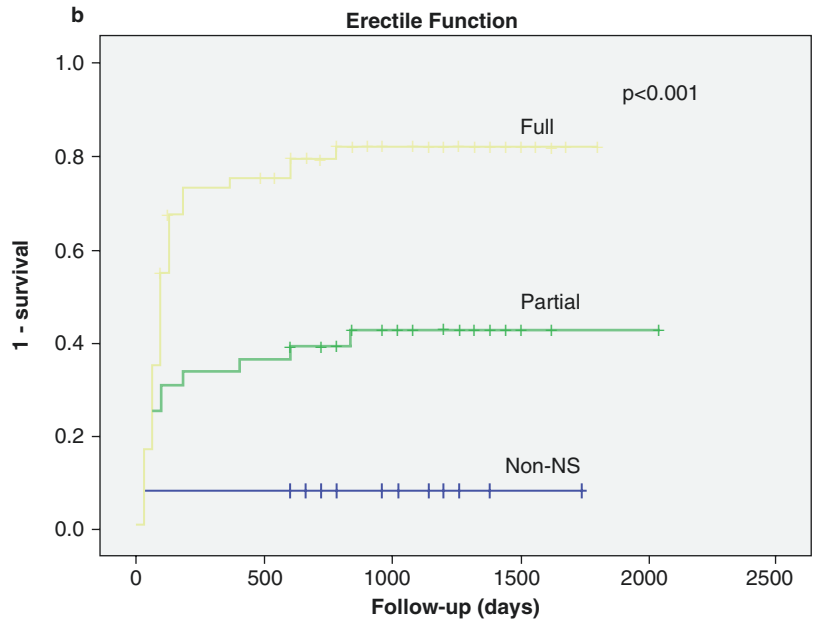

Fig. 22.19 Kaplan-Meier curves estimating erectile function recovery in patients <65 years old, with a good preoperative erectile function, stratified for nerve-sparing approach (full, partial or non nerve-sparing)

only preoperatively potent patients, the rate raised up to 65% of cases.

Considerations

The main strength points of RSP are the rapidity of execution, the low complication rate, and the good functional results. The main reasons for this success should be found in the anatomical respect of the surrounding structures. In fact, looking at the possibility that important vessels and nerves could be present in the anterior layers that cover the prostate and that are usually disrupted during the standard RARP procedures (e.g., in the Santorini plexus), we do believe that the only procedure deserving the denomination of "full nerve-sparing" should be the 360° intrafascial dissection of the RSP; on the contrary, the other so-called "full nerve-sparing" surgeries miss at their best one quarter of the 360° of the prostate surroundings [19].

According to the IDEAL (Innovation, Development, Exploration, Assessment, Long-term studies) system [20, 21], the most known system of surgical development appraisal, our technique has already overcome the first steps, with Innovation and Development reached with the first publications [3], and Exploration reached in 2013 with the publication of the 1-year follow-up results of the first 200 patients operated on [22] and confirmed by a second report by the Vattikuti Institute of Detroit [23], reporting a no pad urinary continence rate of 95% 4 weeks after surgery. Currently, Assessment against the current standard has been performed only in a comparative non randomized experience: a Korean group performed a match-paired comparison between 50 RSP and 50 standard RARPs, reporting a 4-weeks continence (no pad or 1 safety liner) of 92%, with a shorter console time and without worsening of the early oncological results [24]. The first randomized comparison between RARP and RSP has been completed at the Vattikuti Institute of Detroit by Mani Menon, and the results will be presented in late 2016. However, preliminary results show also in this experience a palpable difference in continence recovery in favor of RSP (data not shown).

Finally, long-term results are still needed. At the end of 2016, the first 200 patients will complete their 5-year follow-up. A new analysis of data could provide new results in 2017.

Special Cases

Beginning with a new experience, we decided to start only with the ideal cases: young thin men, normal prostates, low risk prostate cancer. After the first 50 cases were completed, we broadened our indications to intermediate and high-risk patients, and gradually began performing RSP also in the most complex cases. After the first 100 cases, we elected to operate all patients with an indication to radical prostatectomy with the RSP approach.

To date, we performed this surgery in several special cases.

Previous Heavy Abdominal Surgery

Currently, we performed RSP in more than 50 cases with previous major abdominal surgery (that is pancreaticoduodenectomy, liver transplant, hemicolectomy, sigmoid or rectal resection, previous temporary ileostomy, abdominal trauma, abdominal aortic aneurysm correction, and so on); in these cases we had 2 intraoperatively corrected ileal lesions and 2 unrecognized bowel lesions that needed a postoperative laparotomy.

Large Median Lobes

In our experience, median lobes are well managed with the Retzius-sparing approach. Median lobe is easily recognized from the posterior aspect of the bladder neck; going towards the lateral aspects of the prostate allows to surround it and spare almost completely the muscle fibers of the bladder neck (Fig. 22.20). Up-to-date, we performed a formal bladder neck reconstruction with a lateral or posterior suture in very few cases (less than 5); when the bladder neck is sectioned and the caliber of the urethra is smaller than the one of the bladder neck, we perform a parachute anastomosis.

Very Large Prostates

The biggest prostate removed during RSP weighted 300 g (Fig. 22.21). Cases with very large prostates (>100 g, about 6% in our experience) are not for beginners, but with some tips and tricks and following a posterior dissection that extends gradually and symmetrically towards

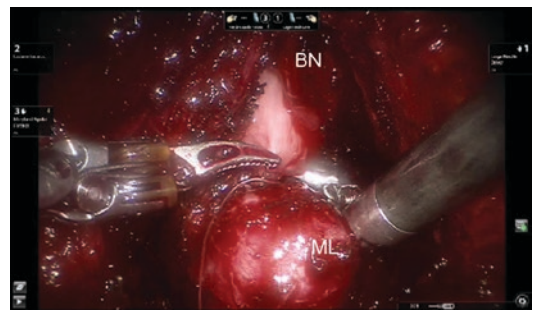

Fig. 22.20 Intraoperative view of the bladder neck (BN) of a large prostate with median lobe (ML); the image shows the BN after it has been opened on its posterior aspect

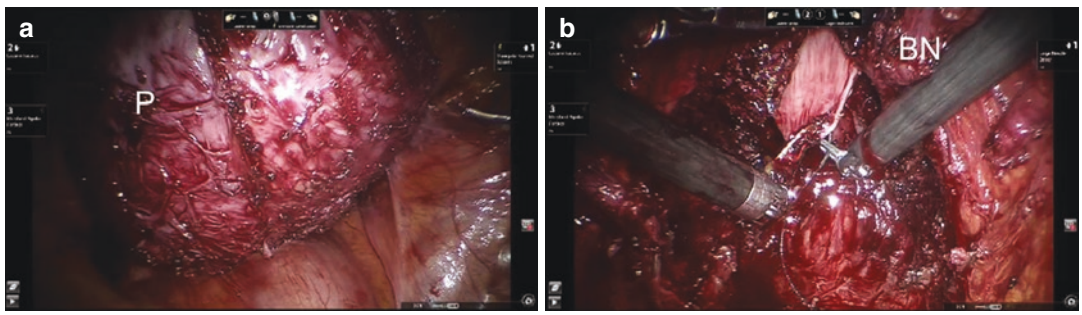

Fig. 22.21 Very large prostate (300 g) (**a**); nevertheless, the bladder neck (BN) was not wide open and a standard anastomosis was completed with a parachute reduction (**b**)

the lateral aspects of the prostate, the surgery is accomplished without complications.

Previous Prostatic Surgery

We performed more than 50 RSPs after TURP, HoLEP or simple prostatectomy. Radical prostatectomy after TURP is quite challenging independently from the technique used. The bladder neck is almost always difficult to spare as it is usually dissected during TURP; adhesions and surgical scars might further confound the surgical plans, and the ureteral orifices might need to be stented in order to avoid damages during dissection or anastomosis; moreover, after simple prostatectomy the Retzius space is already violated and surgery is more difficult. The RSP has the advantage of using a different surgical plan and approaching the trigone from behind (Fig. 22.22). In our opinion, this allows a better preservation of the trigone and consequently a lower risk of ureteral orifice damage. To date, we did not have any ureteral orifice lesion and we did not need to put stents during RSP for prostate cancer (only one case of stenting before RSP for bulky seminal vesicle sarcoma).

Previous Kidney Transplant

It is a quite rare indication (8 cases in our hands—1 with bilateral kidney transplant): these cases were among the most satisfying ones. Usually, radical prostatectomy is a really challenging procedure for kidney transplanted patients, as the kidney occupies a vital space for surgery and the new ureter has an unpredictable course and could be damaged during the procedure. On the contrary, RSP allows to perform the whole surgery passing through a virgin surgical space. After positioning the trocars (the trocars near to the transplanted kidney should be placed carefully and a little bit more medial than usual), the surgeon performs a standard RSP without any adjunctive difficulty (Fig. 22.23).

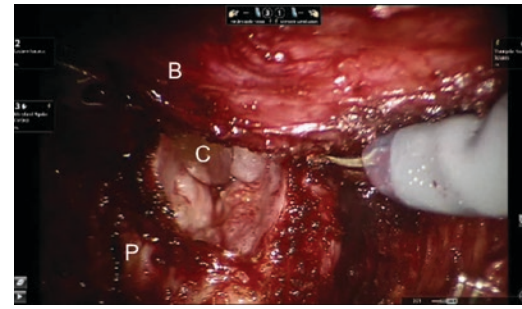

Fig. 22.22 Retzius-sparing prostatectomy after TURP. The posterior aspect of the bladder neck (BN) has been opened and the contour of the prostate (P) can be seen with the urethral catheter (C) crossing the field

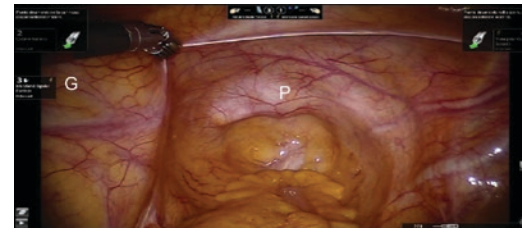

Fig. 22.23 Case of Retzius-sparing prostatectomy in a kidney transplant bearing patient. The graft (G) is far from the surgical field of the prostate (P)

Salvage Prostatectomy

Up-to-date, only 2 salvage prostatectomies occurred. The first one has been a recurrent prostate cancer after HIFU treatment, the second one has been performed after radiotherapy. In both cases, surgical plans have not been recognizable and an extrafascial non-nerve-sparing surgery has been performed. The radio-recurrent case has been complicated by a prolonged UC time (20 days) and pulmonary embolism successfully treated.

Pelvic Sarcomas

Two patients underwent RSP for locally advanced/bulky pelvic sarcomas; in both cases other centers proposed anterior or total pelvic exenteration. The first case occurred in a 44 years old patient with a prostatic sarcoma invading the rectum, who underwent a combined RSP and

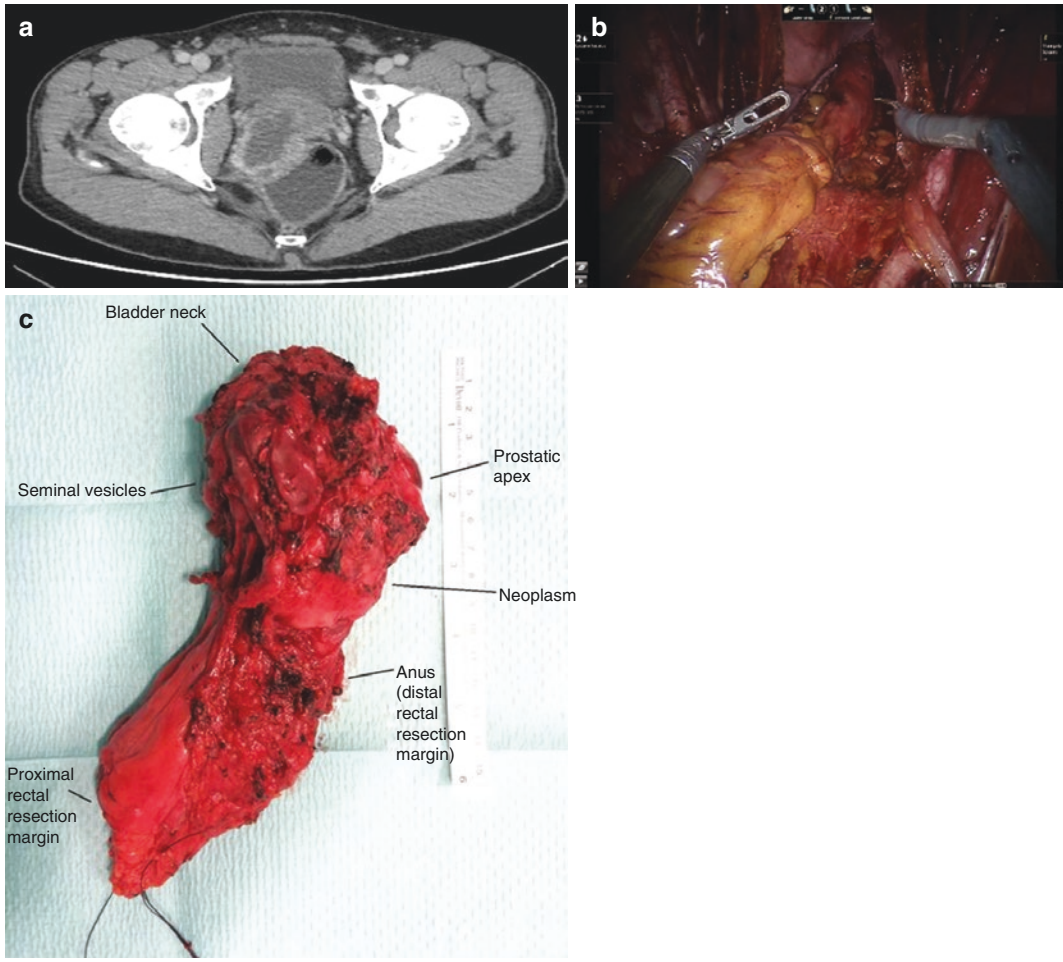

Fig. 22.24 Prostatic sarcoma invading the rectum. Preoperative CT scan (**a**); intraoperative view at the end of surgery (prostatectomy and ultralow rectal resection) (**b**); surgical specimen (**c**)

ultralow resection of rectum (Fig. 22.24). Now, 18 months later, he is continent, potent and has no local recurrence. He is undergoing chemotherapy for micrometastatic lung disease.

The second case involved a 50 years old man with a bulky (10 cm) seminal vesicle sarcoma, who accomplished an uneventful RSP with a previous ureteral stenting. The patient reported immediate continence and quick erection recovery (first intercourse 40 days after surgery); even with negative surgical margins, adjuvant radiotherapy was advised due to the size of the disease but the patient refused because of risks of functional complications. Follow-up is still underway.

Fortune and Diffusion

The RSP is currently spreading worldwide, with a jeopardized diffusion. The first inputs for a diffusion of the technique were the live surgery demonstrations during the most important world congresses. Up-to-date, the technique has been shown in live and semi-live surgery during some of the most known world congresses (5 editions of the Challenges in Laparoscopy and Robotics, 2 editions of the ERUS congress, World Congress of Endourology, Societé Internationale d'Urologie, Heidelberg Semilive Surgery, and so on). This allowed urological robotic surgeons coming from all over the world to replicate the

technique. Dr. Bocciardi has been invited to several prestigious institutions as proctor for the technique; as time passes by, new surgeons modify the original technique and perform it by themselves without the need to be proctored. YouTube, video Journals and web based transmissions permit to have all the instruments to begin such an activity without the need of a formal proctor. We know that currently in Europe, Asia, North and South America there are centers performing the RSP on a regular basis.

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23

Pelvic Lymph Node Dissection for Prostate Cancer and Nomograms

Emanuele Zaffuto, Giorgio Gandaglia, Nicola Fossati, Francesco Montorsi, and Alberto Briganti

Abstract

Pelvic lymph node dissection (PLND) is the most accurate staging procedure for assessing nodal status in patients undergoing surgical treatment for PCa. In particular, an anatomically defined extended template would allow properly sampling up to 75% of possible positive stations. The use of clinical nomograms provides good predictive accuracy and might guide clinicians in the identification of patients at higher risk of LNI, who should therefore receive an extended lymph node dissection. This is reflected also by the current urological clinical guidelines. Of note, PLND also has a role in the context of recurrent disease after primary surgical treatment.

Keywords

Complications · Dissection extent · Nomograms · Lymph node excision · Lymph node invasion

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Introduction

Up to 25% of surgically managed prostate cancer (PCa) patients experience lymph node invasion (LNI) at final pathology [1, 2]. Of note, LNI is a well-known negative prognostic factor associated with adverse oncologic outcomes [3]. The regional lymph nodes represent the most common metastatic site for PCa and the pelvic lymph node dissection (PLND) represents an important mainstay during the surgical management of these patients to perform a correct staging. In this context, an anatomically-defined extended PLND (ePLND) template over limited PLND would result into a more accurate staging in this setting [4–7]. Additionally, the surgical excision of pelvic lymph nodes might also have a possible therapeutic role in node-positive patients [8]. However, PLND is a time-consuming procedure that is not devoid of complications [9, 10]. In consequence, different clinical tools have been developed to accurately identify patients with LNI, thus avoiding unnecessary PLNDs. This is particularly true in the context of low-risk organ-confined disease. While preoperative imaging techniques showed underwhelming results [11–14] and, as such, are not recommended for the purpose of nodal staging [1], the indication to perform PLND is now based on preoperative clinical characteristics. The combination of these parameters is used in currently-available nomograms to reliably predict the risk of LNI and, therefore, to identify patients who should receive an ePLND [15–28]. On the

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other hand, recent studies showed that the use and extent of PLND is decreasing in the recent years. This phenomenon might be related to the widespread diffusion of minimally-invasive surgery, such as robot-assisted RP (RARP) [29, 30], and might be associated with a substantial risk of understaging of nodal status for PCa patients.

The aim of this chapter is to review the role of PLND in the management of PCa. Moreover, the anatomical lymphatic drainage will be discussed with a particular focus on the rationale for an ePLND. We will also carefully analyze the current indications for ePLND, as well as side effects associated with this procedure. Finally, we would describe possible novel approaches, such as the sentinel lymph node technique and the potential role of nodal dissection in the recurrence setting after primary treatment.

Anatomical Lymphatic Drainage of the Prostate

The anatomical lymphatic drainage of the prostatic gland is complex. The original descriptions of the lymphatic drainage system of the prostate was based on anatomic dissection and animal studies. However, these evaluations are nowadays considered limited and not accurate. More recent investigations relied on the injection of contrast agents into the prostatic gland and subsequent execution of lympangiography. For example, Raghavaiah et al. [31] used this technique by injecting ethiodol in the prostate of 12 healthy patients. A similar technique was used by Brossner et al. [32, 33], who relied on computed tomography (CT). These studies allowed identifying three main lymphatic drainage routes:

1. From the prostate to the lymph nodes along the lateral bony wall of the pelvis to the angle of internal/external iliac lymph nodes to the common iliac lymph nodes;
2. From the prostate to the perineal floor to the pudendal lymph nodes to the angle of the internal/external iliac lymph nodes to the common iliac lymph nodes;
3. From the prostate to the presacral lymph nodes.

Precise knowledge of these lymphatic routes is of paramount importance when performing PLND, in order to correctly perform a surgical excision of all possible metastatic lymph nodes, thus and to reduce the risk of understaging in patients with PCa. However, more recent studies suggest that such description of the lymphatic drainage of the prostate does not accurately include all possible sites of spread for metastatic cancer cells. In 2008, Mattei et al. [6] published a landmark study after performing intraprostatic injections with radioactive technetium-based nanocolloids in 34 patients. They identified the primary lymphatic landing sites with a gamma probe and demonstrated that approximately 36% of them were located along pararectal, presacral, common iliac or paraortic stations. This observation had profound implications on the definition of the anatomical extent of PLND. Indeed, the use of a limited PLND template, which usually includes the surgical excision of obturator with or without the external iliac lymph nodes, would miss almost two thirds of the primary lymphatic landing sites in patients with PCa. Conversely, the use of an extended PLND template, which should include the removal of obturator, internal iliac and external iliac, common iliac, and presacral lymph nodes, would correctly remove 75% of all possible anatomical landing sites [6]. This consideration is confirmed by a recent study performed by Joniau et al. [7] who showed that, while it is true that internal, external iliac lymph nodes and obturator lymph nodes account for about 60% of primary lymphatic landing sites, in a non-negligible proportion of cases the primary lymphatic site is in common iliac (19%), paraortic (10%), presacral (7%), aortic bifurcation (4%) or pararectal (3%) stations. As a consequence, an anatomically-defined extended PLND template that includes these regions is mandatory when PLND is indicated in PCa patients.

Nodal Staging in Patients with Prostate Cancer: The Role of Imaging

Correct nodal staging is essential in patients with PCa in order to correctly identify individuals with LNI and, therefore, proceed with PLND. Indeed,

PLND is not devoid of complications, and some patients would not benefit from this approach. For this reason, the use of several different imaging techniques has been assessed in order to evaluate their accuracy to correctly predict LNI and to provide indication for the performance of PLND.

One of the most commonly used imaging techniques is represented by CT scan [11]. This imaging modality, however, has been proved to be limited by the use of dimensional criteria to define LNI. Specifically, only lymph nodes greater than 8–10 mm would be considered suspicious [12, 13, 34]. In consequence, this definition fails to correctly identify metastatic lymph nodes when the size is less than 8 mm. This translates in the risk of missing the majority of patients with LNI, as nodal involvement in PCa is often characterized by micrometastatic invasion [34, 35]. In this context, Briganti et al. [11] showed that, while it is true that CT scan is characterized by a high specificity (96%), the sensitivity of this technique is low (13%) and the accuracy is only 54%. In consequence, the use of CT scan for predicting LNI risk is comparable to a coin toss in men with localized PCa. On the other hand, CT scan might help in presence of clearly pathologic lymph nodes. However, this technique should not be used as a decision tool for PLND in patients with localized PCa.

More recently, the role of multiparametric magnetic resonance (mpMRI) scan has been assessed. Similarly to CT scan, MRI shares the same limitations such as low sensitivity and a definition of suspicious lymph nodes based on dimensional criteria [12–14]. However, the main advantage of MRI stems from the availability of different contrast agents, as well as different image acquisition techniques. In this regard, a recent study evaluated the role of specific superparamagnetic nanoparticles that are able to specifically target the reticulo-endothelial system [36]. Heesakkers et al. [34] evaluated 375 individuals with this technique and were able to identify 50 metastatic lymph nodes out of 60 patients who showed LNI at the final pathology. Moreover, of these 50 metastatic lymph nodes, 40 were normal-sized and would have been considered as normal in a regular CT scan. This translated into a very high negative predictive value of 96% [34]. However, the results from this study need to be considered with caution as some limitations apply. Most importantly, all the patients included in the study were treated with a limited PLND and ePLND was performed only in 15 patients because it was guided by the results from the imaging. Therefore, the negative predictive value of this technique might be falsely higher than in real clinical scenarios. Nonetheless, these preliminary results are interesting and deserve further investigation, as the inclusion of imaging into preoperative nomograms is not actually capable of increasing the predictive accuracy of these tools [11].

The role of positron emission tomography/computed tomography (PET/CT) scan is currently under extensive investigation. In fact, although PET/CT scan is still influenced by the size of nodal metastases, this technique is also able to identify suspicious lymph nodes based on the metabolic activity of tumor cells. A meta-analysis concluded that choline PET/CT provides low sensitivity in the detection of LNI in the preoperative setting, even in patients at high risk for nodal involvement [14]. This is probably related to the high rate of false positives due to inflammation and the high rate of false negative due to the presence of micrometastatic tumor not identifiable with current scanners [37]. For this reason, more recent studies focused on alternative tracers such as 18F-FABC or 68Ga-PSMA. As reported by Nanni et al. [38], the use of 18F-FABC resulted superior than choline for the detection of metastatic lymph nodes. Similar data have been reported for 68Ga-PSMA [39, 40]. Of note, Budaus et al. [40] were the first to demonstrate the role of 68Ga-PSMA PET/CT scan prior to RP, while other authors focused on recurrent disease after treatment. Nonetheless, more studies are required in order to properly determine the role of this imaging technique before primary treatment.

Taken together, the current literature suggests that preoperative imaging has still a limited role in predicting LNI and should not be used as a decision tool for PLND [1].

Assessing the Risk of LNI: The Role of Preoperative Nomograms

The limited performance characteristics of currently available imaging techniques underlines the need for other instruments to identify PCa individuals at higher risk of LNI. For this reason, recent studies proposed several prediction tools based on different preoperative clinical parameters. Indeed, nomograms represent the most widely used tools in order to assess the risk of LNI (Table 23.1) [15–28]. These stratification tools are usually based on PSA at diagnosis, biopsy Gleason score, clinical T stage and the number of positive cores at biopsy. The model developed by Briganti et al. [15] also included the percentage of positive cores, which represents the most important independent predictor of LNI [17].

In general, all available nomograms show high accuracy at internal validation, ranging from 76% to 97.8%. However, several limitations may represent barriers to their applicability to clinical practice. First, some of these studies represent single-institution series and involve a small cohort of patients. This limits generalizability in other clinical settings. Second, these studies evaluated historical patient cohorts. In consequence, the applicability of these results in contemporary patients is not warranted. Last but not least, a non-negligible proportion of these models was developed after evaluating cohorts of individuals treated with limited PLND.

Indeed, nomograms developed in limited PLND series are associated with a significant risk of underestimation of the real presence of nodal metastases. For example, Briganti et al. [41] showed that the removal of less than 10 lymph nodes yields a very low probability of finding LNI. Similarly, Abdollah et al. [4] demonstrated that an extended dissection template with removal of at least 20 lymph nodes yields a 90% probability of correctly staging the LNI status, regardless of risk group [4]. Kluth et al. [5] further confirmed the ability to correctly identify the presence of LNI at the final pathology is associated with the number of removed lymph nodes. In their analyses, the sensitivity of PLND in correctly staging the nodal status exceeded 80% when the number of removed lymph nodes was higher than 10 [5]. Taken together, these studies suggest that nomograms developed in limited PLND series could be inaccurate in daily clinical practice. For this reason, whenever the risk of nodal metastases is assessed, this should be evaluated using models based on extended nodal dissection series.

Very few models have been developed on patient cohorts in which only ePLND was performed. For example, the nomogram by Godoy et al. [19] is based on PSA, clinical stage and biopsy Gleason sum and achieves an accuracy of 86.2%. Similarly, Briganti et al. [15] based their model on PSA, clinical stage, primary and secondary Gleason score and the percentage of positive cores at biopsy. This latter model showed a slightly better accuracy (87.6%) and, recently, has been externally validated by other studies [7, 42]. This is reflected in the current European Association of Urology (EAU) guidelines [1], which recommend PLND when the risk of LNI is higher than 5% according to the Briganti nomogram. The same guidelines underline that, when PLND is considered, it should be performed according to an extended template.

Current Indications for PLND

Nomograms do not directly recommend PLND. As they return the risk of harboring LNI as a probability, the decision whether to perform PLND must be taken after risk stratification according to cut-offs. Different cut-offs are given by different guidelines. For example, according to the European Association of Urology (EAU), PLND should be performed in all men with a risk of lymph node metastasis higher than 5% based on the updated Briganti nomogram [1, 15]. Similarly, the National Comprehensive Cancer Network (NCCN) guidelines recommend PLND when the risk of LNI is 2% or higher. At the same time, they recommend ePLND over limited PLND. Finally, the American Association of Urology (AUA) guidelines are the only ones that do not explicitly adopt a cut-off nor they specify the extent of PLND. However, they recommend

Table 23.1 Summary of different studies evaluating predictive mdoels for the presence of lymph node invasion (LNI) in patients with prostate cancer (PCa)

First author	Year	Population size	Extent of PLND	Covariates included in the model					Accuracy of the model
				PSA	Clinical stage	Biopsy Gleason score	Percentage of positive cores	Other (specify)	
Bishoff et al.	1995	481	Limited	X	X	X	–	–	NA
Roach et al.	1994	212	Limited	X	–	X	–	–	NA
Narayan et al.	1994	932	Limited	X	–	X	–	–	NA
Cagiannos et al.	2003	7014	Limited	X	X	X	–	–	76%
Poulakis et al.	2004	201	Limited	X	X	X	–	Pelvic MRI findings	84%
Wang et al.	2006	411	Limited	X	X	X	–	Pelvic MRI findings	89.2%
Briganti et al.	2007	278	Extended	X	X	X	–	–	83.7% (internal validation)
Briganti et al.	2007	565	Extended	X	X	X	–	–	76%
Makarov et al.	2007	5730	Limited	X	X	X	–	–	88.8%
Godoy et al.	2011	4176	Extended	X	X	X	–	–	86.2%
Briganti et al.	2012	588	Extended	X	X	X	X	–	87.6% (internal validation)
Briganti et al.	2012	982	Extended	X	X	X	X	–	71%
Kim et al.	2014	541	Extended	X	X	X	–	–	88.3% (internal validation)
Kluth et al	2014	4770[a] 3595[b]	Extended	X	X	X	–	Number of retrieved lymph nodes	> 80% (when at least 11 LNs are examined)

RP radical prostatectomy, *PLND* pelvic lymph node dissection, *PCa* prostate cancer, *PSA* prostate specific antigen, *LN* lymph node, *LNI* lymph node invasion, *MRI* magnetic resonance

[a]Development cohort

[b]Validation cohort

Table 23.2 Current guideline recommendations regarding the need for and the extent of pelvic lymph node dissection in prostate cancer

Guidelines	Indication	Extent of PLND
European Association of Urology	ePLND should be performed in intermediate-risk PCa patients if the estimated risk for positive lymph nodes exceeds 5%	Limited PLND should not be performed
National Comprehensive Cancer Network	PLND can be excluded in patients with <2% predicated probability of nodal metastases by nomograms	An extended approach is preferred when PLND is performed
American Urological Association	Should be considered for patients at higher risk of nodal involvement	*Not specified*

PLND pelvic lymph node dissection, *ePLND* extended pelvic lymph node dissection

risk stratification for LNI, as they state that PLND should be performed in men with higher risk of LNI. Current guidelines recommendations for PLND are synthetized in Table 23.2.

The Importance of an Extended Nodal Dissection

As previously discussed, several studies evaluated the extension of PLND on the ability to detect LNI in patients with PCa [4, 5]. However, an important consideration has to be made before further discussing this topic. Many reports in the literature discuss about the extension of PLND taking into account the number of removed lymph nodes. In the past, this was not always considered a reliable proxy of the extent of PLND [43]. Because of anatomical disparities between patients, it is possible that patients who received limited PLND might have a high number of retrieved lymph nodes. At the same time, other patients might receive ePLND but a limited number of lymph nodes could be retrieved, because of limited representation of lymphatic tissue in the pelvis. This example underlines that the extent of PLND should ideally be defined by anatomical templates. Specifically, an ePLND should at least include the removal of obturator, internal iliac, external iliac, common iliac and presacral lymphatic tissue. This allows clearing of at least 75% of all anatomical landing sites [6].

Today, the literature is slowly accepting the number of retrieved lymph nodes as a reliable proxy of the extent of PLND. Heidenreich et al. [44] showed that patients with ePLND have a higher number of retrieved lymph nodes, compared to their counterparts treated with limited PLND. This observation was confirmed by other authors [45, 46]. Moreover, it has been demonstrated that an extended dissection template is also associated with an increased ability to detect LNI [4, 5]. These results suggest that an extended dissection template should be preferred over limited PLND, if the procedure is recommended at all [1], in order to retrieve a higher number of lymph nodes and, as such, to perform a more accurate staging. In this regard, a prospective study performed on 19 high-risk PCa individuals demonstrated that metastases in the retroperitoneal region can be identified only in patients who also have positive common iliac lymph nodes [47]. These results further underline that common iliac nodes represent critical landmarks for accurate nodal staging. However, they would not be removed in the context of limited PLND. The role of presacral lymph nodes, on the other hand, is more debated, albeit a previous study demonstrated that the probability of removing all metastatic lymph nodes can go up to 97% if the presacral region is added to the ePLND template [7].

That being said, it might be asked if the role of PLND is limited to staging or if it also heralds a therapeutic role. In this regard, several studies have been performed in order to specifically evaluate if an extended PLND template is associated with better oncologic outcomes. Conflicting results are reported. Specifically, while some authors did not find any statistically-significant difference in patients treated with ePLND [48–50], others demonstrated that the extent of the dissection is associated with better oncologic outcomes [51–53].

In the year 2012, the publication of the results from the first prospective trial directly comparing limited vs. extended PLND [54] raised great interest among the scientific community. However, the study has been retracted because of academic misconduct and data falsification [55]. In the absence of definitive answers, the current literature, albeit based on retrospective studies, suggests that a higher number of removed lymph nodes is directly associated with better oncologic outcomes. Since the extent of PLND directly influences the probability of retrieving positive lymph nodes, ePLND should be preferred in order to achieve more correct nodal staging. This would allow for more correct planning of additional systemic treatments after RP, such as androgen deprivation therapy. In fact, patients with more than two positive nodes are associated with significantly worse survival rates [56]. Abdollah et al. [8] later confirmed that, in these patients, ePLND and a higher number of removed lymph nodes are factors clearly associated with better survival outcomes.

Taken together, the current literature, even in the absence of valid data from prospective trials, suggests that a thorough dissection of pelvic lymph nodes might remove all the potential metastatic landing sites of PCa cells [4–7]. In consequence, limited PLND should be avoided, while ePLND should be the only contemplated approach [57], when PLND is recommended. This might have also a therapeutic role. However, level 1 evidence is needed to support this statement.

Extended Lymph Node Dissection in the Minimally Invasive Era

Recent studies reported a decrease in the use and extent of PLND. This phenomenon seems to be associated with the increased adoption rate of minimally-invasive surgery, such as robot-assisted RP (RARP) [29, 30]. Gandaglia et al. [29] evaluated 5804 patients treated with either open or robot-assisted RP for non-metastatic PCa and showed that patients treated with minimally-invasive surgery were less likely to receive PLND (71.2 vs. 48.6%; $p < 0.001$). Moreover, the extent of the dissection was more limited for patients treated with RARP, as an inferior number of lymph nodes were retrieved in the latter group. Finally, these results held true both in low-risk and high-risk patients [29].

The lower adoption rate for patients treated with minimally-invasive approaches might have several explanations. First, concerns about increased operative time and increased risk of post-operative complications might represent barriers to widespread adoption of ePLND among clinicians. Second, ePLND is a more challenging procedure, and, especially for the early adopters of RARP, might have been associated with a learning-curve phenomenon, with reduced ability to correctly perform a thorough nodal dissection. As far as the risk of post-operative complications is considered, conflicting results are reported. While Briganti et al. [18] showed that ePLND in patients receiving RARP is associated with an increased rate of complications, they showed in subanalyses that this only applied to lymphocele. Specifically, they showed that the rate of lymphocele in the ePLND cohort was 10.3% compared with 4.6% in the limited PLND cohort ($p < 0.01$) [18]. However, several authors did not find any statistically-significant difference in complication rates between patients treated with open RP (ORP) vs. RARP [44, 58].

Several studies suggest that a high number of lymph nodes can be retrieved at ePLND even during RARP. This implies that ePLND is feasible regardless of the surgical approach. Although no prospective trial is available in the context of prostate cancer, these are available for bladder cancer. Specifically, the study performed by Nix et al. [59] was a noninferiority study aimed to comparing open vs. robot-assisted radical cystectomy with regard to the nodal yield at final pathology. They showed that the mean number of removed lymph nodes was comparable between the two groups (18 vs 19; $p = 0.5$) and demonstrated that robotic ePLND is not inferior to the open approach. More recently, Silberstein et al. [60] evaluated 330 PCa patients and showed that individuals treated with ORP had a higher nodal yield compared to their counterparts treated with RARP (20 vs. 16, $p = 0.015$). However, this

difference borders clinical significance. More importantly, a great variability in the nodal yield was observed in patients who received RARP according to individual surgeons (from 11 to 28 lymph nodes yield) [60]. As such, they concluded that the individual surgeon commitment to perform PLND is more important than the surgical approach. A recent review of the literature from Yuh et al. [61] concluded that ePLND can be performed safely and thoroughly during RARP. Therefore, recent studies suggest that PLND can be performed with an extended template regardless of the surgical technique. On the other hand, individual surgical commitment is the only factor that matters when planning the extension of the PLND. More efforts should be done in order to improve widespread use of ePLND regardless of the surgical approach.

Complications

Generally, PLND is considered a safe and well-tolerated procedure. However, this procedure is not completely devoid of complications [9, 10]. Post-operative morbidity is associated with prolonged hospitalization and might limit the oncologic benefit associated with PLND.

The most common complication associated with PLND is lymphocele. The reported incidence rate for this complication ranges between 5 and 10.3% [9]. It has been hypothesized that the use of an extended template during lymph node dissection might be associated with a higher risk of developing post-operative lymphoceles [18]. However, it should be noted that most of the post-operative lymphoceles are asymptomatic and, therefore, get unnoticed. In fact, Solberg et al. [62] observed that the rate of asymptomatic lymphocele can be as high as 50%, although it requires active treatment only in very select cases. Treatment of lymphoceles ranges from percutaneous drainage to injection of sclerosing agents [9]. Surgical marsupialization is reserved to select cases, for example when conservative management has proven ineffective. However, as observed by Musch et al. [10], almost 50% of all reinterventions after RP is for lymphocele management.

The second most common side effect associated with PLND is composed by thromboembolic events. Although they are way less common then lymphoceles and their frequency ranges from 0.2% to 8% [9], they are associated with a substantial increase of post-operative mortality rate. In a study performed by Alberts et al. [63], 30-day mortality rates increased from 0.1% to 2.8% ($p < 0.001$) in presence of venous thromboembolism. Therefore, major efforts should be made in order to prevent this potentially fatal side effect. Prevention of thromboembolism is done via the use of a correct pharmacologic prophylaxis, such as the use of subcutaneous low-molecular-weight heparin. Of note, anticoagulants are associated with an increased incidence of lymphocele [10]. This, in turn, might indirectly promote thromboembolic events due to compression of the pelvic vessels. Therefore, optimal management of the anticoagulant therapy is advised.

PLND is also associated with a risk of neurological or vascular injury. Nerve injury in infrequent, however might occur in up to 3.2% of patients treated with PLND [9]. The most commonly injured nerve is represented by the obturator nerve. The genitofemoral nerve might be also injured during ePLND. Vascular damages, on the other hand, are very rarely reported. However, they should be considered, given the fact that the pelvic lymphatic tissue is often in close anatomical relationship with large vessels such as the iliac arteries and veins.

Future Perspective: Is There a Role for Sentinel Lymph Node Dissection?

The concept of sentinel lymph node dissection is widely accepted for other malignancies, such as breast cancer [64] and melanoma of the skin [65]. This idea is based on the hypothesis that, although complex, the lymphatic drainage from the prostatic gland follows certain pathways from the prostate to the retroperitoneal lymph nodes [47]. In consequence, could the first lymph node of the chain be identified, it could be analyzed in order

to decide whether to perform PLND or not. In fact, a negative sentinel lymph node would be equivalent to the absence of LNI. Conversely, a positive sentinel lymph node would give indication to perform an extended PLND. This technique could significantly improve our ability to better identify individuals with LNI, while decreasing the number of unnecessary PLND.

Traditionally, the identification of the sentinel lymph node is performed by injection of a technetium-based colloid into the prostate and the use of a gamma probe. In this regard, several authors praised the high predictive accuracy of this technique. Kjölhede et al. [66], for example, showed that this technique could be used to identify positive lymph nodes even outside the ePLND template. In their study, this occurred in 13 out of 72 patients [66]. Moreover, in 6 out of these 13 patients, the final pathology confirmed the presence of LNI. On the other hand, other authors expressed concerns about the low sensitivity of sentinel node identification in PCa. For example, Van der Bergh et al. [67] showed that only 28 out of 37 patients with LNI had a positive sentinel node. This resulted in a sensitivity of 76%.

The use of the traditional technetium-based technique for identification of sentinel nodes in PCa is now considered inaccurate, as several limitations to its use in clinical setting apply [68]. For example, real-time detection of the sentinel node within the surrounding anatomy is challenging. Specifically, identification of specific lymph nodes with radioactive tracers in an anatomically-complex area such as the pelvic region might not be always feasible, although newer technologies might overcome this limitation. For this reason, the use of different tracers has been proposed. Specifically, the use of fluorescent dyes, that can be injected into the prostatic gland before surgery, represents another possible instrument that, without the drawbacks associated with the use of radioactive tracers, could allow for real-time visualization of possible sentinel lymph nodes.

The latest version of the Da Vinci surgical system includes a fluorescence imaging system (Firefly™ system). This allows detection of dye indocyanine green (ICG) in real time during surgery. Although the data on the use of fluorescence imaging in the context of urological malignancies is limited, high sensitivity was reported in preliminary analyses. However, this comes with a cost of a relatively low specificity. For example, Hruby et al. [69] evaluated 38 patients with intermediate or high-risk PCa and demonstrated that the use of fluorescence imaging during RP for prediction of LNI comes with a sensitivity of 97.7% and specificity of 69.1%.

More recently, a novel tracer has been developed by combining the technetium-based colloid with ICG, therefore combining the advantages of both. Van der Poel et al. [68] were the first to use this new tracer in clinical setting and demonstrated that this approach is feasible. Specifically, they showed a high correlation between the radioactive and fluorescence signals in the removed lymph nodes. Moreover, the fluorescence signal proved extremely useful in areas near the injection site. These promising data will need further investigation in future studies.

Taken together, the current literature suggests that dissection of sentinel lymph node might be a promising technique in the future. However, several limitations should be taken into account when considering adopting this technique. Most importantly, a high rate of false negative has been reported by several authors. In consequence, the risk of LNI would be significantly underestimated. Moreover, this also comes with a substantial lack of expertise, at least for now, and high costs. For this reason, sentinel node dissection is not actually recommended by urological guidelines and should be considered only as experimental [1].

Can Nodal Dissection Be Performed in Patients Who Experienced Disease Recurrence After Primary Treatment?

Although RP is associated with excellent long-term oncological outcomes, some patients will nonetheless experience recurrence of disease after surgery. The most common form of recurrence is represented by a steadily increase of PSA values, which defines a biochemical recurrence

(BCR). Indeed, these patients could harbor systemic disease in the form of metastatic spread. However, some investigators hypothesized that select patients without clinically-confirmed metastases could have a recurrent disease limited to pelvic and/or retroperitoneal lymph nodes [70, 71]. In this regard, the idea has been proposed that a PLND could be performed in order to remove nodal-confined metastatic disease, to correctly stage these men, and, ultimately, to improve cancer control [70–72]. This would potentially delay the need for other systemic treatments, with a subsequent increase in the quality of life.

When salvage lymph node dissection (sLND) is planned, accurate patient selection is mandatory. In fact, not every patient benefits from PLND during RP in the first place, and even less individuals can be considered eligible for sLND at BCR [72]. Moreover, similarly to PLND performed during RP, sLND is not devoid of complications [70, 73].

The best candidates for sLND are patients with PSA less than 4 ng/mL and in whom nodal recurrence is limited to a small number of lymph nodes in the pelvic region [70, 71]. As such, identification of suspect lymph nodes in patients with BCR becomes of pivotal importance. The use of imaging techniques such as 11C-Choline PET/CT scan in this setting allows for identification of patients with disease recurrence in the pelvic lymph nodes. However, the ability of detecting a specific positive lymph node is poor. In this regard, Passoni et al. [74] showed that the use of PET/CT scan for identification of a single positive lymph node at sLND comes with a positive predictive value of only 24%. This implies that a significant proportion of metastatic lymph nodes were not identified by PET/CT scan [74]. Therefore, imaging techniques could help to identify patients with nodal metastases at BCR but cannot be used to define the dissection site or extent. In consequence, it has been suggested that sLND should be performed according to an extended dissection template [72]. Specifically, all lymphatic tissue should be removed along the obturator fossa, internal iliac, external iliac and presacral regions. Common iliac lymph nodes should be excised up to the aortic bifurcation. Moreover, if the patients has positive or suspect lymph nodes in the common iliac region, lymph node dissection should also be performed in the retroperitoneal region until the emergence of the renal vessels [72].

Oncologic outcomes of sLND are still matter of debate. Rigatti et al. [70] performed a prospective evaluation of 72 individuals with BCR and treated with sLND. They showed that only 56.9% of patients achieved a biochemical response. Moreover, only 10.3% of these individuals did not experience a subsequent BCR in the following 10 years. More encouraging results were reported later by Suardi et al. [71]. Of note, the authors confirmed that most of the patients treated with sLND will eventually experience a new BCR event. However, 38.2% will be free from clinical recurrence after 8 years of follow up, and 80.6% will not experience cancer specific mortality [71]. Other authors reported similar results [72, 73]. Although the lack of a control group certainly represents a major limitation in these studies, the current literature suggests that sLND might be a feasible option in select patients and good oncologic outcomes might be expected. Nonetheless, the lack of strong evidence on this matter must still be considered. Moreover, further studies assessing the advantages of the robotic approach in this setting are still needed.

Conclusions

PLND is the most accurate staging procedure for assessing nodal status in patients undergoing surgical treatment. In this regard, the use of ePLND should be preferred over limited PLND, as it heralds a better ability to identify patients with LNI. An extended PLND template includes the surgical excision of obturator, internal iliac, external iliac, common iliac and presacral lymph nodes. Moreover, ePLND is also associated with better oncologic outcomes. That being said, the recent introduction of minimally-invasive surgery has been accompanied by an unjustified decrease in the use and extent of PLND. Recent studies demonstrated that individual surgical commitment, rather than the technique itself, is the main driver of the performance of an anatomically defined ePLND. Therefore, more efforts should be

made in order to promote widespread use of ePLND regardless of the surgical approach. Of note, concerns have been expressed for PLND being a relatively morbid procedure. In consequence, accurate patient selection is advised. As currently available imaging techniques suffer from poor predictive accuracy in predicting LNI, today preoperative risk assessment is performed through the use of clinical nomograms. These are based on routinely available preoperative data such as PSA, clinical T stage and biopsy Gleason score. A possible role of the sentinel lymph node dissection technique has been proposed. However, this procedure should still be considered experimental nowadays. Finally, PLND also has a role in the context of recurrent disease after primary surgical treatment. Indeed, salvage PLND can be safely performed in select patients in order to improve BCR-free and CSM-free survival rates.

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24

Current Concepts in Cavernosal Neural Anatomy and Imaging and Their Implications for Nerve-Sparing Radical Prostatectomy

Daniel Sagalovich, Thomas Bessede, and Ashutosh K. Tewari

Abstract

Much of the progress achieved in the past 2 decades in improving potency outcomes after radical prostatectomy has been wrought through an improved appreciation of the anatomic basis of the nerves responsible for erections. Recent advances in the anatomical course of these cavernosal nerves have led to various innovative techniques for improving nerve-sparing radical prostatectomy. Developments in various imaging technologies have led urologists to explore the potential for improved visualization of the erectogenic neural scaffold during nsRP.

Keywords

Prostate cancer · Radical prostatectomy · Nerve-sparing · Cavernosal neural anatomy

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Introduction

With radical prostatectomy delivering better survival outcomes [1, 2], preservation of sexual function has become an increasing priority for patients deliberating upon surgery as first-line treatment. Despite advances in surgical technique and technologies, return of erectile function sufficient for sexual intercourse at a year after surgery varies from 15 to 87% in contemporary series of radical prostatectomy [3–5]. For younger men, postprostatectomy erectile dysfunction (PPED) significantly affects their sense of masculinity and their daily interactions with women [6, 7]. Patient age, clinical and pathologic stage of cancer, preoperative potency status, and aggressiveness of nerve sparing are the most significant factors for recovery of potency after surgery [8–10]. Other reported variables include surgeon experience and surgical volume, intraoperative neurovascular bundle injury, penile ischemia and subsequent fibrosis, and veno-occlusive disease for successful return of sexual function following surgery [11, 12].

Much of the progress achieved in the past 2 decades in improving potency outcomes after radical prostatectomy has been wrought through an improved appreciation of the anatomic basis of the nerves responsible for erection. Diminished innervation of the corpora cavernosal tissue prevents the release of nitrous oxide from non-adrenergic, non-cholinergic nerves; decreases the

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production of cyclic nucleotides within the vascular smooth muscle; and causes impairment of vascular engorgement. Vascular injury, namely arterial insufficiency and veno-occlusive leakage, has also been proposed as possible etiologies for PPED, although the evidence for this is still early [13–15]. Recent advances in the anatomical course of these cavernosal nerves have led to various innovative techniques for improving nerve-sparing radical prostatectomy (nsRP). In addition, developments in fiber optic imaging technologies have led urologists to explore their potential for improved visualization of the erectogenic neural scaffold during nsRP.

Anatomic Basis of Erectogenic Nerve Preservation

Neurovascular Bundles and Cavernosal Nerves

The autonomic neural system is directly responsible for penile erection. The inferior hypogastric plexus (IHP) is responsible for the mechanisms of erection, ejaculation, and urinary continence. The IHP contains sympathetic and parasympathetic components. The sympathetic fibers arise from the T11–L2 ganglia, while the parasympathetic fibers originate from the ventral rami of S3 and S4. The IHP is a dense network of neural fibers located within a fibro-fatty, subperitoneal plate between the urinary bladder and rectum [16].

Walsh and Donker [17] first detailed the anatomy of the nerves supplying the corpora cavernosal in male stillborns. Subsequent cadaveric and intraoperative studies by Walsh and colleagues [18, 19] demonstrated that the neurovascular bundles (NVB) run posterio- lateral to the prostate between two layers of lateral pelvic fascia—the prostatic fascia medially and levator fascia laterally (Fig. 24.1). These neurovascular bundles consist of (1) the cavernosal nerves (CN) directly responsible for erectile function, which originate from the most inferior portion of the IHP; (2) the arterial branches from the inferior vesical artery; and (3) venous vessels. The majority of these cavernous nerve fibers, approximately 6 mm wide, then run caudally at the 3 and 9 o'clock position of the membranous urethra beneath the striated sphincter at the prostatic apex (Fig. 24.2).

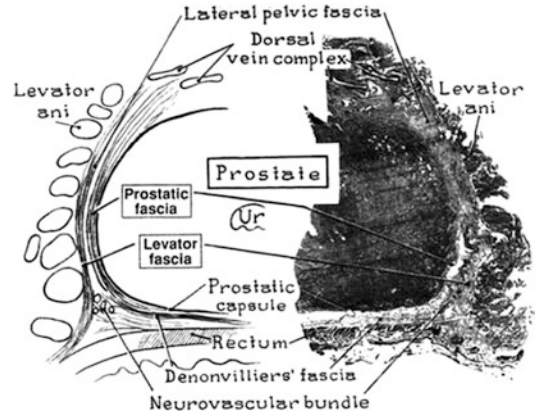

Fig. 24.1 Cross-section of adult prostate demonstrating the posterolaterally situated neurovascular bundle running between the layers of the lateral pelvic fascia—the levator fascia lies lateral and the prostatic fascia lies medial to the bundle (© Brady Urological Institute). Reprinted from Journal of Urology, 160(6), Patrick Craig Walsh, Anatomic radical prostatectomy evolution of the surgical technique, Copyright 1998, with permission from Elsevier

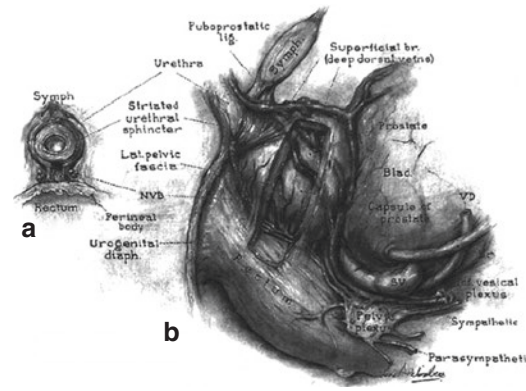

Fig. 24.2 (**a**) Cross section of membranous urethra just distal to the prostatic apex,demonstrating the relationship of the neurovascular bundle to the striated urethral sphincter and the perineal body. (**b**) Lateral view of the neurovascular bundle, tracing its course from the pelvic plexus through the layers of the lateral pelvic fascia distally to lie lateral to the membranous urethra (© Brady Urological Institute). Reprinted from Journal of Urology, 160(6), Patrick Craig Walsh, Anatomic radical prostatectomy evolution of the surgical technique, Copyright 1998, with permission from Elsevier

Anatomic Variants of Cavernosal Nerves

There have been numerous studies with proposed variants to the course of cavernosal nerves previously described by Walsh. Costello et al. [20] demonstrated that the NVBs in male cadavers descend posteriorly to the seminal vesicles, converging at the mid-prostatic level and then diverging on approaching the prostatic apex into indistinguishable fibers. Takenaka [21] highlighted the lattice- like distribution of the NVB on the lateral surface of the prostate, demonstrating that the NVB is more a net-work of multiple fine dispersed nerves than a distinct structure. Kiyoshima et al. [22] further reported that these dispersed nerve fibers are located between the prostate capsule and the lateral pelvic fascia. Eichelberg et al. [23] also found that only 46–66% of all nerves were found in the classical posterolateral location as described by Walsh, while 21–29% were found on the anteriolateral surface of the prostate.

Using histologic sections of cadaveric prostates, Clarebrough et al. [24] demonstrated that most neural tissue was located in the posterolateral region, however, the proportion surrounding the anterior part of the prostate increased toward the apex with a median of 11.2% versus 6.0% and 7.6% at the base and mid zone regions, respectively. Alsaid et al. used 3D reconstruction of immunohistochemical sections to evaluate the distribution of nerve fibers within the neurovascular bundle [25]. The investigators found that at the level of the prostatic apex, the NVB was noted to divide into cavernous nerves and corpus spongiosum nerves (Fig. 24.3). The cavernous nerve fibers were found to be a continuation of the anterior and antereolateral fibers at the apex of the prostate, and the corpora spongiosum nerve fibers were a continuation of the posterolateral NVB. These findings suggest that the ideal dissection plane includes a high release of prostatic fascia to preserve anterolateral cavernous nerve fibers.

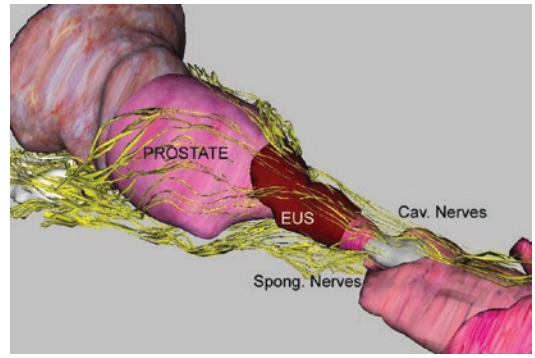

Fig. 24.3 Three-dimensional computer-assisted anatomic dissection from transverse immunolabelled histologic sections of a cadaver of a 74-year-old man. Left anterolateral views of the supralevator nerve pathways. The NVBs contain two divisions: the cavernous nerves, forming a continuation of the anterolateral fibers extending towards the corpora cavernosa and the penile hilum, and the corpus spongiosum nerves, which represent the distal course of the posterolateral NVBs reaching the corpus spongiosum bulb [25]. Reprinted from European Urology, 59, Alsaid B, Bessede T, Diallo D, et al., Division of autonomic nerves within the neurovascular bundles distally into corpora cavernosa and corpus spongiosum components: immunohistochemical con- firmation with three-dimensional reconstruction, 902-9, Copyright 2011, with permission from Elsevier

Trizonal Hammock Concept

Tewari and colleagues [26, 27] proposed that the periprostatic nerves consistently fell into three broad surgically identifiable zones: the proximal neurovascular plate (PNP), the predominant neurovascular bundle (PNB), and the accessory neural pathways (ANP) (Fig. 24.4). The predominant neurovascular bundles are usually located in a posteriolateral groove on the side of the prostate. Significant variations in the location, shape, course, and composition of this bundle occur. They can be widespread on the rectum, Denonvilliers' fascia, and lateral prostatic fascia or they can be circumscribed on the posterolateral groove enclosed in the triangular space. The PNB is closely related to the prostatic pedicle and prostatic fascia, and its branches can sometimes be intermingled with the lateral pedicles of the prostate (Fig. 24.5). Correlating their anatomic findings from cadaveric dissections to intraoperative

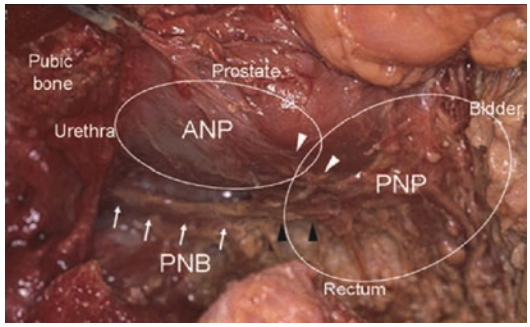

Fig. 24.4 Gross anatomy photograph (right) showing the proximal neurovascular plate (PNP) and predominant neurovascular bundle (PNB). From Tewari A, Takenaka A, Mtui E, Horninger W, Peschel R, Bartsch G, et al. The proximal neurovascular plate and the tri-zonal neural architecture around the prostate gland: importance in the athermal robotic technique of nerve-sparing prostatectomy. BJU Int: 2006 Aug;98(2):314–23. Reprinted with permission from John Wiley and Sons

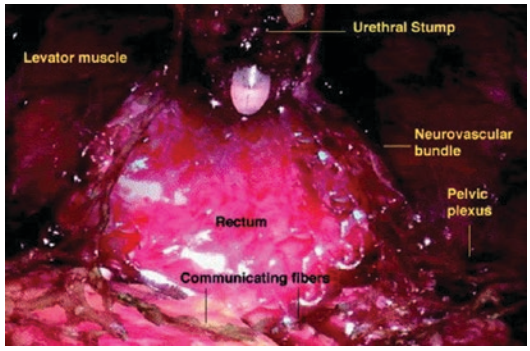

Fig. 24.5 Final view showing computer enhanced location of the neurovascular bundles following radical prostatectomy [28]. Modified from European Urology, 43(5), Tewari A, Peabody JO, Fischer M, et al., Operative and Anatomic Study to Help in Nerve Sparing during Laparoscopic and Robotic Radical Prostatectomy, 444–454, Copyright 2003, with permission from Elsevier

video footage and final histology slides, Tewari's group observed accessory neural pathways in several locations around the prostate: specifically, between the prostatic and lateral prostatic fascia, posterior to the prostate and in the layers of Denonvilliers' fascia, in several planes between the layers of periprostatic fascia, and even in the outer layers of the prostatic capsule. The superficial layer of Denonvilliers fascia has cross-communicating fibers between the left and right neurovascular bundles. Distally, these bundles coalesce to form a retro-apical plexus. In up to 35% of cases, this distal plexus penetrates the rectourethralis muscle (Fig. 24.6). Being the final exit pathway for the cavernous and retro-apical nerves, these delicate structures may easily be damaged during urethral transection and anastomosis. Tewari observed that the overall architecture of these delicate erectogenic nerves coursing around the prostatic capsule is similar to suspension of a weight in a hammock (Fig. 24.7). and that nerve preservation should not be considered a discrete technical maneuver, but rather an overarching surgical priority to be pursued at all stages of this complex procedure for achieving optimal outcomes [28].

Situated between the bladder and rectum, one must additionally consider the PNP when performing a pelvic lymph node dissection. With medial dissection of the hypogastric artery towards the bladder wall, the pelvic plexus and erectile nerves are at risk for injury. Indeed, worse erectile functional outcomes have been demonstrated in patients with a more extensive lymph node dissection [29, 30]. Therefore, extended PLND may be counterproductive to the aims of nerve sparing in a lower risk population.

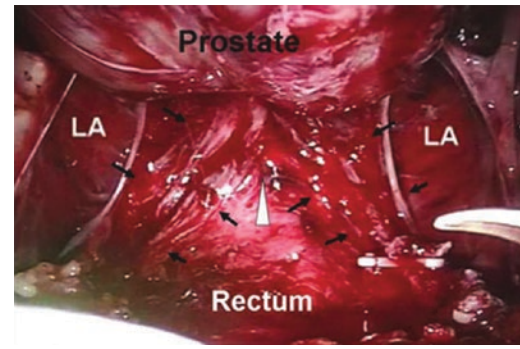

Fig. 24.6 Retro-apical region of prostate has a rich plexus of nerves formed by cross-communicating fibers between the left and right neurovascular bundles and fibers (LA, Levator ani, Black arrows, neural tissue). From Tewari A, Takenaka A, Mtui E, Horninger W, Peschel R, Bartsch G, et al. The proximal neurovascular plate and the tri-zonal neural architecture around the prostate gland: importance in the athermal robotic technique of nerve-sparing prostatectomy. BJU Int: 2006 Aug;98(2):314–23. Reproduced with permission from John Wiley and Sons

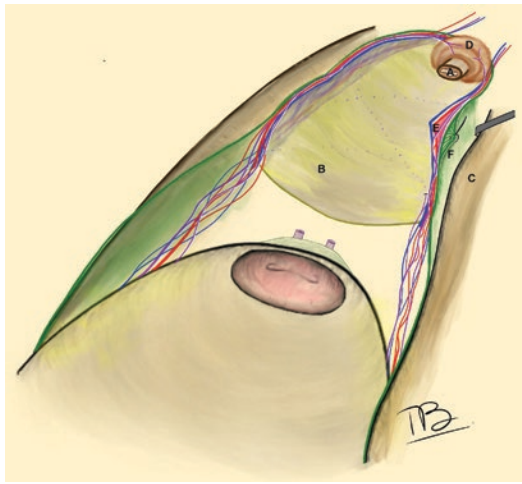

Fig. 24.7 A = Urethral stump; B = Prostatic fossa after complete nerve sparing robotic prostatectomy; C = Levator ani muscle; D = Sphincter; E = Layers of lateral prostatic fascia; F = Levator ani fascia; purple = Periprostatic Nerves; Blue = Veins; Red = Arteries

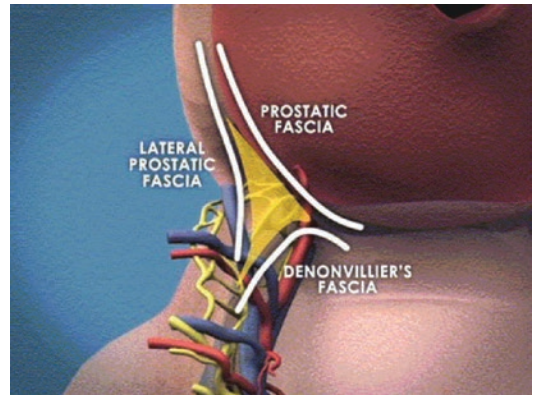

Fig. 24.8 Graphical representation of the neurovascular triangle, which is a potential avascular space bounded posteriorly by the Denonvilliers' fascia, laterally by the levator fascia, and medially by prostatic capsule covered by prostatic fascia. From Tewari AK, Patel ND, Leung RA, et al. Visual cues as a surrogate for tactile feedback during robotic- assisted laparoscopic prostatectomy: posterolateral margin rates in 1340 consecutive patients. BJU Int. 2010;106(4): 528–536. Reproduced with permission from John Wiley and Sons

Fascial Planes Surrounding the Prostate Capsule

Correlating their intraoperative observations during robotic-assisted radical prostatectomy with histological specimens, Tewari and Menon recognized that numerous nerve bundles are present in the different layers of fascia enveloping the prostate [31] (Figs. 24.8 and 24.9). The lateral pelvic fascia (LPF)—a multilayered fascial covering—surrounds the prostatic capsule. The medial, well-defined component of the LPF is known as the prostatic fascia and directly wraps around the prostate capsule. The laterally defined part of LPF is the levator fascia, which lies on the levator muscles. Interposed between the prostatic fascia and the levator fascia are the periprostatic venous plexus and the fascia, and its branches can sometimes be intermingled with the lateral pedicles of the prostate neurovascular tissue that travel distally to supply the sphincter, urethra, and cavernous tissue. These neural fibers can travel close to the vessels or occasionally, independently, on the surface of prostate or laterally on the rectum (Fig. 24.10).

There has been controversy regarding the terminology for the prostatic capsule. Since the outermost prostate surface is formed by transversely arranged fibromuscular layers of condensed smooth muscle, with a variable number of glands recognized peripherally, some authors have preferred the term "pseudocapsule" [32, 33]. In fact, from a microscopic point of view, one would be correct in referring to this landmark as condensed smooth muscle or outer edge; however, from a surgical point of view, a distinct outer most edge analogous to a capsule is visible [32, 34].

Techniques for Optimizing Cavernosal Nerve Preservation

Techniques for Retropubic Radical Prostatectomy

Based on their anatomic elucidations of the neurovascular bundles, Walsh [35] proposed the following technical considerations to avoid inadvertent NVB injury during open retropubic radical prostatectomy: (1) Securing venous backbleeding on the anterior prostate after ligation and division of the dorsal venous complex—this should be achieved with a V-shaped running suture instead of apposing

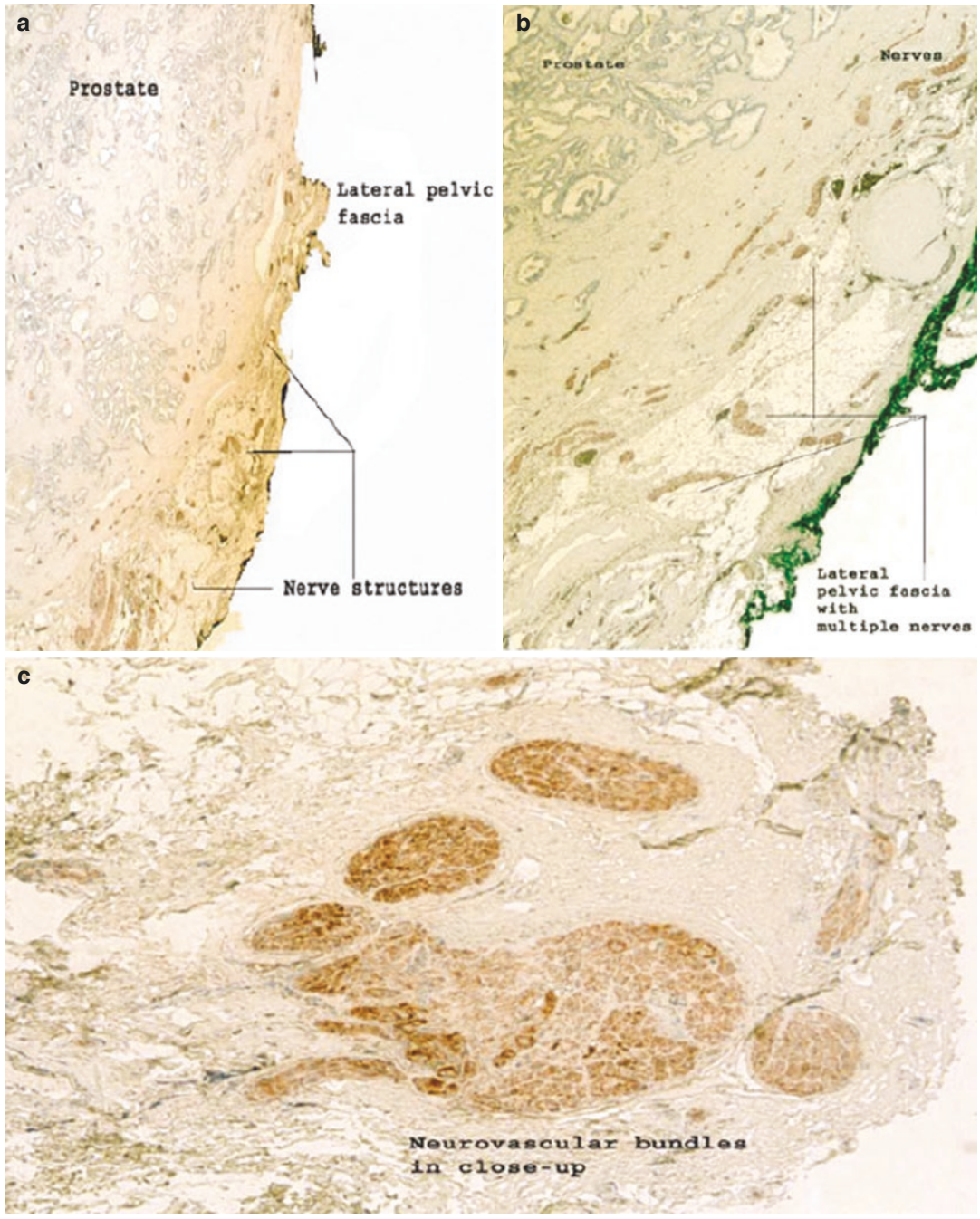

Fig. 24.9 Microscopic images of the nerves in the lateral pelvic fascia (brown structures) (note the small nerves posterior and anterolateral to the prostate): (**a**) low magnification; (**b**) medium magnification; (**c**) high magnification [27]. Reprinted from European Urology, 43, Tewari A, Peabody JO, Fischer M, et al., An operative and anatomic study to help in nerve-sparing during laparoscopic and robotic radical prostatectomy, 444–454., Copyright 2003, with permission from Elsevier

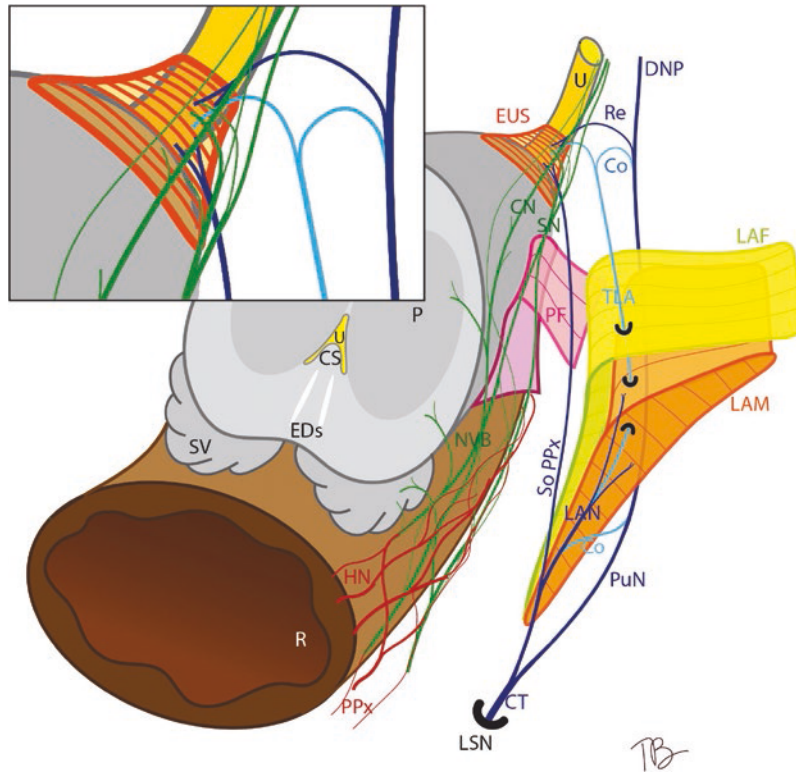

Fig. 24.10 Integrated representation of the possible urinary sphincter innervation pathways. Somatic pathway in dark blue; neurovascular bundle in green; pelvic plexus in red; communications in light blue. Co communicating branches, CN cavernous nerve, CS, colliculus seminale, CT common trunk of the LAN and PuN, DNP dorsal nerve of the penis, EDs ejaculatory ducts, EUS external urethral sphincter, HN hypogastric nerve, LAF fascia of levator ani, LAM levator ani muscle, LAN levator ani nerve, NVB neurovascular bundle, P prostate, PF pelvic fascia, PPx pelvic plexus, PuN pudendal nerve, Re recurrent branches of the DNP, SoPPx somatic pelvic plexus, SN spongious nerves, LSN lesser sciatic notch, SV seminal vesicle, TLA translevator ani branch, U urethra [97]. Reproduced from World Journal of Urology, Neural supply of the male urethral sphincter: comprehensive anatomical review and implications for continence recovery after radical prostatectomy, 2016, Bessede T, Sooriakumaran P, Takenaka A. With permission of Springer

the edges toward the midline, as the latter causes medial displacement of the NVB at the apex, making accurate dissection difficult; (2) transecting the membranous urethra only at the lateral edges while refraining from blind dissection of the prostatic apex; (3) releasing the superficial layer of the lateral pelvic fascia, which facilitates dissection of the posteriolateral groove between the prostate and the rectum posteriorly and augments intraoperative appreciation of the NVBs; (4) avoiding excessive traction on the NVBs during the posteriolateral dissection by gently rolling the prostate side to side; and (5) careful dissection of the seminal vesicles to avoid injury to distal branches of the inferior hypogastric plexus.

Alternative approaches to preservation of the NVBs described by Ruckle and Zincke [36], Scardino [37], and Klein [38] involve incising the lateral pelvic fascia medial to the NVBs on the anterolateral prostate prior to apical dissection and division of the deep venous complex.

Periprostatic Planes of Fascial Dissection

Deviating from Walsh's technique of leaving prostatic fascia on the prostatectomy specimen, Menon and colleagues [39] from the Vattikuti Urology Institute adopted an aggressive nerve-sparing

approach during robotic-assisted radical prostatectomy called the "veil of Aphrodite" technique, wherein the lateral pelvic fascia is dissected down to the glistening prostatic capsule surface and the veil of periprostatic tissue teased away in a relatively avascular plane (Fig. 24.11). In their cohort of 154 men, 96% reported return of potency (either with or without medical assistance) at 12 months follow-up, with a positive margin rate of 5% [40]. Adopting this aggressive intrafascial approach of dissection down to the shiny prostatic capsule for laparoscopic radical prostatectomy, Stolzenburg [41] also reported return of potency in 89.7% of their patients aged less than 55 years at 12 months following surgery, with margin positivity rates of 4.5% in pT2 and 29.4% in pT3 disease. Interestingly, Walsh's group [42] also adopted this approach in performing *high anterior release of the levator fascia* during bilateral nerve- sparing retropubic RP and reported similar sexual function outcomes without compromise of surgical margins.

Trizonal Risk-Stratified Nerve-Sparing Approach

Based on their anatomic findings of the trizonal distribution of the erectogenic neural lattice, Tewari et al. propose the following technical modifications for optimizing nerve preservation (Table 24.1) [43].

To balance the competing goals of optimizing potency preservation with avoiding positive surgical margins, Tewari's group also employed a risk-stratified approach toward aggressiveness of nerve sparing according to the patient's likelihood of ipsilateral extraprostatic extension of cancer, which involves varying degrees of

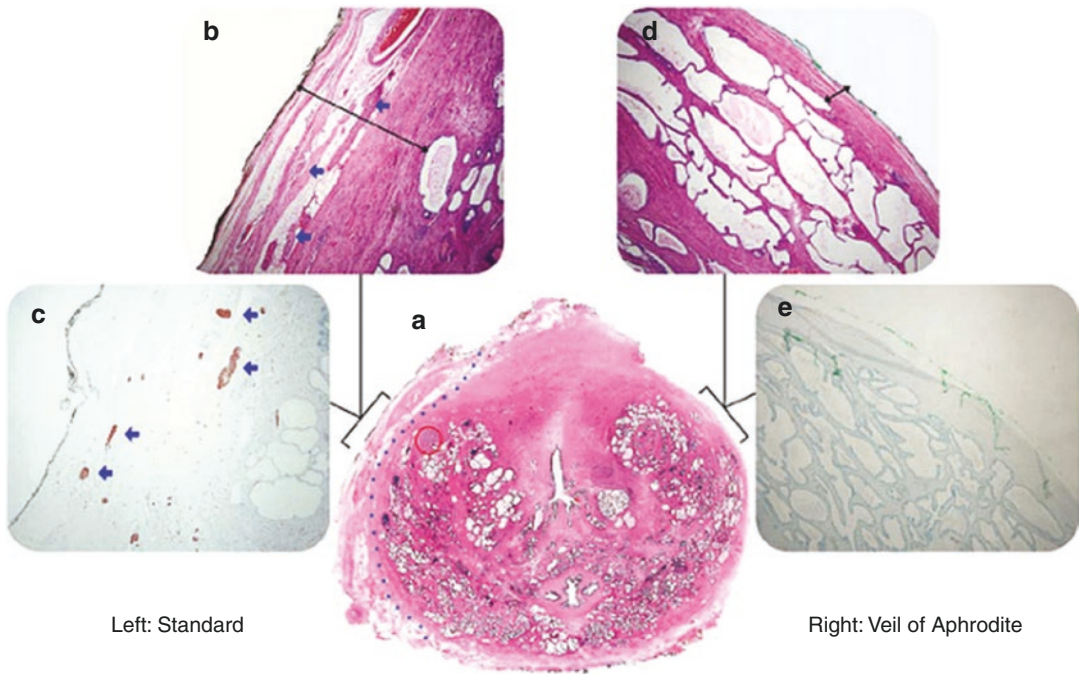

Fig. 24.11 (**a**) H&E of whole mount radical prostatectomy specimen demonstrating Walsh's conventional nerve-sparing technique on left and "veil of Aphrodite" technique on the right. Note the presence of tumor (red circle) and the lateral pelvic fascia on the left and absence of LPF external to the prostatic capsule on the right. (**b**, **c**) H&E of the lateral pelvic fascia, demonstrating nerve bundles and extended margin to the capsule. (**d**, **e**) Absence of LPF and close proximity of margin to the capsule [37]. Reprinted from European Urology, 49, Savera AT, Kaul S, Badani K, Stark AT, Shah NL, Menon M, Robotic radical prostatectomy with the "veil of aphrodite" technique: histologic evidence of enhanced nerve sparing, 1065–1074. Copyright 2006, with permission from Elsevier

Table 24.1 Technical maneuvers for athermal trizonal nervesparing robotic prostatectomy

Zone 1	Preservation of primary neurovascular plate (PNP) • Athermal dissection when opening endopelvic fascia around the proximal prostate • Perform bladder neck incision from the midline • Avoiding PNP injury during athermal seminal vesicle dissection from medial avascular plane outward using clips to control pedicles
Zone 2	Preservation of predominant neurovascular bundles (PNB) • Athermal dissection of seminal vesicles and neurovascular structures • Use of clips for controlling lateral pedicles • Risk-stratified approach to nerve sparing based on patient's likelihood of extracapsular extension of cancer (see Fig. 24.9)
Zone 3	Preservation of accessory neural pathways • Athermal posterior and apical dissection to preserve peri-apical and retro-apical neural cross-fibers

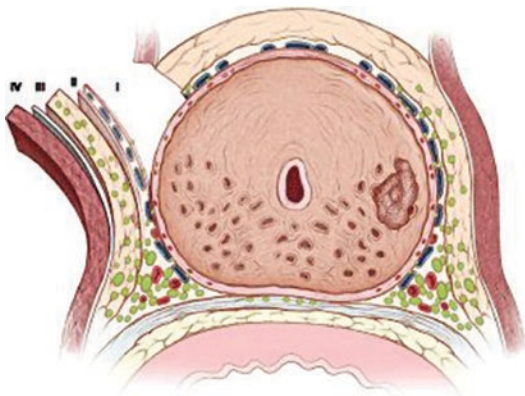

Fig. 24.12 Diagrammatic representation of the four regions of NS [31]. From Tewari AK, Patel ND, Leung RA, et al. Visual cues as a surrogate for tactile feedback during robotic- assisted laparoscopic prostatectomy: posterolateral margin rates in 1340 consecutive patients. BJU Int. 2010;106(4): 528–536. Modified with permission from John Wiley and Sons

preservation of the nerve fibers in the periprostatic fascial planes (Fig. 24.12). Grade 1 nerve sparing (NS), or the greatest degree of NS possible, consists of an incision of Denonvilliers' and lateral pelvic fascia (LPF) just outside the prostatic capsule [44]. For complete hammock preservation, Grade 1 NS is performed medial to the venous plane and is for patients with no or minimal risk of EPE. Grade 2 NS consists of an incision through the Denonvilliers' (leaving deeper layers on the rectum) and LPF is taken just outside the layer of veins of the prostate capsule, performed for men with low risk of EPE. Grade 3 NS is performed with an incision taken through the outer compartment of the LPF (leaving some yellow adipose and neural tissue on the specimen), excising all layers of Denonvilliers' fascia. This is performed for patients with moderate risk of EPE. Lastly, Grade 4 NS consists of a wide excision of the LPF and Denonvilliers' fascia and is reserved for men at high risk for EPE.

Tewari et al. preoperatively risk-stratified patients into risk grades 1 to 4 (Figs. 24.13 and 24.14) where risk group 1 received grade 1 NS, and so on for risk grades 2–4 [44]. Those with grade 1 NS had the highest post-op ability to have sexual intercourse and SHIM >21 (or return to baseline sexual function) with rates of 90.9% and 81.7%, respectively, as compared with grades 2 (81.4% and 74.3%), 3 (73.5% and 66.1%), and 4 (62% and 54.5%). There was no significant difference in positive margin rates for patients across NS grades, despite the rate of EPE significantly increasing across all risk groups 1–4.

Alternatives to Electrocautery

Collateral thermal injury to the neurovascular bundles during radical prostatectomy is a well-recognized phenomenon and it is thus prudent to avoid extensive cautery during NVB dissection. Tissue coagulation is achieved with temperatures above 45 °C; tissue denaturation ensues at 57–60 °C and protein coagulation at temperatures above 65 °C [45]. Ong and colleagues [46] elegantly demonstrated a decrease in erectile function following application of thermal energy to the neurovascular bundles in a canine model. In their series of robotic-assisted radical prostatectomies, Ahlering et al. [47] reported that avoidance of thermal energy results in nearly a fivefold improvement in early

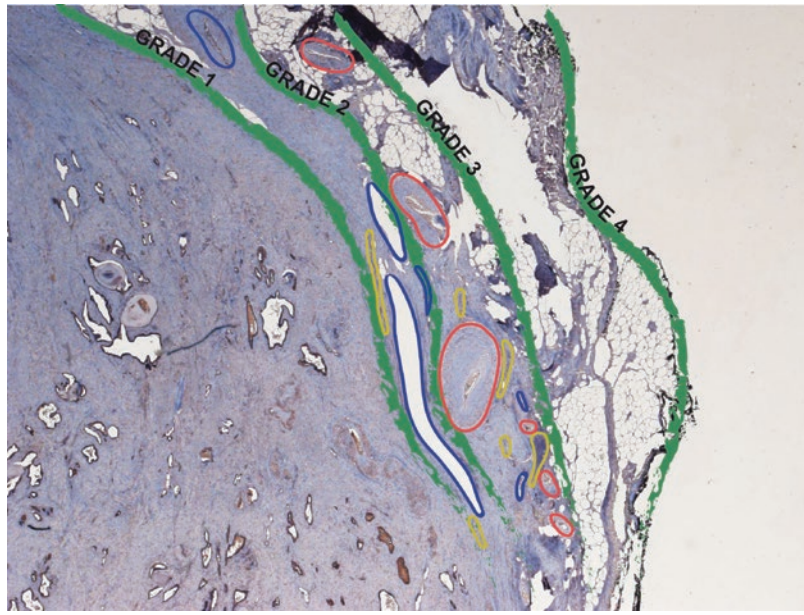

Fig. 24.13 Green = Planes for nerve-sparing grading; Yellow = Periprostatic nerves; Red = Arteries; Blue = Veins

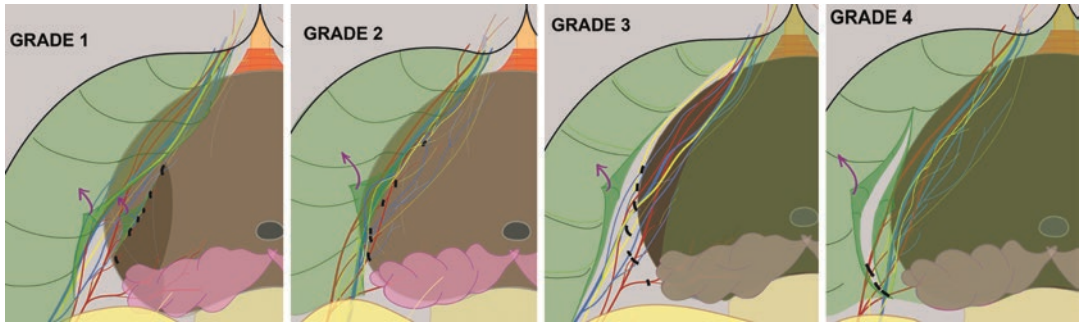

Fig. 24.14 Brown = prostate; Pink = seminal vesicules; Yellow = periprostatic nerves; Red = arteries; Blue = veins; Purple arrows = opening of the pelvic fascia (superficial) and of the prostatic fascia (deep); Black = surgical clips during nerve-sparing

return of sexual function, and that thermal injury induces a pronounced but mostly recoverable injury after 2 years from time of surgery. Tewari's group [48] also reported that bipolar cautery during robotic-assisted radical prostatectomy causes significantly higher and more persistent rise in temperature to tissues within 1 cm of its use, compared to monoploar cautery applied at the same distance, challenging the widely held belief that bipolar cautery causes less collateral tissue damage. Using a porcine model, Khan et al. [49] also demonstrated that the lateral prostatic pedicles serve as a heat sink during bladder neck transection using cautery, protecting the NVBs from thermal injury.

Various alternatives to thermal energy have been explored. Ahlering and colleagues [50] reported their experience placing laparoscopic bulldog clamps on the lateral pedicles 1 cm from the prostate, followed by division of the lateral pedicles with cold scissors. After mobilization of the neurovascular bundle off the prostatic capsule, FloSealTM was applied along its entire length and the NVB covered with a dry 1 × 4 cm sheet of GelfoamTM. The bulldog clamps were sequentially withdrawn following completion of

prostatectomy and 3-0 figure-of-eight sutures used for hemostasis of bleeding from the lateral pedicles. Shalhav's group [51] also reported 47% of patients returning to baseline potency at 1 month after robotic prostatectomy using an antegrade dissection of the neurovascular bundle that avoided the use of clips or monopolar cautery.

Gill and colleagues [52, 53] from the Cleveland Clinic adopted an energy-free technique of lateral pedicle ligation during laparoscopic radical prostatectomy, wherein the lateral prostatic pedicles were first controlled with atraumatic bulldog clamps, then divided using cold scissors and the NVBs preserved with blunt and sharp dissection. Hemostasis was then secured with superficial suturing of the transected pedicle. Using real-time Doppler transrectal ultrasound guidance, they demonstrated that application of bulldog clamps on the lateral pedicles did not impair blood flow through the NVBs throughout this maneuver. These investigators subsequently reported their preliminary experience comparing the KTP laser against ultrasonic shears and athermal cold EndoshearTM scissors dissection of the lateral pelvic fascia during laparoscopic unilateral NVB mobilization in a canine radical prostatectomy model [54]. Measuring peak intracaver- nosal pressure upon cavernous nerve stimulation both acutely and at 1 month follow-up in 36 dogs, they found that the KTP laser was comparable to the athermal technique, and superior to the ultrasonic shears, for preserving cavernous nerve function. In addition, intraoperative thermography revealed less collateral thermal spread from the KTP laser than from the ultrasonic shears. These animal studies suggest laser energy as a less traumatic alternative for periprostatic fascial dissection, and their feasibility in human trials is awaited.

Nerve Reconstruction and Regeneration

Quinlan and Walsh first reported successful return of erectile function in rats using interposition cavernous nerve grafts after iatrogenic denervation [55]. Kim and Scardino [56, 57] subsequently reported excellent results using bilateral sural interposition nerve grafts (SNG) in 23 erstwhile potent patients with aggressive cancer undergoing non-nerve-sparing retropubic radical prostatectomy with deliberate wide NVB resection, compared to a control group of 12 men undergo- ing similar surgery who did not have SNG. Of the patients receiving bilateral SNG, 26% had spontaneous medically unassisted erections sufficient for pene- trative intercourse; 26% reported spontaneous erections insufficient for intercourse; and 43% had inter- course with sildenafil. The greatest return of potency occurred at 18 months follow-up, although none of the patients reported erections before 5 months. This technique was subsequently adapted by other investigators for laparoscopic-and robotic-assisted radical prostatectomy with similar encouraging results [58, 59]. However, a randomized phase II trial involving a cohort of 107 men undergoing unilateral nerve-sparing radical prostatectomy failed to demonstrate any additional improvement of potency with unilateral sural nerve grafting at 2 years following surgery [60].

Tewari and colleagues [61] proposed an alternative approach of nerve advancement during robotic prosta- tectomy, wherein they performed end-to-end reconstruction after partial resection of the neurovascular bundle in clinically high-risk patients with MRI evi- dence of extracapsular extension of disease, most of whom had pT3 disease at final histology. In these patients, athermal partial resection of the NVBs was performed outside the lateral pelvic fascia, and the proximal and distal ends of the severed NVB then mobilized and approximated without tension using 6-0 polypropylene interrupted sutures. At a median of 20 months follow-up, five of these seven patients reported recovery of erections with or without phosphodiesterase inhibitors and a median SHIM score of 18.

Most recently, there has been interest in utilizing growth factors and anti-inflammatory substances for prostatic NVB regeneration. Patel and colleagues investigated the placement of dehydrated amnion/chorion membrance (dHACM), a source of implantable neurotrophic factors and cytokines, around the NVB following full nerve

sparing RALP [62]. Neurotrophic factors present in dHACM promote nerve cell survival and maintain target organ function by facilitating axon regeneration [63]. DHACM has been shown to facilitate wound healing and has been used to treat burns, corneal injuries, chronic venous ulcers, and chronic wounds [64]. At 8 weeks, potency returned in 65.5% of the dHACM patients and 51.7% of the no-dHACM group (p = 0.132). Alhough this was not statistically significant, the mean time to potency was enhanced in the dHACM group at 1.34 months versus 3.39 months in the no-dHACM group. Additionally, post-operative SHIM scores were higher in the dHACM group (16.2 vs 9.1).

Atala and colleagues [65] reported significant recovery of erectile function in adult male Sprague-Dawley rats with bilateral cavernous nerve excision, using acellular nerve matrices processed from donor rat corporal nerves for interposition nerve grafting. Subsequent electromyography of the acellular nerve grafts at 3 months after surgery demonstrated adequate intracavernosal pressures, confirming their feasibility as an alternative to autologous nerve grafts in aiding recovery of cavernosal nerve function. Other innovative approaches currently being explored in animal models include use of embryonic stem cells [66] and growth factors [67] to augment cavernous nerve regeneration.

NeuroSAFE for Nerve Sparing Optimization

To ensure that oncological outcomes are not compromised with nerve sparing technique, the neurovascular structure-adjacent frozen-section examination (NeuroSAFE) technique may be utilized. With this technique, frozen sections of the prostate specimen are sent off intraoperatively to provide the surgeon with immediate feedback on the patient's margin status. In the initial 2012 study on NeuroSAFE which included 11,069 RRP patients, positive margins were detected in 25% of RRP specimens leading to a successfully secondary resection of the ipsilateral neurovascular tissue in 86% of these patients [68]. Patients undergoing NeuroSAFE had a higher frequency of NS (97% vs. 81%) and lower positive margin rate (15% vs. 22%) than in the matched non-NeuroSAFE RPs.

In a 2014 study, Beyer et al. assessed NeuroSAFE in a population of 1570 patients undergoing RALP [69]. Again, the NS rate significantly increased with NeuroSAFE (97% vs. 81%) and the positive surgical margin rate dropped significantly (16% vs. 24%). There was no significant difference in blood loss or operative time with NeuroSAFE. Dr. Tewari's group has been using the NeuroSAFE technique since 2014 in conjunction with risk stratification for NS (i.e., grades 1–4). With an interdisciplinary team of dedicated genitourinary pathologists on standby for every RALP, NeuroSAFE has proven to be efficient and of particular value in higher risk cases by increasing the likelihood of potency preservation. Further studies from Dr. Tewari's group on NeuroSAFE are underway.

Advances in Cavernosal Neural Imaging

In recent years, significant efforts have been made to improve real-time identification and preservation of the cavernosal nerves during radical prostatectomy. Optical magnification of the operative field with surgical loupes has been demonstrated to improve earlier return of potency and lower rate of positive surgical margins following retropubic radical prostatectomy [70, 71]. Intraoperative nerve stimulation and tumescence monitoring using the CaverMapTM has been reported to help improve potency outcomes, although its specificity for accurate NVB identification has remained weak with considerable background variables contributing to penile tumescence [72–74]. In their experience with real-time power Doppler transrectal ultrasonography imaging of the neurovascular bundles during laparoscopic radical prostatectomy, Ukimura and Gill reported that real-time TRUS helped the surgeon identify the anatomic course of the NVB, measure the number of visible vessels, and quantify arterial blood flow resistive index in the NVB

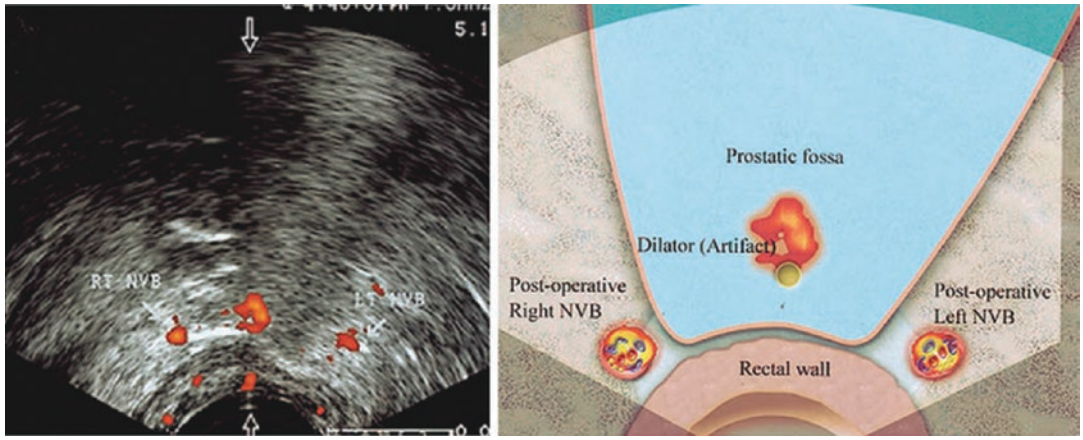

Fig. 24.15 Neurovascular bundles seen with power Doppler ultrasonography after bilateral nerve-sparing laparoscopic radical prostatectomy. A urethral dilator (typical ultrasound reflector, hyperechoic) and irrigation fluid (water-echo-texture, hypoechoic) are used as imaging contrasts to identify the NVBs on the surface of relatively hyperechoic periprostatic tissues [75]. Reprinted from Journal of Urology, 172, Ukimura O, Gill IS, Desai MM, et al., Real-time transrectal ultrasonography during laparoscopic radical prostatectomy, 112–118J. Copyright 2004, with permission from Elsevier

[75] (Fig. 24.15). However, the variability of NVB imaging with positioning of the ultrasound probe, insufficient resolution for defining microscopic structures, and operator dependency of this approach have not resulted in this technique being adopted by other centers.

In contrast, promising advances have been made in fiber optic-based imaging technologies for visualizing biologic structures at a cellular and microscopic level, and we review some of these potential applications for identifying cavernosal nerves.

Optical Coherence Tomography

Optical coherence tomography (OCT) was first developed in 1991 as an imaging modality to visualize tissue microstructures [76]. Similar to B-mode ultrasonography but using near-infrared light instead of acoustic waves, OCT works by focusing an optical beam into the tissue and then measuring the time delay of reflected light from the internal microstructure at different depths by interferometry. A two-dimensional cross-sectional view of the cellular structures is then obtained by analyzing the intensity of backscattered light at different transverse positions as the optical beam is scanned across the tissue. Notable features of OCT for its use as a real-time intraoperative imaging tool are (1) its compact size and portability; (2) its compatibility with existing surgical platforms such as handheld probes, laparoscopes, and needles; (3) its ability to operate without tissue contact, avoiding visual obstruction of the operative field; (4) delivery of localized, high-resolution images of the area of interest, without requiring a distal imaging transducer; and (5) its relative affordability given the prevalent use of this tech- nology in telecommunications industry. Nonetheless, image resolution is limited by signal attenuation with increasing tissue depth, with useful information only obtainable at depths of less than 1 mm.

Using the NirisTM OCT system and an 8 Fr handheld probe (Imalux Corporation, Cleveland, OH), Fried and Rais-Bahrami [77] from Johns Hopkins performed real-time in vivo imaging of the cavenosal nerves and periprostatic tissue in male Sprague- Dawley rats (Fig. 24.16). These nerves appeared as relatively intense, linear structures distinct from the underlying prostatic stroma and glands and correlated well with images obtained at final histopathology. However, poorer tissue discrimination between nerves and underlying prostate was reported by these same

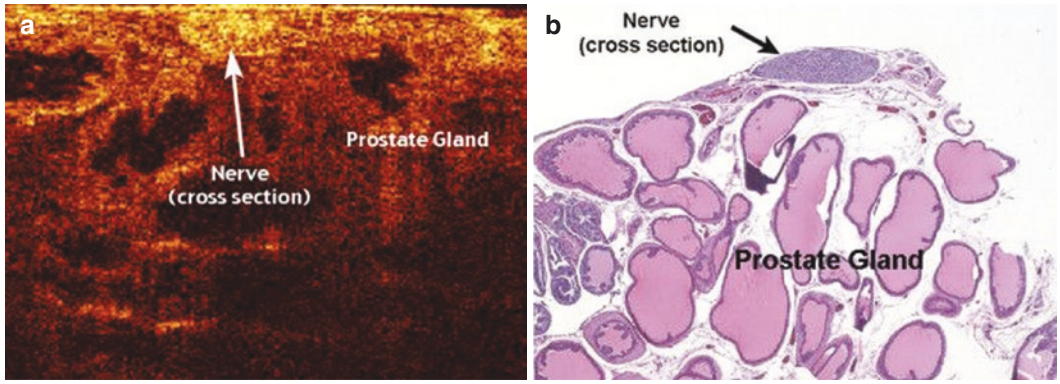

Fig. 24.16 13OCT imaging and histologic (hematoxylin-eosin) correlation of rat CN (**a**, **b**) in cross-section [78]. Reprinted from Urology, 72(1), Rais-Bahrami S, Levinson AW, Fried NM, et al., Optical coherence tomography of cavernous nerves: a step toward real-time intraoperative imaging during nerve-sparing radical prostatectomy, 198–204. Copyright 2008, with permission from Elsevier

investigators on using OCT to image fresh ex vivo human radical prostatectomy specimens [78]. The thicker capsule and dense stroma of human prostates, as well as the abundance of blood vessels and fat found alongside the neurovascular bundles in human specimens, resulted in significant loss of signal contrast. Similar results were reported by Aron and colleagues [79] from the Cleveland Clinic, who demonstrated the feasibility of deploying the 8 Fr Niris probe through a 5-mm laparoscopic port for real-time in vivo imaging of the NVBs during laparoscopic- and robotic-assisted radical prostatectomy. More recently, Patel and col- leagues [80] examined the use of OCT for predicting margin positivity on 100 ex vivo radical prostatectomy specimens. On correlation with final histopathology, they reported sensitivity, specificity, and negative predictive value of 70, 84, and 96%, respectively, for predicting final margin positivity, suggesting it may have an intraoperative role in helping surgeons identify true negative margins around the NVBs and avoiding overzealous dissection to optimize nerve preservation.

Functional OCT of the prostate has been shown to differentiate between cancer and healthy prostate tissue. However, up until now. OCT images of the prostate were solely based on the qualitative image interpretation, without further quantitative analysis of the OCT signal. Muller et al. used the attenuation coefficient to discriminate between malignant and benign tissue within the prostate [81]. His group concluded that the optical attenuation coefficient was significantly higher in malignant tissue compared to benign prostate tissue. Although further studies are required to validate these initial results, the prospect for the use of this technology in real-time during RALP NS is particularly exciting.

Spectroscopy

Alternative imaging modalities using reflected light include elastic scattering spectroscopy, Raman spectroscopy, and coherent anti-Raman spectroscopy (CARS). *Elastic scattering spectroscopy* (also known as diffuse reflective spectrometry) detects photons that are reflected and scattered by cell and tissue constituents. Capturing signals of reflected light at the same wavelength as emitted source, elastic spectroscopy detects differences in wavelength intensity. It does not yield anatomic images, but may be useful in distinguishing tissue constituents. As such, its clinical use to date has been limited to imaging of bladder urothelium via a cystoscope to distinguish malignant from benign tissue [82]. *Raman spectroscopy* operates on a similar principle to elastic scattering, except that it depends upon molecule-specific inelastic scattering of photons to analyze cellular constituents.

Crow and colleagues reported an accuracy of 86% in distinguish- ing malignant from benign/inflammatory snap-frozen prostate samples collected during transurethral resection of prostate [83].

Baykara et al. investigated the use of elastic light single-scattering spectroscopy (ELSSS) for the potential to detect positive surgical margins intraopertatively during RRP. ELSSS spectrum provides information about scatter size, therefore, morphologic alterations, such as increased nuclear size, result in a spectrum that is different from the spectrum of noncancerous tissue [84]. ELSSS spectral data was compared to final pathology and ELSSS was determined to have a sensitivity and specificity of 86% and 97%, respectively, in differentiating benign from malignant margin status [84]. Although this was a pilot study, ELSSS is a promising technique for in vivo determination of margin status.

Fluorescent Imaging

Fluorescent imaging technologies capture light emitted from target tissues in response to photons absorbed by specific target constituents and/or markers [85]. Two broad strategies employing this optical phenomenon for imaging and diagnosis have been (1) *exogenous fluorescence techniques,* which rely on introduction of fluorescent markers or labels into target tissue to visualize specific structures or distinguish between healthy and diseased targets and (2) *endogenous fluorescence techniques*, wherein specific tissue constituents emit characteristic their own autofluorescence upon photon excitation. In the latter approach, normally endoge- nous molecules such as collagen, elastin, amino acids, and other cellular proteins display autofluorescence and have been used to provide information on cellular interactions (e.g., nicotinamide adenine dinucleotide) and connective tissue integrity in normal and cancerous host tissue. Its primary limitations are the bulky footprints occupied by attendant equipment and complex software required for image processing.

Exogenous Fluoroscopy

This approach involves the administration of small molecules into the target tissue by a variety of routes, either systemically or location specific. The inherent advantages with this modality are its potential for specific identification of altered cellular/tissue archi- tecture when conjugated to specific biomarkers, avoiding confounding signals generated by neighboring autofluorescent tissue. Comparing five different fluorophores administered via penile injection in male Sprague-Dawley rats, Davila and colleagues [86] demonstrated successful retrograde uptake of Fluoro-Gold in the NVBs and major pelvic ganglion of the rats after 3 days. More recently, Boyette and colleagues [87] successfully demonstrated in vivo fluorescent imaging of the rat cavernosal nerves at 40 μm resolution using the Cellvizio fibroptic confocal microscope (Mauna Kea Technologies, Cambridge, MA, USA) following injection of the fluorescent retrograde nerve tracer CTb-488 (Fig. 24.17). As well as demonstrating the absence of tissue toxicity/mutagenicity caused by these fluorophores, Boyette's group reported no compromise in cavernous nerve function following fluorophore administration on subsequent intracavernosal pressure manometry with electrical stimulation of the cavernosal nerves. These studies highlight the potential for using fiber optic confocal fluorescent microscopy as an intraoperative imaging tool for identifying the cavernosal nerves during radical prostatectomy.

One of the major issues with the use of exogenous fluorescent agents has been the lack of specificity for prostate cancer cell lines. For example, the well-studied agent indocyanin green (ICG) has been utilized intraprostatically as a lymphangiographic agent in the detection of sentintel lymph nodes during prostatectomy [88, 89]. Unfortunately, free ICG lacks biochemical specificity to prostate or prostate cancer cells. In a recent article, Sonn et al. identified an antibody fragment (cys-diabody, cDb) against prostate stem cell antigen (PSCA), which is expressed on the cell surface of virtually all prostate cancer

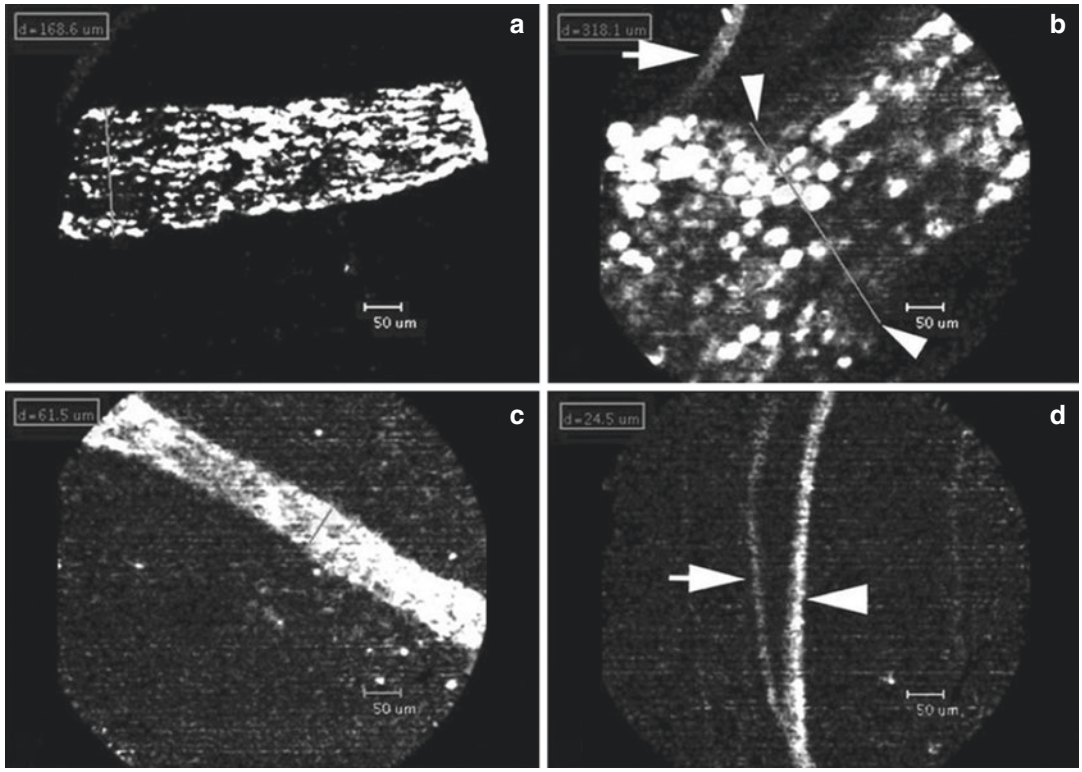

Fig. 24.17 Variation in rat cavernosal nerve (CN) appearance and thickness was noted during sequence acquisition 9 days after CTb-488 injection. (**a**) Sharply granular appearing CN with distinct parts of nerve containing no fluorescent signal (diameter 186.6 m). (**b**) Junction of CN with MPG (arrowheads) (diameter 318.1 m) and accessory nerve branching from MPG (arrow). (**c**) Evenly distributed bright fluorescent nerve image (diameter 61.5 μm). (**d**) Accessory nerve branching into larger (arrowhead) (diameter 24.5 μm) and smaller (arrow) (diameter 10.0 μm) bundles. Scale bar represents 50 μm [87]. Reproduced from Journal of Urology, 178, Boyette LB, Reardon MA, Mirelman AJ, et al., Fiberoptic imaging of the cavernous nerve in vivo, 2694–2700. Copyright 2007, with permission from Elsevier

with minimal background in normal prostate tissue, and conjungated it to a far-red fluorophore [90]. In a prospective, randomized study comparing surgical resection with and without fluorescent guidance (intravenous Cy5-cDb), residual tumors that were missed on initial white light surgery were identified and resected using fluorescence guidance, which reduced the incidence of positive surgical margins to 0 of 8 mice, compared with white light surgery alone (7 of 7 mice). With the increasing incidence of intermediate and high-risk PCa, in-vivo use of fluorescent agents may prove particularly valuable in the future by providing oncologically safe nerve sparing.

Endogenous Autofluorescence

Nobel laureate Maria Goeppert-Mayer first proposed in 1931 that absorption of two low-energy photons can cause sufficient excitation of electrons to emit a fluorescence normally produced by the absorption of a single high-energy photon [91]. This optical phenomenon, known as two-photon or multi-photon excitation, was later developed as an imaging technology in the form of *multiphoton nonlinear microscopy* (MPM) by Denk and Webb from Cornell University in the 1990s [92]. Since then, MPM has been used extensively to image cellular and subcellular processes, offering increased depth of tissue imaging (500–600 μm),

higher spatial resolution, less phototoxicity and photobleaching, and minimal background fluorescence compared to confocal microscopy [93].

Yadav and colleagues [94] reported their initial experience with ex vivo imaging of cavernosal nerves in a Sprague-Dawley rat model using multiphoton microscopy in combination with second harmonic generation. They demonstrated good correlation between MPM images of neural and prostate tissue with those obtained at final histopathology and also highlighted the capability of using this modality for high-resolution "optical sectioning" of tissue at various depths (Figs. 24.18 and 24.19). *Coherent anti-Raman Spectroscopy (CARS),* a new type of multiphoton microscopy, has also generated significant interest. This third-order nonlinear optical imaging modality operates by generating two spatially and temporally overlapping pulsed laser beams (a pump beam and a Stokes beam) with different wavelengths [95]. The difference in wavelengths, when tuned to match a certain molecular vibration energy level, significantly enhances the CARS signal to produce vibrational contrast.

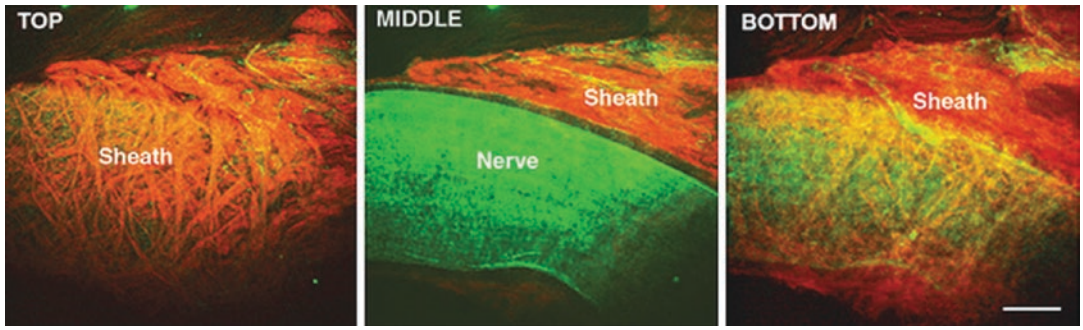

Fig. 24.18 High-magnification (×20) multiphoton microscopy image of rat femoral nerve. Seen are the second harmonic generation signal from the fibrocollagenous sheath (red) and autofluorescence (green) from the nerve, presumably coming from the axoplasm and the cytoplasm of Schwann cells. Note how the sheath wraps around the nerve bundle at different optical depths. Scale bar: 100 μm. Reproduced with permission from Yadav R, Mukherjee S, Hermen M, et al. Multiphoton microscopy of prostate and periprostatic neural tissue: a promising imaging technique for improving nerve-sparing prostatectomy. J Endourol. 2009;23:861–867. Copyright © 2009. Mary Ann Leibert, Inc.

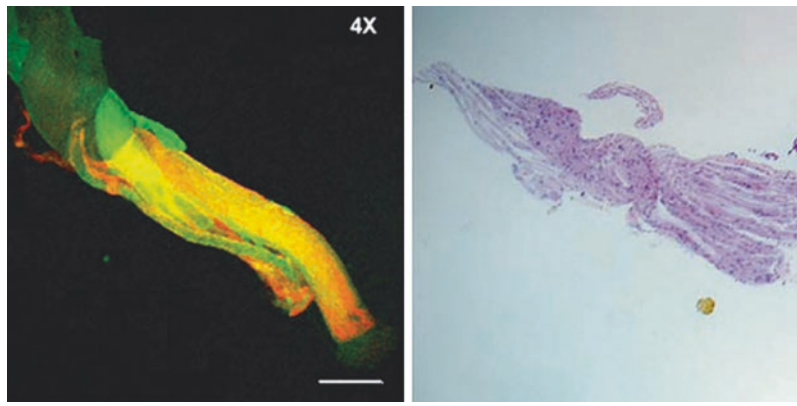

Fig. 24.19 Low-magnification (×4) multiphoton microscopy image of rat cavernous nerve. A single optical section from the middle of the tissue is shown. Second harmonic generation signal is from the fibrocollagenous sheath (red) and autofluorescence (green) is from the nerve. Scale bar: 500 μm. Reproduced with permission from Yadav R, Mukherjee S, Hermen M, et al. Multiphoton microscopy of prostate and periprostatic neural tissue: a promising imaging technique for improving nerve-sparing prostatectomy. J Endourol. 2009;23:861–867. Copyright © 2009. Mary Ann Leibert, Inc.

Huff and Cheng [96] successfully demonstrated in vivo CARS imaging of the sciatic nerve in mice. Using a wavelength difference of 2840 cm^{-1}, the peak frequency of CARS band for symmetric CH2 stretch vibration, a large E-CARS signal was observed from the myelinated axons in the sciatic nerve as well as the surrounding fat cells. Further combination of CARS with second harmonic generation (SHG) facilitated high signal-to-background ratio, three-dimensional spatial resolution images of the nerves and surrounding tissue without the need for exogenous fluorophore labeling. However, the primary drawback of CARS remains its limited depth of pene- tration at ~100 μm.

Conclusion

Better appreciation of the variable and often invisible anatomical course of the cavernosal nerves continues to engender innovations in surgical technique to optimize their preservation. Nonetheless, most current fiber optic-based imaging systems remain limited by image attenuation with increasing tissue depth and their sizable footprint. Exciting frontiers of research include efforts in stem cell neural regeneration and development of specific fluorophores and biomarkers which may provide much needed breakthroughs to improving potency outcomes following radical prostatectomy in this current age of improved life expectancy and heightened patient expectations.

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25 Robot-Assisted Radical Prostatectomy for Large Glands and Median Lobe

Weil Lai, Uğur Boylu, and Raju Thomas

Abstract

Large prostates and median lobes can present challenging scenarios during robotic-assisted radical prostatectomy. They may complicate the performance of the bladder neck dissection. Median lobes may obscure identification of ureteral orifices and increase risk of ureteral injury and obstruction during urethrovesical anastomosis. Large prostates decrease the working space within the deep pelvis and may require reconstruction of the bladder neck. In this chapter, we discuss the management of large prostates, median lobes, and methods to reconstruct the large bladder neck.

Keywords

Large prostate · Median lobe · Bladder neck reconstruction · Prostatectomy · Ureteral orifices · Urethrovesical anastomosis · Tennis racket closure

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Introduction

With the introduction of robotic surgery, robotic-assisted radical prostatectomy (RARP) is rapidly becoming the preferred surgical approach for management of localized prostate cancer. The rate of open prostatectomies has decreased from 95% in 2003 to 12% in 2013, with RARP accounting for 87% of all radical prostatectomies in 2013 [1]. However, with increasing numbers of RARPs, the robotic surgeon can expect to be confronted with various challenging scenarios given the variation of anatomy from patient to patient, such as large-sized prostates and varying sizes and configurations of median lobes.

Embryology of the Prostate

The prostate gland develops as multiple endodermal outgrowths of the urogenital sinus. Between the 11th and 16th week of gestation these simple tubular outgrowths develop in five distinct groups. These prostatic ducts branch multiple times and result in a complex system that meets the mesenchymal cells around this segment of the urogenital sinus. The muscular stroma is markedly developed by the 22nd week. Five lobes are eventually formed from the five groups of epithelial buds: anterior, posterior, median, and two lateral lobes [2]. Although these lobes are widely separated initially, they later converge without any

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dividing septa. The tubules of the posterior lobe extend posterior to the developing median and lateral lobes and form the posterior aspect of the gland. According to Glenister [3], the epithelium covering verumontanum has a composite origin from a mixture of endodermal urogenital sinus cells, mesodermal mesonephric or Wolffian cells, and paramesonephric or Mullerian cells. The median lobe is developed from the upper limit of the mixed epithelium covering the verumontanum. Therefore, the median lobe of the prostate behaves differently from the rest of the prostate in disease and under experimental conditions.

RARP for Median Lobe

Not all patients have a clinically discernable median lobe. The estimates of a clinically significant median lobe encountered during surgical procedures vary between 8 and 18% [4, 5]. Obviously, the larger the median lobe, the greater the challenge and increase in variables, such as operative time, size of bladder neck requiring reconstruction, injury to the ureteral orifices, and level of frustration, especially to the relatively novice robotic surgeon.

Although the presence of a large median lobe is often discovered at the time of surgery, the diagnosis can be made preoperatively. A large median lobe can be diagnosed based on the patient's voiding history and voiding pattern, such as urinary intermittency, and can also be visualized on preoperative abdominal and even transrectal ultrasound as a protruding smooth mass from the bladder neck. Additionally, cystoscopy may help in diagnosis of a large median lobe preoperatively. However, the necessity of such preoperative interventions to determine the existence of a large median lobe prior to RARP is debatable. Although the presence of a large median lobe does not necessitate a change in surgical approach for the experienced robotic surgeon, it may be challenging for the initial cases of one's robotic learning curve. Therefore, during the early phases of the learning curve for RARP, we suggest appropriate patient selection, and if the patient's voiding history is suspicious for the presence of a median lobe, appropriate preoperative workup, such as performing a preoperative abdominal or transrectal ultrasound or cystoscopy, is highly recommended. Presence of a known median lobe should be cause for appropriate patient counseling regarding the challenges that may be encountered intraoperatively.

The main concerns regarding the existence of a large median lobe during RARP is the possibility of ureteral injury during dissection of the median lobe/bladder neck and risk of ureteral obstruction during urethrovesical anastomosis [6]. Additionally, in an attempt to remove the complete median lobe, a wide excision of the trigone results in a large bladder neck defect and leaves the ureteral orifices closer to the bladder neck's resected margins [7].

Literature Review

Some studies have evaluated the impact of encountering a median lobe on the outcomes of RARP. Jenkins et al. [4] published a retrospective review of 29 patients (8%) with median lobe in a series of 345 patients undergoing RARP. In all patients, the existence of a large median lobe was found at the time of surgery. A comparison of surgical, clinical, and pathologic outcomes between these patients and 29 consecutive patients without a median lobe was performed. The authors found the presence of a median lobe did not increase operative time required for bladder neck dissection or urethrovesical anastomosis. Additionally, there was no difference in surgical margin status and time to continence between patients with median lobe and control group. Meeks et al. [5] reported the impact of prostatic median lobe on RARP. Of the 154 patients, 29 (18%) were found to have large median lobes. Contrary to the previous study, the authors reported greater operative time because of increased dissection requirements around the posterior bladder neck and seminal vesicles in patients with median lobes. Moreover, estimated blood loss and hospital stay were significantly greater in men with large median lobes.

More recent studies report conflicting results on the presence of median lobe to RARP outcomes. Jung et al. [8] report that in their 119

patients (out of 791) with median lobe, those patients had decreased positive surgical margin rates (16% vs 24.4%). However, after adjusting for clinicopathological variables (i.e., PSA, Gleason score, pathologic stage, prostate volume), the surgical margin rate was not statistically significant. In a larger series of 323 patients with median lobe (out of 1693 patients) from a single high-volume surgeon, there was no significant difference in estimated blood loss, operative time, length of hospital stay, pathologic stage, complication rates, positive surgical margin rates, and rates of urinary continence recovery [9].

In a different study where outcomes were stratified by significant median lobe (n = 42; defined as greater than 1 cm in Huang et al.), the authors report higher estimated blood loss and longer operative times [10]. More recently, Jeong et al. measured the "protrusion of the median lobe" (PML) on pre-operative MRI in 655 men [11]. Logistic regression suggested that patients with ≥10 mm of PML have higher odds of having at least pathologic T3 disease, positive surgical margin at the prostatic base, pre-operative PSA, prostate size, and pathologic stage.

Surgical Technique

Trocar placements and the steps for proceeding with a routine RARP are unchanged until the presence of a median lobe is suspected. During dissection at the anterior bladder neck, deviation of the Foley catheter to one side and significant intravesicular prostatic extension are the hallmarks of the presence of a large median lobe. Traction on the Foley catheter should better delineate the presence of a median lobe. Once the median lobe has been identified, either preoperatively or intraoperatively, the robotic surgeon needs to make adjustments to appropriately and safely handle the median lobe. If the median lobe is relatively small, approximate total volume of 5–10 cc, then this may not be very challenging and no significant adjustments need to be made. In this case, we recommend that the surgeon score the mucosa at the very top end or the caudal end of the median lobe close to the bladder neck (Fig. 25.1), peel the mucosa off the median lobe, dissect out the median lobe, and then evaluate if this would pose a significant technical challenge in proceeding with the prostatectomy. If the median lobe visually obstructs the surgical field of dissection, the recommended option is to excise only the median lobe to be sent off as a separate specimen. Due to its known embryological origin the median lobe is usually benign.

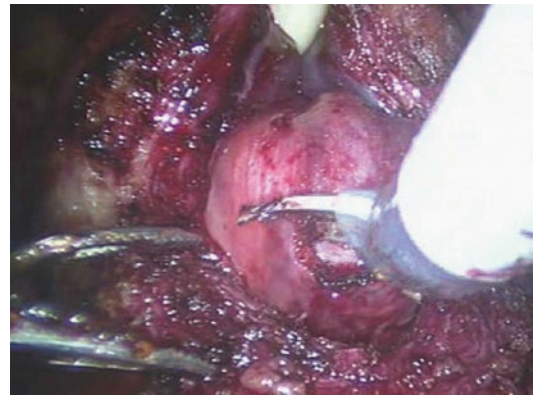

Fig. 25.1 The mucosa of the median lobe is scored and cut, as distally as possible, with scissors

If the median lobe is of significant volume and a challenge for intraoperative dissection, the recommendation is as follows: As mentioned above, the mucosa is scored, then peeled off the median lobe, and then lateral dissections are carried out to free up the median lobe, hopefully in its entirety. If possible, a 30° down lens is placed to see if the ureteral orifices can be identified. Every effort should be made to identify the ureteral orifices, so as to protect them. Intraoperative administration of indigo carmine or methylene blue may also be useful in the identification of the orifices, thus avoiding any possible injury. The optics of the robotic camera can be affected by either of these dyes staining the tissue and impairing vision by darkening the operative field during the procedure [7]. Other techniques used to avoid injury to the orifices include extra upward traction on the Foley balloon, use of a 30° down lens, and increasing magnification. If the median lobe is of a significant size, it might obscure the identification of the ureteral orifices. In these cases, extreme caution should be exercised to prevent trauma to the trigone and ureteral orifices. With this caution in mind, several techniques may be

employed to manipulate the median lobe out of the operative field, from left to right or from right to left, so as to adequately visualize the operative field as one proceeds with the remaining portion of the RARP.

After the median lobe has been completely dissected free of the mucosa and of the trigonal area, the recommended means of retracting this off the operative field would be as follows:

1. If the surgeon has the 4-arm robot, the 4th arm can be used to retract the median lobe as needed, be it from left to right, right to left, or from the inferior to the superior aspect, to expose the appropriate surgical plane, to proceed with the prostatectomy. The median lobe can be retracted with either the Prograsp forceps or the Tenaculum forceps (Fig. 25.2).
2. If this option is not available or impossible, we recommend using 2-0 or 1-0 polyglactin sutures on a CT-1 needle for traction (Fig. 25.3). This large needle can adequately affix a firm suture or sutures to the median lobe so as to promote adequate traction, either by the 4th arm of the robot or by the assistant, on either side, using grasping forceps to retract the median lobe away from the surgical field. Often, depending on the size of the median lobe, more than one traction suture may be needed.

Once the median lobe has been adequately retracted away or excised, further dissection is continued as per the surgeon's preference whether it is to move toward the posterior bladder neck and the ampullae of the vas or to move laterally so as to drop the pedicles before further developing the plane between the bladder and the prostate.

Management of the Ureteral Orifices

An important aspect of performing a safe robotic prostatectomy (or for any radical prostatectomy) is to adequately locate and ensure that the ureteral orifices or ureter is not compromised or

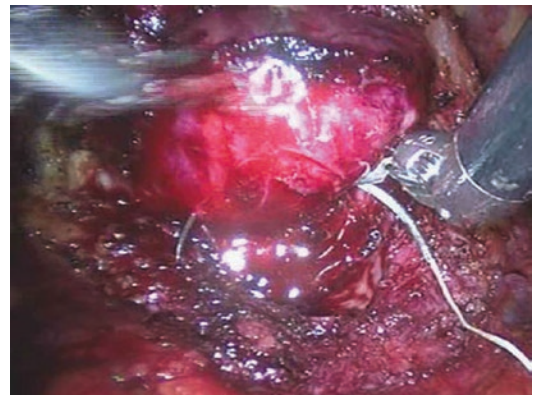

Fig. 25.3 2-0 polyglactin sutures on a CT-1 needle being placed for traction of the median lobe

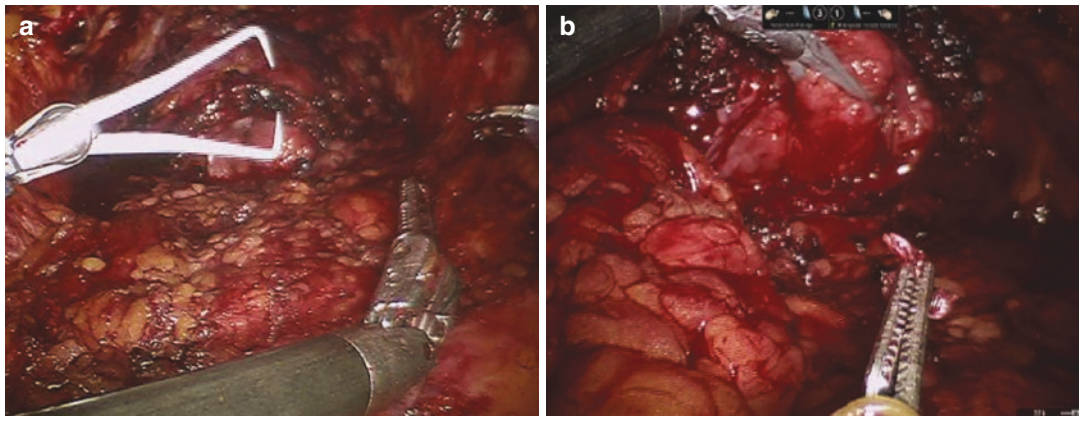

Fig. 25.2 (**a**) The Robotic Tenaculum being deployed. (**b**) Median lobe placed on upward traction with Robotic Tenaculum

traumatized in any way during the dissection underneath the significant median lobe.

One recommendation we have followed successfully, after the median lobe and/or the prostate is removed off the field, is to identify the ureteral orifices as follows:

1. A 30° down lens is usually required for this maneuver. We highly recommend a 5 Fr infant feeding tube be used instead of the usual ureteral catheters, since the infant feeding tubes are softer, less traumatic, and more rounded at the tips. The valve end of the infant feeding tube is cut and removed prior to inserting it into the laparoscopic trocars. We recommend both orifices to be individually catheterized and that the two distal ends be clipped with Hem-o-lok clips, so as to ensure its presence in the orifice without being extruded or pushed into the bladder by ureteral peristalsis (Fig. 25.4).
2. If the robotic surgeon is comfortable with the distance of the orifices from the resected margins, intravenous indigo carmine or methylene blue with efflux of blue-tinged urine may be adequate.

In any case, we recommend the orifices be clearly identified prior to closure of the bladder neck or prior to the urethrovesical anastomosis in the presence of a significant median lobe.

If the ureteral orifices are relatively close to the excised margin we recommend that the infant feeding tubes be left in as the posterior bladder neck is very carefully rolled over the mucosa to make the ureteral orifices roll into the bladder during closure of the posterior aspect of the bladder or with the urethrovesical anastomosis. Once the anastomosis is approximately 70% completed and the subsequent sutures are away from the posterior aspect of the bladder, we recommend

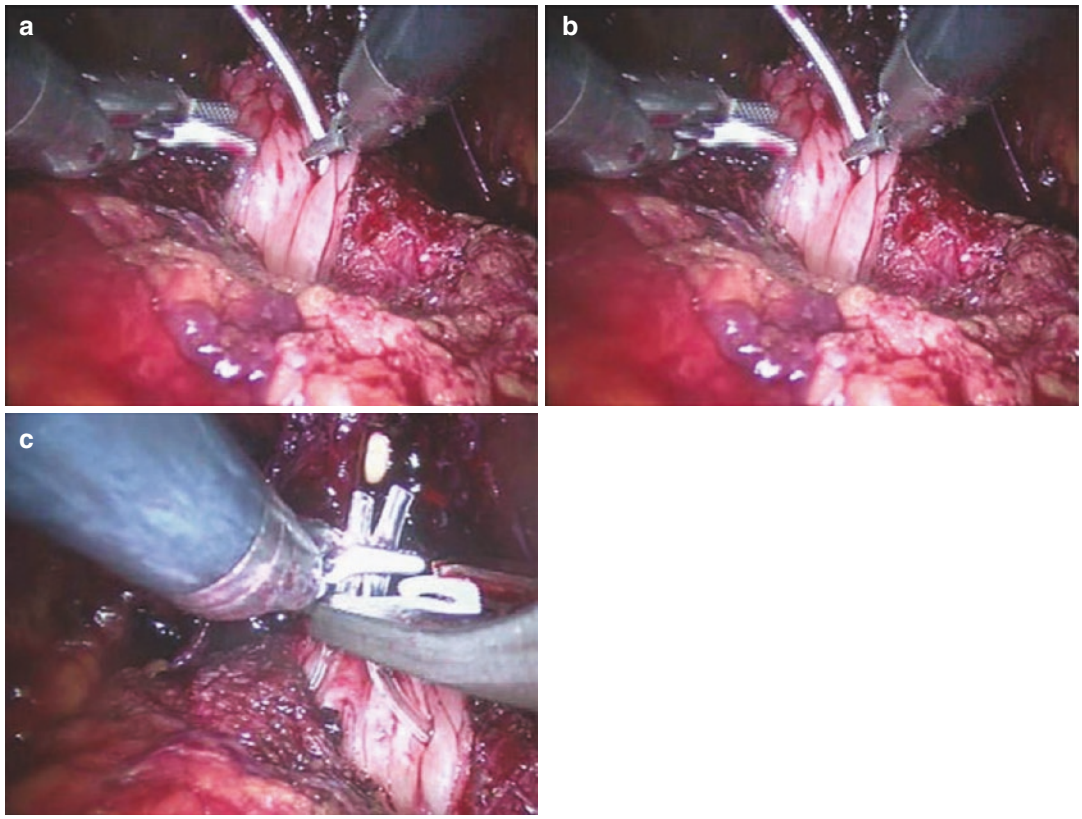

Fig. 25.4 (**a**) Right ureteral orifice being catheterized with 5 Fr infant feeding tube. (**b**) Both infant feeding tubes in place. (**c**) The distal ends are clipped together with Hem-o-lok clips

that the infant feeding tube be removed prior to completion of the urethrovesical anastomosis. As a cautionary note, we recommend careful monitoring of the urine output postoperatively to ensure there is no inadvertent pressure on the ureteral orifices.

In case of any question or concerns, or if the patient does have any unexpected postoperative discomfort, an ultrasound or other appropriate imaging, such as CT scan, is recommended to ensure the absence of silent hydronephrosis secondary to edema around the ureteral orifices. Further management, if hydronephrosis is encountered, will include measures such as percutaneous placement of nephrostomy tube or a gentle attempt to percutaneously place ureteral stents. Careful clinical correlation with objective findings, prior to any postoperative invasive procedures, is highly recommended.

In conclusion, if at all possible, it is important to make a preoperative diagnosis of not only the presence, but also the size of the median lobe. Once the median lobe is encountered, adequate traction should delineate the operative field and thus not only protect the ureteral orifices, but also facilitate the RARP.

RARP for Large Prostate

RARP in patients with a massive prostate gland that fills the pelvic outlet is a technical challenge, as compared to performing prostatectomy on smaller glands. The difficulty in performing RARP in patients with larger-sized prostates concerns the smaller working space of the pelvis, which reduces the ability to manipulate, retract, and rotate the gland. Additionally, a large prostate displaces the neurovascular bundles posteriorly [12]. There is no definition as to what constitutes a large prostate, in the radical prostatectomy literature. Previous studies have used values 70–80 g to define a large prostate [13–18]. Published open and laparoscopic prostatectomy series have demonstrated an inverse relationship between prostate volume and both extraprostatic extension and positive surgical margins [13–16].

El-Hakim et al. [19] reported their athermal RARP technique in 30 men with prostates larger than 75 g. The mean operative time was 193 min and mean estimated blood loss was 208 mL. All surgical margins were found to be negative. The authors concluded that although RARP for patients with large prostates is challenging, the robotic approach does not compromise oncologic control. Zorn et al. [18] reported a series of 375 men undergoing RARP. The patients were divided into four groups as less than 30 g (n = 20), 30–50 g (n = 201), 50–80 g (n = 123), and larger than 80 g (n = 31). The authors found no significant difference in operative time, estimated blood loss, hospital stay, length of Foley catheterization, and complication rates. The positive surgical margin rates were significantly different among the groups, demonstrating a trend of increase in surgical margin positivity with lower prostate volumes. Yadav et al. [17] studied 700 RARP procedures. The authors compared surgical and oncologic outcomes among small prostate (<40 cc, n = 217), intermediate size (40–70 cc, n = 375), and large prostate (>70 cc, n = 108) groups. Cumulatively, 14.6% had extraprostatic extension and 8.6% had positive surgical margins on final pathology. The authors, however, found greater incidence of extraprostatic extension in the small prostate group (16.7%) compared to the larger prostate (7.3%) group and concluded that small prostates have a higher cancer density and, therefore, a greater incidence of extraprostatic extension. Msezane et al. [20] performed a multivariate analysis in a series of 709 men who underwent RARP and found an inverse relationship between prostate volume and extraprostatic extension and positive surgical margins. The authors concluded that prostate volume is an independent predictor of both extraprostatic extension and positive surgical margins. While the aforementioned studies were performed transperitoneally, Boczko et al. [21] evaluated the effects of prostate size on treatment outcomes after extraperitoneal RARP. In this study, patients with prostate weight < 75 g (n = 319) were compared with those having glands ≥75 g (n = 36). The authors found a large prostate

volume is associated with an increase in postoperative urinary complications. A significantly higher percentage of cases of urinary tract infection (1.5% vs. 8.3%) and urinary retention after catheter removal (<1% vs. 13%) occurred in patients with larger prostates. The 6-month continence rate was significantly lower (84% vs. 97%) in the large prostate group.

Technical Modifications for Large Prostates

As with patients with large median lobes, traction sutures may have to be deployed so that the assistant (or 4th arm) can retract the prostate appropriately to visualize the prostatic pedicles and the rectum. In these cases, the traction sutures are placed laterally and posteriorly. Despite these efforts, management of large and wide-based prostates is challenging and will require patience and increased operative time. An additional challenge facing the robotic surgeon in this clinical situation is the probability of additional robotic instrument-induced bleeding, because of lack of adequate space between the prostate gland, the pubic bones, and the pelvic sidewall.

Preoperative assessment of the prostate size is crucial to prevent any complications or frustrations during RARP. Adequate patient counseling regarding outcomes, based on published literature as mentioned above, is important.

Management of the Large Bladder Neck

It is possible that after RARP for patients with large median lobe or a large prostate gland, the resulting bladder neck will be larger than is normally expected. Most urethro-vesical anastomosis factors in a bladder neck that is much larger than the urethral margin, with the robotic surgeon making appropriate adjustments to take wider "suture-bites" on the bladder side as compared to the urethral side. Occasionally, if this maneuver is insufficient, the residual bladder is closed anteriorly.

However, if the bladder neck defect is too large, then the two following techniques are suggested:

(a) *Fish-mouth closure*: In this technique, sutures are taken at 3 and 9 o'clock on the bladder neck and run medially until the bladder neck is of a sufficient size to meet the surgeon's comfort level (Fig. 25.5). Once this has been accomplished, the remainder of the vesicourethral anastomosis is continued in a usual manner. Caution should be exercised to safeguard the ureteral orifices.

(b) *Anterior tennis racket technique*: With this technique, recommendations are to proceed with the anastomosis as is usually performed, knowing that there will still be a substantial anterior bladder defect (Fig. 25.6a). Thus, once the anastomotic sutures circumferentially complete the anastomosis, these sutures are tied together. The anterior bladder neck defect is then closed in a side-to-side manner using 2-0 or 3-0 polyglactin sutures (Fig. 25.6b) similar to bladder closures for other surgical procedures when the bladder has to be opened. This closure mimics a tennis racket and hence the name.

In summary, RARP for patients with larger prostates appears to have similar surgical outcomes when compared to smaller prostates. Although there is no randomized prospective

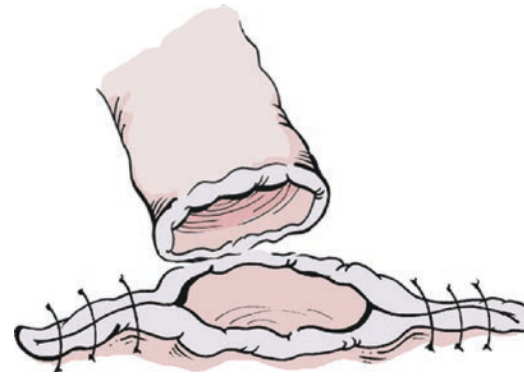

Fig. 25.5 Fish-mouth closure: Anterior view of large open bladder neck (BN); sutures from 3 and 9 o'clock positions are run medially, decreasing the BN size

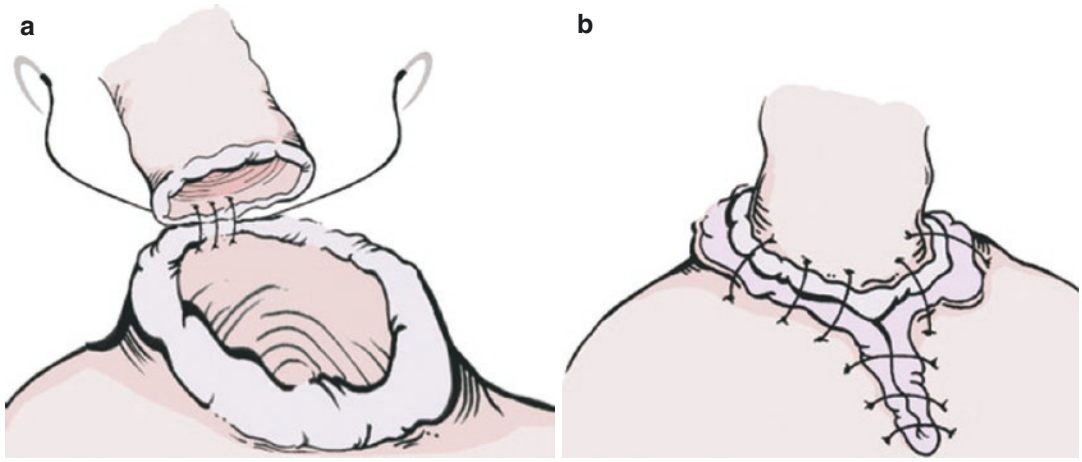

Fig. 25.6 (**a**) Anterior view showing start of vesico-urethral anastomosis in standard fashion. (**b**) The residual large bladder neck is closed anteriorly (tennis racket closure)

study, all retrospective studies demonstrated lesser incidence of positive surgical margins with the increasing prostate volume, though increased operative time should be allocated. Challenges will be encountered in these patients because of limited operating space between the large prostate gland and the pelvic sidewall.

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Robot-Assisted Laparoscopic Radical Prostatectomy in Patients with Clinically High-Risk Prostate Cancer

Malte W. Vetterlein, Mani Menon, and Firas Abdollah

Abstract

Patients with high-risk prostate cancer have a greater risk of biochemical recurrence, metastasis, the need for additional therapies, and prostate cancer-specific mortality. Although robot-assisted laparoscopic radical prostatectomy has largely supplanted open surgical approaches in localized low-risk disease, its role in the high-risk setting is still controversial, as evidence from the literature is limited. The aim of the following chapter is to summarize contemporary evidence from currently available data.

Keywords

Robotic surgical procedures · Prostatectomy · Prostatic neoplasms · Surgery · Treatment outcome

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Introduction

Despite the widespread dissemination of prostate-specific antigen (PSA)-based screening for early detection of prostate cancer (PCa), up to 25% of PCa patients still harbor high-risk features at the time of diagnosis [1]. Commonly used definitions for clinically high-risk PCa include the D'Amico criteria [2] (clinical tumor stage ≥cT2c, biopsy Gleason score ≥8, and/or serum PSA >20 ng/ml at initial presentation) and the National Comprehensive Cancer Network (NCCN) classification (clinical tumor stage ≥cT3, biopsy Gleason score 8–10, and/or serum PSA >20 ng/ml) for preoperative risk stratification. It is unequivocal that high-risk tumors are associated with higher risk of biochemical recurrence (BCR), metastasis, additional therapies, and cancer-specific mortality [1, 3, 4]. Although robot-assisted laparoscopic radical prostatectomy (RARP) has largely supplanted open surgical approach, especially in the US [5, 6], data on the outcomes of high-risk patients undergoing RARP remain sparse [7, 8] and are limited to few high volume centers [9, 10]. However, a recent systematic review by Yuh et al. [11] showed that the last years witnessed increasing efforts to address the role of robot-assisted surgery in treating high-risk prostate cancer patients.

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Technical Considerations in Robot-Assisted Laparoscopic Radical Prostatectomy for Clinically High-Risk Prostate Cancer

Sparing of Neurovascular Bundle

Due to inter-provider heterogeneities in surgical technique, approach, and procedural standards, the utilization of nerve-sparing RARP to treat high-risk PCa seems to be highly variable. Additionally, differences in tumor characteristics, surgeon preference, and/or the underlying population might also reflect those inconsistencies with nerve-sparing procedures ranging from 0% to 100% [12, 13]. The risk of harboring an extraprostatic extension in clinically high-risk patients is significant, and many surgeons are reluctant to retain neurovascular bundles in an attempt to mitigate the risk of positive soft tissue surgical margins. In a single-institution series from Mount Sinai Medical Center by Lavery et al., the authors showed that nerve-sparing RARP in high-risk patients is feasible and can be performed safely [14]. Of 123 high-risk patients, 58% and 15% underwent bilateral and unilateral nerve-sparing, respectively. Patients who had proven seminal vesicle invasion, extracapsular extension or patients with high volume of high-grade disease were excluded from nerve-sparing prior to RARP. In this cohort, nerve-sparing was not associated with higher rates of BCR or a positive soft tissue surgical margin status [14]. Similar results were found in a study by Casey et al., where no association of nerve-sparing with positive margins or BCR could be demonstrated in 35 patients with pT3 disease who underwent RARP [15]. In 2011, Tewari et al. from the Weill Medical College of Cornell University introduced a risk-stratified approach to nerve-sparing during RARP [16]. These authors focused on 2317 patients, who were preoperatively categorized into four risk groups, depending on biopsy Gleason score, serum PSA levels, results of the digital rectal exam, and magnetic resonance imaging [16]. Subsequently, the extent of the nerve-sparing procedure was determined by risk grade and ranged from total preservation of the neural hammock (nerve-sparing grade 1) to sacrificing the neurovascular bundle (nerve-sparing grade 4) in patients with high-risk of extraprostatic extension. This risk-stratified approach allowed the effective improvement of potency outcomes in high-risk PCa patients without compromising tumor control by using a more detailed and risk-adjusted algorithm [16]. Of nerve-sparing grade 1 patients, 90.9% had intercourse and 81.7% returned to baseline sexual function after surgery. Conversely, nerve-sparing grade 4 patients had intercourse in 62.0% and returned to baseline sexual function in 54.5%. Of note, overall positive surgical margin rates did not differ significantly between the different nerve-sparing risk groups (range: 7.2% in nerve-sparing grade 3 patients to 9.9% in nerve-sparing grade 1 patients; $p = 0.636$) [16].

Lymph Node Dissection

While an adequate lymph node dissection improves pathological staging and likely provides therapeutic benefits [17], contemporary studies reporting outcomes after RARP for clinically high-risk PCa mainly do not specify dissection templates [14, 18–22] or report about only limited lymph node dissections [23]. Lymph node positive rates range from 1% to 33%, and the highest rates are seen in patients undergoing extended lymph node dissection [12, 13]. Relying on the Surveillance, Epidemiology, and End Results (SEER) Medicare-linked database, Gandaglia and colleagues evaluated 5804 patients with non-metastatic PCa undergoing open radical prostatectomy (ORP) or RARP between 2008 and 2009 [24]. The authors found that the proportion of patients treated with pelvic lymph node dissection was higher among ORP vs. RARP patients (71.2 vs. 48.6%; $p < 0.001$). This finding remained robust in multivariate analyses, where ORP was associated with 2.7- and 1.3-fold higher odds of undergoing pelvic lymph node dissection as compared to RARP (both $p < 0.001$) [24]. However, patients with higher risk PCa had a

higher probability of receiving lymph node dissection, regardless of surgery type. Similar results were observed in a recent report that focused on data originating from the Shared Equal Access Regional Cancer Hospital database [25]. Overall, 1425 men undergoing radical prostatectomy (RP) with varying surgical approaches were included into the study and 67% underwent pelvic lymph node dissection. In this study, pelvic lymph node dissection was performed significantly less frequently in patients undergoing RARP, relative to their counterparts receiving ORP. However, the authors showed increasing utilization of pelvic lymph node dissection during RARP in both low- and high-risk PCa patients over time (2006–2013) [25], which might reflect the growing awareness towards the need of reasonable local tumor control in advanced disease and robot-assisted settings.

Other Technical Issues

Another technical issue, which is especially pertinent for high-risk PCa patients treated with RARP, is the lack of tactile feedback in the robot-assisted setting. This issue has recently been mitigated by developing a modification to the Vattikuti Institute Prostatectomy technique of RARP, which allows modified organ retrieval after excision and intra-operative examination or frozen-section analysis (the MORE technique). In summary, by using a hand-access platform (GelPOINT™), the prostate specimen can be extracted without undocking the robot or losing the pneumoperitoneum. Thus, the specimen can be examined by the surgeon on-table and frozen-section biopsies may be taken from areas suspicious for positive surgical margins. While waiting for those frozen-section results, the surgeon can continue with pelvic lymph node dissection and hence, operative time is not prolonged significantly. Promising results have been shown using this technical modification. Indeed, in patients with pT3a disease, the positive surgical margin rate dropped by 26.6% ($p = 0.04$), when the MORE technique was used [10, 26].

Perioperative Outcomes

Certain perioperative outcomes are of particular interest when assessing feasibility and safety of RARP in the high-risk PCa setting. Contemporary publications mostly evaluate the amount of blood loss during the procedure, operative time, length of hospital stay, and the time of transurethral catheterization to define complication and quality metrics after RARP [11]. Nevertheless, investigations focusing on perioperative parameters are quite limited in current literature. Table 26.1 shows a summary of perioperative outcomes in a contemporary series of studies reporting short-term outcomes after RARP for high-risk PCa. In those publications, mean operative time ranged between 111 and 214 min and hospital stay was recorded between about 1 and 6 days. In two available comparative evaluations of blood loss during surgery, both research groups found significantly decreased estimated blood losses in high-risk PCa patients undergoing RARP, relative to patients who received open surgery [27, 28]. Conversely, in the retrospective, propensity score-matched analysis by Gandaglia et al., no difference was found in 30-days overall complications between patients treated with RARP and ORP ($p = 0.6$) [27]. Notably, the hospital length of stay was significantly shorter in patients undergoing RARP, when compared to their ORP counterparts (1.0 vs. 2.0 days; $p < 0.001$) [27]. When assessing time of transurethral catheterization, reports vary widely (range: 6–13 days), which is presumably rarely related to immediate postoperative complications but rather to different intra-institutional standards. Notably, many series did not fulfill the Martin criteria requirements for reporting perioperative outcomes and complications [29]. Thus, underreporting of adverse events might have occurred and skewed the presented results. Regarding intraoperative complications and outcomes directly related to the surgical procedure, evaluation of data is generally scarce and only few studies reported on lymphoceles (range: 2.5–6.6%) [12, 13, 30, 31], ileus (range: 2.5–3.3%), anastomotic leakage (range: 0.8–10.05), or rectal injury (range: 0.0–1.7%) [13, 31].

Table 26.1 Summary of perioperative outcomes in a contemporary series depicting short-term robot-assisted laparoscopic prostatectomy outcomes in patients with high-risk prostate cancer

Author	Year	Cases (n)	Operative time (min)	Estimated blood loss (ml)	Length of stay (days)	Catheter time (days)	Overall complication rate (%)
Gandaglia et al. [27]	2014	353	–	Lower rate of blood transfusions in RARP patients vs. ORP	1	–	28.3
Koo et al. [41]	2014	101	199	284	–	–	12.8
Ou et al. [19]	2013	148	153.8	166.8	3.4	9	7.4
Punnen et al. [28]	2013	233	–	217; Lower rate of blood transfusions in RARP patients vs. ORP	1.6	–	–
Rogers et al. [18]	2013	69	175	150	1	7	5.8
Sagalovich et al. [12]	2013	82	111	150	–	–	2.4[a]
Jung et al. [30]	2012	200	190	250	4	–	–
Lavery et al. [14]	2012	123	147	84	1.6	–	–
Yuh et al. [31]	2012	30	186	200	1	–	30
Zugor et al. [20]	2012	147	164	183	–	5.7	14.2
Jayram et al. [42]	2011	148	–	150	1	6	4
Ham et al. [13]	2009	121	214	432	5.8	12.9	8.3

Abbreviations: *ORP* open radical prostatectomy, *RARP* robot-assisted laparoscopic radical prostatectomy
[a]Complication reporting is restricted to lymphoceles

Oncologic Outcomes

The evaluation of local cancer control in PCa is crucial regarding the prognostic relevance of the surgical margin status, time to BCR, and utilization of additional therapy (i.e., radiation therapy (RT) or androgen-deprivation therapy (ADT)). Only a handful of research groups have published data on oncological outcomes in high-risk PCa patients undergoing RARP, mainly focusing on short-term or perioperative outcomes. Table 26.2 summarizes the oncological outcomes in patients with high-risk PCa from select contemporary RARP series. The rates of BCR varied from 9% to 26% at one year of follow-up [14, 18]. Two authors reported an intermediate-term BCR at three years of 14% [18] and 55% [23]. Notably, only two study groups evaluated long-term oncological outcomes in this particular setting. Abdollah et al. recently published data from a multi-institutional collaboration evaluating 1100 high-risk PCa patients undergoing RARP. One-year, 5-years, and 10-years BCR were 19.2%, 37.7%, and 49.6%, respectively [9]. Overall, 4.8% and 1.1% of patients received adjuvant RT and adjuvant hormonal therapy, respectively. The 10-years salvage therapy rate was 37.0% and overall clinical recurrence-free survival rate was 87.0% at 10 years. Furthermore, the authors created a novel risk model based on BCR-free survival and stratified patients into five risk groups according to biopsy Gleason score and serum PSA levels. 10-years BCR-free survival varied significantly between the groups, ranging from 85.5% in risk group 1 (Gleason score ≤6) to only 26.2% in risk group 5 (PSA >10 ng/ml and Gleason score ≥8). Likewise, 10-years clinical recurrence-free survival varied from 99.0% in risk group 1 to 55.0% in risk group 5 ($p < 0.001$) [9]. A second publication conducted by Diaz et al. reported long-term oncological outcomes of RARP evaluating a single-institution series

Table 26.2 Summary of oncological outcomes in a contemporary series of studies evaluating patients undergoing robot-assisted laparoscopic radical prostatectomy with high-risk prostate cancer

Author	Year	Cases (n)	Median follow-up (months)	PSM (%)	Additional therapy (RT and/or ADT) (%)	Recurrence rate[a] (%)	Time to recurrence (months)
Abdollah et al. [9]	2015	1100	48.5	34.8	5.9	1-year-BCRFS: 81 5-year-BCRFS: 62 10-year-BCRFS: 50	–
Rogers et al. [18]	2013	69	37.7	42	13	1-year-BCRFS: 91 3-year-BCRFS: 86	9.7
Ou et al. [19]	2013	148	26.7	53.3		1-year-BCRFS: 80	–
Sagalovich et al. [12]	2013	82	–	12	–	–	–
Zugor et al. [20]	2012	147	19.6	33.3	–	BCRFS at follow-up (median 19.6 mo): 80	–
Connolly et al. [23]	2012	160	26.2	38	–	2-year-BCRFS: 56 3-year-BCRFS: 45	–
Lavery et al. [14]	2012	123	12.5	31		1-year-BCRFS: 74	4.6
Jung et al. [30]	2012	200	22	37.4[b] 55.6[c]	9	1-year-BCRFS: 80	–
Yuh et al. [31]	2012	30	–	26.7	–	–	–
Jayram et al. [42]	2011	148	18	20.5	23.3	18-mo-BCRFS: 79	–
Yee et al. [21]	2009	62	–	22.6	–	–	–
Shikanov et al. [22]	2008	70	9.6	24.2	–	1-year-BCRFS: 82	5.7

Abbreviations: *ADT* androgen-deprivation therapy, *BCRFS* biochemical recurrence-free survival, *PSM* positive surgical margins, *RFS* recurrence-free survival, *RT* radiation therapy

[a]BCR was defined as a serum PSA ≥2 ng/ml, except in the study by Shikanov et al., where PSA ≥1 ng/ml was set as a threshold

[b]In patients undergoing standard pelvic lymph node dissection

[c]In patients undergoing extended pelvic lymph node dissection

retrospectively [32]. BCR-free survival was 43.2% at 10 years. In another study on intermediate-term outcomes, Sukumar et al. evaluated 1556 patients with non-organ confined disease undergoing RARP from 2001 to 2010 at a single tertiary care center and showed a BCR of 18.3% at a mean follow-up of 34.6 months [33]. In the aforementioned studies, BCR was mostly defined as a serum PSA ≥2 ng/ml, except in a study by Shikanov et al. [22] where the threshold was defined as a serum PSA ≥1 ng/ml.

In addition to investigating oncological outcomes, Abdollah et al. [34] established a nomogram to predict favorable pathological outcomes (i.e., specimen-confined disease, pT2-T3a, node negative, and negative surgical margins) in clinically high-risk PCa patients undergoing RARP and identified PSA level, clinical stage, primary/secondary Gleason scores, and maximum percentage tumor quartiles as independent predictors of such. This nomogram allows the preoperative identification of clinically high-risk patients who will harbor a specimen-confined disease at surgery, and thus will probably not need a multimodal treatment. Such information can be very beneficial in counseling patients preoperatively. Similarly, Uberoi et al. [35] found that PSA level, PSA density, and the percentage of positive biopsy cores predicted specimen-confined disease, according to the aforementioned definition.

In the contemporary RARP series, positive surgical margins varied between 12% [12] and 56% [30] and there are only few studies reporting of additional therapy after RARP. In the series of

69 high-risk patients published by Rogers et al. [18], nine patients underwent additional therapy (ADT: $n = 2$; RT: $n = 6$; combined ADT and RT: $n = 1$).

These reported results regarding BCR and positive surgical margins are indeed comparable to those from studies evaluating oncological outcomes in high-risk patients undergoing ORP. In a large-scale retrospective European multi-institutional series of 1366 patients undergoing ORP for high-risk PCa, Briganti et al. found mean 5-years and 10-years BCR rates of 31% and 46%, respectively [36]. Interestingly, the BCR rates found by Abdollah et al. in the cohort of 1100 high-risk patients undergoing RARP were slightly higher at 5- and 10-years (38% and 50%, respectively) [9]. Of note, almost 50% of the patients in the study by Briganti received adjuvant therapy [36], whereas only 6% of patients in the study by Abdollah received adjuvant treatment [9], which might explain differences in BCR-free survival rates.

Other studies focused on positive surgical margins rate as a proxy for oncological outcomes. For example, Harty et al. compared RARP, ORP, and laparoscopic RP (LRP) [37] in 445 high-risk patients. Positive surgical margins rates did not differ significantly between those groups (53% in ORP, 50% in RARP, and 41% in LRP; $p = 0.16$). These oncological outcomes were corroborated by Pierorazio et al., who evaluated 913 men undergoing RARP and LRP for high-risk PCa [38]. For both positive surgical margins rate and BCR rate, there was no significant difference between the two treatment groups.

Functional Outcomes

Only a handful of investigations have assessed the functional outcomes (i.e., continence and potency) after RARP in high-risk PCa patients. Among those, the reported outcomes are quite heterogeneous, which can largely be explained by different use, definitions, and techniques of nerve-sparing during the procedures. Table 26.3 summarizes a contemporary selection of studies reporting functional outcomes after RARP for high-risk PCa. In one of the most recent studies, Sridhar et al. assessed the recovery of erectile

Table 26.3 Summary of functional outcomes in a contemporary series depicting short-term robot-assisted laparoscopic prostatectomy outcomes in patients with high-risk prostate cancer

Author	Year	Cases (n)	Potency definition	Potency rate at 12 months (%)	Continence definition (pads/day)	Continence rate at 12 months (%)
Sridhar et al. [39]	2016	531	IIEF-5 score ≥21	24[a]	–	–
Ostby-Deglum et al. [40]	2015	285	Erection adequate for sexual intercourse	19	–	–
Koo et al. [41]	2014	101	–	–	0	56
Ou et al. [19]	2013	148	Erection adequate for sexual intercourse	60	0	95
Rogers et al. [18]	2013	69	Erection adequate for sexual intercourse	33[a]	0–1	82[a] (51 with 0 pads)
Lavery et al. [14]	2012	123	IIEF-5 score ≥16	56	0–1	78
Jayram et al. [42]	2011	148	IIEF-5 score ≥17	52	0–1	92[a]
Yee et al. [21]	2009	62	–	–	0–1	92[a] (84 with 0 pads)

[a]Long-term rates from beyond 12 months. *IIEF* International Index of Erectile Function

function (EF) in 531 men undergoing RARP for high-risk PCa in a single-institution series [39]. Return of EF was seen in 23.5% of patients at 18 months. Notably, age ≤ 60 years, a preoperative International Index of Erectile Dysfunction (IIEF-5) score ≥22, and bilateral nerve-sparing were significantly associated with an increased likelihood of a return to baseline EF [39]. In another study from 2015, the authors evaluated the EF of 982 men with PCa ≥1 year after undergoing RARP [40]. Based on the questionnaire data, two major outcomes were defined as the ability to have a sufficient erection for intercourse as well as the use and effects of additional erectile drugs. Within the 285 (29%) patients harboring high-risk disease, 19% reported a sufficient erection with or without the use of erectile drugs ≥1 year after RARP. Interestingly, EF outcomes in patients harboring high-risk PCa were not inferior to those presenting with low-risk or intermediate risk PCa [40]. Rogers et al. conducted another single-institution study at the Vattikuti Urology Institute in Detroit, retrospectively evaluating 69 patients who had undergone RARP and harbored high-risk disease between 2001 and 2009 [18]. Promising results were found regarding functional outcome metrics. Fifty-three patients (82%) reported the utilization of ≤1 pad per day 23 weeks after surgery. Of these patients, 51% did not need any pads and reported full continence. Likewise, at a median follow-up of 26.2 months, in 33% of those patients who had a SHIM (Sexual Health Inventory for Men) score ≥21 preoperatively, sufficient erections for penetrative intercourse could be achieved post-RARP (with or without the assistance of erectile aids) [18]. Koo et al. evaluated 101 high-risk PCa patients undergoing RARP between 2005 and 2012 [41]. Continence was defined as using <1 safety pad per day and 56% of patients were continent at 12 months. Notably, potency outcomes were not assessed in this study [41]. The aforementioned more recent studies corroborate the findings of a systematic review on the role of RARP in high-risk PCa by Yuh et al. [11]. In several studies between 2009 and 2013 [14, 18, 19, 21, 42], the 12-months continence rate ranged between 78% and 95%, using a 0–1 safety pad definition. Restricting continence definition to "no pad utilization" exclusively, continence rates were reported from 51 to 95%. Remarkably, lower continence rates (51%) were significantly associated with an older cohort [18]. EF rates one year after surgery ranged from 52 to 60%. Nevertheless, definition of potency varied widely between the different studies and the validated SHIM questionnaire was infrequently used to assess postoperative EF.

A study from two high-volume tertiary care centers in the US and Italy (Detroit, Milan) evaluated 769 high-risk PCa patients undergoing RARP between 2001 and 2014. Urinary continence recovery at 12, 24, and 36 months after surgery was 85.2%, 89.1%, and 91.2%, respectively, while 33.8%, 52.3%, and 69.0% of preoperatively potent men (SHIM score ≥17) (n = 548; 71.3%) recovered EF [43].

General Role of Surgery in High-Risk Prostate Cancer

As of now, RP is a feasible option for patients harboring high-risk PCa and contemporary outcomes are encouraging regarding the reasonable utilization of RARP in this patient subpopulation. Pathological, perioperative, and functional outcomes are comparable with high-risk patients undergoing ORP. Furthermore, performance of an extended lymph node dissection can provide an adequate postoperative histopathological staging in patients receiving RARP.

When talking about high-risk PCa one has to acknowledge the wide spectrum of the disease, as it is dependent on its definition. As of now, there is no single definition, which is able to characterize all men with high-risk PCa but instead clinical stage, Gleason score, and PSA are used to predict disease recurrence, progression, and PCa-related mortality [2]. Notably, when comparing six different definitions of high-risk PCa, Nguyen et al. did not show significantly varying 5-years BCR-free survival rates [44].

Although there is a consensus on high-risk PCa patients requiring multi-modal treatment approaches, RT with simultaneous ADT has still

been prioritized over surgical approaches due to given concerns regarding functional adverse effects, unresectable tumors or high rates of positive lymph nodes. Nevertheless, RP is considered an adequate alternative to RT plus ADT, which is supported by numerous retrospective series suggesting superior long-term outcomes with RP when compared to non-surgical therapies. Tewari et al. evaluated 453 patients with high-risk disease (i.e., Gleason score ≥8) undergoing observation, RT, or RP, and found that the risk of PCa-specific mortality was lower in patients following RP compared to RT and observation (−68% and −49%; $p < 0.001$ and $p = 0.053$, respectively) [45]. Another notable finding was made by Zelefsky et al. [46]. Patients with clinically localized PCa (T1c-T3b) were treated with either RT or RP. In this study, patients with high-risk PCa who underwent RP had a lower risk of metastatic progression and PCa-specific mortality than their counterparts receiving intensity-modulated RT [46]. Similarly, Cooperberg et al. reported a greater risk of PCa-specific mortality in a population of 7538 men with localized disease in those who underwent RT relative to RP. Remarkably, these differences increased substantially in patients with intermediate and high-risk [47]. Boorjian et al. investigated the comparative effectiveness of RP vs. RT in high-risk patients and found that overall survival was better in patients undergoing radical surgery relative to those who received bimodal RT plus ADT (RP overall survival: 77% vs. RT + ADT overall survival: 67%; $p < 0.001$) [48]. Similar results were published by Abdollah et al., using competing-risks analyses in a population of 404,604 patients from the SEER registries [49]. 10-years PCa-specific mortality rates were significantly better in patients undergoing RP as compared to RT or observation (3.6%, 6.5%, and 10.8%, respectively; $p < 0.001$) [49]. As of now, randomized studies specifically evaluating the comparative effectiveness of various treatment approaches for high-risk PCa are still lacking. Nevertheless, there is evidence from high-risk subsets of randomized controlled trials (RCTs), assessing different treatment modalities for all-risk PCa. Wilt et al. conducted an RCT comparing RP versus observation for the treatment of localized PCa in 2012 and performed subanalyses showing that high-risk PCa patients benefited from RP in terms of significantly reduced PCa-specific mortality, relative to those undergoing RT (11.5% vs. 20.0%; $p = 0.05$) [50]. Similar results were published in a Scandinavian RCT by Bill-Axelson et al., showing that high-risk patients were benefited by surgery as compared with those receiving watchful waiting [51].

Specifically considering the biology and heterogeneity of high-risk disease, RP offers distinct advantages as compared to non-invasive treatment. RP is the only modality providing adequate pathological specimens for precise staging. Given that up to 35% of patients are staged erroneously [52] and almost half of high-risk patients turn out to have more favorable histopathology after final pathological review [53], RP represents the most sufficient tool to accurately offer targeted therapy to patients without increasing risks of unnecessary treatments and iatrogenically induced therapy-related morbidity. In addition, RP guarantees definite debulking of the tumor, which might improve overall outcomes, due to the important role of the primary tumor in terms of cytokine and growth factor production as well as tumor shedding [54].

Finally, although this approach is still highly controversial, RP has been recently proposed as the first step of treatment in a certain subset of patients presenting with metastatic PCa. Specifically, Löppenberg et al. showed in a sample of 15,501 patients harboring metastatic disease that those with a relatively low tumor risk and good health status appeared to benefit from local treatment (i.e., RP or RT targeted to the prostate) [55]. Likewise, Fossati et al. showed that local treatment of the primary tumor in a metastatic setting was associated with a higher cancer-specific mortality-free survival in patients with a predicted cancer-specific mortality risk <40% [56].

However, these reports are mainly originated from ORP data and still need to be validated and verified in robotic cohorts.

Conclusion

In summary, the outcomes following RARP for the treatment management of high-risk PCa are equivalent to ORP and RARP seems to be an effective and safe option for select high-risk patients. The preservation of the neurovascular bundles is feasible and may contribute to improved functional outcomes. Similarly, an adequate extended pelvic lymph node dissection can be performed robotically and may also increase the detection of positive lymph nodes to improve histopathological staging. However, further longitudinal and specifically prospective research studies are necessary to identify the possible long-term survival benefits of a primary RARP in men harboring high-grade PCa. A key role is the prediction of patients who may harbor organ-confined disease in spite of their clinical high-risk features, since they would be ideal candidates for RP and gain the most benefit from radical surgical procedures alone, such as RARP.

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27 Techniques to Improve Urinary Continence Following Robot-Assisted Radical Prostatectomy

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Abstract

Robot-assisted radical prostatectomy (RARP) has become the most common surgical procedure for prostate cancer with nearly 80% of prostatectomies performed robotically in a given year [1]. RARP has been shown to have a quicker recovery time and, given the better visualization and dexterity, may allow for improved functional and oncologic outcomes as well.

Post-prostatectomy incontinence, a bothersome complication for both the open and robotic procedure, has a tremendous impact on quality of life. Efforts to improve postoperative incontinence have led to many modifications in the surgical technique as well as preoperative and postoperative manipulations. This chapter highlights the various interventions described in the literature geared toward improving urinary incontinence post-RARP.

Keywords

Robotic prostatectomy · Stress urinary incontinence · Detrusor instability · Nerve-sparing prostatectomy · Anastomosis · Bladder neck sparing · Pelvic floor muscle training · Male urethral sling · Artificial urethral sling

Introduction

Robot-assisted radical prostatectomy (RARP) has become the most common surgical procedure for prostate cancer with nearly 80% of prostatectomies performed robotically in a given year [1]. RARP has been shown to have a quicker recovery time and, given the better visualization and dexterity, may allow for improved functional and oncologic outcomes as well.

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Definitions

The current International Continence Society (ICS) defines urinary incontinence as "the complaint of any involuntary leakage of urine" [2]. Studies vary greatly in how to quantify the degree of post-prostatectomy incontinence. Quantification of incontinence has been crudely defined by the number of incontinence pads per day (PPD). *Total continence* is often defined as the use of zero PPD and *social continence* as the use of a security pad or one PPD. When evaluating postoperative incontinence, one must consider the preoperative continence status of the individual patient.

Background

Historically, retropubic radical prostatectomy (RRP) had been considered the gold standard for the surgical treatment of prostate cancer. Robotic-assisted radical prostatectomy has gained favor over both open and laparoscopic approaches, providing improved recovery times and possibly improved function and oncologic outcomes [3–6].

The data regarding postoperative incontinence from various series for RRP, LRP, and RARP is summarized in Table 27.1. Most series utilized validated questionnaires, including UCLA-PCI and EPIC, for the assessment of urinary incontinence. RARP studies included additional substratifications of "early continence" showing promising data as early as 1 week postoperatively [16].

The studies of post-RRP demonstrate the continence rates approximating 92–93% at 18-month follow-up [8, 10]. Likewise, the best continence rate achieved by RARP was 96% with slightly shorter 12-month follow-up [25]. The highest LRP continence rate was 84% at 6-month follow-up [14].

In initial studies comparing RRP and RARP, Krambeck et al. reported no significant difference in continence at 1 year between RARP and RRP patients (RARP 91.8%, RRP 93.7%, $P = 0.344$) [26]. Similarly, Ahlering et al. reported that at 3-month follow-up there was no significant difference in continence (RARP 76%, RRP 75%, and $P \geq 0.05$) [27]. In contrast to the above studies, Tewari et al. with their VIP (Vattikuti Institute Prostatectomy) technique for RARP showed a significant difference between the RRP and RARP. Figure 27.1 shows the difference between the two groups (RARP/VIP vs. RRP). Patients achieved continence much quicker after VIP than after RRP. As shown in Fig. 27.1, 50% of the follow-up population recovered continence in 44 days compared to 160 days, in VIP and RRP groups, respectively ($P < 0.05$)0.11 More recent studies show some variation in continence results when comparing robotic technique to open, but show clear advantage of robotic to laparoscopic [28]. Ficarra et al. showed in a meta-analysis of 5 studies from 2009 to 2011 that 12-month risk of incontinence was 11.3% after RRP and 7.5% after RARP, which was shown to be a statistical advantage in favor of RARP [17]. Other studies have shown quicker time to recovery as well.

Tewari et al. showed a post-operative RARP continence (PoC) rate of 35, 50, and 62% at the 1-, 3-, and 6-month time points, respectively ($n = 214$) [16]. Kim et al. showed a median time to continence in RARP of 1.6 months compared to 4.3 months in RRP, after factoring in initial experience in the robotic arm [29]. Geraerts et al. showed a statistically significant time to continence in favor of RARP with median time to continence of 16 days for RARP and 46 days for RRP. They also showed less voiding symptoms in the RARP than the open group at 1 and 3 months after surgery [6].

Mechanism of Urinary Incontinence After Radical Prostatectomy

In males, continence is controlled by five structures: detrusor muscle, the internal sphincter, the ureterotrigonal muscles, the levator muscles, and the rhabdosphincter. The male urethral sphincter complex has a smooth and skeletal muscle component. The smooth muscle portion forms the internal and external sphincters. The internal sphincter controls passive continence and keeps

Table 27.1 Continence results following open, laparoscopic or robotic prostatectomy

Study	Year	Type	No. of cases	Method of assessment	Definitions used	Continence at 3 months	Continence at 6 months	Continence at 12 months	Continence at 18 months	Continence at 24 months
Benoit et al. [7]	2000	RRP, mixed pool data	25,651	Medicare claim	–	–	–	92	–	–
Catalona et al. [8]	1999	RRP	1325	Questionnaire	0 PPD	–	–	–	92	–
Steiner et al. [9]	1991	RRP	593	–	0 PPD	47	75	89		92
Kundu et al. [10]	2004	RRP	2737	Questionnaire	0 PPD	–	–	–	93	–
Kao et al. [11]	2000	RRP, multicentric	1013	Questionnaire	Drops of urine	–	34	–	–	–
Rassweiler et al. [12]	2006	LRP, multicentric	5824	Questionnaire	0 PPD	–	–	85		
Guillonneau et al. [13]	2002	LRP,	341	Questionnaire	0 PPD	–	73.3 ($n = 341$)	82.3 ($n = 255$)	–	–
Stolzenburg et al. [14]	2005	LRP	700		0 PPD	–	840 ($n = 500$)	92 ($n = 420$)	–	–
Badani et al. [15]	2007	RARP	1110	Questionnaire	0 PPD	–	–	93		
Tewari et al. [16, 17]	2008	RARP	214	Questionnaire	0 PPD	50	62	82	–	–
Link et al. [17, 18]	2008	RARP	1847	Interview	0–1 safety pad			92.5		
Finley et al. [17, 19]	2009	RARP	666	Questionnaire	0 PPD	69				
Greco et al. [17, 20]	2009	RARP	180	Questionnaire	0–1 safety pad	65	79	89	–	–
Lee et al. [17, 21]	2010	RARP	107	Not reported	0 PPD	–	–	91	–	–
Novara et al. [17, 22]	2010	RARP	308	Questionnaire	0 PPD	–	–	90	–	–
Shikanov et al. [17, 23]	2010	RARP	1436	Questionnaire	0 PPD	–	–	69	–	–
Samadi et al. [17, 24]	2010	RARP	1181	Not reported	0–1 safety pad	–	–	91	–	–
Patel et al. [17, 25]	2011	RARP	1111	Questionnaire	0 PPD	86	94	96	–	–

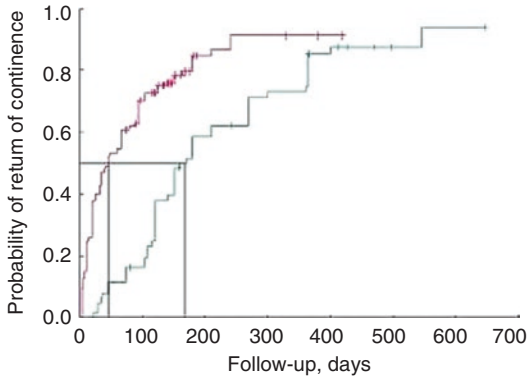

Fig. 27.1 Kaplan–Meier analysis of return of continence, in the RRP (*green*) and VIP (*red*) groups

urine at the level of the bladder neck. The rhabdosphincter is composed of the skeletal muscle and surrounds the membranous urethra from the prostatic apex to the corpus spongiosum, in an inverted horseshoe shape, and continues over the anterolateral prostate as the semilunar cap. This structure allows for active continence, allowing rapid and forceful closure which can be controlled. The nervous supply to these structures is from the cavernous nerve, the hypogastric and pelvic nerves for sympathetic and parasympathetic innervation, respectively, and the pudendal and pelvic nerves to the external sphincter [30].

Incontinence after radical prostatectomy can be due to intrinsic sphincter deficiency or dysfunction (ISD) or bladder dysfunction [31]. Intrinsic sphincter dysfunction can be the result of direct trauma to the sphincter, its nerve supply, or the supporting structures. In addition, the proximity of the rhabdosphincter and its innervation to the apex of the prostate places it at danger as well [30]. Any increases in abdominal pressure or gravitational stress will increase the risk of stress urinary incontinence with ISD.

Bladder dysfunction can be due to pre-existing bladder outlet obstruction leading to detrusor instability, to age-related changes in detrusor function, and to damage to detrusor muscle or innervation during surgery. Removal of the prostate and the obstruction can unmask the detrusor instability and reduced detrusor compliance which may manifest as urge incontinence [30]. Bladder dysfunction, caused by partial bladder denervation, may also result from surgical trauma [32].

Many cases of post-prostatectomy incontinence will be a mixed picture from stress and urge components [33]. Ficazzola et al. in their study using multichannel video urodynamics have shown ISD as the main culprit responsible for incontinence in post-prostatectomy patients. ISD was present in 90% of the patients [34]. Bladder dysfunction was not always a significant contributor (45%). Overall incontinence due to ISD was 67%, combined ISD and bladder dysfunction was 23%, and pure bladder dysfunction was 3%. Another study by Chao et al. showed that 57% had sphincter weakness alone, 39% had detrusor instability and/or decreased compliance combined with ISD, and only 4% had detrusor instability alone [35].

However, other studies such as those by Goluboff et al. and Leach et al. underscore bladder dysfunction as the predominant cause [36, 37]. According to Goluboff, the most common etiology for incontinence was detrusor instability alone, which was present in 40% after radical retropubic prostatectomy. Stress incontinence alone was present in only 8% after RRP. Detrusor instability with stress incontinence was present in 52% after RRP. Goluboff demonstrated that stress incontinence alone was a relatively rare cause of post-prostatectomy incontinence, with detrusor instability present in more than 90% of the patients [36]. Leach et al. in a similar study reported stress incontinence to be present in 40%, stress plus bladder dysfunction in 42%, and bladder dysfunction alone in 14% of post-RRP patients [37].

Matsukawa et al. in a retrospective urodynamics comparison demonstrated comparable degradations in both urethral sphincter function and bladder compliance between the RRP and LRP groups. Bladder function as measured by bladder compliance was significantly better in the laparoscopic group than the open group (45.7 vs. 25.8 ml/cm of water $P = 0.03$) [38].

Obstruction can be another cause of incontinence after radical prostatectomy and is usually the result of a narrowed vesicourethral anastomosis due to urethral stricture or bladder neck contracture.

This obstruction can cause overflow incontinence and urge incontinence secondary to detrusor instability [34]. The incidence of bladder neck contracture after RARP is 1.1% at 1 year in a large series reported by Msezane et al. In their study, there was no significant impact on urinary continence or QoL after appropriate management of the bladder neck contracture [39]. This is remarkably low compared to other series of RRP that demonstrate bladder neck contracture rates of 2.5–32% [40–42].

Factors Influencing Continence After RARP

Age

Increasing age is an important predictor for post-prostatectomy incontinence. With advancing age there is atrophy of the rhabdosphincter, neural pathway degeneration, and prolonged obstructive changes to the detrusor muscle. Several studies in patients with RRP have shown the negative impact of increasing age in recovering continence after surgery [43–45]. Greco et al. reported a comparative study between men older and younger than 70, and their continence outcome after RARP [46]. Continence rates, as defined by requiring one precautionary pad or less per day, were equivalent between older and younger men at 1, 3, and 12 months after RARP. However, older men had a significantly lower continence rate at 6 months (60 vs. 79%, $P = 0.04$). Older age is also associated with occasional urinary leaks after pad-free status has been achieved after RARP [47].

Many studies have also shown similar outcomes with in older patients undergoing RARP as well, most likely due to improved surgical technique over time. Mendiola et al. reported in a follow-up of 300 patients that younger men have an earlier return of continence compared to older men after RARP. However, this difference disappeared after 1 year of follow-up [48]. Kumar et al. showed in 2015 that 3-year continence rate and time to continence in patients greater than or equal to 70 (mean age of 72) versus those less than 70 (mean age 62) were statistically insignificant with rates if 87.3% vs 91.3% and 3.2 months vs. 3.1 months, respectively [49]. Life expectancy and functional status may be better determinants of outcome than age itself.

Prostate Size

Larger prostate size has been shown to be correlated with lower continence rates and longer time to recovery of continence. Boczko et al. in a series of 355 extra-peritoneal RARP patients reported the 6-month continence rate in patients with a prostate volume less than 75 g to be 97% vs. 84% in patients with prostate volumes greater than 75 g ($P < 0.05$) [50]. In another study by Link et al. increasing prostate size was associated with more postoperative urinary leaks but overall continence recovery was not affected as shown in Fig. 27.2 [18]. Skolarus et al. showed in 2010 that patients with a prostate over 100 g also have slower return of continence (62.2 days) compared to those with prostates smaller than 50 g (44 days) (Fig. 27.3). Interestingly, men with prostate cancer and enlarged prostates had increased pre-operative urinary symptoms. For example, those with prostates larger than 100 g had more irritative voiding symptoms. But, after RARP, at 3 month follow-up there was no difference in irritative voiding symptoms in these groups [51].

Pathology

Most large RRP series have found no correlation between the stage of disease and incontinence rates [8, 43]. In certain cases, the stage of disease may affect the surgical technique (i.e., nerve-sparing status), which may then have resultant effect on continence [43].

Nerve Sparing

Eastham et al. have shown a positive impact of nerve sparing in regaining continence after RRP [43].

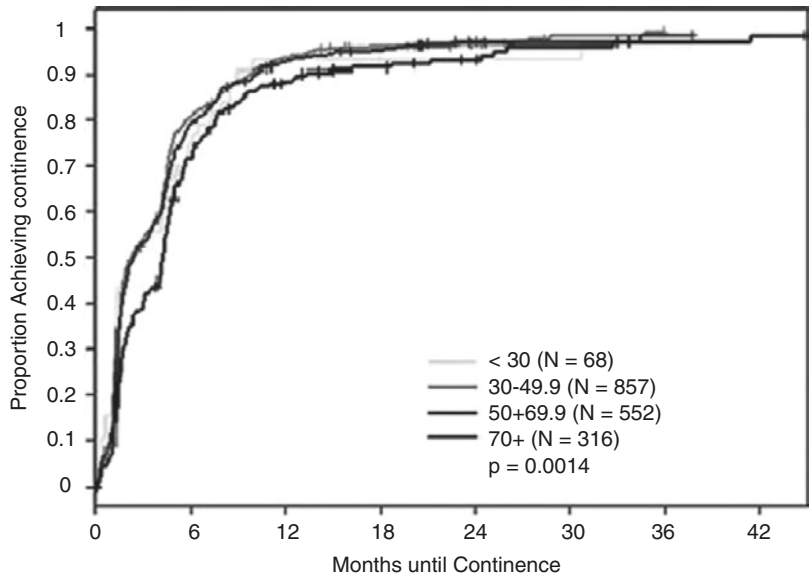

Fig. 27.2 Prostate size in grams and return to continence

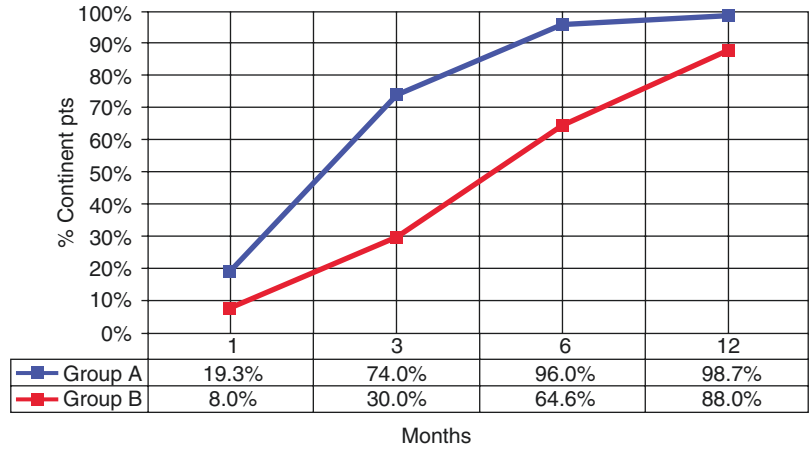

Fig. 27.3 Shows difference in return of continence between PMFT and non-PMFT groups. Group A = structured PFMT; Group B = no PFMT

Similarly in a large series by Sacco et al. recovery of continence was significantly worse in patients in whom both neurovascular bundles were resected during RRP ($P = 0.030$) [52]. In a study by Takenaka et al. the continence rate in a group of patients without attempted nerve sparing was significantly lower at both 3 months ($P = 0.0046$) and 6 months postoperatively ($P = 0.0356$) [53]. Steineck et al. performed a prospective study again confirming the importance of nerve-sparing in urinary continence after RARP. The relative risk for urinary incontinence adjusted for multivariate cofounders was correlated with the degree of nerve-sparing from lowest relative risk to highest relative risk: bilateral intrafascial dissection (1.00), one side interfascial and one side intrafascial dissection (1.28), bilateral interfascial dissection (1.53), bilateral partial dissection on each side (2.04), unilateral/inter/intrafascial dissection (2.01), uni/bilateral partial dissection (3.13), or no neurovascular dissection (3.11) [54]. There is some noise in this data most likely due to surgeries being performed in multiple different institutions; however, the trend is significant.

Anastomotic Strictures

Several studies have reported that anastomotic stricture is an independent and significant risk factor for incontinence. The incidence of

incontinence is directly proportional to the incidence of anastomotic strictures [43, 52] Chao et al. reported anastomotic strictures in 26% of men with post-prostatectomy incontinence which they found to be associated with sphincteric dysfunction by video-urodynamic evaluation [35]. Ahlering et al. noted a lower incidence of fossa navicularis stricture when using an 18 vs. 22 Fr catheter [55]. This simple maneuver decreased this risk of stricture from 6.9% in the 22 Fr catheter group to 0.9% in the 18 Fr catheter group in their experience ($P = 0.03$).

BMI (Body Mass Index)

BMI is associated with poor post-prostatectomy continence outcomes. Wiltz et al. in a prospective study, using a validated questionnaire in 945 patients with RARP, found that men with normal weight had a significantly higher continence rate when compared with overweight and obese men, at both 12 months (70 vs. 68 vs. 57%, $P = 0.03$) and 24 months postoperatively (75 vs. 71 vs. 57%, $P = 0.04$) [56]. In a similar study by Ahlering et al., using multivariate analysis, they demonstrated that only BMI predicted for pad-free continence at 6 months of follow-up ($P = 0.016$). Also, in this study, at 6-month follow-up, only 47% of obese patients vs. 91.4% of non-obese patients had achieved pad-free urinary continence ($P \leq 0.001$) [57]. Other studies, however, were unable to show similar predictive significance of BMI in recovery of postoperative continence [58–60].

Effect of Previous Surgery/Radiation

Menard et al. in a comparative study of patients undergoing LRP with or without TURP reported 86 and 95.8% continence rates, respectively ($P = 0.77$). However, neurovascular bundle preservation was performed in only 56.5% in those with a prior history of TURP vs. 78.9% in those without a prior TURP ($P = 0.02$). There is considerable difference between two groups, though, not statistically significant. This may be accounted for the difference in nerve sparing in two groups to some extent [61]. Colombo et al. have shown superior continence results following RRP for those without any previous prostate surgery (Table 27.2) [62]. Kumar et al. showed no statistical difference in continence rate after bladder neck procedure. However, they did show a difference in time to continence with those with previous bladder neck surgery taking 3.4 month in study group compared to 2.4 months in control to regain continence [63]. Yu-Kai et al. showed no statistical significance during RARP in those with previous TURP procedure in continence. However, they did show a difference in urinary symptoms including urinary stream at 12 months after surgery [64].

Kumar et al. also showed that previous radiation causes a longer time to recovery of incontinence (8.3 months) as well as reduced overall continence rate (85.8%) at 1 year compared to control groups (2.4 months, 95.1%) after salvage prostatectomy [63].

Evaluation of Incontinence After RARP

History and Physical Examination

A thorough history is an important part in evaluation of men with postoperative incontinence. Symptoms such as leakage with maneuvers increasing intra-abdominal pressure, urgency, incomplete emptying, slow or split stream, frequency, dysuria may better characterize and elucidate specific causes for incontinence. The number of pads per day and relative degree of bother can also aid in the stratification of mild to severe incontinence. Stress incontinence defined as incontinence associated with a sudden increase in abdominal pressure (grade 1), incontinence with moderate activity (grade 2), and incontinence with minimal activity or gravitational incontinence (grade 3) may be suggestive of the presence of ISD [34].

Preoperative voiding function should be used as a baseline measure. Significant voiding

Table 27.2 Difference in post prostatectomy continence recovery in patients with previous prostate surgery and those who had none

	Group 1 (43 pts)			Group 2 (120 pts)		
	Baseline	6 mos	12 mos	Baseline	6 mos	12 mos
No. complete continence (%)	100	32 (74)	37 (86)	0	110 (92)	114 (95)
No. incontinence (%)						
Mild (%)	0	16 (37)	4 (9)	0	5 (4)	5 (4)
Severe	0	10 (23)	3 (7)	0	3 (2.5)	0

Group 1 = previous prostate surgery (for BOO, TURP or open prostate surgery) and RRP
Group 2 = only RRP
Functional outcomes at baseline and 6- and 12-month follow-up [54]

difficulties preoperatively may predispose to early postoperative continence issues. Past medical history should suggest any underlying neurological deficit and prior surgery and/or radiation therapy may contribute to treatment failure and frustration. Medication history is also important, particularly, tricyclic antidepressants (imipramine, amitriptiline), anticholinergics (atropine), cholinomimetics (bethanechol, neostigmine), and antihistaminics (diphenhydramine).

Physical examination will revolve around the standard urologic examination. Bladder palpation, rectal examination, Valsalva, and cough maneuvers as well as a neurologic exam will provide a comprehensive evaluation. A simple voiding diary may be an important objective measure of the degree and type of incontinence.

Further Investigation

Urinalysis and microscopy as an initial test should be performed in all cases. Concomitant infection should be excluded as a cause of irritative symptoms. In addition, a urodynamic investigation (UDS) may be warranted. Uroflowmetry and postvoid residual urine volumes are readily available in the office setting. UDS may help in objectively differentiating various causes of postoperative incontinence. In addition to detrusor pressure measurements, simultaneous fluoroscopy may prove to be a helpful adjunct in the evaluation of sphincteric dysfunction. Cystoscopic evaluation may be necessary in cases where stricture or bladder neck contractures are suspected as a cause of persistent incontinence.

Magnetic resonance imaging (MRI) can also be used for preoperative analysis of the prostate and surrounding soft tissues including muscle and urethra. In a prospective study, using MRI as the imaging and measurement tool, Song et al. have shown that pelvic diaphragm thickness and the ratio of levator ani thickness to prostate volume are independent factors predictive of post-prostatectomy incontinence. They concluded that patients with better developed pelvic floor muscles, especially in relation to the size of the prostate, can be expected to achieve earlier recovery of continence after radical prostatectomy [65]. In a study by Tienza et al., they showed by using 1.5 Tesla MRI imaging with multivariate analysis and adjusting for cofounders that pre-operative membranous urethral length, prostate volume, and urethral wall thickness influenced urinary continence postoperatively [66].

Non-operative Strategies to Improve Continence Following RARP

Smoking Cessation

Cigarette smoke contains nicotine, which has well-studied pharmacological effects on the urinary bladder. Nicotine produces phasic contraction of isolated bladder muscles in vitro. These contractions may lead to increased detrusor activity that has been shown to be induced in vivo in the feline model. Another indirect mechanism may arise from the increases in intra-abdominal pressure caused by chronic coughing in smokers [67].

Research has shown that smoking is strongly associated with lower urinary tract symptoms in men; cessation may result in decreased symptoms [68]. Cigarette smoke has also been shown to have a strong relationship in the development of bladder neck contractures after RRP [69]. In a study by Borboroglu et al. smoking was the strongest predictor of bladder neck contracture when compared to coronary artery disease, hypertension, and DM [69].

In contrast, Wille et al. could not find a statistically significant relation between smoking and post-prostatectomy incontinence [59]. Certainly, smoking cessation is also beneficial to general health and improved recovery in the perioperative period due to improved airway health and anesthesia tolerance.

Pelvic Floor Muscle Exercise/Therapy (PMFT)

The pelvic floor muscles such as levator ani are an important group of muscles that contribute to pelvic anatomy and physiology. Their proper function may be compromised in the post-prostatectomy patient due to the anatomic and physiologic distortion created by prostatectomy. PMFT therefore plays a very important role in augmenting the continence mechanism.

A randomized controlled trial by Manassero et al. suggested that an early intensive and prolonged pelvic floor exercise can further increase the number of continent patients and this improvement persists in the first 12 months [70]. Filocamo et al. conducted a randomized controlled trial, with 300 consecutive patients who were to undergo standard RRP, and compared those with PMFT (group A) vs. no PMFT (group B). In their first treatment session, group A was taught how to perform a dominant pelvic muscle contraction while in the supine position without contracting the antagonist muscle group. At home, for 10 days, the patients performed three sets daily. In the second treatment session, patients were taught PMFT in all positions: sitting, standing, squatting, and going up and down stairs. After 1 month continence was achieved by 29 patients (19.3%) of group A as opposed to 12 (8%) patients of group B ($P = 0.006$). After 3 months 111 (74%) patients of group A and 45 (30%) of group B ($P < 0.001$) were continent. At 6 months the rates were 144 (96%) and 97 (64.6%), respectively ($P < 0.001$) (Fig. 27.3) [71].

Several studies support the above fact that PMFT helps in early recovery of continence [72–74]. A Cochrane Review by Campbell et al. and study by Chang et al. have recently supported the benefits of PMFT post-prostatectomy as well [75, 76]. Pelvic floor exercise, with or without biofeedback enhancement, significantly improves continence rates in comparison to men not having undergone PMFT [74].

Pharmacotherapy

There is no established pharmacotherapy for stress-related post-prostatectomy stress incontinence. Various available drugs such as anticholinergics and B3-adrenergic medications are being used with variable results in patients with evidence of bladder dysfunction or overactivity as a cause of incontinence [77].

Intraoperative Techniques

Preservation of the Puboprostatic Ligaments

Some have advocated for a puboprostatic ligament sparing technique to facilitate rapid return of urinary continence after RRP without compromising the oncologic efficacy of the procedure [78, 79]. This can be combined with minimizing the endopelvic fascia incision during the apical dissection. In addition, preservation of the puboperinealis muscle and arcus tendineus may aid in return of early continence [80, 81]. Stolzenburg after a comparative study proposed that the use of puboprostatic ligament sparing in endoscopic radical prostatectomy is beneficial in the recovery of early continence after nerve-sparing procedures, without any negative effect on margin status (Fig. 27.4) [82].

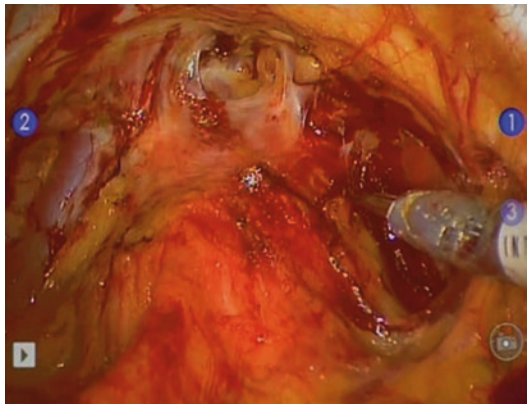

Fig. 27.4 Preservation of puboprostatic ligament

Suspension of the Dorsal Venous Complex

A periurethral suspension stitch has been used after DVC ligation. A 12 in. monofilament polyglytone suture on a CT-1 needle may be passed from the right to the left between the urethra and DVC, and then through the periosteum on the pubic bone. This can be done as a simple stitch or as a figure-of-eight fashion and then tied. Patel et al. have shown that this approach yields statistically shorter continence recovery times and higher continence rates at 3 months [83].

Placement of Bladder Neck Sling

The use of a bladder neck sling has been studied to evaluate efficacy in improving continence by recreating the pre-prostatectomy anatomy. Bahler et al. described a technique using absorbable porcine small intestine submucosa in 73 patients compared to no sling in 74 patients. The sling was placed posterior to the urethra and bladder neck prior to anastomosis. One end was sutured to Cooper's ligament. After anastomosis, the other end was sutured to the periosteum of Cooper's ligament. The sling was tightened until the first movement of the vesicourethral anastomosis was seen. The operative time was 20 minutes longer in the study group. The overall continence rates were similar between the study and control group at 1 month (55.2% and 47.1%, respectively) and at 12 months (94.5% and 86.7%, respectively). No statistical difference was seen, although the procedure did not have any significant adverse events either [84].

Bladder Neck Preservation

Bladder neck preservation is an alternative maneuver. Careful dissection of the prostatovesical junction can maintain most of the circular muscle fibers of the bladder neck reducing the risk of anastomotic stricture and accelerating the return of urinary continence. Gaker et al. have reported earlier return of continence without an adverse affect on oncologic outcomes when preserving the continence mechanism at the level of the bladder neck and prostatic urethra [85]. Deliveliotis et al. could not find a significant difference in the final continence outcome with bladder preservation but did report that the time to recovery of continence was reached earlier in the bladder preservation group. Surgical margins were unaffected [86]. Selli et al. and Sakai et al. reported similar continence outcomes [87, 88]. Lee et al. presented the idea that bladder neck preservation may be a graded outcome based on the degree of robot-assisted bladder neck preservation. Those with more definitive bladder neck preservation had higher overall continence at 3 months However, at 1 year there was no difference in continence based on bladder neck preservation grade [89].

Nerve Sparing

The rhabdosphincter is innervated by an intrapelvic branch of the pudendal nerve (somatic) and the mucosal and smooth muscle components by way of the urethral branch of the inferior hypogastric plexus (autonomic) [90]. Preservation of an intrapelvic branch of the pudendal nerve (long pelvic nerve) has been shown to improve and maintain rhabdosphincter function after RRP [91]. Hollabaugh et al. in a prospective comparative study reported the effect of nerve preservation on recovery of continence after RRP. Although

the overall continence rates were similar for the two groups (98.3% for nerve preservation vs. 92.1% without), nerve preservation decreased the time to achieve continence [92].

Montorsi described a nerve-sparing technique involving incision of the levator and prostatic fascia high anteriorly (1- and 11-o'clock positions) thereby developing the plane between the prostatic capsule and prostatic fascia thus sparing the neurovascular network. This allows for a minimal-touch dissection of the external urethral sphincter and a very efficient dissection of the neurovascular bundles at the level of membranous urethra and prostatic apex [93].

Lunacek described modified 'curtain dissection' to improve preservation of the cavernosal nerves running in the neurovascular bundle based on fetal and adult studies. The cavernosal nerves running in the neurovascular bundle assume a concave curtain shape covering both lateral lobes of the prostate. Caudal to the prostate, the nerves are not only lateral but also dorsal to the membranous urethra. The lateral pelvic fascia must be incised and the dissection of the neurovascular bundle should be carried out more anteriorly [94]. Menon et al. further described this technique as the "veil of Aphrodite." In their series they report encouraging continence recovery (95.2%) at 12 months. The potency rates were also very promising with 70 and 100% of the patients reported to have intercourse at 12 and 48 months, respectively [3]. While the basic principle of the "veil" nerve-sparing technique is to improve potency rates, it appears to play a role in the recovery of continence as well. Kaul et al. assessed 154 patients with the "veil" technique and reported excellent recovery of erectile function (both intercourse rates and return of normal erections) at 1 year after surgery, without compromising surgical margins and oncological outcomes [95].

In a prospective study of 151 patients, Van der Poel et al. found that the extent of fascial preservation at the lateral aspect of prostate is the best predictor of urinary continence at 6 and 12 months post-RARP [96]. They used a facial preservation scheme as depicted in Fig. 27.5. In their study the fascial preservation (FP) score is an important determinant of postoperative continence (FP score 6.4 vs. 4.4, $P = 0.001$).

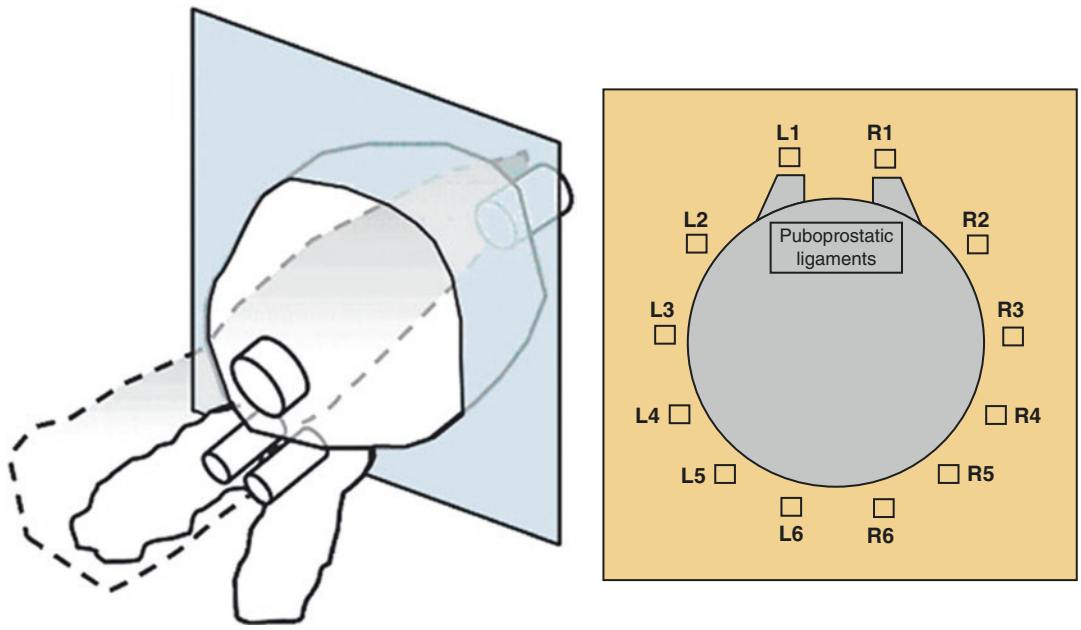

Fig. 27.5 Fascia preservation (FP) score scheme. The example shows preservation of L5 and L6 only, with a total FP score of 2

In patients with low-risk disease, some have moved toward a seminal vesicle sparing approach. Limiting dissection toward the tips of the seminal vesicles minimizes injury to the visceral pelvic plexus coursing posterolateral to the prostate. John et al. note a significant improvement in continence as well as potency recovery when employing this technique [97]. Some investigators have suggested that the close approximation of the seminal vesicles to the neurovascular bundle, pelvic plexus, and vascular supply of the bladder neck blood may play a major role in postoperative urinary and erectile function and have developed algorithms to predict seminal vesicle involvement before surgery [98].

Hypothermia of the Pelvic Floor

Hypothermic nerve sparing is novel concept described by Finley et al. introducing the concept of limited iatrogenic injury to the neurovascular bundle by cooling the pelvic floor. Utilizing a 24 Fr three-way Foley catheter within an elliptical latex balloon the prototype endorectal cooling balloon system was created. Ice cold saline at 4 °C was continuously infused at 40 cm of H_2O pressure. Additionally 4 °C irrigation was used intracorporeally as an adjunct. In a prospective study patients were found to return to continence significantly earlier in the hypothermia group (median 39 days) compared with the control group (median 59 days, $P = 0.002$), representing a 33.9% improvement in the interval to continence. At 3 months, 86.8 ± 5.8% of the hypothermia group and 68.6 ± 2.0% of the control group were pad free. The use of traditional nerve sparing did not improve early continence rates [99].

Apical Dissection

Myers described the importance of prostatic apical anatomy, its variation, and implication of this variation in prostatectomy. He recognized two basic apical shapes: one with a "notch" and another without a "notch" (Fig. 27.6) [100].

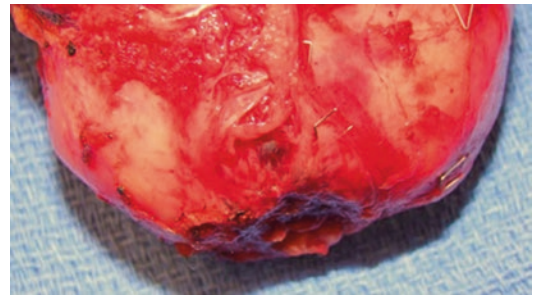

Fig. 27.6 Apical notch in a post-prostatectomy specimen

Whether a notch exists depends on the degree of lateral lobe development and the position of the anterior commissure. Excessive manipulation at the apex may lead to sphincter damage and is a risk factor for delayed recovery of continence. Thus meticulous dissection around the prostatic apex is of utmost importance [43]. Understanding the anatomy of the apex and the surrounding structures is essential for fine apical dissection [101]. Lee et al. studied the importance of prostatic apical anatomy and concluded that variations in the shape of the prostatic apex in relation to the membranous urethra may significantly affect the recovery of urinary continence after RRP. In their study, the group which was composed of patients with the prostatic apex not overlapping the membranous urethra at all on MRI (Fig. 27.7) had an early return to continence (83.3 vs. 66.7%, $P = 0.014$) [102]. In this context, Menon et al. have described a technique for apical dissection and have emphasized its significance in early recovery of continence. After exposure of the dorsal vein, urethra, and striated urethral sphincter, the puboperinealis muscle covering the urethra is dissected bluntly from the apex of the prostate. Next the urethra is freed at the apex with as little dissection as possible from underlying neurovascular bundle (Fig. 27.8). A #0 polygalactin suture on a CT-1 needle is used to ligate the deep dorsal vein while avoiding the puboprostatic ligaments. A second suture is placed through the anterior commissure of the prostate and the long tails of this suture are used as a traction handle. The distal complex is fixed by pulling the stay suture located over the proximal part of the prostate such that the exact plane

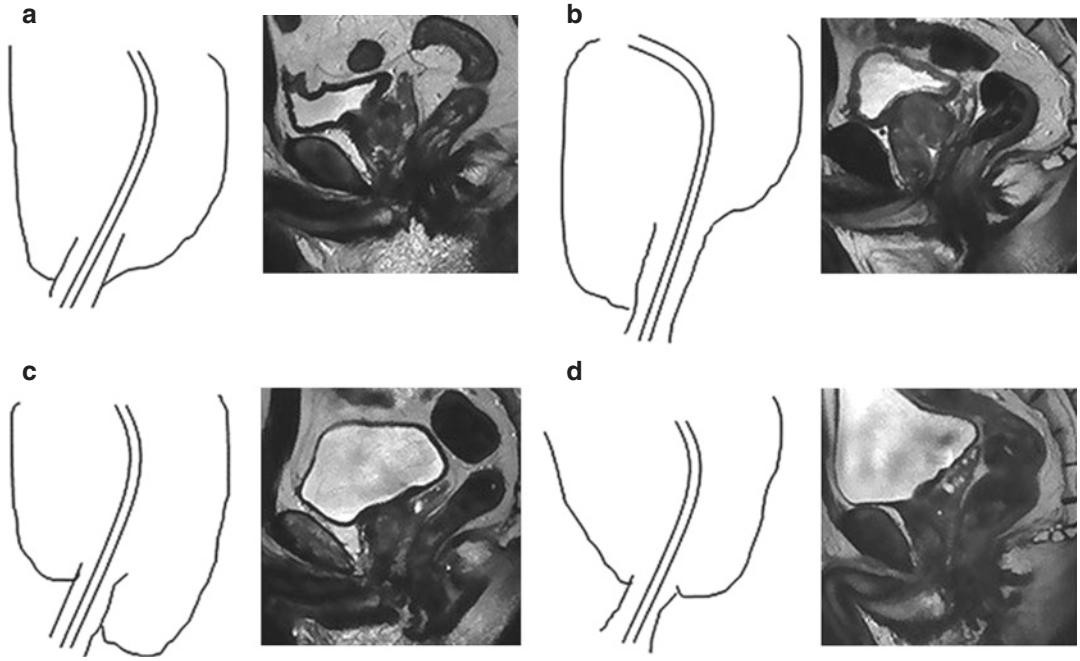

Fig. 27.7 Subjects were grouped according to the shape of prostatic apex observed on mid-sagittal MRI scan: (**a**) apex overlapping membranous urethra both anteriorly and posteriorly; (**b**) apex overlapping membranous urethra anteriorly; (**c**) apex overlapping membranous urethra posteriorly; and (**d**) no overlapping observed between apex and membranous urethra

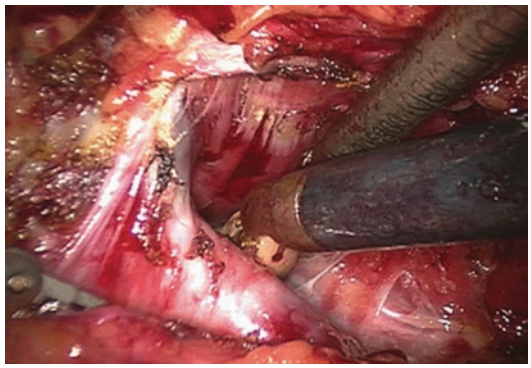

Fig. 27.8 A close view of the urethra at the prostatic apex, depicting the dorsal venous complex. The urethra is being freed posteriorly from the neurovascular bundles using blunt dissection

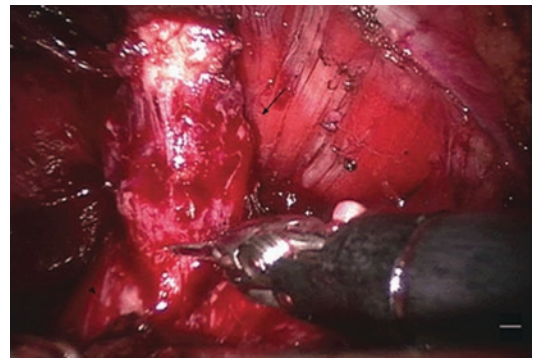

Fig. 27.9 Division of the urethra (*arrow*) distal to the prostatic apex (*arrow head*) with the help of articulated scissors

on anterior surface of the prostate can be identified, which helps in avoiding inadvertent entry into the prostate and in ensuring appropriate excision of the striated sphincter musculature. This results in a good urethral stump (Fig. 27.9) without compromising positive apical margin rate (Fig. 27.10) [103].

Preservation of Urethral Length

The membranous urethra is an important part of the continence mechanism. Several studies have emphasized that preservation of urethral length is an important determinant in the preservation of urinary continence [104–106]. Coakley et al. employ the use of endorectal MRI in preoperative

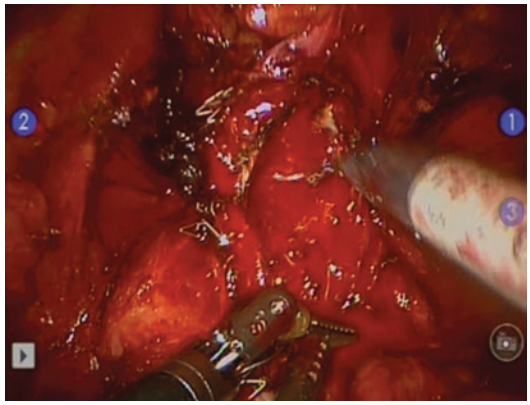

Fig. 27.10 Apical dissection. Note the staples in the edges of the dorsal vein in this case where the laparoscopic stapler was used

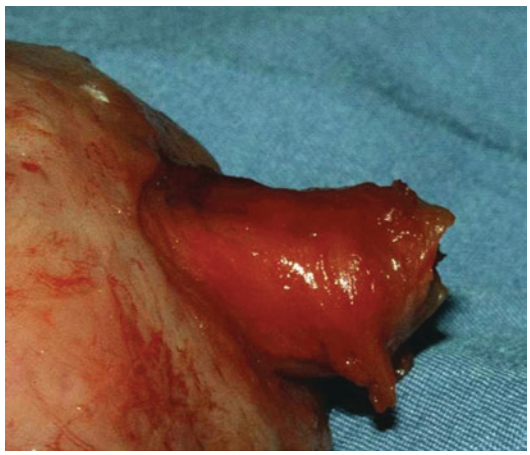

Fig. 27.11 Post-prostatectomy specimen showing well-defined urethro-prostatic junction

patients undergoing RRP, reporting that urethral length is directly related to early recovery of continence postoperatively [107]. Nguyen et al. found that urethral length may be used as a predictive measure of time needed to achieve continence in patients undergoing RARP [108].

The challenge lies in precisely identifying the junction between the prostatic apex and the proximal urethra (Fig. 27.11); this will maintain maximal urethral length without compromising apical margin status. In their series, Ahlering et al. describe a technique which combines precise transection of the apical–urethral junction with ligation of the puboprostatic ligaments during RARP. With this technical modification, positive margin rates decreased from 36 to 16.7%, and continence outcomes improved at 3 months (73 vs. 81%, $P = 0.24$). Of note, the authors utilized a laparoscopic stapler for control of the DVC which facilitated accurate apical–urethral transection [109]. Van Randenborgh prospectively used a technique for preservation of the intraprostatic portion of urethral stump via craniodorsal retraction of prostate. They reported that this technique led to improve continence outcomes (89 vs. 76%, $P < 0.05$), without compromising surgical margins.

Posterior Repair

The rhabdosphincter is invested in a fascial framework which is supported below by a musculofascial plate that fuses with the midline raphe—a point of origin for the rectourethralis muscle [110]. Both the dorsal and ventral supports contribute to the competence of the sphincter.

Posterior rhabdosphincter repair is a novel technique first introduced by Rocco et al. as a modification to ameliorate urinary incontinence after open radical prostatectomy. Reapproximation of the posterior semicircumference of the rhabdosphincter to the cut edge of Denonvilliers' fascia avoids caudal retraction of the urethrosphincteric complex prior to completion of the vesicourethral anastomosis. In addition, tension is taken off the anastomosis itself as an additional strength layer is added to the reconstruction (Figs. 27.12, 27.13, and 27.14). In their study, patients with a posterior repair achieved significantly better continence at discharge (62.4 vs. 14.0%), at 1 month (74.0 vs. 30%), and at 3 months of follow-up (85.2 vs. 46%), though long-term recovery was similar in the two treatment groups (94 vs. 90%) [111]. Similar results in post-prostatectomy continence were demonstrated in LRP patients when the posterior reconstruction technique was added to the standard procedure [112]. Nguyen et al., in a prospective study, concluded that posterior repair contributes to improved urinary function outcomes in both LRP and RARP patients [113]. Tewari et al. also emphasized the importance of

the posterior repair in continence recovery and reported improved outcomes [16].

By comparison, Menon et al., in a randomized controlled trial, described a circumferential reconstruction of the periprostatic tissue, with an additional anterior layer, in comparison to the Rocco technique alone [114]. The continence rates at 1, 2, 7, and 30 days were 26 vs. 34%, 49 vs. 46%, 51 vs. 54%, and 74 vs. 80% for patients undergoing simple anastomosis and anastomosis with peri-anastomotic tissue reconstruction (double layer anastomosis), respectively (statistically not significant).

Walsh Intussusception Stitch

Walsh in 2002 described buttressing sutures used to intussuscept the bladder neck to achieve early continence recovery after RRP. These sutures decrease the tension on the bladder neck as the bladder fills [115]. The described technique is as follows: a 2-0 Maxon suture is placed on the edges of the posterior bladder wall mainly in the adipose tissue, where the bladder was previously attached to the prostate, approximately 2 cm from the reconstructed bladder neck. The suture is then tied

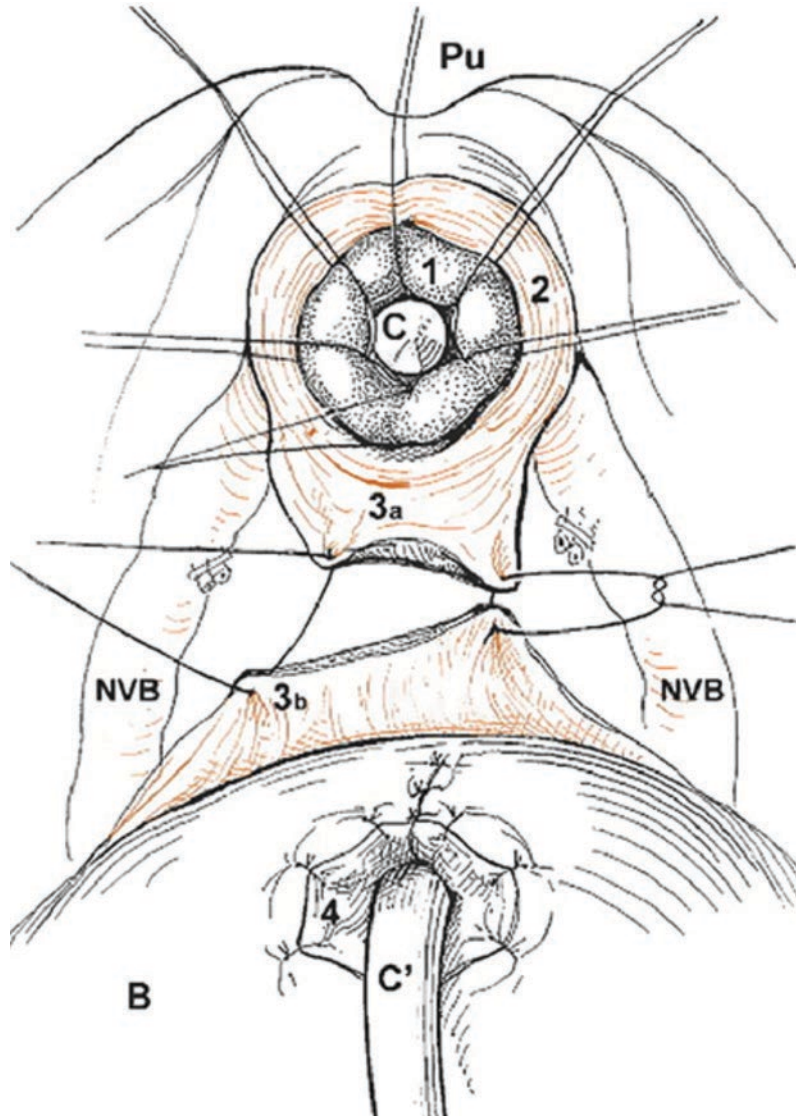

Fig. 27.12 Suturing the RS and median fibrous raphe to the remaining Denonvilliers' fascia. Pu = pubis; C = membranous urethral catheter; C′ = bladder catheter; B = bladder; NVB = neurovascular bundle; 1 = membranous urethra; 2 = anterolateral wall of RS; 3a = sectioned posterior wall of RS and MFR; 3b = sectioned Denonvilliers' fascia; 4 = bladder-neck eversion

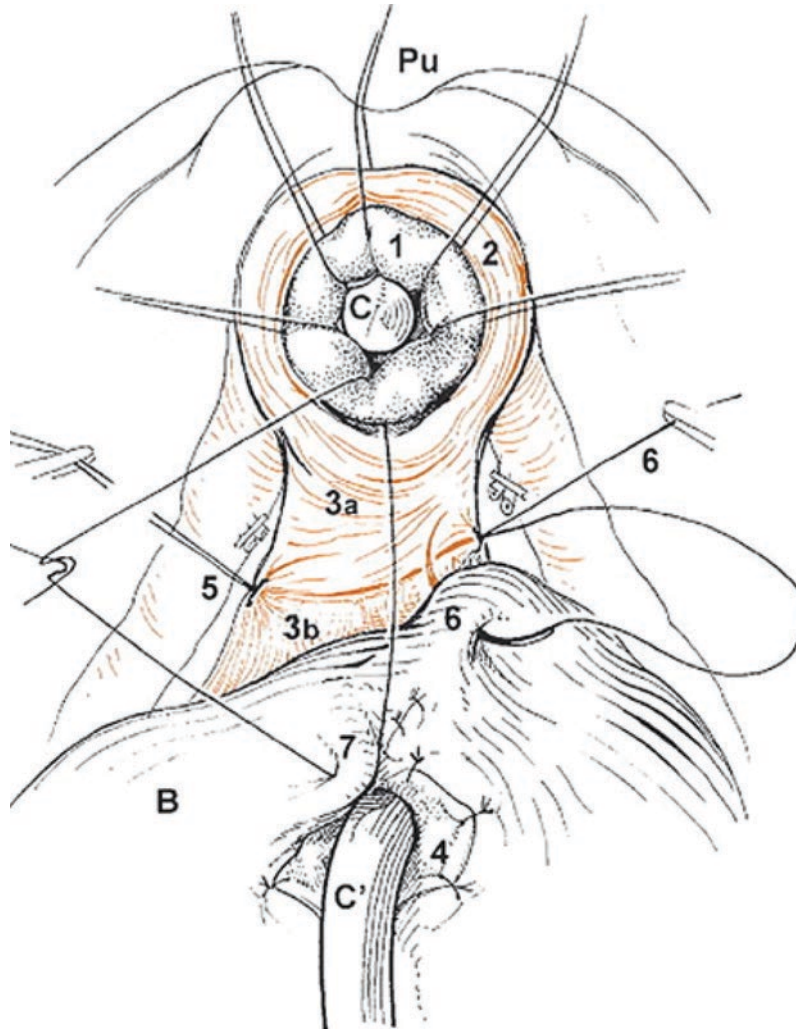

Fig. 27.13 Fixation of the RS and DV [5] to the posterior wall of the bladder about 2 cm dorsocephalad to the new bladder neck [6]. Pu = pubis; C = membranous urethral catheter; C′ = bladder catheter; B = bladder; 1 = membranous urethra; 2 = anterolateral wall of RS; 3a = sectioned posterior wall of RS and MFR; 3b = sectioned Denonvilliers' fascia; 4 = bladder-neck eversion; 7 = posterior urethrovesical anastomosis

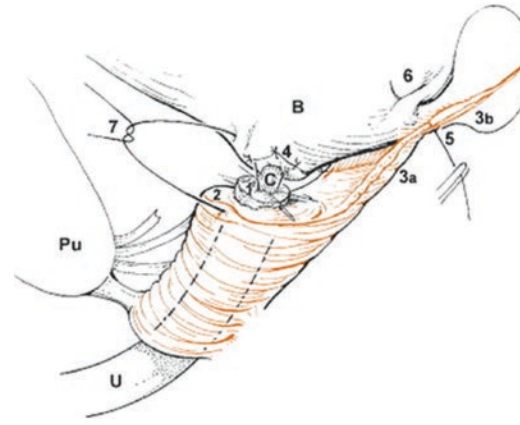

Fig. 27.14 Lateral view of action depicted in Fig. 27.15. Fixation of the RS and DV [5] to the posterior wall of the bladder about 2 cm dorsocephalad to the new bladder neck [6]. Pu = pubis; C = catheter; B = bladder; U = urethra; 1 = membranous urethra; 2 = anterolateral wall of RS; 3a = sectioned posterior wall of RS and MFR; 3b = sectioned Denonvilliers' fascia; 4 = bladder-neck eversion; 7 = posterior urethrovesical anastomosis

in the midline. The next suture is a figure-of-eight 2-0 Maxon placed 2 cm lateral to the bladder neck on each side. At this point, the bladder neck should protrude beneath the anterior hood of tissue created by the anterior stitch, similar to a turtle head outside its shell. After installation of saline, the bladder neck should be competent with very little leakage. Wille et al. in a comparative study reported that intussusception of the bladder neck resulted in a significantly greater continence rate of 77 vs. 60% at 3 months postoperatively although the continence rates at 12 months were not significantly affected. In addition, overall urinary symptoms were significantly better in the intussusception group as compared to controls [116].

More recently, Lee et al. described a robotic technique to plicate the bladder neck similar to the open technique. After the anastomosis was completed, a 3-0 Maxon single suture was placed in a figure-of-8 fashion. The suture was placed about 2 cm form the bladder neck and placed laterally on the bladder from the 3 o'clock position to the 9 o'clock position. The suture is then tied down to create a funnel configuration in which the 10-ml foley balloon can no longer be retracted to the anastomosis if pulled on. They compared 159 patients with plication stitch to 175 without a plication stitch. The time to social continence was significantly lower in the study group compared to the control (3.63 vs. 5.33 weeks (p = 0.004). Time to total continence was also improved in the study group compared to the control (5.10 vs. 8.49 weeks, p = 0.002). The probability of total continence was also improved at 1, 3, and 12 months [117].

Creation of a Watertight Anastomosis

It has been proposed that excessive extravasation secondary to a poor vesicourethral anastomosis can lead to fibrosis and scarring at the vesicourethral junction [118, 119]. Van Velthoven has described a simple, running laparoscopic suture technique for accomplishing a watertight anastomosis during laparoscopic radical prostatectomy and is easily replicable in RARP (Fig. 27.15) [120]. The running suture is prepared by tying the ends of two 6 in. sutures of 3-0 polyglycolic acid: one suture is dyed and the other un-dyed to aid identification of either end. The running stitch is initiated by placing both needles outside-in through the bladder neck and inside-out on the urethra. The sutures are run from the 6:30 and 5:30 positions toward the 9- and 3-o'clock positions, respectively. After this, gentle traction is exerted on each thread simultaneously or alternately. This is an important step to ensure the water-tightness of the anastomosis by ensuring the integrity of the posterior layer. The suture line is continued up to the 12-o'clock position on either side and a single knot is tied at the top. Long-term continence and stricture outcomes are similar for the interrupted technique [121, 122] Poulakis has reported a decrease in dorsal leak rates with the running technique as compared to interrupted suturing [122].

Barbed suture is an additional factor which has helped improve the ease of the vesicourethral anastomosis. In a systematic review and meta-analysis, Bai et al. analyzed ten studies which compared outcomes with barbed suture with conventional suture. 378 cases utilizing barbed suture were compared with 369 controls, and the results showed shorter operative time (mean difference 10.54 min), shorter vesicourethral anastomosis time (mean difference −5.35), and a shorter posterior reconstruction time (mean difference −0.56). No significant differences were found in continence recovery, urinary leak, or bladder neck stricture. Barbed suture may be most beneficial in reducing tension on the anastomosis and improving the ease of this step [123].

Postoperative Surgical Therapies for Post-prostatectomy Incontinence

Injection Therapy

Since its introduction in 1993, bovine glutaraldehyde crosslinked (GAX) collagen has been used extensively as a periurethral bulking agent in the treatment of ISD in men. Injection of a bulking agent beneath the urethral mucosa to improve competence of bladder outlet has been used

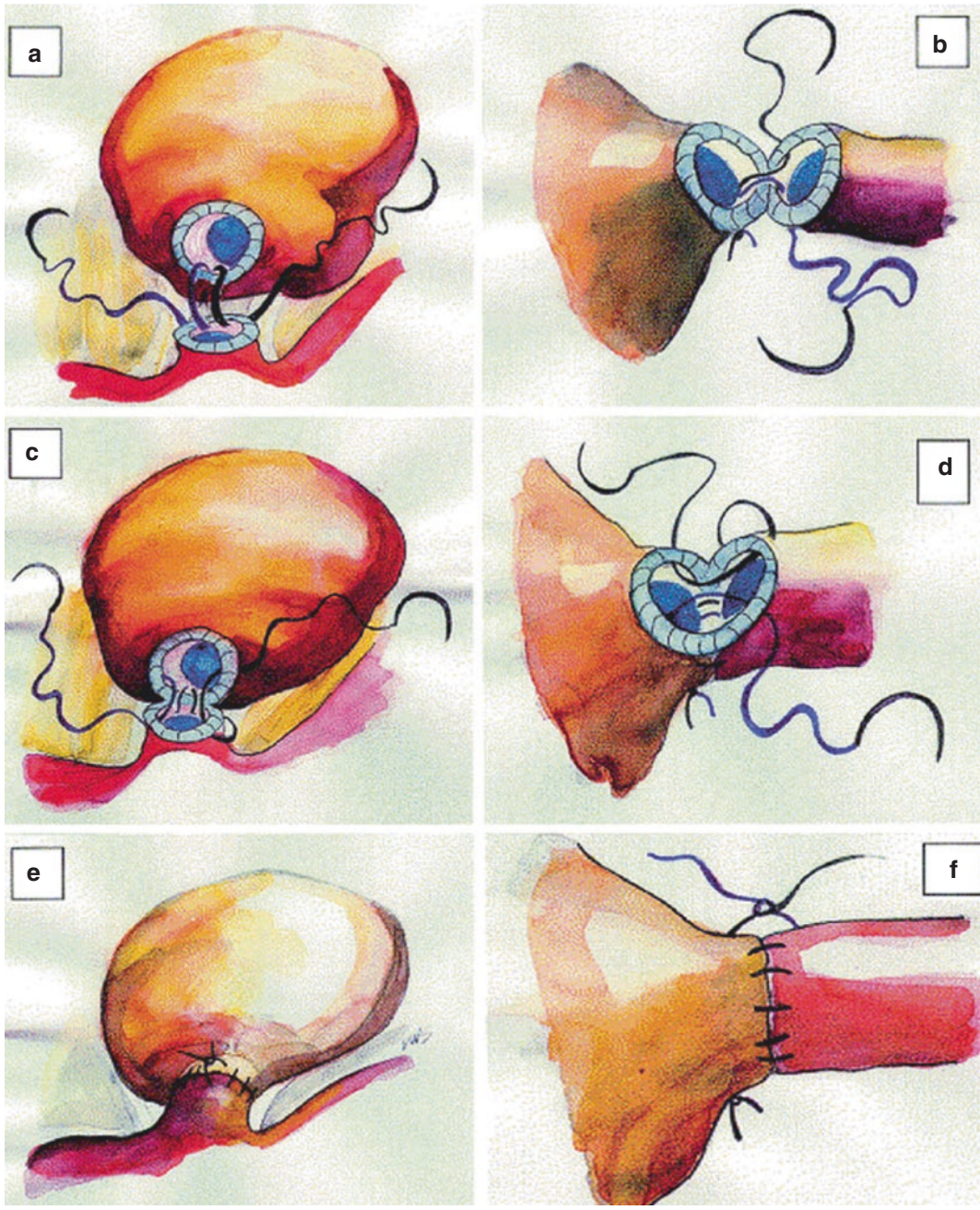

Fig. 27.15 Van Velthoven urethro-vesical anastomotic technique. (**a**) A double armed stitch is started outside in on the bladder neck at the 6 o'clock position. (**b**) These arms are then taken inside out on the urethra. (**c**) After several throws, the slack is taken out to coapt the posterior wall. (**d**) The separate arms are then run individually up to the 12 o'clock position. (**e**) View of the completed anastomosis. (**f**) Note that there is only a single pretied knot at the 6 o'clock position and one intracorporeal knot at the 12 o'clock position

successfully in women with sphincter deficiency. Transurethral collagen injections are a minimally invasive option in men with post-prostatectomy incontinence.

Westney et al., in a study of 307 patients with RRP, concluded that these patients (RRP) had a favorable response in terms of achieving continence after transurethral collagen injection [124].

Quality of response correlated positively with duration of response with patients maintaining continence for a mean of 1 year after injection therapy. On an average three to four injections were required to achieve a plateau response.

The Male Sling

Slings are also a widely accepted treatment for ISD. It is the more preferred treatment when compared to AUS (92% of men chose a male sling over AUS for postprostatectomy incontinence), which most likely is the reason for the increased usage of the male sling. In 2001, it accounted for 15% of post-prostatectomy incontinence surgeries and in 2011 this rose to 51% [125].

The concept of the male sling is based on the upward compression of the bulbous urethra with or without proximal urethral approximation. In contrast to the artificial urinary sphincter (AUS), the sling procedure allows physiological voiding. Many types of slings have developed over time including the bone-anchored male sling (BAMS), the transobturator sling (TO), the quadratic sling, and the adjustable sling. The BAMS works via direct compression of the distal bulbar and perineal urethra against the gentitourinary diaphragm. Titanium bone screws are used to affix the mesh. Success rates range from 65 to 80% when 1 pad per day used a definition of continence after 3–5 years. The TO sling works through mild compression of the bulbar urethra but mainly on proximal urethral relocation by 2–3 cm. Success rates range from 54 to 80%. The quadratic sling combines the efforts of the BAMS and the TO slings. It has shown a 79% objective success rate. Lastly, the adjustable slings allow for postoperative tightening or loosening. The success rate of these vary quite significantly from 17 to 79%. These adjustable slings have a higher explantation rate [125].

Comiter et al., in a prospective study in 48 men with stress incontinence, reported intermediate-term results of the bone-anchored male perineal sling with a median of 4 years and minimum of 2-year follow-up. They demonstrated the success rate comparable to that of the AUS (80% ≤1 pad daily) with very low morbidity [126]. Similarly, Migliari et al. reported 77, 67, and 63% of the patients to be socially continent at the 3-month, 1-year, and 3-year follow-up, respectively [127].

Each class of slings can be associated with significant side effects including postoperative perineal pain, osseous complications (in BAMS), urinary retention, genital paresthesias, bladder injury, infection/erosion, and progressive failure over time [125].

Castle et al. in another study with post-prostatectomy patients found that success after sling procedures is associated with the degree of preoperative incontinence. Success with sling is more likely in patients with mild to moderate incontinence. Severely incontinent patients may benefit more from an AUS as compared to sling [128]. Thus, a male sling may be best suited for patients with a 24-h pad volume less than 400 g/day [125].

Patients with a history of previous radiation or an artificial urinary sphincter were at high risk for failure as well (Fig. 27.16).

The efficacy of repeat sling may be dependent on the time to sling failure and the residual sphincteric function. If the patient never achieved sling efficacy or if the patient experiences sling failure prior to 6 months, then the efficacy of repeat sling surgery was lower (20% cure, 20% improved at 1 year) than those with failure after 6 months (63% cure, 13% improved at 1 year) [125, 129].

Artificial Urinary Sphincter (AUS)

The artificial urinary sphincter is perhaps the most effective long-term treatment option for

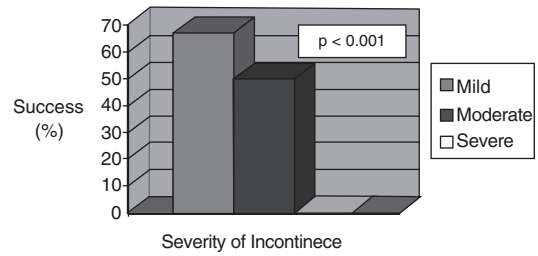

Fig. 27.16 Success after sling procedures was associated with the degree of preoperative incontinence

sphincter insufficiency in patients with severe incontinence or who have failed the above interventions. The most commonly used AUS consists of three parts: an inflatable cuff, a pressure-regulating balloon, and a control pump. The AUS has the longest track record with the widest experience with respect to the number of patients treated over any other treatment. Leibovich et al. in their experience with 458 AUS patients (417 men) reported an overall continence rate of 88.2%, a reoperation rate of 23.1%, and a mechanical reliability of 88%. Patient satisfaction rate was greater than 90% [130].

Trigo et al. in a prospective study investigated the long-term efficacy of the AUS for post-prostatectomy incontinence. Forty consecutive patients were treated with follow-up ranging from 27 to 132 months (mean = 53.4 ± 21.4 months). They found a significant reduction in pad count from 4.0 ± 0.9 to 0.62 ± 1.07 diapers per day ($P < 0.001$) leading to continence in 90%. Surgical revision rate was 20% [131].

Lai et al. in a 13-year retrospective experience with 218 patients with a mean follow-up of 36.5 months (60 = prostatectomy and pelvic radiation, 116 = prostatectomy without radiotherapy) concluded that AUS is a safe and durable treatment for male intrinsic sphincter deficiency even in patients with a history of AUS complications, neurogenic bladder, pelvic radiation, bladder neck contracture, failed injectables, or male slings [132].

Conclusion

Postoperative incontinence after RARP is a major concern and is one of the direct predictors of postoperative satisfaction [133]. Important aspects in achieving improved continence rates include the following:

1. Sound knowledge of the pelvic anatomy, especially of the prostatic apex, the surrounding musculature, and rhabdosphincter.
2. Meticulous dissection with emphasis on sphincter identification and preservation, hemostasis, and minimal distortion of the sphincter anatomy.
3. Specific technical modifications that show promise for improved results. While a comprehensive evaluation and targeted therapy should be instituted if incontinence occurs, the emphasis should be concentrated on improving surgical technique to minimize any unwanted morbidity and decreased quality of life. Further research is absolutely required to establish 'gold standard' techniques for optimizing post-RARP continence.

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Techniques to Improve Sexual Function Following Robot-Assisted Radical Prostatectomy

Nicola Fossati, Alberto Briganti, Giorgio Gandaglia, Alexandre Mottrie, and Francesco Montorsi

Abstract

Penile rehabilitation aims at improving cavernosal oxygenation, preserving endothelial structure, and preventing smooth muscle structural changes. The most commonly adopted approaches for penile rehabilitation following robot-assisted radical prostatectomy are represented by phosphodiesterase type-5 inhibitors (PDE5-Is), intra-corporeal injection therapy, vacuum erection devices (VED), and the combination of these treatments. In this chapter, the most relevant studies concerning penile rehabilitation after radical prostatectomy will be analysed and discussed. Nowadays, many strategies have been developed to facilitate the recovery of erectile function. However, clear and validated protocols for penile rehabilitation after robot-assisted radical prostatectomy still have to be defined. A combination of modalities might provide optimal preservation of erectile function. On-going and future studies will elucidate who is the optimal candidate and which is the optimal program for penile rehabilitation. New therapies emerging from pre-clinical studies will improve the clinician's armamentarium and increase the potential of penile rehabilitation.

Keywords

Prostatectomy · Erectile dysfunction · Penile rehabilitation · Phosphodiesterase 5 inhibitors

Introduction

Erectile dysfunction (ED) is one of the most common complications in patients treated with robot-assisted radical prostatectomy (RARP) despite the nerve sparing technique, with a significant negative impact on patients' health-related quality of life [1]. Penile rehabilitation is defined as the use of any intervention to achieve erections sufficient for satisfactory of sexual intercourses, and to recover erectile function (EF) similar to pre-operative levels [2]. The pathophysiology of erectile dysfunction (ED) following RARP represents the key concept for penile rehabilitation. In healthy men, there is a considerable increase of penile oxygenation from 35–40 to 75–100 mmHg during erectile status, with a constant oxygenation of penile tissues. On the contrary, three main factors may cause ED in patients undergoing RARP:

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1. ***Venogenic factor***. ED is principally due to hypoxia-induced fibrosis and consequent venous leakage. In a study by Mulhall et al. that evaluated duplex Doppler and cavernosography in men treated with nerve-sparing RP, 26% of patients had venous leakage [3]. In this study, the presence of venous leakage was a significant risk factor for post-prostatectomy ED. The pathophysiological mechanism is still little known. Similar to direct trauma, fibrosis may reduce nervous vitality and it may alter smooth muscle stretch capacity. Therefore the corporeal veno-occlusive mechanism may be compromised.
2. ***Arteriogenic factor***. This second pathophysiological factor is related to the direct excision of accessory and aberrant pudendal arteries. These vessels may originate from external iliac, hypogastric, or obturator arteries. Their presence varies from 4% to 75%, and they perfuse the corpora cavernosa both uni- or bilaterally. In some patients, the corpora cavernosa vascularization may be completely supplied by these arteries [4]. As a practical consequence, surgeons should carefully preserve these vessels during RARP.
3. ***Neurogenic factor***. Patients undergoing RARP may experience neuropraxia, a phenomenon that is due to direct trauma, inflammation, heating, and ischemia affecting the cavernous nerves, regardless of nerve-sparing degree [5]. The chronic postoperative absence of erections related to neuropraxia results in a state of persisting flaccidity [6].

The concept of penile rehabilitation aim at improving cavernosal oxygenation, preserving endothelial structure, and finally preventing smooth muscle structural changes. Nowadays, the most commonly adopted approaches for penile rehabilitation following RARP are represented by phosphodiesterase type-5 inhibitors (PDE5-Is), intra-corporeal injection therapy, vacuum erection devices (VED), and the combination of these treatments [7].

Phosphodiesterase Type-5 Inhibitors

The administration of PDE5-Is represents the most commonly employed strategy for 12–18 months penile rehabilitation after RARP [8, 9]. A recent meta-analysis was performed to evaluate data from clinical trials comparing PDE5-Is to placebo [10]. Patients in PDE5-Is group showed significant improvement in the International Index of Erectile Function-Erectile Function domain score (IIEF-EF), Global Assessment Questionnaire (GAQ), Sexual Encounter Profile question 2 (SEP-2) and SEP-3. Furthermore, the safety profiles were acceptable, with low incidence of discontinuation rate due to adverse events. In details, seven randomized controlled trials (RCT) were included. In three out of seven, patients were treated with vardenafil [11–13], while in two of them patients were randomly selected to receive tadalafil [14, 15]. Finally, sildenafil and avanafil were used in Padma-Nathan's [16], and Mulhall's study [17], respectively.

Vardenafil

Brock et al. [11] randomized 440 men with ED after nerve sparing radical prostatectomy to take placebo, or 10 or 20 mg vardenafil. Efficacy was measured after 12 weeks. They found that vardenafil significantly improved key indices of erectile function, such as IIEF-EF and GAQ. A second study on the same' population further demonstrated that on demand treatment with vardenafil during a 3-month period significantly improved key aspects of the sexual experience important to patient quality of life [12]. Finally, *Montorsi F* and colleagues randomly assigned 628 men to placebo, nightly vardenafil, or on demand vardenafil after bilateral nerve sparing radical prostatectomy [13]. In this study, vardenafil was efficacious when used on demand, supporting a paradigm shift towards on demand dosing with PDE5 inhibitors. The superiority of the on-demand dosing during the double-blind treatment period might be related to the pharmacokinetic of

vardenafil, its onset of action, and the half-life of this drug [18]. Patients receiving the drug on-demand might have had the full effect of the treatment when needed, while those in the nightly group had an effect so far as their sexual activity coincided with the administration of vardenafil. On the other hand, difficulties to reach a steady state with a single daily administration might limit the efficacy of chronic vardenafil dosing in terms of preservation of erectile tissue after surgery. Overall, vardenafil was well tolerated in these RCT's. Common adverse events were headache, vasodilatation and rhinitis.

Tadalafil

This PDE5-I was tested in two RCT's by Montorsi et al. [14, 15]. In the first study, Tadalafil 20 mg, taken on-demand, was an efficacious and well tolerated treatment for erectile dysfunction following bilateral nerve sparing radical prostatectomy. A total of 303 men (mean age 60 years) with pre-operative normal erectile function who had undergone surgery 12–48 months before study were randomized (2:1) to tadalafil (201) or placebo (102). Patients receiving tadalafil reported greater improvement of IIEF-EF and GAQ. For all randomized patients who received tadalafil, the mean percentage of successful penetration attempts was 54% and the mean percentage of successful intercourse attempts was 41%. For the subgroup with evidence of postoperative tumescence these values were 69% and 52%, respectively. Of all patients randomized to tadalafil 62% and of the subgroup patients randomized to tadalafil 71% reported improved erections. Headache (21%), dyspepsia (13%) and myalgia (7%) were the most commonly reported adverse events. In the second study, 423 patients were randomized (1:1:1) to 9 months of treatment with tadalafil 5 mg once daily, tadalafil 20 mg on demand, or placebo. Interestingly, Tadalafil once daily was most effective, and data suggested a potential role for tadalafil once daily provided early after surgery in contributing to the recovery of EF after prostatectomy and possibly protecting from penile structural changes.

Sildenafil

Padma-Nathan et al. [16] randomized 76 patients treated with nerve-sparing radical prostatectomy to sildenafil nightly vs. placebo for 36 weeks followed by a 8-week drug-free period. The return to baseline EF was more marked for men treated with sildenafil compared to placebo group. Moreover, the mean IIEF-EF was substantially higher in the sildenafil group. Although this study reported encouraging results and introduced for the first time the concept of penile rehabilitation using PDE5-Is, enrolment ceased early owing to interim analyses showing a lower response rate than expected. Moreover, the lack of a group receiving on-demand dosing limits the applicability of these findings. However, a recent RCT did not show a statistically significant difference between patients receiving sildenafil on-demand vs. nightly at 13-month follow-up [19]. However, these results were limited by the small number of patients evaluated (n = 100), and by the lack of a placebo group.

Avanafil

A recent RCT by Mulhall et al. [17] evaluated the safety and efficacy of 100 and 200 mg avanafil for the treatment of adult males with erectile dysfunction after bilateral nerve sparing radical prostatectomy. A total of 298 patients were randomized to 100 or 200 mg avanafil or placebo (taken 30 min before sexual activity) for 12 weeks. Avanafil in 100 and 200 mg doses was effective and well tolerated in improving erectile function after prostatectomy. Results suggested a rapid onset of action and sustained duration of effect, with all 3 primary end points (successful vaginal insertion, successful intercourse, and change in score on the IIEF-EF domain) being achieved at both dose levels.

Taken together, these observations highlight that penile rehabilitation might improve post-operative EF in patients treated with nerve-sparing RARP. However, the superiority of daily over on-demand administration of PDE5-Is is still debated. Moreover, the beneficial effects of

penile rehabilitation protocols using PDE5-Is compared to placebo do not seem to be maintained after the washout period. Finally, a recent study demonstrated that a 9-month double-blind treatment period was too short to achieve satisfactory EF recovery in the majority of the patients enrolled [20]. Therefore, longer treatments could be considered in future studies. Further well-designed and well-performed studies with proper patient selection are needed to finally address these topics.

Intracavernosal Injections

Intracavernosal injections are the first form of pharmacological treatment for ED that were firstly reported [21]. Initially, papaverine and phenoxybenzamine were used. Now, PGE1, commonly used in combination with papaverine and phentolamine, is the primary pharmacological agent [22]. ICI agents are vasoactive, initiating relaxation of the cavernosal smooth muscle and corporeal engorgement directly. Thus, ICI effectively bypasses cavernous nerve signalling, unlike PDE5Is, which potentiate cavernous-nerve-mediated erectogenic neural stimuli. This mechanism of action makes ICIs particularly useful for the treatment of ED following non-NSRP.

The first RCT on penile rehabilitation with intracavernosal injections was performed by Montorsi et al. [23]. A total of 30 potent patients with clinically localized prostate cancer underwent nerve-sparing radical retropubic prostatectomy and were subsequently randomized to alprostadil injections 3 times per week for 12 weeks (group 1, 15 patients) versus observation without any erectogenic treatment (group 2, 15 patients). Twelve patients (80%) completed the entire treatment schedule and were evaluated at follow-up. Eight patients in this group (67%) reported the recovery of spontaneous erection sufficient for satisfactory sexual intercourse, compared with 3 patients (20%) in group 2. Although the study was limited by the relatively small number of patients, early administration of alprostadil significantly increased the recovery rates of EF after surgery. However, the intracavernosal administration of alprostadil was not devoid of complications, since two men (13%) had a penile nodule and one further patient (6%) had prolonged penile erection. This study was the first one that hypothesized a better tissue oxygenation with vasoactive cavernous injections. Subsequent studies have shown the effectiveness of ICIs in the context of ED following radical prostatectomy; however, those studies had not been designed to adequately address whether ICI therapy leads to true erection rehabilitation [24, 25].

Although intracavernosal injections have several drawbacks, such as its invasive nature, risk of developing priapism, ecchymosis and haematoma, several studies have shown higher satisfaction rates for intracavernosal injections than PDE5-Is in some patients who have used both modalities [26]. In addition, ICI therapy can be effective in the treatment of ED refractory to oral PDE5Is, partly because ICIs do not require functioning nerve stimuli to facilitate erections [24]. Given the availability of less invasive treatments for ED, ICI monotherapy is unlikely to emerge as an erection rehabilitation regimen. Nevertheless, ICIs will remain a useful adjunct to other therapies for difficult-to-treat ED, including for men who underwent non-NSRP.

Vacuum Erectile Devices

Vacuum erectile devices are placed around the penis to generate a negative pressure that facilitates penile engorgement and subsequent erection. This results into a transient increase in arterial flow and oxygen supply to the erectile tissues [27]. Three relevant studies addressed the role of vacuum erectile devices for EF recovery after radical prostatectomy [28–30].

The first RCT was performed by Raina et al. [28]. Overall, 109 patients were randomized to vacuum constriction device use daily for 9 months (group 1, $n = 74$) or observation without any erectogenic treatment (group 2, $n = 35$). Treatment efficacy was analyzed by responses to the Sexual Health Inventory of Men (SHIM). Patient outcome regarding compliance, change in penile length, return of natural erection, and

ability for vaginal intercourse were also assessed. In Group 1, 80% (60/74) successfully used their vacuum constriction device with a constriction ring for vaginal intercourse at a frequency of twice/week with an overall spousal satisfaction rate of 55% (33/60). In all, 19 of these 60 patients (32%) reported return of natural erections at 9 months, with 10/60 (17%) having erections sufficient for vaginal intercourse. The abridged IIEF-5 score significantly increased after vacuum constriction device use. After a mean use of 3 months, 14/74 (18%) discontinued treatment. The early use of vacuum constriction device following RP facilitated early sexual intercourse, early patient/spousal sexual satisfaction, and potentially an earlier return of natural erections sufficient for vaginal penetration.

Subsequently, an interesting study by Basal and colleagues compared the sexual outcome of 203 patients who underwent bilateral nerve sparing RARP [29]. After surgery, patients were treated with PDE5Is (n = 9), a vacuum erection device (n = 22), the combination of them (n = 73), or none of them (n = 99). Treatment success was defined as a rigid erection suitable for successful sexual intercourse. Penile rehabilitation programmes with PDE5Is, including the combination of PDE5Is and vacuum erection device, had a beneficial effect on erectile function recovery across all levels of baseline erectile function.

Furthermore, the timing of vacuum device use was evaluated by a RCT that included 28 men undergoing radical prostatectomy [30]. Patients were randomized to early intervention (1 month after RP, group 1) or a control group (6 months after RP, group 2) using a traditional VED protocol. Only patients in whom unilateral or bilateral nerves were spared were subsequently randomized. Patients in group 1 followed a daily rehabilitation protocol consisting of 10 min/day using the vacuum erectile device with no constriction ring, for 5 months. The IIEF scores were significantly higher in group 1 at 3 and 6 months, and the initiation of the use of a vacuum erectile device protocol at 1 month after radical prostatectomy improved early sexual function and helped to preserve penile length.

In conclusion, vacuum erectile devices alone or in association with PDE5-Is might represent a treatment option for penile rehabilitation in patients treated with nerve-sparing RARP. However, large well-designed and performed prospective randomized studies assessing the superiority of this approach compared to PDE5-Is and/or intracavernous injections are still lacking. The currently available studies do not support a long-term effect of this approach on postoperative EF recovery. Despite this, vacuum erectile devices might represent a treatment option in selected patients.

Conclusion

Many strategies have been developed to facilitate recovery of erectile function following radical prostatectomy. Currently available penile rehabilitation protocols are based on the administration of PDE5-Is, intracavernosal injections, and vacuum devices. However, clear and validated protocols for penile rehabilitation after robot-assisted radical prostatectomy still have to be defined. A combination of modalities might provide optimal preservation of erectile function. On-going and future studies will elucidate who is the optimal candidate and which is the optimal program for penile rehabilitation. Furthermore, new therapeutics emerging from preclinical studies will hopefully broaden the clinician's armamentarium and increase the potential of erection rehabilitation therapies.

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29 Functional and Oncological Outcomes of Robotic Radical Prostatectomy

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Abstract

Robot assisted radical prostatectomy (RARP) is an established procedure and has certain technical advantages over open and laparoscopic procedure. In this chapter we evaluate the oncological and functional efficacy of the procedure in terms of risk of positive surgical margins, rate of biochemical recurrence free survival, continence and potency. We also compare the outcomes of (RARP) with those of open and laparoscopic surgery in order to critically evaluate its clinical efficacy.

Keywords

Radical prostatectomy · Robotic surgery · Continence · Potency · Patient outcomes

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Introduction

In the treatment of any illness, the most important aspect is the outcome of the patient. In prostate cancer, it is not just the oncological outcomes that matter, the functional outcomes, in terms of continence and potency, also hold an equal importance. Due to the increasing use of screening for prostate cancer, younger men are being diagnosed with prostate cancer and hence the functional outcomes become extremely important [1].

Surgery is the frequently utilized modality to treat prostate cancer, especially in men with extended life expectancy. Nowadays, robotic surgery has become an integral part in the management of this tumor. More and more centers in the United States and around the world prefer robotic surgery over open or laparoscopic in the treatment of prostatic cancer. Indeed, it has been estimated that more than 75% of prostatectomies in United States and Europe are being performed robotically [2]. This chapter aims to critically evaluate the functional and oncological outcomes of the patients who had a Robot assisted radical prostatectomy (RARP).

Oncological Outcome

The importance of oncological outcomes is obvious, given their direct impact on patient overall survival. The best endpoints to examine

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oncological outcomes in prostate cancer are arguably overall survival, cancer-specific survival, and progression free survival. However, a valid evaluation of these endpoints would require a long-term follow-up, which was not always available for RARP patients, given the novelty of the procedure. For this reason, most of the reports addressing oncological outcomes of RARP patients used surrogate markers for oncological outcome, such as margin positivity and biochemical recurrence.

Margin Positivity

Definition of Positive Surgical Margin

Positive surgical margin (PSM) is defined as the presence of tumor at the inked margin of the specimen [3]. Although controversial, it has been often suggested that margin positivity can be predictor of biochemical relapse [4, 5]. The advantage of using positive surgical margins in evaluating the oncological outcomes is that the results are immediately available to the clinician after surgery. It is also an important surgeon dependent factor that has an impact on the outcomes of the patient.

In case of prostate cancer, margin positivity can also be there due to inadvertent intra-prostatic incision, crush artefact, pathological processing etc. [3] There is a significant controversy among the pathologists regarding what should be labelled as a PSM. In 2009, the International Society of Urological Pathology (ISUP) proposed that the tumors extending close to the margin of the capsule should not be labelled as PSM [6]. This change had a major impact on the rates of PSMs as shown by Maxeiner el al., where 26.6% of their PSMs were re-classified as negative margins [7]. The rate of positive surgical margins varies in different series. In order to have a good comparison between the reported data, it is imperative to consider the clinical and pathological stages of the examined cohorts.

Factors Affecting the Rate of Positive Surgical Margins

The expertise of the surgeon has been reported to be a very important factor in reducing the rate of PSMs. The estimated number of surgeries required to bring down the rate of PSMs to less than 10% has been reported to vary from 1000 to 1500 cases in RARP [8]. Thompson et al. found that during the initial part of their learning curve for RARP, the odds of having a PSM for RARP in patients with pT2 disease were 6.19 times higher than open radical prostatectomy (ORP). These odds decreased over time and after 400 cases, where RARP surgery offered a 55% lower PSM possibility in comparison to ORP [9]. Samadi et al. assessed their rate of PSMs in 1181 patients and found that the rate of PSMs decreased with the increased experience of the surgeon [10]. Similar results were observed at our institution, when the results of first two hundred cases of RARP were compared to the last two hundred cases in a series of 2766 patients. The PSM rate decreased significantly from 7 to 4% despite the fact that the last two hundred patients had a relatively higher Gleason score [11]. It is implied that with the experience, the surgeon is able to have a better control over the operating console, has better understanding of the pelvic anatomy and also tends to modify the technique in order to have low rates of PSMs. Fellowship training in RARP can also have a positive effect on the PSM rates. Trinh et al. evaluated the effect of the hospital volume, availability of residency and fellowship on the outcomes after radical prostatectomy and found more favorable outcomes in hospitals that had a teaching facility [12]. As the experience and training continues, the experience of the robotic team and the assistants also increases which may effect on the rate of PSMs.

The clinic-pathological stage of the patient also determines the rate of margin positivity. Novara et al. assessed the case series published from 2001 to 2008, with at least hundred patients in each series. The overall PSM rate was reported to be 15%. This rate increased as the pathological stage increased ranging from 9% for pT2 tumors to 37% for pT3 and 50% for pT4 tumors [2]. Ficarra et al. also found that prostate volume, cT stage and pT stage independently predicted the overall rate of PSMs. Likewise, the attempts for an overzealous nerve sparing during surgery in high risk tumors can adversely affect the rate of PSM [13].

Ziberman et al. evaluated the effect of the BMI on the rate of PSMs in patients after RARP. They divided the patients in to four groups as per their BMI <25, 25–29.9, 30–34.9 and >35. They did not find significant differences in the PSM rates between the examined groups (17%, 24%, 19% and 21% respectively) [14]. Sundi et al. stratified 987 according to their BMI and performed a multivariate analysis using logistic regression to evaluate its effect on the outcome after RARP. They found that although the operative times were longer and the extent of nerve sparing was inferior in obese men, there was no difference in the amount of blood loss, rate of PSMs or biochemical recurrence across the BMI categories [15].

There is a controversy in the literature regarding the effect of prostate size and anatomy on the rate of PSMs. It was observed in earlier studies that the size of the prostate has a significant impact on the PSM rates. Patel et al. reported an inverse relationship between the size of the prostate and the PSMs [16]. Allaparthi et al. also support this finding of inverse relationship of margin positivity with increased prostate volumes [17]. On the contrary, Huang et al. retrospectively evaluated 951 patients who had a RARP and analyzed the outcomes based on the weight of the prostate, history of surgery for benign hyperplasia and presence of median lobe (>1 cm). They found that although increased prostatic weight was associated with longer operative time, it had no effect on the PSM rate. Similarly, the presence of median lobe or the history of previous surgery did not have any effect on the rate of PSMs [18].

Effect of Technical Modification on PSM Rate

Various modifications in the surgical techniques have been advocated for reducing the rate of PSMs (Table 29.1). Most of these techniques have been reported in case series and have not been validated in randomized trials. Menon et al. reported the technique of delayed ligation of the dorsal venous complex. This method helps in proper identification of the prostate-urethral junction in a relatively bloodless field facilitating the precise incision hence reducing the rate of PSMs [19]. Guru et al. compared the results of incision of the DVC without ligation to the incision with ligation. They found that the risk of apical PSMs reduced significantly from 8 to 2% when DVC was incised without ligation [20]. Wu et al. demonstrated that staple ligation of the DVC was better than suture ligation as it decreased the operative time, blood loss and also the PSM rate (13.4% vs 2.1%) [21]. Tewari et al. have reported a technique of synchronous anterior and posterior urethral transection. This

Table 29.1 Technical modifications for reducing the positive surgical margins

Author (year)	Type of study	Technique assessed	No. of patients	Effect on PSM
Guru et al. [20]	Prospective case control	Apical dissection before vs after suture ligation of DVC	145 without ligation and 158 after ligation	Apical PSM of 8% in the ligation group vs 2% in the other group
Wu et al. [21]	Prospective case control	Stapled vs suture ligation of DVC	95 in stapled group and 67 in suture group	Apical PSM rate of 2.1% in stapled vs 13.4% in suture group.
Tewari et al. [22]	Prospective case control	Simultaneous anterior and posterior transaction of the urethra	209	Lower apical PSM rates than the control group (1.4% vs 4.4%, $P = 0.04$).
Akand et al. [23]	RCT	Extraperitoneal v/s transperitoneal	60 patients in each group	No effect on PSM ($p = 0.12$)
Capello et al. [24]	RCT	Extraperitoneal v/s transperitoneal	31 patients in each group	No effect on PSM
Nyarangi et al. [25]	RCT	BNP v/s standard procedure	95 in BNP vs 104 in no BNP group	No significant difference on PSM (12.5% vs 14.7%, $p = 0.65$).

Abbreviations: *DVC* dorsal venous complex, *RCT* randomized controlled trial, *PSM* positive surgical margin, *BNP* bladder neck preservation.

modification has decreased their PSM rate from 4 to 1.4% [22]. The approach to the prostate, extraperitoneal versus transperitoneal, has shown no effect on the PSMs [23, 24]. The preservation of the bladder neck or the technique of dissection of NVB (extrafacial vs intrafascial) too do not seem to have an impact on the PSM rates [25].

PSM Rates in RARP vs ORP and LARP

It is a difficult to compare the results of ORP, laparoscopic assisted radical prostatectomy (LARP) and RARP as there is significant heterogeneity in the data. Menon et al., during the time of the learning curve of RARP, assessed their results of ORP, and compared it RARP patients (30 patients in each group). They found similar rates of PSMs for both procedures (29% vs 26%) [26]. The PSM rates significantly decreased in the follow up study comparing 100 patients of ORP to 200 of RARP (9% in RARP vs 23% in ORP) [27]. This highlights the fact that surgeons experience is an important factor in decreasing the rate of PSM. Silberstein et al. evaluated the results of high-volume surgeons operating on prostate cancer patients at Memorial Sloan-Kettering Cancer Center. They found that irrespective of the stage, RARP had lesser rate of PSMs compared to ORP [28]. In a recent meta-analysis, Robertson et al. evaluated the results of one randomized and 57 non-randomized reports including 19,064 men. They observed that RARP had a significantly lesser rate of positive surgical margin as compared to LARP (17.6% v/s 23.6%) [29]. De Carlo et al. evaluated the results of 44 studies and found that the cumulative PSM rates are similar in ORP and LARP (22.04% vs 22.45%) but they were significantly lower for RARP (21.14%, $p < 0.001$) [30].

Biochemical Recurrence Rates

Definition and Clinical Implications

Ideally, serum PSA level should be undetectable after radical prostatectomy. The definition of biochemical recurrence after a radical prostatectomy has been a subject of debate. The American Urological Association and the European Association of Urology have defined BCR as a rise of PSA of >0.2 ng/ml on two consecutive occasions [31, 32]. The National Comprehensive Cancer Network includes two aspects, firstly, the PSA persistence which is the inability to reach an undetectable level of PSA after radical prostatectomy or secondly, an undetectable level after surgery but a subsequent rise that has been confirmed on two or more tests [33]. Biochemical failure generally calls for the administration of some form of additional therapy. Pound et al. evaluated the PSA levels in 304 men after radical prostatectomy and observed that men with PSA > 0.2 ng/ml who did not receive any form of adjuvant therapy had a 63% 5-year metastasis free survival [34]. It has also been suggested that some men may continue to have detectable PSA levels after prostatectomy due to the remnant benign glands or from other tissue sources [35]. Hence it is important to assess all the clinical and pathological parameters available before embarking on the additional therapy after a BCR.

Factors Affecting the BCR Rates

Multiple factors have been shown to affect the risk of biochemical relapse. In a review of 2766 patients at our institute, we found that at a median follow up of 22 months; the BCR rate was 7.3% and the BCR- free survival was 84% at 5 years. The preoperative PSA level, Gleason score and the pathological stage were independent predictors of BCR [11]. In our subsequent study of 1384 patients who were treated with RARP, we observed that at 1-, 3-, 5- and 7-year the BRF-free survival was 95.1%, 90.6%, 86.6% and 81% respectively. Preoperative PSA level, Gleason score, D'Amico's risk group, perineural invasion, lymphovascular invasion, and status of the surgical margin were independent predictors of BCR [36]. Shikanov et al. evaluated 1398 patients who had a RARP and found that the BCR rate was 4% at 12-month follow up [37].

Sooriakumaran et al. evaluated the BCR-free survival in a cohort of patients who were treated with RARP and had a minimum follow up of 5 years after surgery. They found that the BCR-

free survival rate was 84.8% at a median follow up time of 6.3 years. Preoperative PSA >10 ng/ml, pathological T3 cancers, pathological Gleason score ≥4 + 3, PSM and the expertise of surgeon were independent predictors of BCR risk [38]. To examine more definitive endpoint, Abdollah et al. evaluated 5670 patients who were treated with RARP and originated from a multi-institutional cohort. They found that BCR-free, clinical recurrence free survival and the cancer specific survival rates were 83.3, 98.6, and 99.5% at 5-year; 76.5, 97.5, and 98.7% at 8-year; and 73.3, 96.7, and 98.4% at 10-year follow-ups [39].

Engel et al. evaluated 73 high risk patients defined as PSA > 10 ng/ml, Gleason score >7, stage pT3b. Their BCR at 1-, 2- and 3- years were 77%, 69%, 59% respectively. These authors reported that Gleason score had the maximal impact on BCR risk. In another report, Abdollah et al. evaluated the oncological outcomes of 1100 patients with D'Amico high-risk tumors who were treated with RARP and originated from a multi-institutional cohort. They reported a BCR-free survival rate of 50% at 10-year, while the recurrence free survival rate was 87%. In this cohort, x% received any adjuvant therapy, while 37% received any salvage treatment [40]. Based on these finding, it seems that RARP can offer long lasting recurrence free survival in the majority of patients with a high risk disease.

Zorn et al. sought to evaluate the impact of surgical expertise on BCR rate after RARP. Specifically, they divided their cases in three groups, first 300 were in group 1, next two hundred in group 2 and the last two hundred in group three. They did not find any improvement in BCR rates as the experience of the surgeon increased [41]. Likewise, patient characteristics like BMI, prostate volume, history of prior surgery were not independent predictors of BCR in that report. Likewise, Moskovic et al. stratified 1212 patients treated with RARP according to their BMI in three groups and found that BCR rate was similar among all the groups [42]. Ginzburg et al. assessed the effect of the history of prior abdominal surgery on the BCR (defined by a PSA ≥0.2 ng/ml any time after the surgery) and found that the rate was 6.3% in patients who had no previous abdominal surgery vs. 5.5% in patients with a history of surgery [43].

BCR Rates in RARP vs ORP and LARP

Few studies to compared BCR rate in ORP, LARP and RARP and have found that the rate remains largely unaffected by the surgical technique. Barocas did a retrospective analysis of 491 patients treated with ORP and 1413 patients treated with RARP. They found that at three years, the BCR-free survival rate was similar in both procedures (83 vs 84%) [44]. Likewise, Magheli et reported that the 3-year BCR-free survival rates were 93%, 94% and 94% in ORP, LARP and RARP patients, respectively [45]. In a recent article by Ploussard et al., a total of 1377 cases of LARPs and 1009 RALPs were stratified according to the D'Amico risk stratification and the authors observed that the BCR-free survival rates were similar between the two procedures irrespective of the risk groups. They also reported that the learning curve had a significant effect on BCR-free survival in the LARP group with the improvement observed after first 300 cases but this effect was not seen in RARP group [46].

Functional Outcomes

The anatomical location of the prostate is such that any intervention on it has the potential to have a detrimental impact on urinary continence and sexual potency after surgery. The functional outcomes have started gaining more importance as younger patients are being diagnosed with prostate cancer. These patients are most often preoperatively continent and have an active sexual life. The obvious expectation of these individuals is to get cured of the cancer without compromising their postoperative urinary continence and sexual potency.

Urinary Continence

Definition

Urinary incontinence in the postoperative period is perhaps the most distressing of all the compli-

cations of a prostatectomy. It can have tremendous effect on the quality of life of patients. Incontinence, as defined by the International Continence Society, means involuntary leakage of urine that is a social or hygienic problem [47]. The number of pads used and the weight of the pads are the most commonly used markers to assess the severity of incontinence. It was reported by Tsui et al. that pad weight is a better predictor of the severity of urinary incontinence [48]. Various other terms have been used like social continence, which implies the use of pad only for security reasons, total continence in which the patient uses no pads and total incontinence. The incontinence after radical prostatectomy commonly manifests as stress incontinence but can also present as urge or mixed or total incontinence.

Mechanism of Urinary Incontinence

Urinary continence predominantly depends on multiple factors including he integrity of the external sphincter, integrity of the internal sphincter, intact neural innervation and bladder stability. After prostatectomy the major causes of urinary incontinence are the intrinsic sphincter deficiency and bladder dysfunction. The damage to the sphincter may be due to direct surgical trauma, damage to its nerves, etc. Bladder dysfunction may be due to bladder denervation during surgery or preexisting detrusor over activity which manifests as urge incontinence after the removal of prostate [49].

Kadono et al. performed a urodynamic evaluation of sixty-three patients before, immediately after and 1 year following RARP. The mean compliance of the bladder and mean urethral closure pressure decreased immediately after RARP, but it recovered after one year. On the other hand, the mean pressure of the detrusor at the maximal flow rate also decreased immediately after RARP, but remained so even at the end of one year. Although none of the patients showed intrinsic sphincter deficiency in the preoperative evaluation, 53 patients had it in the immediate postoperative period. At the end of one year, 7 patients continued to show intrinsic sphincter deficiency. Authors concluded that sphincter dysfunction is the main reason for the incontinence after RARP [50]. Chao et al. reported that the intrinsic sphincter weakness was a major factor in 57% of the patients, combined sphincter weakness and the bladder dysfunction were responsible in 39% while only bladder dysfunction was found in 4% of the patients [51].

Factors Affecting the Continence after RARP

Various patient related and surgery related factors can have an effect on the post-operative urinary continence rate. Increased patients age has been reported to have a significant impact on the recovery of urinary continence. It has been proposed that older patients tend to have weaker rhabdosphincter muscle and also preexisting bladder dysfunctions [49]. However, several studies showed that even in elderly people, with time, the recovery of urinary continence can achieve satisfactory levels. Hence, elderly patients should be counselled accordingly. Mendiola et al. divided 300 patients who were treated with RARP according to age (50 years, 50–59, and >60 years). They observed that men aged 60 years or more had a significantly late recovery of continence as compared to younger patients ($p = 0.02$). However, the continence rates improved after one year. At that time point, there was no significant difference in urinary continence rates base on age [52].

Prostate volume was also suggested as a factor that can influence urinary continence recovery after surgery. In this context, Link et al. divided 1847 patients into four groups according to prostate volumes, group 1 < 30 cm^3, group 2 30–49.9 cm^3, group 3 50–69.9 cm^3 and group 4 ≥ 70 cm^3. They observed that urinary continence rates at 1 year of follow up were similar among these groups (93%, 94%, 93% and 88%, respectively) [53]. Boczko et al. assessed 355 patients who had an extraperitoneal RARP and divided them according to prostate size less than 75 g or greater. The 6-month continence rate in patients with a prostate volume <75 g was 97% versus 84% in patients with larger prostate volumes (add *p* value) [54]. On the contrary, Labanaris et al. evaluated 4000 patients who

underwent a RARP and divided them into two groups based on prostate size, group 1 with ≥100 gm and group 2<=50 gm. A total of 185 patients with large prostate volumes were matched with those of lower volume. They found that the continence rates at one year follow up in both the groups were similar (75.1% vs 76.8%) [55].

Wiltz et al. assessed the effect of BMI on the continence rates and concluded that the patients with a higher BMI had significantly less favorable urinary continence recovery at 12 and 24 months of follow up [56]. Kumar et al. evaluated the effects of increased age, higher BMI, history of previous surgery, prostate volumes >80 cc and salvage prostatectomy on the rates of urinary continence recovery and compared it to a cohort of patients without these risk factors. They found that patients with history of previous surgery had the most dismal results. Although the rates of continence were higher in the group of patient with no risk factors, the differences were not statistically significant as compared to those having a risk factor/s. Another observation was that patients without a risk factor became continent significantly faster than those who had risk factor/s [57].

The effect of the extent of nerve sparing, and urethral length on urinary continence recovery rate has also been studied. Many suggested that nerve-sparing surgery has a beneficial impact not only on sexual function recovery, but also on urinary continence recovery. For example, Sacco et al. reported that urinary continence rates are worse in patients who had a bilateral resection of the neuro-vascular bundle (NVB) [58]. Menon group reported that the Veil of Aphrodite technique can further improve urinary continence recovery (97% at 12 months) [59].

Kim et al. assessed 452 patients who were treated with RARP, and had a minimal follow up of 3 months. On a multivariate analysis, they found that men who were younger than 70 years, had high pre-operative Sexual Health Inventory For Men (SHIM) score, harbored lower clinical stage, had lower Gleason score, had lower BMI, and prostate size of <40 cc had more favorable urinary continence recovery rates ($p < 0.05$) [60]. Barnoiu et al. suggested that urodynamic parameters like a bladder compliance of <27.8 ml/cm of water, and urethral closure pressure of <50.3 cm of water can also affect the recovery of continence after RARP [61].

Technical Modifications to Improve Continence After RARP

Bladder neck preservation encompasses dissection of the prostatovesical junction with efforts to preserve all the circular muscular fibers at the bladder neck. Nyarangi et al. conducted a randomized controlled trail comparing the results of continence after bladder neck preservation with the standard procedure and found that the social continence rates at 3, 6 and 12 months were uniformly higher in the bladder neck preservation group (55.3% vs 84.2% ($p < 0.001$), 74.8% vs 89.5% ($p = 0.05$) and 81.4% vs 94.7% ($p = 0.027$), respectively) [25]. Lee et al. evaluated the impact of the extent of bladder neck preservation on urinary continence recovery. They found that patients who had the maximal bladder neck sparing during RARP fared better in terms of post-operative continence, while their oncological outcomes were not affected [62]. Similar effects with bladder neck preservation were observed by Freire et al. at 4 and 12 months of follow up. In their long term follow up, this difference diluted and the patients had similar continence rates irrespective of the bladder neck status at 24 months [63].

Sparing of the pubo-prostatic ligaments, minimal dissection of the endopelvic fascia, preservation of the pelvic floor musculature especially the puboperinealis may also improve continence rates [64–66]. The various technical modifications have been tabulated in Table 29.2. Hypothermic NVB dissection may also have a positive effect on the continence rates. Finley et al. evaluated patients who were treated with RARP and divided the patients in two groups, group 1 received hypothermic nerve sparing with endorectal balloon and cold saline irrigation while group 2 had a standard nerve sparing (historic cohorts). They observed that the return of continence was better in patients who had hypothermic dissection at 3 months and 12 months [67].

Table 29.2 Technical modifications to improve the continence rates

Author (year)	Type of study	Technique assessed	No. of patients	Effect on continence
Lee et al. [62]	Retrospective analysis	Graded bladder neck preservation (grade 1–4)	Grade 1 in 18, Grade 2 in 85, grade 3 in 235, grade 4 in 261	The continence rates were higher in those who received grade 4 BNP compared with grade 1 ($P = 0.043$) and grade 2 ($P = 0.006$)
Freire et al. [63]	Prospective case control study	BNP v/s standard procedure	348 in BNP and 271 in standard group	BNP increased rates of early continence ($p = 0.032$)
Nyarangi et al. [25]	RCT	BNP v/s standard procedure	95 in BNP vs 104 in no BNP group	The social continence rates were higher in BNP group 3, 6 and 12 months (55.3% vs 84.2% ($p < 0.001$), 74.8% vs 89.5% ($p = 0.05$) and 81.4% vs 94.7% ($p = 0.027$), respectively)
Finley et al. [67]	Prospective case control study	Hypothermal dissection of the NVBs	115	12-month continence rates 96.3% for the hypothermia groups versus 86.6% for controls.
Rocco et al. [68]	Prospective case control study	Posterior reconstruction	161	The continence rates in posterior reconstruction were 72%, 78.8% and 86.3% at 3, 30 and 90 days vs 14%, 30%, 46% in the standard technique.
Coelho et al. [69]	Prospective case control study	Modified posterior reconstruction v/s standard technique	803, 473 had posterior reconstruction, 330 had standard reconstruction	The continence rates were 22.7%, 42.7%, 91.8%, and 96.3%, respectively at 1, 4, 12, and 24 weeks postoperatively; in the PR group while they were 28.7%, 51.6%, 91.1%, and 97%, respectively in standard group
Sammon et al. [70]	RCT	Preiprostatic tissue reconstruction v/s standard technique	59 had reconstruction, 57 had the standard technique	The continence rates of 96% in single layer anastomosis vs 100% in double layer anastomosis ($p = 0.59$)
Haga et al. [72]	Prospective case control study	Evaluation of urethrovesical anatomical features after RARP	60	Membranous urethral length of >17 mm improved early continence (Odd' s ratio 1.94)
Polland et al. [73]	Prospective case control study	Use of barbed sutures for urethrovesical anastomosis	84	No effect on continence recovery
Asimakopoulos et al. [75]	Prospective case control study	Preservation of the entire pubovesical complex	30	Urinary continence was 80% at catheter removal and 100% at 3 months after surgery.
Galfano et al. [74]	Prospective case control study	Space of Ritzeus sparing surgery	200	1-year continence was 96%.
Kowalczyk et al. [93]	Prospective case control study	Countertraction versus no countertraction	342 in co countertraction group and 268 in standard group	At 5 months, continence rate of 69.7% in no countertraction group v/s 64% in standard group ($p = 0.049$)

Abbreviations: *RCT* randomized controlled trial, *NVB* neurovascular bundle, *BNP* bladder neck preservation, *PR* posterior reconstruction.

The role of anterior, posterior and total reconstruction has also been evaluated. The repair of the posterior rhabdosphincter was proposed by Rocco et al. They found that patients who had a posterior repair attained continence earlier as compared to the ones who didn't, although long term recovery rates were similar in both the groups [68]. Coelho et al. also showed higher continence rates with posterior reconstruction at one and four weeks but after a longer follow up, there was no significant difference between the two groups [69]. Other modifications, including combined anterior and posterior reconstruction has also failed to show significant impact on the long term continence rates [70]. Our own results have failed to find a significant impact of posterior/circumferential reconstruction on the continence rates [71].

Preservation of urethral length has been found to be an important factor in the recovery of continence. Haga et al. found that a longer mean urethral length improved continence rates after RARP. The outcome was still better if neurovascular sparing was performed [72].

The use of barbed suture in the urethrovesical anastomosis too did not seem to have any effect on urinary continence rates [73]. Other techniques like the space of Retzius sparing, sparing of the entire pubvesical complex have also been described to affect the continence rates [74, 75].

Continence Rates in RARP vs ORP and LARP

Majority of the studies comparing urinary continence recovery in patient treated with ORP vs RARP have shown that RARP fares better. Tewari et al. compared 100 patients treated with ORP to an equal number of patient treated with RARP. The definition of continence was no pad usage. They found that the RARP group became continent significantly faster as compared to ORP (median time to recover was 44 days vs 160 days) [27]. Di Pierro et al. assessed their results in 75 patients treated with ORP compared to 75 patients treated with RARP. They found that urinary continence rate was 89% for RARP group vs 80% for the ORP group at 12 months follow up [76].

Asimakopouls et al. conducted a RCT comparing the results of LARP versus RARP in the treatment of localized prostate cancer. All cases had a bilateral nerve sparing surgery. They found that the total urinary continence recovery rate at 12-month, defined by no pad usage, was higher in RARP as compared to LARP (94% vs 83%, $P = 0.07$) [77]. A systematic review done by Carlo et al. in 2014 found the mean continence recovery rate to be 73.71% for ORP, 63.82% for LARP and 89.12% for RARP at 6 months. The RARP patients continued to fare better even after 12 months over ORP and LARP patients ($p = 0.001$).

Sexual Potency

The male sexual health is an important aspect after prostate cancer surgery, which might have an important impact on post-operative quality of life. Walsh and Donker described a complex and tortuous plexus of nerves that runs from the pelvic plexus to the inferolateral aspect of the prostate [78]. The nerves then continue towards the urethra, pierce the urogenital diaphragm and supply the corporal bodies. Later research showed that the nerves are not just arranged as two bundles, but also have numerous interconnections behind the prostate within the Denonvillier's fascia. The nerves are positioned like a hammock around the prostate whilst the major plexus is present just lateral to the rectum and in close relation to the tip of the seminal vesicle. It was later shown that a significant number of nerves lie also in relation to the anterior surface of the prostate [79–81].

Evaluation of Sexual Potency

The results of sexual potency recovery vary widely in different studies. This might be explained, at least partially, by the difficulty to objectively assess sexual potency after surgery. Questionnaires like The International Index of Erectile Function (IIEF), SHIM have been described for the assessment of this aspect, but have not been used uniformly in all the studies. The Majority of the available studies rely on

personal interviews and sexual potency has been accepted as a penile rigidity, which is enough for vaginal penetration. This issue has been addressed by Shikanov et al., who compared sexual potency as measured by validated questionnaire and compared it to physician interview. They found that the potency rates assessed by the questionnaire were uniformly lower as compared to the rates observed by physician's interview (44%, 50%, 62%, 69% vs 57%, 63%, 82%, 93% at 3-, 6-, 12-, and 24-month, respectively) [82]. Another factor that might explain the wide variation in sexual potency recovery rate after surgery is the variation in the utilization of pre- and the post-surgical penile rehabilitation protocols, which are often not described in the studies.

However, the mere evaluation of sexual potency after surgery might not be sufficient, as various other associated factors can have an impact on the male sexual health. The issues related to sexual desire, retrograde ejaculation, orgasm are few of these other factors that need to be addressed separately from sexual potency, as they can also have a detrimental impact on the patients' quality of life [83].

Determinants of Sexual Potency

Previous reports argued that patient age, preoperative sexual potency, comorbidity and sparing of the neurovascular bundles are the most important determinants of the post-operative potency recovery rates [30, 84]. Briganti et al. used a regression tree analyses and stratified patients into three groups based on their probability or recovering sexual potency after surgery. The low risk group consisted of patients ≤60 years of age with baseline IIEF-6 scores of >21 and a Charlson's comorbidity index f ≤1, the intermediate risk group consisted of patients between 66 and 69 years with IIEF-6 scores of 11–21 and a Charlson's comorbidity index ≤1. Finally, the high risk group consisted of patients ≥70 years old with IIEF-6 score of ≤10 and the Charlson's score ≤2 [85]. Novara et al. used this stratification and found that the sexual potency recovery rates at twelve months were 81.9%, 56.7% and 28.6% in the low, intermediate and high-risk groups, respectively [86].

The extent of nerve sparing seems to have an important impact on sexual potency rate. In a meta-analysis, Ficarra et al. reported that the cumulative results of potency recovery after unilateral nerve sparing surgery at 3-, 6-, and 12-month was 32%, 53% and 69% vs. 56%, 69% and 74% for bilateral nerve sparing surgery [84].

Moskovic et al. evaluated the effect of BMI on sexual potency recovery rates after RARP. They found that that BMI did not have any significant impact on the potency rates at 3-, 6- and 12-month follow up [42]. Similar results were observed by Uffort et al. in 2011 [87]. Kwon et al. have also observed similar oncological and functional results in men with or without metabolic syndrome. In their study men with metabolic syndrome had larger prostates but even this did not have any effect on the final outcome [88]. However, it has been reported that the quality of nerve sparing can be inferior in obese men [15].

Technical Modifications and Their Effect on Potency

As the anatomy of the neurovascular bundle became more clear, various techniques were described to salvage the maximum amount of the neural tissue in order to have a more favorable post-operative sexual function (Table 29.3). For example, in 2003, Menon et al. developed the veil of Aphrodite technique to save the neural tissue that runs on the antero-lateral aspect of the prostate. They compared of 35 men who had veil of Aphrodite bilateral nerve sparing to 23 patients who had a conventional nerve sparing. All the patients harbored an organ confined disease and had a SHIM score of >21 without the use of any medications. Patients were encouraged to use PDE-5 inhibitors as early as four weeks after the surgery. At the twelve month follow up, men who had a standard nerve sparing technique had significantly lower rates of sexual potency as compared to those who had the veil approach (74% s 97%, all *p* value) [89]. Encouraged by the results, the same group subsequently described a super veil technique of NVB dissection where the tissue between 11 o'clock and 1 o'clock was also preserved. The results were evaluated in 171 patients who had a SHIM score of >17, PSA<4 ng/ml and

Table 29.3 Technical modifications to improve the potency rates

Author (year)	Type of study	Technique assessed	No. of patients	Effect on potency
Menon et al. [89]	Prospective case control study	Veil of Aphrodite vs standard technique	35 in veil group and 23 in standard group	97% of patients with veil dissection were potent at 12 months
Menon et al. [90]	Prospective case control study	Super veil technique	171	94% potency rates at 18 months
Ahlering et al. [91]	Prospective case control study	Athermal dissection of the NVB	51 in athermal dissection, 36 in standard dissection	47% potency at three months in athermal group vs 8.3% in standard group ($p = 0.003$)
Finley et al. [67]	Prospective case control study	Hypothermic dissection of NVB	115	At 15 months potency rates were 83% in hypothermal group vs 66% in controls
Kowalczyk et al. [93]	Prospective case control study	Countertraction versus no countertraction	342 in countertraction group and 268 in standard group	At 5 months, potency rate of 45% in no countertraction group v/s 28.4% in standard group ($p = 0.039$)

focal Gleason 6 cancer. At a median follow up of 18 months, 94% of the patients treated with this new technique were potent. It was also demonstrated that the super veil technique did not adversely affect the oncological outcomes as only one patient in this series had a PSM [90].

The use of thermal energy during the nerve dissection has also been shown to cause damage to the NVB. Cautery free or athermal as well as hypothermic dissections of the NVBs has been described. Ahlering et al. compared the results of RARP using cautery free vs traditional dissection of the NVB in men younger than 66 years and with a preoperative IIEF scores of 22–25. Sexual potency was defined as rigidity enough for the vaginal penetration. At three months, 47% of those who had a cautery free dissection reported to be potent as compared to 8.3% in the group where cautery was used [91]. Fagin et al. divided their patients into three groups, group 1 had selective use of bipolar cautery, group 2 had an athermal dissection with the use of Weck clips, and group 3 had an athermal dissection with a high dissection of the NVB. All men were younger than 66 years and had a SHIM score of greater than 14. Sexual potency rates at three months were 14%, 24% and 71% in the respective groups showing that athermal dissection increases the potency rates, especially in the early follow up period [92]. Use of hypothermia by using a cooling balloon in rectum and use of cold irrigation in the surgical field has also been described. Finley et al. compared the potency rates in men who had a standard procedure of NVB dissection to men who had hypothermic NVB dissection, using both the rectal balloon and local cold saline irrigation. They found that men in whom hypothermia was used had significantly higher sexual potency rates after surgery [67].

It has also been hypothesized that counter traction during the NVB dissection may affect potency rates. Kowalczyk et al. evaluated this in a prospective study with 35 patients in the group having RARP without counter traction and 58 patients in whom counter traction was used. Although at the three month follow up they observed higher rates in the group that had no counterattraction, this difference was not seen at twelve months of follow up [93].

Potency Rates in RARP vs ORP and LARP

The overall sexual potency recovery rate after RARP vary widely from 54 to 98% at the end of one year. Menon et al. evaluated the results of RARP in 85 patients who were preoperatively potent, with median age of 55 years using a bilateral nerve sparing and a super veil technique. At 6–18 months of follow up, the reported rate of potency was 94% with a median SHIM core of 18 [90]. Shikanov et al. evaluated 816 men who were preoperatively potent and found the potency rate to be 75% after 12 months of RARP [94]. In a recent meta-analysis which included studies

having at least 100 patients, mean sexual potency recovery rates were 50%, 65%, 70% and 79% at 3-, 6-, 12- and 24-month respectively [84].

Tewari et al. compared the results of 100 patients who were treated with ORP to 200 patients who received a Vattikuti Institute Prostatectomy (VIP). These authors found that patients who had a VIP had a faster recovery of sexual potency as compared to ORP patients (180 vs 440 days, $P < 0.05$) [27]. Kim et al. compared a group of 122 patients treated with ORP to 373 patients treated with RARP. They used athermal technique of NVB dissection in both the groups. At the end of 12 months, sexual potency recovery rate was 57% in RARP patients vs. 28% in ORP patients. The potency rates in ORP group increased to 47% at 24 months but it was still significantly low as compared to the RARP group (84%) [95]. Various other studies have found similar results.

Sexual potency recovery rates show similar trend in favor of RARP when compared to LARP. In a randomized trial, Asimakopoulos compared the results of 64 men who were treated with LARP to 52 men who received RARP. All these men were potent preoperatively and their median age was 59 years. All the patients had a bilateral sparing of the NVB by the use of athermal, interfascial dissection. The definition of the potency used in this study was rigidity that was sufficient for penetration. At 12 months, 32% of the men who received LARP were potent vs. 77% of the men who received RARP [77]. Park et al. evaluated their results of LARP versus RARP and found a higher rate of sexual potency recovery in patients who had a RARP (47.6% vs 54.5%) [96].

Quality of Life (QOL)

Patients who are operated for prostate cancer tend to have long life spans and hence it is extremely important to assess what impact does the surgery has on their quality of life. In prostate cancer, the priorities of surgeon may vary from the priorities of the patient and this may have a significant impact on the patient's decision, and on the choice of modality of treatment acceptable to him. For most patient, functional outcomes and quality of life are very important as the majority of these patients undergoing surgery had a good quality of life pre operatively and hence expect to have a good post-operative quality of life. Sanda et al. evaluated the quality of life and satisfaction outcomes in patients after radical prostatectomy. They found that the changes in the quality of life were directly related to post-operative satisfaction rates [97].

Various tools have been validated and can be used to assess the QOL following surgery. Some of these tools have been translated into various languages to help in their wider applicability. The most commonly used tools are International Prostate Symptom Score (IPSS), IIEF, RAND Patient Satisfaction Questionnaire (PSQ), Expanded Prostate Cancer Index Composite (EPIC), UCLA Prostate Cancer Index (UCLA PCI) etc. They can be used in isolation or combination to get a better picture of the quality of life following surgery. The criticism of these tools is that they tend to over objectivize the issue of quality of life. Indeed, sometimes, it may not be possible for the patient to accurately answer the questions used in these tools. Besides, these tools are often based on the patients' memory and can lead to recall bias. It has been reported that the quality of life after RARP is comparable, if not clearly superior as compared to ORP or LARP [98].

The Concept of "Trifecta"

The word "trifecta" was coined by the group at Memorial Sloan-Kettering Cancer Center to indicate that the patients were free of biochemical recurrence, had recovered urinary continence and sexual potency after radical prostatectomy [99]. Since then, multiple groups have reported their results in terms of trifecta outcomes. There are certain problems with the evaluation of trifecta. The exact time period at which the results should be evaluated is still controversial. It is well known that the continence and the potency rates increase over time, while the contrary happen to BCR-free survival rates. The other issue is the definition of

potency and continence after surgery and the lack of standardized tool to evaluate them. Moreover, potency and continence are not so simple issues that can be graded as required in the assessment tools used presently. This has led to a high variability in the trifecta results in different reports. The trifecta rates after RARP range from 57 to 86% at 12 months [82, 100]. Patel et al. have taken this concept of cumulative reporting of results a step further by combining the complication rates and margin positivity rates to coin the term "pentafecta rate" [101].

Conclusion

The expectations of the patients regarding the outcome are progressively increasing, emphasizing the need for technical advancement and refinement of technique that could minimize the morbidity and maximize the outcomes. The results of robotic surgery have matched or even exceeded those of open or laparoscopic techniques in terms of treating prostate cancer. RARP technique is evolving continuously and the modifications have contributed significantly in improving the functional and oncological outcomes. The technique is also easy to learn and teach as the learning curves are shorter than those of laparoscopic prostatectomy. Given that robotic radical prostatectomy is currently the most common surgical modality for treatment of prostate cancer, increasing experience with the technique and development of further nuances are expected to translate into superior outcomes.

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Technical Modifications for Salvage and Complex Radical Prostatectomy

30

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Abstract

Robotic radical prostatectomy is a procedure that has evolved considerably in the last 15 years as one of the main treatments for localized prostate cancer. Published literature currently describes in detail the procedure and outcomes. However, as widespread as it may be, we believe that certain technical modifications have greatly improved our technique, hence improving early and medium-term outcomes. After having performed close to 10,000 cases (single surgeon series—VP), our technique has evolved significantly, including several refinements to reduce patient morbidity and further improve the functional outcomes. In the present manuscript, we perform a detailed description of our surgical technique of Robotic-Assisted Laparoscopic Radical Prostatectomy and provide practical recommendations based on available reports and personal experience.

Keywords

Robotic-assisted laparoscopic radical prostatectomy · Salvage radical prostatectomy · Nerve sparing · Technical modifications

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Introduction

Robotic radical prostatectomy is a procedure that has evolved considerably in the last 15 years as one of the main treatments for localized prostate cancer. Published literature currently describes in detail the procedure and outcomes. However, as widespread as it may be, we believe that certain technical modifications have greatly improved our technique, hence improving early and medium-term outcomes. These include placement of the suspension stitch, athermal dissection of the seminal vesicles, athermal early retrograde release of the neurovascular bundle, the modified posterior reconstruction of the rhabdosphincter for recovery of early continence,

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instant toggling of camera for improved visualization and use of biological tissue grafts for improved healing. Since, the first report of retropubic radical prostatectomy in 1905 by Young, the prostate has represented a difficult surgical challenge. These technical challenges (location in pelvis and significant blood supply) led to increased surgical morbidity, threatening the life of the patient. Over the subsequent decades the procedure has been refined significantly into one that is less harmful to the patient and provides improved quality of life. However, it is still associated with a high perioperative morbidity, which led to the search for less invasive options.

The need for continuous improvement resulted in less invasive approaches that offered decreased blood loss and perioperative pain, shorter hospital stay, and faster convalescence with a more rapid return to normal activity while maintaining oncologic efficacy. The addition of robotic technology to the armamentarium of urologists is one such example. Robotic technology was introduced to overcome these limitations and helps the surgeon to transition from open surgery to the minimally invasive arena. The interface was created to enhance technique and reduce learning curve by providing 3D-vision, wristed instrumentation with seven degrees of freedom of motion, lack of tremor, and a comfortable seated position making it ideal for a technically challenging reconstructive procedure. This technology has the potential to provide significant surgical advantages especially in challenging areas of a patient's anatomy and difficult-to-access structures deep in the pelvis.

Our Step-by-Step Approach to Robotic Radical Prostatectomy

Our technique is based upon a fusion of the open approach as described by Walsh [1], laparoscopic radical prostatectomy technique and the initial robot assisted laparoscopic radical prostatectomy described by Menon et al. [2] However, after having performed close to 10,000 cases (single surgeon series—VP), our technique has evolved significantly, including several refinements to reduce patient morbidity and further improve the functional outcomes. In the present manuscript, we perform a detailed description of our surgical technique of RALP and provide practical recommendations based on available reports and personal experience. We herein describe the surgical technique we currently perform at our institution.

Preoperative Preparation

One hour prior to incision, the patient receives 1 g IV Cephazolin (first-generation cephalosporin). Prior to induction of anesthesia, sequential compression devices are placed on the lower extremities and the patient receives 5000 units of subcutaneous heparin. At this point the patient is positioned in low lithotomy, ensuring that thighs are not overextended to avoid neuropraxia. All pressure points including shoulders, elbows and wrists are carefully and thoroughly padded (Fig. 30.1). The patient is placed within a bean bag, which is fixed to the table aided by adhesive tape. Abdominal hair is trimmed and the patient is prepped and draped in a sterile fashion. An orogastric tube is inserted before insufflation along with an 18-French Foley catheter with 15 cc sterile water in the balloon.

RALP commonly performed by transperitoneal approach and authors also prefer the same. Pneumoperitoneum created using a Veress needle and the abdomen is insufflated to a maximum pressure of 15 mmHg. Six trocars are placed under direct vision, as shown in Fig. 30.2. The patient is then placed in a 25° steep Trendelenberg position and the robot docked. The robotic and laparoscopic instruments used during RALP are presented in Table 30.1.

Step 1: Incision of the Peritoneum and Entry into the Space of Retzius

A transverse peritoneal incision is made through the median umbilical ligament and extended on both sides in an inverted U fashion to the level of the vasa deferens laterally. The fourth arm provides countertraction for this step. The peritoneum is dissected down to the pubic tubercle,

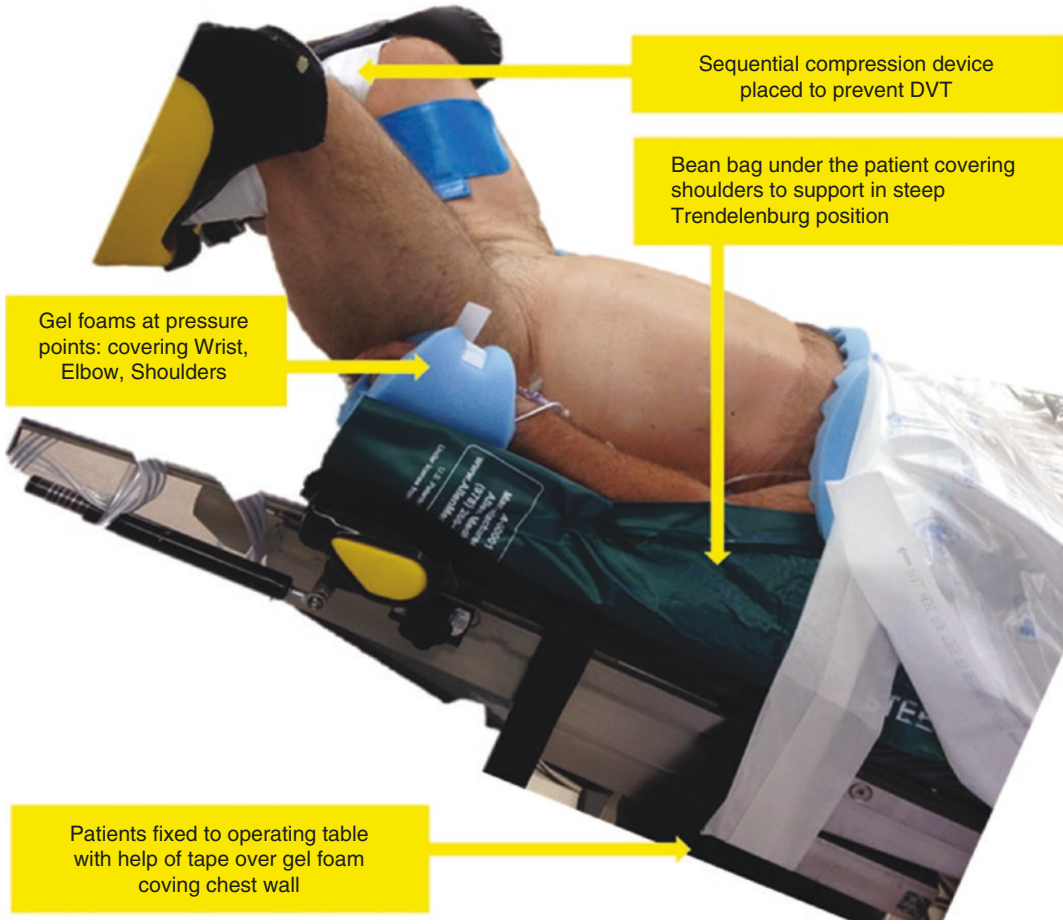

Fig. 30.1 Patient positioning for RALP

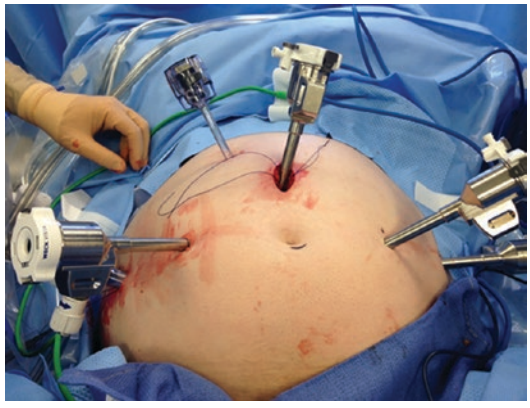

Fig. 30.2 Port in place for da Vinci Xi surgical robot-assisted radical prostatectomy

which is the anatomical landmark used to follow the pubic rami lateral and horizontally so as to not produce inadvertent injury to epigastric vessels above the rami. It is important to dissect the peritoneum all the way up to the base of the vasa for optimum release of the bladder to allow a tension-free vesicourethral anastomosis.

Step 2: Incision of the Endopelvic Fascia (EPF) and Identification of the Dorsal Venous Complex (DVC)

The important landmarks are bladder neck, base of the prostate, levator ani muscles, and apex of the prostate. After defatting the prostate, the fourth arm is used to retract it contralateral side so as to provide adequate exposure and tension on the EPF. The EPF is opened (with

Table 30.1 Instruments used during steps of robot-assisted radical prostatectomy

Surgical Step	Lens	Right Robotic Instrument	Left Robotic Instrument	Fourth Robotic Arm	Assistant Port
Step 1: Incision of the peritoneum and entry into the retropubic space of retzius	0° binocular lens	Monopolar scissor (25 W)	Bipolar forceps (26 W)	Prograsp	Microfrance grasper and suction
Step 2: Incision of the endopelvic fascia (EPF) and identification of the dorsal venous complex (DVC)	0° binocular lens	Monopolar scissor (25 W)	Bipolar forceps (26 W)	Prograsp	Grasper and suction
Step 3: Ligation of the DVC and Periurethral	0° binocular lens	Robotic needle driver	Robotic needle driver	Prograsp	Laparoscopic scissor and suction
Step 4: Anterior bladder neck dissection	30° binocular lens directed downward	Monopolar scissor (25 W)	Bipolar forceps (26 W)	Prograsp	Microfrance grasper and suction
Step 5: Posterior bladder neck dissection	30° binocular lens directed downwards	Monopolar scissor (25 W)	Bipolar forceps (26 W)	Prograsp	Microfrance grasper and suction
Step 6: Athermal seminal vesicle dissection	30° binocular lens directed downwards	Monopolar scissor (25 W)	Bipolar forceps (26 W)	Prograsp	Microfrance grasper and suction
Step 7: Denonvillier's fascia and posterior dissection	30° binocular lens directed downwards then changed to upwards	Monopolar scissor (25 W	Bipolar forceps (26 W)	Prograsp	Microfrance grasper and suction
Step 8: Nerve-sparing: "Athermal early retrograde release of the neurovascular bundle"	30° binocular lens directed downwards then changed to upwards	Monopolar scissor (25 W)	Bipolar forceps (26 W)	Prograsp	Microfrance grasper and suction
Step 9: Apical dissection	30° binocular lens directed downwards	Monopolar scissor (25 W)	Bipolar forceps (26 W)	Prograsp	Microfrance grasper and suction
Step 10: Modified posterior reconstruction of the rhabdosphincter and Urethrovesical anastomosis	30° binocular lens directed downwards	Robotic needle driver	Robotic needle driver	Prograsp	Suction and scissor

sharp dissection) toward the base of the prostate (Fig. 30.3) and then followed toward the apex of the prostate to identify the notch between DVC and urethra where the DVC ligation and suspension stitch will be placed (Fig. 30.4). This step is performed using cold scissors and taking extra caution in identifying any accessory pudendal arteries that may travel along the EPF. Proceeding from the base to the apex, the fibers of the levator ani are dissected off the prostate with the round edge of the scissors until the DVC and urethra are visualized. Use caution when dissecting and cutting the puboprosatic ligaments because if carried out too medially it will definitely lead to injury of the DVC and unnecessary bleeding. Full dissection of the apex is best performed at the end of the procedure.

Step 3: Periurethral Suspension Stitch and Ligation of the DVC

Originally described by Walsh [1] as a means to decrease blood loss during division of the DVC or prevent damage to the striated sphincter, the use of pubourethral suspension stitches or the application of sutures anchoring the vesicourethral anastomosis to the ligated dorsal vein complex (DVC) also helps in improving early urinary continence rates after RRP [3].

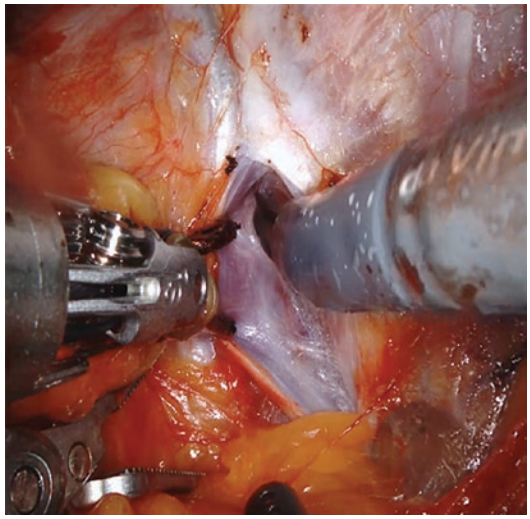

Fig. 30.3 Incision of endopelvic fascia

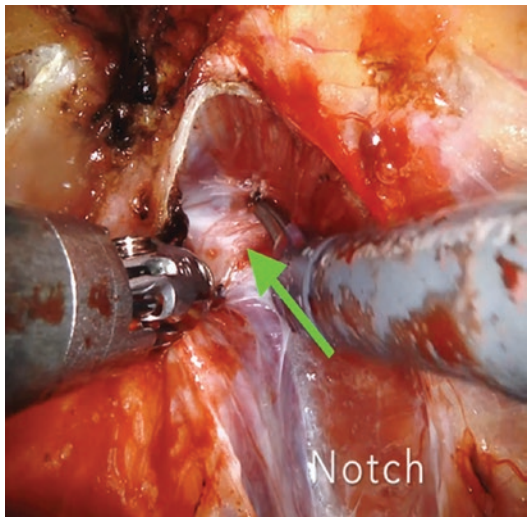

Fig. 30.4 Identification of notch between dorsal venous complex and urethra

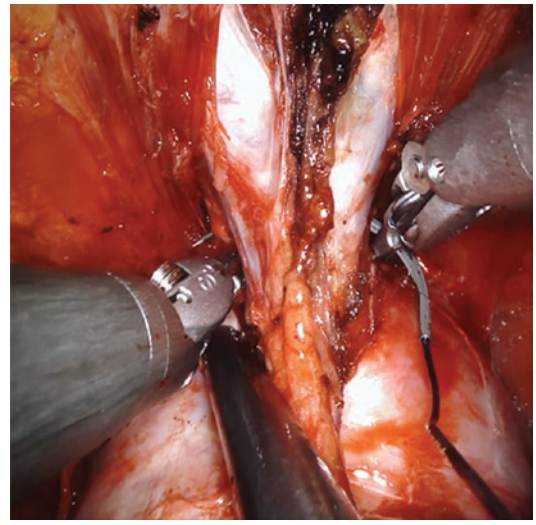

Fig. 30.5 Passing needle for suspension stitch and ligation of dorsal venous complex

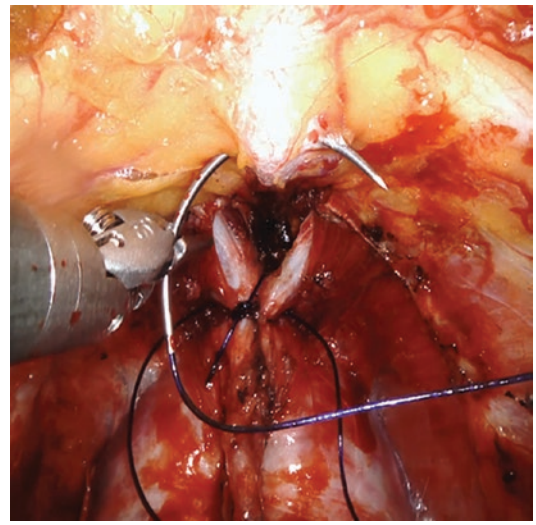

Fig. 30.6 Suspension stitch anchored to the periosteum of the pubic symphysis

The DVC is ligated using a no. 1 barbed monofilament suture with variable loop, 12 inch in length on a VLP 2015 needle (Quill™ knotless tissue closure device). The stitch was passed between the urethra and DVC (Fig. 30.5) then through the periostium of the pubic bone (Fig. 30.6). The suture was passed again through the DVC forming a loop. A mild amount of tension to suspend the DVC was formed. The barbed suture passed through the periosteum of pubic bone in reverse direction to fix it. Then the same suture is used for DVC ligation in a figure-of-eight configuration and then tied. This maneuver can help to control the venous bleeding and provides a recapitulation of the puboprostatic ligaments, supporting the striated sphincter. The DVC was typically divided later during the operation, prior to the apical dissection of the prostate and division of the urethra.

These technical variations showed a significant effect on the earlier recovery of urinary continence without compromising oncological outcomes [3, 4]. We analyzed our data of 331 consecutive patients who underwent RALP [5]. Ninety-four of these patients underwent RALP without the placement of suspension stitch (group 1) and 237 patients underwent RALP with the application of the suspension stitch (group 2). In the suspension group a periurethral retropubic stitch was placed using the same monofilament used for DVC ligation. The only difference between the groups with and without suspension stitch was the placement of the pubo-periurethral stitch after the ligation of the DVC. In group 1 the continence rate at <1, 3, 6, and 12 months postoperatively was 33%, 83%, 94.7% and 95.7%, respectively. In group 2 the continence rate at <1, 3, 6, and 12 months postoperatively was 40%, 92.8%, 97.9 and 97.9%, respectively. The suspension technique resulted in significantly greater continence rates at 3 months after RALP ($p = 0.013$), although the rates at 6 and 12 months were not significantly affected. The interval to recovery of continence was significantly lower in the suspension group (median = 6 weeks, mean = 7.33 weeks; 95% CI: 6.38–8.28) than in the non-suspension group (median = 7 weeks, mean = 9.58 weeks; 95% CI: 7.56–11.61, log-rank test $p = 0.002$).

Our results showed a higher recovery of complete urinary continence at 3 months after the RALP with the placement of the suspension stitch. Positive margin rate was unaffected. Complete removal of the cancer is still the primary endpoint of the RALP and any modifications of the surgical technique must not compromise the oncological outcome. The exact mechanism of the early recovery of continence using the suspension stitch is unclear. We believe that the suspension of the periurethral complex can provide better vision, urethral length, and additional anterior support to the striated sphincter, stabilizing the posterior urethra in its anatomical position in the pelvic floor. This stabilization aids in the preservation of urethral length during the dissection of the prostatic apex facilitating the vesicourethral anastomosis and preventing descent and destabilization of the continence mechanism. Furthermore, we have experienced that the suspension stitch helps to control the venous bleeding from the DVC and enables the surgeon to visualize more clearly the plane between the anterior prostatic apex and the DVC, as emphasized by Walsh previously.

Step 4: Anterior Bladder Neck (BN) Dissection

The scope is changed to a 30° down-facing lens for the BN dissection. Although some authors use 0° scope throughout the case, we believe that this angled lens is optimal to see inferiorly and to visualize the correct planes. Key points here to correctly identify the BN is identifying where the bladder fat ends on the prostate in the form of an inverted "U" (Fig. 30.7); another trick is to pull on the Foley catheter and visualize the balloon as it reaches the base of the prostate. However, although useful, this can be misleading in patients with prior transurethral resection of the prostate (TURP) or in the presence of median or anterior lobes. The robotic arms also provide a moderate amount of visual feedback to facilitate localization of the boundaries (double-pinch maneuver). This step is begun by cauterizing the superficial veins that are located in the midline with the bipolar forceps. Then the bladder is dissected off the prostate in the midline using a continuous sweeping motion of the monopolar scissors and traction

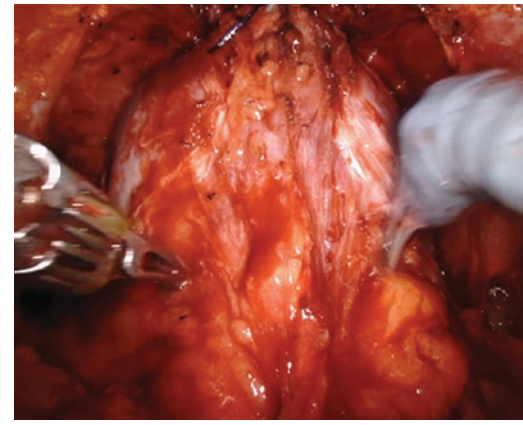

Fig. 30.7 Identifying anterior bladder neck by fat line and pinching with robotic arms

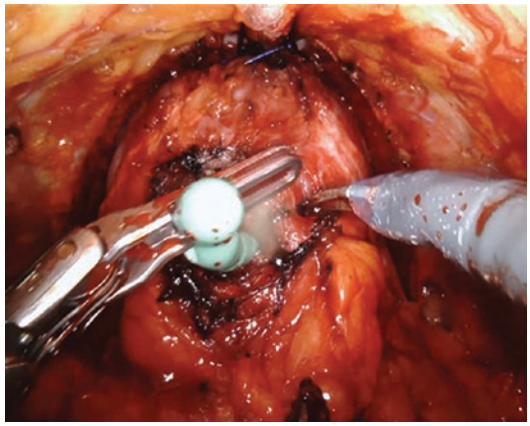

Fig. 30.8 Incision of anterior bladder neck and Foley catheter is retracted out of the bladder using the fourth arm, in an upward manner to expose the posterior bladder neck

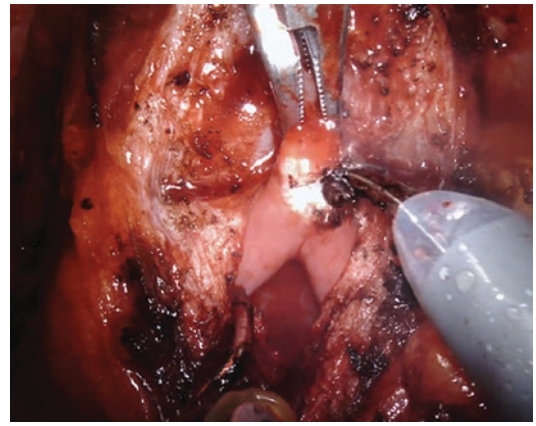

Fig. 30.9 Initiation of the posterior bladder neck dissection

with the bipolar forceps while visualizing the bladder fibers. The key is to stay in the midline to avoid lateral venous sinuses until the anterior bladder neck is opened and the Foley catheter visualized. Once the anterior urethra is divided, the Foley catheter is retracted out of the bladder using the fourth arm, in an upward manner to expose the posterior bladder neck (Fig. 30.8).

Step 5: Posterior Bladder Neck Dissection

The posterior BN dissection is generally considered to be the most challenging step of the operation for the novice robotic surgeon. The difficulty is in appreciating the posterior tissue plane between the bladder and prostate and the direction and depth of dissection necessary to locate the seminal vesicles. After incising of the anterior BN, any remaining peripheral bladder attachments should be divided to flatten out the area of the posterior bladder neck and allow precise visualization and dissection of the posterior plane (Fig. 30.9). The full thickness of the posterior bladder neck should be incised at the precise junction between the prostate and the bladder. The lip of the posterior BN is then grasped with the fourth arm and retracted upward (Fig. 30.10). The bipolar forceps is then used for traction thus visualizing the correct plane between prostate and bladder. The dissection is directed posteriorly and slightly cephalad (toward the bladder) to expose the seminal vesicles. It is important to avoid dissecting caudally (toward the prostate) as there is a possibility of entering the prostate and missing the seminal vesicles completely.

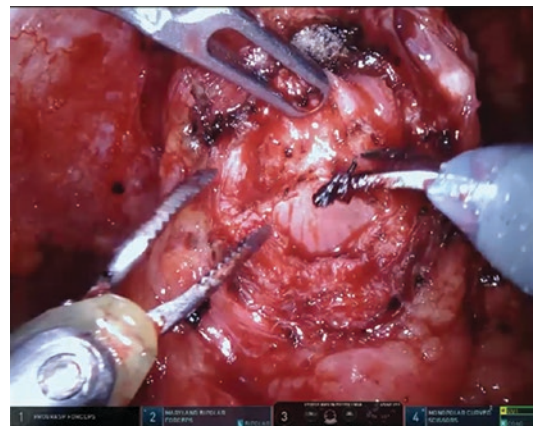

Fig. 30.10 Lip of the posterior bladder neck is grasped with the fourth arm and retracted upward

Step 6: Athermal Seminal Vesicle (SV) Dissection

The anatomy and location of the seminal vesicles (SVs) warrant an athermal and careful dissection due to their proximity to the hypogastric plexus and cavernous nerves. We have developed a simple technique for dissection and liberation of the SVs without trauma [6]. After dissection of the posterior bladder neck, the vas deferens is

identified. The fourth arm is used to grasp and elevate first the left vas deferens. Blunt dissection starts on the medial surface developing an avascular plane between vas deferens and the SV. Once the SV is identified, the fourth arm is used for upward and lateral traction to continue dissection until the tip is reached. Once this occurs, a 10 mm hem-o-lock clip is placed on the vas deferens increasing exposure of the tip of the SV being able to place a following clip on the vascular supply entering at the tip (Fig. 30.11). Dissection is then continued until the base of the SV is reached. Important to point out is that no thermal energy is used during this step of the procedure due to the proximity of neurostructures (hypogastric plexus and cavernous nerves) to the tip of the SVs. Dissection of the right SV is carried out in a similar manner. Once performed dissection of the posterior plane (separation of rectum from prostate) can be carried out safely preparing for the nerve-sparing part of the procedure.

Once the posterior BN dissection is complete, the vasa and SVs can be identified. The thin fascial layer over the SVs and vasa should be opened to free the structures for retraction. The fourth arm is used to retract the left vas superiorly and laterally. Dissection continues on the medial side of the vas due to the inexistence of vessels in this area, until the tip of the left SV is reached. When this occurs it is grasped and retracted with the fourth arm elevating it away from the neurovascular structures that lie beneath (hypogastric plexus). The vas is then clipped with a 10 mm hem-o-lock followed by clipping of the vessels of the tip of the SV. Then the SV is dissected completely to the base. This procedure is carried out similarly on the right side.

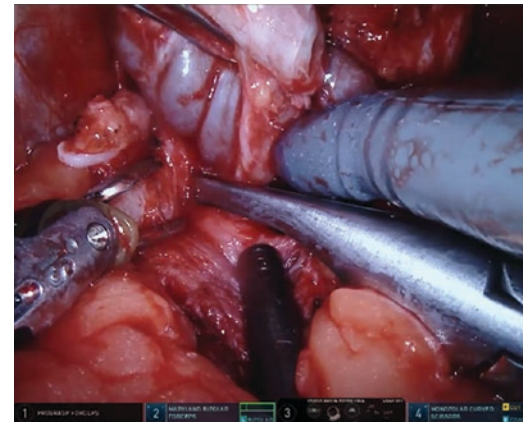

Fig. 30.11 Athermal dissection of the seminal vesicle

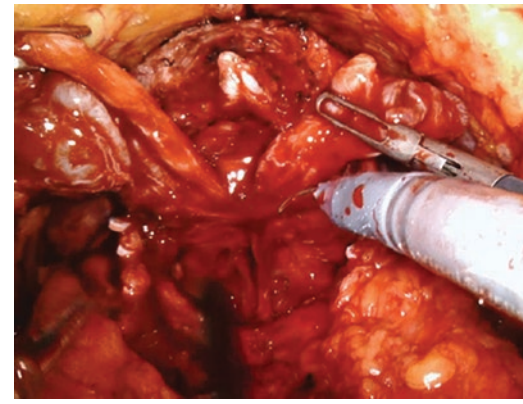

Fig. 30.12 Identification of Denonvilliers fascia with the fourth arm and assistant helping to retract upward and laterally

Step 7: Denonvilliers' Fascia and Posterior Dissection

Once the SVs have been dissected completely to the base, the right SV is handed over to the assistant for upward traction; the left SV is retracted using the fourth arm (Fig. 30.12). Downward traction of the undersurface of the prostate with the bipolar forceps is applied and blunt dissection using the monopolar scissors on the base of the SVs correctly identifies Denonvilliers' fascia (visualized as a bright pearly white plane–Fig. 30.13). Denonvilliers' fascia is then entered and dissected laterally and caudally until reaching the apex of the prostate.

Step 8: Athermal Early Retrograde Release of the Neurovascular Bundles (NVB)

Precise identification and delineation of the neurovascular bundle during nerve-sparing radical prostatectomy is a challenging but critical component of the operation. The neurovascular bundle can be damaged at various locations along its path and by various methods of injury. Damage can occur via transection, ligation, thermal injury, or excessive

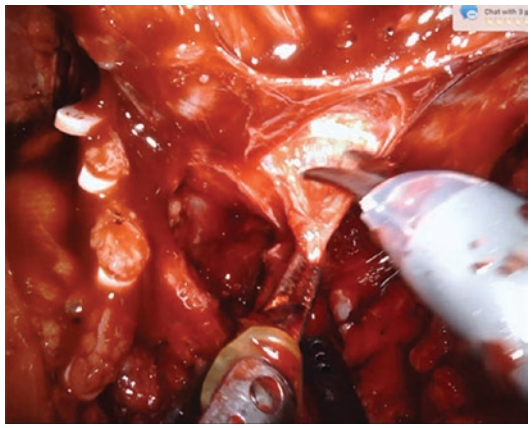

Fig. 30.13 Incision of Denonvilliers' fascia

traction. Common points of injury include at the prostatic pedicles, seminal vesicles, during the apical dissection, and inadvertent inclusion of the neurovascular bundle during the vesicourethral anastomosis [7]. Different operative techniques present various unique challenges during nerve-sparing radical prostatectomy. In open radical prostatectomy the levator fascia is opened and the neurovascular bundle is released from the prostate beginning at the apex and moving toward the base of the gland. The neurovascular bundle is released from the prostate prior to controlling the vascular pedicles. Challenges of the open retropubic technique include obtaining adequate hemostasis and visualization to allow the surgeon to perform such an intricate dissection.

The standard approach to nerve sparing with laparoscopic or robotic radical prostatectomy is antegrade. Here the prostatic pedicle is controlled and divided and then the neurovascular bundle is released from the prostate beginning at the base and moving toward the apex of the gland. Advantages of the laparoscopic approach include improved visualization with magnified vision and improved hemostasis secondary to the pneumoperitoneum. With the antegrade approach, however, the neurovascular bundle risks inadvertent injury during control of the vascular pedicle prior to precise delineation of the path of the neurovascular bundle. Hence the need for a technique, which can overcome these limitations, is required.

Based upon our experience with both the open and standard laparoscopic approaches we developed a hybrid technique for nerve preservation during RALP [8, 9]. Our approach to RALP is an antegrade prostatectomy; however, prior to controlling the vascular pedicles we release the neurovascular bundle from the prostate beginning at the apex and extending back toward the base of the gland. Our approach is based upon the philosophy of minimal traction, use of no thermal energy, and early release of the neurovascular bundle with precise identification of its location at the base of the gland prior to ligating the prostatic pedicle. A complete posterior dissection is critical to successful nerve sparing. It is essential to maximally release the prostate from the rectum all the way to the apex and laterally to the bundles. The assistant helps with identification of the lateral fascial attachments by rotating the prostate laterally. The importance of the assistant in this step cannot be stressed enough as they are in charge of maintaining a bloodless operating field for clear visualization of the bundle as well as contralateral traction. Early release of neurovascular bundle is then performed. Our group described a standardized nerve spare grading system based on intraoperative visual cues [10] and the role of the prostatic vasculature as a landmark for nerve sparing during robot-assisted radical prostatectomy [11].

Instant Toggling of 30° Endoscope to Improve Visualization

The da Vinci Xi robotic surgical system has some new applications built in to try to achieve a more precise sparing procedure. For instance, the laparoscope has a digital end-mounted camera for improved vision. The scope can be placed into any of the robotic arms and has autofocus. The new endoscope is far easier to set up and delivers sharp, high-definition 3 D images. The Xi version of surgical robot has a feature to rotate the 3D camera lens with 30° down angles to 30° up angle instantly (180° instant rotation of camera controlled from touch panel). This rotation without removing the camera from the trocar helps to place the camera under guidance

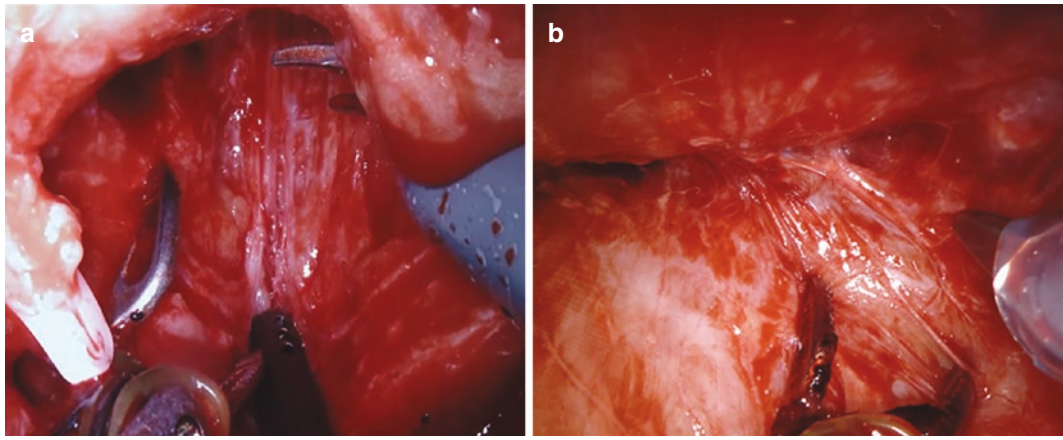

Fig. 30.14 Instant toggling of the camera with the da Vinci Xi surgical robot. (**a**) View with the 30° down angle in the posterior plane of the prostate—difficult to visualize the plane of neurovascular bundle. (**b**) View with the 30° up angle—clear visualization of the plane of neurovascular bundle

in difficult to visualize angles. We found this feature useful in the posterior surface of prostate for nerve sparing, underneath the narrow pubic arch for DVC ligation, and anastomosis in deep-narrow pelvis.

Instant toggling of camera can facilitate a more direct view to identify plane of NVB in order to start releasing it from the posterior surface of prostate. After fully dissecting the posterior plane up to the apex and laterally to the bundles, early release of NVB is initiated. Camera in 30° up angle greatly improves the vision in this plane (Fig. 30.14). At the level of the apex and mid-portion of the prostate, the avascular plane between the neurovascular bundle and prostatic fascia is developed with caution (Fig. 30.15). Ultimately, this approach may provide the surgeon with guidance for exact placement of a first hem-o-lock clip to pedicle above the level of the released NVB (Figs. 30.16 and 30.17).

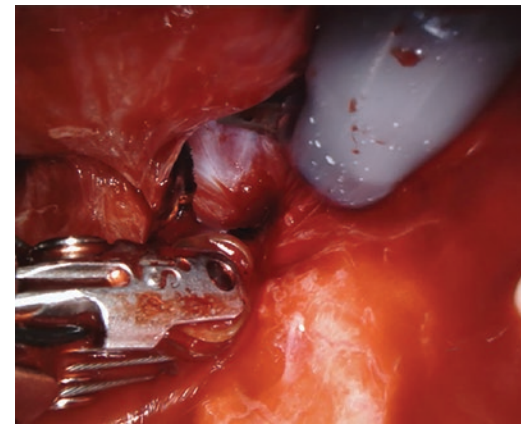

Fig. 30.15 Early retrograde release of the right side neurovascular bundle

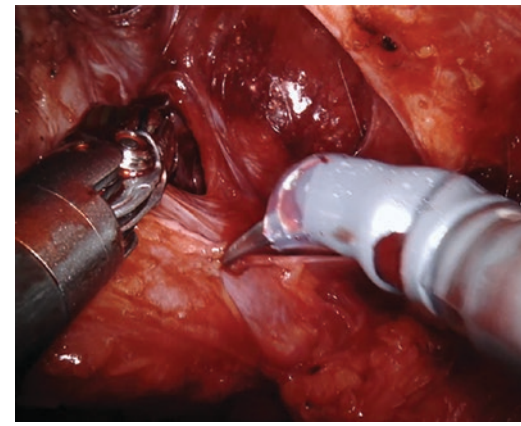

Fig. 30.16 Right side neurovascular bundle preservation

Step 9: Apical Dissection

The landmarks are the ligated DVC, urethra, apex of the prostate, and NVB. Again, it is essential to have securely ligated DVC to prevent bleeding, which may interfere with the apical dissection and division of the urethra under direct vision. Cold scissors are used to carefully divide the DVC and create a long

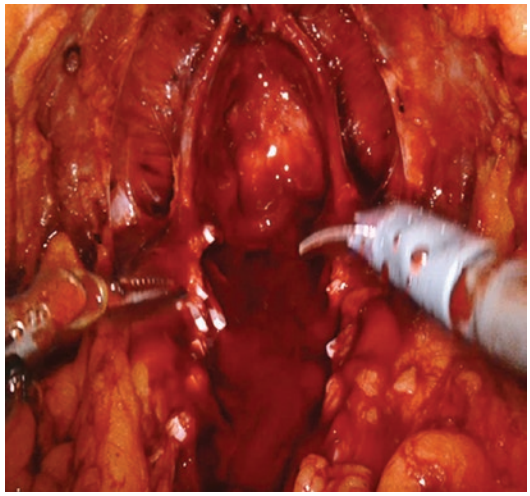

Fig. 30.17 Bilateral preserved neuro-vascular bundle

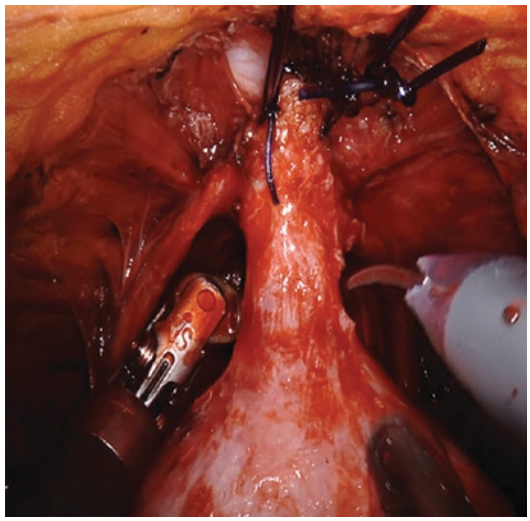

Fig. 30.18 Apical dissection

urethral stump facilitating the anastomosis. Complete dissection of the apex and urethra is facilitated by the 10× magnification that the robot provides. Once the urethra has been identified, the bipolar forceps is used to create a plane on the posterior surface of the urethra separating it from the musculofascial plate before incising with cold scissors (Fig. 30.18). The rhabdosphincter is then incised with caution, avoiding any posterior lip that the prostate may have at this location (Fig. 30.19).

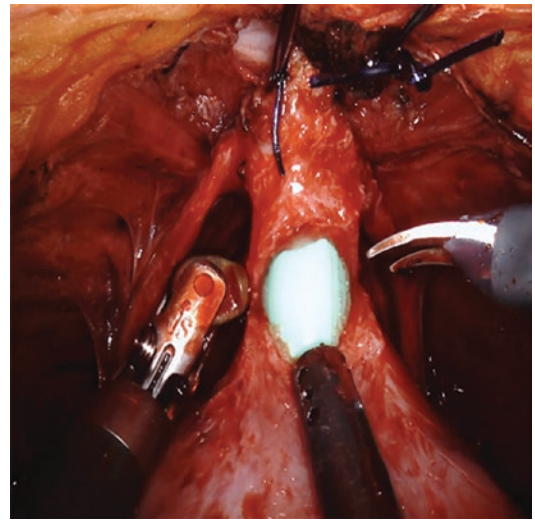

Fig. 30.19 Transection of urethra with adequate stump length

Step 10: Bladder Neck Reconstruction, Posterior Reconstruction and Vesico-Urethral Anastomosis

Bladder Neck Reconstruction

We published our technique of modified transverse plication of the bladder neck earlier [12]. It takes less than 5 min and is also very simple, ergonomic and effective way of bladder neck reconstruction. Before starting the bladder neck reconstruction it is essential to check the position of ureteral orifices and their distance from the edge of the bladder neck. Bilateral plication over the lateral aspect of the bladder is then performed using sutures of 2-0 Quill Monoderm® 8 cm long in VP 2000Q needle (16 cm double armed suture cut in to equal half). The suture begins laterally and runs medially until the bladder neck size matches that of membranous urethra (Fig. 30.20).

Modified Posterior Reconstruction of the Rhabdosphincter

After extraction of the specimen, posterior reconstruction is performed prior to beginning the vesicourethral anastomosis. This is performed according to the two-layer reconstruction described by Rocco et al. [13, 14] with

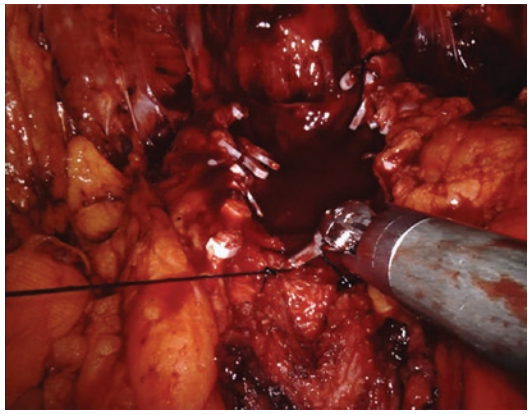

Fig. 30.20 Modified transverse plication of the bladder neck

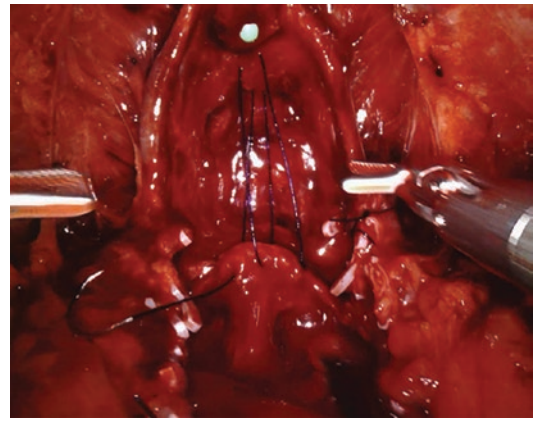

Fig. 30.21 First layer of the posterior reconstruction—Denonvilliers' fascia sutured with the rhabdosphincter

some technical modifications. Prior to performing the vesicourethral anastomosis, we perform a modified reconstruction of the pelvic floor, reattaching Denonvilliers' fascia to the rhabdosphincter. For this step, we use a 2-0 Quill™ variable loop suture 20 cm length (Quill knotless tissue closure device). We proceed to identify the free edge of Denonvilliers' fascia, which is approximated to the posterior aspect of the rhabdosphincter and posterior median raphe running one of the arms of the suture and tied (Fig. 30.21). A second layer is then run with the second arm of the suture, approximating the posterior bladder neck to the posterior lip of the urethra (Fig. 30.22).

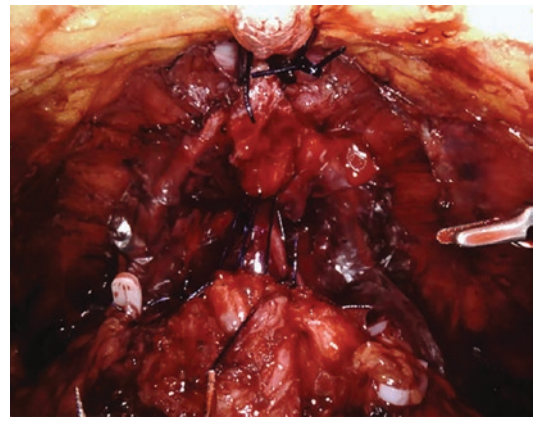

Fig. 30.22 Second layer of the posterior reconstruction—posterior bladder neck with rhabdosphincter

The free edge of the remaining Denonvilliers' fascia is identified following prostatectomy. It is located anterior to the rectum just caudal to the bladder and seminal vesicle dissection. This edge is approximated to the posterior aspect of the rhabdosphincter and the posterior median raphe using one arm of the continuous monocryl suture. Typically four bites of Denonvilliers' fascia and the rhabdosphincter/posterior median raphe are taken; then we incorporate the posterior bladder neck in the second layer. This second layer is continued with the same 2-0 Quill™ variable loop suture approximating the posterior bladder neck to the initial reconstructed layer of posterior rhabdosphincter and Denonvilliers' fascia. The running suture takes the posterior rhabdosphincter/Denonvilliers' complex, and incorporates the posterior bladder neck preparing for a tension-free vesicourethral anastomosis. Care must be taken to avoid potential complications, such as damage to the neurovascular bundles, urethra, and/or ureters during the placement of reconstruction sutures. Careful identification of target anatomy and accurate suture placement is of the utmost importance for prevention.

Our analysis showing complete 'early continence' rate (defined by use of no pads) of 58% at 1 week is encouraging. If the definition of continent is broadened [13, 14] (0 or 1 pad per day) the rate is 72% [15].

Human Amniotic Membrane Allograft Nerve Wrap Around the Prostatic Neurovascular Bundle

Clinical use of growth factors and anti-inflammatory substances for prostatic NVB regeneration is novel, and human amnion membrane allograft (dHACM) is a source of implantable neurotrophic factors and cytokines. We published a propensity-matched analysis of patients underwent placement of dHACM (AmnioFix; MiMedx Group, Marietta, GA, USA) around NVB [16]. We enrolled 58 patients who were preoperatively potent (Sexual Health Inventory for Men [SHIM] score >19) and continent (no pads) underwent full NS RALP. The dHACM allograft was cut into two longitudinal pieces and placed over each NVB as a nerve wrap (Fig. 30.23). The wrap was placed circumferentially around the NVB after posterior reconstruction and before vesicourethral anastomosis (Fig. 30.24). This group was propensity score matched with a similar group of patients who did not receive allograft placement. Post-operative outcomes were analyzed between both groups, including time to return to continence, biochemical recurrence and potency. Potency at eight weeks returned in 65.5% of the patients in the dHACM group and 51.7% of the patients in the no-dHACM group. The mean time to potency was significantly shorter in the graft group (1.34 months) than in the non-graft group (3.39 months; $p = 0.007$). SHIM scores were also higher for the dHACM group than for the no-dHACM group (mean score 16.2 vs. 9.1). Our short-term results were encouraging for patients undergoing full NS RARP and dHACM placement. So, we currently use dHACM graft regularly in suitable patients.

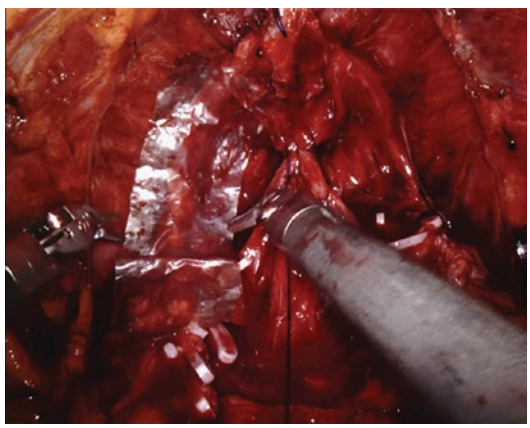

Fig. 30.23 Dehydrated human amnion–chorion membrane placed over the left side neurovascular bundle

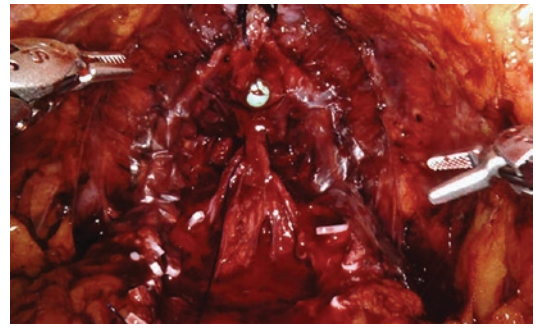

Fig. 30.24 Dehydrated human amnion–chorion membrane wrapped around bilateral neurovascular bundle

Vesicourethral Anastomosis

A continuous modified van Velthoven vesicourethral anastomosis is then performed [17]. Single 2-0 Quill Monoderm® loop double armed suture of 16 cm long on VP 2000Q needles are used for the anastomosis. The posterior urethral anastomosis is performed first with one arm of the suture starting at the 5 o'clock position until reaching the 10 o'clock position in a clock-wise fashion. This is followed by completion of the anterior anastomosis with the second arm of the suture in a counterclockwise fashion (Fig. 30.25) and then tying both sutures on the urethral stump. The key to performing an efficient rapid watertight anastomosis is to use both hands when suturing; that is, the left hand feeds the suture to the right and so forth. Having a long urethral stump, normal-sized bladder neck, clear operative field, and exerting perineal pressure (in some instances) contribute to this also. Once the anastomosis is completed, a new 18 Fr Foley catheter is placed and saline solution is used to irrigate and eliminate any clots and also to confirm a watertight anastomosis. A Jackson–Pratt drain is placed at the pelvic rim and then all trocars are removed under direct vision.

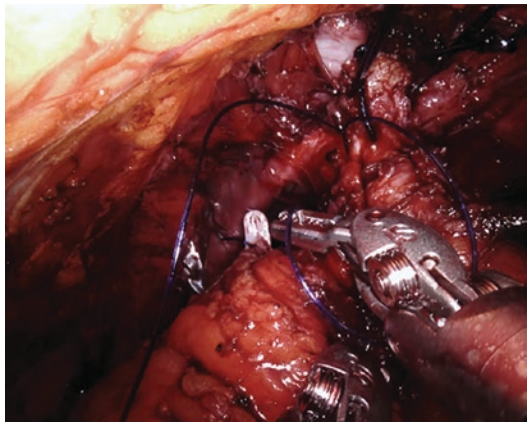

Fig. 30.25 Completion of vesicourethral anstomosis

Scaffolding Tissue Biograft to Bolster Vesicourethral Anastomosis During Salvage Robot-Assisted Prostatectomy (sRALP)

The vesicourethral anastomosis after salvage robot-assisted laparoscopic prostatectomy (sRALP) for recurrent prostate cancer can be complicated by an anastomotic leak in up to 18–33% of cases. VUA leaks play a major role on patient outcome and contribute to a significant amount of morbidity. Patients who experience VUA leaks are at an increased risk of developing urethral strictures, bladder neck contractures and other clinical manifestations that require increased catheterization time. Intraperitoneal urine leak and urinoma may lead to a protracted course of postoperative ileus and metabolic derangements. In may necessitate interventional procedure and rarely reconstructive procedure to repair a defect in anastomotic wall. As such, minimizing this problem can be beneficial for patients. As a rule of thumb, in the case of sRALP, tissue friability and post operative necrosis as a result of prior therapy creates a technical challenge in performing a sound anastomosis. Even if the VUA is intact the tissue around it can undergo necrosis and lead to a urinary leak.

Clinical use of connective tissue for the reenforcement of the VUA and distal bladder neck is a novel approach. Recently we published the usage of extracellular matrix scaffold incorporated into the base of the vesicourethral anastomosis (Figs. 30.26 and 30.27) following salvage robot assisted radical prostatectomy [18]. The scaffold used in this study is the MatriStem® (ACell®, Inc., Columbia, MD, USA). It is an acellular and resorbable scaffold derived from the basement membrane and subjacent lamina propria of the porcine urinary bladder extracellular matrix, which is a source of implantable collagen, protein and carbohydrates. We reported 15 patients that underwent sRALP with use of a urinary bladder extracellular matrix (UB-ECM) scaffold in the posterior aspect of the VUA and distal bladder neck (Group 1) and 45 patients that underwent sRALP with standard suturing without use of the graft (Group 2). A clinically

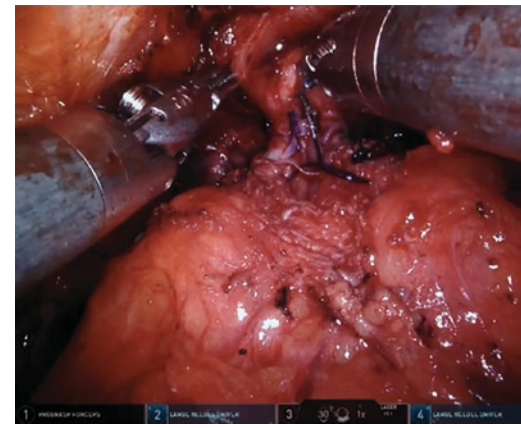

Fig. 30.26 Scaffolding tissue biograft sutured at the posterior vesicourethral anastomosis during salvage robot-assisted prostatectomy

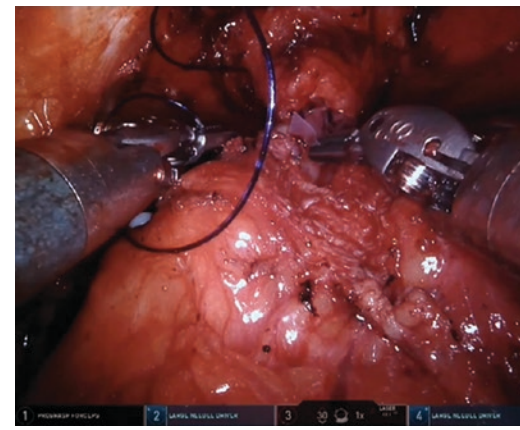

Fig. 30.27 Scaffolding tissue biograft to bolster vesicourethral anastomosis during salvage robot-assisted prostatectomy

significant VUA/bladder neck disruption was observed in 16 patients (35.5%) in group 2, with a median catheterization time of 17.4 d (9–47 d), while in group 1 only one patient (6.66%) had a significant anastomotic leak on cystography ($p = 0.045$), with median catheterization time of 11.2 d (10–52 d) for this group ($p < 0.05$). We suggest that incorporation of a UB-ECM scaffold into the base of the VUA and distal bladder neck should be considered as an option to decrease morbidity associated with sRALP since it decreased the rate of VUA disruption, enhanced healing, and reduced catheterization time.

Conclusions

Radical prostatectomy remains today the gold standard for the treatment of organ-confined prostate cancer.

Robotic prostatectomy has evolved to challenge the former offering comparable and in some instances improved outcomes regarding continence, potency, and oncologic control with the modifications herein described. However, experience is a crucial factor in these outcomes and only the availability of long-term outcomes will determine its true validity.

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Robot-assisted Simple Prostatectomy

31

Giacomo Novara, Alessandro Morlacco, Riccardo Autorino, and Alexandre Mottrie

Abstract

Simple prostatectomy (SP) is a viable option for surgical management of lower urinary tract symptoms (LUTS) in men with large prostatic adenoma. Robotic simple prostatectomy (RASP) has been popularized in the last years and combines the benefits of minimally-invasive surgery with the efficacy of conventional simple prostatectomy. In this chapter we present the different RASP techniques described in current literature (transvesical and transcapsular approach, with intra and extraperitoneal access). Moreover, we discuss the perioperative and functional outcomes of RASP, also in comparison with laparoscopic SP and Holmium laser enucleation (Holep).

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Keywords

LUTS · BPH · Prostatic adenoma · Adenomectomy · Simple prostatectomy · Robotics · RASP

Introduction

Both EAU and AUA guidelines recommend surgery as the standard treatment for patients with male lower urinary tract symptoms (LUTS) unresponsive to conservative management and drug therapy as well as for those with complications. Transurethral resection of prostate is considered the gold-standard treatment for the above mentioned type of patients for prostate size ranging from 30 to 80 ml (100 ml in the AUA guidelines). Open simple prostatectomy (SP) and holmium laser prostatectomy (Holep), conversely, are suggested for those patients with prostate size larger than 80 ml (100 ml in the AUA guidelines), according to patient's presentation, anatomy, the surgeon's level of training and experience, and a discussion of the potential benefit and risks for complications [1, 2].

The increasing diffusion of laparoscopy and robotic surgery in the treatments of several urological conditions has led to the introduction and implementation of laparoscopic SP (LSP) first and robot-assisted SP (RASP) later in the armamentarium of several urological teams.

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The purpose of the present chapter is to report the different surgical techniques for RASP and report the associated perioperative and functional results available in the literature.

Surgical Techniques of Robot-Assisted Simple Prostatectomy

Several techniques of RASP have been described. Besides expected nuances among different Centers and surgeons in terms of patient positioning and trocar placement, two main routes have been used to reach the prostatic adenoma, as originally described for open surgery: the transvesical approach and the retropubic approach. Moreover, as for radical prostatectomy, both the transperitoneal and the extraperitoneal access have been adopted for RASP.

Transvesical Technique with Transperitoneal Access

The technique was original reported by Sotelo et al. in a series of only 7 patients [3].

A step-by-step description of this technique developed at the OLV hospital, Aalst, Belgium was reported by Pokorny et al. [4]:

1. The patient is placed in lithotomy position with a steep Trendelemburg. Five trocars are placed, similarly to what happens for radical prostatectomy, including a 12 mm camera trocar placed supraumbilically; two 8 mm robotic trocars bilateral on a line between the camera port and the iliac crest at 8 cm from the camera port; and another 8 mm robotic trocar on the left side at 8 cm from the other robotic port and at the level as the camera port. A lateral 12 mm port is placed 2 cm cranial of the iliac crest on the right side for the assistant (Fig. 31.1). If needed, an additional 5 mm trocar may be placed in between the camera port and the right robotic port for a suction device. Only hot Shears monopolar curved scissors, ProGrasp forceps, and a large needle driver are routinely used.
2. The bladder is filled with 100 ml of saline via the catheter and then released from the abdominal wall. At this point, a 3–4 cm midline longitudinal cystotomy is made, starting above the prostate–vesical junction (Fig. 31.2).
3. Careful inspection of the bladder mucosa is necessary to determine the position of ureteral orifices. This is a capital point of the procedure in order to prevent injury to the orifice. The bladder mucosa is then incised between the 12 and 2 o'clock position on the edge of the adenoma. Once the correct plane between the adenoma and the peripheral zone is found, it

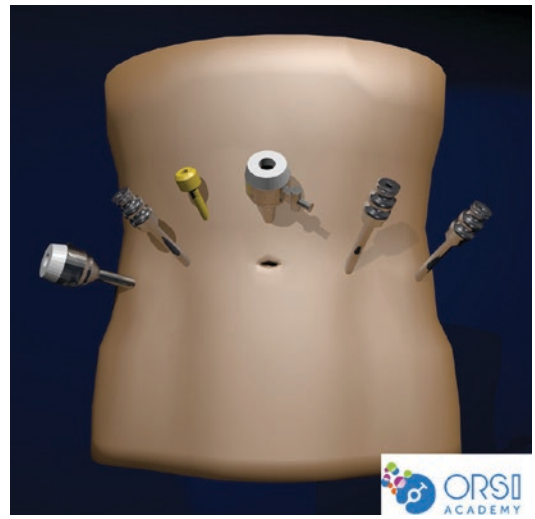

Fig. 31.1 Port placement. Reprinted from Pokorny et al. [4] with permission from Elsevier

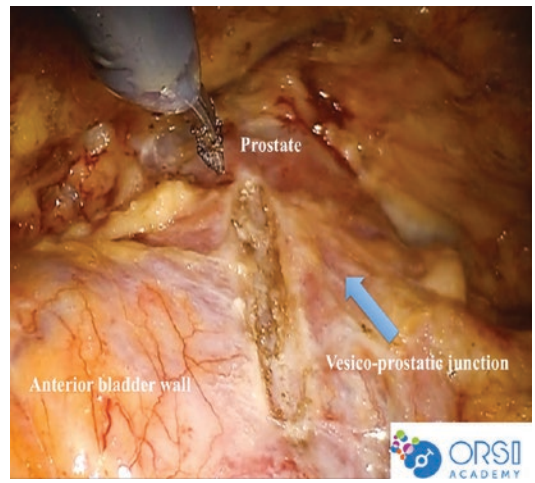

Fig. 31.2 Incision of the anterior bladder wall. Reprinted from Pokorny et al. [4] with permission from Elsevier

is developed using a combination of blunt and sharp circonferential dissection on both sides. Stay sutures, usually made of 1-0 Vycril preloaded with hemolock clips, are used to evert the bladder mucosa in order to improve visualization, as well as to provide traction on the adenoma to assist the dissection (Fig. 31.3).

4. The dissection of the adenoma is carried out distally until the prostatic commissura. Then an anterior commissurotomy is made and the apex of the adenoma is released using sharp dissection to maximize precision (Fig. 31.4).

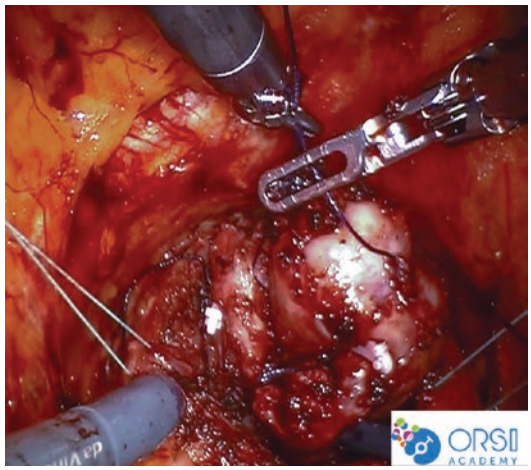

Fig. 31.3 Traction of the adenoma by 1–0 vicryl stay stitches preloaded with hem-o-lock clips. Note presence of Vicryl stay sutures to evert the bladder edges and improve vision. Reprinted from Pokorny et al. [4] with permission from Elsevier

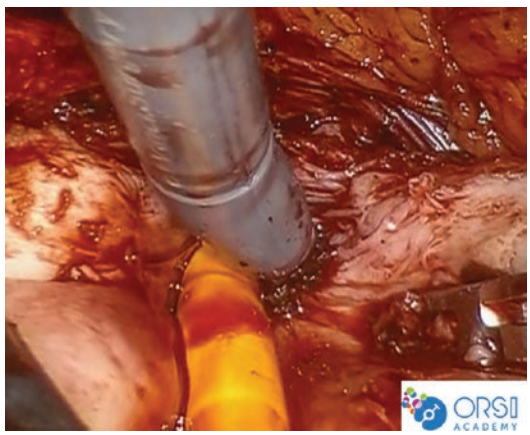

Fig. 31.4 Anterior commissurotomy to free the apex of the adenoma with precise, safe dissection. Reprinted from Pokorny et al. [4] with permission from Elsevier

5. The hemostasis is ensured 3-0 monocryl to seal bleeding vessels in the prostatic bed. The, retrigonization of the prostatic fossa is obtained by advancing the bladder neck mucosa till the level of the prostate apex using a double-layer 3-0 V-Loc (Covidien) running suture, taking care to avoid incorporation of the ureteric orifices (Fig. 31.5).
6. After placing a 20 Fr three-way irrigation catheter, the midline cystotomy is closed using a 3-0 V-Loc with a two-layer suture, a pelvic drain is left in place for 1–2 days. Bladder is typically irrigated for 24 h, whereas the catheter is kept in site for 48–72 h [3].

Conversely, Leslie et al., reporting the initial experience with the surgical technique at the University of Southern California, Los Angeles, CA, USA, proposed to performe a very similar approach thorugh a midline cystotomy at the level of the bladder dome [5].

Conversely, Castillo et al. [6] proposed a modification of the technique for retrigonization of the prostatic fossa, performing a halfway vesico-urethral anastomosis, similarly to what is done during radical prostatectomy. In their technique, a double-needle barbed suture is used to create a posterior urethorvesical anastomosis with the Van Velthoven technique.

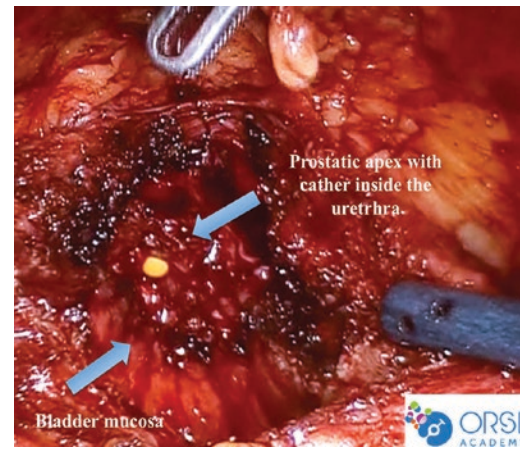

Fig. 31.5 Appearance of the prostatic fossa after advancing the bladder neck mucosa as far distally to the prostate apex as possible using a double layer 3-0 V-Loc™ running suture. Reprinted from Pokorny et al. [4] with permission from Elsevier

Being careful to avoid the ureteral orifices, the posterior bladder neck and urethra are sewn between 3 and 9 o'clock to create a halfway urethrovesical anastomosis [6].

More recently, Clavijo et al. [7] reported an original technique, which denominated "intrafascial" RASP. The technique consists in a complete transperitoneal intrafascial prostatectomy with preservation of the puboprostatic ligaments, periprostatic fascia, and seminal vesicles. The procedure starts with bladder dropping, defatting of the anterior prostate surface, and control of the lateral prostate pedicles. A back-bleeding suture is placed to control the anterior prostatic veins and to ease prostate retraction. Then, endopelvic fascia is incised ventrally, medial to the puboprostatic ligaments, in order to release the neurovascular bundles. Dorsal venous complex is then transected and ligated. Subsequently, sharp and blunt dissection of the neurovascular bundle and contiguous visceral endopelvic fascia is performed in a retrograde manner. The urethra is then dissected and transected as far proximally within the anterior prostate notch as possible to maximize urethral length. Subsequently, a transvesical approach is adopted to transect the median lobe, if present, and dissect completely the lateral prostatic lobes. Notably, the seminal vesicles are identified, transected at the prostate base, and preserved. After controlling of bleeders, two separate sutures are used for the vesicourethral anastomosis in a running fashion. The anterior aspect of the prostatic fascia is finally sutured to the anterior bladder wall [7]. The authors claimed the complete removal of the prostatic tissue together with preservation of sexual function and urinary continence. However, the real advantages of the technique in term of voiding symptoms are not clear as compared with the standard technique and the risks of incontinence and impotency seem to be higher than those of the standard approach. Moreover, if we consider that only the results of 10 patients at 1-month follow-up are reported, the technique has to be considered as investigational.

Transvesical Technique with Extraperitoneal Access

An extraperitoneal approach to RASP has been described by Stolzenburg et al. [8] and John et al. [9]. The extraperitoneal space can be developed in the standard fashion, and the rest of the procedure follows the same steps described above for the transperitoneal technique.

Transcapsular Technique with Transperitoneal Access

This has been described by Sutherland et al. [10]. After reaching the bladder–prostate junction with a tranperitoneal access, a transverse capsular incision is made in the midline with electrocautery, approximately 1–2.5 cm from the prostate–bladder junction. The plane between adenoma and capsule was developed thoroughly using blunt and sharp dissection with Maryland dissector and EndoShears, similar to the transvesical approach. Notably, the authors in the initial cases placed emostatic sutures to control the Santorini plexus, whereas in the subsequent cases controlled the Santorini bleading only with minimal bipolar cautery. Once the adenoma is completely dissected and removed, the interior of the prostate capsule is examined using the 30° down laparoscope and inadvertent capsulotomies are closed primarily with absorbable suture. Subsequently, retrigonization is performed by advancing the posterior bladder neck to the posterior surface of the capsule by interrupted absorbable [10].

Outcomes of Robot-Assisted Simple Prostatectomy

Using the National Inpatient Sample, a database which represents the largest all-payer inpatient database in the US (representing roughly one-fifth of all admissions in the United States), Parisier et al. [11] identified all patients undergoing simple prostatectomy for BPH between 2002 and 2012. The results show that only 1% of

patients underwent SP with minimally invasive (either laparoscopic or robotic) approach. However, using only data from 2008 to 2012, the authors identified minimally invasive approach as one of the conditions associated with lower risk of perioperative complications at multivariable analysis (OR 0.41, $p = 0.014$). Moreover, an increasing trend in the use of minimally invasive techniques was seen, with 5% of the procedure performed that way in the last study year [11].

Tables 31.1 and 31.2 summarize surgical and functional results of RASP in selected published series.

The largest outcome analysis of the minimally-invasive approach to simple prostatectomy is a multicenter series presented by Autorino et al. [12] which examined 1330 minimally invasive simple prostatectomies between 2000 and 2014 at 23 centers. Of these, 487 (36.6%) were robotic and 843 (63.4%) were pure laparoscopic. However, a significant trend towards robotic approach was observed, going from 0% in 2000–2005 to 10.6% in 2006–2008 to 74.3% in 2012–2014. To identify better a favorable SP result, a *trifecta* outcome was defined, combining postoperative International Prostate Symptom Score (IPSS) <8, maximum flow rate >15 ml/s, and no perioperative complications, while the IIEF-5 (International Index of Erectile Function-5) score was used to estimate the impact of the procedures on sexual function. With regard to RASP, 306 (62.8%) of cases were performed using a Millin technique, while 181 (37.2%) with other approaches; 390 (80%) were done transperitoneally and 97 (20%) extraperitoneally. Median OR time was 154.5 (interquartile range 100–180) and the median estimated blood loss was 200 ml (interquartile range: 100–400) and median hemoglobin level on POD1 of 12 (interquartile range 11–13). An intraoperative complication was recorded in 3.2% of cases, and the conversion rate was 3.1%. Median length of stay was 2 d (range: 1–4). Overall postoperative complication rate was 16.6%, mostly of low grade. Specifically, 6.5% of complications were of grade 1 (mostly acute urinary retention requiring catheterization and hematuria requiring catheter irrigation) and 8% were Clavien grade 2 (mainly, urinary tract infections). With regards to grade 3 complications (2%), the most commonly reported were urethral/bladder neck stricture requiring endoscopy (3 cases, 0.6%) and hematuria/clots requiring endoscopy (3 cases, 0.6%). Finally, 1 grade 4 complication (one cases of cardiac heart failure, 0.2%) and 1 grade 5 complication (one death due to incarcerated hernia, sepsis, and multiorgan failure, 0.2%) were reported. Median time to Foley removal was 7 days (IQR 5–9), time to drain removal was 2 days (IQR 1–3), length of stay was 2 days (IQR 1–4). With regard to functional outcomes, median IPSS declined from the preoperative value of 23 (interquartile range: 18–27) to 7 (interquartile range 4–9). Similarly, median Qmax improved from 8 ml/s (interquartile range 5–11) to 25 ml/s (interquartile range 20–33). Median PSA declined from 6.2 ng/ml (interquartile range. 3.7–11) to 1.1 ng/ml (interquartile range 0.5–2), indicating a major reduction in prostatic volume. As far as the impact on sexual function is concerned, baseline and 12-month follow-up values of the IIEF-5 score were substantially unchanged [median 15 (interquartile range 9–21) vs 15 (interquartile range 8–21). At a median follow-up of 12 months, trifecta outcome was achieved in % of the RASP. However, there was no statistically significant difference between the laparoscopic and the robotic group ($p = 0.136$; OR: 1.6) [12].

More recently, Pavan et al. [13] compared the outcomes of laparoscopic and robotic simple prostatectomy, reporting on 319 consecutive cases of LSP and RASP done between 2003 and 2014 at 3 participating institutions. The two groups did not differ at baseline in terms of age, BMI, and Charlson Comorbidity Index, whereas a higher proportion of patients with history of previous surgery (32% vs 21%, $P = 0.02$), higher IPSS scores (median 23 vs 17, $P < 0.001$) and QoL score (median 6 vs 5, $P = 0.001$) and larger total prostate volume (median 118.5 ml vs 109 ml, $P = 0.02$) were all present in the RASP group. The median operative time and EBL tended to be higher in the RASP group, but without reaching statistical significance. No difference was found in terms of intraoperative complications, conversion rate, catheterization

Table 31.1 Demographics and surgical outcomes in selected RASP series published in the literature

Reference	Case	Median preop. Prostate volume (IQR)	Median preop. IPSS (IQR)	Median preop. Qmax, ml/s (IQR)	Median preop. PSA, ng/ml (IQR)	Median operative time, min (IQR)	Median estimated blood loss, ml (IQR)	Postop.any grade and high-grade complication rates	Median in-hospital stay, days (IQR)	Median catheterizatio, days (IQR)
Transvesical technique with transperitoneal access										
Sotelo [3]	7	78 (40–106)	22 (10–32)	18 (7.5–28)	12.5 (4.22–20)	195 (120–300)	382 (60–800)	0	1 (1–2)	7.6 (6–10)
Leslie [5]	25	149.6 (91–260)	23.9 (9–35)	11.3 (4–20)	9.4 (1.9–56.3)	214 (165–345)	143 (50–350)	20%/12%	4 (2–16)	9.0 (7–23)
Pokorny [4]	67	129 (104–180)	25 (20–28)	7 (5–11)	6.5 (3.8–12)	97 (80–127)	200 (115–360)	30% / 9%	4 (3–5)	3 (2–4)
Castillo [6]	34	117 (99–146)	23.5 (22–27)	7.3 (9.5)	7.3	96 (78–126)	200 (100–300)	20%/3%	2 (1–4)	5 (4–6)
Clavijo [7]	10	81 (47–153)	18.8 (5–31)	12 (4.6–24)	5.8 (1.9–11)	106 (60–180)	375 (150–900)	Not reported	1 (0–3)	8.9 (6–14)
Transvesical technique with extraperitoneal access										
Stolzenburg [8]	10	144 (90–250)	21.9 (16–30)	9 (5–11)	7.31 (4.2–11.9)	122.5 (85–140)	228.8 (50–540)	10%/0	8.4 (7–9)	7.4 (6–8)
John [9]	13	100 (90–180)	Not reported	Not reported	Not reported	210 (150–330)	500 (100–1100)	Not reported	6 (5–15)	6 (3–15)
Multi-center series with mixed techniques and accesses										
Autorino [12]	487	110 (86–140)	23 (18–27)	8 (5–11)	6.2 (3.7–11)	154 (100–180)	200 (100–400)	17%/2%	2 (1–4)	7 (5–9)
Pavan [13]	130	118 (100–140)	23 (19–27)	9 (7–12)	6.1 (3.6–9.7)	150 (98–180)	250(127–450)	18%/2%	5 (5–6)	5 (4–6)

Table 31.2 Functional results in selected RASP series published in the literature

Reference	Case	Median/mean follow-up duration, mo (IQR)	Median/mean postop.IPSS (IQR)	Median/mean postop. Qmax, ml/s (IQR)	Median/mean postop. PSA, ng/ml (IQR)
Transvesical technique with transperitoneal access					
Sotelo [3]	7	Not reported	7.25 (2–13)	55.5 (36–83)	–
Leslie [5]	25	6	3.58 (0–6)	20 (12–35)	1.48 (0.06–4.0)
Pokorny [4]	67	6	3 (0–8)	23 (16–35)	0.6 (0–1.3)
Castillo [6]	34	6	7	23	–
Clavijo [7]	10	1	2.2 (1–5)	33 (17–47)	0.2 (0–0.8)
Transvesical technique with extraperitoneal access					
Stolzenburg [8]	10	6	3	22	–
John [9]	13	13 (2–18)	Not reported	23 (3–33)	Not reported
Multi-center series with mixed techniques and accesses					
Autorino [12]	487	12	7 (4–9)	25 (20–33)	1.1 (0.5–2)
Pavan [13]	130	10	5 (4–10)	22 (18–28)	2 (0.5–3.1)

time, time to drain removal and hospital stay. RASP group showed similar prevalence of high-grade complications (2.3% vs 2.1%, respectively), although the low-grade complications were more commonly reported in the robotic group. However, no grade 5 complication was recorded in either group. Achievement of the trifecta outcomes was not significantly influenced by the type of procedure (OR: 0.44, $p = 0.09$), while age and BMI had a significant impact on the functional outcome [13].

Umari et al. [14] recently reported a single institution comparative analysis of 81 RASP and 45 Holep performed from 2008 to 2015 in patients with large prostates (>100 ml) and severe LUTS. Patients undergoing RASP were younger (median age: 69 vs. 74 years, $p = 0.032$), with higher comorbidity score (CCI ≥ 2: 62% vs. 29%, 12 $p = 0.0003$), and with a higher preoperative IPSS (25 vs. 21, $p = 0.049$). The median OR time (105 vs 105 min; $p = 0.9$) and post-op hemoglobin level (13.2 vs 13.8 g/dl; $p = 0.08$) were similar in RASP and HoLEP, respectively. The median catheter time (3 vs 2 days; $p = 0.005$) and length of stay (4 vs 2 days; $p = 0.0001$) were shorter for the HoLEP group. Despite no differences in preoperative reported prostate volume, the postoperative median prostate weight was different with 89 g in the RASP group and 112 in the Holep one. Postoperative complications were similar in both groups. Both groups showed a similar improvement of maximum flow rate (+15 vs +11 ml/s, $p = 0.7$), a significant reduction of post-void residual urine (−73 vs −100 ml, $p = 0.4$) and IPSS Score (−20 vs −18, $p = 0.8$), without significant difference between the two groups. Notably, 1.2% (1 case) of the RASP patients and 8.9% of the Holep group (4 cases) reported transient urinary incontinence with resolution within 6 months from the surgery [4]. Although extremely interesting, this retrospective comparative study is small, lacks of multivariable analyses which might have adjusted for the observed differences in baseline patients characteristics and, above all, represent the experience of a single center. Moreover, detailed analyses of learning curve and costs comparisons are lacking in the literature.

Conclusions

The optimal treatment for large prostatic adenomas is still under discussion. While RASP is being implemented in Centers with an active robotic urologic program, many urologists continue to prefer the endoscopic approach, due to the availability of bipolar resectoscope or Holep, which, in experienced hands, may allow treatment even in case of large adenomas. All the techniques have advantages and disadvantages, with endoscopic approach potentially being associated with lower invasiveness, shorter catheter time and hospital

stay, and lower overall cost. Conversely, especially Holep is associated with a steep learning curve, supposed to be at least 50 to 70 cases [15–18]. Moreover, according recent data [14] the risk of transient urinary incontinence might be higher following Holep.

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Robot-Assisted Simple Prostatectomy

32

Daniel Melecchi Freitas, Nariman Ahmadi, Sameer Chopra, and Monish Aron

Abstract

In the growing number of options in the management of benign prostatic hyperplasia, robotic-assisted simple prostatectomy has gained significant momentum in recent years. Since the first report in 2008, confirming the feasibility and safety of this treatment modality, several other techniques and modifications have been described. In this chapter, we mainly focus on our institution's current operative technique of robotic simple prostatectomy and provide a brief review of a few alternative approaches within the literature.

Keywords

Prostatectomy · Hyperplasia · Robotic · Robot-assisted · Adenoma

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Introduction

Benign prostatic hyperplasia (BPH) is a common condition in men, caused by non-malignant enlargement of the prostate gland due to stromal and epithelial prostatic tissue hyperplasia. The management options range from watchful waiting and medical therapy to endoscopic and open surgical management. Despite the numerous endoscopic surgical treatment options previously described, in cases where the prostate volume is large, or there are concurrent pathologies such as bladder stones or large bladder diverticulum, open simple prostatectomy provides advantages over the endoscopic therapies. In the past 2 decades, minimally invasive surgical techniques have evolved significantly with the aim of minimizing post-operative pain and length of stay as well as reduction in blood loss and transfusion rates. Two studies compared laparoscopic simple prostatectomy to open suprapubic prostatectomy, finding significantly lower perioperative complication rates, estimated blood loss as well as reduced length of catheterization and length of hospital stay in the laparoscopic group [1, 2]. Robot-assisted simple prostatectomy (RASP) was first performed in 2008, where authors introduced the surgical techniques and confirmed its feasibility and safety [3]. The robotic platform overcomes some of the limitations of laparoscopic surgery

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by providing three dimensional visualization and improved dexterity during resection and suturing. In a recent systematic review, RASP demonstrated decreased blood loss, transfusion rates, length of hospital stay and postoperative complications with comparable functional outcomes compared to open simple prostatectomy [4]. These findings were further confirmed by a multi-institutional study that included 23 institutions [5]. Our group has previously published our preliminary experience with robot-assisted simple prostatectomy using a transperitoneal, transvesical, suprapubic approach [6]. Herein, we describe our surgical technique and provide a brief overview of the alternative approaches in robot-assisted simple prostatectomy.

Preoperative Evaluation

The preoperative evaluation of patients being considered for RASP includes history, physical examination, digital rectal exam (DRE), laboratory testing including kidney function tests, urinalysis and reflex culture, and prostate specific antigen (PSA). Patients are requested to fill out validated questionnaires including International Prostate Symptom Score (IPSS) and Sexual Health Inventory for Men (SHIM). Uroflowmetry with peak flow rate (Qmax) and bladder scanning for post void residual volume assessment, as well as ultrasound or CT scan assessment to estimate prostate volume are also utilized in the preoperative setting. Prostate cancer should be excluded in patients with high clinical suspicions such as elevated PSA levels or abnormal DRE. Patients are counseled about all treatment alternatives, risks-benefit analyses as well as potential complications including the possibility of conversion to open surgery. Antiplatelet and anticoagulant medications are discontinued for a sufficient length preoperatively and medical clearance is obtained if necessary. Preoperative bowel preparation is usually not required. Prophylactic intravenous antibiotics are administered at induction of anesthesia prior to skin incision and are usually discontinued 24 h after surgery.

Operative Room Setup

Operative room set up is shown in Fig. 32.1. The assistant and the scrub technician are both positioned on the left side with a mayo stand directly in front of the assistant where frequently used instruments are placed. The da Vinci® Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) will be docked in between the patient's legs for the Si robot or on the right side of the patient for the Xi robot. The instrumentation and equipment list are provided below:

Instrumentation and Equipment list

Equipment

- 0° robotic scope (Intuitive Surgical, Inc., Sunnyvale, CA).
- Monopolar Scissors (Intuitive Surgical, Inc., Sunnyvale, CA) × 1.
- ProGrasp™ Forceps (Intuitive Surgical, Inc., Sunnyvale, CA) × 2.
- Needle Drivers (Intuitive Surgical, Inc., Sunnyvale, CA) × 2.
- Tenaculum Forceps (Intuitive Surgical, Inc., Sunnyvale, CA) x 1.

Trocars

- 12 mm trocars × 2 (1 for the Xi).
- 8 mm trocars x 3 (4 for Xi).

Assistant Instruments

- Suction irrigator device (Bariatric length).
- Laparoscopic spoon forceps.
- Hem-o-lok applier (Teleflex Medical, Research Triangle Park, NC).
- Medium (purple) Hem-o-lok clips (Teleflex Medical, Research Triangle Park, NC).
- Laparoscopic Needle driver.
- Laparoscopic scissor.
- 10 mm specimen entrapment bag.

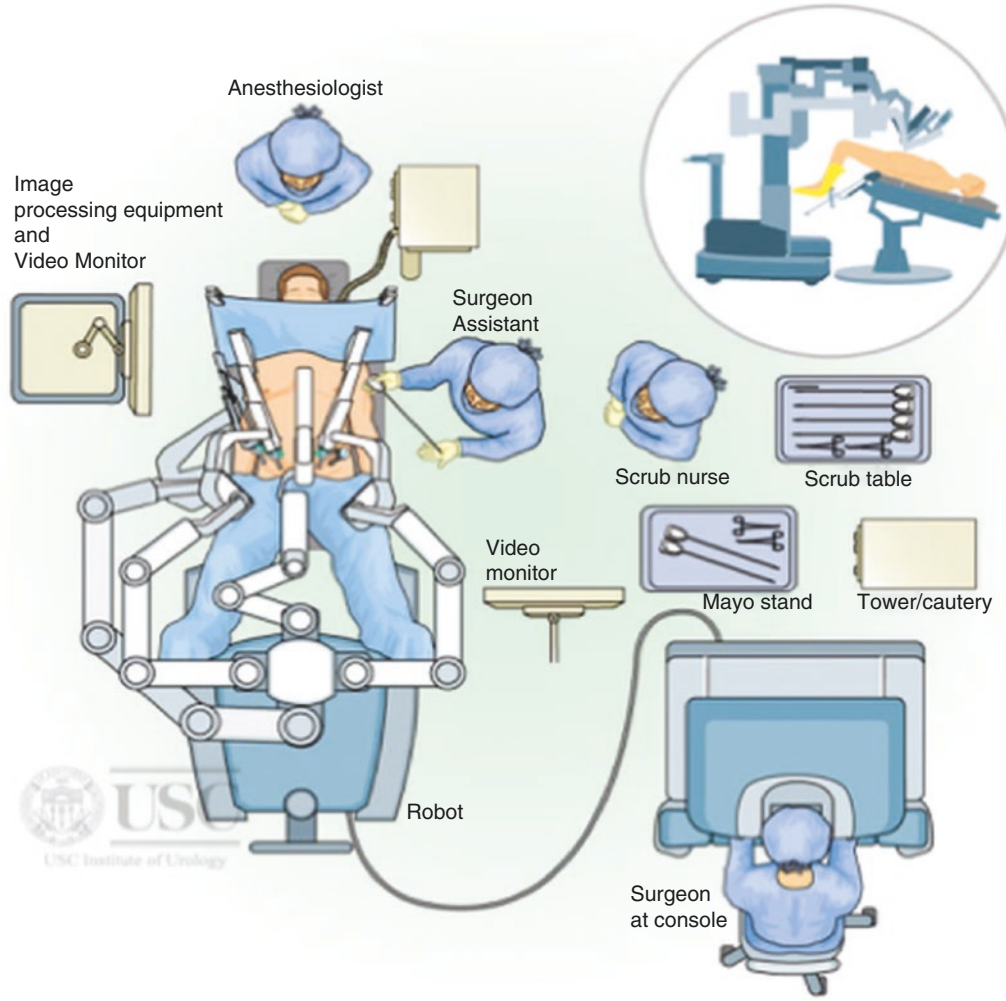


Fig. 32.1 OR Set up

Operative Technique

Transperitoneal, transvesical suprapubic approach is the current preferred technique for RASP at our institution. Under general anesthesia and after sterile preparation and draping, a 16F urethral catheter is inserted with 10 ml in the catheter balloon. A 12 mm midline incision is made 2 fingerbreadths above the level of the umbilicus. Pneumoperitoneum to 15 mmHg is established using a Veress needle and the 12 mm camera port (8 mm with Xi system) is inserted. Our robotic port placement mimics that of robotic assisted radical prostatectomy with 8 mm working trocars all placed at the horizontal level of the umbilicus with a separation of 8–10 cm between trocars. We prefer to keep the 4th robotic arm on the right side of the patient. A 12-mm assistant trocar is placed in the left upper quadrant taking care to avoid being too close to the camera trocar or the left robotic arm (Fig. 32.2). Currently we prefer to use the AirSeal® (ConMed, Utica, NY) trocar as the assistant port. The patient is then placed in steep Trendelenburg position and the robotic is subsequently docked and the instru-

ments inserted under direct vision. Sigmoid colon and small bowel loops are mobilized out of the pelvic cavity if necessary, and the bladder is filled with 150–200 ml of normal saline. The dome of the bladder is subsequently identified and a vertical midline cystotomy is made to gain access to the bladder lumen (Fig. 32.3). We deploy 2-4 stay sutures (2-0 Vicryl on CT-1 needle, 6 inches long) to retract the cystotomy edges laterally and anchor them to the abdominal wall to obtain adequate exposure and access to the prostate adenoma and bladder neck (Fig. 32.4). In cases where the median lobe is protruding intravesically, a retraction suture (2-0 Vicryl, 6 inches long suture, on CT-1 needle with a hem-o-lok clip tied into the tail end) is utilized to aid in the dissection of the median lobe by providing vertical retraction during dissection (Fig. 32.5). Both ureteral orifices are identified prior to commencing enucleation. A circumferential mucosal incision is made at the junction of the prostate with the bladder neck, taking care to avoid injuring the ureteral orifices. In cases with a very large intravesical adenoma, or where ureteral orifices are too close to the prostate, or where simultaneous bladder diverticulectomy is to be performed, 5F ureteric catheters or double J stents can be inserted (Fig. 32.6) according to surgeon preference. Intravenous Indigo carmine can be used to help identify ureteric orifices in heavily trabeculated bladders. Following the mucosal incision, with the median lobe retracted vertically upwards, the plane between adenoma and the compressed peripheral zone of the prostate is identified (Fig. 32.7). Enucleation is performed using a combination of blunt and sharp dissection with pinpoint monopolar coagulation of the perforating vessels (Fig. 32.8). A concurrent hemostasis approach during enucleation will improve visualization of the correct enucleation plane and reduces operative blood loss. The plane of dissection should hug the pearly white surface of the adenoma and care should be taken to avoid transgressing the compressed peripheral zone and the prostate capsule. Once enough of the adenoma has been freed up, the previously placed stay suture in the median lobe is removed and the adenoma is grasped with a robotic Tenaculum forceps, brought in under vision through the fourth

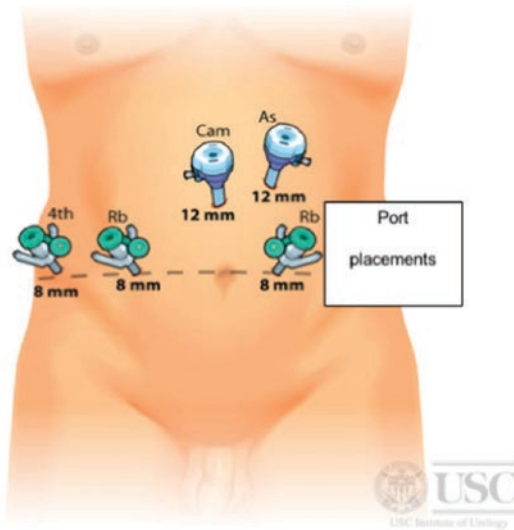
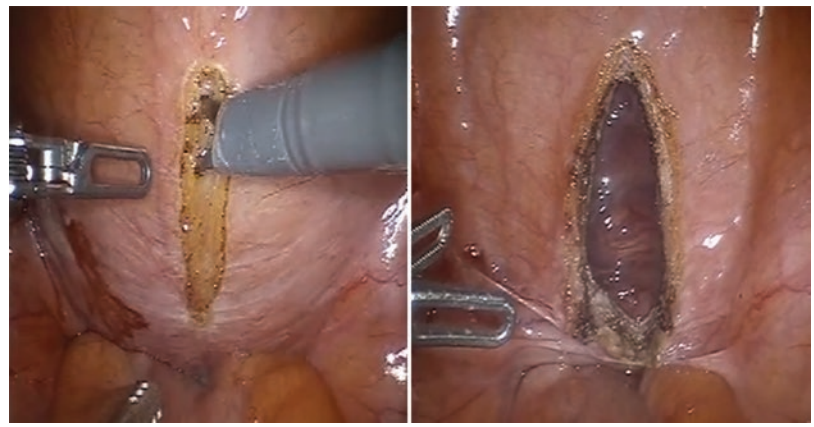


Fig. 32.2 Trocar placement

Fig. 32.3 Vertical midline cystotomy



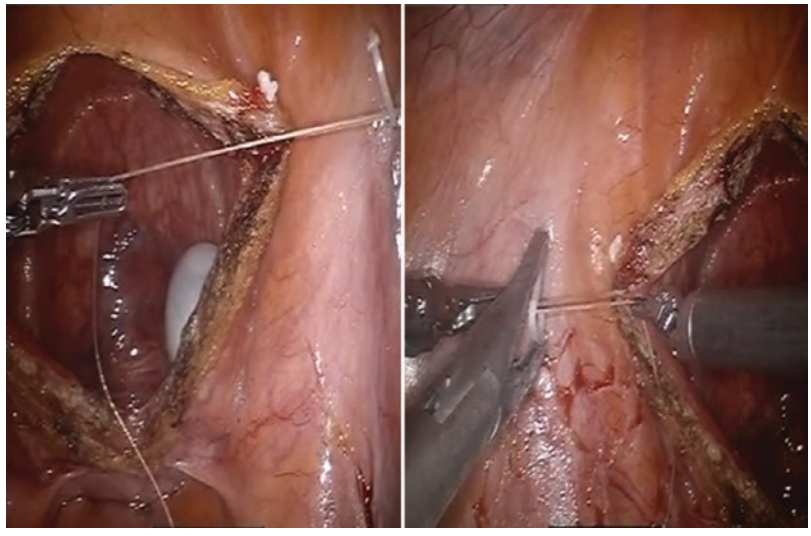


Fig. 32.4 Stay sutures to keep the edges of the cystotomy apart

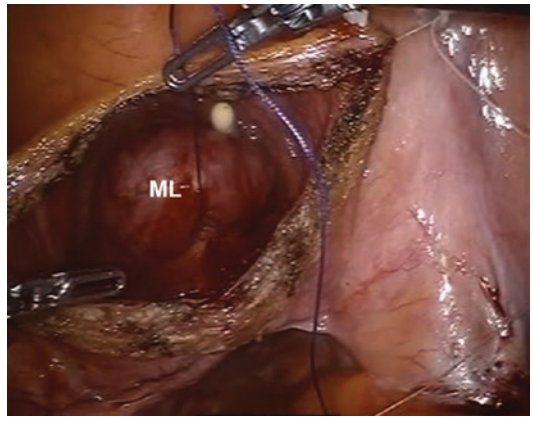


Fig. 32.5 Median lobe traction suture, ML: median lobe

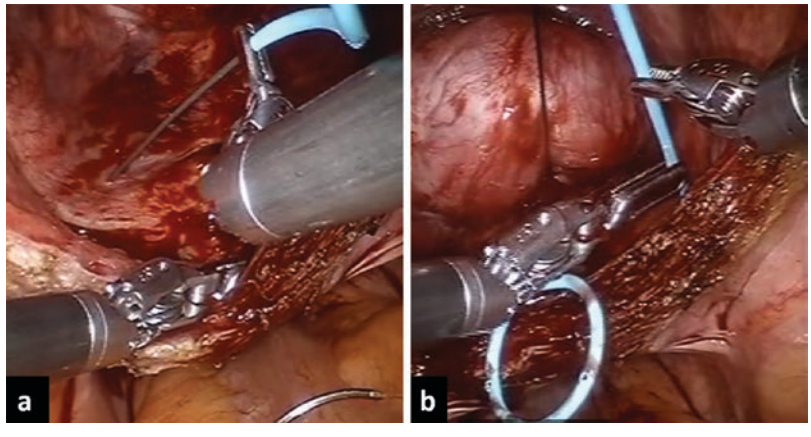


Fig. 32.6 Ureteral stent insertion, (**a**): left ureteral orifice, (**b**): right ureteral orifice

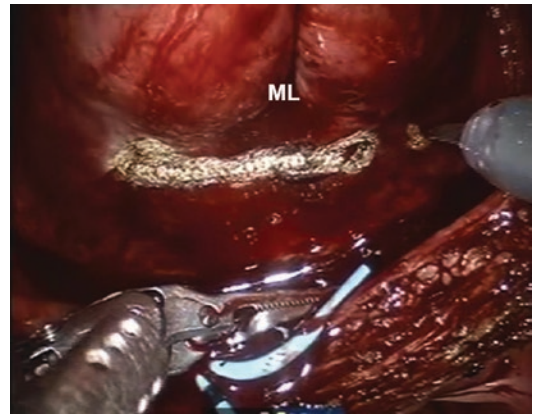


Fig. 32.7 Bladder mucosal incision, ML: median lobe

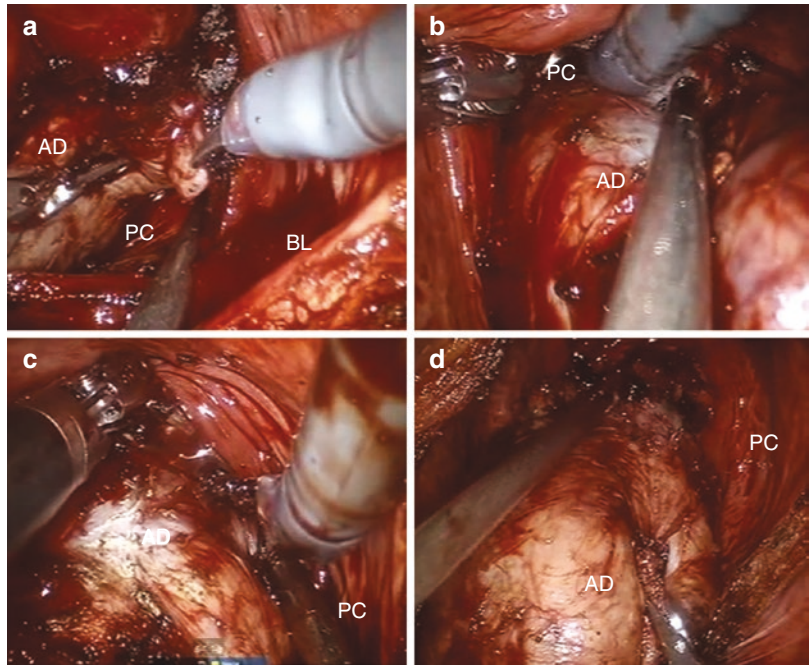


Fig. 32.8 (**a**) Posterior dissection, (**b** and **c**) Anterior dissection and (**d**) completing adenoma enucleation.
PC = prostate capsule, BL = bladder, AD = adenoma

robotic arm. The Tenaculum forceps provides an excellent grip on the adenoma, and allows strong retraction and counter traction to aid in the dissection of the adenoma. The lateral aspect of the adenoma is subsequently mobilized down towards the apical tissue, where the lateral shoulders of the adenoma start tapering medially towards the membranous urethra. At the apex, the urethral mucosa is sharply incised and adenoma is completely released from the prostate peripheral zone and placed in a retrieval bag (Fig. 32.9). The prostatic fossa is now carefully examined for

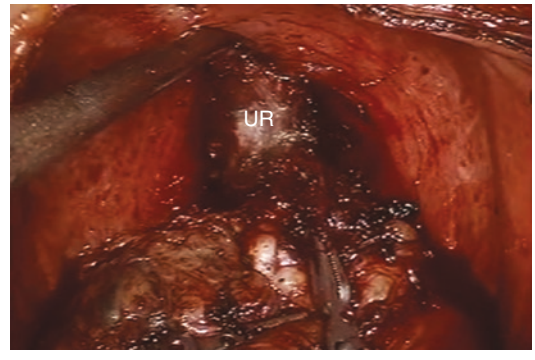


Fig. 32.9 Urethral exposure, UR: urethra

any residual adenoma, especially in the apical region, which can then be excised. Meticulous hemostasis is achieved by direct pinpoint electrocautery or suture ligation of the bleeding points. The main blood vessels are commonly located at the 5 and 7 o'clock position distal to the bladder neck and smaller vessels are at similar locations closer to the prostatic apex. We do not routinely re-trigonize the prostatic fossa. After perfect hemostasis is achieved, a 22F three-way catheter is placed through the urethra, and the balloon inflated with 30 ml of sterile water. The catheter is subsequently placed on gentle traction. The stay sutures at the edges of the cystotomy are now released and removed. The bladder is now closed in 2 layers with 2-0 V-loc sutures (Covidien, Norwalk, CT, USA) (Fig. 32.10) and a 19F corrugated suction drain is placed through the trocar site of the 4th robotic arm, and positioned in the rectovesical pouch. The bladder is distended with 300 ml of saline to check for leaks from the cystotomy. Continuous bladder irrigation is then initiated to ensure a clear return without any clots. The robotic instruments and ports are subsequently removed under direct vision, the robot is undocked and the patient is returned to supine position. The camera port incision is extended according to the size of the specimen and the adenoma is extracted. The fascia is closed with 0-PDS figure of eight sutures and port sites are infiltrated with local anesthetic and closed with absorbable subcuticular 4-0 monocryl sutures. Post operatively, compression stockings and subcutaneous heparin are used during the hospital stay to prevent thromboembolic events. Continuous bladder irrigation is stopped on the first postoperative day if the urine is clear or light pink in color. The drain is removed prior to discharge after confirming absence of any urine leak with a drain fluid creatinine. Our current median length of hospital stay is 3 days. The urethral catheter is removed on post-operative day 7 with a voiding trial. A follow up visit is scheduled at 3 months for review of symptoms, uroflowmetry, post-void residual urine assessment and patients are requested to fill out IPSS and SHIM questionnaires. Our current experience with this technique exceeds 150 cases. We previously described our initial outcomes in 25 patients who underwent RASP via a transvesical suprapubic approach in 2014. The mean blood loss was 143 ml with a mean preoperative TRUS prostate volume of 149.6 ml. The mean operative time was 214 min and the mean length of hospital stay was 4.0 days (range 2–16). Early functional outcomes demonstrated significant improvement from baseline with an 85% reduction in mean IPSS ($p < 0.0001$), an 82% reduction in mean PVR ($p = 0.014$), and a 77% increase in mean Qmax ($p = 0.20$) [6].

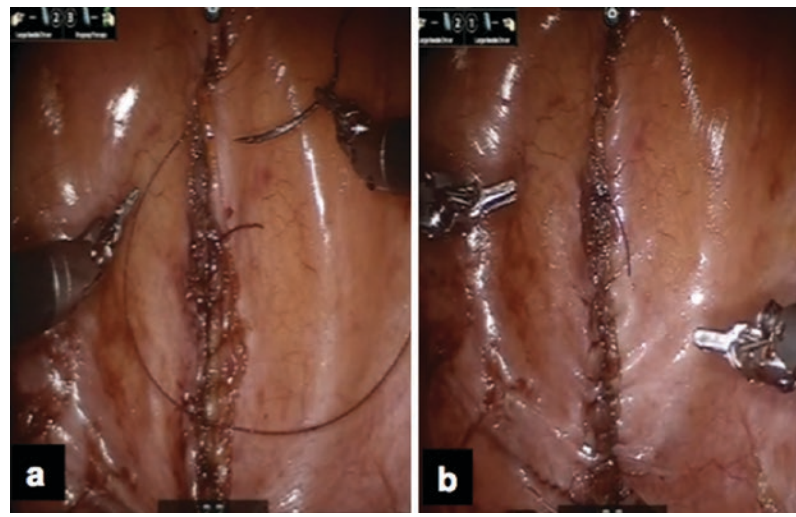


Fig. 32.10 (**a**). Bladder closure. (**b**). Final aspect

Transperitoneal Retropubic Transvesical Approach

Unlike the previously described approach, in this technique, the bladder is dropped from the anterior abdominal wall in a fashion similar to the robotic assisted radical prostatectomy technique. The periprostatic fatty tissue is excised and prostatovesical junction identified. The bladder is retracted cephalad using the fourth robotic arm and a transverse cystotomy is made about 2 cm proximal to the bladder neck and extended laterally to provide exposure to the bladder neck and adenoma. Following identification of bilateral ureteral orifices, a retraction suture is placed and enucleation is performed in a manner similar to the previously described technique. Following hemostasis and placement of a 24F 3-way catheter, the bladder is closed in 2 layers with 2-0 V-Loc sutures. The bladder is flushed and the closure is tested for any leak. A pelvic drain is placed adjacent to the bladder and the specimen is extracted.

Sotelo et al. [7] described their initial experience using this technique in 7 patients, demonstrating safety and feasibility of RASP. The mean operative time was 195 min with mean estimated blood loss of 380 ml. The mean specimen volume was 50.58 g and the mean length of hospital stay was 1.33 days.

Pokorny et al. [8] published their experience with 67 patients with a retropubic transvesical approach. The bladder incision was performed just above the prostatovesical junction. Following enucleation of the adenoma, bladder neck mucosa was advanced and sutured to the distal prostatic fossa for re-trigonization using 3-0 V-loc sutures. The median operative time was 97 min and estimated blood loss was 200 ml. The median catheterization time was 3 days and length of hospitalization was 4 days. At follow-up, the median IPSS improved from 25 to 3 and median maximum flow rate increased from 7 ml/s to 23 ml/s.

In an attempt to decrease perioperative bleeding and postoperative bladder irrigation, Coelho et al. [9] suggested three technical modifications. Using a transperitoneal retropubic transvesical approach, the adenoma was enucleated, hemostatic sutures were applied at the 5 and 7 o'clock position, and the posterior prostatic capsule was plicated. Instead of retrigonization, the bladder neck was anastomosed to urethra using continuous sutures and the anterior prostatic capsule was sutured to anterior bladder neck. The authors reported their outcomes in 6 patients with mean prostate volume of 157 cm [3]. All patients were discharged on postoperative day 1 without requiring any post-operative bladder irrigation.

We do not favor dropping the bladder for a robotic simple prostatectomy, because this will make a subsequent robotic radical prostatectomy more difficult, in the event that a patient is later diagnosed with prostate cancer and opts for surgery.

Extraperitoneal Transvesical Approach

In this technique, the peritoneal cavity is not entered; instead, the preperitoneal space is expanded using a balloon dilator (spherical or bean-shaped), and the surface of the bladder is exposed. A vertical or horizontal cystotomy is made to expose the prostatic adenoma and the bladder neck. The remaining steps of the procedure are similar to previously described techniques.

Stolzenburg et al. [10] published their experience with an extraperitoneal approach with a modified vertical bladder incision extending on to the anterior prostatic capsule. Following application of stay sutures and lateral retraction of the edges of the cystotomy, the adenoma was enucleated and hemostasis achieved using bipolar cautery and hemostatic sutures. Re-trigonization was performed. Following insertion of a 3-way catheter, the vertical cystotomy was closed in two layers. In a series of ten patients with mean prostate volume 129.4 ml (range, 90–170 ml), the mean operative time was 122.5 min (range, 85–140 min), and estimated blood loss was minimal (mean value, 230 ml). Mean catheterization duration was 7.4 days (range, 6–8 days). In addition to avoiding entry into the peritoneal cavity, another potential advantage of the extraperitoneal approach is that less of a Trendelenburg tilt is required during the procedure.

Transcapsular Retropubic Approach

After accessing the space of Retzius, the transition between the bladder and prostate is identified. A transverse capsulotomy is performed through the prostatic capsule and the peripheral zone is compressed, approximately 2 cm distal to the bladder neck. The 4th arm is used to retract the bladder cephalad. Careful identification of the median lobe and ureteral orifices must be done. Subsequently, the plane between the adenoma and peripheral zone is identified and a blunt and sharp dissection is performed similar to previous techniques. Following completion of enucleation and obtaining hemostasis, the capsulotomy is closed with absorbable suture(s). A 3 way Foley catheter is inserted in the bladder. A drain is positioned in the retropubic space.

Yuh et al. [11] described the first series in 2008 in 3 patients with a transperitoneal retropubic transcapsular approach. The mean TRUS prostate volume was 323 ml with a median weight of 301 g excised. Mean operative was 211 min and mean estimated blood loss was 558 ml. The mean length of hospital stay was 1.3 days.

Sutherland et al. [12] reported a series of 9 patients with a transperitoneal retropubic transcapsular approach. They reported a single case of conversion to open surgery due to excessive bleeding. The mean prostatic TRUS volume was 136.5 ml and 82% of the TRUS volume was excised.

While this approach is most similar to a Millin's open prostatectomy and avoids opening the bladder itself, it does require dropping the bladder and entry into the space of Retzius, and in our opinion does not offer any benefit over the transvesical approaches.

Robotic Single-Port Transvesical Approach

Fareed and colleagues reported their initial experience of robotic single-port extraperitoneal suprapubic transvesical RASP [13]. The procedure begins with a cystoscopic transurethral incision of the mucosa of the prostatic urethra at the apex. The bladder is then distended and a skin incision is made three finger-breadths above the pubic symphysis. Two stay sutures are placed at the dome of the distended bladder and the bladder is entered sharply. A Gelport™ (Applied Medical, Santa Margarita, California, USA) is deployed in the bladder through the incision at the dome and four ports are placed through the gel: a 12 mm camera port, a 8 mm robotic port, and two 5 mm robotic ports. The adenoma is enucleated under pneumovesicum at 20 mmHg using a harmonic scalpel in the right hand with a 30° up scope. Digital rectal assistance may be required at the apex. After obtaining hemostasis in the prostatic fossa, a large caliber 3-way catheter is indwelled and the adenoma extracted through the ring of the Gelport™. In their series of 9 patients, the mean prostatic TRUS volume was 146 g (range 83–304) with a mean pathology resection weight of 78 g (range 32–261). The median operative time was 3.9 h and median estimated blood loss was 425 ml with two patients requiring transfusion. The median length of hospital stay was 4.5 days [13].

At our institution, we have some experience with this technique, and we feel it adds substantially to the complexity of the procedure, and does not offer advantages that justify the added technical complexity.

Intrafascial Total Prostatectomy

In 2013, Clavijo et al. [14] described a technique of "Intrafascial Robotic Simple Prostatectomy (IF-RSP)". This is an intriguing approach where they performed a total prostatectomy using a technique similar to intrafascial radical prostatectomy, with complete resection of the prostatic volume on pathologic assessment. By using an intrafascial technique, they reported the ability to preserve the puboprostatic ligaments, the periprostatic fascia and the seminal vesicles. In this approach, sutures are placed in the lateral pedicles and in the anterior prostatic veins. The endopelvic fascia is incised just medial to the puboprostatic ligaments and the neurovascular

bundle is dissected away from the prostate. After incising the urethra, a horizontal cystotomy is made at the prostatovesical junction. The prostate is dissected away from the bladder neck and the seminal vesicles are transected at the base. The excision of the prostate is performed in an intra-fascial plane. They reported their findings on the initial 10 patients. Mean preoperative prostatic volume was 81 ml and on final pathology, the mean specimen weight of was 81 grams [14].

Garzon et al. [15] analyzed 236 eligible patients that underwent three different surgical techniques for simple prostatectomy by a single surgeon; laparoscopic simple prostatectomy (n = 82), conventional RASP (n = 79), and RASP via an intra-fascial approach (IF-RSP, n = 75). The IF-RSP was found to have resulted in highest percentage of prostate volume removed (98.6% vs. 85% vs. 94.6% for IF-RSP, RASP, and laparoscopic simple prostatectomy, respectively); however this difference was statistically not significant. Continence at one and three months statistically favored RASP and laparoscopic simple prostatectomy over IF-RSP, however at 12 months, the continence rates were similar between the 3 groups. Erectile function at one and six months favored RASP and laparoscopic simple prostatectomy over IF-RSP, however at 12 months, there was no difference [15].

Complications

Potential complications that can occur following RASP include the following:

1. Bleeding

Bleeding is the most common complication during and after surgery. The best approach to minimize postoperative bleeding is to achieve meticulous hemostasis intraoperatively, using either direct cautery or suture ligation of the bleeding vessels. Time spent during the surgery to obtain perfect hemostasis will directly result in decreased postoperative bladder irrigation requirement and shorter length of hospital stay. Communication with the anesthesia team is important so they are aware of the need for a smooth reversal of anesthesia and extubation. Bladder irrigation should continue until the return is clear or light pink. This is usually the case within the first 24 h. If necessary, the catheter can be placed on gentle traction, and can help with minor bleeding by providing compression in the prostatic fossa. Restarting antiplatelet therapy and therapeutic anticoagulation should be weighed against their benefits and individualized to patients based on their clinical scenario.

2. Urinary tract infection (UTI)

UTI is the second most common complication after RASP with approximately 4.5% of patients undergoing RASP developing post-operative UTI [8]. Preoperative evaluation must be performed to exclude urinary tract infection and any preexisting UTI must be treated prior to surgery.

3. Urinary Incontinence

Post-operative urinary incontinence has been reported in about 0.3% of 1330 patients undergoing minimally-invasive simple prostatectomy [5]. Urinary incontinence in RASP is most likely due to external sphincter injury, however it is not uncommon for patients with BPH to have concurrent detrusor overactivity. The most crucial step to minimize sphincter injury is the apical dissection. Care should be taken to avoid undue traction and thermal injury during apical dissection.

4. Sexual Dysfunction (impotence and retrograde ejaculation)

Erectile dysfunction can be evaluated using the Sexual health inventory for men (SHIM) questionnaire. It has been reported in less than 5% of patients, both in open and minimally invasive series [5, 16]. Generally it is transient and the majority of patients recover their pre-existing erectile function in a few months. Post-operative

PDE5 inhibitors can aid in recovery of erectile function. Retrograde ejaculation is extremely common after RASP, and all patients should be counseled about this preoperatively.

Postoperative Care and Follow Up

While in hospital, intermittent compression stockings and subcutaneous heparin are used to prevent thromboembolic events. The patient also receives continuous bladder irrigation on the first day and this is stopped once the return is clear, or a light pink color. The suction drain is removed before discharge from the hospital after confirming absence of urine leak with a drain fluid creatinine. Our current median length of hospital stay is three days and patients return to clinic on day 7 for a voiding trial [6]. Routine cystograms are not necessary. The patient then returns for a follow up visit three months after the surgery for symptom check, uroflowmetry, postvoid residual urine measurement, and administration of continence and sexual function questionnaires. Subsequent follow up visit can be scheduled in 6 months and then annually thereafter.

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Robot-Assisted Radical Prostatectomy: A Prostate Surgeon's Perspective

Hao G. Nguyen, Cole Davis, Helena Chang, and Peter R. Carroll

Abstract

The availability and promulgation of robotic technology have resulted in a paradigm shift in the use of radical prostatectomy. Historically radical prostatectomy was performed using an open approach, usually the retropubic approach and rarely using a laparoscopic approach. Recently, however, robotic-assisted radical prostatectomy (RARP) [1] has swept across the United States at an extremely rapid rate, accounting for greater than 85% of cases performed in 2011 [2, 3]. While the early adopters and promoters of RARP were laparoendoscopic specialists, the robotic-assisted approach is becoming the procedure of choice for urologic oncologists as well. In addition, residents are being trained in the use of such technology. The actual costs, benefits, and risks of robotic as compared to open radical prostatectomy remain somewhat controversial. Often lost in such debate is the role of radical prostatectomy, by whatever approach, in the management of prostate cancer, given the considerable stage/grade migration that has occurred because of widespread PSA testing and the mounting concerns regarding prostate cancer over detection and treatment.

Keywords

Robotic prostatectomy · Open prostatectomy · Surgical outcomes · Cancer control · Urinary function · Sexual function

Introduction

The availability and promulgation of robotic technology have resulted in a paradigm shift in the use of radical prostatectomy. Historically radical prostatectomy was performed using an open approach, usually the retropubic approach and rarely using a laparoscopic approach. Recently, however, robotic-assisted radical prostatectomy (RARP) [1] has swept across the United States at an extremely rapid rate, accounting for greater than 85% of cases performed in 2011 [2, 3]. While the early adopters and promoters of RARP were laparoendoscopic specialists, the robotic-assisted approach is becoming the procedure of choice for urologic oncologists as well. In addition, residents are being trained in the use of such technology. The actual costs, benefits, and risks of robotic as compared to open radical prostatectomy remain somewhat controversial. Often lost in such debate is the role of

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radical prostatectomy, by whatever approach, in the management of prostate cancer, given the considerable stage/grade migration that has occurred because of widespread PSA testing and the mounting concerns regarding prostate cancer over detection and treatment.

Annual prostate cancer mortality in the United States has declined steadily and substantially over the past 15 years, from a peak of nearly 40,000 deaths in 1994 to a projection of 26,730 in 2017 [4]. The explanations for this encouraging trend are controversial, but are almost certainly multifactorial, reflecting advances in both screening and treatment timing and type. This favorable trend is offset, however, by the annual number of new diagnoses which far exceeds the number of deaths—161,360 in 2017 [4]. The United States Preventative Services Task Force (USPSTF) recommendations to omit PSA screening for men have resulted in lowering the number of expected new diagnoses, 180,890 in 2016. The USPSTF will release new recommendations shortly. The natural history of prostate cancer, in many cases, may be protracted and/or indolent even in the absence of treatment [5]. Essentially all available treatments may have adverse side effects including declines in health-related quality of life (HRQOL) [6].

Radical Prostatectomy in Perspective

Radical prostatectomy has been shown in a large, well-controlled randomized trial to offer improved prostate cancer survival compared to watchful waiting [7]. Declines in HRQOL, risks of incontinence, and erectile dysfunction after surgery were offset by progressive local symptoms in the observation arm, with little difference in overall subjective well-being between both groups [8]. Randomized trials comparing prostatectomy to other active treatments, on the other hand, have not been completed successfully, and most retrospective comparative studies have been performed with biochemical endpoints and have been confounded by issues of patient selection, case-mix adjustment, and variation in definition of recurrence [9]. A recent systematic review of the literature determined that no conclusions could be drawn regarding the benefit of any local treatment approach over another for most patients [6].

In the absence of clear guidelines or evidence, great variation has been noted in the use of radical prostatectomy, as well as other treatments for prostate cancer [10, 11]. Radical prostatectomy is the most common treatment for localized prostate cancer, particularly among those with low-risk disease [12]; with increasing risk, use of prostatectomy falls in favor of radiation and androgen deprivation therapy [13]. Increasingly, active surveillance in lieu of immediate treatment, including radical prostatectomy, may be considered for men with low-risk disease [12, 14]. In their analysis of 10,472 men with localized prostate cancer, Cooperberg and Carroll observed a sharp rise in active surveillance use for low risk disease (from 6.7% in 1990 to 14.3% in 2009 to 40% in 2010) [15]. Conversely, recent series have reported favorable outcomes for men with high-risk prostate cancer, suggesting that prostatectomy might have a greater role in this setting [16–19]. Other studies have demonstrated additional benefit to adjuvant radiation or androgen deprivation therapy [20, 21], suggesting that multimodal therapy including prostatectomy may be an increasingly important strategy for those with high risk disease as defined by serum PSA, T stage, and cancer grade.

As alluded to in the introduction, a significant paradigm shift in the technique of radical prostatectomy has occurred. The open technique of radical prostatectomy was refined considerably over the past 25 years. Many have emphasized the importance of a clear understanding of the pelvic anatomy surrounding the prostate and meticulous surgical technique to ensure urinary control and sexual function while avoiding incomplete cancer excision. Clear visualization with magnification, appropriate lighting, and fine instruments are required for the achievement of good outcomes. The use of fixed retraction, a limited incision followed by complete dorsal vein control, and anatomic nerve-sparing technique are hallmarks of the modern retropubic radical prostatectomy [22, 23]. A high standard has been set over many years of outcomes analysis at

centers of excellence with high-volume, advanced open surgeons. In our series at UCSF, we have seen a 5-year survival rate of 97% and very low perioperative morbidity associated with open radical retropubic prostatectomy (rectal injury 0.018%, ureteral injury 0.018%, hospital stay 1.8 days with 37% leaving in day 1, median blood loss of 400 cc, and transfusion rate of 1%). This with a patient cohort composed of 67% intermediate and high-risk patients.

After being introduced in 2002, the use of robotic assisted laparoscopic prostatectomy has grown at an exponential rate with 10% of prostatectomies performed robotically in 2004 growing to over 80% by 2016. Several factors have influenced the dramatic dissemination of this technology leading to patient and hospital demand. Ultimately surgeon preference driven by postoperative outcomes and costs should be the primary factors influencing surgical technique in a healthcare system already overburdened with costs and unacceptable variability in outcomes, quality, safety, and access. Unfortunately, definitive oncologic outcomes often require many years of follow-up. Therefore, in order for new techniques and technology to progress at a reasonable pace, surgeons may rely on surrogate oncologic outcomes, as well the documentation of cost, perioperative morbidity and HRQOL endpoints, and their own experience to draw conclusions on a new technique's value. To this end, we incorporated robotic-assisted laparoscopic prostatectomy at UCSF in 2005 and have accumulated a large and rapidly growing experience to date. Robotic technology has improved and refined our ability to identify important anatomic details through its 3D view and 10× magnification, dexterity through "endowrist" instrumentation, very limited blood loss, and perhaps a refined approach to the neurovascular pedicles. Experienced open surgeons are already quite familiar with pelvic anatomy and the necessary steps to ensure cancer control and preservation of sexual and urinary function. Studies evaluating surrogate oncologic endpoints as well as surgical morbidity have largely shown at least equivalence with the historical, gold standard, open radical retropubic approach. The wide variation in results of these studies must be interpreted with caution due to the heavy influence of selection bias. Some have shown that patients who underwent a robotic—assisted radical prostatectomy had higher levels of regret compared to those who underwent an open approach, suggesting that patients' expectations for an improved outcome with the use of new technology may be higher [24]. A recent review of case series evaluating comparative data between surgical approaches for radical prostatectomy indicated an overall advantage to the robotic approach [25]. Operative time has been a major factor influencing the open surgeon's consideration for implementation of a laparoscopic or robotic-assisted program. However, the comprehensive review found that operative times for open RP, robotic RP, and laparoscopic RP have become similar with weighted means of 147, 164, and 227 min, respectively [25].

Surgical learning curves exist for all procedures, and radical prostatectomy is no exception. The learning curve for open techniques has been described by several authors including Catalona et al. as requiring greater than 100 cases to acquire baseline proficiency [26]. The shift from open to laparoscopic radical prostatectomy requires a completely new skill set for the open surgeon due to its decreased range of motion, two-dimensional vision, and reduced haptic feedback [27]. It has been estimated that laparoscopic radical prostatectomy requires 50–100 cases before the learning curve begins to level [28]. While some insist robotic-assisted laparoscopic prostatectomy requires similar effort for proficiency, considerable debate exists as to the number of cases needed. The robotic interface to laparoscopic surgery provides a much more comfortable environment for an experienced open surgeon to work within. Magnified vision with loupes is replicated and potentially improved by the robotic camera; the disorientation is reduced as are the range of motion problems encountered during the learning curve of laparoscopic techniques. A large portion of the open prostatectomy learning curve involves acquiring a detailed understanding of the anatomic relationships associated with good nerve-sparing technique and interpretation of tissue planes to ensure negative

margin status. This observation has led several high-volume experienced surgeons to conclude that a much shorter learning curve is may be required for mastery of the robotic approach if a firm base of open experience has previously been achieved. Alternatively, Herrell and Smith have stated that surgeons advanced in open radical retropubic prostatectomy are likely to hold higher standards for their performance and thus prolonging the learning curve required to achieve results similar to large open series [29]. If a 4-h operative time is considered an indicator of proficiency for robotic RP, then Zorn et al. found that 120 cases were required to consistently achieve this goal [30]. On the other hand, Ahlering et al. reported a decrease in 4-h operative time and 150 mL blood loss after just 12 robotic-assisted laparoscopic prostatectomy cases (though a positive margin rate of 35%) in the hands of an experienced open surgeon [31]. However, experience counts and all surgeons, whether open, laparoscopic, or robotic, need to be committed to having the necessary volume, environment, and commitment to life-long surgical learning that will best ensure good outcomes for their patients.

Ultimately oncologic outcomes must be the primary concern of any urologist performing prostatectomy by any approach available. Evaluation of the large, multi-institutional community, and university-based CaPSURE database revealed a positive surgical margin after radical prostatectomy for localized disease is an independent predictor of recurrence [32]. Data from another large international database indicated 10-year freedom from recurrence drops from approximately 80–40% with a positive surgical margin [33]. Relatively long-term oncologic outcomes data are still lacking for robotic RP, but given the predictive ability of positive surgical margins, the oncologic efficacy discussion regarding surgical approach becomes a debate, to some degree, on surgical margins. Starting in 2010, there has been a trend toward surgery in treating men with high risk cancer [15]. 67% patients with high risk cancer treated with robotic RP alone remained clinically recurrence-free at 10 years, although 37% required salvage therapy [16]. A retrospective analysis of high-risk patients treated with open RRP or RARP at UCSF from 2002 to 2011 indicated no significant differences in immediate surgical outcomes, such as positive surgical margins and pathological stage, or in recurrence-free survival at 2-year (84% and 79%) and 4-year follow up (68% and 66%) [34]. Review of our institutional database has supported the use of the robotic approach. Previously, our open RP and robotic-assisted RP patient cohorts had similar clinical and pathologic stage and grade. In the contemporary cohort, most patients who opted for robotic-assisted RP had intermediate or high clinico-pathological grade and stage (Fig. 33.1). There was a slight increase

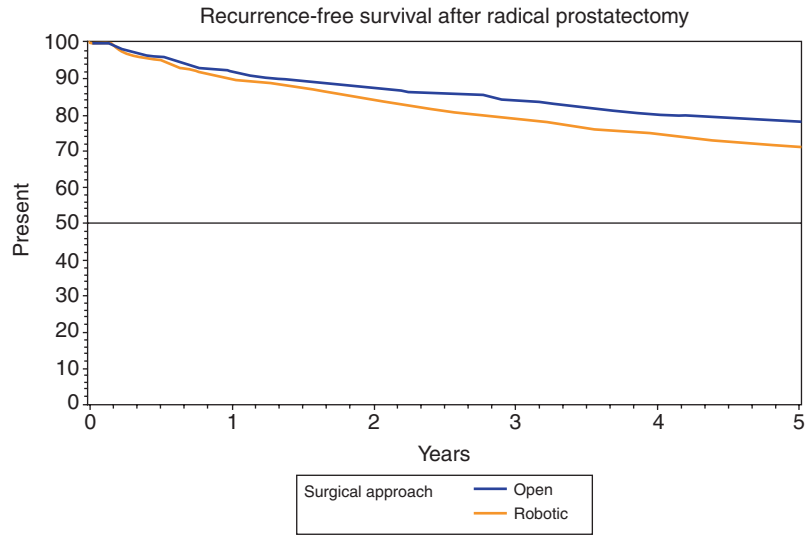

Fig. 33.1 PSA relapse-free or second treatment-free survival for contemporary men undergoing open ($N = 1662$) or robotic-assisted ($N = 1866$) radical prostatectomy with adequate follow-up ($p < 0.01$)

in the overall rate of positive surgical margins between open RP (17%) and robotic RP (24%) ($p < 0.01$) in unadjusted analysis (Table 33.1). However, when we adjusted for clinico-pathological grade and stage, there was no significant difference seen in positive surgical margin rate between open or robotic-assisted RP [34]. Pathologic stage was the most significant predictor of positive surgical margins, regardless of surgical approach. More importantly, the biochemical-free survival rates did not differ between open RP (78%) and robotic RP (71%) at 5 years incorporating our entire robotic RP series (Fig. 33.2). Our data is consistent with recent report of a randomized trail showing no differences in rate of positive surgical margins in patients treated with open or robotic prostatectomy [35]. However, the robotic approach has shown advantages in length of stay, estimated blood loss, and transfusion rates (Table 33.2). However, such benefits, though statistically significant, may lack the clinical significance that might be seen elsewhere, given the very positive experience documented with the open technique at UCSF. The risk of bladder neck contracture, although low with the open technique, appears to be reduced with the robotic approach. Comprehensive reviews of outcomes comparing open RP, laparoscopic RP, and robotic RP reveal an advantage with the robotic approach when evaluating estimated blood loss, complication rate, and positive margin rate while requiring

Table 33.1 Immediate surgical outcomes survival for contemporary men undergoing open ($N = 1662$) or robotic-assisted ($N = 1866$) radical prostatectomies

Characteristic	Open	Robotic	p value
Length of stay, median (interquartile range)	2 (2, 3)	1 (1, 2)	<0.01
Blood loss, median (interquartile range)	500 (300, 750)	150 (100, 250)	<0.01
Positive margins	17%	24%	<0.01
Bladder neck contracture	3%	1%	0.02

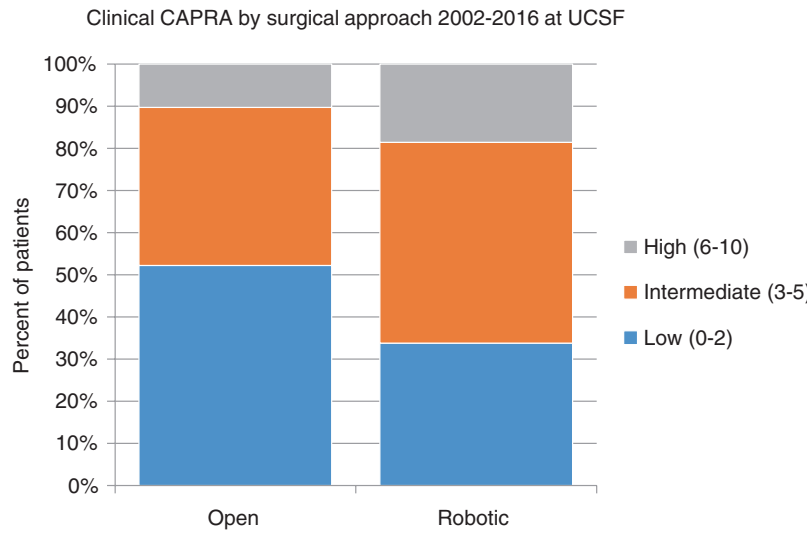

Fig. 33.2 Graphs showed median clinical CAPRA score by surgical approach for 3284 men at UCSF

Table 33.2 Life table: recurrence-free survival after RP

Surgical approach	Total N	Recurrence within 5 years N	Recurrence-free 1 year (%)	2 years (%)	3 years (%)	4 years (%)	5 years (%)	Log-rank p value
Open	1662	302	92	88	84	81	78	<0.01
Robotic	1866	330	90	84	79	75	71	

similar operative time [25, 29]. Several reports have described the equivalence of positive margin rates for laparoscopic/robotic prostatectomy vs. open prostatectomy [31, 36–40]. Smith and colleagues reported positive margin rates of 24.1% for open prostatectomy compared to 9.4% for robotic-assisted prostatectomy in pT2 patients and 60 vs. 50% in the open vs. robotic groups, respectively, for pT3 patients [41]. Additionally, the review data reveal a mean positive margin rate of 12.5, 19.6, and 23.5% for robotic RP, laparoscopic RP, and open RP, respectively, although the open series had more pT3 patients [25]. The apparent equivalence or even advantage in positive margin rate with the use of robotic assistance seems to hold true even with decreased robotic experience in the hands of experienced open and laparoscopic surgeons as evidenced by Trabulsi et al. Their study found an 18% positive margin rate in 150 laparoscopic RPs, followed by a 6% rate in their first 50 robotic RPs. The difference remained significant even when considering only pT2 disease [42]. Obviously, positive margin rates are affected not only by technique but also by patient selection. Low positive margin rates are seen most often in those with low-grade, low-volume disease, a patient population that may be equally good candidates for surveillance in lieu of immediate treatment. Alternatively, avoiding surgery in those with higher risk disease because of concerns about positive margins may deny this group of patients treatment, which may be associated with improved outcomes as compared to the initial use of other therapeutic modalities as alluded previously.

A report by Hu et al. has called into question the oncologic efficacy of robotic-assisted laparoscopic prostatectomy. The authors reported a statistically significant decrease in the length of stay for patients undergoing the robotic-assisted and laparoscopic approaches as compared to the open approach, but a significant increase in the requirement for salvage therapy was seen in the robotic group (27.8 vs. 9.1%) as well as a significant increase in postoperative anastomotic strictures [43]. This difference became insignificant when evaluating the results of high-volume robotic and laparoscopic surgeons. Studies have also shown equivalence in hospital stay length and recovery time for robotic and open approaches [44]. High variability is seen in the rates of continence and potency with consistently high rates being reported from high-volume surgeons within high-volume centers (continence 95%, potency 65–85%), and very few prospective studies evaluating HRQOL comparing open vs. laparoscopic vs. robotic prostatectomy have been reported. In their recent randomized trial comparing robotic vs open prostatectomy, Yaxley et al. reported no significance difference in HRQOL (EPIC urinary and sexual domain) between the two groups at 6 weeks follow up. Longer term evaluation is needed [35].

There is little debate as to the cost ineffectiveness of a robotic prostatectomy program when compared directly to a stable or growing open radical prostatectomy practice. With high purchase prices, costly maintenance contracts, slightly longer operative times, similar hospital stays, and fixed reimbursement, conversion to a robotic prostatectomy program can be costly. In a meta-analysis using models based on the literature and local costs, Lotan and colleagues found a US $1726 per-case cost advantage of open radical retropubic prostatectomy over the robotic approach. This advantage remained US $1155 even after discounting the original purchase price of the robot [45, 46]. Actual costs rather than models were used in a more recent study that found the open retropubic approach to be less expensive (US $2315) per case than the robotic approach. This cost difference was generated primarily by the surgical supply cost since purchase and maintenance costs of the robot were excluded [47]. However, such costs can be offset by potentially improved outcomes, shorter hospital stay, earlier return to work, improved HRQOL, and less preoperative morbidity.

Various practitioners have advocated many minor techniques in the performance of either open or robotic surgery. Unfortunately few have been the subject of properly controlled trails. This is a problem with the field of surgery in general and should be addressed. At UCSF an initial trial of autologous sling placement showed what appeared to be an improvement in

urinary continence. (Reference) However, we recently tested this technique in a randomized trial [48] that failed to demonstrate a benefit to placement of an autologous sling at time of RARP on early return of complete continence at 6 month follow up. Age was a better predictor of continence after RARP in the adjusted model. As with any novel therapy, a new surgical innovation should be subjected to rigorous evaluation through randomized trial prior to wide spread adoption.

Summary

Radical prostatectomy is an important and effective treatment modality for a very large number of men with prostate cancer. Its use, whether performed open or with robotic assistance, will be refined in the coming years, given the current emphasis on comparative effectiveness. Cancer control, urinary function, and sexual function after prostatectomy are more dependent on surgeon training and technical expertise than approach. The use of robotic assistance for laparoscopic prostatectomy has enabled high-volume open surgeons to translate their experience and expertise into precisely executed laparoscopic steps without the prohibitively long learning curve required for standard laparoscopic radical prostatectomy.

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Robotic Radical Prostatectomy: Margins Positivity and Implications on Cancer Control

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Abstract

Robot-assisted radical prostatectomy (RARP) is the standard surgical treatment for localized prostate cancer in the United States. After more than a decade of experience with the robotic approach, its oncological safety has been confirmed with margins positivity comparable to the open approach. Large scale RARP series yielded positive surgical margin (PSM) rates between 9 and 19%. PSM rates are strongly associated with preoperative disease characteristics (i.e., PSA, Gleason score, and clinical stage). As more patients with intermediate and high risk disease undergo RARP, the overall rates of PSM may potentially increase. While PSMs have been repeatedly shown to predict biochemical recurrence (BCR), their impact on more meaningful outcomes, such as the development of metastatic disease and cancer-specific mortality is not completely clear. Gleason score at PSM and PSM margins length are important features of PSM that seems to have influence on the long term impact of PSM. Various surgical techniques and tailoring nerve preservation based on disease severity appear to improve cancer control during RARP. Post radical prostatectomy radiation therapy (RT) also improves oncological outcomes. Level I evidence from open radical prostatectomy literature, demonstrated improved biochemical recurrence-free, metastasis-free, and overall survival when adjuvant radiation therapy was given to patients with adverse pathological features, including PSMs. Yet, the optimal timing of when to deliver additional RT is still unknown and awaits the results of several randomized clinical trials.

Keywords

Prostate cancer · Robotic assisted radical prostatectomy · Open radical prostatectomy · Pathology · Surgical margins · Gleason score · Biochemical recurrence · Prostate cancer-specific mortality · Urinary function · Sexual function · Radiation therapy

Abbreviations

BCR	Biochemical recurrence
BMI	Body mass index
BRFS	Biochemical recurrence-free survival
CRPC	Castrate-resistant prostate cancer
DVC	Dorsal venous complex
LRP	Laparoscopic radical prostatectomy
mpMRI	Multi-parametric Magnetic Resonance Imaging
NVB	Neurovascular bundle

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ORP	Open radical prostatectomy
PCSM	Prostate cancer-specific mortality
PSM	Positive surgical margin
RARP	Robot-assisted radical prostatectomy
RT	Radiation therapy
SWOG	Southwest Oncology Group

Introduction

Since the beginning of the twenty-first century there have been tremendous changes in the treatment of localized prostate cancer. While active surveillance is more commonly performed for low risk prostate cancer patients, surgery is increasingly utilized for intermediate and high risk disease [1]. Open radical prostatectomy (ORP), the historical gold standard for surgical treatment of prostate cancer, has been largely replaced by the robotic approach. Between 2003 and 2013 there was a 376% increase in the utilization of robotic assisted radical prostatectomy (RARP) in the United States. The relatively short learning curve and impressive perioperative outcomes has favored a rapid dissemination of RARP. In 2013, RARP is performed 5 times more commonly than ORP and represent 85% of radical prostatectomies in the United States [2].

Studies of RARP have consistently reported numerous short term advantages compared to ORP, including reduced blood loss, decreased complications, and shorter hospital stay [3–6]. Accumulating data also suggests that RARP offers superior functional outcomes compared to ORP, including more favorable sexual and urinary function during the first year after surgery [7–9]. Intuitively, early studies lacked meaningful oncologic outcomes. But now, with more than a decade of RARP experience, data regarding long term oncological outcomes have emerged. These demonstrate that RARP yields effective cancer control with similar biochemical recurrence, cancer-specific survival, and overall survival compared to ORP [10, 11].

Positive surgical margins (PSM) are considered an adverse oncologic outcome, consistently associated with biochemical failure. However, whether they ultimately affect cancer-specific survival and overall survival is not clear. As high-risk prostate cancers are more commonly being treated surgically [1], the long-term implications of PSM, methods to prevent PSM, and strategies to manage PSM are becoming increasingly important.

The following chapter will comprehensively review the definitions and pathological interpretation of margin status for radical prostatectomy, results in the era of RARP, and contemporary data assessing association with long term end points. Appropriate patient selection and surgical techniques to optimize cancer control will also be addressed. When appropriate, comparisons will be made with historical and contemporary studies of ORP and laparoscopic radical prostatectomy (LRP). Finally, the impact and role of adjuvant radiation therapy (RT) after radical prostatectomy will be outlined.

Definitions and Reporting of Positive Surgical Margins

Variability in documentation of radical prostatectomy surgical margin status has led the International Society of Urological Pathology (ISUP) to publish standardized measures on the handling, staging, and reporting of radical prostatectomy specimens [12]. Surgical margins are defined ‘positive’ if the tumor extends to the surface of the prostate (i.e., tumor cells on the ink). Tumor extending close to the surgical margin should be considered as a negative margin and the distance to ink has generally not demonstrated prognostic implications [13, 14].

PSM result either from incision across malignant cells that are extracapsular (pT3 disease) or from inadvertent intraprostatic (“capsular”) incision into the tumor in organ-confined prostate cancer. The latter can be identified by the presence of both the tumor and benign glands transected in the same area. Controversy exists over the significance of intraprostatic incision in otherwise organ-confined disease. Furthermore, defining the type of PSM may be challenging due to potential artifacts. For example, fibrotic

reaction may give extracapsular extension the appearance of incision into organ-confined tumor. It may also be difficult to differentiate between these two types of PSM in the anterior part of the prostate where the anatomical boundaries are not clear. Whole mount sectioning may reduce the uncertainty and less likely to overlook a PSM compared with the more common step sectioning techniques.

The location of the PSM should be reported as posterior, posterolateral, lateral, anterior, apical, or bladder neck. Although it remains unclear whether the specific site of surgical margin positivity predicts disease progression, it is important that the urologist receives this information to help continually optimize surgical technique. The extent of the PSM should be reported using length in millimeters. The extent, location, number of PSMs and Gleason score at the positive surgical margin may have an independent effect on disease recurrence. These issues are discussed in details below.

Incidence of Positive Surgical Margins in RARP

Several important factors must be considered before comparing PSM rates among reported series. Most importantly, patient, clinical, and pathological characteristics should be similar across studies to reduce any selection bias. At a minimum, pre-operative PSA, Gleason score, amounts of tumor in biopsy cores, as well as clinical and pathological stage, should be similar in order to make appropriate comparisons.

Even the earliest case series of RARP showed that rates of PSM were comparable to those achieved after decades of experience with the open approach. In 2002, Menon et al. performed a non-randomized, prospective study comparing 30 consecutive ORP and 30 initial RARP cases [15]. Preoperative parameters were comparable between groups with the exception of mean PSA being significantly higher in the RARP cohort (9.9 vs. 8.4 ng/ml). Overall PSM rates were 29% and 26% for ORP and RARP, respectively. Even after acknowledging all the limitations of this small study, this early report demonstrated the oncological safety of RARP and, perhaps, encouraged other centers to embark on RARP programs.

Large-scale studies and literature reviews have been published, based on more than a decade of RARP experience, showing equivalent or improved PSM rates of RARP compared to ORP. Table 34.1 summarizes PSM data from large RARP series, stratified by pathological stage. In 2013, a multinational collaboration between 14 institutions in Europe, the United States, and Australia published a retrospective analysis of 22,393 patients who underwent ORP (9778), LRP (4918) and RARP (7697) between 2001 and 2010 [23]. After adjustment for age, preoperative PSA, postoperative Gleason score, pathologic stage, and year of surgery, both

Table 34.1 Positive surgical margins in large RARP series (>500 cases), by pathological stage

Series	*N*	Overall PSM (%)	pT2 PSM (%)	pT3 PSM (%)	pT4 PSM (%)	pT3/T4 PSM (%)
Badani et al. [16]	2766	19	13			35
Patel et al. [17]	1500	9	4	33	40	
Wiltz et al. [18]	945	18	13			40
Carlucci et al. [19]	700	12	10	46		
Shikanov et al. [20]	1398	17	11	41		
Coelho et al. [21]	876	12	7	34	75	
Patel et al. [22]	8095	16	9	37	49	
Sooriakumaran et al. [23]	7697	14	NA	NA		
Kozal et al. [24]	742	16	NA	NA		
Mithal et al. [25]	4051	39	31			65
Suardi et al. [26]	1790	16	NA	NA		

minimally invasive groups had lower PSM than ORP by a relative factor of approximately 25%. Crude rates of PSM for RARP and ORP were 13.8% and 22.8%, respectively. A meta-analysis by Novara et al. showed similar overall PSM rates in RARP but no differences between the minimally invasive and open approaches [27]. They analyzed 79 contemporary RARP series between 2008 and 2011 and found an average PSM rate of 15% (range: 6.5–32%). More extensive cancers had higher risk of positive margins: 9% for pT2, 37% for pT3, and 50% for pT4. A recent study by Suardi et al. evaluated rates of PSMs in RARP and ORP according to D'Amico preoperative risk groups [26]. Their study included 4404 patients treated with ORP and 1790 treated with RARP between 1992 and 2014. RARP was associated with a lower rate of PSMs than ORP in low-risk (11.5 vs.15.4%, $P = 0.01$), intermediate-risk (18.9 vs. 23.5%, $P < 0.008$), and high-risk patients (19.7 vs. 30.1%, $P < 0.001$). Interestingly, multivariable analyses accounting for prostate volume, nerve-sparing status, tumor volume, and year of surgery confirmed reduced PSM's rates in RARP only among high risk patients (OR = 0.69, $P = 0.04$).

Predictors of Positive Surgical Margins

Patient, tumor, and surgeon related factors have been described as potential predictors of the surgical margins in RARP. As mentioned in the previous section, higher preoperative cancer risk category is associated with increased PSM rates [26, 28]. Furthermore, each component of D'Amico classification including PSA [22, 29], Gleason score on biopsy [30] and clinical stage [31, 32] has been shown to independently predict PSM.

Pathological stage is strongly associated with margins outcomes (*see* Table 34.1). Ficarra et al. evaluated potential predictors of any PSM, posterolateral PSMs and multiple PSMs in a cohort of 322 RARP patients. Pathologic T stage was an independent predictor of any positive surgical margin (HR = 11.8, $p < 0.001$) and posterolateral positive surgical margins (HR 7.5, $p < 0.001$). The rates of PSM were 10.6%, 57.5% and 72.2% in pT2, pT3a and pT3b-pT4 disease, respectively. In patients with organ confined disease (pT2) perineural invasion was the only independent predictor of any positive surgical margin (HR = 4.096, $p = 0.028$).

Patient related factors including BMI and prostate size have also been evaluated as potential predictors of PSM. Some studies have found association between BMI and rate of PSM [22, 33, 34] while others have not [18, 31, 32, 35]. Wiltz et al. reviewed 945 RARPs performed at a single institution and stratified patients by BMI into three groups (<25 kg/m^2, 25 to <30 kg/m^2, and ≥30 kg/m^2). They found no significant difference in overall, organ-confined, and pT3 PSM rates among the groups [18]. Another study by Ahlering et al. also found no difference in PSM rates for obese patients [35]. However, in a cohort of 140 RARPs, Castle et al. did observe a significantly higher PSM rate in obese (26.1%) vs. non-obese (13.1%) patients [33]. In their large, multi-institutional study of more than 8000 patients, Patel et al. found high BMI to be independent predictor of PSMs. This was present in the overall cohort and in men with organ-confined disease [22]. Thus, no consensus exists for obesity as an independent risk factor for PSMs, especially since multiple confounding variables are likely involved. In particular, PSA levels often decrease as BMI increases, contributing to a delay in diagnosis of prostate cancer (lead time bias) and the subsequent identification of more aggressive disease at the time of surgery. As such, robotic surgeons should take extra precautions when performing RARP in obese patients.

The effect of prostate weight on PSMs has also been well studied, with most studies showing that larger prostate size correlates with fewer PSMs. In their analysis of 1500 RARPs, Patel et al. identified an inverse relationship between prostate weight and incidence of PSMs. For prostate volumes <50, 50–99 g, and ≥100 g, positive margin rates were 14.3, 9.4, and 5.9%, respectively [17]. Similarly, in a cohort of 690 patients with low-risk prostate cancer, Marchetti et al. reported higher probability of PSM in prostates

with lower weights [36]. Tuliao et al. examined the impact of prostate size on other PSM predictors. They stratified a cohort of 815 RARP patients according to prostate size; <31 g, 31–45 g and >45 g. PSM rates were 17.3%, 12.9% and 11.4% %, respectively. Interestingly, ≥3 positive biopsy cores (OR 2.52, P = 0.043) and a cT3 disease (OR 3.94, P = 0.020) predicted PSM in small prostates, but failed to do so for 31–45 and >45 g prostates [30]. The etiology of this inverse relationship between prostate weight and PSMs is likely multifactorial, including higher density of disease in smaller glands and increased lead time bias from delayed diagnosis. Despite the lack of a standard stratification of prostate size in these studies, the overall increased risk of PSM in smaller prostates should be kept in mind.

Surgical experience plays a significant role in decreasing PSMs. The incidence of PSMs is expected to be relatively high initially, but it generally plateaus with accumulating experience. This is notable considering the application of broader inclusion criteria for surgery for high risk disease over time. Zorn et al. reported PSM rates during the first 700 RARPs performed in a high-volume institution. Cases were divided into 3 consecutive groups; 1–300, 301–500, and 501–700. A reduction in PSM rates in pT2 cancers was noted (15%, 10%, and 7%, respectively). Sooriakumaran et al. described the learning curve for RARP, based on a retrospective cohort study of 3794 patients who underwent surgery by three surgeons from three centers [37]. The number of surgeries required to reduce the PSM rate to a minimum was estimated at 1000–1500. With increasing experience, multiple factors likely contribute to decreasing PSMs including improved appreciation of pelvic anatomy, better control of the da Vinci™ system, and technique modifications that evolve over time. The importance of a dedicated robotic fellowship was demonstrated by Leroy et al. who compared the performance of fellowship trained surgeons to surgeons who are novices at the robotic technique [38]. Significantly lower PSM rates were found in the RARP group performed by the fellowship-trained surgeons (15% compared with 34%, p = 0.008). Improved surgical outcomes are a function of both surgical experience and surgical modifications over time. The impact of different surgical techniques is discussed in details in the section Reducing the Rates of Positive Surgical Margins.

In conclusion, although patient, surgeon and tumor related factors have been linked to PSM after RARP, the latter seems to have the strongest impact on PSM. Special attention should be given to modifiable factors such as surgeon experience and technique.

Characteristics of Positive Surgical Margins

The location, number, and size of the PSMs as well as the Gleason score at the PSAMs have been investigated to better define their oncological effect.

The apex and posterolateral regions are the most common locations for PSM, which together constitute ~70% of all PSM sites in RARP [20, 22, 39]. Several factors contribute to increased risk of PSM at the apex. The location of the apex, deep in the pelvis, beneath the pubic bone reduces accessibility and visibility. Furthermore, the proximity of sensitive structures as the NVBs and rectum adds to surgical complexity. Attempts to divide the urethra close to the apex, in order to minimize damage to the rhabdosphincter and preserve urinary continence, increases the risk for PSM as well. Dissection becomes even more difficult with the presence of an anatomical variant such as apical protrusion of the prostate posterior to the urethra. If not noticed, the plane of dissection from the urethra might pass through the protruding prostatic tissue. Finally, the lack of a condensed fibromuscular band (i.e., pseudocapsule) around the apex makes the dissection planes less discrete.

The main reason for the relatively high rate of PSM in the posterolateral prostatic area is the proximity to the NVBs and the desire to preserve maximal sexual and urinary functions. Based on pre- and intra-operative data the urologist should assess the location and extension of the tumor

and appreciate his ability to preserve the NVB in a safe oncological plane. Complete nerve sparing poses the highest risk for PSM and is performed by dissecting medial to the prostatic fascia, directly on the prostate capsule (intrafascial plane). Risk for PSM is minimized by performing a complete resection of the NVB with the prostatic fascia, in a plane lateral to the prostatic fascia (extrafascial plane) [40]. Further discussion regarding strategies to reduce PSM in these locations is provided in the section Reducing the Rates of Positive Surgical Margins.

The impact of PSM location on BCR has been described in several ORP series with contradictory results. For example, Watson et al. analyzed 215 ORP cases and did not find the site of margin involvement to be an independent predictor of progression [41]. Conversely, Salomon et al. reported that a PSM at the apex yielded the worst prognosis of all locations, with only 54.5% 3-year biochemical-free progression [42] Eastham et al. reviewed the results of 2442 ORPs and also observed that margin location impacted the rate of biochemical recurrence [43]. In this study, however, the posterolateral location was associated with an increased risk for recurrence. Other ORP studies have shown that a PSM at the prostate base or bladder neck confer the highest likelihood of biochemical recurrence [44, 45]. There is much less data from RARP series. Shikanov et al. found no association between PSM location and BCR [20]. In their cohort of 1398 RARP patients, 11% of patients with PSM experienced recurrence during a median follow-up of 12 months, compared with only 3% with negative margins. The presence of a PSM at any site and the length of the PSM were independent predictors of BCR, but the location of margin positivity was not. Similarly, Sooriakumaran et al. did not find a prognostic role of PSM location in relation to BCR [46]. Nevertheless, a recently publication by Dev et al. showed posterolateral margins conferred smaller risk of BCR compared to apical margins [39]. Among 4001 patients, 37% of patients with PSM and 10% of patients without PSM developed BCR during a median of 58 months. On multivariable Cox regression analysis of the positive margin cohort, only apical margins significantly predicted BCR relative to other margins (HR = 2.03, 95% CI:1.01–4.09). In conclusion it is unclear whether the location of PSMs has prognostic significance, but the fact that the apex and posterolateral sites remained the most common locations for PSMs in the era of robotic surgery warrants extra caution during the dissection in these areas.

Gleason score at the PSM has been recognized as an important prognostic factor that should be documented and reported. Kates et al. analyzed a cohort of 405 patients who underwent radical prostatectomy between 2010 and 2014, had a Gleason score of 7 or greater of the primary nodule and PSMs [47]. Gleason score at the positive surgical margin was the same as in the primary prostatic nodule in 44% of patients, and was lower in 56% of patients. During a mean follow-up of 22 months (range: 12–48), 22% developed biochemical recurrence. In multivariate Cox models having a lower grade margin was associated with a decreased risk of biochemical recurrence (HR 0.50, OR 0.25–0.97). The long term impact of having high Gleason score at the surgical margins was demonstrated by Viers et al. [48]. In their cohort of 338 patients with PSM after radical prostatectomy, the 15 years progression free survival and cancer specific survival were significantly worse among patients with Gleason grade 4 at surgical margins compared to patients with Gleason grade 3 (74% vs. 90%; $p < 0.001$ and 86% vs. 96%; $p = 0.002$, respectively). On multivariable analysis, the presence of PSM Gleason grade 4 was associated with increased risks of systemic progression (HR: 2.77; $p = 0.003$) and PCSM (HR: 3.93; $p = 0.02$). These studies highlight the importance of documenting Gleason score at the surgical margins and incorporating this data into risk stratification following surgery.

The length of positive surgical margins also affects BCR rates after robotic prostatectomy. The first to show this association was Shikanov et al. from the University of Chicago [20]. In their retrospective study of 1398 RARP patients, 243 patients (17%) had PSMs, of which 161 were available for secondary review and margin length measurement. PSM length was associated with

BCR when assessed as a categorical variable (1–3 mm—HR = 9.6, p = 0.03; greater than 3 mm—HR = 14.8, p = 0.01) and as a continuous variable (HR = 1.08 per mm, p = 0.008). Interestingly, outcomes for patients with negative margins were similar to those with PSMs <1 mm, suggesting that very small PSMs may be false positives or that with relatively short follow-up, microscopic residual disease has not yet translated into recurrence. A recently published paper by Kozal et al. supports Shikanov's findings [24]. Among 742 RARP patients, 80 had BCR, during a median follow up time of 34 months. The percentage of patients with BCR at 5 y was 80.3% and 72.3% for patients with PSM length of ≥3 mm and <3 mm, respectively (p = 0.02). At multivariate analysis, margin length ≥3 mm predicted BCR (HR = 1.25, P = 0.04). The previously mentioned study by Dev et al. also showed the importance of PSM length [39]. Margin lengths of more than 3 mm predicted BCR rates, with a 2.18-fold greater risk of time to BCR compared with margins of <3 mm in length (95% CI:1.34–3.57, p = 0.002). These authors also showed that compared with PSM length, multifocality confers less harm in terms of BCR risk. While multifocality carried an increased risk of time to BCR compared with negative surgical margins, multifocality did not predict BCR on multivariate analysis of the PSM cohort. Supporting this, multifocality was not an independent predictor of BCR in the large RARP study of Shikanov et al. [20]. These finding imply that while a single PSM poses negative prognosis, additional positive sites do not have a cumulative effect. It should be kept in mind that these studies evaluated the impact of PSM on BCR, a surrogate for long term oncological outcomes. The next section discusses the potential influence of PSM on long term end points.

Impact of PSMs on Oncologic Outcomes

Our understanding of the influence of PSM on oncologic outcomes has grown over time. This was first evaluated for ORP, since the longstanding utilization of this technique has allowed numerous large studies with meaningful oncologic follow-up ranging from 10 to 20 years. One must be cognizant that oncologic outcomes have changed as screening has evolved. The adoption of PSA improved outcomes, as Roehl et al. first showed in their assessment of 3478 consecutive ORP cases performed by a single surgeon over a 20-year period [49]. With a mean follow-up of 65 months, 10-year estimated biochemical recurrence-free survival (BRFS) was 68%. PSA, clinical stage, Gleason sum, pathological stage, and era of treatment (before 1991) were independently associated with cancer progression. This study included patients dating back to 1983, a significant proportion of cases were from the pre-PSA era, resulting in more advanced disease for that subset men. Similar results were demonstrated in cohorts of 2402 and 5679 men who underwent ORP at Johns-Hopkins University and Mayo Clinic, respectively [50, 51]. Importantly, these classic studies demonstrate that caution must be taken when comparing these outcomes to more recent RARP series that only include patients from the PSA era, as significant down-staging and down-grading of disease has occurred.

Several large trials assessed PSM for ORP prior to and early in the PSA era. Karakiewicz et al. assessed 5831 patients who underwent ORP from 1983 to 2000 at eight institutions and showed that PSM yielded a 3.66-fold (CI: 2.65-5.06, P < 0.001) increased risk of biochemical recurrence (BCR) on multivariable analysis controlling for PSA, Gleason score, ECE, SVI, and LNI [52]. BCR was defined as a rising post-operative PSA between 0.1 and 0.4, depending on the center. Simon et al. assessed 1383 patients who underwent ORP by a single surgeon and found that PSM yielded BCR of 19% versus 7% for negative margins [53]. However, they clearly demonstrated an important concept that it is difficult to truly control for all confounders for BCR when considering PSM. Multivariate analysis demonstrated that after controlling for PSM, PSA > 20, Gleason score, SVI, and EPE all were independently associated with BCR as well.

Minimally invasive techniques were first adopted in the 1990s, and studies first assessed midterm oncologic outcomes for LRP. Defining relapse as a PSA of ≥0.2 ng/ml, Pavlovich et al. reviewed the results of 528 LRPs performed between 2001 and 2005 at a single institution [54]. With a mean follow-up of 13 months, overall 3-year BRFS was 94.5% (98% for organ-confined and 79% for pT3 and/or N1 disease). Pathological Gleason sum and stage were the only independent predictors of recurrence. The presence of a PSM trended toward, but did not attain, statistical significance. Importantly, this study represented a screening-detected patient population from the United States with less aggressive clinical features than prior ORP studies.

Studies have most recently assessed oncologic outcomes for PSM following RARP. In one of the first studies, Shikanov et al. reviewed 1398 men who underwent RARP, and with a median follow-up of 12 months, 4% of patients experienced biochemical recurrence (PSA ≥ 0.1 on two occasions) [20]. The presence and length of PSM were both independent predictors of BCR after controlling for pre-operative PSA, pathological stage, and pathological Gleason score. BCR was observed in 11% of patients with PSM compared with 3% in those with negative margins. Murphy et al. assessed the oncologic outcomes in their first 400 RARP cases [55]. During a median follow up time of 22 months, fifty-three patients (13%) experienced biochemical recurrence, and the 5-year BRFS was 74%. Patients with PSMs were more likely to experience PSA relapse than those with negative margins ($p = 0.0001$).

Large studies of PSM and RARP became available over time. Stephenson et al. assessed 7160 patients treated with RARP at 3 institutions of which 1501 patients had PSMs [56]. In this large series, they found PSM was significantly associated with BCR (HR 2.3, $p < 0.001$) on multivariable analysis controlling for age, PSA, Gleason score, stage, and year of surgery. Furthermore, multiple versus solitary PSM and extensive versus focal positive margins were found to predict BCR (HR 1.4 and 1.3, respectively, both $P < 0.01$). In 2015, Diaz et al. published on 483 who underwent RARP between 2001 and 2003 with greater than 10 years of follow-up [10]. Controlling for PSA, tumor volume, pathologic Gleason score, stage, PNI, and year, PSMs independently predicted for BCR (HR 3.24, CI: 2.02-5.19, $p < 0.001$).

BCR is important, especially for guiding adjuvant therapy. However, some have questioned the relevance of this endpoint compared to more clinically meaningful outcomes. While PSMs have clearly been shown to increase BCR, this may not result in castrate-resistant prostate cancer (CRPC), metastases, and death. There have been mixed results from trials assessing the association between PSMs and these longer term outcomes. The first evidence stemmed from a large analysis of the SEER database between 1998 and 2006 that identified 65,633 post-radical prostatectomy patients. This study demonstrated that PSM independently predicted prostate cancer-specific mortality (PCSM) (HR 1.70, CI: 1.32-2.18) after controlling for age, race, registry, year of diagnosis, grade, stage, and additional radiation status [57]. However, a subsequent study by Shah et al. questioned the accuracy of PSM by SEER, showing that in 2007, 30% of PSMs were coded inaccurately [58]. Furthermore, several recent publications have questioned the association between PSMs and non-BCR outcomes. In 2016, Mithal et al. assessed the Shared Equal Access Regional Cancer Hospital (SEARCH) database to identify 4051 patients treated at VA hospitals with 1600 PSMs between 1998 and 2013 [25]. Primary endpoints for this study included development of CRPC, metastases and PCSM. After controlling for age, race, PSA, Gleason score, SVI, ECE, year or surgery and surgical center, PSMs conferred increased risk of BCR (HR 1.98, CI: 1.75–2.23, $P < 0.001$) but not CRPC (HR 1.20, CI: 0.96–1.83, $P = 0.408$), metastases (HR 1.29, CI: 0.88–1.88, $P = 0.186$), or PCSM (HR 1.28, CI: 0.78–2.11, $P = 0.327$). Importantly, similar results were seen when patients who underwent adjuvant radiotherapy were excluded. A study by Mauermann et al. demonstrated similar findings

[59]. In their retrospective cohort of adjuvant treatment naïve, post radical prostatectomy patients, 1121 were margin-negative (65.5%), 281 patients (16.4%) had solitary PSMs and 310 patients (18.1%) had multiple PSM. During a median follow-up of 74.9 months, 280 patients (16.4%) experienced BCR, 15 patients (0.9%) developed CRPC, 19 patients (1.1%) developed metastatic disease and 13 patients (0.8%) died from prostate cancer. Salvage radiation therapy was administered to 197 patients, which represents 70.4% of patients with BCR (59%, 85.5%, and 75.0% for patients with negative, solitary and multiple PSM, respectively).While the ten-year Kaplan-Meier estimates for BCR-free survival were higher in the negative margins compared to the PSM groups (82% vs. 59%, $p < 0.0001$), time to metastatic disease, CRPC, or PCSM did not differ significantly among the groups ($p = 0.991$, 0.988 and 0.889, respectively). On multivariable analysis, solitary and multiple PSMs were associated with BCR (HR: 1.711; $p = 0.001$ and HR:2.075; $p < 0.0001$), but could not predict metastatic disease, CRPC or PCSM (all $p > 0.05$).

These studies suggest that in the absence of other high-risk features, PSMs alone may not predict worse long-term outcomes. However, certain features of PSM were not included in those analyses. Gleason score and length are two examples for highly important characteristics of PSM, as discussed in previous sections of this chapter. Improved delineation of margins positivity might assist in long-term risk stratification.

Adjuvant Radiation for Positive Surgical Margins

Treatment options for patients with high risk features primarily involve adjuvant or salvage radiation therapy (RT). Adjuvant RT is defined by RT administered to patients following prostatectomy who have no measurable disease (undetectable PSA) but at higher risk of recurrence due to risky pathological features, including PSMs. Salvage RT is defined as RT administered to patients following prostatectomy who have a PSA recurrence (PSA $\geq$ 0.2 ng/ml with a second confirmatory level). AUA Guidelines state there is Grade A evidence that "physicians should offer adjuvant radiotherapy to patients with adverse pathologic findings at prostatectomy including SVI, PSMs, or ECE because of demonstrated reductions in BCR, local recurrence, and clinical progression" [60]. The presence of a PSM is an adverse pathologic finding that provides a clear rationale for adjuvant XRT, since radiotherapy can theoretically destroy and remaining local tumor cells. However, many attempt to spare patients from unnecessary surgery since up to 50% of patients with PSMs ultimately do not recur [61]. Ultimately, the decision of whether or not to institute adjuvant therapy after radical prostatectomy is multifactorial and includes other variables including patient age, pathological findings, functional status (urinary control and sexual function), and patient preference.

Three classic randomized controlled trials assessed adjuvant RT for locally advanced disease (pT3/pT4) and/or PSMs following ORP. EORTC 22911 was a randomized trial initiated in 1992 to assess the impact of immediate adjuvant RT (60 Gy) on cancer control for patients with PSMs or pT3 disease [62]; 503 patients were randomized to immediate RT and 502 to a wait-and-see policy until local failure. At a median follow-up of 5 years, BRFS, clinical progression-free survival, and loco-regional control were significantly improved in the irradiated group, and 5-year BRFS was 74 vs. 53% in the RT and wait-and-see cohorts, respectively ($p < 0.0001$). This improvement was noted for all sub-groups, including patients with organ-confined disease and PSMs. No significant differences were observed for cancer-specific or overall survival. Adverse effects were more prevalent in the irradiated group, but severe toxicities were rare in both cohorts. Although the study was randomized and prospective, limitations included the inclusion of patients with detectable PSA levels after surgery and variations in indication and type of salvage therapy in the observation group.

After central pathological review of over 50% of the cases, a repeat analysis of the data revealed that patients with PSMs benefited most from adjuvant RT [63].

Southwest Oncology Group (SWOG) 8794 was a similar randomized trial but with a primary endpoint of metastasis-free survival [64]. Between 1988 and 1997, 425 patients with extra-prostatic extension, seminal vesicle invasion, or PSMs were randomized after ORP to immediate RT (60–64 Gy) or observation. Similar to EORTC 22911, an undetectable PSA was not required for study eligibility. There were no significant differences between groups in metastasis-free or overall survival at a median follow-up of 10.6 years. However, PSA relapse (median BRFS 10.3 years vs. 3.1 years, $p < 0.001$) and disease recurrence were significantly improved with immediate RT. Adverse effects were more common with RT (24% RT vs. 12% observation). An updated analysis with over 12 years of follow-up was published in 2009 and showed that metastasis-free and overall survival were significantly improved with adjuvant RT [65].

More recently, ARO 96-02 randomized 192 men to observation and 193 to immediate post-operative RT (60 Gy) [66]. All patients had pT3N0 disease after ORP, with or without PSMs. Importantly, unlike in the above two studies, patients with a detectable PSA after ORP were excluded. At a median follow-up of 54 months, 5-year BRFS was significantly improved in the immediate RT group (72 vs. 54%, $p = 0.0015$). The number of events was too few and the follow-up too short to assess metastasis-free and overall survival. Among other variables, PSMs predicted an increased effect of the RT. Minor adverse effects were greater with RT, but grade 3 or 4 toxicity was rare in both cohorts.

The above three clinical trials clearly demonstrate a significantly improved BRFS with adjuvant RT after ORP vs. a wait-and-see approach for locally advanced disease and/or PSMs. The updated analysis of SWOG 8794 also demonstrates improved metastasis-free and overall survival with immediate post-operative RT. Although none of the trials included RARP patients, the results should be applicable to all patients fitting the study criteria regardless of surgical technique. Despite the results of these studies, two large trials assessing 51,495 and 130,681 patients with adverse pathologic characteristics in the National Cancer Data Base demonstrated that adjuvant RT is being performed sparingly in practice [67, 68].

Several recent retrospective studies have shown promising efficacy of salvage RT. A large, multi-institutional, retrospective study assessed 1540 men who underwent post-prostatectomy salvage RT (median 65 Gy) after biochemical recurrence [61]. At a median follow-up of 53 months after RT, overall 6-year progression-free probability was 32%, and outcomes were better when treatment was initiated at a PSA level ≤0.50 ng/ml (48% disease-free at 6 years). These results suggest that salvage RT using a low PSA threshold can yield comparable results to adjuvant RT that utilizes adverse pathologic features including PSMs. However, there have been mixed results in other series. Budiharto and associates studied 130 versus 89 patients who received adjuvant versus salvage RT, finding that adjuvant treatment yielded superior outcomes in patients with PSM [69]. More recently in 2012, Briganti et al. performed a propensity matched-controlled multi-institutional study of 390 versus 500 patients who underwent adjuvant and salvage RT, respectively [70]. They found that 5 year BCR-free survival was almost identical between groups (78.4% vs 81.8%, $p = 0.9$). Taking all the data into context, adjuvant RT clearly has shown reduction in BCR, metastases, and survival for patients with adverse pathologic characteristics including PSMs. To provide the most definitive guidance, there are currently ongoing randomized clinical trials called Radiotherapy and Androgen Deprivation in Combination After Local Surgery (RADICALS) and Radiotherapy—Adjuvant Versus Early Salvage (RAVES) that are investigating the timing (adjuvant vs. salvage) of post-operative RT [71, 72].

Reducing the Rates of Positive Surgical Margins

Surgeons' goal during radical prostatectomy is to achieve excellent oncological outcomes while maintaining urinary continence and maximal

erectile function. This is challenging since the areas of prostate near NVBs are prone to PSMs. The questionable long term significance of PSM forces a delicate balance between the degree of radical tumor excision and the preservation of surrounding tissue (i.e., NVB and pelvic floor muscles). In this regard, tailoring the surgical techniques based on risk factors for adverse pathology is of paramount importance.

In recent years, advanced MRI was investigated as a potential supplement to other preoperative clinical variables (DRE, PSA, biopsy Gleason score) used for RARP surgical planning. The ability of mpMRI to modify surgical planning for nerve sparing techniques was demonstrated by Park et al. [73]. In a retrospective study of 353 RARP patients, they planned the extent of NVB sparing on the basis of clinical information and reevaluated their plan after mpMRI. The appropriateness of the change was estimated according to the final pathology; preservation of NVB was considered appropriate if there was no ECE or PSM in the posterolateral area of prostate; NVB resection was considered appropriate if ECE was identified. In 53 patients (15%) surgical planning was altered from an aggressive to a conservative (nerve sparing) dissection. With the information provided by preoperative MRI, patients could theoretically undergo less morbid NVB sparing surgeries without a significant increase in PSM (appropriateness of 91%). The potential advantage of preoperative MRI was similarly demonstrated in other retrospective studies [74, 75]; however, the only randomized control trial that evaluated the ability of preoperative MRI to reduce the rate of PSM did not show a definite benefit [76]. Rud et al. randomized 216 patients to non-preoperative MRI and 222 to preoperative MRI. PSMs were detected in 49 (23%) and 43 (19%) patients in the non-MRI and MRI groups, respectively ($p = 0.4$). Although MRI did not reduce the risk for PSMs in the overall cohort, they did result in a statistically significant reduction in PSM for patients with cT1 disease. The rate of PSMs was 27% in the non-MRI group and 16% in the MRI group ($p = 0.035$). The relative and absolute risk reduction was 41% and 11%, respectively. Thus, although the data support some benefit from preoperative MRI, it cannot be recommended for routine surgical planning. Further studies are needed to determine its role in specific subgroups of patients undergoing RARP [76].

Intraoperative frozen-section has been proposed as another method to control surgical margins. Schlomm et al. studied a cohort of 5392 patients who underwent radical prostatectomy (ORP and RARP) during which the entire neurovascular-adjacent prostatic tissue was submitted for intraoperative assessment ("NeuroSAFE") [77]. PSMs were detected in 1368 patients (25%), leading to secondary resection of the involved neurovascular tissue and conversion to definitive negative margins in 1180 patients (86%). In NeuroSAFE cases, the frequency of nerve sparing was significantly higher (97% vs 81%; $p < 0.0001$) and PSM rates were significantly lower (15% vs 22%; $p < 0.0001$) than in the matched non-NeuroSAFE cases. The authors concluded that the NeuroSAFE approach is a useful adjunct to preoperative surgical planning. Bodman et al. used similar approach in a smaller cohort of 236 radical prostatectomy patients [78]. Frozen section analysis identified PSMs in 22% of cases and 92% of them were converted to negative margins. Although this technique seems promising, it is time consuming and its impact on functional outcomes as well as long term oncological outcomes awaits further evaluation.

As previously mentioned, the two most common locations of PSM are the apex and the posterolateral surface of the prostate. Various surgical strategies have been proposed to optimize the dissection in these areas in order to preserve the surrounding tissue without jeopardizing surgical margins. The three dimensional, improved magnification of the da Vinci™ system further enabled surgeons to stratify the extent of nerve preservation based on cancer severity. Zorn et al. implemented a protocol to select side-specific extent of nerve preservation based on pre-operative disease characteristics: PSA, clinical stage, biopsy Gleason score, percent of positive biopsy cores, greatest percent positive core [79]. Three levels of nerve-sparing were implemented for

differing risk strata: interfascial for lowest-risk, partial extrafascial for intermediate-risk, wide excision for high risk. The extrafascial dissection leaves a thin layer of tissue and blood vessels on the capsule of the prostate. When comparing 150 RARPs performed with the above protocol to 245 cases of non-selective interfascial nerve preservation, the authors found significantly lower overall (12.6 vs. 20.4%, $p = 0.04$) and posterolateral margin rates (37 vs. 70%, $p = 0.04$) with the tailoring approach. At 12 months, potency was reported in 67% of men undergoing partial extrafascial nerve preservation. The extrafascial plane seems to offer acceptable functional outcomes while significantly improving cancer control in select intermediate-risk patients.

Several studies have described surgical techniques to decrease apical PSMs during RARP. Guru et al. compared suture ligation of the DVC followed by apical dissection to cold incision of the DVC and apical dissection [80]. They found a significantly lower apical PSM rate with the cold incision technique (2 vs. 8%, $p = 0.02$). Menon and colleagues reported a similar improvement in organ-confined apical PSMs when suture ligation of the DVC was performed after prostate removal instead of before apical dissection [4]. A different way to overcome the obstruction of the apex by the DVC was presented by Tewari et al. [81]. They proposed a posterior gland approach using a 30 degrees up lens and cephalad retraction of the prostate. After the development of the posterior plane was completed, the posterior urethra was transected, followed by the anterior urethra. The DVC was eventually divided through anterior approach. The rate of PSM decreased from 4.4 to 1.4%.

Optimizing surgical margin rates is multifactorial and includes appropriate patient selection, tailoring surgery based on disease characteristics, and improving the surgical techniques during various steps of the procedure. Maximizing functional outcomes is a competing interest but regardless of which technical modifications are implemented, cancer control should always take precedence.

Conclusion

RARP has quickly become the most common surgical approach performed for prostate cancer and many consider it the new gold standard. In experienced RARP series, overall PSM rates have ranged between 9% and 19%, which are comparable to ORP. The most common locations for PSMs during RARP are posterolateral and apical. Independent risk factors for PSMs include lower surgeon case volume, higher pathological stage and grade, lower prostate weight, higher levels of preoperative PSA and increased PSA density. Some evidence also suggests that biopsy Gleason score and BMI may be risk factors. Similarly, NVB preservation appears to be a risk factor for PSMs; however, it is difficult to control for confounding variables such as surgical technique and disease severity. Tailoring nerve preservation based on disease severity and certain surgical techniques, particularly at the apex, may improve cancer control during RARP. Additional strategies such as preoperative mpMRI and extended intraoperative frozen-section have shown promising results but additional studies are required to determine their definitive role.

While many large series have demonstrated a link between PSMs and BCR, the association with metastases and survival has not been clearly demonstrated. Gleason score at PSM and PSM margins length are important features of PSM that should be incorporated in studies evaluating the long term impact of PSM. Adjuvant RT for locally advanced disease and/or PSMs significantly improves biochemical recurrence-free, metastasis-free, and overall survival compared to observation. Salvage RT, initiated in a timely fashion when PSA levels are low, can provide similar outcomes. While many of these findings stem from open series, it should be applicable to RARP patients as well. The decision to pursue post-operative RT (adjuvant or salvage) is, however, complex and includes consideration of the added survival benefit vs. adverse effects from the radiation. The optimal timing of when to deliver additional RT is still

unknown and awaits the results of several randomized clinical trials.

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Laparoscopy or Robotic Radical Prostatectomy: Pros and Cons

35

Claude Abbou and Leticia Ruiz

Abstract

Radical prostatectomy is currently performed commonly by robotic assistance (RRP) in western world surpassing laparoscopic radical prostatectomy(LRP).Robotic assistance has distinct advantages over traditional laparoscopic surgery, as it improves precision because endowrist technology providing freedom of movements to its instruments in 3-D vision with better ergonomics for the surgeon. The biggest challenge is the cost of the robot, so as the price of its maintenance and instruments. The cost of LRP is much lower than that of the RRP. Of course, the learning curve for laparoscopic radical prostatectomy is steep. Development of newer instrumentation with 4 degree of movements and 3-D vision during laparoscopy may resurrect role of LRP. This chapter focusses on pros and cons of LRP and RRP.

Keywords

Laparoscopy · Robotic · Radical prostatectomy

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Advantages of the Laparoscopic Approach

The cost of laparoscopic radical prostatectomy is lower than that of the robotic-assisted procedure, since there is no need for purchase or maintenance of the robot, and the instruments used are less expensive [1]. These advantages persist even if the operative time tends to be longer for the laparoscopic approach.

Disadvantages of the Laparoscopic Approach

The learning curve for laparoscopic radical prostatectomy is steep. It has been considered to be around 40–60 cases for the experienced laparoscopic surgeon [2]. Most of the initial series published considered the procedure technically demanding [3–5]. Some authors consider that around 200 cases are needed before reaching the learning curve, with the most technically challenging step being the urethro-vesical anastomosis [6, 7]. It is also possible that second- and third-generation surgeons will acquire adequate skills with a smaller series of surgery, specially if mentorship is applied [8] compared to surgeons who started when the technique was just developing.

There is a limited range of movements, since surgery is performed with rigid instruments. This leads to difficulties in dissection and in

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performing the urethro-vesical anastomosis. Intra-corporeal suturing is difficult to master. Investment in training by surgeon is time consuming and costly. The see one, do one, teach one concept does not apply to this technique.

Another disadvantage of the laparoscopic radical prostatectomy is its two-dimensional vision, and the lack of control of the laparoscope by the surgeon who relays on an assistant that must be familiar with the procedure to help the surgeon adequately. In lengthy procedures lack of assistance can lead to even higher increases on operative times. Some centers bypass this difficulty by using the AESOP voice-activated robotic arm to control the laparoscope.

Advantages of the Robotic-Assisted Procedure

The use of the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, California) permits several advantages.

Ergonomy for the surgeon, who comfortably seats at a console: The console can be located in the operating room or in an adjacent room. Eventually, the console could be situated remotely from the patient. This opens the possibility of telesurgery at a distant site. The feasibility of telesurgery and telementoring using the da Vinci Surgical System was demonstrated, by performing four right nephrectomies in porcine models with surgeons operating a console at distances of 1300 and 2400 miles from the operating room [9].

The console is integrated with three-dimensional display stereo viewer and provides 10- to 15-fold magnification. Improved image quality has the potential of improving functional results by permitting more accurate dissection of the neurovascular bundles.

Instruments are wristed, providing 7° of motion, resembling more closely the movements of the human hand and wrist. In addition, movements of the hand are scaled and tremor is corrected. These characteristics enable the laparoscopy-naïve surgeon to acquire the skills to migrate into minimally invasive surgery, since movements are intuitive.

The robot-assisted radical prostatectomy has a shorter learning curve, compared to the laparoscopic procedure, with surgeons without previous experience in laparoscopy acquiring proficiency with as few as 12 cases [10]. Since the definition of learning curve varies widely, so do the cases necessary to attain it, depending on the parameters considered and the studies that are evaluated. Some studies suggest that 20–25 cases are needed for proficiency [11]. Operative time to perform robotic radical prostatectomy is significantly reduced as the surgeon's experience increases. This was demonstrated in a series by Menon and colleagues [12] in which, after 18 procedures, operative times for the robotic procedure became shorter than those of laparoscopic procedures by experienced surgeons. An interesting study showed that intensive 5-day training enabled most participants to incorporate and maintain robotic-assisted prostatectomy into their practices [13].

The presence of a computer between patient and surgeon opens the possibility of developing new applications, such as image-guided surgery (IGS). The potential benefit of adding image guidance to the da Vinci robotic surgical system, by improving dissection and surgical margins, has been demonstrated in a laboratory model [14].

Disadvantages of the Robotic-Assisted Procedure

When the procedure is performed by robotic assistance, there is a lack of tactile feedback [15].

Communication among surgeon, assistant, and rest of the staff can be impaired during the robotic-assisted procedure. Also, the rest of the team does not benefit from the three-dimensional image.

Probably the most important disadvantage is the very high cost of the robot, its maintenance, and consumable equipment. Several studies have addressed this aspect. It has been estimated that 45% of the average direct cost, and a third of the average total cost, corresponds to medical and surgical supplies, while operating room services corresponded to 30 and 35%, respectively, to

average direct and total costs [16]. A study of 643 consecutive patients who underwent radical prostatectomy by either open, robotic-assisted, or laparoscopic approach compared the cost of each modality and found that robotic-assisted radical prostatectomy direct cost (OR time, disposables) exceeded laparoscopic radical prostatectomy by more than $1000, without including the cost of purchase and maintenance of the robot, which depends on case volume at each particular center. Depending on the model and year of purchase of the robot, this cost could approach $2700 if 126 cases per year are performed [1]. If the robot is shared with other specialties, its cost per case could be around $900, considering a case load of 300 per year for 7 years [17]. Models have been developed to evaluate cost depending on operative time, length of stay, and local cost for room and board and demonstrated decreasing cost as operating room time and length of stay decrease, and higher advantages at high-cost hospitals [18].

A study in the United Kingdom considered not only cost of the procedure but health gain resulting from quality-adjusted life-years (QALYs) of 0.08 (0.01–0.15). They concluded that the higher costs of robotic prostatectomy may be offset by modest heal gain resulting from lower risk of early harms and positive margins, provided more than 150 cases are performed each year [19].

A study at Duke University Medical Center showed more regret and dissatisfaction among patients who underwent the robotic procedure, compared to the open approach (19.9 vs 12.9% of dissatisfaction, correspondingly) even if functional results were not statistically different in the laparoscopic and robotic-assisted groups [20]. Authors attributed this finding to higher expectations and different demographics in patients choosing the robotic approach.

Results

Perioperative Results

Regarding perioperative outcomes, cumulative analysis showed no significant difference in complication rates after RALP and LRP, [21] even if some studies reported contradictory results. Analysis of two studies [22, 23] proved that operative time was shorter for RALP and complication rate was lower for RALP, so they hypothesized that increasing surgeon experience might have influenced these results. In contrast, a series from France [24] showed higher rate of complications and transfusion rate in the RALP group compared to the LRP. In centers with extensive laparoscopic experience, when the learning curve is excluded, operative time is similar in both approaches [24].

In general, catheterization time and hospital stay are similar between RALP and LRP, although a study reported that 95% of patients operated by the robot-assisted procedure were discharged within 24 h [25].

Median blood loss was comparable in both techniques in two studies [23, 24] and lower for RALP in other two studies [12, 26].

Both techniques can be performed by either the transperitoneal or extraperitoneal approach [15, 27–29].

Oncologic Outcomes

According to studies reporting oncologic results of laparoscopic and robotic-assisted radical prostatectomy, no difference is noted regarding positive surgical margins [21]. A multinational multi-institutional study of 22,393 patients demonstrated the lowest crude rates of PSM for robotic RP (13.8%), intermediate crude rates for laparoscopic RP (16.3%), however after adjustments for the effects of age, preoperative PSA, postoperative Gleason score, pathologic stage, and year of surgery, no significant differences in PSM were found between the two minimally invasive groups [30]. Positive surgical margins ranged from 11 to 30% after laparoscopic radical prostatectomy and from 9.6 to 26% for robotic-assisted radical prostatectomy [21]. Some authors have looked at additional procedures or treatments (salvage radiotherapy, chemotherapy, or hormonal therapy) after radical prostatectomy to assess cancer control and concluded that unfavorable outcomes decrease with increasing surgical volume [31, 32].

A study at Tulane evaluated 100 patients who underwent robotic-assisted radical prostatectomy, according to the time of surgery. Patients were divided into three groups (I, first 33 cases; II, second 33 cases; and III, last 34 cases), and a statistically significant decrease in positive surgical margins was noted from 45.4 to 21.2 to 11.7%, respectively, as the series progressed [33]. Similar results regarding surgical margins have been observed in other series.

A comprehensive review of robotic and laparoscopic series found an overall weighted mean for positive margin rate of 12.5% for robotic radical prostatectomies and 19.6% for laparoscopic radical prostatectomy. It must be considered that the robotic series had 77.4% pT2 tumors and 21.5% pT3 tumors; the laparoscopic series had 70.4% of T2 tumors [34].

Biochemical recurrence-free survival at 5 years is similar, ranging from 82 to 100% for robotic-assisted prostatectomy [35–37] and 85% in a series of 1115 extraperitoneal laparoscopic procedures, [35] and 90.5% at 3 years for a series of 1000 transperitoneal prostatectomies [38].

Functional Results

Urinary Continence

Continence outcomes have also been evaluated in reviews. At 3 months, urinary continence ranged from 73 to 91% for robotic-assisted prostatectomy and 51–94% for the laparoscopic group, while at 6 months it ranged from 82 to 97% and 73 to 96%, respectively [34, 39]. A study comparing laparoscopic and robotic radical prostatectomy showed no difference in continence rates at 6 months [26].

In a study of 712 patients of whom 614 underwent LRP and 98 RARP. Patients who underwent RARP restored the continence sooner than those in the LRP group in 1 and 3 months after the surgery ($P < 0.001$ and 0.001). For the multivariable analysis, the type of RP procedure was a uniquely meaningful contributing factor ($P = 0.001$, HR = 1.925; 95% CI, 1.299–2.851). In the case of urinary function, the RARP groups showed better IPSS than the LRP groups at the 1-,3- and 6-month visits, respectively ($P = 0.008$, 0.026, 0.001), and the RARP groups early improved compared with LRP groups at the 3-month visit in the case of erectile function ($P = 0.018$) [40].

Erectile Function

Rates for erectile function vary among series, as do definitions for potency, rendering it difficult to compare results [21]. Potency rates for robotic series at referral centers vary from 70 to 80% and from 42 to 76% for laparoscopic series. A non-statistically significant trend favoring the robotic technique was observed in a comparative study [26]. A study of 1151 of a mature series of robotic-assisted radical prostatectomy, using the superveil nerve-sparing technique, reported 94% potency at 6–18 months after surgery [41]. This result has not been reproduced in other series.

Conclusions

At this moment, there are no prospective multicenter trials comparing laparoscopic and robotic radical prostatectomy. Results from surgical series have not demonstrated significant differences in operative outcomes, cancer control, or functional results between laparoscopic and robotic-assisted radical prostatectomy. However, results improve as surgeons complete their learning curves. Taking this into account, it is expected that surgeons at high volume centers, regardless of the technique, will attain the best results.

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Complications of Robot-Assisted Radical Prostatectomy

36

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Abstract

Robotic surgery represents a shift in the surgical paradigm and is consequently associated with a unique set of challenges and complications in comparison to open or conventional laparoscopic surgery. For the first time, the surgeon is not directly at the bedside but is rather directing an intermediary machine and a separate bedside team to perform the operation. This, in addition to the lack of tactile feedback, the greater reliance on visual anatomic clues when performing robotic surgery, and the inherent risk of malfunction or mechanical failure of robotic components may all contribute to complications noted during robot-assisted radical prostatectomy (RARP). In this chapter, we outline the risks and incidence of the more common complications associated with RARP and present methods to manage them.

Keywords

Radical prostatectomy · Robotic surgery · Complications · Prostate cancer

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Introduction

Since the approval of the first robotic surgery system by US Food and Drug Administration in 2000, there has been a significant increase in the use of robot-assisted surgery. Robotic technology has been rapidly adopted as part of modern surgical practice and has been embraced by the urologic community in particular. While urologic applications of the technology include robot-assisted pyeloplasty, cystectomy, and partial nephrectomies, the robotic system's largest impact has been in its use for radical prostatectomy. Recent data has shown that utilization of robot-assisted radical prostatectomy (RARP) increased from 1.8% in 2003 to 85% in 2013 [1]. Given the lower morbidity in comparison to open surgery and increasing inter-hospital competition to offer the latest technology to patients, robotic surgery is expected to remain widely utilized [2].

Robotic surgery represents a shift in the surgical paradigm and is consequently associated with a unique set of challenges and complications in comparison to open or traditional laparoscopic surgery. For the first time, the surgeon is not directly at the bedside but is rather directing an intermediary machine and a separate bedside team to perform the operation. Advantages to the robotic interface include the visualization benefits of laparoscopic surgery plus three-dimensional magnified vision, six degrees of surgical freedom, and enhanced tremor filtration

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[3]. Disadvantages unique to the robotic approach include a lack of tactile feedback compared to open and traditional laparoscopic approaches as well as the inherent risk of malfunction or mechanical failure of robotic components.

In this chapter, we outline the risks of complications associated with RARP and suggest methods to manage them. An overview of the most common complications of RARP from large published series and meta-analyses is provided in Table 36.1. We have also identified specific instances when complications may occur and provide suggestions to minimize them. It is essential for the surgeon to understand these complications prior to undertaking an operation in order to prevent them from occurring, to direct the surgical team towards safe troubleshooting of complications when they do occur, and to recognize and treat them swiftly. The importance of having an experienced surgical team that understands and is ready to manage perioperative complications cannot be overemphasized.

Overall Complications: Robotic vs Open Approach

Despite the rapid adoption of RARP, no large-scale randomized controlled trials have demonstrated its superiority over open radical prostatectomy (ORP) with regards to complications [1, 4, 5]. There is, however, a growing body of evidence suggesting that robotic prostatectomies may be associated with lower complication rates, although the majority of such evidence so far has largely come from observational cohort studies and meta-analyses [6, 7].

The complication rates of ORP reported from centers of excellence are low and range from 6% to 10% [8, 9]. Encouragingly, multiple comparative studies have demonstrated significantly fewer 30-day complications, blood transfusions, anastomotic strictures, decreased postoperative pain and shorter length of stay (LOS) in RARP compared to ORP [10, 11]. A recent comparative study of 5915 Medicare patients treated with either ORP or RARP between 2008 and 2009 found no differences in complications, readmissions, or additional cancer therapies, however a significant benefit with regard to blood transfusions and length of stay (LOS) was identified [12]. Another population-based study over the same time period with 19,462 patients of all age groups and insurance statuses found significant decrease in transfusion rate, LOS, intraoperative and postoperative complications for RARP compared to ORP [13]. A recently published population-based study between 2003 and 2013 with over 600,000 patients demonstrated lower 90 day postoperative complication rates including blood transfusion rates and shorter LOS for patients undergoing RARP, even among patients with multiple comorbidities [1]. The overall complication rate for RARP is approximately 9% based on a recent systematic review and meta-analysis of over 100 published studies, and almost 80% of these complications were considered low grade (Clavien-Dindo I or II) [7].

An additional factor that must be considered in the modern healthcare environment is the contribution of cost to the delivery of surgical treatments. The most recent large database cohort study of ORP versus RARP revealed the mean 90 day direct hospital costs of RARP to be approximately $4500 higher than for ORP, although this cost difference was noted to lose significance when comparing only high-volume surgeons [1]. A follow up study to this one examining surgeon and hospital-level RARP cost variation in more detail demonstrated that high-volume surgeons and hospitals were associated with increased odds of a lower-cost RARP [14].

Complications Related to Patient Positioning

Appropriate and safe positioning of the patient on the operating table is critical to the success of the operation, and the two primary considerations in this regard are adequate exposure of the operating field as well as prevention of positioning-related injuries. After induction of general endotracheal anesthesia, the patient's arms and hands should be carefully tucked and padded at the sides with egg-crate padding to avoid injury

Table 36.1 Overview of RARP complications from prior large series and meta-analyses

Authors	Year	Patients (N)	Thromboembolic complication incidence (%)	Transfusion rate (%)	Bowel injury incidence (%)	Ileus incidence (%)	Lymphocele incidence (%)	Urine leak incidence (%)	Anastomotic contracture incidence (%)	Overall complication rate (%)
Hu et al. [30]	2006	322		1.6		2.8	0.9	7.5	0.6	15
Fischer et al. [46]	2008	210		1	1.5		0.5		0.5	26.1
Coelho et al. [47]	2010	2500	0.52	0.48	0.08	0.72	0.36	1.4	0.12	5
Siddiqui et al. [17]	2010	4000	0.3	1.9	0.5	0.7	0.2	0.7		5
Novara et al. [7]	2012	Meta-analysis of 110 studies	0.2	2	0.2		3.1	1.8		9

to the median and ulnar nerves and subsequent upper extremity palsies. Deliberate padding of vulnerable bony prominences such as the hips, shoulders, knees, and calves is important to prevent pressure injuries and neuromuscular complications. Because the patient's arms will be tucked at the side and difficult to access intraoperatively, it is critical to work with the anesthesia and nursing teams to ensure accurate pulse oximetry, blood pressure cuff placement, and intravenous access are established prior to beginning the case and that these processes do not become compromised during the positioning process.

The patient's legs should be placed in lithotomy stirrups or secured on a split-leg table with egg-crate padding and tape, and abducted slightly in order to allow intraoperative access to the rectum and perineum by the bedside assistant as necessary. The authors prefer the use of a split-leg table as this provides broad and uniform support of the lower extremities. Sequential compression devices should additionally be utilized to reduce the risk of deep venous thrombosis. Extension at the hip should be kept to the minimum necessary so as to allow successful docking of the robotic arms; over-extension may lead to postoperative lower extremity neuropraxia. Patients are at unique risks for specific lower extremity neuropathies secondary to the steep Trendelenburg positioning with hip extension, especially following prolonged surgeries [15]. The frequency of these lower extremity neuropathies appears to be low (1.3%) and predominantly transient in nature. Exaggerated extension of the operating table at the level of the hips while docking the robotic arms may increase the risk for femoral neuropraxia. The etiology of this injury is thought to be secondary to either stretch injury or compression of the femoral nerve as it courses beneath the inguinal ligament with resultant transient motor and sensory neuropathy. Presenting symptoms of femoral neuropraxia include anterior thigh numbness and quadriceps muscle weakness, and when present the patient will generally begin displaying symptoms soon after waking from surgery.

Once appropriately positioned, the patient is then secured firmly to the table using 3 in. heavy cloth tape and egg-crate padding across the chest or in a criss-cross fashion to help prevent the patient from sliding cephalad while in the steep Trendelenburg position during the operation. Fixed shoulder rests should be avoided altogether as these devices can result in compression injury to the shoulder joints, muscles, and brachial plexus when in prolonged steep Trendelenburg. An orogastric tube should be placed to decompress the stomach prior to trocar access, and a foley catheter should be placed under sterile conditions so that it may be accessed during the procedure.

Anesthesia-Related Complications

The primary anesthetic considerations during RARP relate to physiological changes in the cardiopulmonary, ocular, and intracranial systems that occur in the steep Trendelenburg position in the setting of CO_2 pneumoperitoneum especially during prolonged surgeries [16].

Sinus bradycardia can be observed and is likely attributable to increased abdominal pressure from pneumoperitoneum producing a vagal response from stretching of the peritoneal structures. This can often be managed successfully with prompt desufflation of the abdomen and administration of atropine [17]. More commonly, sinus tachycardia is observed which is thought to be secondary to pharmacologic sympathetic stimulation by increased arterial pCO_2 as well as a compensatory mechanism for the decreased cardiac return of blood flow during periods of elevated intraabdominal pressure.

Assessment of volume status is particularly challenging during RARP given that much of the patient's urine output will be draining into the operative field during the case, and the elevated intraabdominal pressure can additionally cause an independent decrease in urine output and glomerular filtration rate [18]. Excessive hydration during the case leading to increased urine output can be detrimental as it can obscure the operative field and make the anastomosis more challenging to perform. Fluid overload in a steep Trendelenburg position can also cause significant

facial edema, especially early in the surgeon's learning curve when operative times may be lengthy [17]. For these reasons, consideration should be given to limiting intravenous fluid administration to approximately two liters of crystalloid solution in healthy patients and even smaller volumes in patients with baseline cardiovascular or renal dysfunction.

The steep Trendelenburg position, particularly in the setting of pneumoperitoneum, has also been associated with temporary increases in intraocular pressure, which seem to resolve upon return to the supine position [19]. Amongst other potential causes, the two operative variables which have been identified to contribute significantly to this effect are operative time and hypercarbia. Mechanistically, it is thought that elevated central venous and ocular venous pressure secondary to the steep Trendelenburg position is exacerbated with prolonged operative time. This effect is further aggravated by choroidal vasodilation secondary to increased arterial pCO_2 resulting from the pneumoperitoneum. While the clinical relevance of this transient phenomenon is unclear and its effects are generally unapparent in the majority of healthy individuals, it may pose particular concern in elderly patients who have elevated intraocular pressures at baseline, such as glaucoma patients. It is unknown whether this effect is causally associated with the rare reports of acute visual loss following minimally invasive prostatectomy as a result of posterior ischemic optic neuropathy [20]. Nevertheless, it is advisable that both surgeon and anesthesiologist inquire about preexisting ocular disease in the preoperative screening of patients who select to undergo RARP. Furthermore, it is strongly advised to keep operative times as short as possible as many of these anesthesia or positioning complications are more common with prolonged surgery. The additional potential ophthalmologic complication of corneal abrasion, which is generally of limited long-term significance but can cause significant pain in the recovery period, is easily prevented with adequate eye lubrication and protection maintained during the procedure and early recovery room period.

Both steep Trendelenburg positioning and establishment of pneumoperitoneum cause increased intracranial pressure (ICP). The clinical endpoint of cerebral perfusion, however, is generally not compromised as CO_2 mediated vasodilation and increased mean arterial pressure have been shown to keep cerebral perfusion pressure above the autoregulation threshold. Special consideration should be taken when operating on patients with known intracranial pathology who may not be able to autoregulate their cerebral perfusion pressure as efficiently. Special care should also be taken in patients with ventriculoperitoneal shunts, as the expected increases in abdominal pressure from pneumoperitoneum and ICP from the positioning may change the flow dynamics within the shunt, and for this reason preoperative neurosurgical consultation should be considered in patients with shunts who are undergoing RARP.

Throughout the case, it is imperative that the surgeon and anesthesiologist maintain continuous awareness of the patient's end-tidal CO_2 level and intraabdominal insufflation pressure as the potential consequences of prolonged pneumoperitoneum and hypercarbia including oliguria, acidosis, and decreased cardiac output can be significant. Prompt adjustments in minute ventilation may be required by the anesthesiologist in the event of rising end-tidal CO_2 levels or worsening hypercarbia on repeated arterial blood gas testing [21]. Adjustments in CO_2 insufflation pressures may also be required by the surgeon to reduce the risks associated with prolonged hypercarbia. The authors generally recommend maintaining insufflation pressures between 12 and 15 mm Hg. When left untreated, prolonged hypercarbia can progress to life threatening systemic acidosis and multiple organ system dysfunction, and should therefore be minimized.

Access-Related Complications

Vascular and Bowel Injuries

Deliberate and safe access into the peritoneal cavity and trocar placement is an essential element of performing successful RARP. Though a

seemingly minute part of the greater procedure, this task is not without risk, and reports estimate an access injury incidence of between 5 and 30 per 10,000 cases [22], the vast majority of which are either vascular or bowel injuries. There are numerous methods by which attainment of pneumoperitoneum and placement of trocars can be achieved. Commonly, a Veress is used to access the peritoneal cavity quickly and initiate pneumoperitoneum, followed by placement of the first trocar under direct vision using an optical trocar and 0° lens. Generally, the umbilicus is used as the insertion site for the Veress, however care should be taken to avoid placing the Veress through a prior abdominal scar due to the risk of adhesions and subsequent accidental puncture of intra-abdominal organs. Sharp or bladed trocars should be avoided. Prior to insufflation, a syringe should be used to draw back on the Veress and ensure that there is no return of either blood or visceral contents, and a drop test should be performed to confirm appropriate placement. Once satisfied with the needle position, insufflation with CO_2 may proceed. The insufflator should be closely monitored to ensure low intraabdominal pressure (4–6 mmHg) with good CO_2 flow initially, which again reassures that the needle is in the appropriate position. Alternatively, if there is heightened concern for the presence of adhesions based on the patient's surgical history, the Hasson technique can be utilized [23]. Ultimately the optimal choice of access technique is the one in which the surgeon is the best trained and most comfortable.

The mean incidence of vascular injury during laparoscopic access is less than 0.05% [24]. Although rare, the outcomes can be devastating, with one series reporting a 44% mortality rate for major visceral vessel injury sustained during laparoscopic access. The most commonly injured vessels during pelvic laparoscopy are the aorta and the common iliac arteries [25]. Rarely a major mesenteric vessel can be involved if it is trapped within an adherent loop of bowel near the site of access and is punctured. Signs of significant vascular injury include profuse bleeding from trocar sheath, rapidly accumulating blood within the abdominal cavity or an expanding retroperitoneal hematoma, and hypotension with associated tachycardia. Once identified, rapid management must ensue with laparotomy if necessary, identification of the bleeding vessel, and primary repair. Less significant vascular injuries in which visualization and the patient's hemodynamics are not compromised may be managed laparoscopically. Abdominal wall vessels are also at risk during trocar placement, namely the inferior epigastric arteries that lie within the lateral rectus sheath and may be compromised during para-rectus trocar placement. This injury is often recognized when blood is noted to be dripping down from the trocar sheath into the abdomen, or at the end of the case when the trocar is removed under direct vision. When apparent, care should be taken to ensure vessel ligation or, when that is not possible, a Carter-Thomason device can be used to broadly pass a suture around the terminal ends of the vessel and secured to tamponade the bleeding [26]. The use of abdominal transillumination to clearly visualize the epigastric vessels and their branches in addition to the use of blunt instead of bladed trocars has been shown to decrease the risk of significant abdominal wall bleeding [27].

Small and large bowel are also at risk during laparoscopic abdominal access, and the incidence of bowel injury as a complication of laparoscopy has been reported to be 0.22%. Approximately 40% of those injuries occur during access [28]. Like vascular injuries, the surgeon may elect to perform laparoscopic primary repair with multiple layer closure for less significant injuries, and open repair may be necessary for more significant injuries. In either case, general surgery consultation at the time of injury recognition is advisable.

Based on the risks inherent to accessing the abdomen and placing trocars, it is prudent to visually inspect all trocar sites and underlying abdominal contents following access. This quick and simple maneuver will allow early identification and treatment of any potential injuries which, if left untreated or unrecognized, could increase exponentially in conferred morbidity or mortality to the patient in the postoperative setting. Once safe trocar placement is established and the robot

has been docked, care must be taken throughout the operation to avoid injury along the path of the multiple instruments, which typically must be interchanged and directed toward the pelvis numerous times throughout the course of the operation. The guided-instrument exchange function of the robot should be utilized with each instrument exchange performed by the bedside assistant in order to minimize the potential for injury and complications from blind passage or "past-pointing" of the instrument tip.

Gas Embolism

In additional to the sequelae of blood loss following a vascular injury during access, gas embolism represents a rare but potentially fatal complication which occurs when a blood vessel is punctured by the Veress needle and insufflated during access. The presentation of gas embolism is acute cardiovascular decompensation characterized by bradycardia, hypotension, and a sudden drop in end-tidal CO_2 followed by declining oxygen saturation. When suspected, the treatment is immediate desufflation of the abdomen, transfer to the left lateral decubitus Trendelenburg position, and hyperventilation with 100% oxygen administration. A central line can be placed to attempt to aspirate the gas from the right atrium. This complication is highly preventable through the use of the aspiration and drop tests described previously, which, if performed, would identify intravascular placement of the Veress needle and allow correction prior to CO_2 insufflation.

Intraoperative Complications

Rectal Injury

Rectal injuries are relatively uncommon during RARP (0.1–1.25%) [29–31]. There are numerous identifiable risk factors that may predispose patients to rectal injury, including: prior abdominal or pelvic surgery (e.g., TURP), history of diverticulitis, history of prior pelvic radiation, or locally invasive cancer. These injuries have been reported to be managed successfully by laparoscopic means in several series [32–34]. Intraoperative recognition and repair of the injury is of paramount importance. Multilayered primary closure with or without interposition of omentum between the rectum and anastomosis and copious irrigation can usually prevent long-term problems and ensure good healing in the majority of patients. In cases where there is a significant injury with fecal spillage or in patients who have been radiated or otherwise have factors for poor wound healing (i.e., chronic steroid use, immunosuppression), intraoperative colorectal consultation is advisable for consideration of more extensive repair or potential intestinal diversion. Inadequate closure or lack of recognition can result in devastating complications, such as rectourethral fistula or peritonitis. If a small rectal injury is suspected but not readily visible, insufflation of air into the rectum using a catheter inserted into the rectum with fluid within the pelvis (i.e. air bubble test) can often be used to localize an otherwise undetectable injury. In the authors' experience, rectal injury occurs most commonly during the distal-most extent of the posterior dissection near the apex, where visualization is more likely to be compromised. In efforts to minimize rectal injury, dissection should be taken as close to the prostatic surface as possible when performing the posterior dissection of the prostate, maintaining awareness that the rectum may be tented up to the prostate due to prior biopsies, infections, or fibrosis.

Ureteral Injury and Obstruction

Rare and uncommonly reported in large series, ureteral injury during RARP may occur during the posterior dissection where it is misidentified as the vas deferens, or during extended lymphadenectomy where the ureter crosses over the iliac vessels. If recognized intraoperatively, a minor injury may be treated with primary repair and stent placement. A more significant injury may require uretero-ureterostomy or re-implantation.

A more common scenario, particularly in patients with large median lobes, are ureteral

orifices which fall close to the level of the posterior bladder neck transection and are therefore at risk of becoming obstructed by the anastomosis or even by the foley catheter balloon. This classically presents postoperatively with rising creatinine and ipsilateral flank pain. When suspicion is aroused that a ureteral orifice may be obstructed in the post-operative period, CT-urogram can be helpful in identifying hydronephrosis or other potential sources of the problem. If the imaging study correlates clinical concern for ureteral obstruction, a reasonable first step is partial deflation of the foley catheter balloon with simultaneous gentle advancement of the catheter a few centimeters, securing it in its new location, and serial serum creatinine monitoring to assess for improvement. If no improvement is noted, consideration should be given to percutaneous nephrostomy placement followed by antegrade nephrostogram once the foley catheter is removed. If the obstruction is due to edema at the anastomosis or as a result of obstruction by the foley balloon, this often will resolve once the foley is removed. A direct ureteral injury on the other hand may require endoscopic or open surgical repair.

Ultimately, obstruction of ureteral orifices that are located at the edge of the posterior bladder neck margin can be minimized by imbrication of the ureteral orifices using interrupted sutures at the 3 and 9 o'clock position prior to completion of the anastomosis [35]. Otherwise, ureteral stents may be placed temporarily and later removed once the anastomosis is well healed.

Obturator Nerve Injury

During pelvic lymph node dissection, the obturator nerve can be at risk for injury due to poor visualization of its anatomic course. Clinical presentation of such an injury is generally characterized by weakness of thigh adductors in the post-operative period. Prospective identification of the obturator nerve and dissection of the lymph nodes away from the nerve can aid in preventing inadvertent thermal injury, transection, or mechanical injury from a hemoclip. In cases when obturator nerve injury occurs, successful repair with perineural nerve sheath reapproximation has been described with good functional outcomes [30, 36].

Intraoperative Bleeding and Transfusion

Virtually all published reports have documented a distinct advantage for laparoscopic and robotic surgery in diminishing the amount of bleeding that occurs during radical prostatectomy. Transfusion requirements of 2% or less are commonly reported [37]. The tamponade effect of the pneumoperitoneum compresses venous bleeding intraoperatively, and the superior visualization within the deep pelvis allows timely identification of bleeding vessels that require precise hemostasis. Both of these factors represent significant advantages over the open surgical approach. However, despite these distinct advantages, there is the possibility of postoperative bleeding which becomes unmasked once pneumoperitoneum is relieved. For this reason, the pelvis and surgical field should be carefully inspected for the presence of bleeding at the end of the operation under low insufflation pressure.

Equipment Malfunction

The surgeon is highly dependent on sophisticated technology and equipment for performance of RARP. Equipment malfunction, especially with RARP, can create problems that make it impossible to progress with surgery and may result in case cancellation or conversion to conventional laparoscopic or open surgery. One review of >8000 robotic cases found a 0.4% non-recoverable malfunction rate in their multi-institutional study of high-volume RARP centers [3]. Within this group of cases, 70% of the errors were able to be identified prior to the start of the procedure and the majority were recoverable errors. Although extremely rare, patients need to be properly counseled about the possibility of conversion to a conventional laparoscopic or open surgical approach in the event of an unrecoverable equipment malfunction.

Open Conversion

Open conversion is rare (<2%) and has been cited in the literature, usually during a surgeon's early experience with RARP, typically as a result of failure to progress or uncertainty of dissection planes [38]. Occasionally, as noted previously, open conversion is required for the management of significant vascular or gastrointestinal injury. The key to minimizing the need for open conversion starts with proper patient selection. Novice robotic surgeons are best advised to avoid patients with large prostate glands >75 g, obesity, prior prostate or lower pelvic surgery, or previous radiation or androgen ablation therapy at least early in their experience. With increasing surgeon experience, however, the need for open conversion is rare. Nonetheless, patients must be properly counseled regarding the potential necessity of open conversion with this or any minimally invasive operation.

Postoperative Complications

Postoperative Bleeding

Although rare, postoperative hemorrhage must be considered in the patient with hypotension and worsening blood count parameters after surgery. When this occurs, these patients should be placed on bed rest and transfused as necessary. Should their parameters continue to decline, prompt surgical re-exploration should be considered earlier rather than later as the presence of a pelvic hematoma can lead to partial disruption of the vesicourethral anastomosis, a prolonged hospital course, and catheterization with potential scarring leading to a bladder neck contracture [38]. It is reasonable to perform re-exploration robotically using the same sites as the original operation.

Thromboembolic Complications

The 2008 American Urological Association Best Practices Statement recommends the routine use of intermittent pneumatic compression devices for laparoscopic and robotic urologic procedures. However, it does not recommend routine use of prophylactic anticoagulants for these procedures unless a patient has multiple known risk factors such as obesity, advanced age, malignancy, immobility or a prior history of deep venous thrombosis (DVT). Nonetheless, because of the known venous stasis and hypercoagulable state that can occur during pelvic surgery in patients with known malignancy, RARP patients are considered to be at risk for thromboembolic complications. Performance of pelvic lymph node dissection (PLND) during RARP appears to increase this risk, with one study reporting a 2.6% incidence of DVT or pulmonary embolism (PE) following RARP with PLND versus a 0.4% incidence following RARP alone [39]. Additionally, the incidence of mortality associated with such a complication following RARP has been recently reported to be approximately 3%, thus justifying efforts to minimize its occurrence [39]. Based in part on this apparent paradox between professional guidelines recommending no pharmacologic prophylaxis and surgeons' desire to avoid this morbid and mortal complication in their patients, the issue of DVT prophylaxis in the RARP perioperative period has been identified as an area with high priority need for research by at least one expert panel [40]. With respect to DVT prophylaxis, the authors utilize only pneumatic compression devices in the perioperative period following RARP with instructions to ambulate early in the postoperative setting. Anticoagulants are used primarily in patients with a history of thromboembolic events or who are debilitated and physically compromised such that early ambulation is not possible.

The low overall incidence of thromboembolic complications after RARP has been is perhaps due in part to Trendelenburg positioning and quicker postoperative patient mobilization following a robotic procedure. Both of these factors decrease venous stasis in the lower extremities as compared to open surgery [41]. Factors which have been identified to increase risk of thromboembolic events following RARP include a history of thrombosis, pT4 stage, Gleason score of 8 or higher, and performance of lymph node dissection [39]. The clinical presentation of DVT in the lower

extremities in the postoperative period should prompt immediate diagnostic evaluation with Doppler ultrasound, consideration of obtaining a pelvic CT scan to exclude a lymphocele, hematoma, or urinoma that could be compressing the external iliac vein contributing to lower extremity venous stasis, and prompt anticoagulation if deemed necessary. If respiratory symptoms such as dyspnea, pleurisy, hypoxia, or chest pain are also present and the suspicion of a pulmonary embolus is high, prompt administration of systemic anticoagulation followed by contrasted chest CT scan or ventilation-perfusion scan is strongly advised.

Ileus and Unrecognized Bowel Injury

Transient postoperative ileus following RARP is not uncommon, however prolonged ileus is an uncommon event that typically occurs in 0.7–2.8% of patients [2, 29–31]. The exact pathogenesis of ileus is multifactorial and complex, and the body's response to surgical stress can lead to disorganized electrical activity and paralysis of intestinal segments. Physiologic ileus following RARP usually spontaneously resolves within 2–3 days after RARP, and patients are best managed with bowel rest and gastric decompression, if indicated. Prolonged adynamic ileus may occur secondary to a pelvic hematoma or urinary ascites and should prompt the surgeon to pursue further diagnostic evaluation and treatment.

Unrecognized bowel injury which goes unrepaired at the time of surgery can be one of the most serious potential complications of RARP or of any minimally invasive surgery. Injury to small bowel segments has also been reported between 0% and 0.7% [29–31]. Injuries may occur while obtaining access (i.e., trocar-related injury), during enterolysis of adhesions secondary to prior abdominal surgeries or inflammatory processes, or due to thermal spread during use of electrocautery. In particular, inadvertent use of monopolar electrocautery may cause thermal injury to surrounding viscera. In addition, micropunctures in the insulating sheath around the monopolar scissors can result in electrical arcing and thermal injury to nearby structures such as bowel. As such, the insulating sheath should be replaced if overt tears are noted. These injuries, when they occur, may be subtle and go unnoticed, presenting in a delayed fashion with low grade fevers and mild abdominal tenderness but occasionally with persistent bowel activity [2]. Early recognition of bowel complications is particularly important as patients may rapidly deteriorate clinically secondary to sepsis. Abdominal CT scan with oral and intravenous contrast is the diagnostic test of choice. A discussion of the management of bowel injuries noted intraoperatively is discussed above.

Lymphocele

A common complication related to PLND is lymphocele due to disruption of lymphatic vessels. The published incidence of post-operative lymphocele following RARP with PLND ranges between 30.4% and 51%, and these numbers vary widely depending on both postoperative imaging modality (CT versus ultrasound) as well as imaging time interval after surgery. Despite the high reported incidence, it has been reported that only 15.4% of these lymphoceles become symptomatic, corresponding to 7% of all patients who undergo RARP with PLND [42]. The incidence of postoperative lymphocele has also been shown to be dependent on the extent of lymph node dissection [43]. Patients with symptomatic lymphocele typically present with complaints of pelvic pressure, abdominal distention, worsening lower urinary tract symptoms, or lower extremity edema. Should the lymphocele become progressively symptomatic or infected, percutaneous drainage is often required. Postoperative lymphoceles are best minimized by judicious use of hemoclips to ligate any divided lymphatic vessels. Mechanical ligation with hemoclips is superior to any thermal device in securing lymphatics.

Anastomotic Complications

A urinary leak is one of the most feared post-operative complications which can occur

following RARP. As mentioned previously, a postoperative pelvic hematoma can cause partial disruption of the anastomosis. Failure to achieve a tension-free, watertight approximation of the anastomosis can result in urinary extravasation This can be even more problematic with a transperitoneal (vs. extraperitoneal) surgical approach because the entire abdominal cavity is accessible for urine egress. The output of increased volume of clear fluid from the surgical drain will often alert a surgeon to the presence of potential urinary extravasation and should trigger evaluation for this problem, as detailed below:

1. The first and simplest step in the diagnostic process is to perform gentle bedside catheter irrigation of the patient's foley catheter to confirm good placement within the bladder and to rule out any element of clot obstruction.
2. Next, if the drainage persists, a sample of the drain output should be sent for creatinine analysis. A creatinine value at or near the serum measurement is reassuring that the fluid represents serous fluid only. An elevated creatinine above the serum value confirms a urine leak.
3. At this point, with elevated drain output of high-creatinine fluid, imaging can be performed but is often not necessary. Withdrawing the pelvic drain away from the anastomosis and placing it to gravity (vs. bulb suction) is advised to encourage urine egress through the foley and not out of the drain. If there is any element of concern for possible ureteral injury as a result of the procedure, consideration should be given to comprehensive assessment of upper tracts with a CT-urogram.
4. Most small anastomotic leaks will resolve spontaneously with prolonged urethral catheter drainage, and these patients may be re-evaluated in 10–14 days as an outpatient with resolution cystogram. A large leak may require catheterization for up to a month or possibly longer to completely heal. If complete disruption of the anastomosis has occurred, surgical revision is indicated, even within the first few days after surgery.

Aside from causing elevated drain output and prolonged catheterization for the patient, a significant urine leak has the potential to cause chemical peritonitis which may lead to postoperative ileus. If imaging reveals incomplete drainage of abdominal fluid in the setting of urinary ascites or peritonitis, consideration should be given for placement of an additional percutaneous drain which would function to better drain the problematic fluid accumulation and decrease the risk of additional downstream problems, such as abscess or fistula formation.

Anastomotic stricture resulting in bladder neck contracture is another potential complication following prostatectomy, although it seemingly occurs at a lower rate after RARP compared with open surgical approaches, especially in the hands of experienced surgeons. Rates of less than 2% have been reported [44, 45]. Again, achievement of a tension-free, watertight anastomosis with good mucosal approximation is a key measure in preventing anastomotic leaks and postoperative bladder neck contracture.

Lastly, "erosion" of hemoclips into the lumen of the bladder at the anastomosis can rarely occur. Patients may present with new onset obstructive voiding symptoms, gross hematuria or urinary tract infections prompting cystoscopy which identifies a hemoclip partially protruding into the lumen of the bladder at the anastomosis. This likely occurs due to partial disruption of the anastomosis by hemoclips that have been placed near the anastomosis. As such it is advised to minimize placement of hemoclips at or near the anastomosis at the time of surgery when possible. Once identified, these hemoclips can be removed cystoscopically under anesthesia. Titanium clips are relatively easy to remove, whereas Hem-o-lok polymer clips may require the use of a holmium laser to divide "unlock" the two arms of the clip to facilitate removal.

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Part IV

Adrenal, Kidney, and Ureter

Robotic-Assisted Adrenalectomy

37

Mark W. Ball and Mohamad E. Allaf

Abstract

Robotic-assisted adrenalectomy is increasingly utilized as an alternative to laparoscopic surgery, and appears to confer decreases in hospital length of stay and blood loss compared to laparoscopic surgery. Robotic surgery has successfully been used for a variety of adrenal lesions, including resection of large tumors, pheochromocytomas, adrenocortical carcinomas (ACC), partial adrenalectomy and adrenal metastasectomy. The perceived advantage of robotics includes improved magnification, stereoscopic vision, and greater range of motion compared to traditional laparoscopy. This chapter will outline the surgical technique of left and right transperitoneal robotic-assisted adrenalectomy.

Keywords

Adrenalectomy · Minimally invasive surgery · Robotics · Adrenal gland · Pheochromocytoma

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Introduction

Minimally invasive adrenalectomy is the standard of care for benign adrenal lesions. Its adoption has led to decreased post-operative pain, lower blood loss, faster convalescence, less ileus, and shorter hospital stays compared to open surgery [1–9]. Multiple refinements to standard laparoscopic have been trialed, including retroperitoneoscopic surgery, laparoendoscopic single-site surgery and robotic surgery. Robotic surgery is increasingly utilized as an alternative to laparoscopic surgery [10], and appears to confer additional decrease in hospital length of stay and blood loss compared to laparoscopic surgery [11]. Moreover, a recent International Consultation on Urologic Diseases and European Association of Urology consultation considers robotic adrenalectomy as an alternative to laparoscopic adrenalectomy [12]. Robotic surgery has successfully been used for a variety of adrenal lesions, including resection of large tumors [13], pheochromocytomas [14], adrenocortical carcinomas (ACC) [15], partial adrenalectomy [16] and adrenal metastasectomy [17]. The perceived advantage of robotics includes improved magnification, stereoscopic vision, and greater range of motion compared to traditional laparoscopy [18].

This chapter will outline the surgical technique of left and right transperitoneal robotic-assisted adrenalectomy.

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Planning

Surgical planning begins with proper patient selection. Indications for adrenalectomy include hormonally active adrenal tumors, enlarging lesions, masses with concerning radiographic characteristics, and large lesions >4–6 cm, as the risk of ACC increases over this threshold [19]. Hormonally inactive tumors <3 cm are almost uniformly benign adrenal adenomas that do not require intervention, unless signs of hormonal activity develop or they increase in size. For masses concerning for ACC or with contiguous organ involvement, our practice is to approach these lesions with open surgery.

A detailed history can reveal symptoms of hormonally active tumors, local symptoms, concomitant medical conditions that may raise suspicion for a syndrome, such as Von-Hippel Lindau disease, multiple endocrine neoplasia type 2, neurofibromatosis type 1, or other familial syndromes, which may have implications for genetic testing [20]. A hormonal evolution is necessary for all patients to determine if the lesion is hormonally active. This is particularly important in preoperative planning, as blood pressure control, electrolyte status, and volume resuscitation strategies require adjustments in patients with functionally active lesions. At the minimum, a screen for hypercortisolism with a 1 mg overnight dexamethasone suppression test and for pheochromocytoma with measurement of plasma fractionated metanephrines and normetanephrines or 24-h total urinary metanephrines should be undertaken [19]. An endocrinology consultation for hormonally active tumors can be beneficial both in the pre-operative and post-operative period.

Imaging evaluation can reveal characteristics associated with adenoma, pheochromocytoma, and other lesions, and is also needed to evaluate vascular anatomy and to assess for adjacent organ involvement in large masses concerning for ACC. For larger tumors found to be locally invasive or otherwise concerning for ACC during minimally invasive adrenalectomy, most authors recommend an open conversion [21, 22].

Operative Team and Positioning

The operating team consists of a console surgeon, bedside assistant, scrub nurse, circulating nurse and anesthesiologist. The scrub nurse and assistant surgeon stand opposite of the robot, while the anesthesiologist stands at the head of the bed. The patient is initially placed in the supine position. After induction of general anesthesia, a nasogastric tube and Foley catheter are inserted. Patients are placed in the modified left or right flank position with the side of the lesion facing up. The patient's abdomen is brought to the edge of the bed, and the inner leg is flexed while the outer leg is extended.

All pressures points are carefully padded with a combination of pillows and foam, and the patient is secured to the surgical table with tape. The patient's arms are placed in a mildly flexed position either over an arm board or tucked next to the body. We do not routinely use an axillary role, raise the kidney rest or flex the bed, but these maneuvers can be used if the patient's body habitus require them.

While both transperitoneal and retroperitoneal approaches have been described to access the adrenal gland, we prefer the transperitoneal approach which allows greater working space than the retroperitoneal approach with familiar anatomic landmarks. This can be especially beneficial for larger tumors and in obese patients [23].

Trocar Configuration

After initiating pneumoperitoneum with a Veress needle, a 12-mm camera port is placed superolateral to the umbilicus. A 30° down scope is inserted, and additional ports are placed under direct vision as shown in Fig. 37.1. Two 8-mm robotic ports are placed – 1 below the costal margin at the later border of the rectus and the other cephalad to the anterosuperior iliac spine. All robotic ports should have at least 8 cm of distant between them to prevent clashing. A 12-mm assistant port is placed between the camera port and lower robotic port. For right-sided cases, a 5-mm can be placed below the xiphoid process to

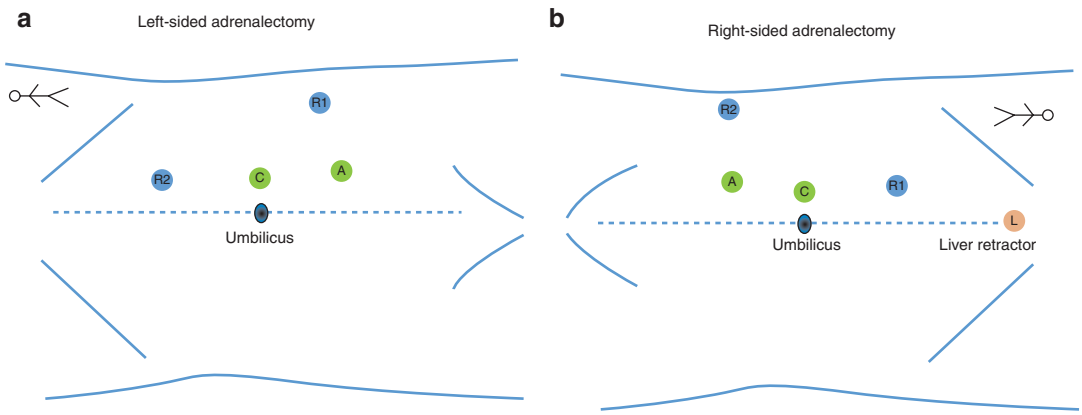

Fig. 37.1 Left-sided (**a**) and right-sided (**b**) robotic adrenalectomy trocar placement. C – Camera port; R1 R2 – 8-mm robotic arms; A – 12-mm assistant port; L – 5-mm liver retractor

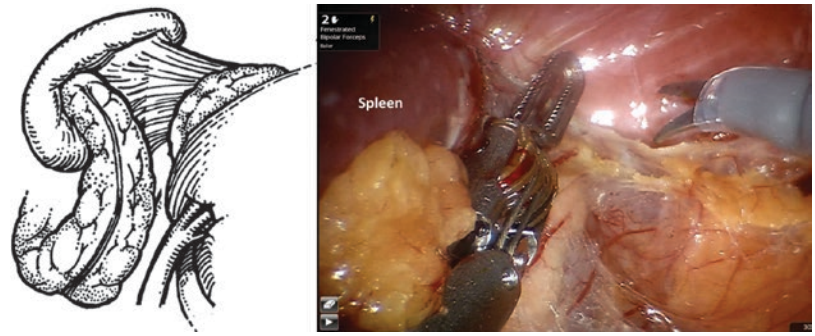

Fig. 37.2 Mobilization of the spleen to expose the left adrenal gland

place a liver retractor. The robot is docked coming over the patient's ipsilateral shoulder, and the system is checked for appropriate range of motion. Finally, instruments are inserted. The authors prefer monopolar scissors in the right hand and fenestrated bipolar in the left hand. The assistant uses a suction irrigator to keep the field clean and to apply gentle counter-traction when appropriate.

Left Robotic-Assisted Adrenalectomy

Left-Sided Exposure of the Adrenal Gland

The procedure commences by mobilizing the splenic flexure along the white line of Toldt, medializing the colon and exposing Gerota's fascia. The splenorenal and splenocolic ligaments are divided, medializing the spleen. Early mobilization of the spleen will allow the spleen to act as a weight, aiding in fully medializing the colon and exposing the tail of the pancreas and adrenal gland. (Fig. 37.2).

Identification of the Left Adrenal Vein

Gerota's fascia is incised and with minimal use of electrocautery, and the renal vessels are identified and exposed. The insertion of the adrenal vein into the renal vein is identified, and the adrenal vein is traced superiorly to the inferior border of the adrenal gland (Fig. 37.3). The adrenal vein is circumferentially dissected. The vein is doubly ligated near the IVC and single ligated near the adrenal gland and transected. A clip applicator can be introduced by the assistant, or if the angle

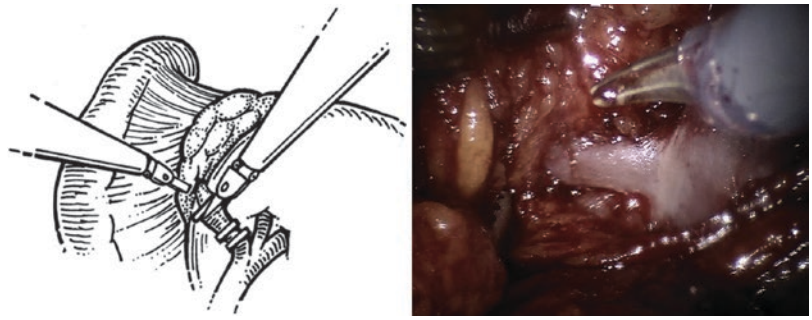

Fig. 37.3 Identification of the left adrenal vein

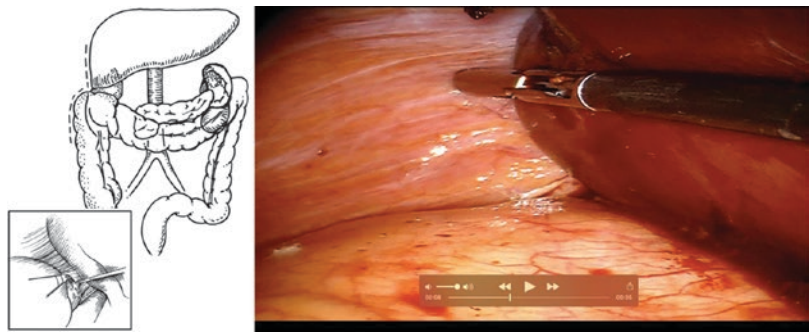

Fig. 37.4 Mobilization of the right colon and liver (**a**) and retraction of the liver with a locking grasper (**b**)

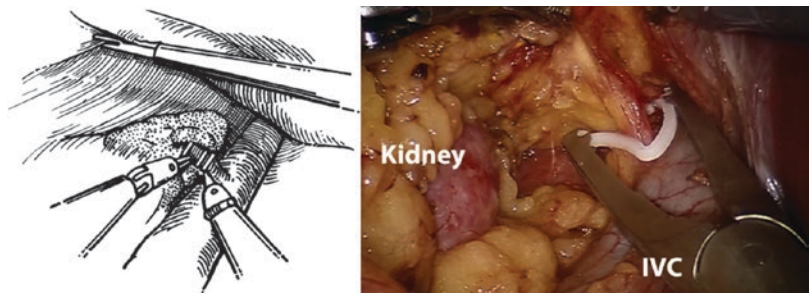

Fig. 37.5 Identification and ligation of the right adrenal vein

is not favorable, a robotic clip applier can be used by the console surgeon.

Right Robotic-Assisted Adrenalectomy

Exposure of the Adrenal Gland

For right-sided adrenal tumors, the triangular ligament of the liver is released and the liver is retracted superiorly. The liver is held in place using a locking grasper to grasp the lateral abdominal wall (Fig. 37.4). The hepatic flexure is freed. The right colon is medialized if necessary to expose the duodenum. The duodenum is Kocherized to expose the inferior vena cava (IVC), and the lateral border of the IVC is dissected, starting just superior to the right renal hilum. Dissection proceeds cephalad until the right adrenal vein is identified as it inserts into the IVC.

Management of the Right Adrenal Vein

The adrenal vein is circumferentially dissected. The right adrenal vein is relatively short, and care should be taken to not place excessive traction on the vein to gain length. The vein is doubly ligated near the IVC and single ligated near the adrenal gland and transected (Fig. 37.5).

Dissection of the Adrenal Gland

After ligation of the adrenal vein, the adrenal gland is dissected circumferentially, first by dissecting the gland off of the upper pole of the kidney and working medially. The arterial blood supply can be controlled with clips or a bipolar tissue sealing device. Gerota's fat on the upper pole of the kidney can be taken with the adrenal gland to avoid direct manipulation of the gland itself if there is minimal fat on the gland either the right or the left hand can be placed posterior to the adrenal gland and the gland displaced anteriorly allowing for a no touch dissection. Once the adrenal is completely dissected, it is placed in an entrapment sac. At this point, hemostasis should be ensured by lowering the insufflation pressure. The adrenal gland is then removed by extending one of the port sites. Routine placement of a drain is not required. The robotic is undocked, and the abdomen closed in the standard fashion.

Post-Operative Management

Post-operative pain management is typically oral narcotics and ketorolac if not contraindicated. Special attention to blood pressure and glucose control is required in hormonally active tumors, and here again, an endocrinology consult may be beneficial in some situations. A nasogastric tube is not required, and diet can be advanced as tolerated. The patient should ambulate early, and the Foley catheter is removed on post-operative day 1.

Complications

Complications can occur at any step during this process, but their effects can be mitigated with immediate identification. Careful inspection of the abdomen upon entry, and again before closure are essential in identifying occult injuries. Vascular injuries can be avoided gaining adequate exposure, employing careful dissection around the renal hilum and great vessels and avoiding excessive traction. Bowel injury can be avoided by placing trocars under direct vision and minimizing the use of electrocautery near the bowels.

Conclusions

Robotic adrenalectomy offers a minimally invasive alternative to laparoscopic adrenalectomy, that is safe and has comparable outcomes. It is potentially advantageous in terms of shorter hospital LOS and less EBL, though these benefits may come at the cost of increased surgical expense [24]. Careful surgical planning and adherence to surgical principles can allow the robotic surgeon to successfully tackle this procedure.

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Robotic or Laparoscopic Renal Surgery: Pros and Cons

38

Pieter Uvin, Cedric Leys, Giorgio Gandaglia, Nicola Fossati, Ruben De Groote, and Alexandre Mottrie

Abstract

The widespread use of routine abdominal imaging has led to an increased proportion of patients diagnosed with asymptomatic small renal masses. Minimally invasive renal surgery has become one of the main treatment choice for the management of small renal masses. In this chapter the pros and cons of minimally invasive renal surgery will be analyzed for both benign and malignant diseases.

Keywords

Minimally invasive surgical procedures · Robotic surgical procedures · Laparoscopy · Carcinoma · Renal cell

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Malignant Disease

Partial Nephrectomy (PN)

Introduction

Renal cancer accounts for 3% of all malignant tumor and was estimated as the sixth most common cancer in men and the eight most common cancer in women in the USA in 2015 [1]. Renal cell carcinomas (RCC) generally arise from the renal epithelium [2]. The classic presentation of patients with renal cell carcinoma includes the triad of hematuria, flank pain and an abdominal mass. However, only very few patients present in this manner nowadays [2]. In recent years, the widespread use of imaging studies have led to a significant increase in the early detection of asymptomatic renal masses. Indeed, the detection of small renal masses has increased threefold in the last two decades [3, 4].

The incidence of renal cell carcinoma (RCC) has also increased in the last two decades but up to 70% of these are small and localized tumors [5]. Surgical excision is the primary treatment for patients with a suspected RCC [2]. Historically, Robson et al. introduced radical nephrectomy (which includes removal of the kidney *en bloc* with Gerota's fascia, the regional lymph nodes and the adrenal gland) as the standard treatment for every RCC [6]. For most of these tumors however, radical nephrectomy can be seen as overtreatment which can be a significant risk

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factor for the development of chronic renal insufficiency with its specific morbidity including hip fractures and cardiovascular problems [7]. Both radical and partial nephrectomy provide excellent oncological results, as was reported by Van Poppel et al. in a prospective, randomized phase 3 EORTC study [7]. In the contemporary practice, partial nephrectomy is the gold standard for a single small renal tumor in patients with a contralateral healthy kidney, although the true importance of a partial nephrectomy is probably found in patients without healthy contralateral healthy kidney. Also, open partial nephrectomy (OPN) was being performed successfully in larger renal masses (up to 16 cm) [8]. In the last decades, many minimally invasive alternative treatments have been presented. In particular, laparoscopy has shown benefits over OPN like reduced postoperative pain or morbidity, improved cosmesis, shorter recovery and length of stay in the hospital, and earlier return to work, but with equivalent efficacy in terms of functional and oncological outcomes [9, 10].

Laparoscopic nephrectomy was first reported in 1991 by Clayman et al. and has accelerated the evolution toward minimally invasive surgical management of renal cell carcinoma [11]. Out of this procedure, the laparoscopic partial nephrectomy evolved, which is a technically difficult procedure with initially a high risk of perioperative complications [12]. In recent years, laparoscopy has gained popularity and laparoscopic partial nephrectomy (LPN) is nowadays considered as one of the standard treatments for RCC. Later, the concept of hand assistance was introduced to reduce the technical challenges of laparoscopic surgery. Nisen et al. investigated the perioperative, functional and oncological outcomes of hand assisted LPN by comparing it with OPN [13]. Between January 2006 and May 2014, 139 patients underwent hand assisted LPN and 165 patients underwent OPN for tumors of 7 cm or smaller. Fewer intraoperative complications were encountered in hand assisted LPN than in OPN ($p = 0.043$) and hand assisted LPN patients had less postoperative complications ($p = 0.037$). The authors reported no difference in overall survival or recurrence free survival during the mean follow-up of 35 months. While expert surgeons have developed also other novel techniques to facilitate LPN, the procedure remains technically challenging, which probably contributes to its underutilization [14, 15].

The recent introduction of robotic technology to urology and, later on, its application to renal surgery with robot-assisted partial nephrectomy (RAPN) has given us another option for minimally invasive nephron-sparing surgery. Getman et al. reported the first series of RAPN in 2004 [16]. Indeed, the robotic technology offers the known advantages of high definition three-dimensional vision, a greater range of wristed-instrument motion and scaling of surgeon movements with tremor elimination. In order to maximize the safety, checklists have been developed [17]. The results from Ganpule et al. suggest that prior experience of LPN shortens the learning curve for RAPN as seen by shorter warm ischemia and operative times [18].

Indications and Contraindications

In general, indications for partial nephrectomy in laparoscopy or robotics are the same as originally described for open surgery: *absolute indications* for PN include a localized lesion in solitary kidney, patients with bilateral renal lesions, or chronic renal insufficiency [19, 20]. *Relative indications* include hereditary forms of RCC like Von Hippel–Lindau syndrome, hereditary papillary RCC, Birt–Hogg–Dubé syndrome, or tuberous sclerosis in which there is a high risk of future development of metachronous renal malignancies. *Relative indications* also exist for patients with unilateral lesion but with the risk of future renal insufficiency such as in patients with hypertension, diabetes mellitus, nephrolithiasis or chronic pyelonephritis [21]. An *elective indication* is a localized, incidental, unilateral tumor with a normal contralateral kidney. There are also *contraindications* to PN like renal vein or inferior cava involvement, massive tumor size, or local invasion. *Relative contraindications* are very large tumors, lymphadenopathy or bleeding diathesis. PN is well established and considered to be the standard management for all organ-confined tumors up to 4 cm in diameter, but

several publications have shown the possibility to perform LPN in tumors larger than 4 cm with excellent operative efficacy and oncological outcomes. Simmons et al., in a retrospective review of 425 LPN procedures, comparing three groups (control group 1: tumor <2 cm, control group 2: tumor 2–4 cm, and study group: tumor >4 cm), have proven that the tumor size >4 cm does not increase significantly the risk for positive margins (0 vs 0.5 vs 6.5%, respectively, $p = 0.19$), intraoperative (9 vs 8 vs 7%, respectively, $p = 0.4$), or overall postoperative genitourinary complications (11 vs 24 vs 24%, respectively, $p = 0.03$) [22]. Simmons et al. [23] have also demonstrated equivalent outcomes in intermediate-term oncologic control for renal tumors >4 cm, comparing retrospectively LPN and radical nephrectomy. The authors mention that a careful patient selection and adequate laparoscopic expertise are absolute prerequisites.

To determine the differences in perioperative outcomes for normal, overweight, and obese patients undergoing LPN, George et al. retrospectively reviewed 488 patients undergoing LPN stratified by BMI [24]. The authors reported that even among the morbidly obese, perioperative outcomes are not significantly different and thus supporting minimally invasive surgery as the optimal intervention for renal surgery, rather than a relative contraindication in the ever-growing clinically obese population. Although technically more demanding, Autorino et al. reported that repeat RAPN can be safely and effectively performed in patients presenting with local recurrence after primary NSS for kidney cancer [25].

Oncological Outcomes

Nowadays, it is generally accepted that partial nephrectomy has a similar oncological outcome as radical nephrectomy [26, 27].

Oncological Outcomes in Laparoscopic Partial Nephrectomy (LPN)

The main aim of renal cancer surgery is removing the whole tumor. In many studies LPN and OPN have similar oncological outcomes, but morbidity is lower in LPN.

The long-term outcome for pT1a tumors treated with OPN in the study of Fergany et al. was excellent with a cancer specific survival (CSS) at 5- and 10-years of 88 and 73%, respectively [28]. In a publication from Permpongkosol et al., comparing 85 LPNs with 58 OPNs, after a mean follow-up of 40.4 ± 18.0 and 49.68 ± 28.84 months for LPN and OPN, respectively, the disease-free survival (DFS) for pT1, was, respectively, 91.4 and 97.6% at 5 years [29]. Gill et al. reported a 3-year CSS for patients with a single cT1N0M0 renal cell carcinoma of 99.3 and 99.2% after LPN and OPN respectively [30]. Moreover, based on multivariate analysis, hospital stay, operative blood loss and operative time were significantly shorter in the laparoscopic group. In the same series, the role of LPN for renal cancers over 4 cm has been proven, as 68 patients in the laparoscopic group and 66 in the open group had a pT1b tumor. Lane and Gill reported the outcomes at 5 years for LPN with an overall survival (OS) and a CSS, respectively, equal to 86 and 100% and a DFS of 97% in 37 patients [31]. More recently, the same authors reported an overall survival (OS) rate of 77.2% at 10 years after LPN [32].

Gill et al. showed their LPN experience in patients with a solitary kidney: 22 patients had undergone LPN for renal tumor (median size 3.6 cm) in a solitary kidney: at a median follow-up of 2.5 years OS, CSS and DFS were 91%, 100%, and 100% respectively [33]. A more recent study from the University of Chicago reported 76 patients with T1a (<4 cm) tumors who underwent LPN over a 4-year period. This group was compared with a matched cohort who underwent OPN over an 8-year different time period. With approximately 20 months of follow-up there were no reported recurrences in either group and preservation of renal function as determined by serum creatinine was seen as equivalent [34]. In a retrospective comparison between LPN and OPN for renal cancer, the mean tumor size was 2.8 cm in LPN group and 2.9 cm in OPN group: the Kaplan-Meier estimate of 5-years OS for pT1 stage RCC was 96 and 85% ($p = 0.1$) in LPN and OPN group, respectively, and the Kaplan–Meier

estimate of 5-year local recurrence-free survival (RFS) were 97 and 98% ($p = 0.9$) for LPN and OPN, respectively [35].

Whether partial nephrectomy should be proposed and performed in all cases of renal tumor masses than 4 cm is still in debate. Simmons et al. compared retrospectively the intermediate-term oncologic and renal functional outcomes of laparoscopic radical nephrectomy (LRN) and LPN for stage T1b-T3N0M0 tumors >4 cm in size [23]. First of all, they did not find any differences in total complication rates in both groups at 19–20% ($p = 0.85$). The median tumor size was 5.3 cm in the LRN group and 4.6 cm in the LPN group ($p = 0.03$) and there were no positive tumor margins in either group in the final pathological findings. If we look at the oncological outcomes after a median follow-up of 57 months in the LRN group and 44 months in the LPN group ($p = 0.14$), we find a RFS rate of 97 and 94% in LRN and LPN groups, respectively, ($p = 0.43$) and in both groups the same OS rate 89% ($p = 0.94$) and the CSS 97% ($p = 0.96$) (Table 38.1). Favaretto et al. retrospectively analyzed data of 150 consecutive patients treated with LPN for renal masses between 2000 and 2010 [36]. Positive surgical margins were found in 1.4% of the patients and 2- and 5-year recurrence-free survival rates were 98% and 95%, respectively. The 2-year and 5-year CSS rates were 99% and 97%, respectively. Patients with pT3a characteristics were more likely to develop disease recurrence and patients with Fuhrman grade 3 were more likely to die of the disease. These mid-term results from Favaretto et al. provide excellent cancer control rates, and LPN seems to be an oncologically feasible and safe option for treating patients with small renal masses.

George et al. retrospectively compared intermediate oncological and renal functional outcomes after LPN for 43 hilar and 445 non-hilar tumors [37]. The mean operative time was shorter for hilar as compared with non-hilar tumors (129 vs 142 min, respectively), whereas mean estimated blood loss was greater for hilar tumors (312 vs 298 ml, respectively). Briefly, George et al. concluded that in the hands of an experienced laparoscopist, LPN can safely be performed for hilar tumors.

Zheng et al. aimed to evaluate the long-term oncologic outcome of LPN in the treatment of localized renal tumors compared with that of OPN [38]. After a systematic search of the literature, six comparative studies were included in their meta-analysis (1495 patients: 555 LPN and 940 OPN). No difference was found between LPN and OPN in 5-year overall survival (OS) rates (odds ratio (OR) = 1.83, 95% confidence interval (CI) 0.80, 4.19), 5-year cancer specific survival (CSS) rates (OR = 1.09, 95% CI 0.62, 1.92), and 5-year recurrence free survival (RFS) rates (OR = 0.68, 95% CI 0.37, 1.26). This meta-analysis revealed that there was no significant difference in long-term oncologic outcome between LPN and OPN in the treatment of localized renal tumors. Liu et al. retrospectively compared the surgical, oncological, and functional outcomes of LPN and OPN for the treatment of renal masses. Between 2006 and 2011, 115 LPNs and 97 OPNs were performed. The LPN group was followed up with a mean time of 29.3 ± 14.4 months and the

Table 38.1 LPN oncological outcomes

Authors	No. of patients	Mean FU	TNM	OS	CSS	DSF
Permpongkosol et al. [29]	85	40.4 ± 18.0 months	pT1	93.75%[a]	NA	91.4%[a]
Gill et al. [30]	771	1.2 years	pT1	NA	99.3%[b]	98.6%[b] (local recurrence)
Lane and Gill [31]	37	5.7 years	pT1	86%[a]	100%[a]	97.3%[a]
Gill et al. [33]	22	2.5 years	pT1	91%	100%	100%
Marszalek et al. [35]	100	3.6 years	pT1	96%[a]	NA	97%[a] (local recurrence)
Simmons et al. [22]	35	44 months	pT1b	89%	97%	97%
Liu et al. [39]	115	29.3 months	pT1	100%	100%	92.4% (60 month Kaplan-Meier estimates)

[a]5 years Kaplan–Meier
[b]3 years Kaplan–Meier

OPN group with a mean time of 31.2 ± 12.6 months. All patients survived and no distant relapse was observed. Kaplan-Meier estimates of 60-month local recurrence-free survival were comparable with 92.4% after LPN and 93.8% after OPN, respectively (p = 0.57). The authors concluded that LPN provides similar results in oncologic and functional outcomes when compared to OPN [39]. Secin et al. conducted a multi-institutional study in Hispanic America from 1992 to 2014 in which each collaborating surgical group submitted clinical, surgical and oncological data of patients who underwent laparoscopic PN with or without robotic assistance [40]. The median age of the patients was 58 years. Because the robotic system has only a limited insertion in Hispanic America, 98% of the PNs were carried out via a pure laparoscopic approach. The median RENAL score was 6. The specimen median maximum tumor diameter was 2.7 cm, with 78.1% classified as pathologic stage T1a. The median positive surgical margin rate was higher with 8.2%, this rate varied significantly among institutions, reflecting varied levels of surgical expertise, variations in histology specimen interpretation or a combination of both. Intra- and postoperative complications were reported in 8.4% and 19.8% respectively of the procedures. Local recurrence occurred in only three patients. The 5-year progression of kidney cancer mortality-free rate was 94% (95% CI 90, 96), the corresponding CSS and OSS was 98.6% (95% CI 96, 99) and 96% (95% CI 94, 98), respectively. Although the oncologic outcomes are far from conclusive due to the limited follow-up, the authors could concluded that LPN has an acceptable perioperative complication rate and short-term oncological outcomes.

All these studies show that LPN has a similar oncological outcome in intermediate term for pT1 RCC as open surgery but furthermore they show that morbidity (blood loss, hospital stay, operative time, or postoperative complications) is probably less and at least comparable with open surgery (see Table 38.1) [29, 30, 34, 41].

Oncological Outcomes in Robot-Assisted Partial Nephrectomy (RAPN)

Deane et al. compared retrospectively 11 patients undergone to conventional LPN with 10 patients to RAPN, and did not find any statistical difference in terms of operating time, blood loss or positive margins at the frozen section, and after a mean follow-up of 16 months, there was no evidence of recurrences in both groups [42]. Rogers et al. showed that in 148 patients, undergone to RAPN between October 2002 and September 2007 at six different private and academic hospital centers, there was no evidence of tumor recurrence at a mean follow-up of 7.2 (range 2–54) months overall and no recurrence in six patients (4.0%) with positive margins after a mean follow-up of 18 months (range 12–23 months) [43]. Mottrie et al. performed between September 2006 and October 2007 a total of 17 RAPNs for RCC (11 pT1a, 5 pT1b and one angiomyolipoma): after a mean follow-up of 19 months (range 14–24) no local or systemic recurrence was reported [44]. Khalifeh et al. reported intermediate term oncologic outcomes of 427 patients who had undergone RAPN since June 2006 [45]. With an average follow-up of 3 year, the overall survival was 97% at 3 year and 90% at 5 year. The cancer-specific survival was 99% at 5 year. A review of the literature published by Borghesi et al. in 2013 aimed to summarize the available perioperative, functional, and oncological outcomes of RAPN performed for complex and/or large (cT1b) renal tumors. They reviewed 278 abstracts and concluded that RAPN has demonstrated to be an effective, safe, and feasible option for the treatment of large (>4 cm) or more challenging renal tumors (high PADUA and RENAL nephrometry scores), at least in the hands of experienced surgeons [46]. Curtiss et al. presented their single-institution experience with RAPN for intrarenal tumors in 2014. They evaluated the safety, feasibility, and comparative efficacy of RAPN in the management of completely intrarenal tumors. Of the 297 patients in the cohort, 30 (10.1%) were identified as having completely intrarenal tumors. There were no significant differences in blood loss, operative time, warm ischemia time, positive margin rate or complication rate between intrarenal tumors and exophytic tumors. With a follow up of 10.6 months, there were no recurrences in either group [47].

The oncological outcomes from RAPN appear to be similar to those reported in laparoscopic and open series (Table 38.2).

Table 38.2 RAPN oncological outcomes

Authors	Dean et al. [42]	Rogers et al. [43]	Kaul et al. [48]	Aron et al. [49]	Mottrie et al. [44]	Curtiss et al. [47]
No. of RAPN (No. of tumors)	10 (11)	8 (14)	10 (10)	12 (12)	17 (17)	30 (30) intrarenal (30) vs 267 (267) exophytic
Mean OR time	228.7 min (95–375)	192 min (165–214)	155 min (120–185)	242 min (130–360)	133 min (105–220)	165 min (139–189) vs 162 min (141–200)
WIT	32.1 min (30–45)	31 min (24–45)	21 min (18–27)	23 min (13–36)	24 min (16–35)	17 min (14–20) vs 17 min (13–20)
TNM (cm size)	pT1a (2.5–4)	12 pT1a, 2 pT1b (2.6–6.4)	pT1a (1.0–3.5)	pT1a (1.4–3.8)	11 pT1a, 5 pT1b (2.2–5.3)	pT1a (2.3 cm) (1.4–2.9) vs pT1a (2.7 cm) (1.9–3.8)
Positive margins	None	None	None	None	None	0% vs 2.4%
Mean FU	16 months	3 months	15 months	7.4 months	19 months	10.6 months
Local recurrence	None	None	None	None	None	None

Authors	Benway et al. [50]	Takagi et al. [51]	Patton et al. [52]	Carneiro et al. [53]
No of RAPD (No of tumors)	183 (191)	100 (100)	90 (90)	44
Mean OR time	210 min (86–370)	190 min (SD±38)	196 min (163–226)	118 min (SD±39)
WIT	23.9 min (10–51)	18 (SD±6.4)	NA	14 (SD±8.7)
TNM (cm size)	pT1a (2.87) (1.0–7.9)	pT1a (2.8) (SD±0.94)	NA	pT1a (3.48) (SD±1.15)
Positive margins	2.7%	None	NA	4%
Mean FU time	16 months	12 months	479 days	Only peri-operative FU
Local recurrence	None	None	NA	NA

Authors	Ganpule [18]	Volpe [54]	Barbier [55]	Ricciardulli [56]
No of RAPD	57 (58)	44 (44)	110 (110)	58 (58)
Mean OR time	129.4 min (70–200)	120 min (60–230)	141.3 min (SD±36.1)	114 (90–120)
WIT (min)	20.9 min (9–39)	16 (5–35)	21.2 (SD±8.8)	19.4 (16–22)
TNM (cm)	pT1b (4.96 cm) (2–15.5)	pT1b 4.2 (1–11) (PADUA ≥score 10)	T1a (2.74 cm) (SD±9.8)	pT1a, 3.2 (2.05–4)
Positive margins	0	4.5%	0%	0
FU (months)	5.15 months	23 months	28.7 months	NA
Local recurrence	None	None	None	NA

Positive Margins

Because the main aim of oncological renal surgery is the removal of the whole tumor, incomplete excision of the neoplasm can leave tumor on the resection bed, which is considered a positive (surgical, resection) margin. During OPN, when a positive margin is found on frozen section, deeper resection is easy to perform before closure of the parenchymal defect. In LPN or RAPN, by the time of the result of the frozen section (if performed), the parenchymal defect is mostly already closed and the hilar vessels are already unclamped in order to reduce ischemia time.

Positive Margins in LPN

In literature, the positive margin rate in LPN is comparable to OPN: Breda et al. [57], in a retrospective multi-institutional survey of 17 centers performing LPN, have found a positive margin rate of 2.4% that is comparable to that reported in contemporary studies on LPN [31, 58] and OPN [32, 59]. Permpongkosol et al. reported 511 LPNs performed by two surgeons and reported nine patients (1.8%) with a positive margin [60]. Seven of the nine patients underwent surveillance: one patient with von Hippel–Lindau disease died of metastatic RCC to the pancreas 10 months after LPN, but the other six patients had no evidence of local or systemic recurrence after a median follow-up of 32 months. In fact, the management of positive margins after RCC is not yet standardized but data from literature suggest that a positive margin does not necessarily lead to a local recurrence or metastatic disease and does not necessarily impair the CSS: if there is certainty that the resection has been complete and only a microscopic (when positive) margin is present, a vigilant monitoring with CT every 6–12 months could be an option [61]. Several laparoscopic series have shown that the tumor size or even the position of the tumor do not correlate with the positive margin rate: Simmons et al. performed LPN in 35 patients with pT1b-T3 RCC (mean size 4.6 cm; range 4.1–7.5), without any positive margins [23]. Ukimura et al. presented their experience with LPN in 21 patients with an incidentally detected stage pT2, pT3a, or pT3b renal mass (mean size pT2 6.5 cm, pT3a 3.2 cm, pT3b 5.8 cm), showing a CSS rate of 95% after a mean follow-up of 29 months (range 1–58), but the renal parenchymal and perirenal fat surgical margins were negative for cancer in all 21 patients (100%) [62]. Interestingly, the importance of *en bloc* excision of the overlying perirenal fat was highlighted by the authors. Rais-Bahrami et al., in a retrospective review of LPN, compared 274 patients with tumor burden <4 cm (mean size 2.3 cm) with 34 patients with tumor burden >4 cm (mean size 5.8 cm); they reported no statistical differences in surgical margins ($p = 0.206$) [63]. Complex cases like multiple or large and centrally or hilar tumors are nowadays treated laparoscopically without increased of morbidity: Gill et al. performed 25 LPNs for hilar tumor (mean tumor size was 3.7 cm) and laparoscopic surgery was successful in all cases without any conversion to open surgery or operative re-interventions. Histopathology confirmed RCC in 17 patients (68%), and all surgical margins were negative [64]. Latouff et al. described 18 LPNs for hilar lesions: mean surgical time was 238 min (range 150–420 min) and only one patient had a positive margin (7.1%) on the surface that was adjacent to the renal artery but after a median follow-up of 26 months, no local or systemic progressions is occurred [65]. Richstone et al. performed LPN for a total of 18 patients with a hilar renal mass. The surgical margins were negative in all cases [66].

Positive Margins in RAPN

Lam et al. performed an extensive review of literature and found that the risk of positive margins during partial nephrectomy could be minimized with a precise visualization of the tumor and tumor margins [67]. Indeed, the development of the da Vinci surgical system (Intuitive Surgical Corp., Sunnyvale, California, USA) allows for simple and complex procedures to be performed more easily by a greater number of surgeons than the conventional laparoscopic approach; its advanced characteristics are three-dimensional visualization, magnification, 7 degrees of freedom at the distal instrument wrist, the absence of the fulcrum effect, and the elimination of tremor. Rogers et al. reported about 11 successful RAPNs for hilar RCC defined as a tumor located in the

region of the renal hilum in physical contact with the renal vessels [68]. The mean tumor size was 3.8 cm (range 2.3–6.4 cm) and the mean operative time was 202 min (range 154–253): in all cases the surgical margins were negative. Rogers et al. also showed the feasibility of RAPN for hilar, endophytic and multiple renal tumors: 14 tumors were resected in eight patients (mean 2.4 cm, range 0.8–6.4 cm), with a mean operating time of 192 min (range 165–214 min) [69]. In all patients RAPN was successfully performed without any intraoperative complications and without positive surgical margins. Mottrie et al. performed 5 of 17 RCCs as an advanced challenge: one patient had a renal tumor of 5.3 cm that was very close to the hilum, two others had two synchronous ipsilateral tumors, and two more patients had a tumor which was endophytic and close to the renal vascular supply [44]. All the patients had negative margins and although the warm ischemia time of these patients was among the longest of the group, their postoperative laboratory results showed no deterioration of their renal function. For the authors, robotic assistance facilitated the laparoscopic approach, especially in the crucial steps of the tumor resection and reconstruction; the magnified three-dimensional visualization, the articulating robotic instruments, and the elimination of tremor ease the maintenance of an accurate plane of tumor resection and renal reconstruction. This makes the whole procedure easier and faster, which avoids positive margins and in the same time reduces the warm ischemia time of the kidney and results in better preservation of the patient's renal function. A review by Shapiro et al. stated that positive margins in RAPN are rare (7/211, 3.3%) and no recurrences have been reported up to 54 months of follow-up in any studies reviewed [70]. A report by Benway et al. in 2010 represents a large RAPN experience (183 patients) and further illustrates the safety and efficacy of the procedure for the management of localized renal malignancies. There results demonstrate excellent oncologic outcomes, with a positive margin rate of only 2.7% (which is consistent with prior published laparoscopic series). All patients with positive margins were observed and at 26 months follow-up no patient had demonstrated evidence of disease recurrence on repeat cross-sectional imaging [50].

Khalifeh et al. reported the oncological outcomes of RAPN in a multi-institutional study. After completion of 943 RAPNs for malignant tumors in five centers, they report only 2.2% positive surgical margins. The importance of positive surgical margins was highlighted in this study, as the risk of recurrence was increased 18-fold.

Partial nephrectomy always requires surgical skills, but for a completely intrarenal tumor, partial nephrectomy can be very challenging due to the difficulties in determining the exact location of the tumor, completing the resection with negative margins (but not exceeding the resection of healthy tissue) and in obtaining good hemostasis [71]. The peroperative use of ultrasound before incision of the renal parenchyma can be very helpful to avoid positive margins. Especially in intrarenal tumors, ultrasonography is absolutely essential [72]. Also, ultrasonography of the specimen can be done intracorporeally (to ensure surgical margins) after placement of the tumor in a laparoscopic endobag filled with a saline solution [73]. Indeed, all efforts to avoid and prevent positive margins should be attempted.

Risk of Tumor Spillage or Port-Site Seeding

Seeding during OPN is rare but can be correlated with a vigorous tumor handling and spillage during the operation. In recent years, with the widespread use of laparoscopy, not only local recurrence but also portsite metastasis has become a concern. In 2005, Curet et al. reported that tumor manipulation increases the risk of tumor metastasis in both open and laparoscopic surgeries [74]. Nevertheless, Rassweiler et al., in a big review of over 1000 laparoscopic procedures for urological malignancies, found only two cases of port-site metastasis (0.18%) [75]. Lee et al. [76] and Rané et al. [77] have reported five and six cases of port-site metastasis respectively, after LRN. In 2007, the first case of port-site metastasis after a LPN was reported [78], but the mechanism of the abdominal wall recurrence is still unclear and the incidence of port-site

metastases (that is higher in TCC), might reflect cancer-related poor prognostic factors rather than the laparoscopic technique. To date, 13 cases of port-side metastasis have been reported after laparoscopic nephroureterectomy for upper urinary tract transitional cell carcinomas [79, 80]. The incidence of port-site metastasis after LPN appears to be similar to that of the abdominal incision scar (0.4%) after OPN [81].

Ito et al. reported that accidental tumor incision (ATI) was present in 7.7% (12/156) of LPNs. Multivariate analysis confirmed that the presence of a pseudocapsule and the maximal tumor diameter were possible predictors of ATI. Unfortunately, no data for RAPN was available. Positive surgical margins and local tumor recurrence was only observed in, respectively, 5 and 1 cases in the non-ATI group, while this was not present in the ATI group [82]. The authors rightfully conclude that ATI during LPN is not necessarily associated with poor oncological outcomes.

Functional Outcomes

It has been shown that partial nephrectomy decreases the risk of progression to renal insufficiency [83]. In a large EORTC randomized trial conducted in patients with a small (≤5 cm) renal mass suspicious for renal cell carcinoma and a normal contralateral kidney, partial nephrectomy reduced the incidence of at least moderate renal dysfunction (eGFR < 60) [84]. In this study population (patients with a normal contralateral kidney) and with a median follow-up of 6.7 years, the beneficial impact of partial nephrectomy did not result in improved survival.

Physiology of Renal Ischemia and Warm Ischemia Time (WIT)

The aim of partial nephrectomy is to remove completely the tumor while obtaining adequate hemostasis in the shortest possible hilar clamping time. Therefore, determining the safe limit of ischemia time is essential to minimize the complications of acute renal failure (ARF) and chronic renal failure (CRF). The mechanism of ischemia–reperfusion injury depends on the metabolic properties of the kidney: oxygenation in the kidney parenchyma is graded with the highest O_2 levels in the cortical zone, a decrease in O_2 tension at the level of the outer medulla, and the lowest O_2 levels in the papillae. The outer cortex has a high O_2 reserve and, thus, cells in this region are relatively protected. Outer medullary epithelial cells are most susceptible to hypoxia because they rely heavily on oxidative metabolism and reside in an area with minimal O_2 reserve. Papillary epithelial cells reside in a constitutively hypoxic environment and they can survive on anaerobic metabolism during short periods of ischemia. Recently, ischemia/reperfusion related increases in the expression of Acute Hypoxia Inducible Factor 1-Alpha (HIF-1α) and Toll-Like Receptor 4 (TLR4) were found in peripheral blood samples in a porcine model of partial nephrectomy [85]. Possibly, these proteins could serve as markers of acute kidney injury during partial nephrectomy. Unfortunately, their first peripheral blood sampling was done after already 30 min. Because renal dysfunction results from both vascular and tubular injury processes, and certain regions of the kidney being more susceptible to ischemic injury, renoprotective agents like intravenous furosemide and mannitol before both clamping and unclamping the renal vessels and a good hydration can promote diuresis and decrease the risk of reperfusion injury and the release of free radicals [86].

In laparoscopy, it is difficult to perform cold ischemia of the kidney. However, efforts to obtain cold ischemia have been attempted like intrarenal cooling via a special endo-vascular catheterization of the renal artery or by using a ureteral catheter to irrigate the kidney with cold solution [87, 88]. Guillonneau et al., using a ureteral catheter and cold saline irrigation to decrease renal temperature, found that the postoperative creatinine level was higher in the group with cold ischemia as compared with no ischemia but not statistically significant [89]. In another retrospective study, Abukora et al. compared 12 patients who had warm ischemia with 14 patients who had cold ischemia, and found loss of function in the group with cold ischemia [90]. For these reasons and for some concerns about complications, in laparoscopy, mainly warm ischemia is used today.

In 2010, Thompson et al. published a retrospective but large study in which partial nephrectomy with hilar clamping was performed in 362 patients [91]. The authors concluded that "every minute counts" when the renal hilum is clamped and that the upper limit of warm ischemia time (WIT) was 25 min. In a prospective study from Choi et al, no significant glomerular filtration rate was seen in patients after a laparoscopic or robot-assisted partial nephrectomy if the WIT was lower than 28 min. Volpe et al. published a large meta-analysis in 2015 in which 91 studies were included. The authors concluded that a WIT of longer than 25 min should be avoided [92]. Zargar et al. analyzed a series of 266 patients between 2009 and 2013, who underwent RAPN for cT1 tumors [93]. The authors concluded that WIT >30 min, preoperative eGFR, and tumor size were the independent predictors of late eGFR deterioration after RAPN. There appeared to be no advantage for zero ischemia when compared to a WIT of 30 min or less. Still, the baseline function of the operated kidney was the most important factor in determining the loss of kidney function ($p < 0.0001$).

Thus, the upper limit of WIT has been accepted to be between 25 and 30 min. Nevertheless, ARF and CRF have multifactorial causes: renal function preservation is not only related to the duration of WIT, but Fergany et al., in a solitary kidney series, found that in the long term, only the percent of parenchyma resected, the patient age, and the congenital solitary kidney or the timing of contralateral nephrectomy, had a statistical effect on postoperative creatinine level [94].

Functional Outcomes in LPN Compared to OPN

Investigators have attempted to identify the influencing factors for functional outcomes after partial nephrectomy. Thompson et al. reported that the kidney quantity and quality are the crucial determinants [95]. Of course, these factors cannot be changed by the surgical technique. Still, the WIT remained an important modifiable feature associated with short- and long-term renal function [95]. Novel methods to predict the renal function after partial nephrectomy, such as the spherical cap surface model, have been developed [96].

There are several studies suggesting that 30 min of WIT is not an absolute limit for ischemia during partial nephrectomy. Bhayani et al. compared patients who did not undergo hilar clamping versus two groups of patients who underwent clamping of less than and more than 30 min. The median creatinine level did not change significantly postoperatively, and none of the 118 patients required dialysis [97]. Porpiglia et al., in a prospective study, performed LPN in 18 patients with WIT >30 min [98]. The glomerular filtration rate (GFR) was not significantly different 3 months after LPN with WIT >30 min. The authors evaluated renal function by nuclear scan and found that contribution of the affected kidney decreased from 48 to 36% after 5 days from surgery. Statistical analysis demonstrated that loss of function was influenced only by the WIT. Nevertheless, contribution of the operated kidney to overall renal function increased to 40% at 3 months and to 43% at 1-year postoperatively. They observed that the maximum loss of renal function was between 32 and 42 min of WIT. Although the overall GFR was maintained and no patients required dialysis in the presence of a normal contralateral kidney, the authors concluded that efforts should be made to maintain the WIT under 30 min. Desai et al. demonstrated similar results, but they noted that when WIT was >30 min, the risk of renal dysfunction was higher in presence of advancing age (age >70 years) and pre-existing renal insufficiency (creatinine serum level >1.5 mg/dL) [99]. Godoy et al. evaluated the effect of WIT on early postoperative renal function following LPN with a multivariate analysis. They found that a WIT of 40 min appears to be an appropriate cutoff. However, only early postoperative follow up was established while Choi et al. reported that the functional damage to the affected kidney evolves until 1 year after a WIT greater than 28 min during LPN [100].

There is still an ongoing debate on a "safe" WIT. It is therefore safe to say that every minute of WIT matters, as was suggested by Patel et al. [101] It is indeed clear that WIT is one of the fac-

tors that has an impact on residual renal function, but other risk factors can influence the renal function as age, poor preoperative renal function, solitary kidney, comorbidities and amount of excised normal parenchyma. In a solitary kidney cohort for LPN, Gill et al. stated that the postoperative decrease in renal function was influenced by various factors, including an age of 60 years or older (serum creatinine increased by 19% in patients younger than 60 years vs 40% in those 60 years or older), 30% or more excised kidney parenchyma (when comparing less than 30 vs 30% or greater excision of the kidney parenchyma, a serum creatinine increased by 34 vs 53%) and a WIT of more than 30 min (when comparing 30 min or less vs more than 30 min, serum creatinine increased by 15 vs 43%) [33]. Gill et al., in a multi-institutional study, also showed 5-year functional outcomes for patients undergone to OPN and LPN: patients in OPN were high risk (older, more comorbidities, decreased performance status, higher percentage with elevated baseline serum creatinine level), whereas patients undergone to LPN had longer warm ischemia time (WIT); the mean WIT in LPN group was higher compared with OPN (30.7 min, range 4.0–68.0 vs 20.1 min range 4.0–52.0 respectively, $p < 0.0001$); the mean operative time for LPN and OPN was 3.3 and 4.3 h, respectively, and on multivariate analysis operative time for LPN was 0.78 times that of OPN ($p < 0.0001$) [30]. Nonetheless, only 0.9% of patients in each group required dialysis for ARF and early functional outcomes were similar in two groups because after 3 months, 97.9 and 99.6% of patients in LPN and OPN groups, respectively, had a functioning kidney. However, LPN offered a decreased operative blood loss and a shorter hospital stay.

Gong et al. compared a cohort of 76 patients having undergone LPN with 77 patients having undergone OPN for solitary tumors, reached the same conclusions showing, a mean follow-up of 20 months, a mean creatinine level of 1.3 mg/dL vs 1.2 mg/dL ($p = 0.272$) in LPN and OPN groups respectively [34]. Marszalek et al. analyzed 200 patients after OPN and LPN for renal cancer, with a median follow-up of 3.6 years [35]. Surgical time and hospitalization were shorter in the LPN group ($p < 0.001$); also WIT in LPN was shorter than cold ischemia time in OPN ($p < 0.001$) but the decline of postoperative GFR (24 h after surgery) was higher after LPN (8.8%) than after OPN (0.8%; $p < 0.001$). After a mean of 3.6 year, however, the decline in GFR was identical in both groups ($p = 0.8$). On preoperative evaluation, 12% of patients in the LPN group and 11% of patients in the OPN group had chronic kidney disease ($p = 0.8$). The respective percentages after 3.6 year were 21% after LPN and 18% after OPN ($p = 0.7$). This significant shift toward higher stages of chronic kidney disease after LPN ($p < 0.001$) and OPN ($p < 0.001$) was similar in both groups ($p = 0.8$). On multivariate regression analysis, preoperative GFR, ischemia time, and surgical access independently predicted the immediate postoperative (24–48 h) GFR decline; surgical access was not a predictor of long-term GFR. GFR at the last follow-up was similar in the LPN and OPN groups when stratified after ischemia times below and exceeding 30 and 20 min, respectively. Springer et al. compared retrospectively 170 patients that underwent OPN with 170 patients that underwent LPN. The median warm ischemia time was 11.7 min in the LPN group and 14.4 min in the OPN group ($p = 0.03$). No damage to the kidney was found after LPN and OPN, with a complete normalization of renal function at 5-year follow-up in both groups. Thompson et al. retrospectively compared the short and long-term renal function outcomes of 362 patients who underwent OPN or LPN in a solitary kidney with clamping of the renal artery with those of 96 patients who underwent no intraoperative renal ischemia [106]. They observed that the warm ischemia group had a significantly increased risk of acute kidney injury and chronic kidney disease during follow up.

Reducing WIT in Laparoscopy

Ideal parameters to assess new surgical approaches to nefron-sparing surgery have not been established, but WIT has been established as a crucial metric. There is a general consensus that "less is better" and nowadays not only the WIT for LPN is shorter in high-volume centers than some years ago, but also many efforts have

been attempted to reduce the ischemia time during LPN. Baumert et al. reported a decrease of ischemic injury in early unclamping after one or two running sutures on the tumor bed [102]. The vascularized renal parenchyma is then closed over a surgical bolster. With this technique, warm ischemia time was reduced from 27.2 ± 5 min (control group) to 13.7 ± 4 min. Bollens et al. tried to reduce WIT with "on-demand clamping" of the hilum: in this technique, the hilum is dissected early but clamped only in the case of excessive bleeding [103]. Out of 39 patients, 31 required on-demand clamping, with a mean ischemia time of 9 min. Nguyen et al. described their technique of early unclamping of the hilum to reduce WIT during LPN [104]. According to this technique, only the initial parenchymal suturing is performed under ischemia, with the remainder of the bolstered renorrhaphy being performed in the revascularized kidney. They found that this early unclamping significantly decreased ischemia time by >50%. Gill et al. reported that the early unclamping technique allowed a significantly shorter WIT (14.4 vs 31.9 min, $p < 0.0001$) during LPN, and resulted in significantly better renal function outcomes (decrease in eGFR within 90 postoperative days : 11% vs 18% and 20%, respectively; $p < 0.0001$). The attempt to decrease intraoperative WIT has also led to the introduction of the concepts of "off-clamp" partial nephrectomy and "selective clamping" of one or more segmental arteries during partial nephrectomy [12]. Verhoest et al. described their initial experience of compression of renal parenchyma by an endoscopic Satinsky clamp inserted percutaneously, without dissection of renal vessels [105]. According to the authors, the main advantage would be the reduction of operative time, and, by a regional ischemia, the preservation of the rest of the normal renal parenchyma and reduce the risk of microscopic lesions and acute tubular necrosis, as observed immediately after LPN when the renal artery has been clamped (Table 38.3). Other novel techniques to decrease the WIT have been developed, such as "sliding clip renorraphy" and advanced visualization techniques to assess the effectiveness of "selective clamping" (such as "Firefly"). Benway et al. described the sliding clip renorraphy technique in 2009 which appeared to contribute to significantly shorter overall operative times and shorter warm ischemia times [106].

Table 38.3 Reducing WIT or providing regional ischemia

Author	No. of patients	Mean WIT	Technique
Baumert et al. [102]	20 control group 20 study group	13.7 ± 4 vs 27.2 ± 5 min ($p < 0.01$)	Modified running suture and early hilar unclamp
Bollens et al. [103]	39	9 min (range 6–40)	Pedicle clamping "on demand"
Nguyen and Gill [104]	50 control group 50 study group	31.1 vs 13.9 min ($p < 0.0001$)	Very early hilar unclamp
Verhoest et al. [105]	5	NA	Regional ischemia by Satinsky clamp on parenchyma
Benway et al. [106]	50	17.8 min	Sliding clip renorrhaphy
Verze et al. [107]	41 control group 68 study group	15.8 min± 3.7 vs 0 min	Clampless partial nephrectomy
Shah et al. [108]	209 control group 106 study group	26 min ± 10 vs 0 min	Clampless partial nephrectomy

The aim of a recent study by Verze et al. was to assess the feasability and safety of "off-clamp" LPN for renal tumors of high surgical complexity [107]. In this study, 109 patients with high tumor complexity (RENAL nephrometry score ≥ 10) were selected between 2008 and 2015. Sixty eight patients underwent clampless LPN, and 41 patients clamped LPN. The perioperative variables were comparable between the clampless and clamped group, except for the WIT which

was of course zero in the clampless group and 15.8 min ± 3.7 in the clamped group and blood loss which was significantly higher in the clampless group with 165 ml ± 106 compared to 121 ml ± 66.8 in the clamped group ($p = 0.0188$). Interestingly, the clampless group had a slightly better preservation of immediate post-operative renal function, although this difference was abolished at 6-month follow-up. Verze et al. concluded that clampless LPN represents a feasible and safe procedure for renal tumours of a high surgical complexity, if performed in highly experienced laparoscopic centres. Shah et al. evaluated wether elective off-clamp LPN offers long-term renal functional benefit compared with the on-clamp approach [108]. In this study, 315 patients underwent LPN between 2006 and 2011, of which 209 patients were performed "on-clamp" and 106 "off-clamp". Here, univariable and multivariable analyses did not show significant differences in postoperative eGFR between both groups up to 5 years follow up. Eliminating transient ischemia during elective LPN does not seem to confer clinical benefit among patients with a normal-appearing contralateral kidney and normal preoperative serum creatinine.

Volpe et al. published a review of the literature in 2015 in which they looked at the predictors of renal function after surgical resection of renal tumors. The time of interruption of renal blood flow during surgery appeared to be an important, modifiable predictor of postoperative renal function [92].

Functional Outcomes of RAPN

Robotic surgery is an emerging technology that offers a number of prospective advantages as magnified stereoscopic vision, elimination of tremor, and absence of the fulcrum effect. Nevertheless, Aron et al. presented the results of a retrospective comparison between 12 patients undergone to RAPN with 12 LPNs and found no differences between the two groups in terms of blood loss, operative time, length of stay, and WIT (23.0 min vs 22.0 min for RAPN vs LPN $p = 0.89$) [49]. Renal functional outcomes, as measured by 3-month serum creatinine and estimated GFR were comparable between the matched groups. The authors concluded that, while technically feasible, RAPN offers no discernible clinical advantage for either tumor excision or sutured renorrhaphy. Dean et al. [42] and Caruso et al. [109] reached the same conclusion. It is to mention that in all these papers, the authors compared their initial experience of RAPN in a small group of patients, with a similar number of patients having undergone LPN and performed by surgeons with an already vast experience in this matter. Nevertheless, Dean et al. [42] mentioned the advantages of a clearly less steep learning curve with RAPN.

Remarkable improvements in operative parameters have been noted as the experience has maturated and as the technique has been refined. By now, many papers have shown that robotic surgery allows complex procedures to be performed successfully, minimizing the technical challenges of laparoscopic approach and considerably reducing WIT. Rogers et al. performed RAPN in 11 patients with hilar tumor: the mean WIT was 28.9 min (range 20–39), the mean operating time was 202 min (range 154–253) and the hospital mean stay was 2.6 days [68]. Surgical margins were negative for malignancy in all cases and no patients experienced a significant postoperative increase in serum creatinine or estimated GFR.

RAPN may now facilitate the advanced maneuvers required to successfully perform partial nephrectomy for renal hilar tumors using a minimally invasive surgical approach. The magnified, three-dimensional visualization and articulating robotic instruments can facilitate precise tumor resection and renal reconstruction even for tumors near hilar structures. Comparing a single-surgeon experience of LPN and RAPN in 102 consecutive patients, Wang and Bhayani found that operative time (140 vs 156 min, $p < 0.04$), WIT (19 vs 25 min, $p < 0.03$), and length of stay were significantly shorter in robotic group (2.5 vs 2.4 days, $p < 0.03$) [110]. Mottrie et al. presented their experience with 50 patients undergone to RAPN. The mean tumor size was 25.6 mm [7–60], the mean console time was 96.5 min [4, 7, 42, 47–168], the mean WIT was 21.2 min [7–37] and the mean hospital stay was 5.3 days [44]. No major intraoperative complications were encountered. Mean GFR and hemo-

globin levels at postoperative day 1 were 67.65 ml/min/1.73 m^2 [17–130] and 12.16 g/dL (8.6–15.3) respectively. At 3 months, no patient experienced a significant change in GFR level. A subset analysis of the first 20, compared to the last 20 patients, showed a mean WIT of 26.1 vs 15.9 min, respectively ($p < 0.05$). Most importantly, they observed that with sliding-clip renorrhaphy of the tumor defect by sliding Hem-o-lok clips without coagulation sponge bolster, they could reduce WIT significantly. The same technique has been described by Benway et al., in order to reduce the ischemia time, with significant decrease of operating time and ischemia time (145.3 min and 17.8 min, respectively) [106]. Ho et al. reported their results after RAPN in 20 patients for renal cell carcinoma less than 7 cm: for a mean tumor size of 30.2 mm, mean operation time and WIT were 82.7 min and 21.7 min respectively [111]. Only in patients who require closure of the pelvicalyceal system, the ischemia time was slightly higher (24.3 min) but after 1 year follow-up, no elevated serum creatinine level, local recurrence, or distant relapse were reported. Moreover, they focused on an important point: although the technique varies from surgeon to surgeon, it is generally felt that the sutures placed during LPN are larger and thus might theoretically result in greater damage to the surrounding parenchyma. In robotic surgery, the three dimensional magnified vision for the console surgeon enhances the ability to detect any pelvicalyceal system entry and they concluded that most pelvicalyceal system entries could be identified in a very precise and accurate manner that only the excellent three dimensional vision offered by the da Vinci robotic system could give. The possibility of rotating and articulating of the arm by the endowrist technology, allows the surgeon to be much more accurate and precise about the amount of healthy parenchyma taken during the suture. They also used absorbable sutures instead of laparoscopic clips for PCS closure, which eliminated the risk of erosion of the collecting system. Benway et al. reported data from 183 patients that underwent RAPN in four institutions between September 2006 and December 2008 [50]. Five patients had multiple tumors which were treated simultaneously, for a total of 191 tumors addressed with RAPN during the course of the study. A total of 191 tumors were excised in 183 patients. Mean tumor size was 2.87 cm (range 1.0–7.9), mean total operative time was 210 min (range 86–370 min), with a mean console time of 141.5 min (range 45–253). Mean warm ischemic times across the entire series averaged 20.7 min (range 0–51 min). Accounting only for those cases where the vessels were clamped, mean warm ischemic time was 23.9 min (range 10–51). Mean preoperative serum creatinine was 1.03 mg/dL (range 0.6–2.0) and the mean creatinine 24 h postoperatively was 1.18 mg/dL (range 0.6–2.4), accounting for a mean change of +0.16 mg/dL; this difference was statistically significant ($p < 0.001$) but on last follow-up, serum creatinine in most cases returned to baseline, with a mean value of 1.04 mg/dL and this value was not significantly different from preoperative values ($p = 0.84$). there were a total of 18 complications (9.8%). Pathologic data were available for 173 patients: overall, 69% of tumors excised exhibited malignant features; positive margins on final pathology were encountered in seven patients (3.8%) and two of these patients were found to have benign pathology (angiomyolipoma) while the remaining five patients had malignant tumors, for an overall positive margin rate of 2.7% for malignancy. The authors concluded that RAPN, offering a magnified, three-dimensional view, and fullyarticulating wristed instruments, the da Vinci Surgical System affords the surgeon unprecedented access and control during renal surgery, especially during the critical steps of tumor excision and renal reconstruction. Moreover, RAPN appears to be associated with a relatively short learning curve, with the potential for technical proficiency in less than 30 procedures for experienced renal surgeons, even in those without prior laparoscopic experience.

Takagi et al. compared surgical outcomes between RAPN and OPN by using volumetric analysis in a propensity score-matched analysis [51]. In their study, 279 patients with normal contralateral kidneys who underwent RAPN or OPN

were analysed between 2012 and 2014. The cohort included 100 patients who underwent RAPN and 179 patients who underwent OPN. After propensity matching, 48 patients were included in each group. The matched RAPN and OPN groups showed no significant differences in the rate of preservation of global renal function (95 vs 92%, respectively) and parenchymal volume of the operated kidney (84 vs 79%, respectively). Overall postoperative complications did not significantly differ between the two groups ($p = 0.1832$) and all surgical margins were negative. However, patients who underwent RAPN had a lower estimated blood loss ($p < 0.0001$) and a shorter length of hospital stay ($p < 0.0001$) than those who underwent OPN. Volpe et al. evaluated the perioperative, postoperative and functional outcomes of RAPN for renal tumours with high surgical complexity (PADUA ≥ 10) [54]. All 44 included renal tumours had a PADUA score ≥10. The authors concluded that, although a slightly higher risk of positive margins was reported (due to the higher surgical complexity), an acceptable complication rate and good long-term renal functional outcomes can be expected with RAPN in experienced hands. Recently, Patton et al. retrospectively reviewed data from 292 patients who underwent PN for renal masses from 1999 to 2013 and wanted to determine if the introduction of robotic techniques has allowed us to treat more complex tumors minimally invasive [52]. The authors conclude that complex tumors previously managed by open PN are now safely managed with the robotic approach. Most importanly, this study adds to the understanding that the robot-assisted approach may now help to close the gap between nephron-sparing surgery and radical nephrectomy.

Until recently, all comparative studies about renal function were focused on total glomerular filtration rate (eGFR), not on split renal function. When considering that around 5% of RCC patients suffers cancer of the contralateral kidney, it seems only logical to assess the renal function of the operated kidney according to the surgical method. Lee et al. compared the postoperative renal function between patients undergoing RAPN and OPN by using Tc-99m diethylenetriaminepentaacetic acid (DTPA) renal scintigraphy [112]. The authors concluded that despite RAPN having a longer WIT (24.4 vs. 17.8 min, $p < .001$), the operative method did not correlate with renal function impairment ($p = 0.704$). Thus, postoperative renal function impairment was similar between patients who underwent OPN and those who underwent RAPN.

Initially, RAPN has been performed for exophytic, small renal masses. With increasing experience however, its application has been expanded towards treating more complex and challenging renal masses. Kim et al. recently aimed to summarize and analyze the contemporary literature of endophytic and hilar renal masses treated with RAPN [113]. The perioperative outcomes including renal function and oncological safety of 6 studies were reviewed, and the authors concluded that RAPN proves to be oncologically safe and functionally effective on completely endophytic renal tumors. Very short hospital stays after RAPN have been reported. Bazzi et al reported a length of hospital stay of only one day in 45% of patients. The length of hospital stay was influenced by age, gender (with women having a longer hospital stay), medical comorbities and tumor size [114].

Complications in LPN and RAPN

LPN is challenging and therefore the reported complication rate was initially higher compared to OPN. Nevertheless, the incidence of complications in series from centers with expertise range from 9% to 33%, which is not significantly different compared to OPN. As for OPN, almost 50% of overall complications are medical. In the combined analysis of the largest series of LPN, hemorrhage is the most common surgical complication (5%), followed by urine leak (4.2%) [115]. Simmons and Gill used a five-tiered scale based on National Cancer Institute Common Toxicity Criteria to assess complication severity and demonstrated a decrease of overall, non-urological, hemorrhagic, and urinary leakage complications by 44%, 23%, 53%, and 56%, respectively (despite an increased tumor and technical complexity) comparing an initial LPN series of 200 patients with the most recent group [115]. The same authors compared data of the OPN series from

Memorial Sloan-Kettering Cancer Center with their own recent LPN cohort and proved an overall complication rate of 26.8% (OPN) and 19% (LPN), respectively. Zimmermann and Janetschek reported overall rates of postoperative bleeding necessitating transfusion and urinary leakage as 2.7 and 1.9% [116]. These rates are significantly lower than in previous studies because of the introduction of sealants or glues and the improvement of techniques of suturing and resection. Shapiro et al., analyzing series of 211 RAPNs, found that major complications were present in 14 procedures (6.6%) and the most common were ileus ($n = 4$) and urine leak ($n = 3$) [70]. Benway et al. reported a complication rate of 8.2% for major complications and 1.6% for minor complications after 183 RAPNs [50]. Curtiss et al. presented in their single-institution experience with 297 RAPNs for intrarenal tumors an intraoperative complication rate of 0% and 0.76% for intrarenal tumors and exothypic tumors, respectively. Postoperative complications occured in 6.7% and 17.6% for intrarenal and exothypic tumors, respectively [47]. Breda et al. conducted a comprehensive literature review in 2009 and concluded that the complication rate of the laparoscopic management of renal masses appears to be similar to that of open surgery [117]. Laparoscopic and robot-assisted partial nephrectomy duplicate the principles of open surgery and after several technical modifications, it has been standardized to a great extent. Nevertheless, it remains a challenging procedure.

Trifecta in Partial Nephrectomy

The concept of "trifecta" was introduced in 2013, in which the three key outcomes of minimal renal functional decrease (sometimes referred to as WIT < 25 min), the absence of perioperative complications and negative margins are simultaneously realized [118]. Despite increasing tumor complexity, the trifecta outcomes occurred more commonly in recent years. In a single-surgeon series of 500 patients, RAPN achieved the "trifecta" in almost 30% of cases, with better operative outcomes and lower perioperative complications than LPN [119]. In a large multi-institutional review by Zargar et al. with 1185 RAPN and 646 LPN procedures, RAPN was superior to LPN for perioperative surgical outcomes such as WIT (18 vs 26 min), complication rate (16.2% vs 25.9%) and positive margin rate (3.2 vs 9.7%). This allowed the authors to conclude that the "trifecta rate" was higher in RAPN, compared to LPN (70% vs 33%) [120]. Minervini et al. did a matched-pair analysis in which 301 patients underwent OPN and 149 LPN. No significant differences in achieving the trifecta were reported. Although LPN was associated with a significantly longer WIT, no significant difference in eGFR at 6 month follow-up was found [121]. In a recent study from Kim et al., the authors reported that after RAPN for T1a and T1b renal masses, the rate of achievement of trifecta was respectively 65.3% and 43.3%. This allowed them to conclude that RAPN is certainly a feasible modality for larger (cT1b) renal masses.

Recently, attempts were made to achieve trifecta with a single-site robotic procedure (R-LESS). Komninos et al. retrospectively analyzed data from 167 patients. The authors found that conventional robotic partial nephrectomy is superior to R-LESS partial nephrectomy with regard to the accomplishment of trifecta [122]. Therefore, they suggest that R-LESS partial nephrectomy should be reserved for patients with a limited tumor size, low PADUA and RENAL scores, and without renal sinus or collecting system involvement. Other authors however, report that R-LESS PN is feasible and safe for tumors >4 cm. Indeed, Tiu et al. compared 20 patients with renal tumors >4 cm and 47 patients with renal tumors <4 cm and demonstrated the feasibility and safety of robotic LESS PN for tumors >4 cm. Although patients with tumors >4 cm had statistically a significant higher mean nephrometry score, a longer ischemia time, and a longer length of hospital stay, they reported no increased risk of adverse outcomes [123].

A Comparison between LPN and RAPN

Several centres have published studies comparing the peri-operative outcomes of RAPN and LPN, but most of these have been substantially limited by the confounding of salient baseline covariates, and the studies have had rather conflicting results.

A description of the initial experience of one surgeon, who compared 15 consecutive patients undergoing LPN with the subsequent 13 patients undergoing RAPN, showed a significant decrease in the WIT. Also, in two patients in the laparoscopic group, conversion of partial to radical nephrectomy was required, while this was never the case in the robotic group [124]. Similar results were reported by Williams et al. They compared 86 consecutively treated patients who underwent LPN ($n = 59$) and RAPN ($n = 27$) [125]. WIT was significantly lower in the RAPN cohort. There was no difference in operative time, estimated blood loss, length of stay, transfusion rate, positive surgical margin, or postoperative decrease in eGFR. There was no difference in mean eGFR decrease after early unclamping (16%) versus traditional clamping (22%); however, 11 (29%) patients had greater than 50% decrease in eGFR after traditional clamping versus zero patients after early unclamping ($p = 0.014$). Hillyer et al. presented a comparative analysis of RAPN versus LPN in a contemporary cohort of patients with bilateral synchronous renal tumors [126]. Overall, 26 patients were included in the analysis, including a group of 17 patients who underwent bilateral LPN and a group of 9 patients who underwent bilateral RAPN. The RAPN group had a tendency toward a shorter warm ischemia time than the LPN group (19 vs 37 min, respectively, $p = 0.056$). The margins were negative in both groups, with no tumor recurrence at a median follow-up of 7.5 months for the LPN group and 7 months for the RAPN group. No difference was found in the complication rate. With RAPN, a trend was seen toward a smaller effect on the postoperative renal function compared with the laparoscopic approach. Wang et al. evaluated the peri-operative, functional and oncological outcomes of RAPN and LPN for moderately or highly complex tumours (defined as renal nephrometry score ≥7 by retrospectively analyzing the medical charts of 216 patients with complex tumours [127]. 135 patients underwent LPN and 81 RAPN between 2008 and 2014. LPN was associated with a longer operating time (149.6 vs 135.6 min, $p = 0.017$) and greater bloodloss (220.8 vs 196.5 mL, $p = 0.013$). The WIT was longer for patients in the LPN group than for the patients in the RAPN group, altough the differences were not statistical significant (22.3 vs 20.5 min, $p = 0.131$). The postoperative complication rate did not differ between the LPN and RAPN groups (22.2 vs 17.3%, respectively, $p = 0.383$). The decrease in eGFR after RAPN and LPN was similar at 6 months (8.7 vs 10.0%, $p = 0.285$) after surgery. Positive section margin rate was similar in the RAPN to that in the LPN group (1.2 vs 1.5%, $p = 0.660$) with a mean follow-up of LPN of 31.4 months and RAPN of 16.5 months. There were no cancer specific deaths and the 3-year recurrence-free survival rate was 95.2% for LPN and 97.1% for RAPN ($p = 0.71$). The authors concluded that RAPN and LPN performed in patients with complex tumours offer acceptable and similar results in terms of peri-operative, functional and oncological outcomes and that both surgical techniques remain viable options. In a recent study, Wu et al. reported the results of a propensity-score matched study comparing the peri-operative and early renal functional outcomes of patients treated with RAPN and LPN [128]. The authors could conclude that after adjusting for potential treatment selection biases, RAPN was superior to LPN for both peri-operative outcomes and early renal functional preservation. Carneiro et al. evaluated the transition from laparoscopic to robotic partial nephrectomy using 'trifecta outcomes' as surrogate marker of efficacy. A prospectively maintained database of 347 partial nephrectomies at their center from 2000 to 2014 was reviewed. Patients that underwent LPN were chronologically divided into two groups and all patients that underwent RAPN were included in a third group. Of the 347 patients included, the first 151 LPN patients were included in group 1, subsequent 152 in group 2 and all 44 RAPN in group 3. When group 1 was compared with group 2, Carneiro et al. achieved lower WIT and less high grade complications (Clavien ≥ 3) in group 2. Interestingly, this trend continued with the transition to RAPN ($p < 0.05$). When discussing the trifecta outcomes, Carneiro et al. reported an overall improvement from group 1 to group 3 ($p = 0.01$). The authors could conclude that, in an

experienced urologic laparoscopic center, transition from LPN to RAPN is feasible and fast without major adverse operative outcomes. Long et al. performed a retrospective analysis for 381 patients who underwent either LPN (n = 182) or RAPN (n = 199). They reported similar functional outcomes but noted that the risk of conversion to radical nephrectomy was significantly lower in the RAPN group [129]. RAPN seems to offer a shorter WIT when compared to LPN, which is a surrogate for final outcomes and achieves an overall better "trifecta" compared to LPN [120, 130]. RAPN has a shorter learning curve than LPN and solves some of the technical difficulties associated with the laparoscopic approach. Commonly cited advantages over LPN include a shorter learning curve with a wider range of indications, comparable or better operative, functional and oncologic outcomes, and better perioperative morbidity [131, 132]. In 2015, Choi et al concluded that RAPN is more favorable then LPN due to a lower conversion rate to radical nephrectomy, a better glomerular filtration rate, a shorter length of hospital stay and shorter WIT [133]. However, Stolzenburg et al. noted that the only safe conclusion that was drawn by Choi et al. was that RAPN is characterized by a lower WIT, while the most important determinant of postoperative renal function is residual functional volume [134]. Choi et al. compared data from 100 consecutive patients who underwent LPN (n = 52) or RAPN (n = 48) between 2007 and 2010 [135]. No significant differences were reported between LPN and RAPN with regard to blood loss, operating time, WIT, intraoperative complications, hospital stay, rate of positive section margins and changes in renal function, with a mean follow-up of 16.2 months (for LPN) and 8.9 months (for RAPN) [135]. Kim et al. presented in 2014 a matched-pair comparison between RAPN (195 patients) and LPN (195 patients) performed in multiple institutions in which they aimed to compare the peri-operative and long-term renal functional outcomes [136]. They reported that the operative time ($p < 0.001$) and WIT ($p < 0.001$) were significantly shorter in the RAPN group. Significant differences were also observed for blood loss ($p < 0.001$) and transfusion rate ($p < 0.001$), both in favor of RAPN. The positive margin rate and postoperative eGFR decrease did not differ significantly between the two groups. Thus, the authors concluded that RAPN has superior functional outcomes to those of LPN.

A meta-analysis performed in 2014 by Zhang et al. included 14 studies and showed that RAPN had similar operative time, length of stay, estimated blood loss and perioperative complications compared with LPN, as well as positive margin rates [4]. RAPN did offer the advantage of a decreased WIT, compared with LPN. This meta-analysis also showed that RAPN could accommodate a wider age range than LPN, as the meta-analysis showed that the participants in the RAPN group are significantly older than participants in the LPN group [4]. Another meta-analysis performed in 2013 by Zhang et al. brought the same conclusion. The authors included seven studies and concluded that RAPN provides peri-operative outcomes equivalent to those of LPN with the advantage of a significantly shorter warm ischaemia time [137]. A meta-analysis performed in 2012 by Aboumarzouk et al. showed the same peri-operative outcomes as Zhang et al. and concluded that RAPN is a feasible and safe alternative to LPN [132]. Mottrie et al. commented on this meta-analysis by stating that LPN, as a challenging procedure with a long learning curve, a limited diffusion, and a favoured application to less complex cases, cannot be considered as a real and fashionable referent for RAPN [138]. Mottrie et al. believe that RAPN was able to bridge the technical difficulties of LPN, and today it must be considered as the real competitor of open surgery. Indeed, a multicenter study comparing 118 consecutive LPNs and 129 consecutive RAPNs performed by three experienced surgeons at three academic centers in the United States, showed significant advantages in favor of RAPN in terms of WIT, EBL, and hospital stay [139]. This comparative study, that wasn't included in the meta-analysis by Aboumarzouk et al, were supported by another comparative analysis published by Mullins et al. [140] Recently, Leow et al. conducted a very comprehensive and elaborate liter-

ature search in which 25 studies, published up to December 2015, were included and in which safety, efficacy and functional outcomes of RAPN and LPN were evaluated. A total of 4919 patients were included (2681 RPN, 2238 LPN). RAPN was associated with decreased likelihood of conversion to open surgery compared to LPN (relative risk = 0.36, $p < 0.001$), less complications ($p = 0.023$), positive margins ($p < 0.001$) and shorter WIT ($p < 0.001$). The authors concluded that RAPN confers a superior morbidity profile compared to LPN. Although this meta-analysis can deliver the strongest available evidence to date (Level 2b), there is a lack of ongoing randomized trials to deliver Level 1 support.

Conclusion

We have to consider robot-assisted laparoscopic nephron-sparing surgery as a new laparoscopic procedure with the advantage of a new sophisticated technology. The 3-D vision associated with the endowrist technology allows for excellent vision of the operative field and the possibility of dissecting the tissue optimally and varying the degree of incidence with the target structures. Robotic technology is associated with decreased ischemia time, which is basically related to the length of the dissection of the tumor. In particular, the suturing phase is faster with robotic da Vinci System. The three-dimensional vision and the endowrist technology could also help to decrease the positive margin rate because they provide optimal dissection angles during the procedure. Moreover, robotic surgery allows an average surgeon to perform more difficult cases, such as large, intraparenchymal, or even perihilar tumors. Indeed, RAPN was revealed to be not only a feasible option but also resulted in adequate resection margins and warm ischemia time for larger lesions. The procedure also provides the surgeon with the possibility to work in a more natural "intuitive" way which is a clear advantage that eases precise extirpation of the tumor, as well as the reconstructive part of the operation. In our opinion, robotic technology allowed us to operate more comfortable on complex tumors. Using the robot, we were able to perform minimally invasive procedures with safety for the patient, respecting the oncologic principles and preserving as much renal function as possible. The robot provides the surgeon with better, high-definition stereoscopic, and enlarged vision that proves very helpful in tumor dissection or recognition of calyceal defects. The fact that the surgeon, the assistant, and the scrub nurse are all sitting during the operation also contributes to less fatigue and consequently better efficacy of the surgical team. These advantages of the robot-assisted partial nephrectomy give us the potential to operate not only on small exophytic tumors but also on more complex cases. The main disadvantages of the robotic-assisted partial nephrectomy are the augmented costs, the need for extra setup time, and the lack of the haptic feedback for the surgeon. The need to have two fully trained surgeons, one on the patient side and one on the console so that in case of an emergency the bedside surgeon can react while the console surgeon is scrubbing, is one more disadvantage. We hope that with the advent of new robotic systems, perhaps from other companies, the costs will reduce with time. The setup time can be minimized if the same team of surgeons, assistants, scrub nurses, and room nurses is used for all robotic procedures so that they become accustomed to the complexity of the robotic setup.

Laparoscopic Radical Nephrectomy (LRN) and Robot-Assisted Radical Nephrectomy (RARN)

Introduction

In 1991, Clayman et al. reported their first laparoscopic nephrectomy (LN) for benign disease [11]. Over the last 25 years, this procedure has gained popularity and the indications for LN expanded: initially LN was performed for removal of non-functioning kidneys but now it can be considered the preferred approach for many diseases of the kidney. Indeed, laparoscopy is considered a primary and well-standardized modality for managing renal tumors. Laparoscopic Radical Nephrectomy (LRN) can be performed as a "pure" laparoscopy procedure through a retroperitoneal or transperitoneal approach. In 2001,

Guillonneau et al. reported the first Robot-Assisted Laparoscopic Nephrectomy [141].

Indications and Contraindications

LN is generally indicated for treatment of benign diseases like removal of multicystic kidneys, diseased kidneys causing renovascular hypertension, end-stage ureteropelvic junction obstruction, or non-functioning or chronically infected kidneys. For malignant diseases, indications for laparoscopic radical nephrectomy (LRN) are usually RCC in stage T1 or T2 although removal of tumors up to 12–18 cm has been described by skilled laparoscopists [142]. It is possible to perform LRN in RCC stage T3a (tumor beyond the capsula) but only if size limitations permit [143]. On the other hand, LRN is probably overutilised in small renal masses as sometimes, too many nephrons are removed when partial nephrectomy is possible [7]. Hopefully, widespread training in partial nephrectomy will tackle this problem in the future. *Relative contraindications* for LN consist in extreme obesity and tumors with renal or caval vein tumor thrombi. *Absolute contraindications* for laparoscopic nephrectomy are uncorrected coagulopathy, sepsis or hypovolemic shock.

Desai et al. published a prospective randomized trial comparing retroperitoneal LRN to transperitoneal LRN [144]. The retroperitoneal technique was associated with more rapid arterial and venous control and decreased total operative time (150 vs 207 min). Both modalities were similar in estimated blood loss, complication rates, analgesia requirements, and length of hospital stay. Patients with a history of extensive abdominal surgery should be treated preferentially with a retroperitoneal approach as this factor can increase the complication rate of transperitoneal surgery. Berglund et al. demonstrated that retroperitoneal LRN could be performed successfully in obese patients [145]. Obese patients undergoing retroperitoneal LRN had more favorable estimated blood loss, operative times, conversion rates, and hospital stay, although the outcome did not reach significance compared with obese patients managed with transperitoneal LRN. Feder et al retrospectively identified 88 patients, of whom 45 underwent LRN and 43 open nephrectomy, and stratified them by body mass index (BMI) [146]. They concluded that LRN is technically more challenging as BMI increases, although feasible and safe in experienced hands. Recently, Arfi et al. reviewed the medical files of 215 patients and divided them in an obese group (with BMI $\geq$30 kg/m^2, n = 52) and a non-obese group (n = 163) [147]. The authors did not find an increased risk of intra- and postoperative complications in the obese group and concluded that the laparoscopic approach is the preferred technique, also in obese patients.

Oncological Outcomes

Laparoscopic techniques for managing RCC, nowadays, are considered to be safe, following wellestablished guidelines for surgical dissection. There are many studies that show that LN is a safe procedure that provides shorter hospital stay, reduced estimated blood loss, decreased pain medication requirements, faster return of bowel activity, improved cosmesis, and an earlier return to full activities compared with the open approach [142, 143, 148, 149].

The long-term oncologic outcome of LRN is comparable to open radical nephrectomy [150–153]. Permpongkosol et al. compared 67 patients undergone to LRN with 54 undergone to open radical nephrectomy. They reported, for transperitoneal LRN, 10-year DFS, CSS, and actuarial survival rates of 94%, 97%, and 76%, respectively, that were not statistically different with open surgery (87%, 86%, and 58%, respectively) [150]. When stratified into T1 and T2 categories, patients undergoing LRN had 10-year disease-free, cancer-specific, and actuarial survival rates of 98%, 98%, and 75%, respectively, compared to 84, 95, and 81%.

Complications

Complication rates associated with laparoscopic surgery decrease as the experience of the operating surgeon expands. Steinberg et al. compared complication rates in patients undergoing open surgery and LRN [142]. Intraoperative complications occurred in 7.2% of patients who were treated with LRN for pT1 tumors, 7.7% of patients who underwent LRN for pT2 tumors,

and 17.6% of patients who underwent surgery with standard open techniques for pT2 tumors. Although there was an apparent higher complication rate for the open group, the difference was not statistically significant. The most common intraoperative complication in each of the groups was vascular injury and hemorrhage. The rates of postoperative complications were similar (19.9%, 21.5%, and 26.5%, respectively). Techniques such as hand assistance were developed in an attempt to reduce the complication rate. Pareek et al. reviewed the reported complications of laparoscopic renal surgery with and without hand assistance [154]. Overall, 10.7% of patients undergoing a pure LRN experienced a major complication compared with 9.3% of patients who underwent a hand assisted LRN (no statistical significance). The most frequent major complications in the LRN group included venous and arterial bleeding (1.8 and 1.0%). In the hand assisted LRN group, the most common major complications included wound infection (1.5%) and arterial hemorrhage (1.0%). Although the overall difference in complication rate was not statistically significant, the wound infection rate was significantly higher in patients managed with hand-assisted LRN compared with patients treated with pure laparoscopic techniques.

Robot-Assisted Radical Nephrectomy (RARN)

The first robot-assisted radical nephrectomy (RARN) was performed in 2001 by Guillonneau et al. using the Zeus system (Computer Motion) [141]. Rogers et al. presented their experience of 42 patients that underwent RAPN and they concluded that, although it is not possible to claim the superiority of robotic nephrectomy over traditional laparoscopy, it can offer some potential benefits as the use of the fourth robotic arm can do the upward retraction on the kidney, in order to have precise dissection of the renal hilar vessels [155].

The amount of significant large series of RARN is rather limited, especially when compared to RAPN. Many surgeons consider RARN as too expensive. Asimakopoulos et al. performed a literature search and included all studies between 2000 and 2013 [156]. They identified six RARN case-series and four comparative studies between RARN and open nephrectomy or LRN. The authors concluded that RARN was feasible and oncologically safe but also that there was no advantage of robotics over standard laparoscopy and that RARN could be seen as "technical overtreatment".

Between 2002 and 2010, the rate of open radical nephrectomies gradually decreased from 54 to 29%, as experienced laparoscopic surgeons are widely available [157]. However, a significant portion of all nephrectomies is still being carried out with an open approach, especially the more complex cases. RARN has proven to be a safe procedure, even when a vena cava thrombectomy or extensive retroperitoneal lymph node dissection is necessary or when contiguous organ invasion is present [158, 159]. Petros et al. reviewed a prospective database of 101 consecutive nephrectomy prcedures by a single surgeon [158]. All these procedures were initiated as RARN. The mean BMI was 31 kg/m^2 and 31 pT3a tumors were included, with 9 renal vein thrombi. Eight tumors had caval tumor thrombi. Contiguous organ invasion required bowel resection, partial hepatectomy and distal pancreatectomy. Conversion to open surgery was never necessary.

The question remains whether performing RARN can be justified from an economic point of view. Abaza et al. compared the costs of 150 nephrectomies, of which 90 LRN and 60 RARN [160]. There was no significant difference between the average total cost of LRN ($12021) and RARN ($11861) ($p = 0.79$). Of course, the purchase of a robot for RARN cannot be justified, but RARN seems to be cost-effective if there is a robot available. Indeed, the cost of robotic instruments was outweighed by the costs of disposable trocars, stapling devices and advanced energy dissection devices. Furthermore, experience with RALN could lead to more complicated cases being treated minimally invasive (as mentioned above) which will reduce morbidity, the need for blood transfusion and length of hospital stay. Another argument for the use of robotic assis-

tance is that RAPN is a technically challenging procedure (as described above), which requires previous renal surgery experience. Indeed, RALN (of course without tumor thrombi or contiguous organ invasion) could be seen as a training platform for acquiring the robotic skill and experience required for more complex robotic renal surgery cases [161, 162].

We are convinced that the technical advantages of the robot system can play a role also in radical nephrectomy. Potential advantages of robotic assistance for radical nephrectomy include a magnified, three-dimensional view, and the articulating robotic instruments that can facilitate precise dissection and ligation of the renal hilar vessels.

Benign Disease

Laparoscopic or Robot-Assisted Pyeloplasty

Introduction

Up to few years ago, the "gold standard" for the treatment of the ureteropelvic junction (UPJ) obstruction was open surgery because in "skilled surgeon's hands" it has a success rate of up to 100% [163–165]. Nevertheless, this procedure has shown to have complications and morbidity correlated to the rather painful flank incision, especially in young patients. At present, besides open surgery, many minimally invasive endourological procedures are available for the treatment of UPJ obstruction, but they have a long-term success rate lower and not comparable to open surgery [166, 167].

Since it was described in the 1990s, the laparoscopic approach for UPJ has maintained the high efficacy of the open surgery without the morbidity of the open incision [168, 169]. In many centers the laparoscopic approach has completely taken over the open surgery in the treatment of this disease, but its availability is mainly in high-volume laparoscopic centers [170]. This phenomenon is likely due to the technical demands, which require specialized training and advanced laparoscopic skills. With the introduction of robotic technology, the situation has rapidly changed because its advanced characteristics like three dimensional high-definition vision and the great degree of rotation movements allow to overtake the limitations of classical laparoscopy. Indeed, robotic-assisted laparoscopic pyeloplasty (RALP) has shown to be equally effective in the treatment of UPJ obstruction, with a 90–95% success rate [171–173].

Indications

The indications for laparoscopic repair of UPJ obstruction include patients who have a physiologically significant obstruction, intermittent flank pain, hematuria or recurrent urinary tract infections, renal stones or secondary hypertension. Crossing vessels or a duplicated collecting system can be treated laparoscopically and even a failed endopyelotomy or failed open pyeloplasty can be managed laparoscopically with excellent outcomes.

Laparoscopic Pyeloplasty (LP) vs Robot-Assisted Laparoscopic Pyeloplasty (RALP)

Over the last 25 years, we assisted to an emergent and increasing interest toward LP. Since 1993 to nowadays the laparoscopic technique and skills have improved remarkably, with a consequent reduction of operating time, complications, and conversion rate to open and with a long-term outcome improvement. In the literature, there are some reports that compare LP with the open approach. Although they are retrospective studies, all of them reach the conclusion that, while the complication rate or intraoperative blood loss was not statistically different, the postoperative pain and the time to return to normal activities were statistically lower in all laparoscopy groups (Table 38.4). Over the last two decades, robotic assistance started to play a pivotal role in minimally invasive surgery. LP still has a long learning curve, with limitations that are intrinsic to conventional laparoscopic surgery: laparoscopic suturing is technically demanding, requires a significant amount of time to master and, sometimes, the relatively low number of pyeloplasty

Table 38.4 Comparative series LP vs open approach

Authors	No. of pts	Success rate (%)	Mean FU (months)	Operating time (min)	Hospital stay (days)	Complication rate (%)
Bauer et al. [169]	Lap 42	98	22 (12–38)	NA	NA	12
	Open 35	94	58 (12–138)	NA	NA	11
Soulié et al. [176]	Lap 26	86	14.3 (6–32)	165 (120–260)	4.5 (3–7)	11.5
	Open 28	86	14.3 (6–32)	145 (80–250)	5.5 (4–9)	14
Klingler et al. [168]	Lap 40	96 (NDP) 73.3	23.4 ± 9.1	NA	5.9 ± 2.1	17.5
	Open 15	93.4	21.9 ± 8.8	NA	13.4 ± 3.8	40.0
Zhang et al. [177]	Lap 56	98	30.2 ± 12.5	80 (70–90) $p < 0.001$	7 (7–8) $p < 0.001$	3.5
	Open 40	98	23.4 ± 9.8	120 (105–125) $p < 0.001$	9 (8–10) $p < 0.001$	7.5
Calvert et al. [178]	Lap 49	98	9	159 ± 33 $p <$ 0.001	5.4 ± 2.2	20
	Open 51	96	12	95 ± 31 $p < 0.001$	5.6 ± 2.1	24
Bonnard et al. [179]	Lap 20	96	24 (12–60)	219 (140–310) $p < 0.001$	2.4 (1–5) $p < 0.001$	NA
	Open 17	100	21 (12–51)	96 (50–150) $p < 0.001$	5 (3–7) $p < 0.001$	NA
Rivas et al. [180]	Lap 62	93.3	45 (6–96)	NA	3.76 (2–5) $p = 0.0362$	3.33 $p = 0.0856$
	Open 30	95	45 (6–96)	NA	5.86 (3–8) $p = 0.0362$	11.11 $p = 0.0856$

NDP non-dismembering pyeloplasty

Table 38.5 Operative and outcomes of RALP

Authors	No. of pts	OP time (min)	Suturing time (min)	Hospital stay (days)	Success rate (%)	No. of complications (%)	FU (months)
Gettman et al. [174]	6	167.5 ± 8.3	74	4	83	1/6	3
Patel et al. [175]	50	122	20	1.1	96	None	11.7
Bhayani et al. [185]	8	210	NA	2.3	88	1/8	NA
Weise et al. [186]	31	199 ± 30.5	76	2.6 ± 0.23	100	2/14 (14%)	6 ± 3.3
Silay et al. [181]	185	173.1	NA	2.1	99.5%	3.2%	12.8
Hopf et al. [182]	129	245.8	NA	2	96.9%	17.8%	33.8
Ganpule et al. [183]	19	155 ± 46.6	NA	3.52 ± 1.5	>90%	NA	18.3 ± 8.2

cases doesn't allow to gain enough experience. Once again, robotic technology was initially looked to as a tool to enable more easily the transition of surgeons from open to laparoscopic surgery but studies soon showed that the robot was in many ways was an improvement compared with standard laparoscopy (Table 38.5). Gettman et al. compared the results of six patients that

underwent RALP with the results of six patients that underwent LP [174]. Mean operative time and suturing time was less for RALP, while blood loss, length of hospital stay and complication rate were similar. Short-term subjective and imaging results at three months were indicative of 100% success. Patel, in one of the largest series with at least 11 months of follow-up, reported about 50 patients that underwent RALP [175]. Crossing vessels were present in 30% of the patients and were preserved in all cases. The operative time averaged 122 min (range 60–330) overall and the time for the anastomosis averaged 20 min (range 10–100). Most patients were discharged on the first postoperative day. There were no complications and blood loss was minimal in all cases. Forty-eight of fifty patients (96%) had both objective and subjective improvement.

Salö et al. compared the results of 84 open pyeloplasties with 39 RALPs. The authors reported that RALP had a significantly longer operative time (249 min ± 52 vs. 167 min ± 79, $p = 0.000$) but a shorter postoperative hospital stay (3.4 ± 2.6 days vs. 4.4 ± 2.2 days, $p = 0.031$), compared to open pyeloplasty. There was no difference in the complication rate. The authors concluded that RALP is safe and efficient, with the typical advantages of a minimally invasive procedure. Rivas et al. retrospectively reviewed 92 cases performed in their department. Two groups were compared: 30 patients were treated with open surgery and 62 with a laparoscopic approach. LP became the standard treatment of UPJO in their department due to similar surgical results, a shorter hospital stay ($p < 0.05$) and better cosmetic results when compared to open surgery. Open surgery may have a place in the UPJO treatment for example in laparoscopic surgery failures or in very complex cases.

Silay et al. compared the outcomes of LP and RALP by retrospectively evaluating the perioperative data of 783 pediatric patients (<18 years old) from 15 academic centers which performed LP or RALP with an Anderson Hynes dismembered pyeloplasty technique [181]. The authors concluded that both minimally invasive approaches were safe and effective in treating UPJ obstruction in children. However, RALP was associated with a shorter hospital stay and a lower postoperative complication rate compared to LP. Hopf et al. conducted a retrospective review of RALPs from 2002 to 2014 to investigate the long-term outcome [182]. The authors could include 129 cases and concluded that RALP is a safe and effective minimally invasive method for correcting UPJ obstruction with lasting improvement in symptoms and resolution of obstruction in most patients. Ganpule et al. compared the outcomes of RALP and LP in children of less than 20 kg [183]. Forty-four patients underwent forty-seven pyeloplasties (19 RALP and 25 LP), with three patients undergoing a bilateral simultaneous laparoscopic procedure. The mean age was 2.7 and 2.4 years for RALP and LP, respectively. RALP was superior in terms of shorter mean hospital stay by one and a half day on average. Both procedures were comparable in terms of complication rate, success rate as well as operating time. Therefore, the authors could confirm the feasibility, efficacy, and safety of RALP in infants and toddlers. Passerotti et al. evaluated the quality of the suture anastomosis and the associated learning curve in RALP, LP, and open surgery on animal models [184]. This interesting study clearly showed that suture anastomosis of the UPJ with robotic assistance was completed in a shorter time compared with free-hand laparoscopy and required fewer cases to approach the times of open surgery. The quality of the anastomosis (as measured by patency and minimal leakage) was better in the RALP group compared with the LP group. Moreover the evaluation of quality of anastomosis, by histological assessment of collagen deposition with inflammatory infiltrates and edema, was better in RALP group where the amount of collagen III appeared to be less. The authors concluded that these findings demonstrate how robotic assistance has many distinct advantages over traditional laparoscopy when performing a pyeloplasty.

Conclusion

Both robotic and laparoscopic pyeloplasties attempt to emulate open surgery, but, with its three-dimensional, enhanced vision, and greater degree of rotational movement, the

robot assistance shows clearly advantages in dissection and tissue handling. Moreover, RALP offers the same results of a minimally invasive technique in terms of morbidity but with the same functional outcomes of an open pyeloplasty. Finally, even for the inexperienced surgeon, laparoscopic suturing is easier to learn at the onset with robotic assistance compared with traditional laparoscopy, without compromising the outcomes.

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39 Robot-Assisted Partial Nephrectomy

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Abstract

Since its introduction in 2004 by Gettman and colleagues [1], robot-assisted partial nephrectomy (RAPN) has been steadily gaining acceptance as part of a new standard of care for the treatment of localized renal malignancy. However, this rise to prominence has not been without its share of difficulties.

Keywords

Partial Nephrectomy · Radical Nephrectomy · Warm Ischemic Time · Laparoscopic Partial Nephrectomy · Robotic Technology

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Introduction

Since its introduction in 2004 by Gettman and colleagues [1], robot-assisted partial nephrectomy (RAPN) has been steadily gaining acceptance as part of a new standard of care for the treatment of localized renal malignancy. However, this rise to prominence has not been without its share of difficulties.

Soon after the introduction of robot-assisted partial nephrectomy, initial studies evaluating operative parameters and immediate outcomes failed to find a significant advantage over other available techniques, namely open and laparoscopic partial nephrectomy [2, 3], leading some to suggest that RAPN had a limited role in the treatment of renal malignancy.

However, as the experience has matured, newer, more robust series have begun to demonstrate remarkable improvements in critical operative parameters, suggesting that robot-assisted partial nephrectomy does indeed have a place in the urologist's armamentarium.

In this chapter, we will discuss the evolution of renal surgery in general, and more specifically, the rising interest in robot-assisted partial nephrectomy, a technique which built upon the foundations forged by the pioneers of the late 20th century. We will then present a detailed atlas of technique for robot-assisted partial nephrectomy, detailing the methods employed by today's top robotic renal surgeons. Finally, we will

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explore the available literature pertaining to robot-assisted partial nephrectomy, detailing the outcomes associated with this burgeoning technique.

The Evolution of Renal Surgery

For many decades, open radical nephrectomy served as the gold standard for surgical treatment for renal cell carcinoma of any size. However, with the advent of high-resolution cross-sectional imaging, there has been a shift in the diagnosis of renal malignancy, away from large, generally symptomatic masses, to small, often serendipitously detected masses [4–8].

Along with this shift in the diagnosis of renal cancer came increased interest in nephron-sparing techniques, which would allow for complete resection of the tumor while preserving the unaffected portions of the kidney. Partial nephrectomy gained acceptance as a new standard of care for clinical stage T1 lesions, demonstrating equivalent cancer control to radical extirpation, as well as equivalent perioperative morbidity [9–14].

Moreover, long-term outcomes have demonstrated that preservation of the healthy, unaffected renal parenchyma is associated with a sharp decrease in the risk for long-term renal dysfunction and improved overall survival. Indeed, maximal preservation of renal functional reserve appears to be associated with a decreased risk of development of numerous diseases, including hypertension, diabetes mellitus, and cardiopulmonary diseases [11, 14, 15].

In the early 1990s, Clayman and colleagues introduced laparoscopic techniques for radical nephrectomy, ushering in the era of minimally-invasive renal surgery [16]. Soon after, Winfield et al. and McDougall et al. described the technique for laparoscopic partial nephrectomy, which rapidly gained acceptance at high-volume centers of excellence [17, 18]. Laparoscopic partial nephrectomy represented a significant leap forward in the treatment of localized kidney cancer. Reports soon demonstrated operative parameters on par with its open counterpart, and reproducible reports of oncologic equivalence were followed [9, 11, 19, 20].

However, despite the clear advantages of laparoscopic partial nephrectomy, the technique has failed to make inroads outside of high-volume academic centers, owing in large part to the formidable technical challenge associated with the approach, namely with regard to tumor excision and renal reconstruction, aspects of the procedure which are performed under the duress of warm ischemia. In fact, two troubling studies published in 2006 found that laparoscopic partial nephrectomy was sorely underutilized by the urologic community at large, with only 12% of all renal masses and less than 50% of renal masses less than 2 cm in size being addressed with nephron-sparing techniques [5, 21].

The introduction of robotic technology into urologic surgery has prompted a renaissance in the minimally-invasive treatment of urologic disease. Offering a magnified stereoscopic view, along with fully articulating wristed instruments, motion scaling, and elimination of tremor, robot assistance allows for precise handling of tissues and instruments, allowing even laparoscopically naïve surgeons to replicate the success of open surgery through a minimally-invasive approach [7, 22].

Robotic surgery's initial applications for minimally-invasive prostatectomy have propelled robotic technology to the fore and have led to a rapid increase in the number of robotic systems available throughout the United States and the rest of the world. Much as robotic technology has refined the minimally-invasive treatment of prostate cancer, robot assistance stands to provide substantial improvements in minimally-invasive nephron-sparing surgery, eliminating much of the technical challenge associated with the laparoscopic approach, and thereby reducing the barrier of entry for the urologic community. These important steps forward may indeed equalize access to the standard of care for all patients who are diagnosed with renal cancer.

Atlas of Technique

Despite the relative ease and short learning curve of robot-assisted partial nephrectomy [23], the technique remains quite challenging, especially

to the novice renal surgeon. While the available robotic systems offer an enhanced three-dimensional view and an unprecedented range of instrument motion, there are significant limitations associated with the technique, chief among them the lack of haptic feedback. This loss of sensory perception requires the robotic surgeon to be intimately familiar with the strength of the robotic arms and to be able to rely largely upon visual cues to gauge the amount of tension being applied to delicate structures, as the robotic arms are capable of exerting an incredible amount of force, even when meeting resistance. Nowhere is this particular facet of robot-assisted renal surgery more critical than when dissecting near the hilar structures.

Therefore, it is recommended that any urologist considering robot-assisted renal surgery should first gain adequate experience with their robotic system. This would include sanctioned hands-on courses which provide the surgeon with thorough instruction in the handling of the robotic system, ideally in an environment which provides a live-animal model. Furthermore, it is recommended that the surgeon become facile with robot-assisted laparoscopic prostatectomy before attempting to employ robotic technology for the purposes of renal surgery.

It is also recommended that the initial transition to robot-assisted renal surgery be focused on radical nephrectomy. Beginning with radical nephrectomy will allow the surgeon to become familiar with the landmarks associated with robot-assisted renal surgery, while also affording the opportunity to become comfortable with hilar dissection using the robotic system.

Patient Selection and Other Considerations

Proper patient selection is critical to the success of robot-assisted renal surgery. While complex central and hilar tumors are capable of being addressed robotically, challenging cases such as these should not be attempted during the initial experience. As such, the ideal initial patients for the novice surgeon would be thin females with exophytic masses and uncomplicated renal vasculature. This particular patient will offer minimal interference from peri-renal fat, which will drastically reduce the difficulty of retraction and hilar dissection. Moreover, an exophytic renal mass is relatively simple to excise and reconstruct, which will minimize the risk of prolonged ischemic times during the initial experience.

It is critical to obtain a thorough patient history, paying special attention to prior abdominal and retroperitoneal surgery, as well as to medical renal disease and other comorbidities such as diabetes mellitus and hypertension. Patients who are on anticoagulation will generally require clearance to have their anticoagulants temporarily suspended in the perioperative period.

Proper informed consent is crucial. Patients must be counseled to the attendant risks of robot-assisted partial nephrectomy, including the risk for hemorrhage requiring transfusion, postoperative urine leak, and inability to completely resect the tumor. In addition, the patient must be counseled regarding the possibility of conversion to radical nephrectomy or to an open procedure.

As dissection of the hilar anatomy can be very difficult, it is recommended that a contrast-enhanced CT scan be performed whenever possible to identify the hilar anatomy. This will allow the surgeon to be prepared for multiple arteries and veins, as well as for anatomic aberrancy.

Patient Positioning and Trocar Placement

The patient should be placed in a flank position, in a manner nearly identical to that of a laparoscopic or open procedure. However, excessive flexion of the table is often not necessary when undertaking a robotic approach. In addition, the arms should be positioned as far cephalad as safely possible, to minimize collisions with the robotic arms. An axillary roll should be placed, and the patient should be secured to the table in a manner that will allow the table to be rolled if necessary.

Sequential compression devices should be placed to provide prophylaxis against deep venous thrombosis. In addition, a preoperative dose of fractionated heparin can be administered

for further prophylaxis and should not lead to increased risk of bleeding complications.

With regard to trocar placement, there are two generally accepted approaches. The first and most widely utilized is a medial trocar arrangement, which places the camera port near the umbilicus. This approach replicates a standard transperitoneal laparoscopic approach and should therefore be familiar to most renal surgeons. The alternative approach locates the camera laterally, providing a closer view that is more akin to a retroperitoneal approach, even though the camera and instruments remain in the peritoneal space. Both approaches have been extensively described and are capable of providing adequate visualization and instrument mobility [1, 23–30].

However, in our center's experience, we find the medial approach to be more favorable for a number of reasons, chief among them the wide viewing angle provided by the relatively greater distance between the camera and the target structures. Not only does this approach allow for easier visualization of the surrounding structures, but it also allows the camera to be panned for tracking of instruments passed by the assistant, thus lowering the potential for iatrogenic injury. Furthermore, the digital zoom of later model robotic systems allows for closer inspection of the surgical field, though this zoom feature is often not necessary. In addition, the medial approach often requires only one assistant port, whereas the lateral approach is generally described as using two assistant ports. In the latter, the assistant is placed at somewhat of a disadvantage, as he or she must work on both sides of the camera arm [26]. A detailed illustration of the medial and lateral approaches can be found in Figs. 39.1 and 39.2.

In patients with excessive peri-renal fat or in instances when a surgeon must work with an inexperienced assistant, the fourth arm can be utilized to allow the surgeon greater control over the retraction [24, 31]. However, the novice surgeon must be cautioned that unlike robot-assisted laparoscopic prostatectomy, including the fourth arm in a robot-assisted partial nephrectomy is actually *more* technically demanding, due to crowding of the instruments and robotic arms into a comparatively smaller working space. As such, a four-arm approach should be considered an advanced procedure. An illustration of the four-arm approach can be found in Fig. 39.3.

When placing the caudad port, the trocar should be introduced approximately 2 cm cephalad to the iliac crest in order to minimize external arm collisions with the hip. For right-sided tumors, an accessory subxiphoid port for a liver

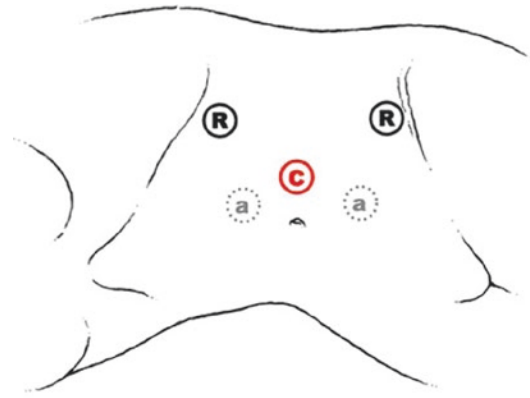

Fig. 39.1 Trocar configuration for the medial camera three-arm approach. A 30° downward-angled lens is used. R, robotic arm; C, camera; a, assistant port (12 mm). The *dotted line* indicates that the assistant port may be placed at either location; only one assistant port is generally necessary. For right-sided procedures, a 5 mm subxiphoid port may be used for placement of a liver retractor (not pictured)

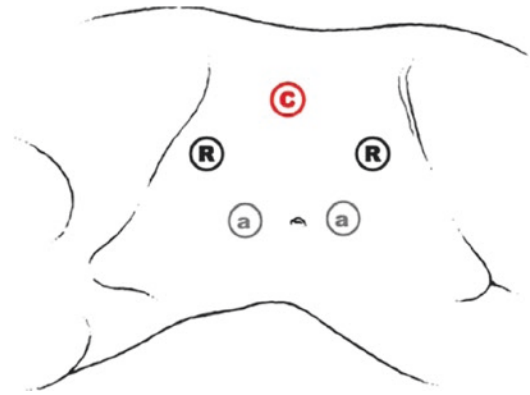

Fig. 39.2 Trocar configuration for the lateral camera approach. A 30° upward-angled lens is used. R, robotic arm; C, camera; a, assistant port (12 mm). Traditionally, two assistant ports are used. For right-sided procedures, a 5-mm subxiphoid port may be used for placement of a liver retractor (not pictured)

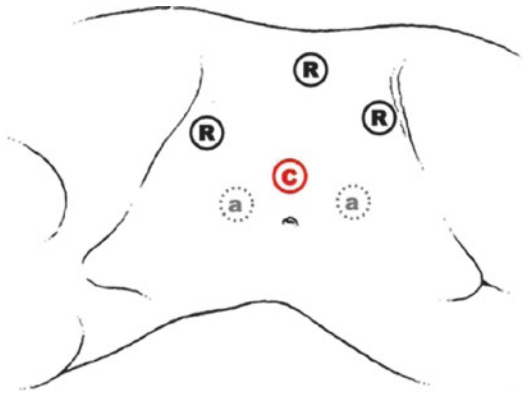

Fig. 39.3 Trocar configuration for the medial camera four-arm approach. A 30° downward-angled lens is used. R, Robotic arm; C, Camera; a = assistant port (12 mm). The *dotted line* indicates that the assistant port may be placed at either location; only one assistant port is generally necessary. For right-sided procedures, a 5 mm subxiphoid port may be used for placement of a liver retractor (not pictured)

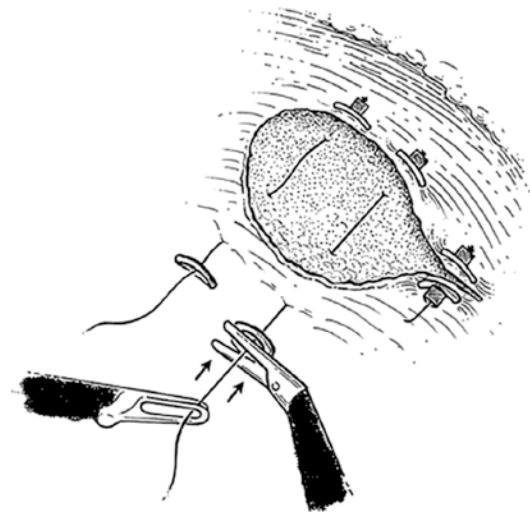

Fig. 39.4 Illustration of the sliding-clip renorrhaphy. Sutures are prepared on the back table by cutting an 0 polyglactin suture to a length of 12–15 cm. A knot is tied at the end, followed by a LapraTy clip and a Hem-o-lok clip. Once the suture has been placed through-and-through, the assistant places a second Hem-o-lok clip on the loose end of the suture, which is then slid into place by the surgeon. The repair is locked in place with a LapraTy clip

retractor is often necessary. This port should be placed as close to the midline as possible, so as not to interfere with the right robotic arm.

Robot Docking and Instrument Selection

The robot should be docked at an angle, on a line connecting the expected location of the renal hilum and the umbilicus. The elbows of the working arms should be pushed out as far laterally as the device will allow, in order to maximize the excursion of the arms and to minimize external collisions.

The right hand should be outfitted with the robotic scissors, which should be connected to monopolar electrocautery. The left hand should be outfitted with the ProGrasp forceps. The assistant should retract with a laparoscopic suction device. Other instruments to have available on the field for the assistant include a Weck (Teleflex, Research Triangle Park, NC, USA) Hem-o-lok clip applier, a LapraTy (Ethicon, Cincinnati, OH, USA) clip applier, a laparoscopic ultrasound probe, and a laparoscopic bulldog applier or Satinsky clamp. In addition, a vascular stapler device with multiple reloads should be readily available, in the event of misadventure requiring emergent nephrectomy.

On the back table, the surgical assistant should prepare the renorrhaphy sutures, as well as sutures for collecting system repair. As we will discuss later, we strongly recommend the use of a sliding-clip technique for renal reconstruction. As the required sutures can be time consuming to prepare, it is crucial that these sutures are fashioned beforehand.

The collecting system sutures should consist of one or two 2-0 polyglactin sutures, cut to a length of 12 cm. At the end, a knot should be tied, followed by a LapraTy clip. Hem-o-lok clips should not be used on these sutures, as they are non-degradable and could erode into the collecting system. The renorrhaphy sutures are 0 polyglactin sutures cut to a length of 12–15 cm. At the end, a knot is tied, followed by a LapraTy clip, then a Hem-o-lok clip (Fig. 39.4).

In addition, bolster material and tissue sealants should be immediately available, should either be necessary to achieve satisfactory closure and hemostasis.

Initial Dissection

The bowel is reflected along the white line of Toldt, thus exposing the retroperitoneum. For right-sided tumors, the duodenum must also be carefully reflected in order to gain access to the hilum. Great care must be taken during this maneuver, as the vena cava lies directly inferior to the duodenum, and is therefore prone to iatrogenic injury.

The lower pole of the kidney should then be identified, and just off the lower pole, the ureter and gonadal vasculature should be identified. It is preferable to leave the gonadal vein intact if at all possible, and therefore, the vein should be dropped medially whenever possible. Great care must be taken to avoid excessive skeletonizing of the ureter, so as not to compromise the blood supply.

The pocket created by elevating the ureter should allow the kidney to be placed on gentle lateral stretch. Dissection should be carried carefully cephalad to reveal the hilar vessels. Astute surgeons may be able to detect the venous impulse which is the hallmark of the renal vein [24]. The artery should lie directly posterior to the vein.

The extent of hilar dissection should be largely dictated by the needs of the preferred method of vascular control. If a laparoscopic Satinsky clamp is to be used to clamp the hilum en bloc, then further dissection between the artery and the vein is not generally necessary. However, if laparoscopic bulldog clamps are to be used, separation of the artery and vein will be necessary. The ProGrasp forceps are best suited for this task, as they are able to bluntly dissect the plane between the vein and the artery. Great care should be taken to eliminate the posterior hilar fat from the field, to ensure that the bulldog clamps are able to fully close.

In some instances, it may be possible to isolate a segmental arterial branch which provides the entire blood supply to the tumor. Selective clamping of this artery may lead to less ischemic insult, as the unaffected portions of the kidney remain perfused. However, while effective for polar tumors, such dissection increases the risk of vascular injury and should be considered an advanced technique [32, 33].

Preparing for Excision

The fat surrounding the tumor should be reflected to expose a 1 cm margin of normal capsular tissue around the mass. This maneuver will greatly aid in reconstruction. The fat overlying the kidney should be left intact, but may be inadvertently released from the surface of the tumor. If this occurs, the fat should be immediately collected and placed with the specimen.

Intraoperative ultrasound should then be performed to assess the extent of the tumor and to delineate the margins of dissection, which should be marked by scoring the capsule. If selective clamping of a segmental renal artery is to be employed, color Doppler flow should be used to assess for complete cessation of flow after temporary occlusion of the segmental artery.

Once the stage is set for excision, the renal vasculature should be carefully occluded with either a Satinsky clamp or bulldog clamps. If a Satinsky clamp is to be used, it is imperative that the assistant closely monitors the clamp and takes steps to avoid external collisions which could lead to avulsion of the vasculature. Due to the inherent risks of the Satinsky clamp method, we prefer the use of bulldog clamps, which are used to occlude the vessels individually. As the bulldog clamps may weaken during reprocessing, it is recommended to clamp the artery doubly whenever possible to ensure complete occlusion. Clamping of the vein is left to surgeon preference, though it is highly recommended, especially for central, anterior, or hilar tumors.

Tumor Excision

The tumor is then sharply excised using the robotic scissors. The ProGrasp may be used to gently spread the tissues and present the underlying parenchyma for dissection. Great care should be taken to follow the expected curvature of the tumor. If the tumor is entered, the last steps should

be retraced, and the tumor should be recaptured. Should this occur, it is recommended to repair this defect on the back table after extraction, to avoid an iatrogenic false-positive margin.

Dissection should be carried out from near to far, using the attachment of the far side as a hinge that will allow for relatively simple retraction as excision is carried out. Any entry into large venous channels or into the collecting system should be noted. Once excision is complete, the tumor should be placed out of the field nearby for later extraction. At this juncture, the assistant may collect a biopsy of the resection bed, if deemed necessary.

Renal Reconstruction

Reconstruction should be undertaken with all deliberate speed. The cortex should be cauterized for hemostasis; however, cautery should not be applied to the medulla. At this juncture, the robotic scissors should be replaced with a needle driver; the ProGrasp should remain on the left hand, as this instrument has the capacity to serve as a needle driver, if necessary. If there has been entry into the collecting system or into a large venous sinus, these areas should be oversewn using the 2-0 polyglactin suture in a running fashion. The repair should be secured with a LapraTy clip to obviate the need for knot tying. Should a bolster or tissue sealants be deemed necessary, they may be applied now or shortly after commencing the renorrhaphy.

Sliding-clip renorrhaphy should then be performed [23–25, 34–36]. The prepared sutures should be placed at 1 cm intervals along the length of the defect. After completing the second throw, the assistant places a Hem-o-lok clip on the loose end. This clip need not be placed in direct apposition to the capsule, as it will be slid into position under tension by the surgeon. However, the assistant should take care to ensure that the suture is placed as close to the middle of the clip as possible, as this will allow the clip to be slid along the suture with greater ease.

The Hem-o-lok clip is then slid into position by straddling the suture with the jaws of the needle driver. Appropriate tension has been placed when the capsule dimples slightly. As this maneuver is being performed, the ProGrasp should hold tension on the loose end of the suture in a direction perpendicular to the capsule, so as to minimize the risk of tearing through the capsule. Once the Hem-o-lok clip has been slid into place, the repair is locked in place by a LapraTy clip. This clip, too, may be slid over the suture, though it does not slide as readily as the Hem-o-lok clip. Once all renorrhaphy sutures have been placed, they may be re-tightened by the surgeon to precisely calibrate the tension upon the repair.

The clamps should then be carefully removed from the hilum, and the repair should be inspected for hemostasis. Should slight bleeding be encountered, a period of observation is warranted, as reperfusion of the kidney will lead to an increase in mass which may further apply tension to the repair and can thus tamponade the bleeding. Should bleeding persist, the clips can be further re-tightened or additional sutures may be placed.

Extraction and Closure

Once hemostasis has been verified, the specimen should be placed in a retrieval bag and the robot should be undocked. The specimen should then be extracted through a widened incision in order to prevent undue compression of the often delicate tumor. A drain may be left in place if deemed necessary.

The fascia of the extraction site should be repaired, though repair of the remaining sites is generally not necessary, as the risk of herniation is low [37]. The skin incisions should be closed after irrigation.

Postoperative Care and Management of Perioperative Complications

Appropriate analgesia should be provided. Serum chemistries and hematocrit should be monitored in the immediate postoperative period and on a daily basis. Mild ileus should be expected, though most patients will tolerate a diet by postoperative

day 1. Ambulation may safely be commenced on postoperative day 0.

Immediate postoperative complications may include cardiac events, deep venous thrombosis, acute renal insufficiency or failure, unrecognized bowel injury, and renal hemorrhage. The latter may be self-limited and may respond to observation and possible transfusion of blood products. On rare occasions, significant bleeding may prompt further intervention, such as selective embolization or return to the operating theatre for completion nephrectomy. Patients who develop renal insufficiency may require nephrology evaluation and may very rarely require dialysis. Provided that ischemic time did not exceed 30 min, it is very likely that renal insufficiency will be self-limited [38].

Unrecognized bowel injuries often have an atypical presentation in the minimally-invasive setting. Unlike open procedures, patients may not develop the classic signs of leukocytosis, peritonitis, and ileus. Rather, they will often develop leukopenia, tenderness limited to the port site closest to the injury, and diarrhea [39]. If bowel injury is suspected, immediate evaluation with abdominal imaging and general surgery consultation is warranted.

Intermediate complications may include urine leak and development of an arteriovenous malformation. Urine leaks may have a delayed presentation and may be heralded by flank pain, excessive drainage from a port site, and fever. Abdominal imaging will confirm the diagnosis. Treatment requires the placement of a ureteral stent and percutaneous drainage of the urinoma; repair is rarely required [40]. Arteriovenous malformation or pseudoaneurysm is a rare complication which can occur at any time and often presents as painless gross hematuria. Arteriography confirms the diagnosis, and treatment often consists of selective embolization or, in rare instances, completion nephrectomy [41–43].

Long-Term Follow-Up

Long-term follow-up consists of periodic imaging and laboratory evaluation, including abdominal CT, chest X-ray, complete blood count, basic metabolic panel, and hepatic function panel. It is of note that if a bolster was used in reconstruction, the material may persist with a defect that appears to contain air. This may often be confused with an abscess unless the radiologist is provided a proper history.

Outcomes of Robot-Assisted Partial Nephrectomy

Initial published reports on robot-assisted partial nephrectomy demonstrated respectable operative parameters and excellent short-term outcomes. Operative times in these series ranged from 142 to 279 min, while warm ischemic times ranged from 20 to 32 min. In addition, rates of positive margins were quite low, with only seven positive margins reported in a total of 256 patients across all series, representing only 2.7% of all patients evaluated. At a period of up to 16 months, no patient in any of the initial series developed disease recurrence [1–3, 22, 29, 30, 44–46]. It is of note that these series represented the initial experience of the early adopters of the technique and were therefore likely confounded by the learning curve of the procedure. Furthermore, each study except for one was hindered by the relatively small number of patients in each experience, with typical study sizes ranging from 8 to 13 patients. Nevertheless, these results provided evidence of feasibility for the procedure.

However, initial comparative analyses pitting robot-assisted partial nephrectomy against laparoscopic partial nephrectomy raised some understandable concern that the additional expense of robot assistance did not justify its inclusion in the renal surgeon's armamentarium. For instance, in the first published comparative analysis between robot-assisted partial nephrectomy and laparoscopic partial nephrectomy, Caruso et al. found that the robot assistance did not confer any specific advantage over a laparoscopic approach, including critical parameters such as overall operative time and warm ischemic time [3]. However, it is of note that the authors focused solely on patients with exophytic tumors, which

are arguably relatively simple to address, regardless of approach. A larger and more recent comparative analysis, however, has found that the benefits of a robot-assisted approach become more apparent as tumor complexity increases [34]. Indeed, robot-assisted partial nephrectomy has been finding increased application in addressing complex central and hilar tumors that might otherwise recommend an open approach [45, 46].

More recent reports, however, have begun to demonstrate substantial improvements in operative parameters, with overall operative times ranging from 83 to 174 min. Perhaps more critical is the profound reduction in warm ischemic times, which range from 18 to 22 min in the most recent analyses [23, 28, 34, 47].

Likewise, contemporary comparative studies have begun to demonstrate a clear advantage of robot-assisted partial nephrectomy over a standard laparoscopic approach. In the largest single-surgeon series to date, Wang and Bhayani found that robot-assisted partial nephrectomy provides significantly shorter overall operative times as well as warm ischemic times, when compared with laparoscopic partial nephrectomy [47]. These results are further corroborated in a large multi-institutional series from Benway and colleagues [34], who found that warm ischemic times were nearly 9 min shorter in the robot-assisted arm (19.7 vs 28.4 min for the laparoscopic approach, $p<0.0001$). A summary of the outcomes of contemporary comparative series is outlined in Table 39.1.

Learning Curve and Technical Refinements

The above-mentioned improvements in operative parameters for robot-assisted partial nephrectomy appear to be multifactorial, likely owing to refinements in technique, coupled with larger study sizes with a greater number of cases performed after the learning curve for the procedure has been surpassed.

As with any procedure, robot-assisted partial nephrectomy presents unique technical challenges during a surgeon's initial experience. As such, the procedure does carry with it a learning curve. A recent analysis evaluating 50 patients who underwent robot-assisted partial nephrectomy by a single surgeon, however, found that the learning curve for the procedure is quite modest. Evaluating by overall operative time, the learning curve could be surpassed in only 19 procedures. However, examining those portions which are performed under warm ischemia, including tumor excision and renal reconstruction, the learning curve is somewhat more substantial, requiring 26 cases to develop proficiency [23].

These figures compare favorably, however, to laparoscopic partial nephrectomy, using the same parameters for evaluation. In a 2005 report from Link and colleagues, the authors found that while overall operative time did appear to decrease with surgeon experience, the learning curve for those portions of the procedure performed under the conditions of warm ischemia could not be identified, even after 200 procedures [48]. As will be discussed later, this striking contrast suggests that most surgeons will be able to develop proficiency with a robot-assisted approach within a relatively short period.

Another important factor in evaluating contemporary literature is an important refinement in technique, which greatly improves the efficiency of renal reconstruction. Sliding-clip renorrhaphy obviates the need for intracorporeal knot tying, which, though comparatively simple to perform using robot assistance, is nevertheless challenging and time consuming. The use of sliding clips allows the surgeon to quickly and efficiently close the renal defect, while exercising unprecedented control over the tension of the repair. A recent analysis evaluating the impact of this refinement found that adoption of a sliding-clip technique can provide reductions in warm ischemic times of up to 8 min [23].

The Case for Robot-Assisted Partial Nephrectomy

As discussed earlier, there has been a striking shift in the diagnosis of renal malignancy toward smaller masses amenable to nephron-sparing

Table 39.1 Overview of contemporary series comparing RAPN to LPN

	Caruso et al. (2006) [3]		Aron et al. (2008) [2]		Deane et al. (2008) [22]		Wang and Bhayanl (2009) [47]		Benway et al. (2009) [23]		Jeong et al. (2009) [49]		Kural et al. (2009) [50]	
	LPN	RAPN	LPN	RAPN	LPN	RAPN	LPN	RAPN	LPN	RAPN	LPN	RAPN	LPN	RAPN
N	10	10	12	12	11	11	62	40	118	129	26	31	20	11
Tumor size	2.2	2	2.9	2.4	2.3	3.1	2.4	2.5	2.6	2.9	2.4	3.4	3.1	3.2
OR time	253	279	256	242	290	229	156	140 ($p=0.04$)	174	189	139	169 ($p=0.03$)	226	185
WIT	29	26	22	23	35	32	25	19 ($p=0.03$)	28	19 ($p<0.0001$)	17.2	20.9	35.8	27.3 ($p=0.02$)
EBL	200	240	300	329	198	115	173	136	196	155 ($p=0.03$)	208	198	388	286
Complications	1	1	1	1	1	1	9	8	8.60%	10.20%	1	1	1	1
Conversions	1	2	0	2	1	0	3	1	4.50%	1.60%	0	1	3	0
PSM	1	0	0	0	0	0	1	1	3.90%	1%	NR	NR	5%	0%
Recurrence	NR	NR	NR	NR	NR	NR	0	0	0	0	2	2	0	0

WIT, warm ischemic time; EBL, estimated blood loss; PSM, positive surgical margin; NR, not reported

surgery. Yet, despite its emergence as a standard of care, partial nephrectomy has struggled to make inroads in the urologic community at large in the laparoscopic era. Certainly, a major barrier to entry for most surgeons has been the formidable and likely forbidding learning curve of laparoscopic partial nephrectomy.

Robot-assisted partial nephrectomy stands to reduce and perhaps eliminate this barrier of entry, providing enhanced visualization and improved dexterity of the surgical instrumentation, compared to a traditional laparoscopic approach. Indeed, Deane and colleagues conclusively demonstrated that after just ten robot-assisted procedures, a laparoscopically naïve surgeon was able to perform robot-assisted partial nephrectomy with a level of competency equivalent to laparoscopic partial nephrectomy performed by experienced laparoscopic renal surgeons [22]. Certainly, these data, coupled with that of Benway et al., suggest that robot-assisted partial nephrectomy is a procedure which is rapidly learned, allowing for a relatively short learning curve to achieve technical competence [23]. This, in turn, indicates that the introduction of robotic technology may stand to level the playing field, allowing most urologists to offer their patients the current standard of surgical care.

Furthermore, the drastic reductions in overall operative times, and perhaps more critically, reductions in warm ischemic times with a robot-assisted approach could theoretically lead to improved long-term functional outcomes, though this particular facet of outcomes has yet to be explored in the robotic literature.

However, there are a few criticisms of the robot-assisted approach which warrant discussion. First, the adoption of robotic technology requires a substantial capital expense, which may render its adoption less attractive to lower volume centers. While comparative cost analysis is presently lacking in the literature, one must consider the potential for cost reductions, in terms of shorter overall operative times and shorter hospital stay [23, 47], as well as the potential for improved functional outcomes, which may reduce the overall cost burden upon the healthcare system.

Also, many authors have raised concerns over the reliance upon the bedside assistant for critical maneuvers, including those employed to establish and protect the means of hilar control [3, 31]. Some authors have described techniques which may reduce the dependence upon the bedside assistant, including the use of the fourth arm for retraction, and even for hilar clamping [31, 32]. However, it should be noted that in our institutional experience, we have not noted any untoward outcomes which could be attributed to the inexperience of the bedside assistant, and therefore, the veracity of these concerns has yet to be rigorously validated [34].

Conclusions

Robot-assisted partial nephrectomy is a safe and efficacious procedure for patients diagnosed with localized renal masses. The relatively slight learning curve, coupled with the potential for drastic improvements in critical operative parameters, indicates that robot-assisted partial nephrectomy may represent the future standard of care for the surgical management of small renal masses.

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40 Robot-Assisted Laparoscopic Radical Nephrectomy for Complex Tumors Including IVC Thrombus

Ronney Abaza

Abstract

Robotic technology adds significant capability to laparoscopic surgery but has been typically reserved for more complex procedures, particularly those requiring suturing. Extirpative procedures like radical nephrectomy are felt by some to lack the complexity needed to benefit from robotic instrumentation. While some advocate using robotics in laparoscopic procedures regardless of complexity, there is a subset of radical nephrectomy procedures that have unique challenges and can benefit from the advanced instrumentation and vision that comes with robotic surgery. This chapter will review such situations where patient and tumor characteristics call for the best instrumentation possible to enable a safe and effective minimally-invasive operation.

Keywords

Robotics · Nephrectomy · Renal cell carcinoma · Renal masses · Vena cava

Introduction

Radical nephrectomy is the standard treatment for renal masses not amenable to partial nephrectomy [1]. Nephrectomy was first performed in the 1860s, and the first radical nephrectomy for cancer was performed by Robson in 1963 [2, 3]. Until the first laparoscopic nephrectomy (LN) was performed in 1991 [4], open nephrectomy was associated with large incisions regardless of tumor complexity.

Laparoscopic nephrectomy is now considered a standard option for tumors and patients of acceptable risk who are eligible for a minimally invasive alternative to open surgery [5]. While LN has shown comparable oncological efficacy, quicker convalescence, reduced blood loss, and superior cosmesis over more than two decades since its introduction [6–8], there remain scenarios where standard laparoscopy has been felt too limited to enjoy widespread adoption, such as for tumors involving the vena cava where minimally-invasive surgery was once felt contraindicated [9, 10].

Role of Robotic Nephrectomy

The initial RALN was performed in a 77-year-old woman with a nonfunctioning right kidney [11]. Since then, a relatively few series of RALN have been published with as little as 5 patients to the largest series of 101 patients [12–15].

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Few studies with small patient numbers have compared robotic-assisted laparoscopic nephrectomy (RALN) with LN and for unselected patients have not shown a benefit to RALN although outcomes were at least as good as with LN [16, 17]. The role of robotic technology in conventional laparoscopy is yet unsettled partly due to the additional cost since standard LN is achievable in the majority of patients requiring renal extirpation. While robotic surgery may or may not improve upon LN in simple cases, the robotic surgical platform may allow a minimally-invasive approach for complex renal masses otherwise requiring an open approach.

RALN for Complex Procedures

Despite the advent of laparoscopy in urology about a decade before the introduction of robotic surgery, several complex urologic procedures were not performed in minimally-invasive fashion with laparoscopy until a robotic approach was described [18–20]. In similar fashion, advocates of RALN have suggested that it may enable complex nephrectomies in minimally-invasive fashion when standard laparoscopy may not be possible.

Tumors with caval thrombi requiring cross-clamping of the IVC had not been reported laparoscopically until RALN was first reported for this in 2011, 20 years after the first LN [21]. Since this initial report, RALN has gained adoption at multiple institutions, suggesting reproducibility among adequately experienced robotic surgeons. (Fig. 40.1) This includes a multi-institutional study of nine centers reported 32 patients who successfully underwent RALN for tumors with caval thrombi [22–24].

In addition to enabling minimally-invasive management of tumors involving the vena cava, RALN has also been used for locally-advanced tumors invading the liver, pancreas, and duodenum and for tumors of all sizes, including >25 cm [15, 25] (Figs. 40.2, 40.3, 40.4).

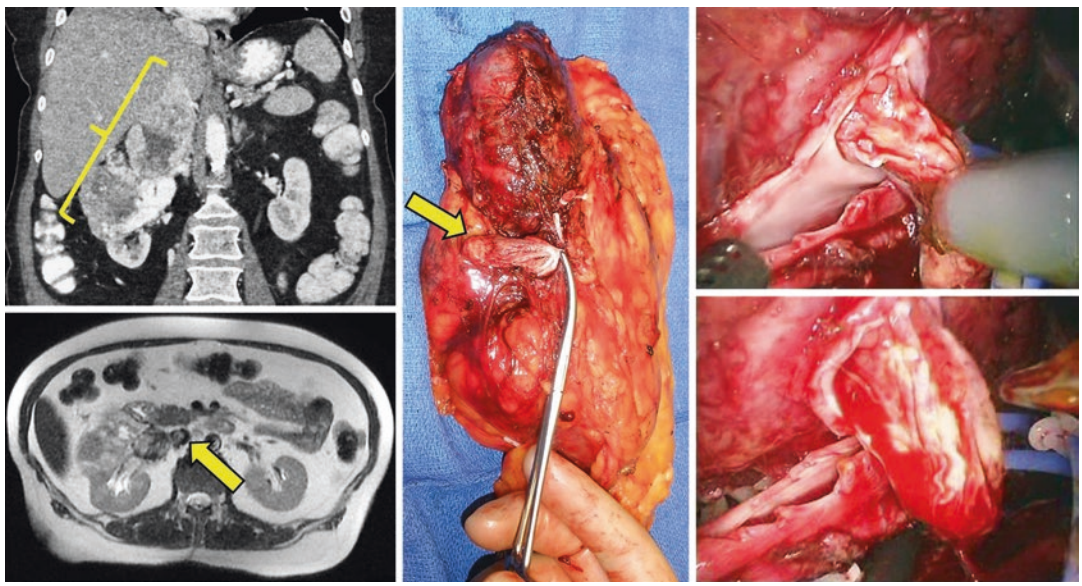

Fig. 40.1 Right renal tumor with invasion of vena cava requiring clamping and opening of cava for thrombus extraction. Reprinted from Urology, 85(6), Firas G. Petros, Jordan E. Angell, Ronney Abaza, Outcomes of Robotic Nephrectomy Including Highest-complexity Cases: Largest Series to Date and Literature Review, 1352–1359, Copyright 2015, with permission from Elsevier

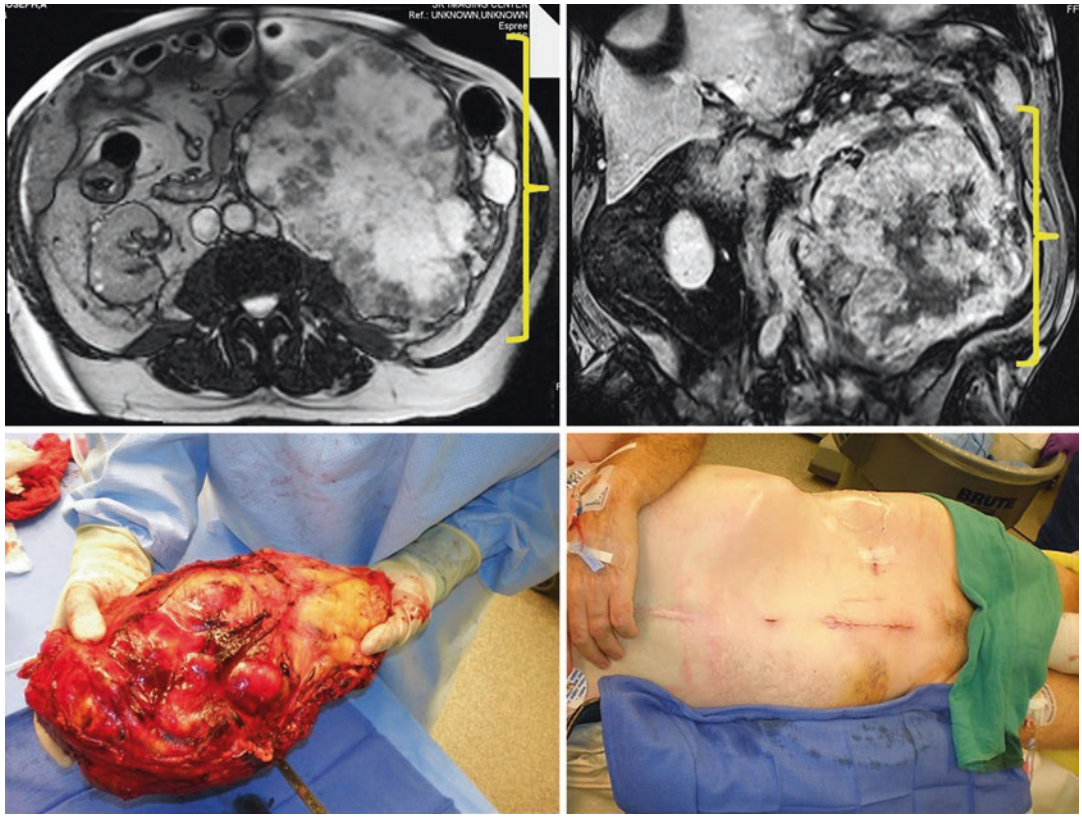

Fig. 40.2 Representative large left renal tumor resected robotically and extracted through a midline suprapubic incision allowing overnight stay only in contrast to open surgery. Reprinted from Urology, 85(6), Firas G. Petros, Jordan E. Angell, Ronney Abaza, Outcomes of Robotic Nephrectomy Including Highest-complexity Cases: Largest Series to Date and Literature Review, 1352–1359, Copyright 2015, with permission from Elsevier

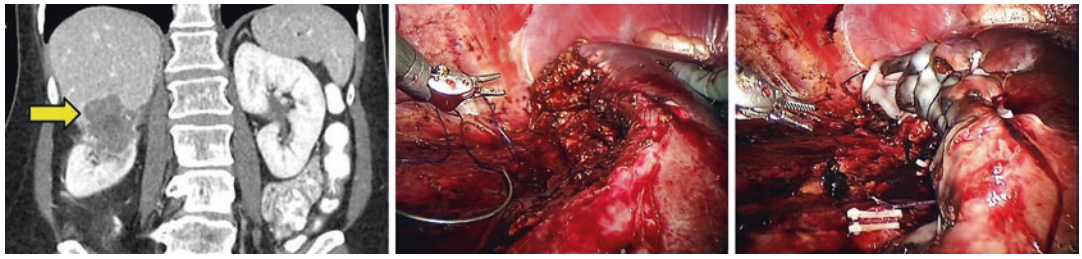

Fig. 40.3 Right-sided renal tumor invading liver and resected en bloc with reconstruction of resected liver segment. Reprinted from Urology, 85(6), Firas G. Petros, Jordan E. Angell, Ronney Abaza, Outcomes of Robotic Nephrectomy Including Highest-complexity Cases: Largest Series to Date and Literature Review, 1352–1359, Copyright 2015, with permission from Elsevier

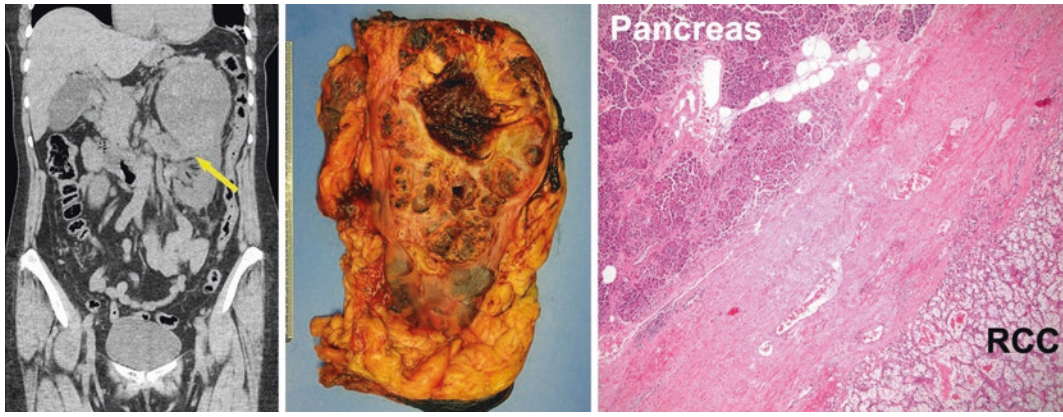

Fig. 40.4 Left-sided renal tumor invading tail of pancreas that required distal pancreatectomy at the time of robotic nephrectomy

Preparation and Operative Steps of RALN

Patient Selection

Patients selected for RALN include those who are candidates for LN, but some cases too complex for LN may be candidates for RALN. In such cases, when RALN is offered as an alternative to open surgery, discussion with the patient of the potential risks and need for conversion to open surgery should take place preoperatively. As long as no critical injuries occur during RALN, converting to open surgery is not harmful as compared with beginning with open surgery and offers the patient the opportunity for a minimally-invasive operation.

The decision to convert to open surgery is difficult and multifactorial, but the patient's best interest should always take precedence without delay that could lead to an unduly prolonged surgery. Also, the oncologic goals of the operation should never be compromised as the benefits of a minimally-invasive approach are temporary while oncologic control is vital. Potential causes for conversion to open surgery are sometimes predictable from preoperative imaging, including potential invasion of contiguous organs, and should be used to plan potential need for resection of such organs or structures.

Patient Preparation and Positioning

The preoperative preparation for RALN is similar as for LN and other robotic procedures. Preoperative thrombosis prophylaxis is based upon surgeon preference. Bowel preparation is also optional unless the possible need for bowel resection is anticipated. Bowel decompression with intraoperative nasogastric or orogastric tube is recommended to provide more intraperitoneal space and ease bowel retraction. A bladder catheter is also advisable particularly for longer procedures. Medical optimization and anesthesia precautions are as for other surgical procedures.

Extreme care should be taken in patient positioning particularly for complex RALN as the operative time will be difficult to predict and prolonged procedures will raise the risk of position injury. Pressure points should be avoided, and the kidney rest should not be used to avoid rhabdomyolysis. The degree of lateralization in the flank position has been variably described at 45, 60 or 90°, but the more perpendicular the patient to the table, the more gravity will provide retraction to the bowel away from the retroperitoneum where nephrectomy will be performed (Fig. 40.5).

Fig. 40.5 Example of challenging nephrectomy due to patient body habitus performed robotically with positioning in full flank at 90° to allow intraperitoneal contents to fall medially away from the kidney

Port Placement

Access can be obtained with multiple including Veres needle, Hasson technique, or optical port insertion under vision at the discretion of the surgeon. Multiple configurations have been described for robotic kidney surgery with variations for the type of robot used as the Xi robot tends to allow more flexibility in arm position. Triangulation of ports around the target anatomy is more important in older generation robotic platforms. Typically, the camera port will be more medial or midline (e.g., periumbilical) with either two additional robotic ports or a 3rd for the robotic 4th arm.

The use of one or more assistant ports is at the discretion of the surgeon. RALN can be performed without any assistant ports as the renal artery and vein can be ligated by the robotic surgeon using robotic clips. For more complex RALN, assistant ports can be useful for liver retraction (e.g., IVC thrombus), to introduce needles for suturing, and for suction.

Operative Steps

The initial steps of RALN are identical to that of robotic partial nephrectomy, including retraction of the colon to access the retroperitoneum and Kocherization of the duodenum on the right and reflection of the spleen and pancreas on the left.

On the right side, the vena cava will be visible as soon as the duodenum is reflected and can be used to locate the right renal vein. The renal artery us typically located posterior to the vein and is most safely accessed by lifting the kidney within Gerota's fascia anteriorly to place the hilum on stretch. The renal artery can be clipped with robotic clips placing at least two on the aortic side or alternatively by the bedside assistant with clips or stapler. The renal vein can be managed in similar fashion either with robotic clips or by the bedside assistant. A robotic stapling device is now available as well and can be used on the artery and/or vein.

On the left side, the initial maneuver after reflecting the colon and other overlying structures is to lift the kidney within Gerota's fascia off the underlying psoas muscle taking care to be medial to and include the ureter and gonadal vein. The psoas plane is then followed cranially until the renal vein is encountered, and the gonadal vein can be used as a landmark to reach the renal vein. The artery and vein are then controlled as on the right side.

After the renal vessels are ligated and divided, the kidney is completely mobilized within Gerota's fascia. If the adrenal gland is uninvolved and to be spared, a plane between the adrenal and kidney is dissected with care to control the small vessels between the two. The lateral attachments of the kidney are divided last so that the kidney remains laterally retracted rather than falling medially. The ureter is clipped and divided prior to releasing the lateral attachments, and the kidney is then extracted in an extraction bag.

Considerations in IVC Thrombus

RALN in the setting of vena caval tumor thrombus shares many of the same steps of more simple nephrectomies up to the identification of the renal vein [21, 22]. Most caval thrombi will involve right sided renal masses. Unlike in typical RALN,

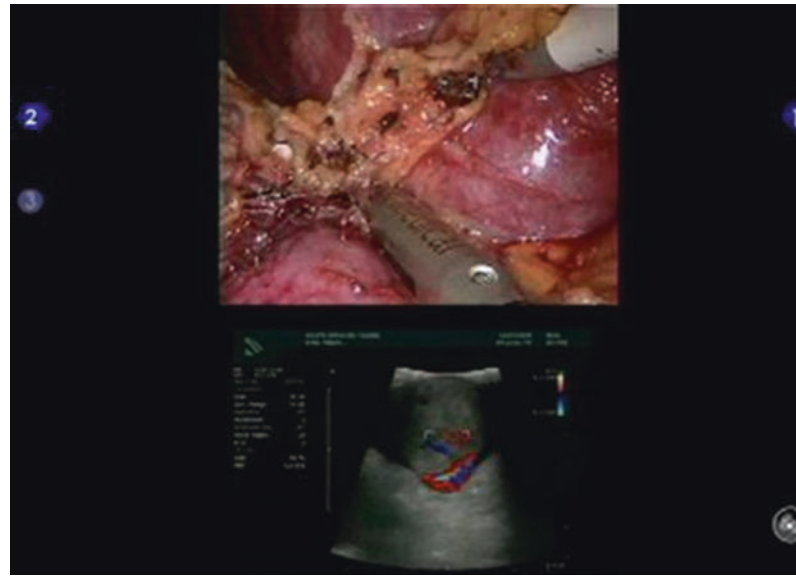

Fig. 40.6 Use of laparoscopic ultrasound to visualize upper extent of tumor thrombus at the liver edge. Tumor thrombus can be seen in the lumen such that clamping will take place above this level where the lumen of the cava is empty

the renal artery may be difficult to access behind the renal vein that is filled with tumor thrombus. A safer approach to the renal artery is in the inter-aortocaval space where the artery can be clipped early with or without division at this point as the artery can be divided later in the procedure after the thrombus has been extracted and renal vein removed.

Once the renal artery is controlled, the tumor thrombus may retract slightly and ease extraction. The next stage of the operation involves achieving complete control of the cava above and below the thrombus as well as control of the contralateral renal vein. The IVC must be circumferentially dissected along the entire length that will be clamped so that all lumbar vessels are ligated. Laparoscopic ultrasound allows identification of the extent of the thrombus prior to clamping (Fig. 40.6).

Clamping of the cava has been described with various techniques including various combinations of laparoscopic Satinsky clamps, bulldog clamps, and Rommel tourniquets. Once the cava above and below the thrombus is clamped as well as the contralateral vein, a small cavotomy should be made to confirm that all inflow has been controlled before opening the cava further. Continued bleeding often signifies a missed lumbar vein, and the small cavotomy should be closed and the missed inflow ligated. Continuing to open the cava until then can lead to massive blood loss and impaired visualization to ensure the entire tumor thrombus is removed. Once the tumor thrombus is extracted, the cava is closed with permanent suture and flushed with heparinized saline prior to completing the closure to remove any gas from its lumen. The clamps and/or tourniquets are then removed restoring blood flow (Figs. 40.7 and 40.8).

Postoperative Care

Postoperative care following RALN is similar to other robotic renal procedures. Overnight stay is typically adequate in robotic renal surgery and can be facilitated by using a clinical pathway. With larger extraction incisions, a subcutaneous catheter for continuous delivery of local anesthetic (ON-Q®, Kimberly-Clark, Lake Forest, CA) may reduce narcotic requirements along with acetaminophen, intravenous ketorolac, and oral narcotics for breakthrough pain only thereby reducing risks of ileus, nausea, and confusion in the elderly. Immediate ambulation is encouraged to improve return of bowel function and reduce the risk of thrombotic events. Oral diet can be advanced as tolerated to regular food immediately after surgery, and most patients can be discharged the day after surgery [15].

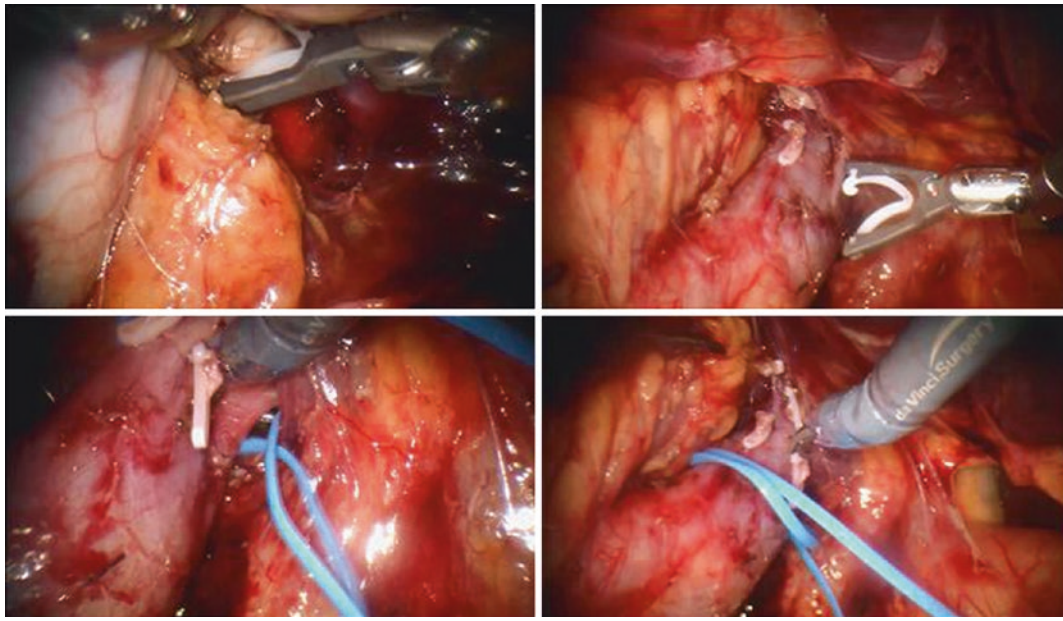

Fig. 40.7 Clip ligation of the right renal artery in the interaortocaval space (left upper), clip ligation of the short hepatic veins (right upper), double wrap of the vessel loop around the cava (lower left) to create a Rommel tourniquet (right lower). Reprinted from Journal of Urology, 195(4), Ronney Abaza, Ahmad Shabsigh, Erik Castle, Mohamad Allaf, Jim C. Hu, Craig Rogers, et al., Multi-Institutional Experience with Robotic Nephrectomy with Inferior Vena Cava Tumor Thrombectomy, 865–871, Copyright 2016, with permission from Elsevier

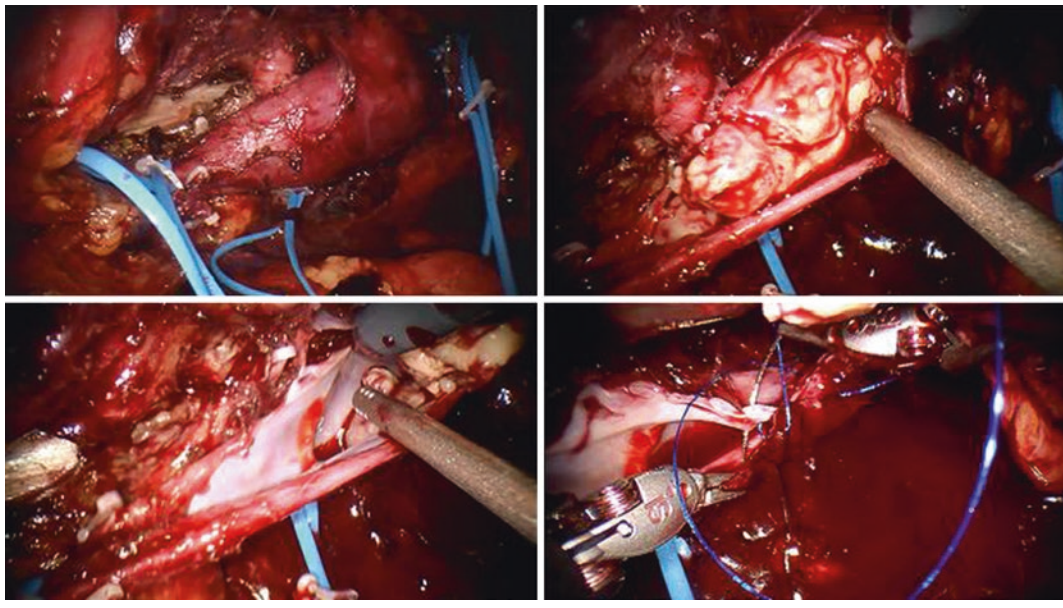

Fig. 40.8 The IVC is clamped after all lumbar vessels are ligated by clamping above and below the thrombus as well as the contralateral renal vein (upper left) after which the cava can be opened (upper right) for extraction of the tumor thrombus (lower left) followed by sutured closure of the cava (lower right)

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41 Robot-Assisted Partial Nephrectomy for Complex Renal Tumors

Deepansh Dalela and Craig Rogers

Abstract

Partial nephrectomy (PN), whether using open or robotic approach, is an oncologically safe alternative for radical nephrectomy (RN) in appropriately selected patients with renal cell cancer (RCC). As urologists become increasingly facile with the robotic platform, robot-assisted partial nephrectomy (RAPN) will be increasingly performed in patients with complex renal tumors. These include tumors that are completely endophytic or hilar in location, ≥cT1b, tumors with a high RENAL nephrometry score, multiple tumors, or tumors in patients with solitary kidney or significant chronic kidney disease (CKD). While the "trifecta" of negative surgical margins, minimal renal functional decline and no urologic complications remains the ideal goal for any PN, its attainment may pose unique surgical challenges in patients with complex renal tumors. In this chapter, we describe some of the approaches for such patients, tailored to the specific clinical presentation. General considerations to optimize outcomes in such cases include additional assistant ports, judicious use of the 4th robotic arm, and use of preclamp check lists. Specific technical maneuvers include use of intraoperative ultrasound probes (for endophytic tumors), tumor enucleation/enucleoresection and modified renorrhaphy techniques (for hilar tumors), cutting wide and deep without excess traction (in cases of cystic/≥cT1b tumors), and minimizing warm ischemia ('on-demand' ischemia and early unclamping of the main renal artery, selective clamping of tumor specific arteries, or regional hypothermia) in patients with multiple renal tumors, solitary kidney or preexisting CKD.

Keywords

Robot-assisted partial nephrectomy · Complex tumors · Renal cell cancer · Hilar tumors · Endophytic tumors · cT1b tumors

Introduction

Surgical extirpation of the renal cell cancer (RCC), either by a partial (PN) or radical nephrectomy (RN), has been the mainstay of treatment of localized disease [1–3]. According to current guidelines, partial nephrectomy is the standard treatment for clinical T1a renal tumors and the preferred treatment for clinical T1b renal tumors [1, 2].

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A growing evidence base suggests that while PN offers equivalent cancer control outcomes as RN [4], it is associated with significantly lesser risk of chronic kidney disease (CKD) [5], which may translate into lower cardiovascular events, hospitalizations and all-cause mortality [6–8]. With the advent of minimally invasive surgery, robot-assisted partial nephrectomy (RAPN) has become an increasingly common approach for performing PN [9].

An ideal PN is characterized by the "trifecta" of negative surgical margins, minimal renal functional (RF) decline and no urologic complications, and these outcomes are intrinsically determined by tumor specific, patient specific and surgeon specific factors (Fig. 41.1). As urologists become increasingly facile with the robotic platform, they are likely to confront more complex tumors for RAPN. These include tumors that are completely endophytic or hilar in location, ≥cT1b, tumors with a high RENAL nephrometry score, multiple tumors, or tumors in patients with solitary kidney or significant CKD. While reports from centers of excellence have described the feasibility of performing RAPN in such patients [10–20], RAPN in these conditions remains challenging.

In this chapter, we highlight some of the technical maneuvers and summarize the contemporary outcomes of patients undergoing RAPN for complex renal tumors.

Port Placement

RAPN for complex tumors may require additional port placement to improve access to the tumor (Fig. 41.2). An additional assistant port may be used to introduce a Satinsky clamp for 'en-bloc' clamping of the renal hilum in cases such as hilar tumors in which visibility or access to the hilum could be compromised. For right sided tumors, passive liver retraction may be performed using a locking grasper through a 5-mm sub-xiphoid port placed under the liver and secured to the diaphragm. The 4th arm may be useful to provide additional autonomy in complex tumors or vascular anatomy, obese patients or abundant perinephric fat.

Exposure and 4th Robotic Arm

As with any oncological surgery, adequate exposure is of paramount importance in complex renal tumor surgery. The goal is wide mobilization of bowel and kidney, such that the tumor/s directly face the surgeon. This may be facilitated by use of the 4th robotic arm, extra assistant ports, or use of lap sponges.

The situations where the 4th arm and extra assistant ports may be useful include:

- Bowel mobilization: Following peritoneal incision along the line of Toldt and medial mobilization of the bowel, the bedside assistant maintains medial countertraction on the bowel initially. The 4th arm can be used at this stage to grasp the anterior Gerota's fascia and retract the kidney anteriorly to facilitate further bowel mobilization (Fig. 41.3a). This can be particularly useful in obese patients with abundant perinephric fat.
- Hilar dissection and clamping: Once a window is created between the ureter and the psoas muscle and a psoas plane is developed to the lateral side wall, the 4th arm can be placed under the ureter to provide upward lift to the kidney and put the renal hilum on stretch (Fig. 41.3b). This allows the surgeon to have both arms free for hilar dissection. Robotic bulldog clamps can be placed to occlude the renal hilum by the surgeon (using the 4th arm), or by a skilled bedside assistant through the assistant ports.
- Tumor exposure and excision: The 4th arm can also be used to mobilize and retract the kidney during dissection of the Gerota's fascia and perinephric fat for optimal tumor exposure (Fig. 41.3c). The primary assistant port may be used to introduce the ultrasound probe, which can then be grasped by the

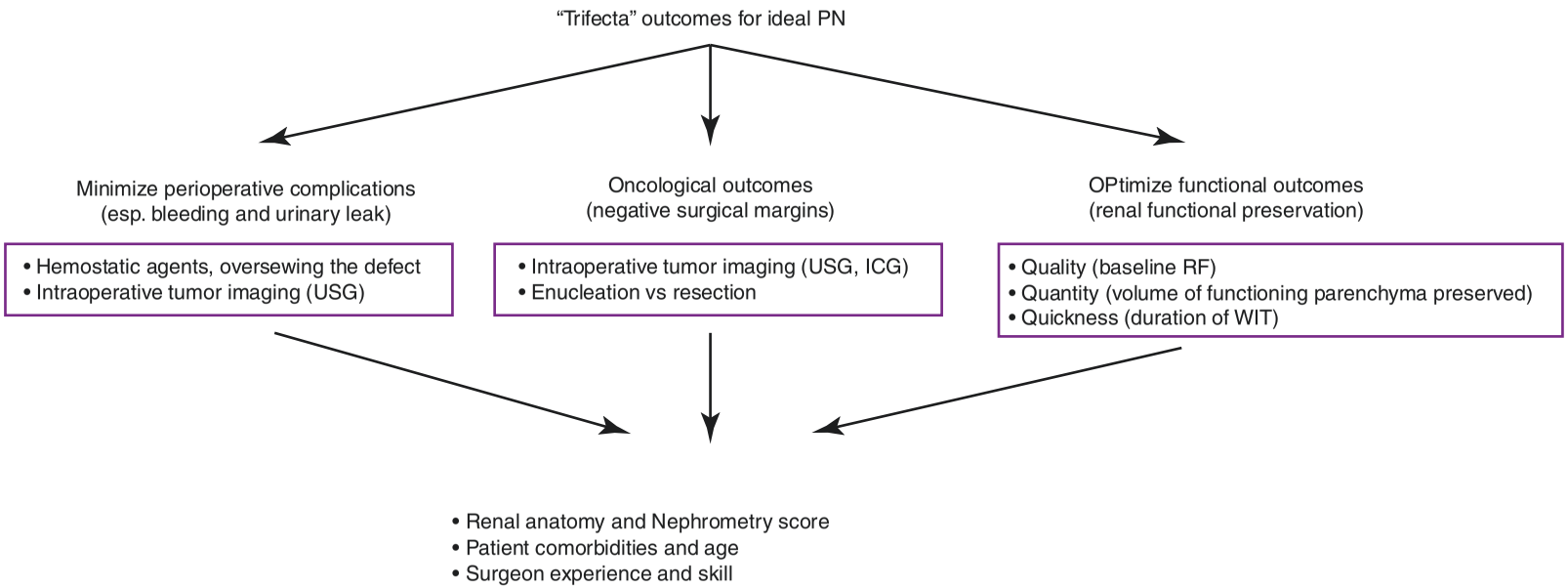

Fig. 41.1 Achieving optimal outcomes in partial nephrectomy (PN). *USG* ultrasonography, *ICG* indocyanine green, *RF* renal function, *WIT* warm ischemia time

4thw arm and moved over the kidney/tumor surface to demarcate tumor margins and borders of resection for more endophytic tumors. Posterior, upper pole tumors require medial mobilization of the kidney for adequate tumor exposure in a transperitoneal approach. In such cases, placement of a lap sponge behind the kidney prevents the kidney from springing back into its normal anatomical position.

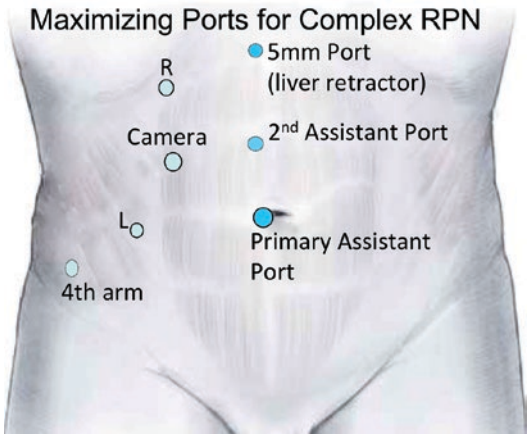

Fig. 41.2 Port placement for complex robotic partial nephrectomy (RPN). Dotted lines represent optional ports

Preparation and Pre-clamp Time Out

It is important to have all the necessary equipment available for complex tumors for any potential occurrences while the kidney is on-clamp and tumor excision is being performed. An example of a pre-clamp checklist includes the following:

- All sutures and hemostatic agents (Floseal, Surgicel) ready and visually confirmed
- Adequate CO_2 for insufflation
- Clean camera and instruments, test needle drivers
- Hydration and mannitol
- Bulldog clamps, Satinsky clamp, GIA stapler, and open tray available
- Robotic/laparoscopic ultrasound probe, indocyanine green (ICG) for near-infrared fluorescence imaging (NIRF)
- No breaks around clamp time

Endophytic Tumors

Renal tumors that are mostly (>50%) or entirely endophytic pose additional surgical challenges for PN (Fig. 41.4). These cases are associated

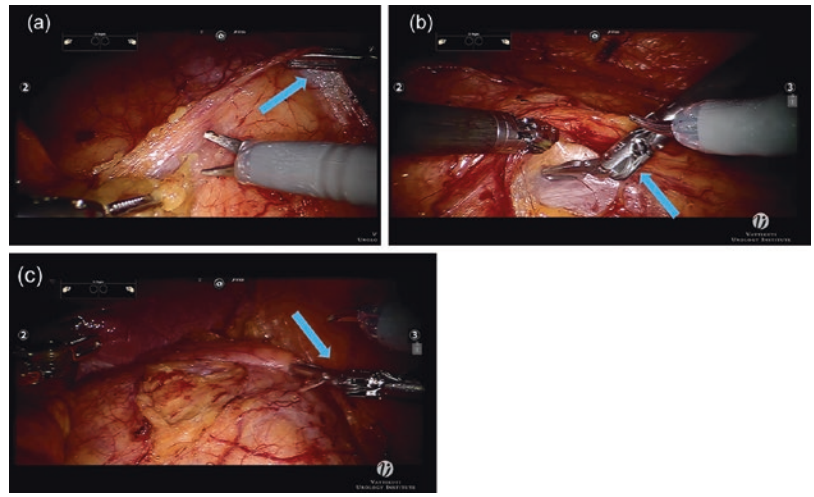

Fig. 41.3 Use of the 4th robotic arm to optimize exposure. (**a**) anterior retraction of kidney to facilitate bowel mobilization in an obese patient with abundant perinephric fat; (**b**) 4th arm under ureter to place renal hilum on stretch for hilar dissection; (**c**) kidney retraction for optimal tumor exposure. Blue arrows represent 4th robotic arm

with poor recognition of mass extension to the collecting system, higher risk of inadvertent vascular or pelvicalyceal system injury, potential for positive surgical margin, difficulty in performing renorrhaphy as well as higher perioperative complication rates from bleeding or urine leak. Use of intraoperative ultrasound can facilitate surgery for endophytic tumors. Important aims of surgery in these cases include wide and deep resection (up to the level of sinus fat or collecting system) based on preoperative imaging and/or intraoperative ultrasound to help ensure an adequate tumor margin.

Intraoperative ultrasound is used to delineate tumor margins and boundaries of resection, to screen for additional small lesions, and assist in obtaining negative resection margins during RAPN. Both robotic and laparoscopic probes can be used for this purpose. Robotic ultrasound probes offer comparable perioperative outcomes and surgical margin rates, with the added advantage of surgeon autonomy [21]. The ultrasound probe is connected to the da Vinci system, allowing the ultrasound view to be displayed on the console screen using the TilePro® system (Fig. 41.5a). Once the tumor margins are identified, the renal capsule can be scored circumferentially (Fig. 41.5b) with an adequate margin around the tumor to serve as a guide for resection.

Fig. 41.4 Representative case of endophytic tumor (*red arrow*)

Hilar Tumors

Similar to endophytic tumors, hilar tumors necessitate careful surgical planning owing to their proximity to the renal vessels and the pelvicalyceal system (Fig. 41.6). The feasibility of RAPN in the setting of hilar tumors has been previously demonstrated [10, 13, 17–19]. It is essential to dissect distal arterial branches supplying the tumor and the sinus plane to minimize inadvertent vascular and/or collecting system injury. Tumor enucleation and enucleoresection techniques (Fig. 41.7a, b) have been proposed to protect critical hilar structures [22, 23]. During enucleative PN, tumor excision is performed immediately adjacent to the tumor edge. The radially oriented renal parenchyma and pyramids lend themselves favorably to developing a cleavage plane for enucleation/enucleoresection

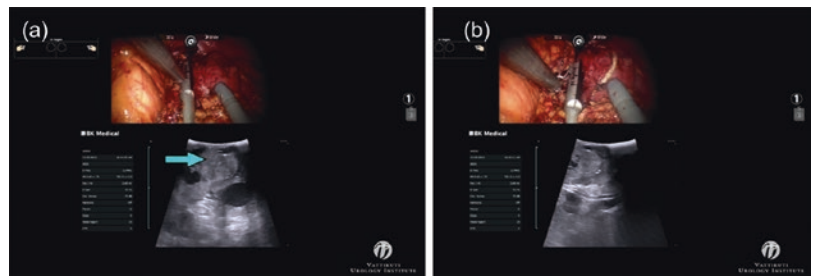

Fig. 41.5 Intraoperative ultrasound using robotic ultrasound probe for (**a**) delineation of tumor (blue arrow), and (**b**) scoring margins of resection

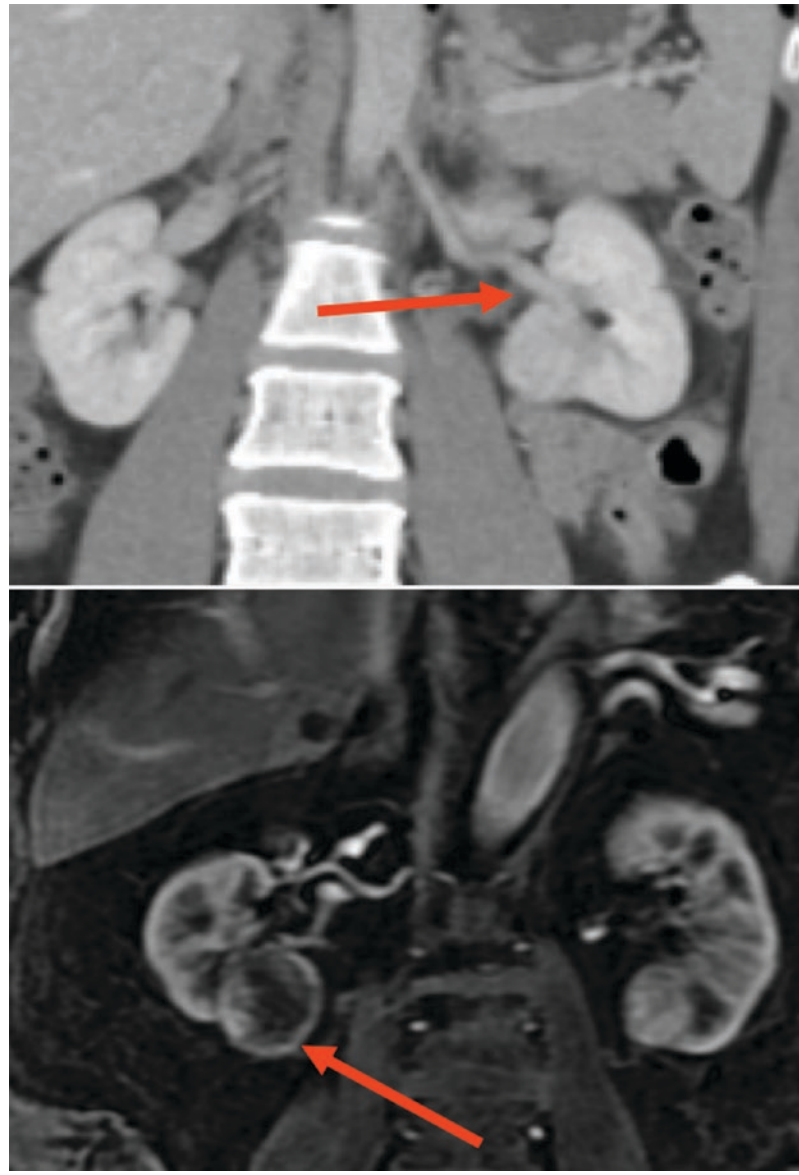

Fig. 41.6 Representative examples for hilar tumors (*red arrows*)

by atraumatic blunt separation rather than sharp cutting. Oncologically, the tumor-parenchyma interface is often marked by a 'pseudocapsule' (consisting of inflammatory and sclerotic tissue at the tumor margin), which forms a surgically favorable plane for enucleative PN. Even when there is pseudocapsular penetration into normal renal parenchyma, a thin rim of renal tissue is generally sufficient for a negative surgical margin when tumor enucleation is performed [1, 2, 23]. Functionally, enucleation helps preserve healthy parenchyma, which is an important determinant of maintaining renal function post-RAPN [24–27].

Following resection of hilar tumors, a careful renorrhaphy is key to minimize vascular and collecting system injury. Kaouk and colleagues [28] proposed a technique of V-hilar suture renorrhaphy for complex hilar tumors (Fig. 41.8). This was performed by using inner

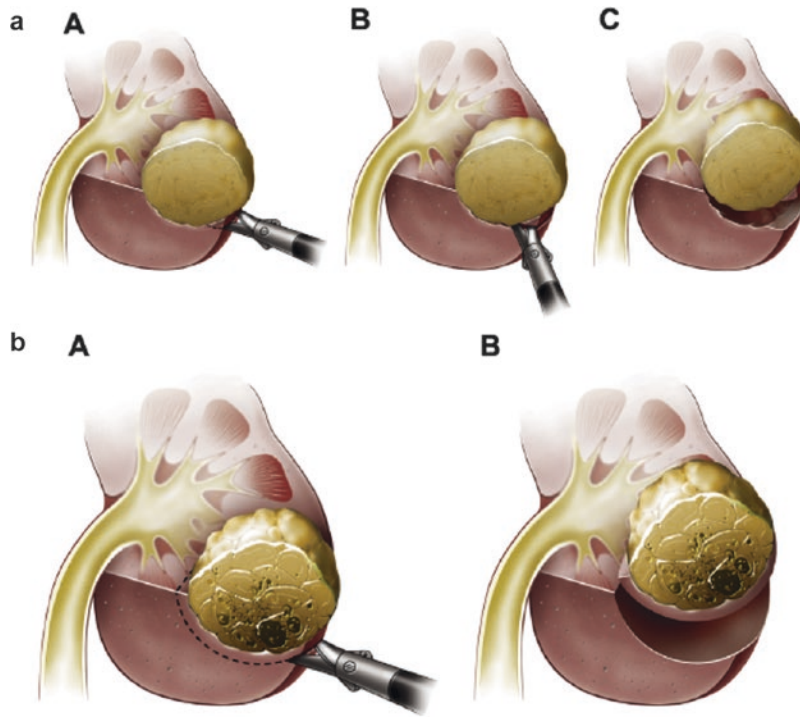

Fig. 41.7 Comparison of enucleoresection (upper panel) and tumor excision (lower panel) approaches for hilar tumors. (**a**) Schematic diagram of enucleation for small renal tumor (left kidney is depicted from anterior aspect, with the anterior half and the lower third removed). In part A, the initial incision is made into normal renal parenchyma close to the margin of the tumor. In part B, the incision is carefully advanced until the enucleation plane adjacent to the tumor pseudocapsule is entered. In part C, the tumor can then be gently separated from the renal parenchyma along this plane. (**b**) Schematic diagram of sharp excision for small renal tumor (left kidney is depicted from anterior aspect, with the anterior half and the lower third removed). The tumor is excised sharply with cold scissors (A), with a thin rim of normal parenchyma surrounding the entire excision (B). Adapted from Urology, 83(6), Anudeep Mukkamala, Christopher L. Allam, Jonathan S. Ellison, Khaled S. Hafez, David C. Miller, Jeffrey S. Montgomery, et al., Tumor Enucleation vs Sharp Excision in Minimally Invasive Partial Nephrectomy: Technical Benefit Without Impact on Functional or Oncologic Outcomes, 1294–1299, Copyright 2014, with permission from Elsevier

layer sutures to reshape the renal parenchymal defect, followed by a continuous horizontal mattress suture to reapproximate the renal capsule.

Cystic/≥cT1b Tumors

Oncological challenges associated with a cystic and ≥cT1b (>4 cm; Fig. 41.9) tumors include the risk of positive surgical margin, pathological upstaging, and, in some cases, greater likelihood of postoperative complications [29]. Important technical points to keep in mind during RAPN in such patients include the need for wider surgical margins (given their high likelihood of pathological upstaging [11] and pseudocapsular invasion [23]) and avoiding excess traction (to minimize the potential for tumor spillage). The first RAPN series comparing outcomes of renal tumors >4 cm to those ≤4 cm was reported by Patel et al. [14]. While patients with larger tumors had longer WIT (25 vs. 20 min, p = 0.01), there were no significant differences in estimated blood loss, total operative time, hospital stay, complication rates, and

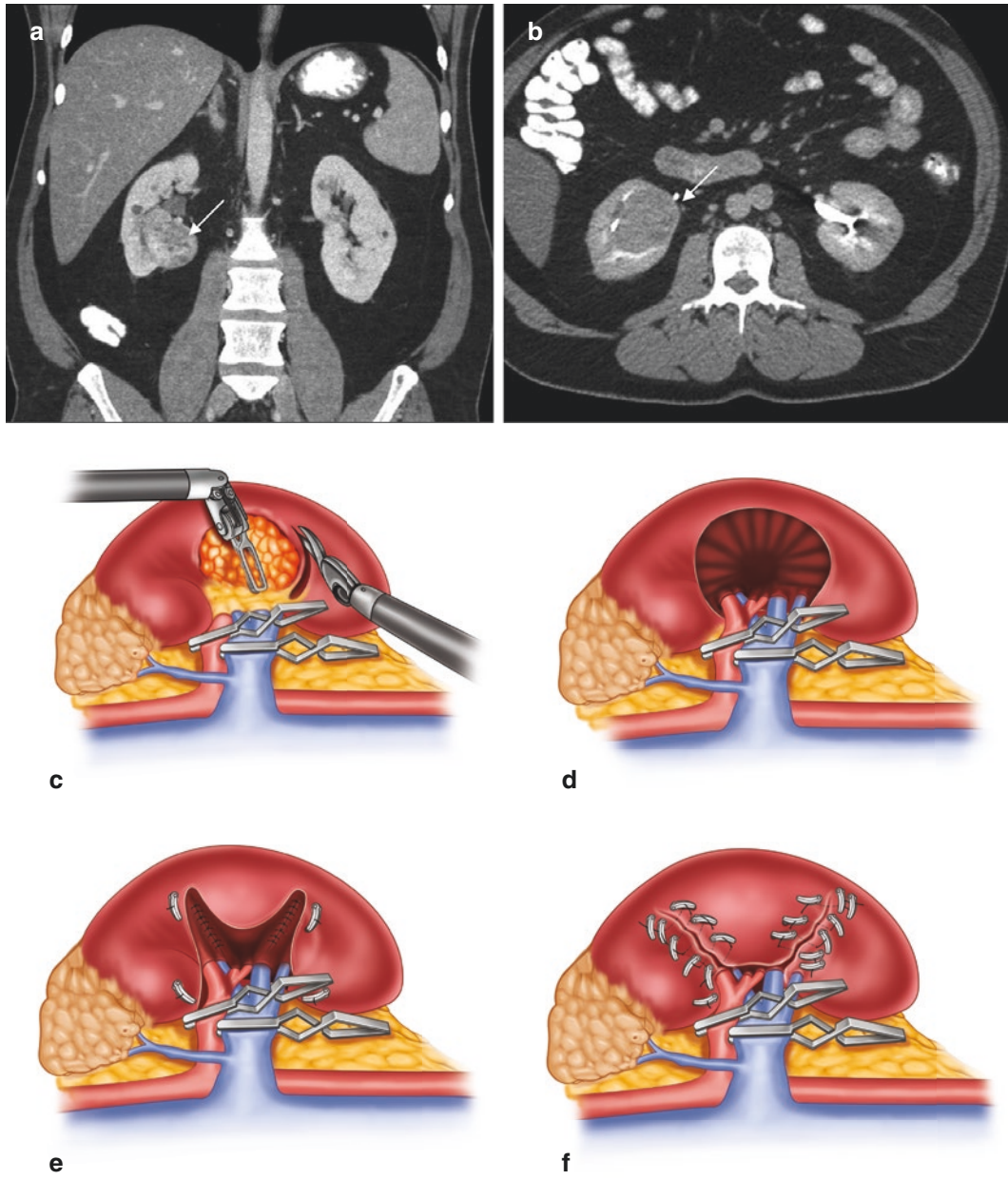

Fig. 41.8 V-stitch renorrhaphy technique (lower panel) for hilar tumors (upper panel, white arrows). Adapted from Urology, 80(2), Ali Khalifeh, Riccardo Autorino, Shahab P. Hillyer, Jihad H. Kaouk, Vhilar Suture Renorrhaphy During Robotic Partial Nephrectomy for Renal Hilar Tumors: Preliminary Outcomes of a Novel Surgical Technique, 466–473, Copyright 2012, with permission from Elsevier

change in estimated glomerular filtration rate between the two groups. Similar results were highlighted in a recent meta-analysis [30] and by Tiu et al. in patients undergoing robotic laparoendoscopic single-site PN, with no increase in the rates of adverse outcomes [31]. Nonetheless, these reports have been confined to centers of excellence with high surgical volume, and it is reasonable to contemplate radical nephrectomy in renal tumors >4 cm that are either likely to be technically challenging or associated with a healthy contralateral kidney.

Renal Tumors in Patients with Pre-existing CKD, Solitary Kidney or Multiple Tumors: Minimizing Ischemia Time

Renal functional (RF) preservation assumes key importance in patients with renal tumors and either pre-existing renal compromise (such as CKD stage 3 [eGFR <60 ml/min/m^2] or greater [12]) or greater likelihood of postoperative RF decline (solitary kidney [32] or multiple tumors). In such a setting, volume preservation and minimizing/attenuating the impact of warm ischemia time are (partially) modifiable, surgeon specific factors to optimize postoperative RF. Figure 41.10 is a schematic representation of factors determining postoperative RF in patients undergoing PN.

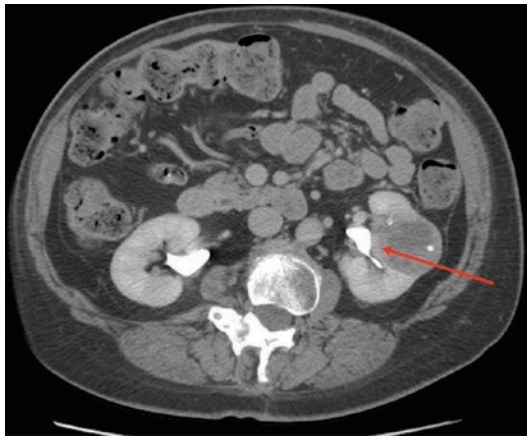

Fig. 41.9 Representative tumor >4 cm with deep extension to the collection system (red arrow)

The definition of the ideal ischemia time threshold during PN is still debated [25, 33, 34]. However, given that duration and type of ischemia are perhaps the only surgeon-specific, directly modifiable risk factors [34], strategies to mitigate the impact and/or duration of warm ischemia have evolved over the last decade [35]. These include "on-demand" ischemia, early unclamping, selective clamping, off-clamp PN, and regional hypothermia.

One approach to decreasing the duration of WIT is "on-demand ischemia": tumor excision is started with cold scissors and the renal pedicle is clamped only when bleeding obscures the surgical

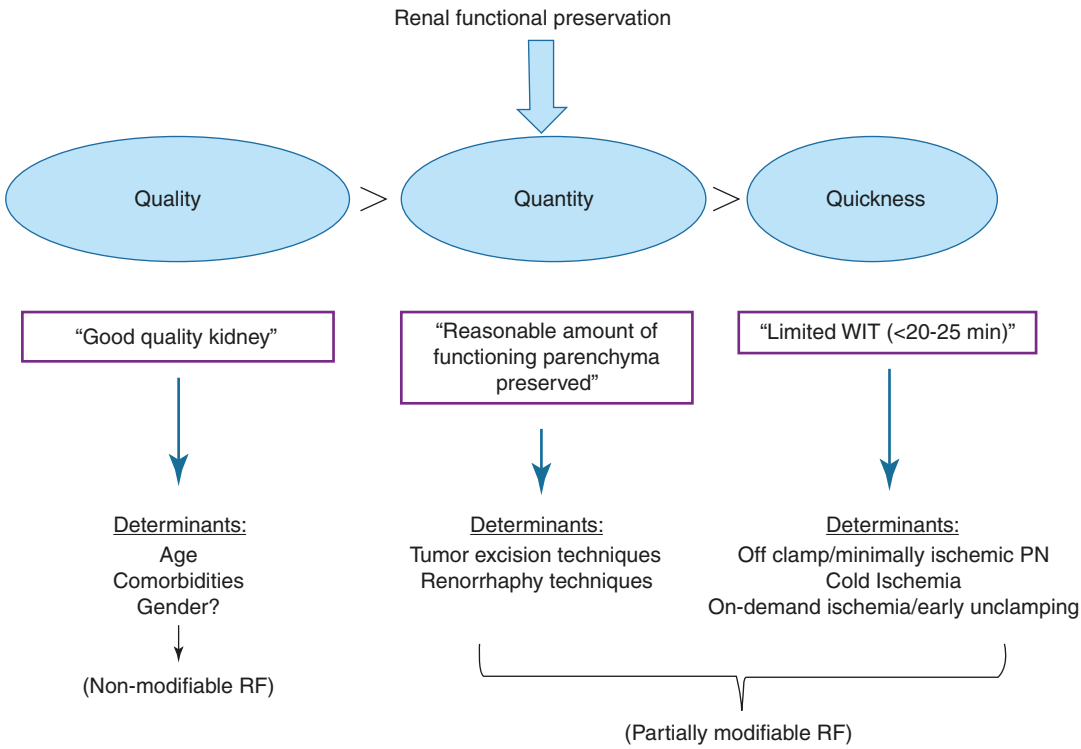

Fig. 41.10 Factors determining renal function in patients undergoing PN. *RF* risk factor, *WIT* warm ischemia time, *PN* partial nephrectomy

field and visualization of tumor [36]. While this approach was initially described for smaller tumors (median size 2.3 cm), it may have utility even for larger tumors that would otherwise necessitate a greater duration of on-clamp resection. Similar to this approach of decreasing global ischemia time, Baumert et al. suggested unclamping of the renal artery immediately following the initial central running suture or inner-layer renorrhaphy ("early" unclamping [37]). The second hemostatic running suture (usually with 2-0 Vicryl) is then performed off-clamp (Fig. 41.11). In case of ongoing bleeding from the tumor bed, additional hemostatic sutures and hemostatic agents may be considered. Peyronnet and colleagues [38] showed that despite larger (mean 3.6 vs. 3.2 cm) and more complex tumors (mean RENAL score 6.9 vs 6.1), patients undergoing early unclamping had shorter WIT (16.7 vs. 22.3 min), higher blood loss (369.5 vs. 240 ml) and no statistically significant difference in transfusion rates. Similar reductions in WIT were noted by other groups (from 31.1 to 13.9 min [39] and 28 to 18.5 min [40]).

Selective clamping of the segmental artery(ies) supplying the tumor (in an effort to spare global renal ischemia) has been demonstrated in OPN [41] and LPN [42] series. After isolation of the renal artery, further dissection is performed to expose multiple segmental renal arteries, and those segmental arteries that appear to supply the tumor are clamped. The region of ischemia (which includes the tumor and surrounding renal parenchyma) can be identified by visual inspection, intraoperative ultrasound with Doppler mode, or near-infrared fluorescence (NIRF) imaging with indocyanine green (ICG) dye (Fig. 41.12). While most tumors <3.5 cm could be resected by clamping one single segmental artery, larger (cT1b) tumors may require clamping of two or three segmental arteries [43] without converting to main renal artery clamping or adversely affecting perioperative complications.

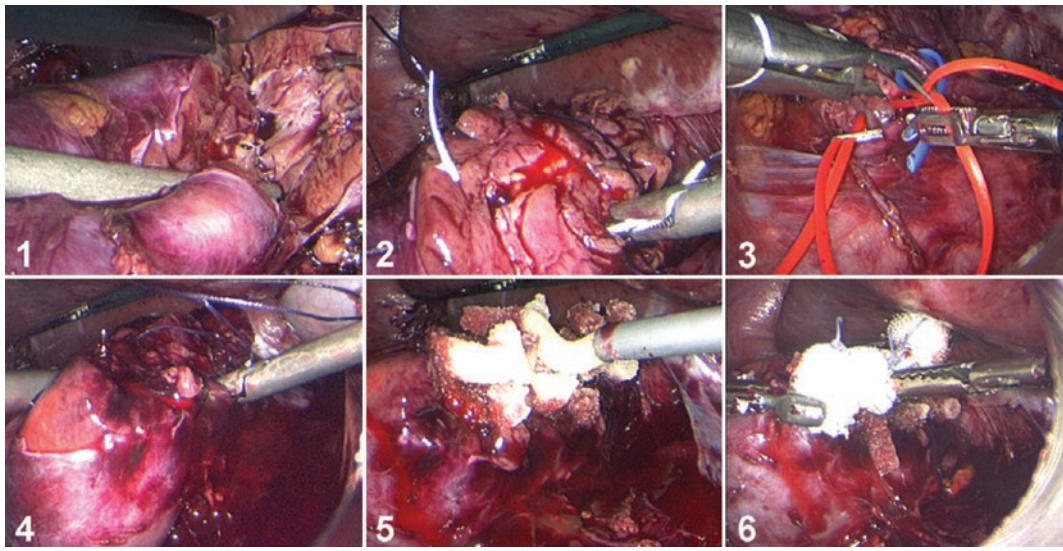

Fig. 41.11 Technique of early unclamping. (1) Upper pole partial nephrectomy, for a 3-cm tumor, using cold scissors. (2) First 2-0 Vicryl running suture to close the collecting system and achieve hemostasis in the same time. (3) Removal of the bulldog clamp, in this case after 10 min of warm ischemia time. (4) Second 2-0 Vicryl runnning suture to improve hemostasis on the vascularized kidney. Note the slight bleeding during this step. In this case, estimated blood loss was 100 cc. If necessary, extra sutures can be applied to visibly bleeding vessels before parenchyma closure. (5) FloSealis applied to improve hemostasis. (6) Closure of the parenchyma over a surgical bolster. Adapted from European Urology, 52(4), Hervé Baumert, Andrew Ballaro, Nimish Shah, Dhouha Mansouri, Nauman Zafar, Vincent Molinié, David Neal, Reducing Warm Ischaemia Time During Laparoscopic Partial Nephrectomy: A Prospective Comparison of Two Renal Closure, 1164–1169, Copyright 2007, with permission from Elsevier

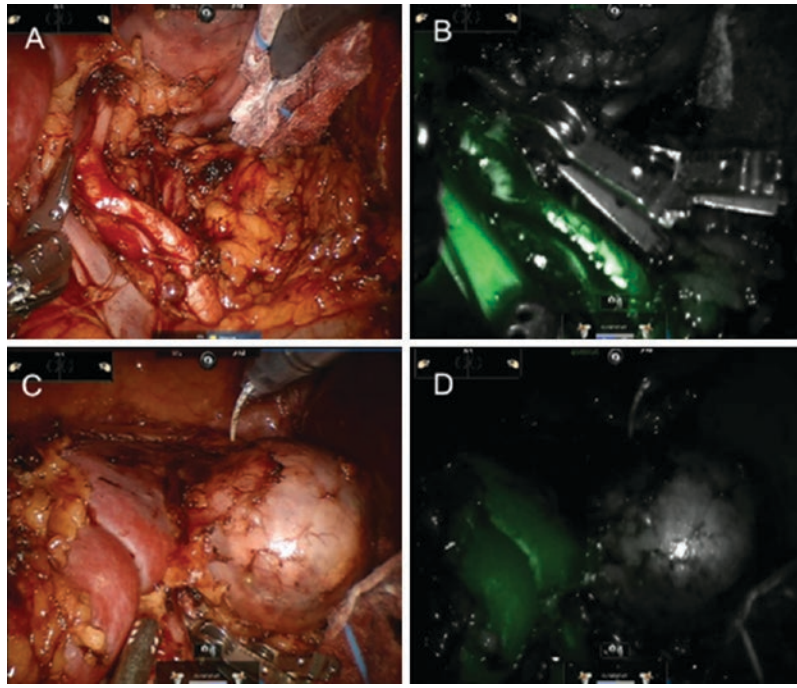

Fig. 41.12 Selective clamping technique using near infrared fluorescence imaging (NIRF) with indocyanine green (ICG) dye. (**a**) Renal hilum exposed to show multiple arterial branches. (**b**) Vascular phase of ICG dye, showing blood flow via multiple vessels (green fluorescence). (**c**) Clamping of the tumor specific arterial branch for cause 'selective ischemia'. (**d**) Parenchymal phase of ICG dye, confirming absence of blood flow to the tumor (hypofluoroscent region) and preserved blood flow to the rest of the kidney (green fluorescence). Reprinted from Current Urology Reports, Near Infrared Fluorescence Imaging with Intraoperative Administration of Indocyanine Green for Robotic Partial Nephrectomy, 16(4), 2015, Marc A. Bjurlin. With permission of Springer

Further refinement of the selective clamp approach resulted in description of the anatomical "zero-ischemia" concept by Gill and colleagues [44, 45]: super-selective clamping of the tumor-specific tertiary or higher-order arterial branches to exclusively devascularize the tumor without compromising perfusion of the surrounding normal parenchyma. The use of selective clamping may be facilitated by NIRF imaging with intraoperative administration of ICG dye [46]. ICG is a water-soluble dye that fluoresces bright green when viewed under near-infrared light (700–1000 nm). ICG binds to albumin when intravenously injected and therefore remains primarily in the vasculature. Following application of bulldog clamps on the secondary, tertiary or quaternary level arterial branches, ICG is administered at a dose of 5–10 mg intravenously (IC-Green, Akorn, Lake Forest, IL, USA). Well-perfused renal parenchyma appears fluorescent green under NIRF imaging, while ischemic tissue and tumor do not (Fig. 41.12), verifying the correct arterial branch has been controlled. The surgeon can toggle between standard white light vision and near-infrared vision on the console view to confirm the plane of excision between tumor and parenchyma, thereby avoiding entry into the tumor.

While off clamp techniques may be a surgical tour-de-force, these techniques require use of advanced preoperative imaging to visualize the arterial anatomy (such as 3-D CT scan, with its higher doses of contrast), are associated with an increased risk of bleeding, and require a technically skilled surgeon and bedside assistant. The beneficial impact of these approaches on estimated GFR has yet to be demonstrated over long term, where volume preservation continues to be a significant prognosticator of outcomes.

Fig. 41.13 Regional hypothermia during robotic partial nephrectomy using application of ice slush over the kidney. (**a**) Modified syringes prefilled with ice slush for cold ischemia. (**b**) Internal view of kidney with ice slush while renal artery is clamped with robotic bulldog clamp. Inset picture demonstrated the external view of injection of the ice slush through the Gelpoint. (**c**) Introduction of ice slush through ice plunger. (**d**) Renal surface temperature (8.8 °C in this figure) can be measured using a temperature probe. Adapted from European Urology, 63(3), Craig G. Rogers, Khurshid R. Ghani, Ramesh K. Kumar, Wooju Jeong, Mani Menon, Robotic Partial Nephrectomy with Cold Ischemia and Onclamp Tumor Extraction: Recapitulating the Open Approach, 573–578, Copyright 2013, with permission from Elsevier

Finally, a number of studies have suggested techniques for intracorporeal (regional) hypothermia to cool the kidney, in an effort to alter the oxygen demand-supply ratio [16, 47–50]. Lane et al. showed that patients with median WIT of 22 min had comparable decline in GFR 3 months after surgery to those with cold ischemia time of 45 min [34], suggesting the potential mitigating impact of the latter technique in patient with complex tumors and longer durations of expected WIT. At our center, we evolved a technique for intra-corporeal cooling and extraction (ICE) [16]: following hilar clamping, ice slush was introduced through the GelPoint™ (via modified Toomey syringes, rigid sigmoidoscopes or dedicated ice plungers) and applied all over the kidney surface (Fig. 41.13), with mean cold ischemia time of 19.6 min. This allowed renal parenchymal temperatures <16 degrees C without significantly affecting the core body temperature. Importantly, the median RENAL score in this series was 8, suggesting tumors of significant complexity may be amenable to ice slush cooling. Additionally, this approach allows immediate extraction of the excised tumor through the GelPoint, allowing gross margin assessment by pathology during the renorrhaphy.

Renal Tumors in Patients with Abdominal Surgery

Patients with extensive abdominal surgery may pose a challenge due to high risk of intra-abdominal adhesions and injury to abdominal structures during transperitoneal PN. One option in such cases is utilization of retroperitoneal approach, the technique for which has been described elsewhere in the book.

Conclusions

RAPN for complex tumors is feasible, however more challenging and associated with a greater risk of complications. Good judgement is needed to determine which surgical approach will optimize the goals of trifecta achievement.

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Retroperitoneal Approach for Robotic Renal Surgery

42

Wooju Jeong, Craig R. Rogers, and Mani Menon

Abstract

We describe key points of the retroperitoneal approach for renal surgery: patient positioning, retroperitoneal space access, port placement, robot docking and surgical landmarks.

The patient is placed in full flank position. An incision is made at the posterior triangle. Retroperitoneal space is created using a kidney-shaped balloon dilator. The robotic instrument ports followed by assistant port are placed in a wide trianglular configuration. The fourth robotic arm can be used per surgeon preference. The patient cart of da Vinci Si is docked from the patient head parallel to the table. In contrast, the patient cart of da Vinci Xi is docked from the patient feet. After the dissection of the renal hilum, the para-renal and peri-renal fat is removed and this is another important step to secure operation space.

These important tips enhance repetitive success to set up and perform retroperitoneal renal surgery.

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Keywords

Retroperitoneal approach · Renal surgery · Nephrectomy · Robotic surgery · Renal mass

Introduction

The conventional approach for renal surgery has been an open approach through the abdominal cavity or retroperitoneal space. According to a randomized study for radical nephrectomy versus nephron sparing surgery, about 39% of the renal surgeries were approached through the retroperitoneal space [1]. Although the utilization of minimally invasive technique has been increasing until recently, but still less utilized than open technique [2]. Retroperitoneal approach for minimally invasive renal surgery was first described in 1993 [3]. However, retroperitoneal renal surgery is less utilized than transperitoneal approach, and applied on selected cases. In the series of retroperitoneal partial nephrectomy, more than 80% of the cases were performed for posterior renal mass [4]. Possible reasons for under-utilization of retroperitoneal approach may be the limited operation space and lack of surgical landmarks [5]. Transperitoneal access to posterior renal tumors require bowel mobilization and full kidney mobilization to flip the kidney medially in transperitoneal approach.

We describe step-by-step and important tips on patient positioning, port placements, as well

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as retroperitoneal space access and distinguish retroperitoneal landmarks.

Patient Positioning

The patient is placed in the full flank position and stabilized using two rolled blankets or low-profile supports to support either side of the patient, and secured well using padding under the knee and the ankle and a axillary bar (Fig. 42.1). The table is fully flexed to maximize the space between the ribs and iliac crest. Care should be taken to ensure to place the hip below the break of the table, to enhance the access to the space. This step maximizes the retroperitoneal access and the exposure of the whole abdomen from the midline of the back and abdomen, allowing for conversion to a transperitoneal approach or open surgery. The dependent arm is padded and secured to an armboard, and the other arm is placed on the dependent arm. Pillows or blankets are placed in between the arms and then secured together with tape, followed by tilting the arms toward head as much as possible, so that minimize collisions between the patient's arms and robotic arms. Tape is placed across the chest, the hip and the knees, followed by securing the patient with straps. A body-warming device may be placed on the upper body.

The patient cart can be docked straight over the patient's head (Fig. 42.2). To enhance docking the patient cart, the table is rotated toward patient back side, so that the patient's face always faces the anesthesia machine. Often extension of aeration tube and vascular access may need before rotating the table. The bed-side assistant stands on the abdomen side.

Retroperitoneal Space Access (Fig. 42.3)

Prior to port placement, the iliac crest, costal margin and axillary lines are identified and marked. One of important landmarks to place the camera port is the posterior triangle, called the triangle of Petit, composed of the iliac crest inferiorly, latissimus dorse posteriorly and external oblique muscle anteriorly. Lower camera port would provide better access for the dissection of the lower pole of the kidney. However, if the camera port is too close to the iliac crest, the range of motion of the camera may be limited by the iliac crest. In case of obese patient, the landmarks are difficult to be identified and the

Fig. 42.1 Positioning. The patient is placed in full flank position with securing pads on the pressure points

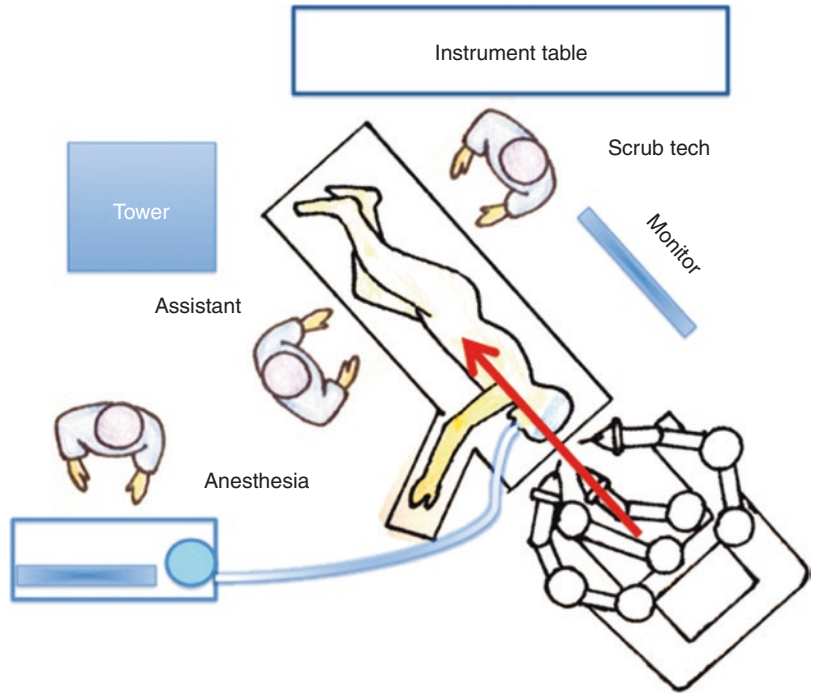

Fig. 42.2 OR setup. The table is rotating 90–135° toward the patient's back. The robot is docking over the patient head parallel to the spine

Fig. 42.3 Stand setup for retroperitoneal access

subcutaneous fat should be considered to identify the actual iliac crest as well as the distance from the costal margin should be checked.

The camera port is made about a fingerbreadth from the iliac crest. About a fingerbreadth of incision starting the superior point of the Posterior Triangle toward the anterior abdominal wall. Using small retractors, the subcutaneous fat is split to expose the external oblique fascia. Once a small incision is made on the fascia, a Kelly forceps is used to penetrate the oblique muscles and transversalis muscle and their fascias, to access into the retroperitoneal space, followed by splitting the muscles using the Kelly forceps. One of important tips is to keep the angle of the tip of Kelly forceps perpendicular to the muscular layers to get into the retroperitoneal space. The index finger can be inserted into the space to identify the psoas muscle. The finger dissection should be gentle and may cause a tear of the peritoneum. A kidney-shaped balloon dissector (OMSPDBS2, Kidney Distension Balloon, Covidien, Mansfield, MA, USA) is then placed into the retroperitoneal space perpendicularly. The insufflation channels of the trocar will face anteriorly, so that the balloon expands in a cephalo-caudal orientation, along the psoas muscle. A 30° 10-mm laparoscope can be inserted in the balloon dissector, to inspect the retroperitoneal space and structures created by expanding the balloon under direct vision. Generally 40–50 compressions of pump are performed. If indicated, 10–20 more compressions can be added slowly. The slow compressions often provide gentle and sustaining force to sweeping the peritoneum. Landmarks are anteriorly the transversus abdominis muscle and the peritoneal fold,

posteriorly, the psoas muscle, and medially, the gonadal vein and the ureter. The lower pole of the kidney within the Gerota's fascia can also be identified. The degree to which the peritoneum has been dissected off the anterior abdomen is noted for subsequent placement of ports. The balloon dissector is deflated and removed.

Port Placement

The position of the camera port within the retroperitoneal space is crucial, as all other port placements are based on this. The configuration of the three robotic arms is wide inverted triangle. Two robotic ports are placed about a centimeter superior to the camera port. In case the dissection of the upper pole is indicated, two robotic ports are shifting to cephalad, about a fingerbreadth superior to the camera port. Prior to place the camera port, the posterior robotic arm is placed under finger guidance. The index finger is inserted through the camera port and placed on the lateral border of the psoas muscle. The posterior robotic port is placed as far as possible from the camera port. A robotic port with blunt obturator is inserted toward the index finger, medial to the psoas muscle, to avoid psoas muscle injury. After placing the posterior robotic port, the camera port is inserted. A long (130 mm) port with balloon (Kii Balloon Blunt Tip System, Applied Medical, Rancho Santa Margarita, CA, USA) is preferred as a camera port, to prevent arm conflict and port expulsion. It is attached to CO_2 to maintain pneumo-retroperitoneum at 15 mmHg. The 30° 10-mm laparoscopic camera is useful to medial robotic ports. A laparoscopic Kittner through the posterior robotic port is used to gently sweep away peritoneum. For the port placement for three robotic arms, further dissection of the peritoneal fold may not be needed. If fourth arm is placed, the peritoneum needs to be dissected to the aponeurosis of the transversalis muscle. A Veress needle can be used to confirm the extend of the peritoneal dissection before the port is placed. All ports should be placed with at least 6-cm space between them. The medial robotic ports are placed under direct vision. The 12 mm

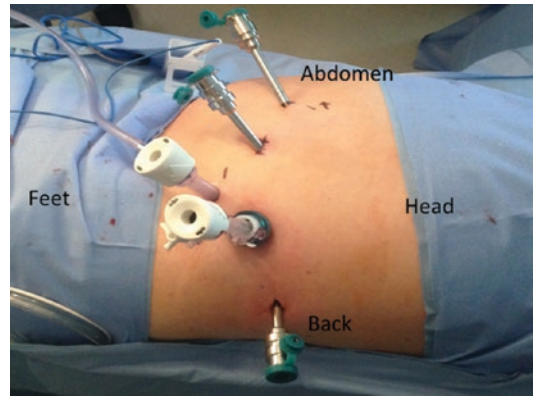

Fig. 42.4 Port configuration

assistant port is placed between the camera and medial robotic port, inferior to the camera port, and above the anterior superior iliac spine. Use of lower pressures is possible when using valveless pressure barrier insufflators (Airseal®, SurgiQuest Inc., Milford, CT, USA). The fourth robotic arm can be placed medial to the medial robotic port (Fig. 42.4). The advantage of the fourth arm is that the kidney can be elevated using a ProGrasp™, thus freeing both working robotic instruments. A fourth arm can also be especially useful in cases where perinephric fat is abundant. If there is a peritoneal breach, the fourth arm can help maintain the retroperitoneal space even with peritoneal insufflation.

Docking

The robot is docked directly over the patient's head parallel to the spine (see Fig. 42.2). The room layout has to accommodate this docking configuration; it is important the anesthesiologist has access to the airway and is comfortable with the patient position and equipment layout. The operation table is often rotated 90–130° toward the patient back, so that the patient's airway is facing to the anesthesiologist. The drapes will often interfere with the docking, and the drapes must be allowed to drop freely. The patient's face side of the drape can be held on the stand after the patient cart is docked. In particular, the patient-side cart is positioned so that the camera arm is

within the far outer part of the sweet spot. This permits greater range of motion of the camera and robotic instruments inferiorly within the retroperitonuem.

We prefer a 0° robotic scope for the rest of the operation, although it is also possible to use a 30° scope.

Operative Landmarks

Once docked, the robotic instruments are inserted (right arm, monopolar scissors; left arm, fenestrated bipolar grasper), and the assistant assesses access to the kidney via the 12-mm port.

One of important steps is to manage the paranephric and peri-nephric fat, to secure enough space for the surgical procedure. This is carefully dissected off the Gerota's fascia. Care is taken medially and anteriorly where the peritoneum can be entered.

The excised fat is placed in the lower retroperitoneum. Next, Gerota's fascia is incised just above the psoas muscle exposing the perinephric fat and kidney. For this, an incision is made parallel to the psoas muscle 2 cm above the psoas tendon (Fig. 42.5a).

Dissection is then carried along the psoas muscle elevating the kidney and perinephric fat. The ureter or gonadal vein can be used as a landmark to identify the renal hilum. Once the hilar vessels are identified, a vessel loop can be place around the renal artery to enhance quick access to the renal artery in case of urgent hilar control (Fig. 42.5b).

The dissection between Gerota's fascia and the peri-nephric fat is carried to the anterior surface of perinephric fat (Fig. 42.5c). A safe spot on the peri-nephric fat is dissected to expose the renal surface, and the dissected perinephric fat is removed to secure the surgical space (Fig. 42.5d).

The rest of the operation follows standard steps of RPN [6]. At the end, the specimen is retrieved through the camera port.

Specific Considerations

da Vinci Xi Surgical System

The Xi system has better range of motion of the robotic arms and uses 8-mm robotic camera which can be inserted through any of 8 mm robotic ports. The Robotic arms are attached to the boom, and all four robotic arms can be rotated at any direction.

The patient cart of the Xi system can be docked from any directions of the patient, and turn the boom to place the robotic arms toward the patient head. The patient cart can be docked from the patient feet to secure the more working space and better access to the monitors for the assistant.

The configuration of the robotic port is similar to the old generation surgical system. However, since the range of motion of Xi is wider than old

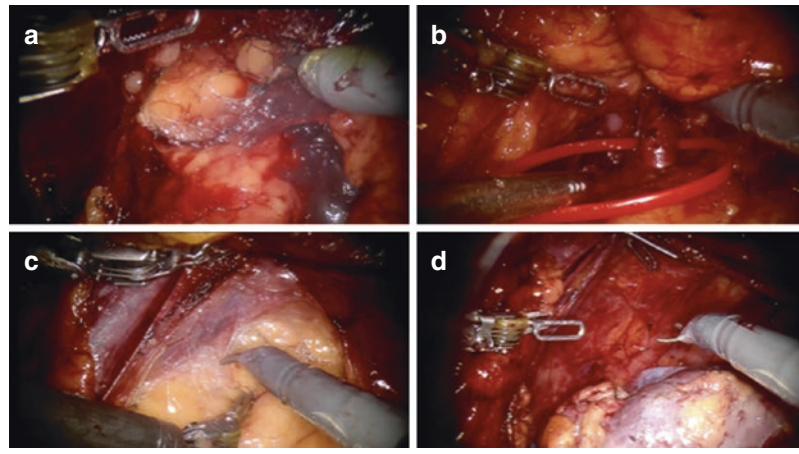

Fig. 42.5 Important landmarks. (**a**) An incision on the Gerota's fascia to access the renal hilum; (**b**) the renal hilum is dissected and a vessel loop is placed around the renal artery; (**c**) the dissection between the Gerota's fascia and peri-nephric fat; (**d**) the secured surgical space after defatting of peri-nephric fat

generation, the shifts of robotic ports to the cephalad is not critical. One of important tips is to set up enough gaps between robotic arms on the boom, to minimize collisions between robotic arms and to maximize the range of motions of robotic arms. Fourth arm robotic port can be put in between the camera and medial robotic port, to secure enough working space for the assistant port.

For the camera port, hybrid technique, which is to place 8 mm robotic/camera port through 12-mm port, is not advisable. Instead, Mini GelPOINT® (Applied Medical Resources Corp, Rancho Santa Margarita, CA, USA) can be used for the camera port site, so that the pneumoperitoneum can be maintained while 8 mm robotic port is placed through the Gelcap. Alternatively, 8 mm robotic port can be put through the camera port site, and a purse string can be placed around the robotic port. In such case, Airseal® system can be maintaining the pneumatic pressure, from possible CO_2 leak from the camera port.

Intracoporeal Cooling and Extraction (ICE) Technique

As Rogers et al. introduced in 2013 [7], ICE technique can be used in retroperitoneal approach. The GelPOINT® (Applied Medical Resources Corp, Rancho Santa Margarita, CA, USA) can be placed on the camera incision after retroperitoneal space creation, or on the assistant port site. The detail surgical step is described in ICE robotic partial nephrectomy paper. Introduced ice slush can be handled and packed around the kidney easier in retroperitoneal approach than the other approach.

Conclusions

The patient is placed in full flank position with secured padding on the pressure point. The landmarks for port placement are carefully marked, such as the costal margin or the ribs, iliac crest and the Triangle of Petite. An incision is made at the point of the Triangle of Petite. The anble of the tip of Kelly forceps should be kept perpendicular to the muscular layer. Retroperitoneal space is created using Kidney shape balloon dilator. The posterior robotic port is placed, followed by inserting a balloon trocar for robotic camera. The anterior robotic instrument port followed by 12 mm assistant port is placed in inverted, wide trianglular configuration. The utilization and port configuration of fourth robotic arm can be determined by surgeon's perference or the generation of the roboic surgical system. The patient cart is docked from the patient head parallel to the table in Si robotic system or from the patient feet in Xi system. With this approach, the access renal hilum is direct and quick. After the dissection of the renal hilum, the para-renal and peri-renal fat is removed and this is another important step to secure operation space. When Xi robotic system is used, specific consideration is required to place 8 mm robotic port through the bigger incision at the camera port site. GelPOINT® can be used for ICE technique.

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Technical and Technological Advances in Robotic Partial Nephrectomy

43

Manish N. Patel, Ram A. Pathak, and Ashok K. Hemal

Abstract

Robotic parital nephrectomy is an ever-changing field with new technologies and techniques being introduced constantly. The goal of all these advances is to achieve the trifecta, meaning no complications, negative margins and minimal decrease in renal function postoperatively. In this chapter, we discuss many of the new techniques and technologies helping urologists achieve the idea of the trifecta for partial nephrectomy.

Keywords

Robot-assisted · Renal cell carcinoma · Partial nephrectomy · Kidney cancer · Indocyanine green · TilePro · Intraoperative ultrasound · Integrated table motion

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Introduction

In 2017, the AUA guidelines for localized renal cancer were updated. Three important differences are noteworthy. First, no longer are 'index patients' utilized. Rather, the panel highlights individualized counseling for patients with renal masses. Second, there is an increased emphasis on functional outcomes, with the panel recognizing that many patients with localized kidney cancer do not succumb to their disease. Lastly, stricter, more restricted, criteria for radical nephrectomy and tumor ablation were instituted. These differences espouse an even greater and more expanded role for partial nephrectomy. In fact, for clinical T1a masses, partial nephrectomy has a primary role in the management of such patients [1]. Thus, it is becoming increasingly important for urologists to be familiar with the technical nuances of nephron sparing surgery [2]. As this technology has been adapted in many high-volume institutions, several techniques and technologies have been implemented to provide improved outcomes; the nomenclature to ensure obtaining these goals is also evolving.

The 'trifecta' is an established gambling term for describing prediction of the exact order of the first three horses finishing a race. This terminology has been adapted to describe outcomes of patients undergoing RPN. Initially described by the University of Southern California Group, the trifecta in RPN includes negative margins, no

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urologic complications, and a minimal decrease in renal function postoperatively. They found a trend toward an increased rate of trifecta with their most recent patients; however, the range of patients achieving this outcome was between 44% and 68% [3]. Early reports of trifecta outcomes demonstrate that using the robotic platform seems to improve the likelihood of obtaining these. Khalifeh and colleagues [4] note that RPN is much more likely to produce trifecta outcomes than a strict laparoscopic approach with an increase from 32% to 59% of patients. Recently, the concept of 'pentafecta' has been introduced combining early and late functional outcomes such as postoperative GFR and chronic kidney disease stage [5] with improved functional outcomes published [6]. In this chapter, we highlight many emerging techniques and technologies and their role in improving patient outcomes for RPN.

Preoperative Technologies to Help Surgical Decision Making

With only 80% of small renal masses identified on computerized tomography being malignant lesions, identifying the appropriate patients to undergo surgical procedures would minimize undue morbidity. Although it was initially reported that there was a poor concordance between renal mass biopsy and final pathology, recent reports have demonstrated improved diagnostic accuracy of the renal biopsy in establishing a pathologic diagnosis. An agreement between biopsy and final pathology was 92% in a recent publication by Halverson and colleagues [7], and this was associated with 100% positive predictive values for a treatment algorithm based on the biopsy.

Preoperative imaging is critical to surgical planning during partial nephrectomy. Standard staging for renal cell carcinoma involves axial imaging of the abdomen and chest X-ray. Use of three-dimensional reconstructions (Fig. 43.1) can help to decrease some of the ambiguity see on conventional imaging. With a three dimensional reconstruction, the radiologist can help the surgeon visualize specific relationships between critical structures to help with approach to the tumor as well as prove information about the ability to perform advanced clamping techniques to decrease warm ischemia.

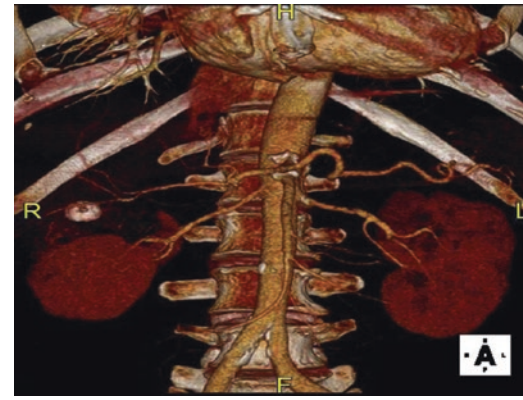

Fig. 43.1 Three-dimensional reconstruction of a CT scan demonstrating the exact location of the tumor and feeding vessels to aid in possible selective clamping

Further advances in imaging has led to the construction of various morphometry scores including the RENAL nephrometry score, PADUA prediction score, and the centrality index (C-index) that focus on tumor characteristics. Unfortunately, these scoring systems fail to account for patient-specific factors that may complicate partial nephrectomy such as adherent perinephric fat (APF). In response to this need, the Mayo Adhesive Probability (MAP) Score was developed which can be used to predict the presence of APF [8] and thus, the degree of difficulty during partial nephrectomy [9]. Moreover, higher MAP scores have been associated with decreased progression-free survival (PFS) in patients undergoing partial nephrectomy, another critical preoperative tool that can be used when counseling patients [10].

Minimizing Warm Ischemia

The role of minimizing ischemic time during tumor excision has been an evolving process. Historically, a maximum of 30 min of warm ischemia time was the goal, although data supporting

this time point are poorly substantiated [11]. There is some clinical evidence in a porcine model that clamping times up to 90 min can be safe [12]. In humans, renal clamping with up to 55 min of ischemia seem to have minimal long-term functional loss [13]. Smith et al. [14] reported zero ischemia or unclamped procedures in open partial nephrectomy.

Gill and colleagues [15] pioneered these techniques in minimally invasive surgery, although this initially required a complicated coordinated effort with the anesthesiologists involving pulmonary artery monitoring and transesophageal echocardiography with which they were able to create hypotension that corresponded to resection of the deepest part of the tumor. In this early cohort of patients, Dr. Gill found no change in serum creatinine or estimated glomerular filtration rate (eGFR) at the time of discharge. Subsequent descriptions of zero ischemia did not include the invasive monitoring or temporal hypotension. Rizkala and colleagues [16] have used a preplaced suture that is used during an unclamped procedure when bleeding is encountered. Novak and colleagues [17] have noted that, in 22 patients without hilar clamping, there was only one transfusion and most patients were stable for discharge on postoperative day 1. Krane and colleagues [18] performed an unclamped RPN and compared outcomes with clamped procedures and did not note any increase in perioperative morbidity.

Techniques for surgical excision with selective versus global ischemia have also been described. Using the high 10× magnification of the daVinci surgical system (Intuitive Surigal Inc., Sunnyvale, CA), there is an ability to perform tumor-specific devascularization without global ischemia to the kidney. In a recent multi-institutional analysis, Desai et al. note that in patients undergoing selective devascularization, the percentage decrease in the estimated decrease in glomerular filtration rate was 17% for the global ischemia group versus 11% in the selective devascularization. They did find a increase in transfusion rate (24% vs 6%) and operative duration (71 min) for the super selective clamping, and also noted similar renal parenchymal preservation between the two groups [19].

Whether or not short-duration ischemia truly impacts renal function postoperatively has been the subject of intense debate. Recent publications have highlighted that the most important determinant of long-term renal function is volume preservation. Krane et al. assessed unclamped partial nephrectomies in a nonrandomized fashion. They did not find a statistically significant difference in the long-term follow-up for unclamped versus clamped (either with artery and vein or simply the artery) procedures [18]. No randomized trials have been created to assess the long-term renal functional data or oncologic outcomes in order to assess the overall superiority or inferiority of an unclamped or selective devascularization procedure compared with the clamping technique. To improve perioperative renal function, other adjuncts have been used. Rogers and colleagues [20] have described intraoperative cold ischemia. Using a gel-port, they were successful in placing ice slush directly on the kidney during hilar clamping and tumor excision. An added benefit of this technique is the ability to remove the tumor very quickly through this port, allowing for immediate pathologic analysis with margin assessment. Olweny and colleagues [21] have adopted the use of hyperspectral light imaging to assess renal oxygenation during RPN. They found that baseline renal hemoglobin oxygenation was inversely associated with preoperative eGFR and eGFR at the most recent follow-up, opening the door for more exploratory studies with this technology.

Use of Indocyanine Green to Delineate Renal Vasculature and Decrease Positive Margin Rate

Indocyanine green (ICG) dye is a well-described adjunct to surgical procedures, having been usedin hepatic and ophthalmologic surgeries extensively. The incorporation of a near-infrared fluorescent camera on the daVinci Si robotic platform has allowed this technology to be introduced into minimally invasive urologic

oncology. ICG is a water-soluble dye, which is highly protein bound following intravascular injection. When bound to protein, it is almost completely restricted to the intravascular space. Additionally, ICG is hepatically cleared; it poses no threat to renal functional outcomes and it is not restricted in patients with renal insufficiency.

The intravascular distribution of the ICG makes it an ideal molecule for selective arterial clamping. Following injection of the dye, within seconds, the kidney is hyperfluorescent with intravascular ICG. Therefore, injection following selective or superselective clamping of the tertiary or quaternary arteries demonstrates perfusion to the remainder of the kidney but not the areas supplied by the clamped artery. This practice ensures only regional rather than global ischemia. Borofsky and colleagues [22] performed a multi-institutional retrospective analysis of this procedure and described the feasibility of this. In addition, they noted that in match-paired analysis comparing ICG with selective clamping to patients with global ischemia, there were significantly improved short-term renal functional outcomes with a decrease of 1.8% of GFR with ICG versus 14.9% without ICG and selective clamping. Harke and colleagues [23] have performed a similar matched-pair analysis with 22 patients undergoing selective arterial clamping and, once again, found a short-term decrease in eGFR to be statistically significantly less following ICG injection and selective clamping.

Bilitranslocase is a transporter molecule located on the proximal tubule, and it has been reported to be downregulated in small renal masses. Following injection of the ICG, these masses appear hypofluorescent when compared with the normal renal parenchyma. An image of a clear cell renal carcinoma before and after ICG administration is seen in Fig. 43.2. The reliability of this downregulation and the ability for ICG to routinely identify malignancy has been called into question. In their retrospective analysis of 100 consecutive cases with ICG administration, Manny and colleagues [24] found that, in hypofluorescent masses, the sensitivity was only 84% and the specificity was just 57%.

ICG has proven to be a useful surgical adjunct to the RPN, but the true utility in terms of patient outcomes is still debated. In 94 patients, Krane and colleagues [25] performed the largest comparative study of ICG in a nonrandomized retrospective analysis. There was a statistically significant improvement in warm ischemia time from 17 to 15 min, but the clinical utility of this is debatable as the margin rate and complications

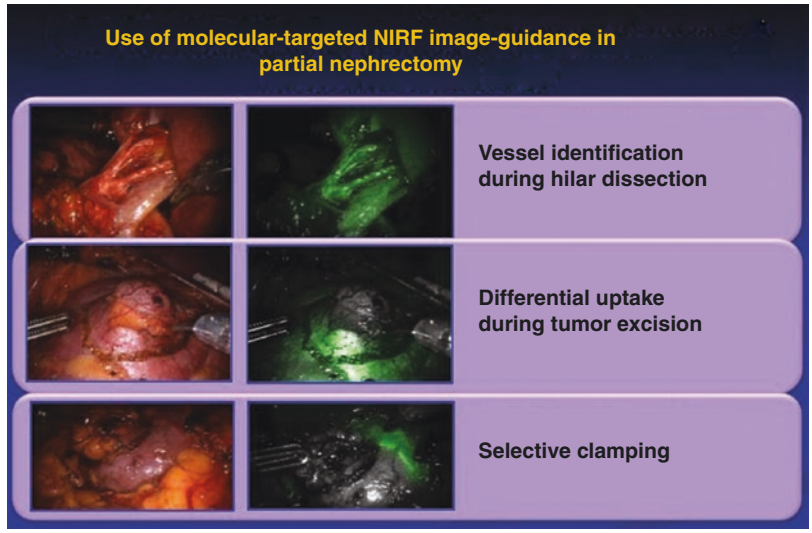

Fig. 43.2 Demonstration of the multiple applications of indocyanine green administration during robotic partial nephrectomy

were similar in both cohorts. ICG is clearly an emerging technology in RPN, but how this technology will fit into improving specific patient outcomes has not been fully identified.

Single Port and Laparoendoscopic Single Site Surgery (LESS) RPN

The utility of the robotic format for adapting single site surgery has been adopted by multiple groups. Single-site laproendoscopic surgery has been advocated because of the improved cosmesis and potential for earlier return to normal daily activities. In this technique, however, there is an increased risk for collision of the robotic arms; often retraction is compromised because of the lack of a fourth arm. Pneumoperitoneal leakage is also reported. The initial studies for applying LESS to RPN were successfully demonstrated by the Cleveland Clinic team [26]. Thereafter, adoption of this into a robotic platform has been reported by several centers. Tiu and colleagues [27] described robotic single-site surgery in 67 consecutive patients. In their analysis, which compared 20 patients with renal masses greater than 4 cm to 47 with smaller masses, they found no difference in the risk of perioperative complications or positive surgical margin. However, in a retrospective study, they did find that in these larger mass tumors, the single-site RPN does not alter changes in postoperative renal function between the two tumor size groups; but they did have a slight increase in warm ischemia time for the larger masses. They describe their intermediate term outcomes for Robotic-LESS surgery and noted that at a minimum of a 2-year follow-up, there was no statistically significant change in eGFR and also that there was only one positive surgical margin in their cohort of 39 patients.

In a multi-institutional retrospective analysis of patients undergoing conventional RPN versus single-incision RPN, Komninos and colleagues [28] found that the likelihood of obtaining a trifecta outcome was significantly less likely in the single site RPN, with only 25.6% of single site versus 42.7% of conventional robotic nephrectomy patients obtaining this result. In this study, the authors report that, in patients who had a single-site incision, there was a statistically significant increase in operative time (25 min), 6 more minutes of warm ischemia time, and a 7% larger decrease in long term eGFR when compared with conventional RPN. As with other advances and emerging techniques for RPN, the utility of this approach in affecting patient outcomes has not been fully described. Additionally, none of these studies have been conducted with the newest version of the daVinci Xi. As the robotic technologies continue to evolve, the safety and efficacy of single-site RPN will need to be constantly updated to ensure surgeons continue to hold themselves to the high standards previously established.

Intraoperative Ultrasound and TilePro

Intraoperative ultrasound is a critical adjunct to provide information concerning renal tumor anatomy, depth of penetration into the parenchyma, vascular anatomy, and the relationship of the pelvicaliceal system on the robotic console using the Tile-Pro integrated software (Fig. 43.3). Ultrasound guidance is helpful in identifying the tumor margin, which is then scored at the capsule around the tumor prior to resection.

The ultrasound also allows the surgeon assess quality of tissue surrounding the renal mass, viewing the real time images within the surgical console [29]. The development of the ProArt drop-in robotic ultrasound probe has provided new technology for the surgeon to use during RPN. The wristed instruments associated with the robotic platform have rendered the drop-in robotic probe more useful in providing surgeon autonomy [30, 31].

This autonomy prevents instrument clashes between the surgeon and bedside assistant. Further evaluations of the role of intraoperative ultrasound for RPN have demonstrated many potential uses. In the first description of using

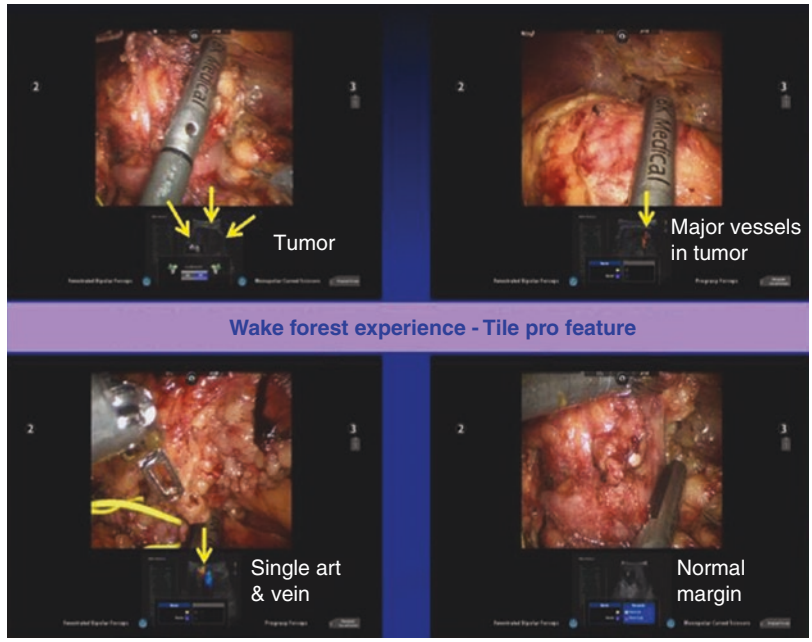

Fig. 43.3 Demonstration of the use of the TilePro feature and use of live intraoperative ultrasound during robotic partial nephrectomy

contrast-enhanced ultrasound, Rao and collaborators [32] used this technology to assess the feasibility of selective arterial clamping. Using SonoVue, they were able to assess the success of selective arterial clamping, document the lack of perfusion in the renal mass at the time of excision, and avoid global ischemia during tumor excision.

Reconstruction of the Renal Defect

Initial reports of renorraphy were described using a sliding Weck clip (Teleflex, Research Triangle Park, NC) technique, which allowed for bolstering of the defect with the use of rolled Surgicel (Ethicon, Somerville, NJ) bolsters [33]. The LapraTy (Ethicon) absorbable clip helped in the performance of renorraphy [34]. The initial use of the Surgicel bolster technique in the closure of parenchymal defects has evolved and is no longer used. Kaouk and colleagues, [35] in the series of 252 RPNs, reported minimal bolster usage and continue to have no change in outcomes. By no longer using plastic nonabsorbable clips, the authors have been able to prevent clip migration following the dissolution of the absorbable suture. Clip migration has been associated with the development of nephrolithiasis [36] and bowel migration in several reports [37]. In addition, nonabsorbable clips could produce imaging characteristics that could produce difficult radiologic interpretations [38].

Cohen and colleagues [39] have evaluated the use of fibrin sealants in perioperative outcomes. In this study, they did not find any adverse or advantageous effects of sealants and, therefore, recommended against their routine use. Surgicel placement could produce imaging abnormalities, including the appearance of a gas-containing infection in the authors' experience. In addition, it can induce granuloma formation or other toxicities [40].

At Wake Forest, our current technique of reconstruction of renal defects involves a 3-layer closure. Following cold tumor excision with scissors, the base of the parenchymal defect and any entry into the pelvicaliceal system is closed using a running 3-0 poliglecaprone 25 suture on a small half circle needle. This practice serves the purpose of oversewing any open vessels, or running a suture at the base takes care of all bleeders at the base that were feeding the excised tumor; this is the most important suture in this repair. It also

allows for approximating the pelvicaliceal system, which prevents urinary leakage and urinoma.

If there are large feeding vessels and major caliceal infundibulum, it can also be clipped with laproclip (Covidien, Dublin, Ireland), which is an absorbable clip. When there is a large tumor base, it is advisable to sew vessels separately from pelvicaliceal system. The renal parenchymal defect is then brought together using additional poliglecaprone suture or barbed suture (V-Loc, Covidien, Dublin, Ireland). Then the renal parenchyma is approximated with a 0 poliglecaprone suture on a CT-1 needle. The sliding Laproclips are used to support the parenchymal closure on opposing ends. The repair is cinched to approximate the ends to eliminate dead space but is not done so tightly to compress the parenchyma.

The final layer is a re-approximation of perirenal and Gerota's fascia covering the repaired kidney defect, preferably with barbed suture. In some case when complete mobilization of the kidney is undertaken, especially in thin patients, the kidney is 'pexied' to ensure anatomic replacement of the kidney. Hemostatic agents and surgical bolsters are used only sparingly. Ureteral catheterization is avoided in almost all cases.

Augmented Reality in Robotic Partial Nephrectomy

Using augmented reality, one can overcome the loss of haptic feedback in robotic surgery by using preoperative imaging to superimpose onto the surgical field of view. This technique provides the surgeon the ability to incorporate visual information from the operative field with images previously obtained. Most of the early studies on this have been feasibility assessments; however, several in vivo studies produce exciting possibilities [41, 42]. Teber and colleagues [43] were able to fuse images from a mobile C-arm initially in a porcine model and subsequently a laparoscopic model to aid in port placement. In ten patients, they found excellent concordance between images and patient anatomy and performed margin-negative partial nephrectomy in all cases. Cheung and colleagues [44] found that when comparing conventional visualization and a fusion system using ultrasound, a faster planning time for resection was achieved using the fusion visualization system in a simulated partial nephrectomy.

Transitioning to the da Vinci Xi® Robotic Platform

When transitioning to the da Vinci Xi® robotic platform, several enhancements are noteworthy. First, port placement may be placed in linear fashion along the lateral boarder of the ipsilateral rectus sheath with the assistant port placed between the cranial and camera ports. Second, the addition of advanced energy instruments such as EndoWrist® Vessel Sealer may be used, especially for highly vascular tumors and difficult dissection. Lastly, with the robot may be synched with OR bed (TruSystem™ 7000dV OR table, TRUMPF Medizin Systeme GmbH & Co. KG, Saalfeld, Germany) which can allow for integrated table motion (ITM) with simultaneous robotic arm and table movement. Especially attractive for larger masses, ITM can facilitate dissection while minimizing arm collision.

Summary

The technique of RPN continues to evolve, but the goals remain the same; minimal patient morbidity, excellent oncologic outcomes, and long term preservation of renal function. Surgeons should continue to keep striving for this standard of excellence. The future continues to be bright for patients and surgeons alike in continuing to perform RPN.

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44 Robotic Assisted Radical Nephroureterectomy with Bladder Cuff Excision and Regional Lymphadenectomy

Manish N. Patel and Ashok K. Hemal

Abstract

Radical nephroureterectomy is a challenging operation as it combines both an extirpative and reconstructive procedure in both the upper and lower urinary tracts. In the past, most surgeons elected to do this procedure either entirely open or with a large open incision to peform the bladder cuff excision and reconstruction. In this chapter, we aim to describe our technique for completely robotic assisted nephroureterectomy with bladder cuff excision and regional lymphadenectomy with tips and tricks to help surgeons perform this procedure easily and efficiently.

Keywords

Robotics · Nephroureterctomy · Upper tract urothelial carcinoma · Retroperitoneal lymphadenectomy · Bladder cuff excision

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Introduction

Upper tract urothelial carcinoma (UTUC) is an uncommon malignancy affecting the renal pelvicalyceal system and/or the ureter with an estimated incidence of 3–5% of all urothelial cancers [1]. Nephroureterectomy with bladder cuff excision and regional lympadenectomy is the gold standard management of high grade or bulky UTUC. Oncologic principles necessitate that the entire ureter along with a bladder cuff be excised during nephroureterectomy in addition to lymphadenectomy in appropriate cases (high grade disease, bulky primary on preoperative imaging, and/or radiological evidence of lymph node involvement) [2]. Oncologic outcomes following laparoscopic nephroureterectomy has been extensively reported as well as being compared to the open approach in multiple prior reports, with advantages of less postoperative pain, less blood loss and quicker recovery with laparoscopic technique [3–5]. Pure laparoscopic bladder cuff excision with watertight closure of the cystotomy with free hand suturing is a daunting task even for experienced laparoscopic surgeons. Robotic assistance with improved dexterity, EndoWrist® instrumentation and 3-dimensional visualization with magnification helps perform nephroureterectomy with bladder cuff excision in minimally invasive fashion. Intermediate term oncologic outcomes are available for the robotic approach and are comparable to the open and lapararoscopic

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approaches [6]. In this chapter, we aim to describe our technique for robotic assisted nephroureterectomy with bladder cuff excision and regional lymphadenectomy with tips and tricks to help surgeons perform this procedure easily and efficiently.

Patient Selection

Indications for robotic nephroureterectomy are similar to those for open and laparoscopic surgery. Patients with radiographic or endoscopic evidence of upper tract urothelial carcinoma are candidates for this procedure. Patient selection should be made carefully. Patients with high-grade disease, bulky disease or those with radiographic evidence of T1 or high disease should be counciled that this is considered the gold standard for therapy. Those patients with low-grade disease, attempt at endoscopic resection should be made prior to consideration of nephroureterctomy unless the tumor is bulky and endoscopic management would leave gross tumor behind.

Contraindications to robotic nephroureterectomy include patients unable to undergo general anesthesia due to severe cardiopulmonary disease or other severe medical comorbidities. Relative contraindications include those patients with locally advance disease or regional lymphadenopathy. In these cases, there should be a strong consideration for neoadjuvent chemotherapy prior to surgery.

Preoperative Preparation

All patients should undergo a thourough history and physical as well as appropriate staging which should include axial imaging of the abdomen and pelvis as well as a chest X-ray. Patients should also undergo basic laboratory testing including a complete blood count, a basic metabolic panel and a urine culture prior to surgery. All patients should be evaluated by the anesthesia team prior to surgery and if necessary should be seen by internal medicine specialists for clearance. Patients on blood thinners should obtain permission from their primary care physician or cardiologist prior to holding these medications, or they should be bridged to lovenox prior to surgery. All patients should continue taking aspirin throughout the perioperative period.

Informed consent is obtained is ideally obtained in the clinic prior to scheduling the surgery. Risks to be discussed include bleeding, infection, damage to adjacent structures (including the bowel, pancreas, spleen, liver), urine leak, hernia formation, testicular pain, renal insufficiency, adrenal insufficiency, tumor recurrence, heart attack, stroke, deep venous thromboembolism, pulmonary embolism and death. All patients should be informed that in the event of difficulty, there is always a risk of conversion to an open procedure.

The 24 h before surgery, all patients should begin a clear liquid diet and drink a bottle of magnesium citrate in the afternoon. All patients should be without anything to eat at midnight before surgery.

Operative Setup

Nephroureterectomy setup can be daunting as it combines an extirpative procedure with a reconstructive procedure in both the upper and lower urinary tracts. We have described a technique for single robot docking which utilize instrument swaps as you proceed from the upper tract to the lower tract without the need to move the patient side cart. In addition we utilize a single port template for nephrouretercotmy to ease transition from upper to lower tract.

At our institution, we initially developed our technique using the da Vinci S (Intuitive Surgical Inc., Sunnyvale, CA) robot beginning in 2008. Since then we have evolved our technique to the da Vinci Si and now we primarily use the da Vinci Xi. We employ a four-armed robotic technique with a single port for a bedside assistant on the contralateral side. The surgical technician is also on the contralateral side next to bedside assistant for ease of instrument passage.

Patient Positioning and Preparation

The patient is initially placed on the operating room table in the supine position for induction of anesthesia. Appropriate intravenous access and other lines are placed as necessary by the anesthesia team. An 18 French Foley urethral catheter is placed. The abdomen is then shaved from the costal margin to the pubic symphysis. The patient is then placed in full flank position with the bottom leg bent about 30° and the top leg straight. An axillary roll is placed under the patient's axilla to prevent brachial plexus injury. The bed is flexed about 30–40° to open up the space between the costal margin and the iliac crest. Back bolsters are then placed behind the patient to secure them in the flank position, and Velcro straps are used to secure the patient around the chest and hips. The contralateral arm is placed on a padded arm board straight out. The ipsilateral arm is either placed in an Allen arm rest with the elbow making a 30–40° angle, or is placed straight down the side of the patient and secured. Typically for smaller patients the arm is placed straight down, and for larger patients it is placed in the Allen arm rest. Once positioned, we ensure that all pressure points are padded and we add extra foam as necessary.

Trocar Configuration

With single robot docking, port placement is simplified to one template and no need to add or change ports when transitioning from upper to lower tract surgery. The port templates for the different generations of robots are slightly different due to the different configuration of the bedside cart robotic arms.

Transperitoneal da Vinci S and Si

Port placement can be seen in Fig. 44.1. The 12 mm camera port is placed just lateral to the ipsilateral rectus sheath and just cranial to the umbilicus. Three additional 8 mm robotic ports are placed: (1) 8 cm cranial to the camera and lateral to the rectus sheath, (2) midline about 6 cm caudal to the umbilicus, (3) 2 cm cranial to the ASIS. A 12-mm assistant port can be placed in the midline between the camera port and the cranial working port. The robot is docked at a 90° angle over the patient's back. For the nephrectomy portion, the cranial port is the left arm, the caudal port is the right arm, and the lateral port is the fourth arm. During the bladder cuff portion, the arms are switched with the caudal port as the right arm, the lateral port as the left arm and the cranial port as the fourth arm. This port template allows seamless transition from upper to lower tract surgery without moving the patient side cart [7].

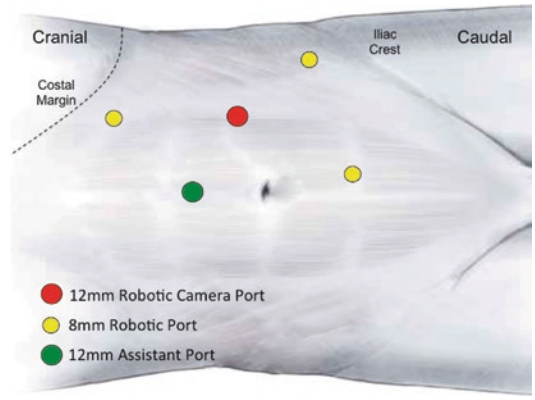

Fig. 44.1 Port placement when utilizing the da Vinci S and Si robotic platforms

Transperitoneal da Vinci Xi®

Port template for the Xi® is seen in Fig. 44.2. The ports are arranged in a linear fashion along the rectus sheath. The camera port is placed along the rectus sheath just cranial to the umbilicus. Three additional ports are placed along the sheath with one about 6–7 cm cranial to the camera, one about 6–7 cm caudal to the camera, and one about 6–7 cm caudal to the third port. A 12-mm assistant port is placed in the midline between the cranial port and the camera port. The robot is docked at a 90-degree angle over the back of the patient. During the nephrectomy and lymphadenectomy portion of the procedure, the targeting feature is

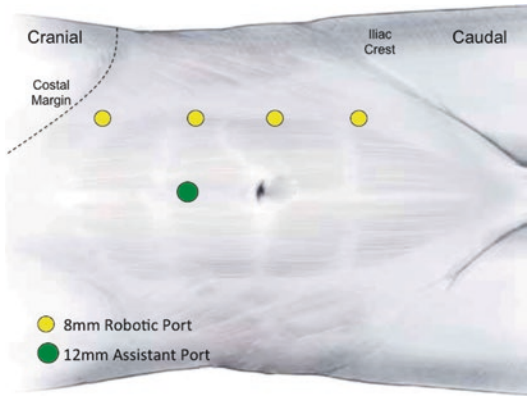

Fig. 44.2 Port placement when utilizing the da Vinci Xi robotic platform

used to direct the arms of the robot towards the renal hilum. Once this portion is complete, the arms are disconnected, and the robot is retargeted towards the bladder cuff. This allows the robotic boom to rotate without moving the patient side cart. In addition, the camera "hops" from the port just cranial to the umbilicus to the port just caudal to the umbilicus.

Again, a distinct advantage with the Xi® is the ability to target and re-target the area of interest allowing the arms to self-deploy and avoid minimal arm collision. Additionally, for the lower ports, the patient clearance function allows rotation of the elbow of the robotic arm to minimize contact with the patient's leg. In our experience, we have found the Xi® to be more user-friendly, intuitive, and easier in installation [8].

Instrumentation and Equipment

Robotic Equipment

da Vinci S/Si/Xi surgical system (Intuitive Surgical Inc., Sunnyvale, CA)
Fenestrated bipolar forceps
Monopolar curved scissors
ProGrasp forceps or tip-up fenestrated grasper
Large needle driver × 2 (or large needle driver and large suture-cut needle driver)
Monopolar hook (optional)
Maryland bipolar forceps (optional)

Trocars

S/Si:
12 mm trocar
8 mm robotic trocars × 3
12 mm Airseal port (Surgiquest Inc., Milford, CT)

Xi

8 mm robotic trocars × 4
12 mm Airseal port (Surgiquest Inc., Milford, CT)

Sutures

3-0 barbed V-lok suture (Covidien, Minneapolis, MN) or 3-0 poliglecaprone suture
3-0 polyglactin suture
0-polydioxanone suture
4-0 poliglecaprone suture
4-0 silk or nylon suture (for drain)

Instruments for Bedside Assistant

Laparoscopic needle driver
Laparoscopic blunt grasper
Laparoscopic suction irrigator
Laparoscopic clip applier
Laparoscopic endovascular stapler with vascular loads (optional)
Jackson Pratt closed suction pelvic drain

Step by Step Technique

Step 1: Abdominal Access

A transperitoneal approach is used to access the abdomen using either a Veress needle inserted medial to the anterior superior iliac spine, or with the open Hassan technique in the midline 3–4 cm cranial to the umbilicus. Once entry is obtained into the peritoneal cavity, the abdomen is insufflated to 14 cm of H_2O. The port for the robotic

camera is placed just lateral to the rectus sheath about 2–3 cm cranial to the umbilicus. For the S and Si systems, this will be a 12 mm trocar, for the Xi system this will be an 8 mm robotic trocar. The abdomen is initially visualized using a 0° lens. Additional trocars are placed as described in Figs. 44.1 and 44.2.

Once all trocars are placed, the robot is docked directly over the back of the patient, in line with the camera port. For the nephrectomy portion of the procedure, typically a 30 degree lens is used to visualize the kidney and renal hilum. Under direct vision, the robotic arms are inserted into the cannulas by the bedside assistant in to the surgical field. The monopolar curved scissors are placed in the right working arm, the fenestrated bipolar forceps are placed in the left working arm and the tips-up grasper is placed in the fourth arm cannula. The cautery is set at 40 cut and 40 coagulation for the S and Si systems and at a setting of 5 for the Xi system. These settings can be adjusted per surgeon preference.

Step 2: Colon Mobilization

The colon is mobilized medially by incising the relatively avascular white line of Toldt. Gentle sweeping motions are made to pull the colon medially ensuring that Gerota's fascia remains intact (Fig. 44.3). The bedside assistant can help this process by using laparoscopic graspers or the tip of the suction irrigator to apply some traction the colon medially. The colon is reflected from the hepatic/splenic flexure to the pelvic inlet to allow for adequate exposure of the kidney and proximal ureter. Often times, adhesions can be seen once the peritoneal cavity is entered. If adhesions are seen, these can be taken down sharply in the avascular plane at the abdominal wall.

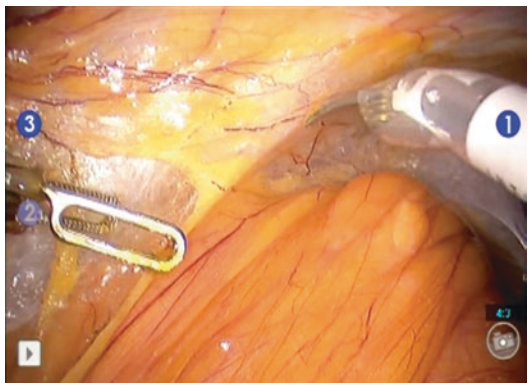

Fig. 44.3 Incision of the line of Toldt and mobilization of the colon

For right-sided cases, the liver may be enlarged and obstructing the view of the colon and/or kidney. In these cases, the right coronoary ligament can be incised to help retact the liver to allow access to Morrison's pouch. If necessary, an additional 5-mm assistant port can be placed in the midline two fingerbreadths below the xiphoid process for a liver retractor. This is usually an atraumatic locking grasper which can be placed under the liver, taking care not to injur the gallbladder, and affixed to the lateral side wall. For left-sided cases, typically the leino-renal ligament must be incised to obtain access to the splenic flexure and upper pole.

Step 3: Dissection of the Ureter and Identification of the Renal Hilum

Once the colon is mobilized fully, the lower pole of the kidney is identified and the tail of Gerota's fascia is opened and the lower pole is lifted anteriorly with the tip-up grasper. The ureter and gonadal vein should be seen travelling medially. The ureter is dissected and lifted anteriorly with the lower pole (Fig. 44.4). For left-sided tumors, the ureter and gonadal vein are lifted together, but for right-sided tumors, the ureter is lifted anterior and the gonadal is kept down. A window is made to the psoas muscle and all tissues over the psoas muscle are lifted anteriorly. With the ureter and lower pole on stretch, the tissues are slowly opened superficially from caudal to cranial. For left-sided tumors, the gonadal vessel can be traced back to its insertion in the renal vein. For right-sided tumors, the gonadal vessel can be traced to its insertion in the inferior vena cava, with the renal vein being the next vessel just cranial to this insertion.

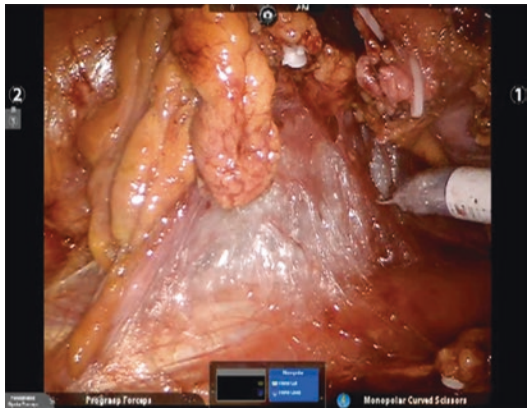

Fig. 44.4 The ureter is lifted anteriorly and the gonadal vein is pushed posteriorly. The lower pole of the kidney then lifted to identify the renal hilum

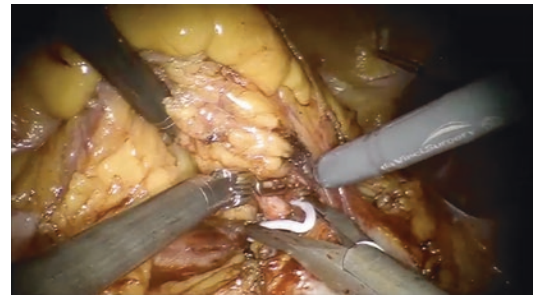

Fig. 44.5 The renal hilum is ligated using clips, an endovascular stapler or suture

Step 4: Renal Hilar Dissection

Fine dissection of the renal hilum can be aided by additional instruments including the monopolar hook and the Maryland bipolar forceps. Typically, we continue to use the curved scissors and the fenestrated bipolar forceps to save on cost and time to switch instruments.

Under gentle anterior retraction by the robotic fourth arm and with the assistance of the bedside assistant using the suction irrigator, the renal hilum is carefully identified and dissected. Small windows should be created it the peri-vascular tissues parallel to the renal vessels. Particular care must be taken to identify accessory renal vessels, lumbar vessels, adrenal vessels and early branching of the main renal artery and vein. In many cases, a dedicated CT scan such as a CT angiogram of the abdomen or a 3D reconstruction of the staging CT scan can be very useful in assessing renal vascular anatomy and identifiying these sturcutres intraoperatively.

During dissection, the assistant can be helpful in retraction of critical structures around the hilum including the ascending colon, vena cava and duodenum for right sided dissection, and the descending colon, pancreas and spleen for left sided dissection. The goal of dissection should be to obtain a skeletonized section of the proximal renal artery and vein about 2–3 cm in length to allow for hilar ligation. Once the renal hilum is dissected, the renal artery is first ligated (Fig. 44.5). This can be done with suture ligation using 0-silk suture, clip placement, or use of an endovascular stapler. If the stapler is used, we typically try to place at least one clip proximally on the artery and vein prior to stapling to secure the vessel further and decrease the risk of future vascular fistula formation.

Step 5: Dissection of the Adrenal Gland and Renal Attachments

Once the renal hilum is ligated, we immediately clip the ureter with a single clip. Clipping is done at this point to prevent any tumor spillage during renal mobilization. It is not done sooner to prevent urine buildup and dilation of the renal pelvis which may make hilar dissection more difficult (Fig. 44.6).

After division of the renal vasculature, the upper pole is mobilized, typically with an adrenal sparing technique. The adrenal gland is typically spared unless there is evidence of tumor extension to the adrenal gland either visually or radiographically. When dissecting the adrenal gland, care must be taken to avoid the complex vasculature surrounding the adrenal including the multiple small arteries and the short adrenal vein. Dissection is carried down to the renal capsule and the upper pole is freed from its surrounding attachments. If necessary, additional

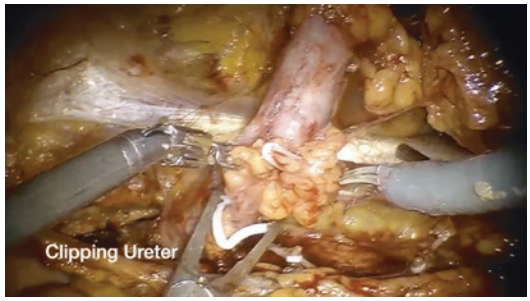

Fig. 44.6 The ureter is clipped after ligation of the renal hilum

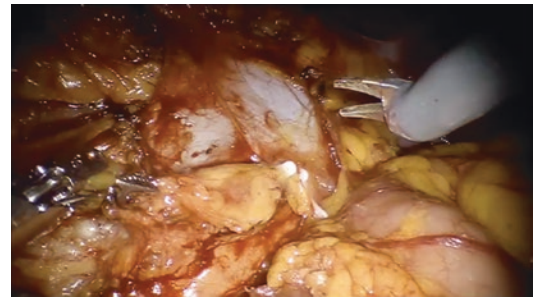

Fig. 44.7 Regional lymphadenectomy. Each lymph node packet is individually dissected and clipped proximally and distally

vascular or tissue loads can be used with the endovascular stapler to aid in separation of the adrenal gland from the upper pole. The lateral attachments to the kidney are then taken down and the kidney is freed. The ureter is dissected distally to the pelvic inlet to allow additional mobilization of the kidney. The kidney is left in the upper quadrant until bladder cuff excision and is removed en bloc.

Step 6: Regional Perihilar Lymphadenectomy

Regional lymphadenectomy is performed commonly in patients undergoing nephroureterectomy. This is performed in patients with bulky tumors, cT3 disease on preoperative imaging, high grade tumors in the renal pelvis, upper or mid ureter, and in patients with evidence of enlarged lymph nodes on preoperative imaging. Regional lymphadenectomy includes hilar, paracaval and retrocaval lymph nodes for right sided tumors, and hilar and para-aortic lymph nodes for left tumors. In patients with distal ureteral tumors an ipsilateral pelvic lymphadenectomy is done.

Lymph node dissection is done primarily with blunt dissection without the use of electrocautery to avoid injury to adjacent vasculature. Each lymph node packet is clipped proximally and distally to minimize the risk of bleeding and lymphocele, and sent separately for pathologic analysis (Fig. 44.7).

Step 7: Dissection of the Distal Ureter and Bladder Cuff

Once attention is turned to the pelvis, adjustments are made to the robotic arms to allow for the transition to lower tract surgery.

da Vinci S and Si

The robotic instruments are removed, and repositioned for pelvic surgery. The camera remains in the same port. The right robotic arm is moved the medial caudal working port. The left arm is moved to the lateral caudal working port, and the fourth arm is moved to the cranial working port.

da Vinci Xi

The robotic instruments are removed and the boom is repositioned. The camera is port "hopped" to the port just caudal to the umbilicus. The camera is then centered on the ureterovesical junction, and the boom is retargeted which is an automatic feature of the Xi robotic system. When it retargets, the boom automatically rotates to give an ideal angulation for working in the pelvis. The right arm is placed in the most caudal port, the left arm is placed in the robotic port just cranial to the umbilicus, and the fourth arm is placed in the most cranial robotic port.

The ureter is dissected distally by continuing to open the peritoneum. The vas deferens in the male and the broad ligament in the female are divided using clips. The medial umbilical artery is also clipped and divided to allow rotation of

the bladder for easy access to the bladder cuff. The peritoneal covering of the bladder is incised allowing visualization of the detrusor fibers of the bladder. The ureter can be grasped and placed on traction by the fourth arm or the bedside assistant to help in identification the ureteral insertion into the bladder.

Step 8: Excision of the Bladder Cuff

Typically an extravesical approach is used to free the bladder cuff. The bladder is emptied via the urethral Foley catheter to minimize the risk of urine spillage and tumor seeding. At this point, a full thickness stay suture using either a 3-0 barbed suture or vicryl is placed on the lateral aspect of the bladder cuff to prevent retraction of the bladder mucosa during excision (Fig. 44.8). The monopolar scissors are then used to incise the detrusor muscle and create a 1 cm margin around the ureterovesical junction (Fig. 44.9).

Fig. 44.8 Pre-placement of a stay suture to prevent retraction of the bladder mucosa during bladder cuff excision

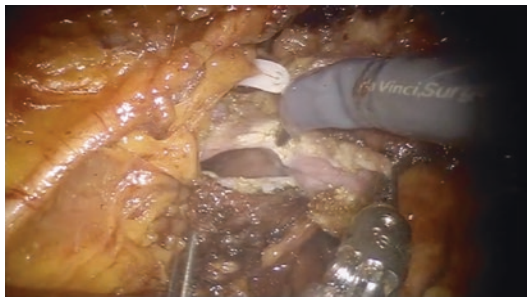

Fig. 44.9 Excision of the bladder cuff

Once the bladder is entered, the contralateral ureteral orifice can be visualized and care is taken not to injure the orifice. Once the bladder cuff is completely freed, the kidney, ureter and bladder cuff are immediately placed en bloc into a specimen bag for extraction.

Step 9: Closure of Cystotomy

The bladder mucosa is closed using either a running barbed suture, or a 3-0 poliglecaprone suture in a running fashion (Fig. 44.10). The stay suture placed previously is then used to run a second full thickness layer of closure. Once the bladder is closed, the integrity of the closure is tested by instilling 200 cc of sterile saline though the Foley catheter. At this point the ureter bed and the pelvis are inspected for any bleeding after decreasing the insufflation pressure to 10 cm H_2O.

Step 10: Specimen Retrieval and Closure

A 15 French Jackson Pratt closed suction drain is typically placed through the most caudal port. All ports 12 cm and larger are closed at the level of the fascia. If a 12-mm camera port is used, a Carter Thompson fascial closure device is used to preplace a fascial suture prior to specimen retrieval. If only 8 mm ports are used, these are typically only closed at the skin level. The specimen is retrieved by increasing the supraumbilical midline incision from the 12 mm AirSeal port.

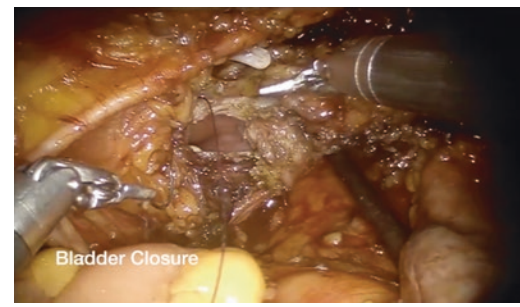

Fig. 44.10 Repair of the cystotomy using a in two layers to prevent urine leak

Once the specimen is removed, the fascia is closed using running 0-polydioxanone suture. Scapas fascia is closed with interrupted 4-0 vicryl suture and the skin is closed with a subcuticular 4-0 poliglecaprone running suture. The port sites are closed with subcuticular 4-0 poliglecaprone sutures. The drain is secured with silk or nylon suture.

Postoperative Management

Postoperatively patients are given a clear liquid diet, maintenance intravenous fluids and intravenous narcotics as need for pain. Typically, patients are also given intravenous ketorolac as an analgesic adjunct to help limit the need for narcotics. Patients are encouraged to ambulate the night of surgery and are required to walk in the halls with assistance on post operative day 1. Diets are advanced as tolerated. Patients are typically discharged on postoperative day 2 with the pelvic drain removed prior to discharge. The urethral catheter is maintained for 7–10 days. Cystogram is typically not ordered prior to catheter removal unless there is clinical suspicion for urine leak.

Steps to Avoid Complications

Robotic assisted nephroureterectomy is a procedure associated with minimal morbidity as long as care is taken to identify appropriate landmarks during the procedure and careful surgical technique is employed. The judicious use of electrocautery to minimize the risk of bowel or vascular injury, the use of clips when performing lymphadenectomy to minimize the risk of lymphatic leak or lymphocele, and performing a two layered closure during cystotomy repair to minimize the risk of urine leak are all recommended.

When ligating the renal hilum, the endovascular stapler is a common instrument used because it is effective and efficient. To use this device, the bedside assistant must position and fire the stapler, so they should be proficient in its use and understand techniques to manage possible misfire. Typically even when using an endovascular stapler, it is recommended to place clips on the artery and vein proximally prior to firing to ensure complete occlusion of the vessels and prevent the risk of potential fistula formation.

During dissection of the ureter distally, there are a number of structures that can be injured in the female. The distal ureter is in close approximation to the cervix and the vagina. Care must be taken during dissection to avoid injury to prevent the creation of a vesicovaginal fistula. The broad ligament must be ligated and transected to ensure complete visualization of this area. In some cases, it may be advantageous to have the bedside assistant place a sponge in the vagina to aide in identification.

Conclusions

Robotic assisted nephrourterectomy is a safe and feasible procedure which is typically associated with minimal morbidity. Several tips to make this procedure easier include (1) placement of ureteral clip immediately after ligation of the renal hilum, (2) placement of stay sutures in the bladder prior to performing cystotomy, and (3) judicious use of the fourth robotic arm for retraction during the nephrectomy and cystotomoy closure to aid in visualization.

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Complications in Robot-Assisted Partial Nephrectomy

45

Weil R. Lai and Benjamin R. Lee

Abstract

Robot-assisted partial nephrectomy is becoming increasingly applied as a surgical technique for the treatment of T1 renal masses. In the hands of experienced urologists trained in minimally-invasive surgery, the complication rates are low. We review complications associated with this surgical approach of robotic partial nephrectomy, including hemorrhage, urine leak, bowel injuries, those related to positioning, and the effects of surgery on progression of chronic kidney disease.

Keywords

Robotics · Partial nephrectomy · Complications · Nephron sparing surgery · Pseudoaneurysm · Urine leak

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Introduction

Robot-assisted partial nephrectomy (RPN) has become an increasingly common procedure for the treatment of clinically localized renal cell carcinoma (RCC). Contemporary urologic literature has shown equivalent or improved oncologic outcomes with partial nephrectomy (PN) compared to radical nephrectomy, while preserving renal function comparatively [1–3]. This paradigm shift coupled with the graded learning curve for PN afforded by robotics has led to a growing number of urologists performing RPN [4, 5]. Indications for robotic partial nephrectomy have expanded to clinical T1b renal masses; bilateral renal masses; masses on solitary kidneys; and endophytic, hilar masses.

Aside from efficacy, the durability of a surgical procedure is directly dependent on its safety and inherent risks. Since the introduction of RPN in 2004, a large number of RPN series have been published. Complication rates vary considerably depending on how the studies report the complications and patient-specific factors, such as the size of the renal mass. In the hands of renal surgeons experienced in minimally-invasive techniques, a multi-institutional study of 445 consecutive patients who underwent RPN showed peri-operative complication rates of 3.9% and 8.4% for renal tumors ≤4 cm and >4 cm in diameter, respectively [6]. In another multi-institutional study of 450 patients, there was an overall 15.8%

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rate of complications, 11.2% of which representing intraoperative complications [7].

On the other hand, in another multi-institutional study focusing on renal tumors >4 cm, the post-operative complication rate was 26.5%, with 23% of these complications representing Clavien grade 3 [8]. Comparative studies between RPN and laparoscopic partial nephrectomy demonstrated no significant difference in complication rates [9–14]. In this chapter, we discuss complications inherent to RPN, including hemorrhage, urine leak, visceral injuries, those related to positioning, and effects of surgery on progression of chronic kidney disease (CKD).

Positioning-Related Complications

RPN is performed with the patient in either a modified or full lateral decubitus position. In non-robotic laparoscopic renal series, this position has been associated with paresthesias, chronic pain, and rhabdomyolysis [15]. Lab findings significant in rhabdomyolysis include elevated serum creatine kinase (CK), which typically peaks 18 h post-operatively. Management of rhabdomyolysis includes hypervolemic therapy, with alkalinization with sodium bicarbonate solution. If the serum CK is >5000 IU/L, a forced diuresis of >60 mL/h urine output is produced. In a series of at least 700 laparoscopic renal procedures between 1992 and 2003 at two institutions, rhabdomyolysis was diagnosed in seven patients [16]. Six of the cases utilized the kidney rest on the bed. The range of operative time for these cases was 5.8–9.4 h, which is longer than typical for a laparoscopic procedure. Two required emergent fasciotomy for gluteal compartment syndrome. All had extended recovery times with sequelae, including 4 with lower extremity weakness, 1 with long-term leg pain and paresthesia, and 1 requiring long-term wheelchair assistance. Based on these findings, the authors recommended minimization of operative times, limiting the use of kidney rest, and attention to padding of the operative table.

In a series of 600 laparoscopic nephrectomies, rhabdomyolysis was identified in 4 patients (0.67%) [17]. Three of these cases utilized bed flexion and the kidney rest. Risk factors cited in the authors' literature review included male gender, elevated body mass index, prolonged operative time, CKD, extracellular volume depletion, and renal hypoperfusion.

In comparison, none of the 3 aforementioned multi-institutional studies on RPN report a complication as a direct result of flank positioning [6–8]. For robotic-assisted nephroureterectomy, in which the patient is positioned similarly to RPN for the nephrectomy portion of the case, there are case reports of rhabdomyolysis. In a multi-institutional study evaluating technique and perioperative outcomes of 43 robotic nephroureterectomies (of which patients are also positioned in flank position), two patients developed rhabdomyolysis [18]. Those patients were morbidly obese and had longer operative times than their non-morbidly obese counterparts.

Spana et al. 2011 and Petros et al. 2012 both report presence of venous thromboembolism in 1.8% of their patients [6, 7]. Such thromboembolic events were thought to be potentially related to a combination of patient positioning and the decreased venous return from the effects of pneumoperitoneum during surgery.

At our institution, we place patients in a modified lateral decubitus position (45–60°) for the transperitoneal approach or in a full lateral decubitus position for the retroperitoneal approach. The patient's back, shoulder, and hip are supported with a gel roll. An axillary roll is used for the full lateral decubitus position to decrease the risk of brachial plexus injury. Neither the kidney bump nor table flexion is used. The dependent lower extremity is flexed at the hip and the knee. The top lower extremity is kept straight. Pillows are placed in between the lower extremities with sequential compression devices as prophylaxis against deep vein thrombosis. The dependent upper extremity is abducted at a 90° angle and supported with the arm extension of the table. The upper extremities are separated by pillows, with care to avoid hyperadduction of the top upper extremity. The patient is secured to the bed with tape and egg

crate foam at the arms, avoiding radial and brachial plexus nerve compression, as well as securing the hip and the lower legs. Prior to prepping the surgical field, the bed is rotated back and forth to make sure the patient stays secured to the bed.

Intraoperative Hemorrhage

Significant intraoperative hemorrhage during RPN is uncommon in this day and age. When such hemorrhage is defined as bleeding requiring a blood transfusion or intervention, the rate has been reported in literature at low rates, e.g., 0.2% [7]. Intraoperative hemorrhage during tumor resection can be caused by inadequate occlusion of hilar vasculature secondary to atherosclerosis, malposition of the bulldog clamps, or an accessory renal artery. This may be mitigated by the use of two bulldog clamps on the renal vasculature to increase occlusion forces. During resection, excessive parenchymal bleeding may also represent the presence of unrecognized additional vessel(s). To minimize intraoperative hemorrhage, we routinely review pre-operative cross-sectional imaging for accessory renal vessels, including those that may arise caudal to the kidney (e.g., branches of iliac vessels). During hilar dissection for non-selective clamping cases, we isolate the arterial vasculature as proximal as possible so that the bulldog clamps are placed on the main renal artery instead of on its segmental branches.

Prior to clamping the vasculature, we also review a surgical team checklist to make sure all equipment and supplies needed during tumor resection are present and working (e.g., robotic needle drivers, pre-made sutures, and hemostatic agents). Extra equipment and supplies are also readily accessible in the operating room. Several studies have demonstrated benefit by utilizing a safety checklist such as recommended by Nepple et al. 2012 [19].

When excessive parenchymal bleeding occur during tumor resection, it is important to determine whether the source of hemorrhage is venous or arterial. The bedside assistant can tamponade the bleeding by applying pressure on the site of bleeding with the tip of the suction irrigator and maintain visualization of the area of bleeding with intermittent suctioning. If the bleeding is venous and the vein is clamped, one option is to remove the bulldog clamp on the vein to reduce the pressure contributing to venous back bleeding. To slow down venous bleeding, an additional option is increase the pneumoperitoneum to 20 mm Hg to slow down the hemorrhage until after the sutures have been placed to ligate the vessels within the resection bed, and the renorrhaphy has been completed. Placing a mini lap pad into the resection bed can also help control small venous oozing and optimize visualization, but this will not stop larger venous bleeding.

When a vessel is seen in the resection bed and not yet divided, it can be clipped prophylactically prior to dividing the vessel. If the vein is already open, it can be ligated with a 2-0 polyglactin suture in a figure-of-eight fashion. The suturing can be performed selectively or during continuous running of the suture within the resection bed. Any residual bleeding can be further tamponaded by tightening down on the cortical renorrhaphy sutures.

If the bleeding remains excessive even with suture ligation, increasing pneumoperitoneum, placement of additional bulldog clamps, or direct pressure with the mini lap pad, then one may need to convert to radical nephrectomy or to an open procedure to establish vascular control.

Postoperative Hemorrage

In comparison to intraoperative hemorrhage requiring blood transfusion, post-operative hemorrhage is more common due to pseudoaneurysm and classically occurs in a delayed fashion. Spana et al. 2011 reports a post-operative hemorrhage rate of 4.9% [7]. In the multi-institutional series of Tanagho et al. 2013, the post-operative hemorrhage rate was 5.8% [20]. Transfusion rates following RPN range between 3% and 10%, which are comparable to those cited for conventional laparoscopic and open partial nephrectomy series [21].

Common etiologies of post-operative hemorrhage include pseudoaneurysms and arteriovenous fistula. Pseudoaneurysms typically occur within 2 weeks and presents with gross hematuria, flank pain. Significant decrease in hematocrit may not occur until late stages of hemorrhage. The incidence of pseudoaneurysms requiring angioembolization is low, ranging from 0.2% to 1.1% [7, 20, 22, 23]. Scoll et al. 2009 reports 1 patient with post-operative hemorrhage who was treated with 5 units packed red blood cell transfusion and angioembolization [23]. In Spana et al. 2011, angioembolization was utilized in 2 of the 22 patients with post-operative hemorrhage, with one performed for symptomatic pseudoaneurysm and the other for an arterial-caliceal fistula [7]. In Tanagho et al. 2013, 10 of 886 patients received angioembolization [20]. In Kaouk et al. 2012, one of 400 patients received angioembolization [22].

The incidence of all pseudoaneurysms is much higher but may not be as clinically relevant. In Kondo et al. 2015, the authors routinely obtained CT angiography on the third post-operative day to prospectively look for renal artery pseudoaneurysms [24]. When pseudoaneurysms were identified, they carried out prophylactic transarterial embolisms for pseudoaneurysms measuring at least 5 mm in diameter. For patients with questionable or uncertain radiographic findings, they repeated CT angiography 3–5 days later. In that study of 96 patients (of which 61 belong in the early unclamping group), the rates of asymptomatic renal artery pseudoaneurysms were 11.4% and 28.6% for the early unclamping and conventional unclamping groups, respectively. The authors concluded that early post-operative CT screening and prophylactic embolization of renal artery pseudoaneurysms reduced their series' rate of delayed hemorrhage from 4.7% to 0.6%.

To perform angioembolization, renal artery angiography is done to identify the locations of the pseudoaneurysms. The angiography is typically performed with the injection of a radio-opaque liquid contrast medium. As illustrated in Fig. 45.1a, b, after identification of the pseudoaneurysm, superselective coil embolization can be then performed to block arterial blood flow into the pseudoaneurysm. This preserves the arterial blood supply to the unaffected parts of the kidney.

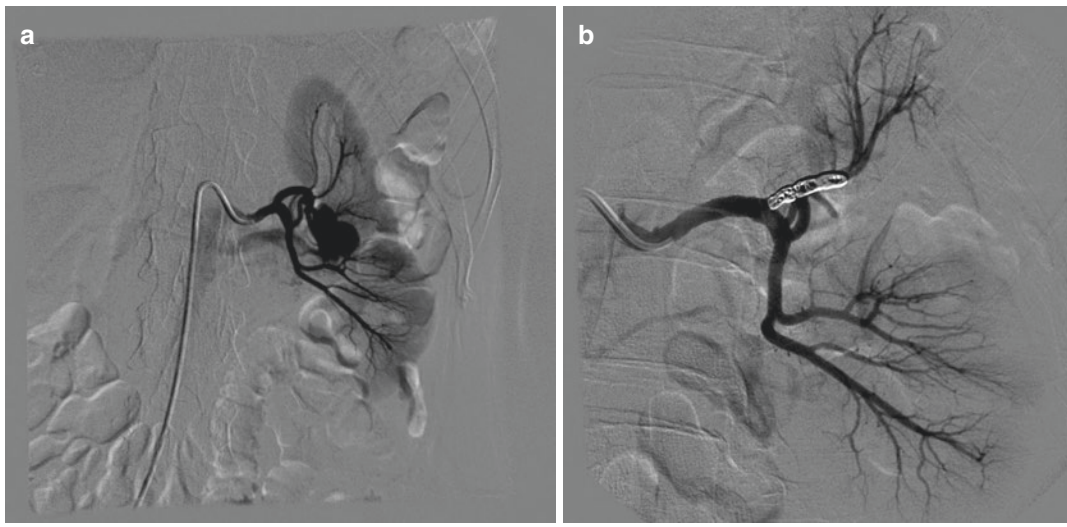

Fig. 45.1 (**a**) Left renal artery angiogram demonstrating presence of a left renal artery branch pseudoaneurysm and an arteriovenous fistula. (**b**) Post-coil angiogram demonstrating successful treatment of the pseudoaneurysm and arteriovenous fistula. The patient developed gross hematuria and flank pain 15 days after a left robotic partial nephrectomy for a 6.1 cm left posterior mid-pole renal mass. After successful placement of superselective coils, her symptoms resolved with no recurrence of gross hematuria

When there is concern for potentiating contrast-induced nephropathy, especially in patients with severe CKD, one alternative is to use carbon dioxide as the primary contrast agent [25]. Compared to non-ionic iodinated contrast medium, carbon dioxide lacks renal toxicity and anaphylactic response [25]. In the case of a patient with baseline severe CKD and symptomatic pseudoaneurysm following a laparoscopic heminephrectomy, carbon dioxide angiography was successfully used as the primary contrast medium to localize the pseudoaneurysm and to facilitate superselective coil embolization [26].

Urine Leak

Increased serous-appearing drain output and elevated drain fluid creatinine levels suggest presence of urinary leak or a urinary fistula. The presence of urinomas can be confirmed on pyelograms or cross-sectional imaging. A literature review conducted by Cha et al. 2011 on single-institution series (i.e., published in the years 2004–2010) of RPN noted that the rates of urinary leaks ranged from 2% to 12.5% [21]. In the larger, more contemporary, multi-institutional series of Spana et al. 2011, Tanagho et al. 2013, and Potretzke et al. 2015, their rates of urinary leak were even lower at 1.6%, 1.1%, and 0.78%, respectively [7, 20, 27].

Signs and symptoms of urine leak manifest in different ways. For the 14 patients (out of 1791) with urine leak after RPN in Potretzke et al. 2015, those patients had presented with the following signs and symptoms: 5 with pain, 4 with gastrointestinal complaints, 2 with fever, 2 incidentally noted, and 1 with leakage from incision [27]. They had presented at a median post-operative day of 13, with 8 of the patients requiring hospital admission. Eight and nine of the patients received drains and ureteral stents, respectively. The drains and stents were removed at a median of 8 and 21 days, respectively. Risk factors identified for urine leak included increased tumor size, increased warm ischemia time, and the need for collecting system repair. Interestingly, the authors suggested that the routine intraoperative placement of drains during RPN might not be needed as most of the patients with urine leaks presented after removal of the initial drain.

In Tanagho et al. 2013, of the ten patients with urine leaks, three were managed with ureteral stent, two with percutaneous drain, and five with prolonged Foley catheter drainage [20].

Our preference is to first confirm leak with biochemical analysis of creatinine content of drain fluid. If it is greater than serum creatinine, then observation with drain on suction is performed initially. If the elevated drain output does not resolve within a few days, a computed tomography (CT) scan with IV and oral contrast is performed to assess for the presence of urinoma or other injuries such as bowel. If a urinary fistula is suspected, then a gentle retrograde pyelogram (e.g., Fig. 45.2a, b) is performed with placement of ureteral stent and urethral Foley catheter to maintain a low pressure system. With time and patience, and the absence of infection, the fistula typically seals without further intervention.

Bowel Injury

Fortunately, bowel injury during RPN remains uncommon. When not recognized intraoperatively, it can lead to sepsis, prolonged hospitalization, and/or death. It is not commonly reported in the RPN literature. It is reported in 1 case (0.1%) in Tanagho et al., of which the injury was recognized intraoperatively and repaired [20].

More data on the incidence and management of bowel injury from urologic surgery may be found in the non-robotic laparoscopic literature. In a series of 1073 laparoscopic upper urinary tract procedures, Schwartz et al. reported eight bowel injuries [28]. They occurred in three laparoscopic partial nephrectomies, two laparoscopic radical nephrectomies, two laparoscopic simple nephrectomies, and one laparoscopic renal cyst decortication. Etiologies of these injuries included tissue dissection, thermal injury, during Veress needle placement, and during trocar placement. Six of these bowel injuries

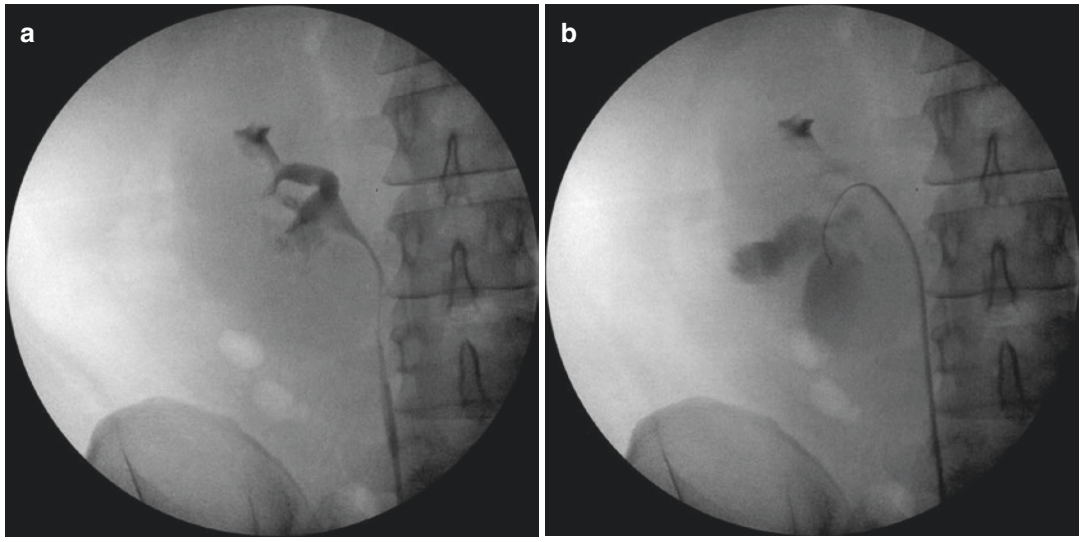

Fig. 45.2 Right retrograde pyelogram demonstrating (**a**) loss of calyceal border in the area of the resection site and (**b**) contrast extravasation into urinoma. The pyelogram was performed 8 days after a right robotic partial nephrectomy for a 2.2 cm right posterior hilar renal mass. The patient had CT imaging done post-operatively to evaluate persistent abdominal pain. This revealed the presence of a perinephric fluid collection. A ureteral stent was placed at the time of the retrograde pyelogram. After confirmation of resolution of the urinoma on follow-up CT imaging, the stent was removed in clinic 10 weeks post-operatively with no further sequelae

were recognized intraoperatively and were either repaired at the time of surgery (including oversewing the injury for serosal tears, performing bowel resection for adjacent enterotomies in one patient, or performing bowel resection for degloving colon injury in another patient) or observed (e.g., Veress needle penetration of colon without gross spillage or visible bowel defect). Those patients recovered without adverse post-operative events.

For the two bowel injuries that were not recognized intraoperatively, the corresponding patients had prolonged hospitalization and required further procedures with associated morbidities [28]. In the first case, a patient presented with a colocutaneous fistula and a retroperitoneal fluid collection 4 weeks after laparoscopic simple nephrectomy for xanthogranulomatous pyelonephritis. The fluid collection was managed with placement of percutaneous drains. The fistula and the fluid collection resolved after 9 weeks without additional surgical procedures. In the other case, the patient developed septic shock and enteric drainage from a port site on post-operative day 4 after retroperitoneal laparoscopic partial nephrectomy. The patient had Crohn's disease, multiple prior bowel resections, and a bilial-enteric anastomosis. The patient underwent two exploratory laparotomies to repair/debride the bowel injury and drain recurrent retroperitoneal abscess. The patient did recover from these procedures, with a hospital length of stay of 34 days.

Schwartz et al. 2010 also performed a literature review of 21 published series reporting bowel injury during urological laparoscopic procedures [28]. Of the 14,447 patients represented in that review, 94 (0.65%) of them were documented as having experienced bowel injury. When compared to retroperitoneal laparoscopic procedures, transperitoneal laparoscopic procedures carried a twofold increase risk of bowel injury (0.8% versus 0.38%). These rates excluded radical prostatectomy and cystectomy procedures. For the 43 patients with unrecognized bowel injury, the most common symptoms included abdominal distension (60%) and localizing trocar site or abdominal pain (46.7%). Fevers, emesis, and leukocytosis were present in 20%, 13.3%, and 6.7% of those patients, respectively.

To recapitulate, bowel injury from laparoscopy does not present like the typical open surgery acute abdomen with rebound tenderness and high fever. Rather, more commonly the patient presents with low grade fever, trocar site tenderness, and leukopenia. CT scan with oral contrast should be performed, and one should maintain a low threshold for re-exploration if bowel injury is suspected.

Conversion Rates

The conversion of RPN to open surgery or radical nephrectomy is also uncommon and can range from 0.5% to 7.8%, typically because of intraoperative hemorrhage, or less commonly failure to progress. Of the 400 RPN cases reported in Kaouk et al. 2012 [22], the number (rate) of cases converted to open partial nephrectomy was 2 (0.5%), laparoscopic partial nephrectomy 4 (1%), and robotic radical nephrectomy 1 (0.25%). Of the 886 cases reported in Tanagho et al. 2013 [20], the conversion rate to open partial nephrectomy was 1 (0.1%), laparoscopic partial nephrectomy 1 (0.1%), radical nephrectomy 4 (0.5%), and hand-assisted RPN 1 (0.1%). However, in a recently published single-institution study of 6 surgeons performing RPN, the rate of conversion to radical nephrectomy was much higher for ≥ T1b tumors (7.8%) compared to T1a tumors (1.2%) [29].

Progression of Chronic Kidney Disease

Compared to radical nephrectomy, partial nephrectomy for small renal masses has been associated with comparable oncologic outcomes and improved renal function. In our series of RPN cases performed on 46 clinical ≥T1b tumors, there was no significant difference between pre-operative and post-operative serum creatinine or glomerular filtration rate (GFR) [30]. At a median follow-up of 24.3 months, none of the patients progressed to dialysis post-operatively.

To study the effects of surgical-induced CKD after renal surgery, Lane et al. 2015 reviewed their database of 4299 patients who underwent renal surgery at Cleveland Clinic [31]. The authors defined CKD as GFR <60. Within that database, 1113 patients had surgical CKD (defined as development of CKD after surgery), 1237 had medical CKD (defined as already having CKD before surgery), and 1949 had no CKD. They found that following statistical adjustments, the group with surgical CKD continued to have stable renal function post-operatively regardless of the magnitude of the new baseline GFR. When they compared CKD progression (defined as 50% decrease in GFR or need for dialysis) among the groups, the medical CKD group had more rapid progression of CKD compared to the other two groups (i.e., surgical CKD and no CKD). The rates of CKD progression over time for the surgical CKD group were found to be comparable to those of the no CKD group.

In addition, for all new baseline GFR, the surgical CKD group had decreased 5 year CKD progression and all-cause mortality outcomes compared to the medical CKD group. In their analyses, a new baseline GFR <45 was notably associated with increased 5 year CKD progression and all-cause mortality outcomes for both surgical CKD and medical CKD groups. Based on that result, they suggested that for select patients with clinical T1b/T2 tumors, radical nephrectomy may be an appropriate option if the contralateral kidney is normal, if there was no evidence of CKD pre-operatively, and if the anticipated post-operative baseline GFR was >45.

Conclusions

With the increased use of RPN for clinical T1 renal tumors, complications associated with RPN remain low. Some of these complications can be minimized or prevented, especially those associated with positioning. Attention to detail in isolating the renal artery and/or accessory arteries proximally during hilar dissection may decrease the risk of intraoperative hemorrhage from unclamped unrecognized

arterial branches. Post-operative delayed hemorrhage should raise suspicion for a symptomatic pseudoaneurysm or arteriovenous fistula. Management of urine leaks can be done conservatively (e.g., prolonged Foley catheter drainage) or with a minor surgical procedure (e.g., ureteral stent placement, percutaneous drain placement). Concerns for bowel injuries should be addressed at the time of surgery. Most common signs and symptoms of bowel injuries in the post-operative period include abdominal distension and localizing trocar site / abdominal pain. Conversion rates to radical nephrectomy remain low. With regards to progression of CKD after renal surgery, patients who develop CKD after surgery have similar CKD progression and survival outcomes as those who not develop CKD after surgery. Compared to patients with either no CKD or with surgical CKD, those with medical CKD at a risk of developing worsening CKD progression and survival outcomes after renal surgery.

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Robot Assisted Pyeloplasty

46

Iqbal Singh and Ashok K. Hemal

Abstract

Aim: To review the global select data on the current technique, peri-operative outcome and follow up literature and to describe the operative technique of robot assisted pyeloplasty (RAP).

Methods: The published English literature (PubMed™) was searched at length using the key words; robot, robot assisted pyeloplasty, laparoscopy, laparoscopic pyeloplasty and ureteropelvic junction obstruction. The selected studies were then reviewed, followed and scrutinized to determine the current role, outcome and status of robot assisted laparoscopic pyeloplasty.

Results: The search yielded about 30 published series on RAP comprising about 1110 cases with a mean operative time, estimated blood loss, crossing vessel prevalence, hospital stay,peri-operative complication rate and follow up duration of 189 min, 47 ml, 47%, 2.3 days, 6% and 18 months respectively.

Conclusion: The initial peri-operative results and intermediate follow up of cases of repair of the ureteropelvic junction obstruction with robot assisted pyeloplasty appear to be favorable and comparable to that of open pyeloplasty, with emerging good long term outcome follow up data also available. The da-Vinci® surgical robotic system is a promising surgical armamentarium in the hands of the modern day urologist for the minimally invasive definitive surgical management of both primary and secondary ureteropelvic junction obstruction.

Keywords

Robot · Robot assisted pyeloplasty · Laparoscopy · Laparoscopic pyeloplasty and ureteropelvic junction obstruction

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History and Introduction

In 1886, Trendelenburg described the first open surgical repair of a ureteropelvic junction obstruction (UPJO), and the first successful pyeloplasty was performed 5 years later by Kuster in 1891 [1]. Over the next 100 years drastic changes occurred in the pyeloplasty techniques like Heineke-Mickulicz by Fenger, plication of the renal pelvis by Kelly, Finney

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pyloroplasty, Y-V pyeloplasty. Culp and deWeerd introduced the spiral flap in 1951, followed by vertical flap by Scardino and Prince in 1953. Until 25 years ago, the gold standard for UPJO repair was an Anderson–Hynes dismembered pyeloplasty through a flank incision with reported success rates of 95–99% [2]. With the development of minimal access techniques, the treatment options available to the urologist have now broadened significantly. In 1983, Wickham [3] described the percutaneous technique of antegrade pyelolysis. Later in 1986 Badlani et al. [4] described their initial series of "Endopyelotomy" in USA. Later in the same year Inglis and Tolley [5] also described the use of retrograde rigid uretero-renoscopy to relieve strictures causing secondary UPJO and in 1993 McClinton et al. [6] described their series of 49 retrograde balloon dilatation (Endoburst) in 42 patients of UPJO. Later in the same year Chandoke and Clayman [7] described the "Acucise ureteral cutting balloon device" for performing retrograde endopyelotomy. The drawbacks of open surgical pyeloplasty include significant postoperative pain and morbidity mainly on account of the flank incision and delayed convalescence. In an effort to overcome these disadvantages of traditional open pyeloplasty other minimally invasive options such as endopyelotomy and laparoscopic pyeloplasty came into existence.

Open surgical pyeloplasty through retroperitoneal access has traditionally been the reference standard for managing ureteropelvic junction obstruction (UPJO) with reported success rates exceeding 90% [8]. With recent advances and global trends toward a near universal adoption of minimally invasive access surgery for managing UPJO, endopyelotomy and laparoscopic pyeloplasty (LP) came into vogue.

Anderson and Hynes dismembered laparoscopic pyeloplasty using four ports in the pediatric patients was first described by Peters and Retik [9]. Later Sung and Gill in 1999 described the feasibility and efficacy of RALPP in a porcine study using the Zeus™ robotic system [10]. The same authors again compared the efficacy of Zeus™ versus daVinci™ robotic system for robot-assisted laparoscopic pyeloplasty (RALPP) in another porcine model demonstrating a shorter total operating room time (61.4 versus 83.4 min; $P = 0.10$) and anastomotic time (44.7 versus 66.4 min; $P = 0.110$) with the daVinci™ system. During RALPP anastomosis, the total number of suture bites/ureter was 13.0 for the daVinci™ system ($n = 6$) and 10.8 for the Zeus system ($n = 6$); they concluded that the intraoperative technical movements appeared inherently more intuitive with the daVinci system than with the Zeus™ robotic system [11]. Subsequently Lorincz and Mc Lorie described the technical feasibility of RALPP in a porcine study using the Zeus™ robot with acceptable morbidity [12].

Dismembered laparoscopic pyeloplasty (DLP) was first described and reported in the English literature way back in 1993 by Schuessler and coworkers [13]. In the same year Kavoussi et al. [14] and later Janetschek in 1994 [15] also confirmed the safety and efficacy of laparoscopic pyeloplasty. Subsequently the results of laparoscopic pyeloplasty (LP) were found to be comparable to open surgery by other workers [16–18]. This prompted certain workers to rename LP as the new reference standard for managing UPJO [19]. The advantages of LP include shorter convalescence, reduced pain, briefer hospital stays, superior cosmesis, with success rates exceeding 90%. LP has traditionally been confined to the domain of high-volume centers of excellence with skilled laparoscopic surgeons [20]. While LP may also be performed safely, effectively, and efficiently in a cost-efficient manner [21], the main current drawback of LP is the relative difficulty of performing intracorporeal suturing that demands significant training and expertise. However, with the emergence of robot assistance in laparoscopic urology, the daVinci™ robotic system and its three-dimensional vision, tremor filtering, Endowrist™ system with 6 degrees of freedom, reconstructive surgery and intracorporeal suturing have become technically easier [22–24]. Initial cases of robot-assisted laparoscopic pyeloplasty were reported by Graham [25], Guilloneau [26], and Gettman and colleagues [23]. Subsequently several workers have successfully described and reported larger series of robot-assisted laparoscopic pyeloplasty (see Table 46.1).

Table 46.1 The salient features of cases of robot-assisted laparoscopic pyeloplasties that have been reported in the published English literature

Salient features of selected worldwide reported series of "robotic pyeloplasty"								
Author (year)	*N*	Approach	Mean ORT (CT) ST[a]	EBL	CV (%)	HS (D)	Complications	Follow-up (MTH)
Gupta et al. [27]	24	T/P-TM-ADP	125 ± 24, 44 ± 15[a]	38.7	–	2.5	1(PD)	12
Kaouk et al. [28]	10	RP-ADP (1° –4, **2° –6**)	175	50	3 (30)	2	Nil	30 (24–36)
Yanke et al. [37]	29	T/P-RA-ADP	–	–	20 (69)	–	Nil	19 (13–25)
Murphy et al. [38]	15	T/P-RA-ADP	187	30	9 (44)	2.2	Nil	–
Mufarrij et al. [39]	117	1° UPJ, T/PRA-ADP	217 (80–510)	58(10–600)	62 (53)	2.1 (0.8–7)	9(M);4 (m)–(11%)	30 (3–63)
	23	**2° UPJ, TPRA-ADP**	**216 (110–345)**	**68 (10–300)**	**15 (65.2)**	**2.1 (1–3)**	**1(M)–(4.2%)**	**24 (5–51)**
Hemal et al. [40]	**9**	**2° UPJ, TPRA-ADP**	**106 (95–150)**	**72.4 (40–200)**	**2 (22)**	**3.4 (2–5)**	**Nil**	**7.4 (2–15)**
Schwenter et al. [41]	80	1° UPJ, TP RA-ADP	108.3(72–215)	<50	45 (48.9)	4.6 (3–11)	3(RS:1, H:1, U:1)–3.2%	39.1
	12	**2° UPJ, TP RA-ADP**						
Olsen et al. [42]	67	RP(Peds) 8-NDP, 59-RA-ADP	146 (92–300)	–	15 (22.4)	1.5 (1–6)	11(UTI:2, H:2, N:2, DJJ stent:3) 16.4%	12 (0.9–49)
Lee et al. [43]	33	RP(Peds)	219 (133–401)	3 (0–50)	11 (33.3)	2.3 (0.5–6)	1(3%)	10
Weise et al. [44]	31	TP RA-ADP	271 (*76*)	<100	23 (74)	2 (1–3)	Nil	10 (1–31)
Yee et al. [45]	8	TP RA-ADP(Peds)	363 (255–522)	13.1	–	2.4	1 (failed), 1 ileus	14.7
Kutikov et al. [46]	9	TP RA-ADP(Peds)	123	–	0	1.4	Nil	–
Patel et al. [47]	50	RP-ADP	122 (60–330)	40	30	1.1	–	11.7
Palese et al. [48]	35	TP RA-ADP	216.4 ± 52.9	73.9 ± 58.3	10 (28.6)	2.89	1 (failed-nephrectomy)	7.9
Palese et al. [49]	38	TP RA-ADP	225.6 ± 59.3 64.2 ± 14.6*	77.3 ± 55.3	10 (26.3)	2.9 (1.1–13)	4(UTI:1, PN:2, GPS:1)	12.2
Atug et al. [50]	7	TP RA-ADP(Peds)	184 (165–204) 39.5 (30–46)[a]	31.4 (10–50)	–	–	Prolonged drain:2	10.9(2–18)
Atug et al. [32]	8	TP RA-ADP(adult)	275.8 (180–345)	48.6 (10–100)	2 (25)	1.1 (1–2)	Nil	12.3 (4–22)

(continued)

Table 46.1 (continued)

Salient features of selected worldwide reported series of "robotic pyeloplasty"								
Atug et al. [51]	37	1° UPJ, TP RA-ADP	219.4 (130–345)	49.5 (10–200)	16 (43%)	1.1 (1–2)	Nil	13.5 (3–29)
	7	**2° UPJ, TP RA-ADP**	**279.8 (230–414)**	**52.5 (20–100)**	**2 (28%)**	**1.2 (1–3)**	**Nil**	**10.7 (3–20)**
Mendez-Torres et al. [52]	32	RA-ADP(31) Fengerplasty(1)	300 (120–510)	52	14 (44)	1.1 (1–3)	2 (UTI:1, stent migration:1)	8.6 (1.5–16)
Bernie et al. [53]	7	T/P RA-ADP	324	60 (50–100)	4 (57)	2.5 (2–6)	2 (UTI:1, hematuria:1)	10 (5–15)
Gettman et al. [23]	6	TP RA-ADP(4)[a] RA Fengerplasty(2)~	140 (80–215) 70 (40–115)[a] 77.5 (75–80)~	<50	–	4	(0) Nil	–
Gettman et al. [24]	7	1° TP RA-ADP	138.8(80–215)	<50	–	4.7(4–11)	1 (11%) open reop	4.1(1–8)
	2	**2° TP RA-ADP**	62.4 (40–115)*					
Hopf HL et al. [74]	**129**	1° RA-AHDP (117) NDP(12)					5 + 18(Clavien I-IIIb)	8 years
Ener et al. [75]	**14**	1° TP RA-AHDP	150.4 ± 17.2 (115–185)	33.6 (10–60)	10 (55)	2.6 (1–6)	Nil	3–35
Avery et al. [76]	**60**	1° TP RA-ADP (infants)	232(189–275)	–	–	–	7 (11%)	
Trauman [8]	**61**	1° TP RA-ADP	195	–	–	–	1 (1.6%) re-opn 3 temp stenting	64
Erdeljan et al. [78]	**88**	1° TP RA-ADP(85) 2°TP RA-YV Plasty (5)	167.7 ± 43.2 (mean anastomotic time ~41.9 ± 14.1	56.6	–	2.5 ± 0.5	2 Reop 5 major+3 minor	–
Cestari et al. [79]	**55**	TP RA-ADP (19) RP-ADP(36)	–	–	–	–	2 (recurrence)	6
MEAN	**1110**		189	47	45	3.4	6.0	18

Most figures are rounded of to the nearest decimal. 1/2° –denotes primary or secondary UPJ obstruction. CV–denotes crossing vessel *Bold font* denotes **2° UPJO** cases.
RP retroperitoneoscopic, *TP* transperitoneal, *TM* transmesocolic, *RA-AHDP* robotic-assisted Anderson–Hynes dismembered pyeloplasty, *NDP* non-dismembered pyeloplasty, *RAF* robotic-assisted fengerplasty, *Mean suturing time, [a]*ST* suture time, *H* hematuria, *U* urinoma, *RS* restented, *N* nephrostomy, *DJJ* displaced JJ stent, *PD* prolonged drainage, *UTI* urinary tract infection, *PN* pyelonephritis, *GPS* gluteal compartment syndrome, *M* major, *m* minor.

Surgical Technique of Robot-Assisted Laparoscopic Pyeloplasty (RALPP)

Pre-operative Assessment

The diagnosis of ureteropelvic junction obstruction (UPJO) is based on symptomatology and is subsequently confirmed by imaging studies such as computed tomographic (CT) urography or an ultrasound/intravenous urography, which also helps in diagnosing co-existing and secondary pathologies such as renal stones, crossing vessels, and megaureter. A pre-operative assessment of the UPJO with MAG3 renal dynamic scan (nuclear renography) is an essential step as it provides a more objective and definitive assessment of UPJO. It provides a baseline quantification of the pre-operative renal function in terms of both the split and the absolute glomerular filtration rate (GFR) that is essential for follow-up. The renogram also confirms the diagnosis of significant renal outflow tract function.

Indications

Symptomatic patients with evidence of significant outflow tract obstruction as evidenced by serial renal scans and/or worsening obstructive hydronephrosis are the candidates that are most likely in need of some form of pyeloplasty. Patients with large baggy pelvis may in addition need a reduction pyeloplasty in order to ensure a dependent drainage. Patients with equivocal UPJO are best observed and kept on regular follow-up with serial renograms.

Contraindications

Patients with prior major intraabdominal surgery/laparotomy should be excluded from undergoing a transperitoneal laparoscopic/robotic procedure. Patients of UPJO with extensive comorbidity on account of general medical problems and/or cardio-pulmonary insufficiency are those in whom a laparoscopic procedure may serve to be a relative contraindication. Patients of UPJO with small intra-renal pelvis and poorly functioning kidneys($\leq$15%), active urinary tract infection and upper tract urothelial carcinoma should be excluded also be excluded from RALPL.

Consent & Pre-operative Preparation

Once a decision for surgical intervention has been arrived at, patients should be briefed and counseled in detail about all surgical options available for managing (UPJO), including endopyelotomy, laparoscopic pyeloplasty, robotic-assisted laparoscopic pyeloplasty (RLP), and open pyeloplasty. The risks and benefits of each procedure should be also carefully explained to allow the patient to arrive at a decision. The type of repair to be performed is dependent on the size of the pelvis, length of the UPJ stricture, the presence of a crossing vessel, and the degree of renal function. Sterile urine cultures must be obtained prior to surgery. Cystoscopy with retrograde pyelography (RGP) may be performed in select cases of renal outflow obstruction with equivocal findings where the diagnosis of UPJO is in doubt or in case concomitant pathological abnormalities co-exist. For a RLP the surgeon should specifically counsel the patient about possible peri-operative complications, need for stenting, economic cost, expected success rate and need for secondary procedures in case of failure from relief of PUJO, as per surgeon's experience.

In our experience pre-operative placement of a JJ ureteral stent is no longer a necessary step. Preoperatively patients are advised a clear liquid diet for 24 h and a rectal suppository on the night prior to surgery. The procedure is performed under general anesthesia and prophylactic antibiotics. In the opinion of these authors, in confirmed cases the pre-placement of a ureteral stent is no longer required; in case any difficulty is anticipated in locating the ureteropelvic junction, 20 mg of furosemide may be administered intravenously in order to distend the renal pelvis and facilitate its identification intraoperatively. The robot is sterile draped and the console camera is re-calibrated prior to initiating the procedure.

Position & Equipment

Position: A Foley catheter is placed and clamped so as to ensure and confirm easy passage of the JJ stent into the bladder by seeing reflux of urine, when antegrade ureteral stenting is done that is removed later. The patient is positioned with the ipsilateral kidney facing upward in the standard kidney/flank position at an angle of 60° with a supplemental kidney bridge and an axillary roll over a flexed operating table (lateral decubitus position) with adequate back supports. The patient is secured by strapping with a wide surgical tape over a foam pad both at the level of the ipsilateral chest/oam pad in a manner so as to facilitate free movement of the robotic arms.

Equipment: For RALPL, da Vinci Surgical System™ (Intuitive Surgical, Inc., Sunnyvale, CA, USA) should be available and the set up may include the following: (1) Right arm – Monopolar da Vinci Hot Shears/Potts Scissors/Large Needle Driver™, (2) Left arm – da Vinci PK™ (Plasma Kinetic; Gyrus ACMI, Southborough, MA) Dissecting Forceps/da Vinci Fine Tissue Forceps/ Large Needle Driver™, (3) Fourth arm is optional – can be avoided as retraction/stay sutures can be deployed to restrict the number of trocars (an additional 5-mm trocar can be used for liver retraction, (4) Assistant – Stryker Flow 2 suction irrigator™ (Stryker, Kalamazoo, MI), (5) Sutures (Anastomotic suture – 4-0 polyglactin on RB-1 needle).

Surgical Approach

Robot-assisted laparoscopic pyeloplasty can be performed by transperitoneal or retroperitoneal approach. The robot should be brought in from the patients back side for docking it at angle of 60° with the patient's spine so as to prevent robotic instrument arm collision and to maximize its maneuverability.

1. Transperitoneal approach is generally the preferred approach for RALPP. This allows clear visualization of all the anatomical structures with adequate space for optimal access and positioning of the robotic and assistant ports. It is also the preferred approach to repair of UPJO associated with the pelvic ectopic kidney and/or the horse shoe kidney. Transperitoneal access may be used for a robot-assisted laparoscopic pyeloplasty by using either the transmesocolic approach that has also been previously described by us elsewhere [27] or the classical colonic mobilization approach to the UPJ. The transmesocolic approach has the advantage of doing away with colonic mobilization, providing the most direct approach to the UPJ after incising the mesocolon through the relatively avascular transmesocolic window and precluding extensive renal mobilization. It is considered to be safe and feasible in patients with a large prominent hydronephrotic pelvis underlying a thin mesentery and is considered to be a highly effective technique [26]. The use of the transmesocolic approach is generally restricted to a left-sided UPJO, because anatomically the left colic flexure lies superior to the right colic flexure and the left UPJ lies beneath the left colonic mesentery. This approach should be avoided in patient with a high BMI and a thick mesentery. The traditional retrocolic access with mobilization of the colon to approach the UPJ is preferred by us in cases of UPJO associated in the right kidney, with morbid obesity, concomitant renal calculi, accessory renal vessels, retrocaval ureter, and/or prior renal surgery where renal mobilization would be needed.

Retroperitoneal laparoscopic approach on the contrary is the preferred surgical approach to the UPJ in patients with prior repetitive transabdominal intraperitoneal surgery where post-operative adhesions may preclude a safe laparoscopic/robotic intraperitoneal access. Retroperitoneoscopic surgery has the advantage of offering direct early surgical access to the ureteropelvic junction, and in case of any leak or infection the urinoma is contained within the retroperitoneum. The disadvantages of retroperitoneal access include lack of space and technical difficulty of intracorporeal suturing due to instru-

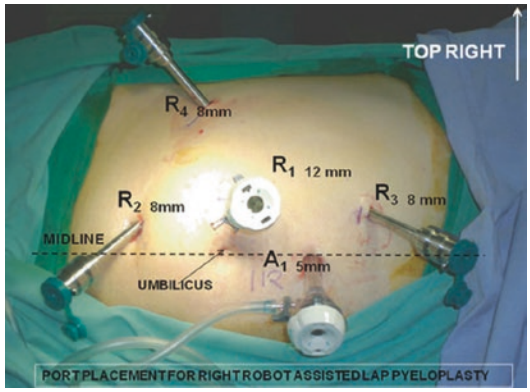

Fig. 46.1 Suggested port placement is depicted for a typical right robot-assisted pyeloplasty where R_1 is the primary 12 mm camera port placed just 2–3 cm lateral to the umbilicus. R_2 and R_3 are the secondary 8 mm robot ports placed about 7–8 cm on either side of the camera port in the same line. R_4 is the fourth robotic arm 8 mm port which is placed in the right iliac fossa. A1 is the assistant 5 mm port for suction which is placed supraumbilically in the midline equidistant from R_1 and R_3. In addition a distance of 7–8 cm should also be maintained in between the port sites to avoid arm collision

ment/port collision/overcrowding. The retrocaval ureter can also be successfully repaired via this approach.

Port Placement: Figure 46.1 shows the port placement that is frequently used by us for a transmesocolic approach. Pneumoperitoneum is established by a Veress needle (Gyrus, ACMI, Inc) at a point just outside the lateral border of the rectus muscle above the umbilicus. Once adequate pneumoperitoneum has been achieved, Veress needle is removed, and the stab incision is extended for placement of a 12 mm camera port. The endoscope is then introduced and the abdomen is inspected for any intraabdominal injury. Two working 8-mm robotic ports are also inserted under direct laparoscopic vision in the ipsilateral midclavicular line on either side of the camera port. In order to avoid any instrument collision between the robotic arms a working distance of about 7–8 cm is maintained with an obtuse docking angle and triangulation of the instruments. One or two additional 5 mm ports are also inserted infraumbilically either in the midline or on the contralateral side for retraction, suction, and suture handling. Alternatively with the four-arm robot (Prograsp™), the fourth robotic trocar may substitute for the additional trocar. After placing the trocars the robot is securely positioned and docked from the back of the patient.

Robot-assisted retroperitoneoscopic pyeloplasty [28]: An incision approximately 1.3 cm long is placed just below and lateral to the tip of the 12th rib. A spherical retroperitoneal balloon trocar PDB™ system (OMSPDB™ balloon 1000 – round shape or a OMSPDBS2™ – kidney shape; Covidien, Autosuture) or (PDB™, US Surgical, Norwalk, CT) is used to dilate and develop the retroperitoneal space. Hasson's convertible trocar blunt tip trocar 12 mm is inserted via this incision, this serves as the primary 12 mm robotic camera port alternatively this may be placed just above the iliac crest. The left and right 8 mm robotic ports are inserted below and parallel to the 12th rib, at the anterior axillary line and at the costovertebral angle, the assistant 5 mm suction port is placed lateral to the camera port. In place of the latter alternatively a fourth port (12 mm) can also be placed anterior to the iliac crest into the ipsilateral retroperitoneal space for the assistant for retraction, suction, or introduction of sutures. The daVinci S™ surgical robot system cart is docked from over the head of patient with a 0 or 30° up lens. The ureter is identified in the retroperitoneum, which is dissected proximally along with its periureteral tissue up to the pelvis and UPJ taking care to preserve any crossing vessels. The area of stenotic UPJ is excised and the ureter is spatulated with the robotic hot scissors. A watertight tension-free ureteropelvic anastomosis is performed over an antegrade JJ stent by using a pair of 4-0 Monocryl™ or Vicryl™ running sutures placed anteriorly and posteriorly in a manner similar to that used for transperitoneal robotic pyeloplasty that are finally tied together.

Excision, Reduction Pyeloplasty, Stenting, and Ureteropyelostomy

RALPP: The robot is wheeled from the patient's back and it is then docked in a manner such that the laparoscope is aligned with the UPJ and robot

(daVinci™ robot comes in at an angle of 15° while the new daVinci-S™ can come straight from the patients back). The colon is reflected at the level of the UPJ. One should avoid dissection of the ureter caudal into the pelvis so as to preserve the periureteral tissues (this is done using a monopolar curved scissors and a Maryland™ fenestrated bipolar forceps or an endowrist™ PK dissector). One should consider placing a stay suture on the pelvis both above and on the proximal ureter just below the UPJ. The renal pelvis is sharply incised and continued anterior and posterior to the UPJ. The ureter is then spatulated for 2–3 cm on its lateral (oriented anterior in flank position) border until it opens up after this dismemberment of the ureter from the pelvis is performed. While handling the UPJ, one should endeavor to make a pyelotomy first and then use the UPJ part of pelvis that will be discarded later as a handle to move the ureter. As far as possible the stenotic UPJ segment should be excised and sent to histopathology as a specimen. The anastomosis starts on the dependent wall beginning at the apex of spatulation using fine monofilament absorbable – usually 10–12 cm long 5-0 Monocryl™ sutures are used to perform a running or an interrupted (less efficient) watertight and tension-free anastomosis. The anastomosis stops at upper end of ureter and the portion of the UPJ stricture and pelvis is then resected and an interrupted suture is placed at the apex. Then second suture on either side of apex stitch is then run along the posterior and anterior rows as described.

The sequential intraoperative steps of robot-assisted laparoscopic pyeloplasty are illustrated in the series of endocamera images in Figs. 46.2, 46.3, 46.4, 46.5, 46.6, 46.7, 46.8, 46.9, 46.10, 46.11, 46.12, and 46.13. A brief 8 min operative video clip demonstrating the salient operative steps of robot-assisted technique of transperitoneal laparoscopic pyeloplasty performed by these authors is also appended to this chapter.

The robotic surgical system arms approach the patient from the back at an angle of 30° cephalad direction; however, with the availability of the new four-arm daVinci-S™ surgical robot it can be set up to directly approach from the back of the patient. The robot is docked in a manner such that the camera port is aligned with the UPJO. If the pelvis is grossly hydronephrotic, a transmesocolic approach is used to expose the pelvis. The basic surgical steps are mimicry of open surgery. The principles followed are (1) preservation of crossing vessels, (2) dismembering the UPJO and excising the narrow portion, (3) spatulating the ureter medially, (4) subtracting the dilated pelvis,

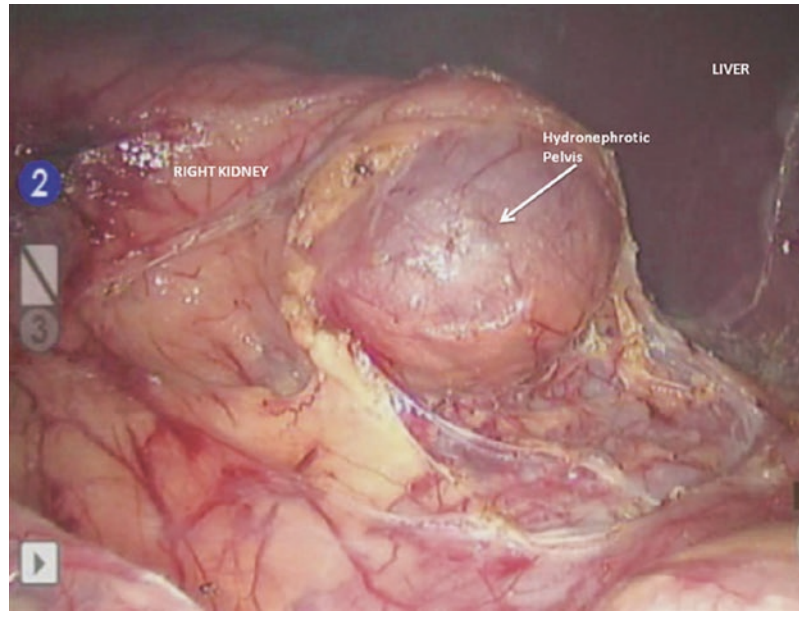

Fig. 46.2 An endocamera view of the hydronephrotic right kidney with a dilated renal pelvis

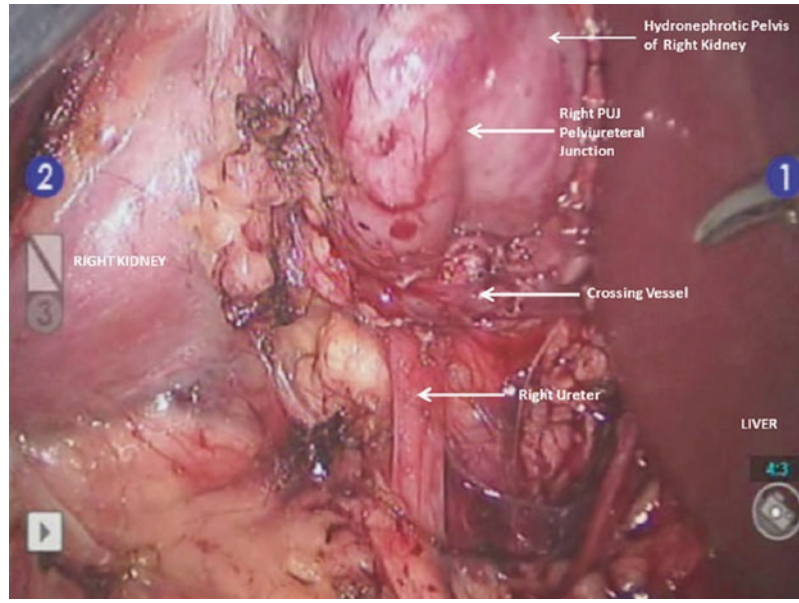

Fig. 46.3 An endocamera view of the dissected right renal hydronephrotic pelvis, the right ureteropelvic junction the right ureter with the crossing vessel at the right ureteropelvic junction

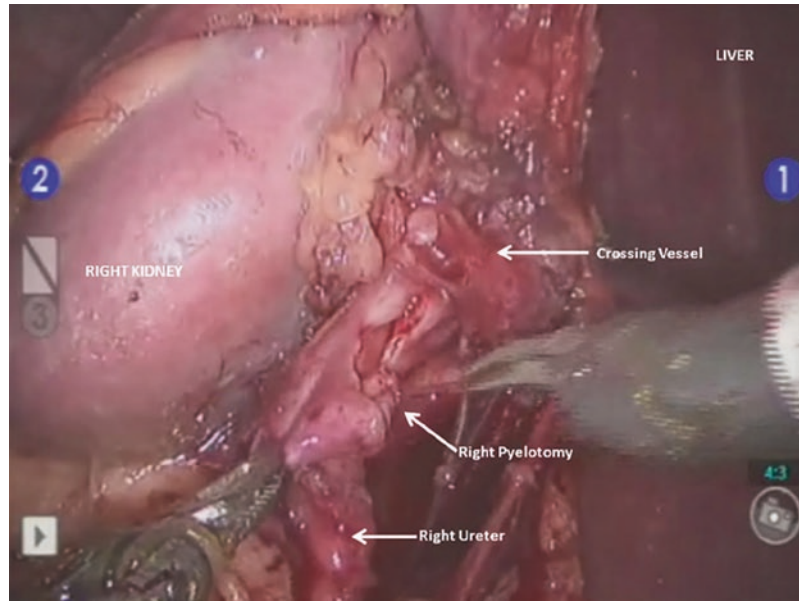

Fig. 46.4 An endocamera view of the redundant pelvis with pyelotomy in preparation for a dismembered Anderson–Hynes reduction pyeloplasty

and (5) creating a watertight-dependent stented ureteropelvic anastomosis.

In the *transmesocolic approach*, the robotic monopolar scissors is used to make an incision, parallel to the mesenteric vessels, through a relatively avascular area in the mesentery overlying the UPJ in a manner so as to avoid injury to any major mesenteric vessel. With a combination of blunt and sharp dissection with the robotic monopolar hot scissors and the robotic bipolar forceps, the UPJ is dissected free from the surrounding soft tissue attachments through the mesenteric window. Excision of the UPJ, reduction pyeloplasty (if indicated), lateral spatulation of the ureter, and a stented anastomosis are performed with robotic assistance. The reduction pyeloplasty is performed by using the robotic hot monopolar robotic scissors and the bipolar forceps in a

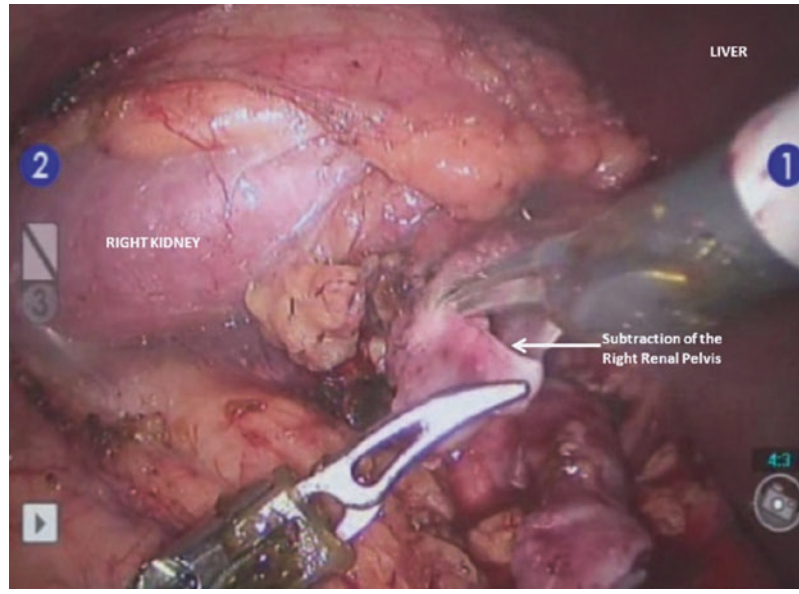

Fig. 46.5 An endocamera view of the subtraction of the redundant pelvis in progress

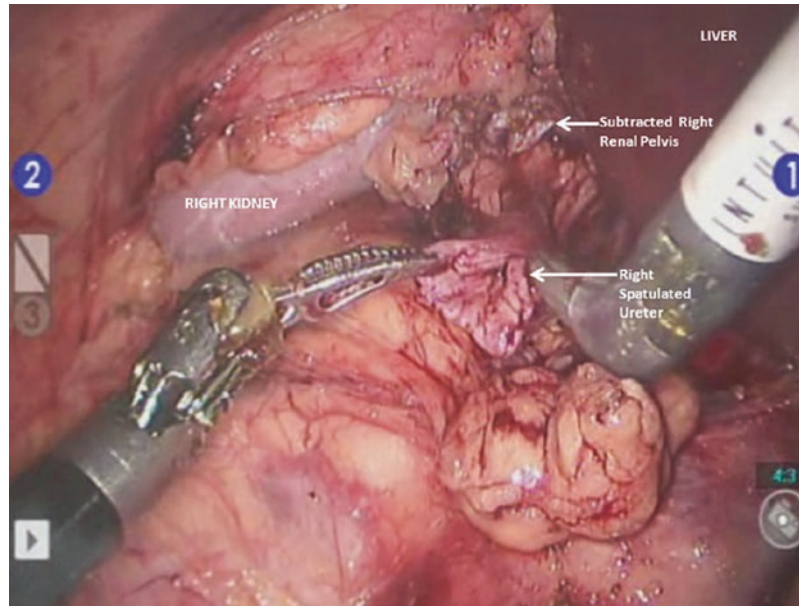

Fig. 46.6 An endocamera view of the subtracted right proximal renal pelvis with the right spatulated ureter fashioned for a dependent anastomosis

manner so as to subtract the redundant pelvis and achieve a proximal residual tapered renal pelvis. The ureteral spatulation is performed by holding the obliquely cut end of the ureter with the robotic bipolar forceps and inserting the robotic hot monopolar scissors and incising it on its lateral aspect for a length of about 1.5 cm. The technique of robot-assisted laparoscopic antegrade stenting has been described by us later in this chapter. After completion of the anastomosis (technique of anastomosis is detailed later in this chapter) the rent in the mesentery is finally closed with a continuous 3-0 vicryl™ sutures.

Under robotic control, by using a combination of blunt and sharp dissection with the right monopolar scissors and a left bipolar PK™ forceps the ipsilateral colon is reflected and retracted medially along the line of Toldt, in order to expose the

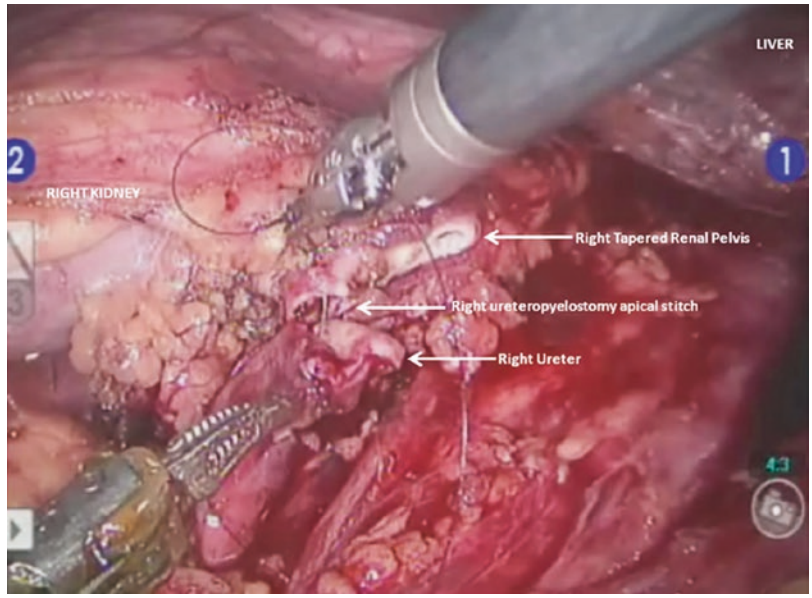

Fig. 46.7 The initiation of the apical stitch for the right ureteropyelostomy

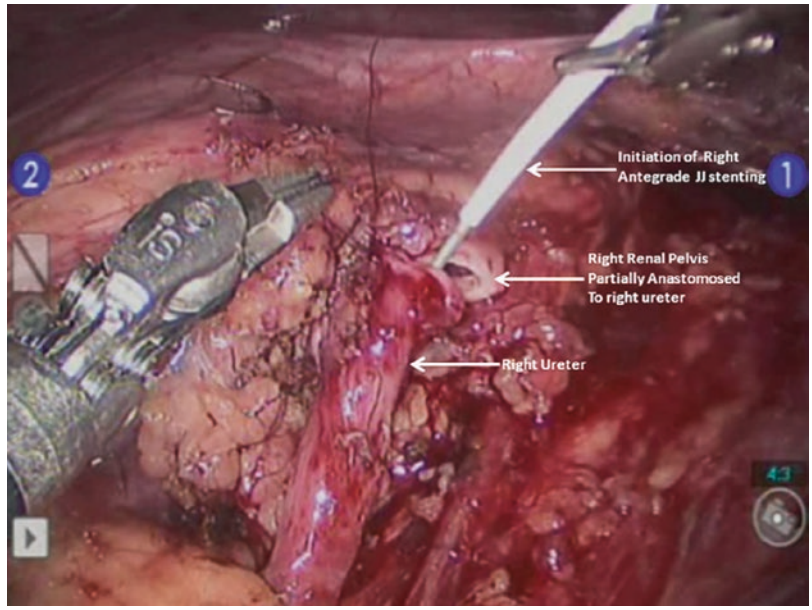

Fig. 46.8 An endocamera view of the partially re-anastomosed right renal pelvis with antegrade placement of the JJ stent in progress

kidney. In the robot-assisted technique of *Retroperitoneoscopic pyeloplasty*, the kidney is approached posteriorly; the psoas muscle is identified with the ureter running anteriorly that is followed till the inferior pole of the kidney and the renal hilum. The renal hilum area is dissected identifying the renal vein, artery, and the renal pelvis. By using the landmark provided by the psoas muscle and the gonadal vein on the right (may be clipped if needed) the ureteropelvic junction is exposed down to the proximal ureter.

After placing stay sutures on the pelvis, the stenotic PUJ segment is transected, excised, and the divided ureteral end is spatulated on the lateral side for a length of 1 cm, and any redundant pelvis is also excised. A JJ ureteral stent preloaded on a guide wire is inserted with its floppy tip facing proximally in an antegrade fashion

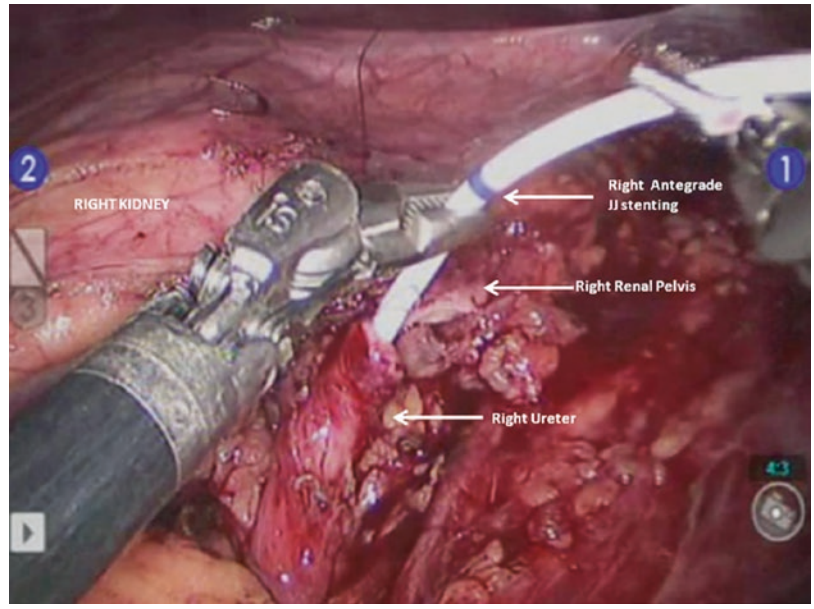

Fig. 46.9 An endocamera view of the partially re-anastomosed right renal pelvis with antegrade placement of the JJ stent in progress

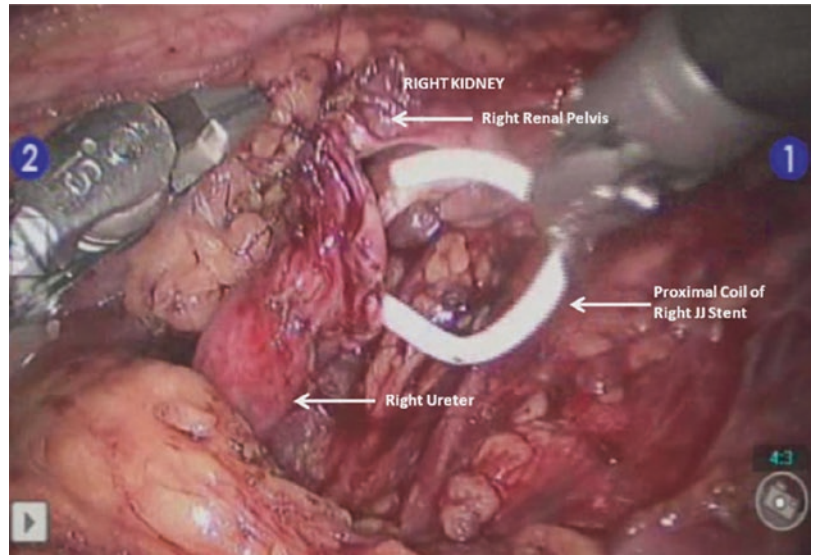

Fig. 46.10 An endocamera view of the partially re-anastomosed right renal pelvis with antegrade placement of the JJ stent in progress

through one of the robotic/costovertebral area ports and is manipulated by the robotic graspers and guided under vision distally into the spatulated ureter first, and the guide wire is then disengaged taking care to grasp the stent with the robotic forceps while the guide wire is withdrawn out via the port by the assistant. The proximal coil of the JJ stent is then manipulated into the tapered renal pelvis. In case any anterior crossing vessels are encountered all attempts are made to preserve them as far as possible and these are either repositioned posterior to the spatulated ureteropelvic anastomosis or the pelvis is simply translocated anterior to it.

For dilated baggy renal pelvis the excess of the endopelvic tissue is excised and by using 5-0 Monocryl® (Ethicon~poliglicaperone) sutures a *Dismembered Anderson–Hynes pyeloplasty* is performed in the usual manner. The initial throw of the same suture is used to secure the spatulated ureter to the dependent part of the renal pelvis, and subsequently two additional running sutures are

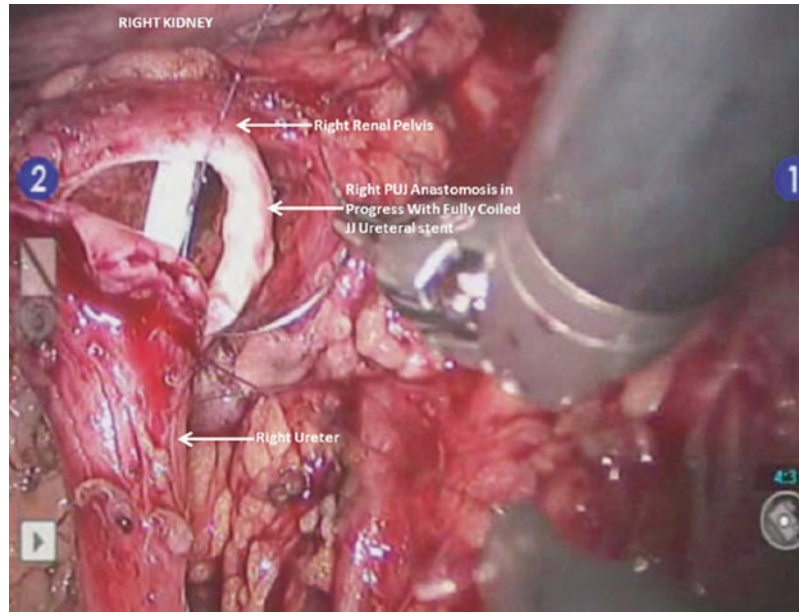

Fig. 46.11 An endocamera view of the right anastomotic pyeloplasty in progress over a JJ stent

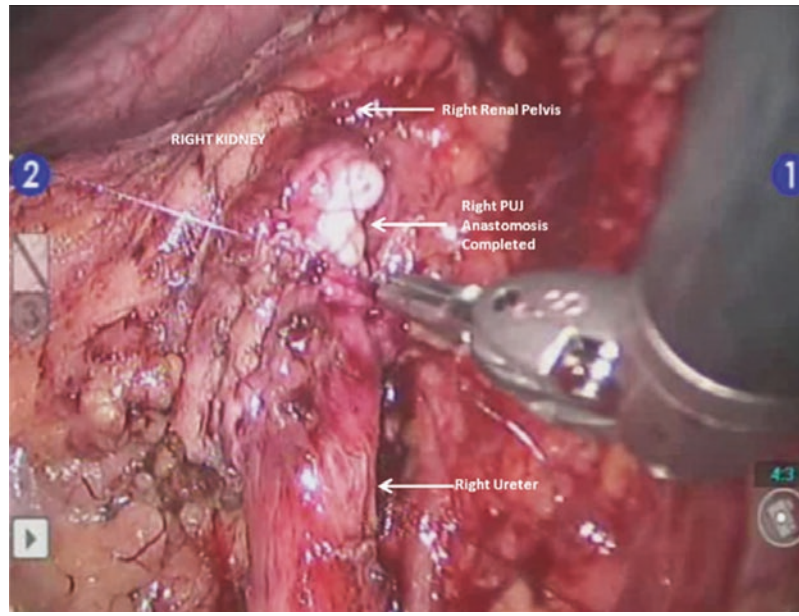

Fig. 46.12 An endocamera view of the completed right re-anastomotic pyeloplasty

placed for completing the anterior and posterior wall of the anastomosis. After completing on one side of the anastomosis, a double-J ureteral stent is placed with a pre-loaded straight guide wire in an antegrade manner inserted through one of the assistant ports, manipulated distally into the ureter and proximally into the pelvis and the rest of the anastomosis is then completed in a sequential manner. The renal pelvis is repositioned behind the renal vessels, and Gerota's fascia is closed using 2-0 Vicryl® (Ethicon~polygalactin) sutures. Alternatively the suture may be prepared by tying two 5-0 monocryl™ (Ethicon~poliglicaperone) sutures (dyed and undyed) to make a single suture with two needles and the rest of the anastomosis is similarly completed in two hemi-circles. After completing the anastomosis the kidney is retroperitonealized by replacing the colon and sutur-

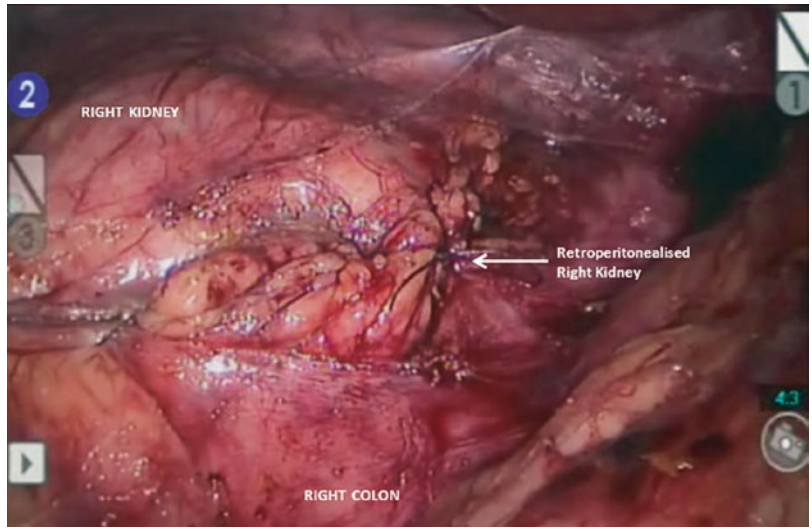

Fig. 46.13 An endocamera view of the fully retroperitonealized right kidney at the termination of the procedure

ing back the peritoneal fold with continuous 3-0 vicryl sutures and the robotic needle driver.

For patients with focal stenosis/without any crossing vessels, in whom a robot-assisted *Non-dismembered Fengerplasty* is intended, a 2 cm longitudinal incision is usually made through the stenotic area straddling the UPJO, extending to about a centimeter on either side of the stenotic area between two stay sutures placed medially and laterally, the incision is then closed transversely using 4-0 Vicryl™ interrupted sutures.

For UPJO associated with a high insertion of the ureter a *Foley Y-V plasty* is preferred where in a "V"-shaped flap is made on the pelvis with its base positioned on the medial aspect of the pelvis and its apex positioned at the UPJ. This is then extended laterally on to the proximal ureter across the UPJ stricture so that the apex of the flap lies alongside the ureterotomy. The anastomosis is then performed between the ureterotomy and the anterior wall of the pelvic flap.

In cases of UPJO associated with multiple and/or extensive proximal ureteric strictures, *Davis intubated ureterotomy* is the preferred surgical approach where in the stricture is incised and is allowed to heal by re-epithelialization over a JJ ureteral stent.

The robot is undocked and a JP® drain (optional) is placed in the perinephric space under laparoscopic vision brought out through a separate stab incision in the lower quadrant. In our opinion the placement of a perinephric drain in the presence of a JJ stent especially in the setting of transmesocolic approach to repair of the primary UPJO is not necessary in a majority of such cases, unless otherwise indicated in its own merit. However, we do advocate the placement of a drain in cases of repair of a secondary UPJO/salvage pyeloplasty due to higher risks of a possible urinary leak or breakdown of the anastomosis. In our opinion the placement of a drain may also be indicated in the setting of a retrocolic approach where colonic mobilization has been performed and also in the situation where extensive renal mobilization may have been performed. The bowel is repositioned and secured with a 2-0 Vicryl™ sutures. The ports are removed and closed at the fascia level using 0 Vicryl™ suture(s). The incisions are closed with 4-0 Monocryl® sutures and sealed with Dermabond™ (2-octyl cyanoacrylate-Ethicon, Inc., Somerville, NJ) adhesive.

Outcome & Follow-Up: In recent appraisal of a series of 24 cases of transmesocolic robot-assisted pyeloplasty reported from a single center, by Gupta and coworkers [27] these authors successfully reported on the safety and feasibility of the transmesocolic robot-assisted procedure with comparable operative times (mean ORT: 125.33 ± 23.48 and suturing time:43.58 ± 15.15 min), a mean hospital stay of 2.5 days and satisfactory long-term outcomes at a

mean follow-up of 12 months. These authors had placed a drain in all their cases without any major complication being reported. One of their patients had fever with prolonged drainage due to a misplaced stent that later required an additional procedure for its cystoscopic repositioning.

Managing Concomitant Surgical Pathologies

1. *Crossing Vessels*: In case(s) of UPJO associated with a crossing vessel(s) every attempt should be made to preserve them. This is done by either dismembering the pelvis and doing a posterior translocation of the crossing vessel and performing the pyeloplasty anterior to it or alternatively by a vascular relocation procedure that involves superior translocation and fixation of the crossing vessel proximal to the UPJO (*Hellstrom's procedure*). The robotic Hellstrom technique of vascular relocation involves mobilization of the crossing vessels and pexing the perivascular tissue to the Gerota's fascia with or without the perinephric fat [29]. Alternatively the crossing vein/artery is mobilized and then the dilated pelvis is folded over it using 5-0 sutures of Vicryl®.
2. *Concomitant renal/pelvic stones*: A concomitant robot-assisted laparoscopic pyelolithotomy can be easily accomplished at the time of the pyelotomy prior to the pyeloplasty. This has also been previously described by these authors [30, 31] and others. *Robot-Assisted Laparoscopic Technique of Extended Pyelolithotomy*: After exposing the renal pelvis a 'V' shaped incision (pyelotomy) is made away from the UPJ or for larger stones this incision can be extended into the intrarenal pelvis (extended pyelotomy). The stones are then extracted from the pelvis and/or the calyces by using the robotic Prograsp™ device. Alternatively a flexible cystoscope/ureterorenoscope device can also be introduced from one of the port sites to retrieve some of the otherwise inaccessible calyceal stone(s) by using a combination of one or more of the following; flushing, helical nitinol stone extractor or holmium laser lithotripsy. The retrieved stones can be placed into an Endocatch™-10 mm (Covidien Autosuture) bag which can be removed later through the 12 mm assistant port. The pyeloplasty is then performed in the usual manner. The pyelotomy can then be closed after a reduction pyeloplasty intracorporeally over a JJ stent placed in an antegrade manner by a running suture as described above in the robot-assisted technique of laparoscopic pyeloplasty. According to these authors [29] transperitoneal stone surgery was safe as it was not associated with any adverse events like fever, peritonitis and prolonged ileus. Concomitant management of renal pelvic stones during a robotic-assisted laparoscopic pyeloplasty has also been described by Atug et al. [32] who had reported a 100% success rate without any delayed complications in eight of their patients with UPJO and nephrolithiasis.
3. *Secondary ureteric stricture(s)/Periureteral granuloma*: Robotic-assisted laparoscopic surgery facilitates the dissection, excision and repair of secondary ureteral strictures. In our experience it is also well suited to the surgical management of periureteral granulomas that can be successfully managed by excision and a stented ureteropyelostomy. We have successfully performed a robot-assisted transperitoneal laparoscopic ureteropyelostomy in two such cases of UPJO due to post-SWL/post-URS periureteral granuloma.

Robotic-Assisted Laparoscopic Surgical Technique (Excision Ureteropyelostomy): Patient position and port placement are similar as for a right-sided pyeloplasty. Pure laparoscopy may be performed to take down some of the adhesions using the laparoscopic scissors and electrocautery. After docking the robot, the right colon is reflected medially and any more adhesions are taken down. Dissection is then continued down to the inferior vena cava (IVC) up to the point where the right gonadal vein was identified as it drained into the IVC. The right gonadal vein was mobilized and divided between Hem-o-Lock™ clips.

After dissecting down to the psoas muscle the ureter can be more easily defined and followed more proximally until the periureteral calcified mass is seen to be intimately associated with the proximal ureter. The dilated renal pelvis is identified and located. The calcified mass and the proximal ureter are then meticulously dissected free from surrounding structure and are subsequently excised en bloc. The distal ureter is mobilized along with the renal pelvis, spatulated and stented (antegrade manner) with a 8.2 × 26 double-J ureteral stent in order to ensure a tension-free and watertight ureteropyelostomy by placing 5-0 Monocryl™ sutures in a running fashion as described above earlier in this chapter. Periureteral and perirenal fat is then replaced over the anastomosis and secured with additional 5-0 Monocryl™ sutures. The specimen is then retrieved via an Endocatch™ bag and a closed-suction Jackson Pratt™ drain is inserted to drain the right pericolic gutter at the termination of the procedure.

4. *Retrocaval ureter:* The Robot-assisted laparoscopic technique as well as the purely laparoscopic technique of excision and successful repair of the retrocaval ureter has been described below which has been previously reported and described by us before elsewhere [33, 34].

Robot-Assisted Laparoscopic Technique of Repair of Retrocaval ureter: The patient is positioned in a manner similar to that for a right transperitoneal pyeloplasty. Port position – A Veres needle is used to create a pneumoperitoneum, and 12 mm port is inserted for the camera at the level of the umbilicus at the lateral border of rectus abdominis muscle. After inspecting the peritoneum, two robotic 8 mm ports are inserted under vision beneath the costal margin in the mid-clavicular line and the other three fingers below the anterior superior iliac spine. Another assistant 5 mm port is inserted 5 cm below the camera port for retraction and suction. The robot is then docked. The right colon is mobilized medially to provide exposure to the right retroperitoneal structures. By a combination of blunt and sharp dissection the right renal pelvis, inferior vena cava, right gonadal vein, right ureter and duodenum are identified. The right renal pelvis is mobilized and right ureterolysis is performed till the level of its disappearance superiorly below the inferior vena cava. The renal pelvis is divided at the ureteropelvic junction and the retrocaval ureteric segment is transposed anterior to the inferior vena cava. A stented (stent with the wire is introduced in an antegrade manner via the 5 mm port, which is grasped with a robotic needle driver, manipulated into the ureter, and passed down into the bladder) pyeloureterostomy is performed with 5-0 monocryl™ sutures in a manner similar to that described by us earlier in this chapter under the section of robot-assisted laparoscopic pyeloplasty. A JP™ drain is inserted via the 5-mm port and the robot is undocked. The ports are then closed at the facial level with 1-0 vicryl™ sutures.

5. Giant Hydronephrosis and Nephroptosis: Concomitant laparoscopic nephroplication and nephropexy along with laparoscopic repair of the UPJO has also been previously described and reported in the literature by these authors [35].

Robot-Assisted Laparoscopic Technique Nephrolysis and Nephropexy: For UPJO associated with significant nephroptosis robot-assisted laparoscopic nephropexy can also be performed that has been described by others [36]. The patient position and port placement are similar to as described by us previously in this chapter under the section for the robot-assisted transperitoneal technique of pyeloplasty. The colon is mobilized along the avascular line of "Toldt" and subsequently the proximal ureter, ureteropelvic junction, and the renal pelvis are also mobilized. The hepatorenal ligament is also divided in order to completely mobilize the kidney and be able to place the nephropexy fixation sutures as cranial as possible. In such cases after performing the dismemberment of the renal pelvis and transposing the pelviureteral junction anterior to the crossing vessels, complete nephrolysis is initially performed by using the right robotic

monopolar scissors and a left robotic bipolar forceps for dissection in the perinephric space. A robot-assisted laparoscopic transperitoneal dismembered reduction pyeloplasty is performed in the usual manner as described above. The nephropexy is then performed using robotic assistance by using a 3-0 Vicryl sutures on a CT-1 needle, with three to four sutures placed through the renal capsule, that are tacked to the fascia of muscles in the bed of the kidney, over the quadratus lumborum muscle at the level of the hepatorenal ligament. Subsequently secondary suture(s) are also placed through the posterior aspect of the lower pole of the kidney which is transfixed and to the fascia of the psoas major muscle. The procedure is terminated by placing a JP™ drain in the perinephric space.

Follow-up: The Foleys catheter and the drain are generally removed at 48 h following surgery. When drainage is less than 30 ml/12 h the drain can be removed and the patient can generally be discharged with an indwelling bladder catheter that is removed 2–3 days later. Alternatively the bladder catheter can be removed first and in case the flank drainage is less than 30 ml/12 h the drain can be removed and the patient is discharged. Stent removal is generally done at 6–8 weeks. Subsequently they are followed up with a diuretic renogram initially at 3 and later at 6 months following surgery and annually thereafter provided the initial renogram(s) is/are satisfactory. A successful result is defined by a combination of patent ureteropelvic junction on the nuclear renogram and a subjective improvement in the patient analog pain scores.

Discussion

Table 46.1 shows the salient features of major published series of robot-assisted laparoscopic pyeloplasty reported and published in the English literature till date [11, 28, 32, 37–53]. Muffraiz et al., have reported one of the largest series of RALPL (140 cases) of RALPL demonstrating the overall safety and durability of robot-assisted repair of both the primary and the secondary UPJO [39].

Approach to RALPL (Transperitoneal or Retroperitoneal): Most RALPLs have been commonly performed via transperitoneal access [32, 37–41, 44–53]. The advantages of the transperitoneal approach include availability of an adequate and considerably larger working space and a greater degree of familiarity with the traditional anatomical landmarks. The transmesocolic approach is anatomically and surgically well suited to lend itself to a robot-assisted laparoscopic repair of the left PUJO. Some workers have also described and reported on the safety and feasibility of robot-assisted retroperitoneoscopic pyeloplasty [28, 42, 43]. The advantages of the retroperitoneoscopic approach include direct access to the UPJO; confinement of any possible urinary leak (urinoma) to the retroperitoneum; and the avoidance of peritoneal transgression, ileus, and minimal chance of bowel injury. Problems of the retroperitoneal approach include limited working space, difficult intracorporeal suturing due to lack of space, difficulty in identifying lower polar anterior crossing vessels, overcrowding of the ports, instrument collision, and the need to position the robot more cephalad than usual [28].

In the opinion of these authors the retroperitoneal approach should be reserved for patients of UPJO with prior multiple transperitoneal surgeries. However, we feel that until more data emerge and long-term follow-up is available the retroperitoneoscopic (robot-assisted laparoscopic) approach should not be the preferred initial approach to repair the UPJO laparoscopically.

Peri-operative Data/Outcomes

1. *ORT*: A review of some major selected published reports on robot-assisted laparoscopic pyeloplasty reveals that the mean ORT is about 207 (60–510) min and depending upon the level of expertise in experienced hands the robot/console time (CT) appears to be just above an hour (50–76) min. The ORT varied depending on whether it was a primary or a secondary (redo) pyeloplasty and whether a transperitoneal or retroperitoneal access was

employed. Some workers have shown that the ORT may be longer in cases of secondary UPJ repair following prior failed pyeloplasty [51]. The initial surgeons learning curve may also impact the overall operating room times [53]. Moreover the ORT may vary depending on whether the duration of cystoscopy, retrograde uretero-pyelography, and/or stent placement was included or not. Most reported studies depicted in Table 46.1 have included these as a part of the overall operative duration. Additional procedures such as stone removal may prolong the ORT [45]. Nevertheless RALPL [17] has decreased the difficulty of intracorporeal suturing and considerably shortened the prolonged ORTs and the steep learning curve that were associated with laparoscopic pyeloplasty [16, 20, 23, 41, 54, 55]. Schwenter et al. reported (in their single center 5-year experience with 92 cases of Robot-assisted AHD pyeloplasty) a mean anastomotic suturing time of 24.8 min [41]. Patel et al. also reported a mean anastomotic (suturing) time of 20 min (mean overall ORT of 91 min) in latter 10 of their 51 cases of RALPL [47]. This also signifies the fact that the operative duration of RALPL, including the suturing time tends to significantly decrease with increasing experience.

2. *Crossing Vessels*: The presence of crossing vessels is commonly known to be associated with the occurrence of UPJO and these may also influence the treatment of UPJO. A review of the selected published data on major cases of RALPL as shown in Table 46.1 reveals that crossing vessels were present in association with UPJO in almost half the cases, with a mean of 45(0–69)%. In our opinion as far as possible anterior crossing vessels should be preserved. In case these interfere with the anastomosis despite mobilization of the ureter and renal pelvis, it is better to transpose the ureter [28].
3. *Estimated Blood Loss (EBL)*: A comparison of the published series depicted in Table 46.1 shows that the mean estimated blood loss in RALPL has been about 50 (0–600) ml [23, 24, 28, 32, 38–41, 43–45, 47–53]. Studies have shown that the EBLs are comparable to pyeloplasty performed conventionally/with robotic assistance, without any statistically significant difference [23, 44].
4. *Length of Hospital Stay (LOS)*: The average length of hospitalization according to major selected series of RALPL depicted in Table 46.1 is about 3.2 (1–11) days; however, in most of these series the duration of hospitalization was about 2 days [28, 32, 38–49, 51–53]. Studies have shown that while the LOS appears to be similar following conventional pyeloplasty/RALPL, the general trend of LOS appeared to relatively shorter with the RALPL cases [44, 53].
5. *Peri-operative Complications*: A review of the published literature on RALPL suggests that the average perioperative complication rate is about 6(0–16)%. Majority of these reported complications were minor related to stent displacement, hematuria, ileus, prolonged drainage, and urinary tract infections [39, 40, 45, 49, 50, 52, 53]. Others have also reported the occurrence of other complications like urinoma, pyelonephritis, compartment syndrome, and nephrectomy too [24, 39, 48, 49]. In one of the largest series by Muffariz et al. comprising 140 cases of UPJO managed by RALPL, the authors reported a 7.1% major and 2.9% minor complication rate [39].

Functional Outcomes

The mean follow-up of the selected series of RALPL as depicted in Table 46.1 is about 14.9 (1–51) months. Bernie et al. reported no difference in the outcomes following laparoscopic pyeloplasty performed with/without robotic assistance [53]. Weise et al. also reported a virtually similar short-term outcome of RALPL versus conventional laparoscopic pyeloplasty [44]. In a single center 5-year experience with 92 cases of RALPL that included 12 cases of secondary UPJO the authors reported a 100% patency rate (96.7 success rate) without any conversions, and appreciable cosmetic outcomes, during a mean follow-up of 39.1 months

[41]. Patel et al. also reported a success rate of 100% in their 51 cases of RALPL during a mean follow-up of 11.7 months [47]. Open surgery continues to be the reference standard against which all current minimally invasive surgical technique(s) for the management of UPJO are likely to be compared against. The published global literature on robot-assisted laparoscopic pyeloplasty has been reviewed previously in detail by us elsewhere [56].

Secondary Pyeloplasty

Redo pyeloplasty is an overall technically difficult and challenging procedure [57]. RALPL [40, 51] and/or laparoscopic pyeloplasty [58] may also be feasible for the repair of select patients of secondary UPJO due to prior failed open/endoscopic repair of primary UPJO. The challenges associated with secondary pyeloplasty are chiefly on account of adhesions and variable reactionary peripelvic fibrosis due to urinary leakage, bleeding, or excessive use of thermal energy (diathermy) in the region of the UPJ following its primary repair (endopyelotomy/open). These workers have shown that the ORT may be significantly greater by about an hour in such cases of secondary pyeloplasty. According to Hemal and colleagues [40] the actual benefits perceived to be associated with robot-assisted laparoscopic redo pyeloplasty were the relative ease of performing a thorough dissection, superior delineation of the prior scarred tissue, and better preservation of the periureteral sheath encompassing the blood supply to the ureter, with a clean and precise tailoring of ureteral and pelvic flaps for suturing a leakproof anastomosis. It is also prudent to be cautious of potential adhesions that may exist between the UPJO especially on the right side while attempting a redo right-sided UPJO repair, due to its anatomical proximity to the inferior vena cava. While secondary UPJO repair appears to be more prone to failure, RALPL appears to be a good modality even for these complicated cases in select situations, with the overall success rate being even higher (91.6%) in at least some series [41] than that has been reported in the past with pure laparoscopic pyeloplasty (80%) [57].

Robot-Assisted Laparoscopic Pyeloplasty in the Children

Robot-assisted laparoscopic pyeloplasty for UPJO has also been successfully performed both via the retroperitoneal and via the transperitoneal approach in the pediatric population, by several workers [42, 43, 45, 46, 50] attesting its feasibility and safety in the children. Though the laparoscopic technique to repair of the UPJO appeared to be technically a highly demanding procedure in the children, the availability of robotic assistance and equipment has considerably decreased the operating time due to the relative ease of intracorporeal suturing. In our opinion the transperitoneal approach should be the initial preferred approach for a robot-assisted laparoscopic pyeloplasty as it may be better suited in the infants and younger children. Due to intraoperative space constraints, we feel that the retroperitoneal approach to repair of the UPJO should be preferred only in the older children with prior history of transperitoneal surgery.

Advantages of Robot Assistance

The advantages of robot-assisted laparoscopic pyeloplasty over pure laparoscopic pyeloplasty include motion scaling, tremor obliteration, three-dimensional stereoscopic vision, and greatly simplified precise suturing of the pelvis. Other workers [23] have also shown that RALPL is associated with overall shorter anastomotic and ORT. Depending on the center of excellence, the degree of expertise achieved and the economic viability of an institution affording a daVinci robot™ the laparoscopic pyeloplasty with or without robot assistance remains an effective and viable option for most cases of UPJO [16, 59] that may even encompass to include patients with renal congenital anomaly [60], presence of a lower pole crossing vessel, failed previous endopyelotomy [40, 51, 57], or even concomitant renal cal-

culi [32, 39]. One of the notable benefits of robot assistance is relative ease of spatulating the ureter, refashioning the pelvic flaps, and the suturing the ureteropelvic junction anastomosis. RALPL for UPJO complicated with concomitant stones, secondary UPJO, anomalous/horseshoe/ectopic kidney/duplex pelvis has also been shown to be feasible, safe, and effective, with durable success rates [61]. According to Leveillee et al. long-term data are now emerging for RALPP that appears to be a feasible and effective alternative to laparoscopy for reconstructive procedures of the ureter [62]. According to Peters et al. [63] the question whether RALPP is better than open surgery would be difficult to prove given overall success rate of above 95% in most series of open and laparoscopic pyeloplasty, as based on the current experience and ease of intracorporeal suturing with RALPP it may be not easy reverting to laparoscopic or open pyeloplasty especially in high-volume institutions where a robotic system may be currently available. In recent meta-analysis review by Bragga et al. [64] the authors suggested the take home message that RALPP appeared to be equivalent to traditional laparoscopic pyeloplasty with regard to operative time, complications, and success rates. However, Novara et al. [65] in an editorial comment to this meta-analysis also commented that strength of this meta-analysis was weak given the fact that the quality of their data, was quite poor, due to lack of any randomized trials and few published reports. Fornara et al. [66] also in an editorial comment to this meta-analysis suggested the actual advantage(s) lay probably for the surgeons who were laparoscopically naïve as RALPP, reduces the learning curve, and makes it simpler to learn the robotic surgical technique versus purely laparoscopic technique. RALPL is believed to be highly effective for managing PUJO, as it is associated with lower morbidity, faster recovery, and overall a durable success rate [67].

Advances

Recently Desai and colleagues have described and reported that their maiden case of a scar-less single-port transperitoneal laparoscopic pyeloplasty was performed by using a triport inserted through a single umbilical incision and a 2 mm sub-costal needlescopic port without any extra-umbilical incision(s). Their reported ORT, EBL, and LOS were 2.7 h, 50 cc, and 2 days, respectively [68]. Subsequently they also reported on two cases of bilateral simultaneous AHDP in bilateral primary UPJO that were performed after a pre-placed JJ ureteral stent, by using the same novel single-access multichannel tri-port (R-port™, Advanced Surgical Concepts, Dublin, Ireland) enabling a scar-less surgery through a single obscured infraumbilical incision [69]. Another multichannel port also available for similar single-port procedures includes the Uni-X™ port (Pnavel Systems, Morganville, NJ, USA). However, though the single-port transumbilical laparoscopy or embryonic natural orifice transumbilical endoscopic surgery (E-NOTES) appears to be encouraging, according to Canes and colleagues, these were plagued with the problems of triangulation, difficult retraction, instrument crowding, restricted vision, and patient limitations [70]. Robot-assisted laparoscopic pyeloplasty has also been successfully described with a transperitoneal approach without isthmusectomy, as a safe and feasible procedure in the management of UPJO in patients with anomalous or horseshoe kidneys [60]. Recently concurrent robot assisted laparoscopic bilateral pyeloplasties in a group of five children have also been described in the literature [71].

In a recent publication by Hemal and colleagues [72] while comparing the outcomes of RALPL (30 patients) versus pure laparoscopic pyeloplasty (30 patients) for UPJO concluded that RALPL was associated with more rapid dissection, reconstruction, and faster intracorporeal suturing with finer sutures with antegrade JJ stenting and shorter ORT though the long-term success rates were equivalent. Further, technical advances and improvements in the technique and instrumentation are likely to expand the entire spectrum of surgery including the way the future laparoscopic ablative and advanced reconstructive urological procedures such as these are likely to be performed. In future flexible (elephant trunk technology based) roof top, magnetic or minia-

turized robotic systems may soon occupy the modern operating room.

Shah & colleagues [73] recently published their data on the feasibility and efficiency of using unidirectional barbed suture's safety, at mean follow-up of 6.8 months for the reconstructive part of their urological procedures (including 9 RALPL cases) in which the authors demonstrated that they did not encounter any complications of urinary leakage, stone formation or fistula or any clinical evidence of urinary tract obstruction due to the use of the barbed suture.

Hopf and colleagues [74] recently published their long term data in a series of 129 patients undergoing RALPL for the correction of UPJO demonstrating a successful outcome in 125/129 (96.9%), with an 8-year failure free survival of 91.5% which was 96.3% when considering only stented pyeloplasties [74]. Ener et al. [75] in their series of 18 patients with RALPL demonstrated a success rate of 100% without conversion to open surgery and without any complication.

In a recently published multi-centre data on largest robotic pyeloplasty series in infants till date by Avery et al. [76] in 60 infants undergoing RALPL the authors demonstrated a mean surgical time of 3 h 52 min (SD ± 43 min) a 91% success rate for reduction or resolution of hydronephrosis, and seven (11%) intra-operative or immediate post-operative complication rate. Trauman [77] and colleagues in a 5 year long follow up data on 61 patients undergoing RALPL, demonstrated a 98% success rate without any conversion and with 1 patient undergoing open redo-pyeloplasty due to recurrent stenosis.

In another large series of 88 patients undergoing RALPL, Erdeljan et al. [78] compared the surgical outcomes between experienced and trainee surgeons, demonstrated a success rate of 94% with short(164 min) operative times and was safe and effective in achieving similar long-term results and that robot-assisted surgery could also be safely transitioned even to surgical trainee.

Recently Cestari et al. [79] in a tertiary care centre compared the feasibility of retroperitoneal vs transperitoneal RALPP and concluded that RALPP performed either retroperitoneally or transperitoneally were both surgically feasible, reproducible for the satisfactory treatment of UPJO.

Complications of RALPL

Although rare, intra-operative complication scan occur in ≤2% patients [39, 80], the combined risk of major and minor complications may occur in <6% of patients undergoing RALPL. However some authors have documented an increased risk of Clavien grade > 3 complications in obese men (BMI > 30 kg/m^2) undergoing RALPL [81]. Complications may include but may not be necessarily limited to the following:

(a) **Hemorrhage: The mean estimated b**lood loss following RALPL has been generally around 50–100 ml with the need for a blood transfusion being felt in <2% of patients. Troublesome bleeding can partly be due to unrecognized crossing vessels which according to literature may be there in up to 38–71% of UPJO and 20% of normal kidneys [82, 83].
(b) **Urine Leak**: Uncommonly uretero-pelvic anastomosis may leak urine from 24 h to many weeks following RALPL, this may require prolonged placement of drain in situ/stenting/foleys catheter to facilitate proper decompression of the urinary tract to promote closure of the leak.
(c) **Sepsis: Patients may develop certain** signs or symptoms of infection after RALPL (fever, drainage, redness around port site incisions, urinary frequency/dysuria, pain).
(d) **Recurrent Renal Outflow tract Obstruction**: While symptomatic relief from obstruction occurs in up to 95% patients, nevertheless RALPL may be associated with a <5–10% risk of recurrent obstruction. This may necessitate laser endopyelotomy to "incise" the fibros scar tissue from within the ureter.
(e) Chronic Persistent Renal Pain: Although rare, obstruction may persist which may be associated with chronic pain, which may not

relent, despite relief from renal outflow tract obstruction. Chronic pain medications or stenting may be of limited use and may rarely warrant nephrectomy.

(f) Adjacent Organ Injury: Although extremely rare inadvertent injury to the adjacent organs including colon, bowel, vascular structures, nerves, muscles, spleen, liver, pancreas and gallbladder may occur during RALPL instrument manipulation/changes which may require additional damage control surgery.

(g) **Incisional Hernia**: Due to numerous port site wounds associated with RALPL it is possible that some patients may develop hernias at these sites, however the same can be minimized by meticulous closure of the robotic port site incisions.

(h) **Inadvertent Nephrectomy**: Rarely excessive bleeding, or surprise detection of tumor within the kidney (undetected on preoperative imaging tests) may compel a nephrectomy via the robotic approach or by conversion to open surgery.

(i) **Conversion to Open Surgery**: Rarely due to occurrence of complications or due to non-progressive dissection of robotic surgery, conversion to open surgery may be required, resulting in a larger surgical open incision and longer convalescence.

Conclusion

A review of the recent selected series from the published English literature (Pubmed™) reveals that currently more than 670 robot-assisted laparoscopic pyeloplasties have been successfully performed world-wide over the past 8 years. This testifies to the overall safety and efficacy of RALPL as a minimally invasive procedure. The short-term results appear to be similar as compared to those achieved with conventional laparoscopic pyeloplasty. The notable advantage of RALPL over laparoscopic pyeloplasty appears to be on account of the relative ease in acquiring skills needed for intracorporeal suturing, that is greatly simplified. The concomitant advantage of tremor-free meticulous dissection, precise suturing, and superior stereoscopic three-dimensional vision also contributes to the overall excellent results achieved following RALPL.

In keeping with the initial high current cost of the robot/equipment and consumables, RALPL apparently remains a costly procedure that outweighs the cost of standard laparoscopic pyeloplasty. The potential cost benefits of RALPL and long-term benefits remain to be ascertained, and this remains an area of ongoing concern.

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Robotic Surgery for Urolithiasis

47

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Abstract

In last few decades there has been a paradigm shift in management options for urolithiasis ranging from open surgery to endourology followed by laparoscopy and robotics. The use of robotic assistance for urolithiasis is a natural extension of this combination of need for open surgery and reconstruction of the pelvi-calyceal system following stone extraction. Robot assisted laparoscopy has been demonstrated to be a safe option for partial staghorn or isolated large renal pelvic stones, especially in ectopic or anolomous kidneys after previously failed endourological procedures and also for ureteric stones. Robotic surgery for urolithiasis is technically feasible and efficacious in specific situations. It allows the advantages on open surgery in conjunction with a minimally invasive approach.

Keywords

Robot · Stones · Kidney · Ureter · Prostate
Laparoscopy

The management of urolithiasis is one of the success stories of minimal invasive advancements in urology. This has been the result of improvements in technology and techniques that have included extra-corporeal lithotriptors, miniaturized scopes, energy sources and stone retrieval devices. These improvements have been reflected in the AUA guidelines for the management of urolithiasis, which now recommend one or the other of these minimal invasive procedures as the first line treatment for all varieties of stones. However, open stone surgery remains one of the treatment modalities in most situations. This is due to the limitations of every minimal invasive technique and the less than perfect results possible even with combination therapies. Further, in certain situations, open stone surgery may even be the treatment modality of choice due to the poor outcomes expected with minimal invasive techniques [1].

In last few decades there has been a paradigm shift in management options for urololithiasis ranging from open surgery to endourology followed by laparoscopy and robotics [2]. Robot assisted laparoscopic surgery has become the minimal invasive modality of choice for a large

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number of reconstructive urology procedures where open surgery was the mainstay of management. This has been most evident in radical prostatectomy for prostate cancer and pyeloplasty for ureteropelvic junction obstruction [3, 4]. In both these procedures, it has enabled precise reconstruction with all the benefits of minimal invasive surgery. The use of robotic assistance for urolithiasis is a natural extension of this combination of need for open surgery and reconstruction of the pelvi-calyceal system following stone extraction. Robot assisted laparoscopy has been demonstrated to be a safe option for partial staghorn or isolated large renal pelvic stones, especially in ectopic or anolomous kidneys after previously failed endourological procedures [5, 6].

In this chapter we review the current indications, techniques and published literature on the use of robotic surgery for the management of urolithiasis.

Indications

The common indications for robotic assistance in urolithiasis are given in Table 47.1.

Renal Calculi with Uretero-Pelvic Junction Obstruction

The most common indication for the use of robotic surgery in the management of urolithiasis is in patients with a concomitant uretero-pelvic junction obstruction (UPJO). Ideal management of such patients requires a simultaneous stone removal and repair of the obstructed UPJ. Endoscopic treatments have less than optimal results in these cases. In a recent review, Eden concluded that the results of balloon dilatation and endopyelotomy techniques for the management of UPJO are about 15–20% inferior to open surgery while those of laparoscopic or robotic surgery match the open surgery outcomes [7]. The poor results of endopyelotomy have led to the search for alternative methods for management of renal stones in kidneys with a UPJO.

Agarwal et al. [8] recently described a combination of percutaneous nephrolithotomy (PCNL) and laparoscopic pyeloplasty for these cases. Two of their patients had failed a previous endopyelotomy. While they managed to execute both procedures simultaneously in 8 of their 10 patients, they needed to change positions between stone removal and pyeloplasty

Table 47.1 Indications for robotic assistance in urolithiasis surgery

Category	Procedure	Indication
Reconstructive procedures with stone removal	Pyeloplasty with pyelolithotomy	UPJ obstruction with secondary stone
	Ureteric reimplantation with stone extraction	Megaureter with stones
	Ureteropyelostomy with pyelolithotomy	Duplex PCS with UPJ obstruction in lower moiety with secondary stone
Stone related features	Extended pyelolithotomy	Large stone/partial staghorn
	Ureterolithotomy	Impacted large ureteric stone
Kidney related features	Pyelolithotomy	Ectopic kidney/Anomlous kidneys
	Nephrectomy/partial nephrectomy	Non functioning kidney
	Nephrolithotomy	Stone in Calyceal diverticulum
	Anatrophic Nephrolithotomy	Complete staghorn
Patient related features	Pyelolithotomy, extended pyelolithotomy	Pediatric patient
Simultaneous management of co-existing pathology	Simple prostatectomy with cystolithotomy	Benign prostatic hyperplasia with vesical stone
	Radical prostatectomy with cystolithotomy	Carcinoma prostate with vesical stone

and had significant operative times. Srivastava et al. [9] described their experience of combined laparoscopic pyelolithotomy and pyeloplasty in a cohort of 20 patients. They achieved complete stone clearance in 75% patients with the remaining achieving clearance with the aid of ancillary procedures. Nambirajan et al. [10] described a wide range of laparoscopic procedures in the management of renal calculi. Their series of 18 cases included patients who required a simultaneous pyeloplasty, partial nephrectomy or extraction of stones in a diverticulum. Other authors have reported similarly good success rates using laparoscopy for the simultaneous management of renal calculi and uretero-pelvic junction obstruction [11, 12].

Robotic assistance has proven to be of significant advantage in the management of UPJO [3]. It naturally follows that it may also be beneficial in the management of concurrent UPJO and stones. Atug et al. [13] reported the first series of eight cases undergoing simultaneous robotic pyeloplasty and pyelolithotomy. All cases had a retrograde catheter placed in the renal pelvis over a guidewire and this was used for the subsequent placement of a ureteric stent at the end of the procedure. Stone localization was achieved using a flexible nephroscope and all stones were retrieved intact without fragmentation. Stone extraction resulted in a mean prolongation of the surgery by 1 h. They achieved 100% stone clearance with no significant immediate or long-term complications at a mean follow-up of over 1 year.

Large/Staghorn Renal Calculi

Large renal calculi can be managed well using PCNL. A number of these stones are composed of calcium compounds, making them relatively hard. The bulk of the stones as well as their composition can often result in significantly long operative times with the possibility of residual calculi. Over a third of patients with large staghorn stones or with grossly dilated systems may have residual calculi following PCNL [14]. The large bulk may also preclude complete clearance in one session and require additional sessions of PCNL or ancillary procedures. A single open/laparoscopic/robotic procedure may allow the removal of an intact stone without fragmentation, thus minimizing the possibility of residual fragments and the need for extended or multiple procedures in these cases [15]. Badani et al. [16] described the use of robotic surgery in the management of patients with large partial or complete staghorn calculi. In 13 patients who underwent robotic extended pyelolithotomy, 12 had complete clearance while one patient with a complete staghorn had residual calculi. The authors concluded that robotic extended pyelolithotomy offered a useful one-time minimally invasive option for the management of patients with partial staghorn calculi. This is supported by more recent data on staghorn stones [17] and gas-containing renal stones [18, 19]. One of these patients underwent a transmesocolic procedure, robotic extended pyelolithtomy, for a 6.5 cm pelvic stone.

Data regarding robotic-assistance for complete staghorn stones is sparse. Sotelo et al. [20] reported robotic surgery in two patients with staghorn stones with mean size of 8 cm with complete clearance and concluded that more experience is required to use this modality for such stones. Recently, there are reports of anatrophic nephrolithotomy with reduction in stone burden by more than 90% [21, 22]. King et al. [21] report the outcomes of this procedure in 7 patients using warm ischemia by clamping the renal vessels. The mean warm ischemia time was 35 ± 7 min. Ghani et al. [22] used ice slush renal hypothermia for 3 staghorn stones with a mean total stone volume 12887.67 mm^3. Intracorporeal temaperature was maintained at less than 9 °C. Mean console time was 167 min. Two patients had residual calculi. Sood et al. [23] demonstrated a new technique for improved delineation of the avascular plane by using Near-infrared flouroscence image guidance for anatrophic nephrolithtomy by using ice slush in porcine models. They concluded that this

approach may help in the future for anatrophic nephrolithotomy. There are also report of bilateral simultaneous robotic pyelolithotomy for large >6 cm renal stones [24]. Recently Swearingen et al. [25] retrospectively analyzed data of robotic pyeloplithtomy and nephrolithotomy in 27 patients from 5 centres with a mean stone size of 2.74 cm (0.8–5.8). The mean operative time and console time was 182 min and 128 min, respectively, with complete stone free rate 95%. Robotic pyelolithotmy allows removal of the intact stone without renal parenchymal injury and minimizes nephron loss.

Pediatric Renal Calculi

Renal calculi in children continue to pose a management dilemma. Despite the miniaturization of nephroscopes, it is often difficult to obtain satisfactory per-cutaneous renal access and complete clearance. Children require general anesthesia for most surgical procedures and also for extracorporeal shock wave lithotripsy (ESWL). This makes it imperative that a procedure offering maximum possibility of a one-time clearance be chosen for the management of their calculi. In cases where open surgery would be considered a reasonable option to obtain these goals, laparoscopy or robotic assistance presents a feasible minimally invasive alternative [26].

Casale et al. [27] presented their experience of laparoscopic pyelolithotomy in eight children. The indication included failed per cutaneous access, failed ESWL and stone burden greater than 2.5 cm^2. They were able to successfully remove the calculi in all eight children and all were retained pain-free.

The benefits seen on pure laparoscopy have been duplicated with robotic assistance. Lee et al. [28] reported their results in five children who underwent robotic assisted pyelolithotomy and highlight the advantages of this procedure. Four of their five patients had a cystine staghorn calculus and all four had failed previous minimally invasive procedures (PCNL/ESWL). The fifth patient had a concomitant UPJ obstruction and was thus ideally suited for this procedure. The authors were successful in removing the stones in four of the five children and failed in one due to the inability of their electrohydraulic lithotripter to break the cystine stone. One patient had a residual calculus that required a subsequent ESWL.

Ectopic Kidneys

Stones in ectopic kidney are often difficult to access percutaneously. This is particularly true for kidneys located in the pelvis or close to the midline where a posterior access is not feasible. These kidneys per-se are predisposed to stone formation and have poorer clearance rates following ESWL when compared with normally placed kidneys [29]. Such ectopic kidneys are generally malrotated with the pelvis pointing anteriorly. A transperitoneal laparoscopic/robotic approach affords direct access to these pelvises, making pyelolithotomy a relatively straightforward procedure. These kidneys may have coexisting UPJO with stones which can be managed simultaneously [30].

Stones in Renal Diverticula

Stones located in renal diverticula are often small but respond poorly to ESWL. The narrow neck of the diverticulum makes clearance unlikely and PCNL with ablation of the lining of the diverticulum is often considered a more efficacious procedure [31]. In the upper pole, these diverticula are often located in the anterior renal cortex and this location makes a percutaneous access difficult and fraught with potential complications. Laparoscopy with the use of intraoperative ultrasound guidance allows a direct access to these diverticular stones with the possibility of thermal ablation of the diverticular cavity. Nambirajan et al. [10] described their successful use of laparoscopy in the management of such cases. Torricelli et al. [32] reported the successful management of anterior middle calyceal diverticular stone sized 2 × 1 cm with previously failed two flexible ureteroscopies by robot-assisted approach, followed by fulguration of the diverticulum mucosa.

Calculi with Associated Anomalies

Apart from the uretero-pelvic junction, another common site of obstruction in the urinary system which may be associated with calculi is the uretero-vesical junction. Congenital megaureters with calculi require simultaneous stone removal and ureteric reimplant with or without tailoring of the redundant ureter. These patients form another indication for the use of robotic surgery [33]. In patients with congenitally anomalous kidneys such as horseshoe kidneys or crossed fused/unfused ectopic kidneys with stones, endourological procedures for stone management are usually difficult and the only options may be open or laparoscopic/robotic approach [34].

Non-functioning Segments/Kidneys

Long-standing/impacted calculi may result in a non-functioning segment of the kidney or at times make the entire renal unit non-functional. If a decision is taken to perform a partial or complete nephrectomy, robotic assistance offers a minimal invasive option to open surgery. This is particularly true for partial nephrectomy where robotic assistance enhances the ability to perform closure of the opened pelvi-calyceal system and renal parenchyma. The advantage of laparoscopy in such circumstances has been previously demonstrated [7].

Ureterolithotomy

According to the AUA guidelines statement 17, patients with ureteric stones who have previously failed shock wave lithotripsy or urerteroscopy can be offered PCNL or laparoscopic or robotic ureterolithotomy [35]. Dogra et al. [36] demonstrated the feasibility of robot assisted ureterolithotomy in stones larger than 2 cm, impacted in the lower ureter. The authors suggested that the ergonomics and short operative time were advantages of the robotic approach as compared to laparoscopy.

Cystolithotomy

Bladder stones can be treated robotically along with simple or radical prostatectomy in patients with benign prostatic hyperplasia or prostate cancer. Stones are retrieved usually after prostatectomy before reconstruction [37, 38].. In case of large bladder stones, the bladder neck may need to be widened for large stones and require a subsequent bladder neck reconstruction [38].

Operative Setup

Retrograde Catheter Placement

Pre-placement of an open ended ureteric access catheter is an optional step practiced at a number of centers. In all cases except those where a nephrectomy is being planned, the patient is placed in a lithotomy position for the insertion of the ureteric catheter into the renal pelvis. A Foley's type catheter is placed in the bladder and the ureteric catheter is secured to this bladder catheter using a suture. Both catheters are kept within the sterile surgical field for intraoperative access. The bladder catheter is kept on continuous drainage.

The ureteric catheter aids in identification of the ureter and pelvis and may be useful during the placement of a ureteric stent. In case the ureteric access catheter is being placed, we do not recommend the placement of a ureteric stent at this stage of the procedure since this hinders stone extraction and the stent may get displaced during stone removal.

Our practice, however, is to proceed without this initial step. We place a Foley catheter into the bladder and clamp the outflow. This allows the bladder to distend with urine. When the JJ ureteric stent is placed intra-operatively, reflux of urine from the lower end of the stent as it enters the urine-filled bladder confirms correct positioning.

Patient Positioning

The patient position varies with the location of the kidney of interest. The following description will be for the more common normally located kidneys with stones or upper ureteric stones. The patient is placed in a 60° lateral decubitus position with the ipsilateral side up. The lower leg is

flexed while the upper leg is kept extended. The kidney bridge is not raised. The upper shoulder is kept at 90° to the torso and the elbow flexed into a neutral position. All pressure points are padded with particular care being taken at the axilla and elbow.

The robot is docked over the back of the patient and is parked almost perpendicular to the table at the level of the umbilicus. Two monitors are used for the assistants, one cranial and one caudal to the surgical cart on the same side as the cart. The assistant stands on the side opposite to the docked robot, in a position similar to that used during robotic pyeloplasty and is described in another chapter. The anesthesiology equipment remains at the head of the patient. In patients with a pelvic kidney or for lower ureteric stones, the patient position mimics that used during a radical prostatectomy with a Trendelenburg tilt of only about 30°. In all cases, an orogastric or nasogastric tube is placed at the beginning of the procedure to empty the stomach and minimize chances of injury. This tube can be removed at the end of the procedure.

Trocar Configuration

Trocar placement is almost similar to that for a robotic pyeloplasty except for the assistant port which should be 12 mm for stone retrieval or insertion of an Endocatch® device. Pneumoperitoneum is created using a Veress® needle at the junction of the lateral and middle thirds of the line joining the anterior superior iliac spine and the umbilicus. This point is subsequently used for an 8 mm trocar for one of the robotic arms.

After the pneumoperitoneum has been created, the primary 12 mm camera port is placed lateral to the umbilicus. One robotic-arm trocar is placed at the site of the Veress® needle insertion while another is placed lateral to the rectus cranial to the umbilicus. The assistant's port is 12 mm in size and is usually sited in the midline periumbilically or on the contralateral side. For right sided surgeries, an additional liver retraction 5 mm port may be needed in the angle between the rib-cage and the xiphoid process.

While using a four-arm robot, certain tricks aid in avoiding robotic arm collision and optimizing port placements. The patient is maintained in a 60–75° decubitus position and the operating table is lowered to its minimum height. The inferior-flexion of the table is maximized to open up the operating space and the 4th arm port is inserted laterally in the lower quadrant. Further, while using the four-arm set up, the camera arm set-up joint must be maneuvered to the side opposite the fourth arm.

For pelvic kidneys or for lower ureterolithotomy, the trocar placement for the robotic arms and the camera are similar to those for a radical prostatectomy. The assistant's port is placed on the right side, 2 cm above and medial to the anterior superior iliac spine.

Instrumentation List

The basic instruments required for this surgery are given in Table 47.2 below.

Additional instrumentation is required for the stone retrieval. This consists of:

1. Flexible nephroscopes
2. Stone removal forceps and Nitinol N® baskets
3. Intracorporeal Lithotripter
4. Nephroscopy vision cart
5. C-arm fluoroscope
6. Laparoscopic ultrasound probe

Table 47.2 Instrumentation required

Surgeon		Assistant
Right arm	Left arm	1. Suction-irrigator 2. Blunt tip grasper 3. Needle driver 4. Laparoscopic scissors
1. Hot shears (monopolar curved scissors) 2. Needle driver 3. Permanent cautery hook 4. Prograsp® forceps (optional: For holding stones)	1. Maryland bipolar forceps 2. Large needle driver	

Step-by-Step Technique: Pyelolithotomy/Pyeloplasty

Step 1: Kidney Exposure: Colon Mobilization

0° or 30° down lens.
Right arm: Hook electrocautery/Monopolar scissors.
Left arm: Maryland grasper.
4th arm (if used): Prograsp® forceps.

The colon is mobilized by making an incision along the line of Toldt. The incision is carried from the cranial-most attachment down to the level of the pelvic brim to allow a generous mobilization and minimize the possibility of an inadvertent injury. This incision can be made using either the hook electrocautery or the monopolar scissors.

Trans-Mesocolic Approach

For patients with left sided surgery and a thin mesentery, a trans-mesocolic approach may also be attempted by creating a window through the mesocolon overlying the pelvis. However this is recommended only if the stone retrieval is anticipated to be simple since the limited exposure does not allow extensive manipulation within the kidney.

Step 2: Pelvis Exposure, Retraction and Pyelotomy

30° lens.
Right arm: Monopolar scissors.
Left arm: Maryland grasper.

The pelvis can be identified by either following the ureter upto the point of its insertion or the gonadal vein cranially. If a ureteric catheter has been pre-placed, it may also be used to identify the ureter/pelvis. At times, in cases with previously scarred tissue, pelvis identification may be aided by distending it with saline or a colored dye through the ureteric catheter. Another alternative is to administer 20 mg of Furosemide intravenously. This distends the pelvis with urine making it easier to identify. Once the pelvis is identified, it is carefully mobilized on all sides using a combination of blunt and sharp dissection. The lower pole of the kidney may also need to be mobilized. During mobilization of the upper anterior surface of the pelvis, care must be taken not to injure the renal vessels that lie in close proximity. Complete pelvis mobilization aids in subsequent lithotomy and also allows identification of any aberrant vasculature that may need to be treated, particularly in cases with a simultaneous UPJO. The posterior surface of the pelvis needs special mobilization right upto the sinus since an extension of the pyelotomy may be required in cases with large calculi.

The pyelotomy is made using the scissors-without electrocautery-on the posterior surface of the pelvis is a manner similar to that made in an open pyelotomy. The ends of the 'smile' incision point towards the upper and lower calyx respectively with the curve of the smile facing the UPJ. This minimizes the risk of an uretro-pelvic avulsion and permits extension of the incision into the calyx for an extended pyelolithotomy if required.

Step 3: Stone Extraction

30° lens.
Right arm: Maryland grasper.
Left arm: Prograsp® forceps/Large Needle driver.
Assistant: Flexible/rigid nephroscope, stone graspers, stone basket.

If the stone lies in the renal pelvis, the simplest method of removal is to grasp it directly with the robotic Maryland® bipolar forceps. In order to avoid using an extra instrument, the Maryland® bipolar forceps previously used in the left arm can be moved to the right arm and a needle driver can be used in the left arm to hold down the posterior lip of the opened pelvis and expose its interior. The anterior lip of the pelvis is held up by the previously placed hitch stitch. Once the stone is visible, it can be brought out by the right arm grasper. At times, the assistant may be able

to use a sturdier laparoscopic stone grasper to remove the stone.

If the stones lie in the calyces and are not readily visible in the pelvis, a flexible nephroscope needs to be used. It is helpful if the assistant is facile in the use of these instruments. Otherwise the console surgeon will need to scrub and do the patient side manipulation. Another assistant will then be required to handle the console since both the robotic arms and the flexible nephroscope may require simultaneous manipulation. The most common technique of using the nephroscope is through the cranial robotic port after de-docking the robotic arm from this port. This port generally allows the most direct access into the pelvis. Inserting the nephroscope through the rubber seal of the port helps maintain the pneumoperitoneum and simultaneous robotic vision and assistance with the caudal robotic instrument can be achieved. The assistant may have to provide continuous suction of the nephroscope irrigation fluid through his port. The pyelotomy is kept open using the hitch stitch anteriorly and the instrument in the caudal robotic arm posteriorly. The nephroscope is gently advanced into the pelvis under direct visual guidance of the robotic camera. Once inside the pelvis, vision is obtained through the nephroscope camera itself and all the calyces can generally be inspected. Small stones may be retrieved intact using nephroscopic graspers or stone baskets. Larger stones may need intracorporeal fragmentation using any of the available energy sources. Pneumatic lithotripters, electrohydraulic generators and the holmium laser have all been used without complications in these cases.

If a flexible nephroscope is not available, a rigid nephroscope may also be used in a similar fashion. However this has limited intra-renal maneuverability and may be associated with a greater risk of bleeding from trauma during manipulation [39].

Small stones may be removed intact through the nephroscope or through the 12 mm assistant port. For larger stones, a specimen bag is used to keep the stones secure inside the abdomen till the end of the procedure. Intraoperative fluoroscopy is generally difficult due to the presence of the robotic cart. It is therefore advisable to have an exact count and localization of the stones before beginning surgery. If there are serious doubts about residual calculi, intra-operative laparoscopic ultrasound probes may be used to localize the stone without removing the robot [40]. In desperate situations, the robot may need to be de-docked to allow fluoroscopy and then re-docked to complete the procedure.

Once the stones have been removed, the pelvicalyceal system is flushed with saline to wash out any gravel or debris. If the cranial robotic arm had been de-docked for nephroscopy, it is re-docked and the needle driver is moved to the right arm while the Maryland® grasper is returned to the left arm.

We prefer to place the JJ ureteric stent in an antegrade fashion by inserting a flexible guide wire through the cranial assistant port and threading the stent over it. An alternative technique is to place the guide wire through a 16G Venflon® directly pierced through the abdominal wall in line with the pelvis and the ureter [41]. Another option is to retain the ureteric access catheter instead of the stent and remove it in the post-operative period. However, this is fairly uncomfortable for the patient and is the least favored approach (Figs. 47.1 and 47.2).

Step 4: Pyeloplasty/Pyelotomy Closure

30° lens.
Right arm: Needle driver.
Left arm: Maryland grasper/Needle driver.

If a pyeloplasty is required, it is performed after the stone retrieval has been completed. The technique of pyeloplasty has been described elsewhere in this book and is similar for these cases. In case a pyeloplasty is not required, the pyelotomy is carefully closed using running or interrupted 5-0 Monocryl® or Vicryl® sutures. In children, 6-0 Poliglecaprone sutures on small needles may provide more precise approximation. The hitch stitch, if placed, is released and the pelvis may be wrapped in the peri-renal fat to minimize scarring/adhesions. A drain may be left by placing it through either the caudal robotic

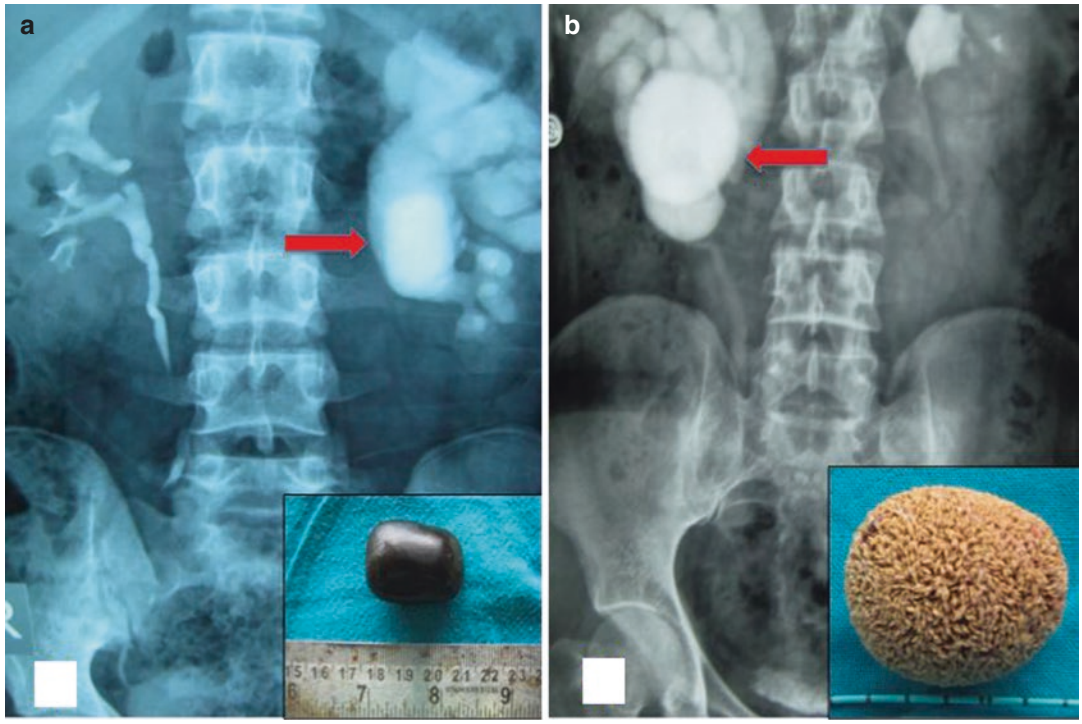

Fig. 47.1 (**a**) IVU (intravenous urogram) depicting left UPJO (ureteropelvic junction obstruction) with secondary stone. (**b**) IVU depicting right UPJO with secondary stones (inset: Retrieved calculus)

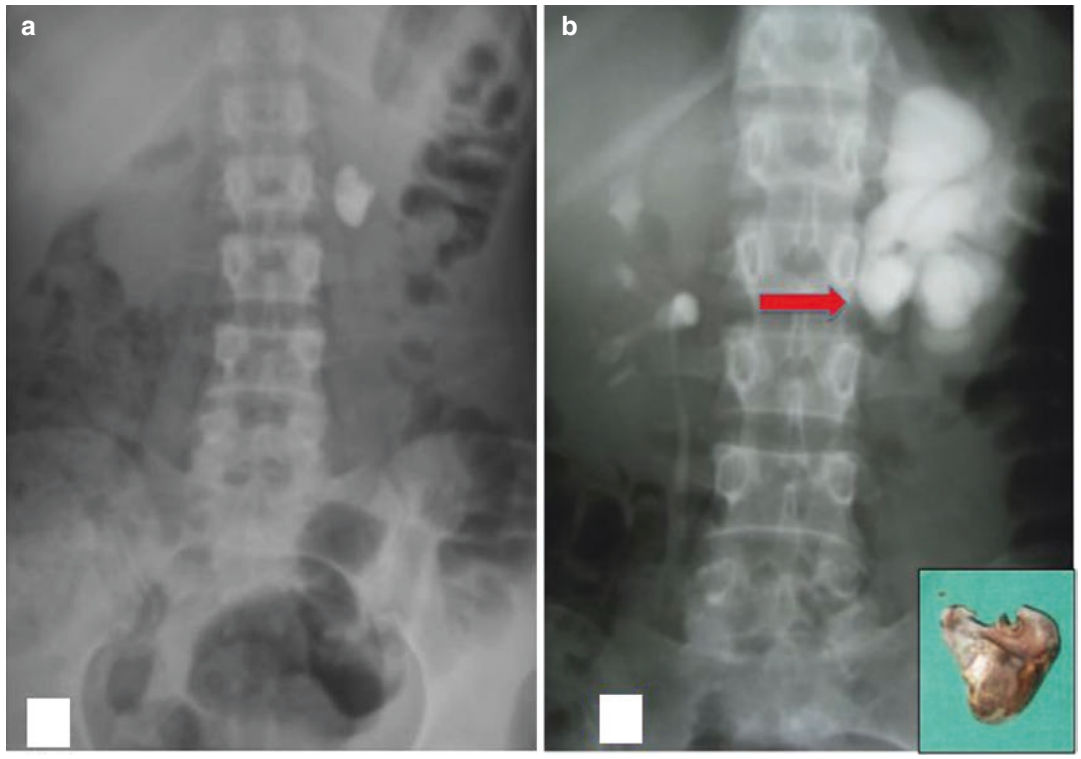

Fig. 47.2 (**a**) Left UPJ stone. (**b**) IVU shows impacted left UPJ stone (inset: Retrieved calculus)

port or through a caudal assistant port. In case the stones are still within the abdomen, they are removed with the bag through the 12 mm assistant port. The robotic instruments are removed under vision and the abdomen desufflated completely. The port sites are closed.

Step 5: Postoperative Care

Post-operative care is similar to that for an open pyelolithotomy/pyeloplasty. The patient may be mobilized and allowed oral intake the same evening. In case the anastomosis/pyelotomy closure was deemed to be perfect and there is minimal drainage, the bladder catheter can be removed on day 1 following surgery and the drain may be removed the next day.

Step-by-Step Technique: Anatrophic Nephrolithotomy

Step 1: Kidney Exposure: Colon Mobilization

0° or 30° down lens.
Right arm: Hook electrocautery/Monopolar scissors.
Left arm: Maryland grasper.
4th arm (if used): Prograsp® forceps.

The initial steps are similar to those previously described for a pyelolithotomy.

Step 2: Hilum Dissection and Warm/Cold Ischemia

Renal hilum dissection is similar as for partial nephrectomy. Warm ischemia can be achieved by clamping renal hilar vessels. For cold ischemia, ice slush can be used using Gelpoint ™ port. Intracoporeal temperature can be decreased to less than 10 °C. A nephrotomy can be made over Brodel's line and dissection through the collecting system is done to retrieve the stone intact.

Step 3: Nephrolithotomy Closure

30° lens.
Right arm: Needle driver.
Left arm: Maryland grasper/Needle driver.

Collecting system and nephrolithotomy can be closed in layers over a double J stent.

Step-by-Step Technique: Diverticular Stones

Step 1: Kidney Exposure: Colon Mobilization

0° lens.
Right arm: Hook electrocautery/Monopolar scissors.
Left arm: Maryland grasper.

The initial steps are similar to those previously described for a pyelolithotomy. However, the renal mobilization needs to be more extensive, particularly over the area of the diverticulum. Peri-renal fat and fat within the Gerota's fascia is completely removed in order to identify the diverticulum.

Step 2: Stone Localization and Removal

0° lens.
Right arm: Hook electrocautery/Monopolar scissors.
Left arm: Maryland grasper.
Assistant: Laparoscopic ultrasound probe.

Renal parenchyma is generally thinned out or scarred in the region overlying the diverticulum. It may also form a visible bulge on the renal surface. The laparoscopic ultrasound probe aids in its identification in difficult cases. Once the diverticulum is identified, a radial incision is made in the parenchyma overlying it using the hook electrocautery or the monopolar scissors. The incision is deepened to enter the diverticulum and visualize

the stone. Once the stone is seen, it is held in the Maryland® grasper or by the assistant and removed. These stones are generally small and may be removed intact. The diverticular cavity can now be inspected and its lining fulgurated with the electrocautery hook. Peri-renal fat may also be placed within the marsupialized cavity.

Step-by-Step Technique: Partial/ Simple Nephrectomy

The procedure for a partial or simple nephrectomy is similar to that described elsewhere in this book for other indications. For a partial nephrectomy, a laparoscopic ultrasound probe is useful in identifying the exact location of the stones to plan the incision.

Specific Situation: Pelvic Kidney

When a pyelolithotomy is being performed for stones in an ectopic/pelvic kidney, the operative steps have to be modified. These kidneys have aberrant vasculature and mobilization as for an orthotopic kidney cannot be performed. The kidney is often seen as a bulge behind the lower mesentery of the bowel. The bowel is mobilized off the anterior surface of the kidney. The pelvis is usually anteriorly located, right below the mesentery. Renal mobilization is difficult and unnecessary. The renal pelvis can be identified either by distending it with saline through the pre-placed ureteric catheter or using a laparoscopic ultrasound probe. It is important to be aware of the aberrant renal vasculature that may course anterior to the pelvis. Once the pelvis is identified, a direct pyelotomy is made after placing the hitch stitch, usually caudal to the site of the incision. The remaining procedure is similar to that previously described.

Upper/Lower Ureterolithtomy

The initial steps are similar to those previously described for a pyelolithotomy for upper ureteric stones. The stone in the ureter (upper/lower) can be identified as a bulge. Careful dissection should be done to prevent upmigration of stones, especially in the upper ureter. In juxtavesical stones, the peritoneum is carefully incised avoiding the iliac vessels. After that, longitudinal ureterotomy is made over the stone with scissor and the stone is retrieved with Prograsp® or Maryland forceps. Double j stent is placed over guide wire and followed by ureterotomy closure mimicking open surgery (Fig. 47.3).

Cystolithotomy with Simple/Radical Prostatectomy

After transvesical robot-assisted simple prostatectomy, the cystotomy can be extended for large stones and then closed after removal of stones (Fig. 47.4).

Avoiding Complications

Four specific complications that should be avoided during robotic stone surgery are injury to the renal vessels, uretero-pelvic junction avulsion, failure to localize the stones and inability to extract the stones. Certain tips to optimize the outcome are given in Table 47.3.

Vessel Injury

Robotic surgery for stones is performed transperitoneally due to the limited space available in the retroperitoneal approach. The transperitoneal approach means that the pelvis is the most posterior structure at the hilum and renal vessels are encountered during pelvis mobilization. The cranio-medial and anterior dissection of the pelvis should be performed carefully to avoid vascular injury. It is usually not necessary to mobilize the vessels off the anterior pelvis wall since the major mobilization and pyelotomy are made on the posterior surface. Mobilization of the lower pole of the kidney improves visibility on the posterior surface of the pelvis, further minimizing the need for extensive dissection on the anterior surface.

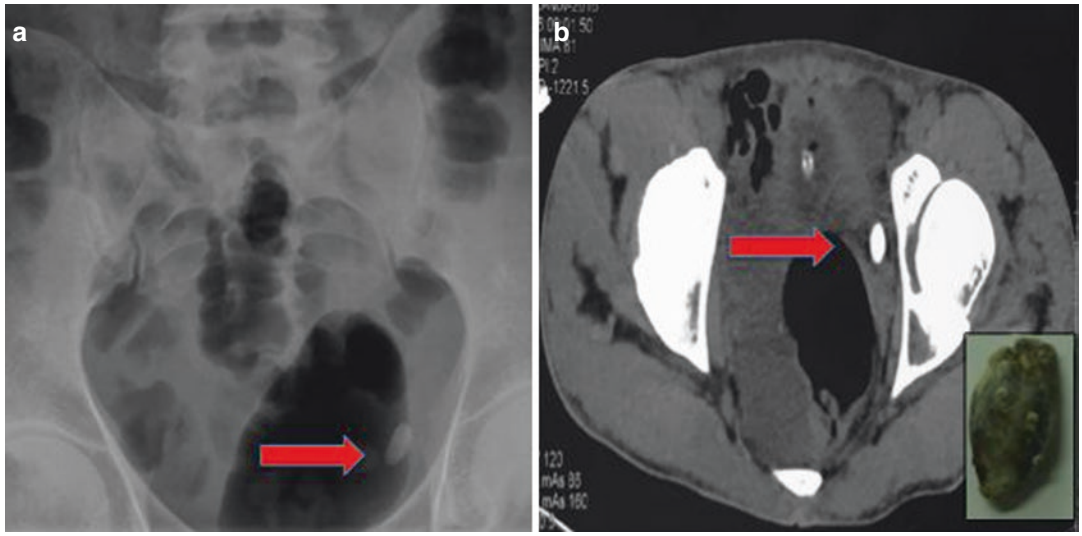

Fig. 47.3 Left lower ureteric stone (inset: Retrieved calculus)

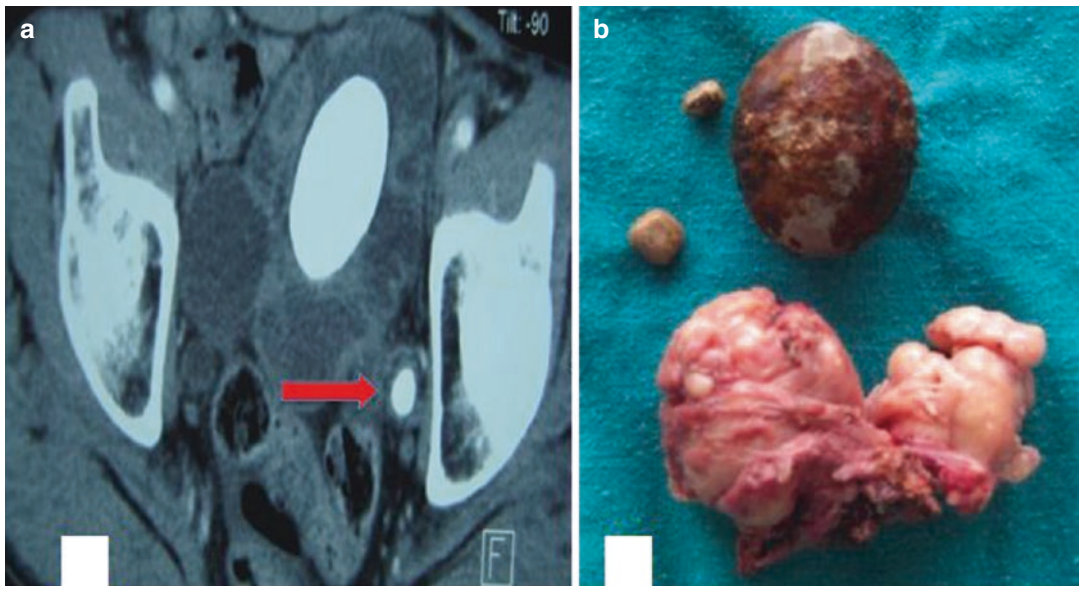

Fig. 47.4 (**a**) Benign prostatic hyperplasia with vesical and left ureteric stone. (**b**) Simple prostatectomy specimen with retrieved vesical and left ureteric stone

Ureteropelvic Junction Avulsion

This usually occurs due to an incorrectly placed pyelotomy and an attempt to remove large stones through a limited pyelotomy. The principles of open surgery need to be rigorously followed. The ends of the pyelotomy should point towards the calyces and a generous lip of the pelvis must remain between the incision and the UPJ. Intracorporeal stone fragmentation should be performed for large stones to avoid tears during extraction.

Failure to localize the stones may occur particularly in patients with multiple calculi or after fragmentation. Intra-operative fluoroscopy is difficult in the presence of the surgical cart. Pre-

Table 47.3 Tips and Tricks

Problem	Solution
Vascular or organ injury	Appropriate site selection for Veress(R) needle insertion
	Incision in skin/sheath wide enough to allow easy port insertion
	All secondary ports inserted under direct vision
	Confirm insulation of all cautery instruments
Emphysema	Ensure entry into peritoneum before insufflation Seal all port sites, avoid excessively large incisions
Difficulty identifying pelvis	Consider pre-placed ureteric cather in initial cases Administer furosemide intravenously
Port crowding	Maintain 60° decubitus Inferior flex the operating table Place 4th port laterally and lower
Robotic arm clashing	Move the set-up joint of camera port to the head end
Nephroscope unable to reach all calyces	Remove robotic instruments and de-sufflate the abdomen
Stone too large to grasp	Intracorporeal lithotripsy
Lost stones	Use of Endocatch® device to place stones
Incomplete stone retrieval	Laparoscopic ultrasound

operative careful assessment of the radiographic images and visual correlation of the extracted stones with the images will help minimize these problems. The availability of laparoscopic ultrasound probes would also help decrease the incidence of residual calculi.

Inability to extract the stones would result from their loss within the peritoneal cavity. This complication is easily avoided by placing all extracted stones within a specimen bag before retrieval.

Conclusion

Robotic surgery for urolithiasis is technically feasible and efficacious in specific situations. It allows the advantages on open surgery in conjunction with a minimally invasive approach.

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Robotic Ureteral Reconstruction

48

Christopher Reynolds and Ashok K. Hemal

Abstract

Advancements in robotic surgical technology have enabled urologists to better meet the demands of minimally invasive ureteral reconstruction. A wide range of benign and malignant disease can be me managed with robotic surgery. Various applications have been described in the literature, and outcomes are generally excellent with low rates of disease recurrence and rare major complications. Herein, we describe basic techniques for robotic ureteral reconstruction as well as more detailed instruction and published outcomes for specific procedures.

Keywords

Ureteral reconstruction · Ureterolysis · Ureteroureterostomy · Ureteroneocystostomy · Psoas hitch · Boari flap · Ileal ureter

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Introduction

Ureteral reconstruction is an excellent application of robotic surgery. While limitations in conventional laparoscopic technology led to a steep learning curve for even experienced laparoscopic surgeons attempting minimally invasive ureteral reconstruction, the strengths of robotic surgery have allowed for novice and expert robotic surgeons, alike, to perform complex upper urinary tract surgery. This chapter aims to guide the urologist in the basic principles of robotic ureteral reconstruction and to describe techniques and outcomes for specific procedures.

Preoperative Work-Up and Counseling

A complete history and physical examination should be conducted preoperatively. The history should focus on the etiology of the ureteral pathology, prior abdominal surgeries, history of nephrolithiasis, urologic malignancy, and chronic kidney disease.

Appropriate preoperative imaging is critical and should provide the urologist with information pertaining to location of the ureteral disease, anatomic landmarks, evidence of obstruction, and renal function. Ureterography and ureteroscopy can provide information regarding the location of ureteral disease. If a nephrostomy tube is in place, combined antegrade and retrograde

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ureterography can be helpful for determining the length and location of ureteral disease. Axial imaging, including CT or MR urography, may help to determine the location of ureteral disease and to delineate anatomy for operative planning. A diuretic renogram may be necessary to confirm ureteral obstruction and document renal function. However, desired investigations are individualized.

The preoperative visit and informed consent should include discussion of all possible procedures for ureteral reconstruction including conversion to open surgery and should also emphasize the importance of follow-up to monitor for disease recurrence.

Technique for Proximal Ureteral Surgery

For disease of the mid to upper ureter, we prefer the full flank position though a lateral or semi-lateral decubitus position with or without modified low lithotomy for possible bladder access can also be used. The anterior abdominal wall is placed at the edge of the table to avoid camera and robotic arm collisions. Table-anchored back rests and Velcro straps, which are applied above the xiphoid and below the pubis, are used to secure the patient. A beanbag may be used, but there is a risk of interference between the robotic arms and the bag. A table-anchored superior arm elevator is used to position the arm as cranial as is safe to prevent collisions with the robotic arms. Alternatively, the arm may be placed at the side of the abdomen, which is a great option and preference in our practice. The abdomen is then prepped from the xiphoid to the pubis.

Pneumoperitoneum is achieved with a Veress needle, or alternatively, a Hasson technique may be used, though we do not use the latter in our practice.

For S/Si systems, the first camera port, a 12 mm trocar, should be placed superolateral to the umbilicus; however, the location is determined according to ureteral pathology and after initial insufflation with the Veress needle with evaluation of space between ribcage and iliac crest (Fig. 48.1). For obese patients, the camera

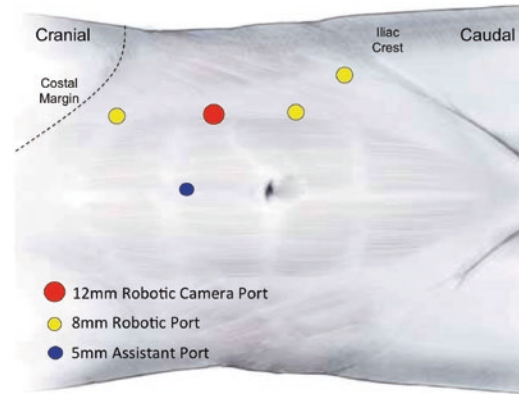

Fig. 48.1 Left sided proximal ureteral surgery for the da Vinci S/Si system. Right-sided surgery would be a mirror image. All ports can be modified for body habitus and internal anatomy

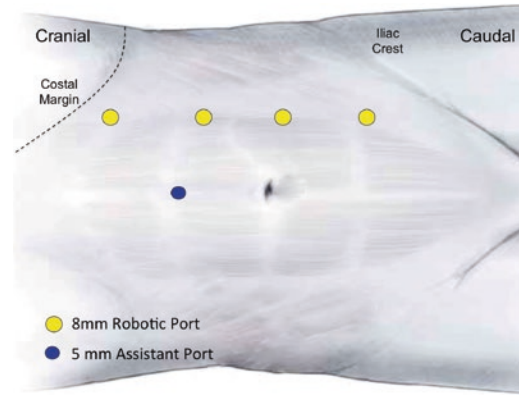

Fig. 48.2 Left sided proximal ureteral surgery for the da Vinci Xi system. Right sided surgery would be a mirror image. All ports can be modified for body habitus and internal anatomy

port should be positioned more laterally. Three bariatric robotic trocars are then placed. The most cephalad of these is placed about 2 cm below the costal margin. The most lateral of these is placed about 3 cm superomedial to the anterior superior iliac spine (ASIS). A third 8 mm trocar is placed between camera and caudal port. A 5 mm port is placed in the midline between the camera and cephalad robotic port as an assistant port. Needles can be passed through the robotic trocars. An additional 5 mm port may be placed below the xiphoid in right-sided cases to assist with retraction of the liver if needed.

For the Xi system, a 8 mm bariatric trocar is used as the camera port and is placed in a similar

location as for the S/Si systems (Fig. 48.2). Two 8 mm trocars are then placed about 6–8 cm cephalad and caudal to the camera port along the paramedian line containing the camera port. A fourth 8 mm robotic trocar is placed in the lower abdominal quadrant and can be placed more laterally or also along the same paramedian line. A 5 mm assistant port is typically placed at or lateral to the midline between the camera and cephalad robotic port.

The robot is then docked at a 90° angle to the OR table. If distal ureteral access is required, it is especially important not to angle the robot towards the shoulder. A bipolar fenestrated grasper is placed in the left robotic arm, a curved monopolar scissor is placed in the right robotic arm, and a Prograsp (Intuitive Surgical, Sunnyvale, California) grasper is inserted in the caudal arm. Alternatively, a large robotic needle driver may be used to save on cost as it will be needed later.

For proximal ureteral exposure, the colon is mobilized medially after making an incision along the white line of Toldt. For right-sided procedures, the duodenum is kocherized. The assistant helps with exposure using a sucker. The ureter can be found after identifying landmarks such as the iliac and gonadal vessels and the lower pole of the kidney. The ureter is found medial to the lower pole of the kidney, traveling with the gonadal vein along the psoas muscle or as it crosses the common iliac artery. The healthy portion of the ureter is located, and a vessel loop can be placed around the ureter to assist with traction for the ureteral dissection. It is Important avoid direct handling and cautery of the ureter to preserve its tenuous blood supply.

Technique for Distal Ureteral Surgery

For access to the ureters below the level of the iliac vessels, patients are positioned in low lithotomy with Trendelenburg position similar to that for robotic radical prostatectomy. Arms are tucked at the side. Foam padding is applied to the hands and arms, and shoulder supports are positioned. The infra-xiphoid abdomen, pelvis, perineum, and upper thighs are prepped and draped in standard fashion. A urethral catheter is placed on the surgical field, and the patient is tilted in a Trendelenburg position after the bladder is drained. Pneuomoperitoneum is achieved with the Veress technique.

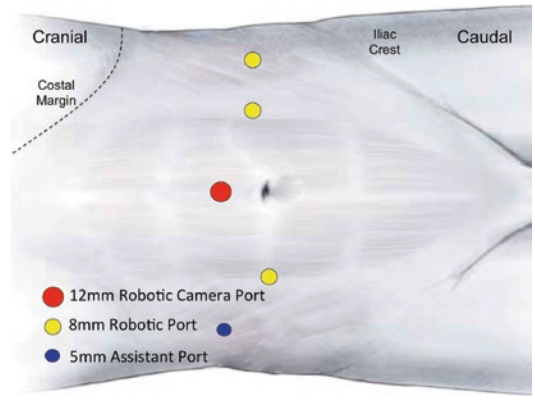

Fig. 48.3 Right sided distal ureteral surgery using the da Vinci S/Si system (mirror image for the left side). Port placement can be modified depending on the patient's body habitus and internal anatomy

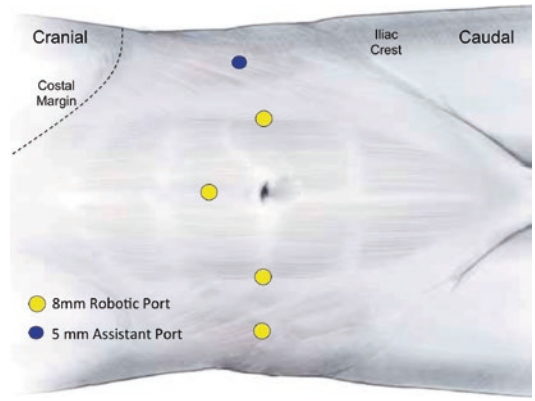

Fig. 48.4 Left sided distal ureteral surgery using the da Vinci Xi system (mirror image for the right side)

A 12 mm robotic camera port for S/Si systems or 8 mm robotic trocar for Xi system is placed about 2 cm above the umbilicus (Figs. 48.3 and 48.4**).** Under direct visualization, two robotic ports are placed about 6–8 cm from the camera port. Another 8 mm robotic port is placed on the contralateral side of the ureteral pathology, 2–3 cm cephalad and 1–2 cm medial to the ASIS. A 5 mm assistant port is placed cephalad to and between the camera and robotic arm on the side ipsilateral to the ureteral pathology.

The robot is then docked between the legs. Alternatively, side docking can be done in the supine position without moving the patient in steep Trendelenburg. A fenestrated bipolar grasper is placed in the left robotic arm, a curved monopolar scissor in the right robotic arm, and a Prograsp or a large robotic needle driver in the fourth arm. For distal ureteral exposure, the posterior peritoneum is incised longitudinally at the level of the iliac vessels. On the left side, the sigmoid colon needs to be mobilized medially to expose to the ureter.

Technique for Pan-Ureteral Surgery

For access to the entire ureter, we typically place the patient in a flank position. We have described our technique for accessing the upper urinary tract without repositioning or redocking [1, 2]. For the S/Si systems, ports are placed as previously described for proximal ureteral access. It is critical that the robot be docked perpendicular to the OR table to allow for distal ureteral access. While moving from proximal to distal, if really necessary, the robot may be undocked, and the table may be tilted to move the patient more in the supine position. The robot is then redocked. It is not necessary to move the patient-side cart. The most caudal robotic arm receives either the monopolar curved scissor or the fenestrated bipolar grasper, and the most cephalad robotic port receives the Prograsp. For the Xi system, camera port hopping can be helpful. Ports are placed as previously described for proximal ureteral access. If moving from proximal to distal, the camera may be moved one port caudally, and the robotic instruments can be exchanged as desired without undocking. The retargeting feature may also be utilized to improve triangulation and ergonomics.

Drain and Catheter Management

For most ureteral reconstruction procedures, a surgical drain is placed close to the reconstruction. We prefer to place the drain to gravity drainage rather than bulb suction to prevent siphoning of urine from the anastomosis. When drainage is less than 30 mL per 12 h, the drain is discontinued. Usually, the drain is removed on postoperative day 1, and the patient is discharged. For cases involving extensive cystotomy or bladder reconstruction, a urethral catheter is left to gravity drainage for 7–10 days post-op and removed with the fill and pull technique after a cystogram confirms no extravasation.

Ureteral Stenting

We prefer stenting across the ureteral repair. Ureteral stent placement is associated with decreased OR time, hospital stay, and complication rates [3]. Our preference is for intracorporeal robotic ureteral stent placement after the posterior portion of the ureteral anastomosis is completed [4]. A hydrophilic wire is inserted into the stent and advanced such that the wire protrudes from the end of the stent at least 4–5 cm in order to uncurl the tip of the JJ stent. A hemostat is used at the proximal end of the stent to hold the assembly together. The wire and stent are then inserted through an assistant port. Alternatively, a 3 mm port or angiocatheter may be used for stent insertion.

If the ureteral stent is being placed for a proximal ureteral repair such as during a pyeloplasty, it is advanced distally about 20 cm. The wire is then pulled back 3–4 cm while the stent is advanced distally. The console surgeon then stabilizes the stent, and the assistant removes the wire, which results in curling of the distal and proximal ends of the stent. The proximal end of the stent is then inserted into the renal pelvis.

If the stent is being placed for distal ureteral repair such as during a ureteroneocystostomy, the wire and stent complex are advanced proximally until an appropriate length of stent has been advanced or until resistance has been met. The wire is then removed, and the distal curl of the stent is inserted into the bladder.

If distal and proximal ureteral stent manipulation is required, such as with a mid-ureteral repair, the wire and stent complex are advanced proximally until resistance is met. The wire is

then removed from the stent but is left intracorporeal, and it is then reinserted distally through the side hole of the stent until the distal end of the stent is uncurled. The proximal end of the stent is held in place, to prevent dislodgement, while the distal end is advanced to the bladder until an appropriate length of stent has been advanced or until resistance is met in the bladder. The wire is then removed while securing the stent in place.

Reflux of urine around or through the stent confirms adequate distal positioning. Importantly, the bladder should be distended at this point in the procedure as the Foley catheter should be clamped and furosemide was previously administered. If there is any doubt as to the location of the distal end of the stent, methylene blue may be injected into the bladder via the Foley catheter to help visualize urinary reflux from the stent.

Distal malposition of the ureteral stent occurred with an incidence of 2% in one large series [4]. We only rely on efflux of urine and do not perform any further investigation unless necessary. Some groups perform flexible cystoscopy immediately after the robotic portion of the procedure to confirm adequate ureteral stent placement. A post-operative x-ray confirms adequate ureteral stent placement. Alternatively, a ureteral stent can be placed retrograde via cystoscopy prior to the robotic portion of the case. Drawbacks to retrograde stent placement include increased OR time, need for patient repositioning, and the potential to cut the ureteral stent. The ureteral stent is typically removed 3–6 weeks post-procedure as indicated.

Intraoperative Identification of the Diseased Segment of Ureter

Identification of the diseased ureteral segment and surrounding healthy tissue is paramount to the success of ureteral reconstruction. Large intraluminal and extraluminal lesions can usually be found under laparoscopic visualization alone. We typically will clamp the Foley catheter and administer IV furosemide to distend the ureter proximal to the diseased segment. When possible, we typically will remove the ureteral stent at least 2 weeks prior to surgery. Ureteral stents can distort gross ureteral anatomy and lead to inflammation of the ureter, which can compromise the reconstruction.

Small intraluminal lesions can be identified with aid of an end-hole catheter at the level of the disease. Some groups routinely perform cystoscopy, insert a ureteral catheter, and secure the ureteral catheter to a Foley catheter prior to moving on to the robotic portion of the procedure. The ureteral catheter can be used to inject indocyanine green (ICG) retrograde or to insert a wire, which can also be used for simultaneous ureteroscopy during the robotic portion of the procedure if contemplated. Light from the ureteroscope can be used to pinpoint the diseased segment of ureter. Lighted ureteral stents can also be utilized. The downsides to these techniques include increased operative time, potential need for patient repositioning, and need for an assistant surgeon at bedside.

In conjunction with the use of near infrared imaging with the Firefly system (Intuitive Surgical, Sunnyvale, California), ICG can be administered antegrade, retrograde, or even paraureterally via a percutaneous needle to help identify the diseased ureteral segment [5]. We typically inject ICG immediately prior to identification of the diseased ureteral segment so as to minimize dissipation of the dye. Catheter/s used for injection are then clamped, and near infrared imaging is employed. Diseased segments are hypofluorescent and healthy ureter is fluorescent.

Robotic Ureterolysis

For ureterolysis, we typically place the patient in a full flank position. Other groups use a modified semilateral decubitus position with legs in stirrups, which can allow for simultaneous ureteroscopy if necessary. A ureteral catheter may be inserted prior to the robotic portion of the procedure for injection of ICG for identification of the ureter. Doppler US can also be utilized to localize the ureter. Good ureteral exposure is critical to help identify the diseased portion of the

ureter. Diseased periureteral tissue is sampled, and frozen sections are sent for pathologic analysis.

Once identified, the anterior capsule of the ureter is split, and a combination of blunt and sharp dissection is used to free the ureter. The use of cautery around the ureter should be avoided.

An omental flap is created using bipolar grasper in the left hand, monopolar scissors in right hand and Prograsp in the 4th arm. Sometimes, in order to prevent retraction at the beginning of the procedure, an omental flap is created and tagged for later utilization. The distal end of flap is brought posterior the ureter and fixed to the sidewall using absorbable suture or clips. The medial edge of the flap is then rolled to cover the anterior surface of the ureter and is fixed to the sidewall. Subsequently, a surgical drain is placed.

Outcomes of robotic ureterolysis are generally good with excellent success rates and few complications. Success was defined as no recurrence of ureteral obstruction. In the largest series reported to date, 40 patients underwent robotic ureterolysis with a mean operative time of 230.8 min, mean length of stay of 3.1 days, and 3 major complications reported [6]. Though eventual success was reported as being 97%, 7 of 40 patients who underwent ureterolysis did have additional procedures for persistent ureteral obstruction after ureterolysis. Persistent obstruction was thought to be secondary to the extensive dissection of the ureter rather than to use of the robotic approach.

Robotic Ureteroureterostomy

Ureteroureterostomy can be performed for malignant and benign disease of the proximal to distal ureter. Ureteral segment excision and ureteroureterostomy are indicated for cases of short segments of low-grade malignancy, less than 3 cm, in the proximal to mid ureter. Exposure of the ureter is achieved as described previously. Thermal injury of the ureter is to be avoided.

For cases of malignancy, proximal and distal segments of ureter are clipped prior to excision to avoid tumor spillage. Frozen sections of ureteral edges can be sent.

For the retrocaval ureter, we generally transect the ureter proximal and distal to the IVC. Alternatively, the distal end can be transected, and the retrocaval portion of the ureter can be dissected if this is feasible and safe.

For the ureteroureterostomy, the distal ureter medially and proximal ureter laterally are spatulated less than 10 mm. A handle of diseased or redundant tissue can be used to avoid directly handling the ureter. A tension- free anastomosis is critical. If the segment of ureter excised is greater than 2 cm, more extensive ureteral mobilization may be required. Nephropexy or psoas hitch may be performed if additional ureteral length is needed. 4-0 or 5-0 poliglecaprone or polyglactin suture may be used for the anastomosis. We typically use interrupted traction sutures of 5-0 poliglecaprone at the 6 and 12 o'clock positions. The back wall is then approximated in a running or interrupted fashion. The ureteral stent is placed robotically via antegrade approach, and the anterior anastomosis is closed.

An alternative technique for the ureteral-ureteral anastomosis employs use of a dyed and undyed suture. The dyed suture can be secured laterally and undyed suture can be secured medially. The posterior wall anastomosis is performed first by passing the medial undyed suture posterior to the ureter to rotate the ureter 180° to expose the posterior ureter. A running anastomosis is made, and the undyed suture is then tied to the dyed suture. The undyed suture is then passed back underneath, the ureteral stent is placed, and the anterior portion of the anastomosis is completed with the dyed suture. Omentum or peritoneum can be secured over the anastomosis to reduce the risk of urine leak.

Excellent success, 91–100%, and low complication rates have been achieved for robotic ureteroureterostomy (Table 48.1) [6–9]. The procedure has also demonstrated good results for distal ureteroureterostomy. In one series, distal robotic ureteroureterostomy was performed in seven cases for disease greater than 2 cm from the bladder with no reported complications or recurrence of strictures in short-term follow-up

Table 48.1 Robotic Ureteroureterostomy

Authors	No. patients (p)/No. ureters (u)	Mean OR time (min)	Mean LOS (days)	Success	Major Complications (Clavien-Dindo III+)
Boris et al. [7]	15 u	227	2.2	100%	0
Buffi et al. [8]	17 u	178	5	94.1%	0
Eun et al. [9]	12 p	190	1.4	91.7%	0
Hemal et al. [10]	7 u (stricture) 4 u (retrocaval ureter)	110 80	3 3	100% 100%	0 0
Stifelman et al. [6]	8 p	201	2.8	100%	2

[9]. Robotic distal ureteroureterostomy may be a good alternative to ureteroneocystostomy as lower urinary tract morbidity, including bladder pain, may be minimized.

Robotic Ureteroneocystostomy

The lithotomy position is utilized for ureteral reimplantation. After the ureter is identified, following the technique for distal ureteral surgery previously described, it is encircled by a vessel loop. With the ureter on slight traction, the diseased segment and healthy surrounding tissue are identified and dissected. The ureter is then transected proximal to the diseased segment with curved scissors, and the proximal end of the ureter is spatulated.

If distal ureterectomy is being performed for urothelial carcinoma, then clips may be applied to avoid spillage of tumor, and the ureter may be dissected to the posterior bladder wall. The distal ureteral segment and bladder cuff are then excised en bloc. The bladder cuff is subsequently closed with a 3-0 absorbable suture.

The bladder is filled with 300 cc of normal saline via an indwelling urethral catheter, and it mobilized off of the anterior abdominal wall by incising the peritoneum lateral to the medial umbilical ligament. The dissection is carried caudal to the pubis, and the median umbilical ligament is then transected to allow for the space of Retzius to be further developed with blunt and sharp dissection.

We prefer a non-tunneled anastomosis similar to the Lich-Gregoir extravesical reimplantation after excision of distal ureteral stricture. A 1.5 cm full-thickness incision is made in the lateral bladder dome. Bladder distension helps with this step. An extravesical anastomosis is then performed using 4-0 or 5-0 poliglecaprone suture in an interrupted fashion. Urothelium to urothelium apposition is critical. A ureteral stent is placed with robotic assistance prior to the anterior anastomosis, or it can be placed cystoscopically. Though a classical tunneled ureteroneocystostomy is not performed, every attempt is made to complete detrusorraphy using 3-0 absorbable suture to prevent retrograde reflux. A second layer of the anastomosis is performed between the serosa of the bladder and adventia of the ureter. The anastomosis may also be covered with perivesical fat. The bladder is then filled to observe for leaks, and a surgical drain is placed.

Robotic ureteroneocystostomy, including use of psoas hitch and Boari flap, has been performed with excellent success, 87.5–100%, and low complication rates (Table 48.2) [6–8, 10–16].

Robotic Psoas Hitch

If a simple ureteral reimplantation is not possible, then a psoas hitch may facilitate a tension-free anastomosis. After dissection of the distal ureter and excision of the diseased ureteral segment, the bladder is filled, and it is mobilized anteriorly and laterally. The contralateral medial umbilical ligament may be divided to allow additional mobilization of the bladder and a tension-free distal ureteral-bladder anastomosis. Should more mobilization be required, the superior bladder pedicle may also be ligated and divided.

A psoas hitch is performed by anchoring the bladder to the psoas tendon using two figure-of-eight or interrupted sutures of 2-0 non-absorbable

Table 48.2 Robotic Ureteroneocystostomy

Author	No. patients (p)/ureters (p)	Mean OR time (min)	Mean LOS (days)	Success	Major Complications (Clavien-Dindo III+)
Boris et al. [7]	22 u	214.4	2.4	90.9%	2
Buffi et al. [8]	21 u	166	8	93.3%	2
Cummings et al. [11]	9 p (3 psoas hitch, 1 Boari flap)	246 (median)	2.7	100%	0
Hemal et al. [10]	5 u	268.5	1.8	100%	0
Malcolm et al. [12]	13 p	282	2.5	100%	2
Patil et al. [13]	12 u	208	4.3	100%	0
Stein et al. [14]	25 p (10 primary, 1 tapered, 4 psoas hitch, 10 Boari flap)	279	3	96%	2
Stifelman et al. [6]	31 p (26 psoas hitch, 3 Boari flap + psoas hitch)	260.3	3	100%	2
Stolzenburg et al. [15]	8 p (8 Boari flap)	171.9	–	100%	0
Leveillee et al. [16]	8 u	247	2	87.5%	0

suture material. Care must be taken to throw the suture parallel to the psoas muscle fibers to reduce the risk of injury to the femoral nerve. Absorbable, rather than permanent, suture is used to potentially mitigate the effect of nerve injury should it occur. The genitofemoral nerve must also be avoided. A nontunneled and stented anastomosis is then carried out as previously described, and a surgical drain is placed.

Robotic Boari Flap

A Boari flap may be selected to bridge a 10–15 cm ureteral defect. We typically assess adequate bladder capacity preoperatively with cystoscopy if a Boari flap is contemplated. A psoas hitch is first performed. It is critical that the blood supply to the bladder not be compromised and that the base of the flap is of adequate width, greater than 6 cm, to prevent ischemia and resulting stricture of the distal end of the flap. The flap should have at least a 2:1 proportion of length to width and is started from the dome of the bladder to a position no closer than 3 cm to the bladder neck. The flap is laid out and tacked to the psoas muscle with interrupted PDS suture. The ureteral-flap anastomosis is carried out with 4-0 or 5-0 poliglecaprone in a non-tunneled fashion. Others have described use of a Politano-Leadbetter type tunneled ureteral anastomosis with good results [15]. A ureteral stent is placed robotically after the posterior anastomosis. The flap is then tubularized using running absorbable suture, and a surgical drain is placed.

Robotic Segmental Ureterectomy for Malignancy

Select cases of urothelial carcinoma of the ureter may be managed with segmental ureterectomy with ureteral reconstruction via ureteroureterostomy or ureteroneocystosotomy for distal ureteral lesions. Cases are typically limited to patients with distal ureteral disease and a contraindication to nephroureterectomy.

Certain steps are recommended for cases of ureteral malignancy [17]. Proximal and distal ureteral clipping, if possible, is advised to prevent spillage of tumor. The bladder should be filled with sterile water to help identify and score the bladder cuff. Simultaneous retrograde cystoscopy may also be performed to help identify the bladder cuff. Bilateral pelvic lymphadenectomy should be conducted. Frozen sections should be sent from the proximal bladder cuff margin and distal ureteral margin.

Four patients underwent robotic distal ureterectomy with bladder cuff excision and ureteroneocystostomy and two patients underwent robotic midureter segment excision with ureteroureterostomy for malignancy in one series [18]. There were no major complications and only one

recurrence in the bladder with a mean follow-up of 33 months. Similar low rates of oncologic recurrence and complications were seen in other series [19–21]. Progression of urothelial carcinoma was limited to cases of pT2 disease.

Robotic Transureteroureterostomy

Transureteroureterostomy is indicated for a duplicated system with an obstructed renal unit. An end-to-side anastomosis is created. A ureteral stent is placed cystoscopically prior to the robotic portion of the procedure. The proximal end is spatulated. A 1 cm ureterotomy is made, and a 5 Fr ureteral stent is placed antegrade alongside the ureteral stent in the healthy distal ureter and then proximally up the donor ureter. A running or interrupted anastomosis is performed in an end-to-side fashion.

Robotic Megaureter Repair

In patients with symptomatic primary obstructive megaureter, surgical repair via robotic-assistance may be performed. In adults, excisional tapering of the ureter is typically preferred over plication as the affected ureter is usually massively dilated and thickened due to delayed presentation and secondary infections. We have reported on our technique for robotic megaureter repair [22]. Excisional tapering of the distal 5–7 cm of ureter is completed over a 10 Fr feeding tube or ureteral catheter, and extravesical ureteral reimplantation is performed. The ureteral reconstruction is carried out with interrupted stitches at each end with a single layer running absorbable suture in between. The ureteroneocystostomy is carried out with interrupted absorbable stitches using a modified Lich-Gregoir technique. A 8.2 Fr ureteral stent is placed robotically prior to completion of the anastomosis.

In our series of nine patients undergoing megaureter repair, mean operative time was 142.5 min. There was symptomatic and clinically significant improvement in obstruction of all renal units undergoing surgery.

Robotic Ureterocalicostomy

Ureterocalicostomy may be performed for proximal ureteral reconstruction when there is a small, intrarenal, and/or obliterated renal pelvis and, ideally, when there is atrophy of the lower pole of the kidney. The diseased segment of ureter is excised and healthy ureter is spatulated. The renal hilum is dissected, and Gerota's fascia and perinephric fat are dissected off of the lower pole of the kidney. The most dependent lower pole calyx is identified using laparoscopic ultrasound. 12.5 g of mannitol may then be administered, and bulldog clamps are applied to the renal vessels. Monopolar scissors are used to transect the lower pole of the kidney to expose the selected calyx. 3-0 poliglecaprone or polyglactin suture are used to ligate open vessels. Cortex can also be cauterized. After hemostasis is achieved, the vessels are unclamped and hemostasis is again achieved by cautery or suture ligation. Tension-free anastomosis of the ureter to the lower pole calyx is then performed using 4-0 polyglactin suture. Nephropexy may be conducted to facilitate a tension-free anastomosis. A ureteral stent is placed antegrade robotically. The proximal ureteral stump is ligated with 2-0 absorbable suture. The anastomosis is covered with Gerota's fascia to prevent extravasation of urine and promote healing. A surgical drain is then placed near the reconstruction.

Outcomes data for robotic ureterocalicostomy, which are limited to rare case reports for adults and to relatively small case series in the pediatric population, show that the procedure is effective with a low complication rate (Table 48.3) [23, 24]. (Larger studies in the adult population are needed to better determine the effectiveness and safety of robotic ureterocalicostomy.

Robotic Ileal Ureter

When a long diseased ureteral segment is present in patients with adequate renal function, an ileal ureter may be performed. Several groups have described techniques for robotic ileal ureter [25–27]. In most descriptions, the patient is

Table 48.3 Robotic Ureterocalicostomy

Authors	No. patients	OR time (min)	LOS (days)	Success	Major Complications (Clavien-Dindo III+)
Schimpf and Wagner [23]	1	180	2	100%	0
Stifelman et al. [6]	1	355	3	100%	0
Kim et al. [24]	9 (pediatric)	168	~1	100%	0

Table 48.4 Robotic Ileal Ureter

Authors	No. patients	Median OR time (min)	Mean LOS (days)	Success	Major Complications (Clavien-Dindo III+)
Berger et al. [25]	3	450	7.7	66.6%	1
Stein et al. [26]	1	420	–	100%	0
Schimpf et al. [27]	1	540	5	100%	0

repositioned between flank and dorsal lithotomy multiple times. The procedure starts with the patient in the flank position as previously described for pan-ureteral surgery. After the diseased ureteral segment is excised, the patient is repositioned in the dorsal lithotomy position, and ports are placed for distal ureteral surgery. A psoas hitch is performed. The ileum and ileocecal valve are located, a segment of ileum of appropriate length is identified at least 15 cm from the ileocecal valve, and it is divided with a 60 mm laparoscopic stapler. 2–3 cc of ICG may be administered via IV to visualize the vascular arcades of the mesentery to avoid bowel ischemia. Bowel continuity is restored with a side-to-side anastomosis using the 60 mm laparoscopic stapler. If a left-sided ileal ureter is to be performed, to facilitate transposition of the ileal ureter, a window is made between the sacrum and sigmoid colon up to transition between descending colon and sigmoid colon. The distal end of the ileum is then anastomosed to the bladder using 3-0 polyglactin in a running fashion. The robot is then undocked, and the patient is moved into the flank position. The renal pelvis is identified, incised, and a side-to-side anastomosis is performed between the ileal segment and renal pelvis using a 3-0 polyglactin suture in a running manner. A ureteral stent is placed antegrade prior to completion of the anastomosis. A large urethral catheter is placed in the bladder as mucous may need to be gently irrigated from the bladder post-operatively to prevent mucous plugging.

Published outcomes for robotic ileal ureter are indicative of the complexity of the procedure. Operative times are long, and length of stay is variable (Table 48.4). One major complication was reported in a total of five cases in three series. Distal ileum herniated behind the mesentery of the ileal ureter, became edematous, and led to occlusion of the blood supply to the ileal ureter necessitating exploratory laparotomy and excision of bowel, including the ileal ureter. The authors felt that the complication was inherent to ileal ureter rather than to the robotic approach.

Robotic Onlay Flaps/Grafts

Onlay flaps and grafts, which have more recently been described, are other options for robotic ureteral reconstruction particularly for the mid and proximal ureter. Potential benefits include less morbidity than procedures such as ileal ureter and greater flexibility of application. Buccal mucosa grafts were used with good success in proximal ureteral reconstruction as reported in one series [28]. In four patients, buccal mucosa grafts were harvested using standard technique, avoiding injury to Stenson's duct. Grafts were 1 cm wide and as long as the defect in the ureter. In two cases, each with 6 cm long proximal ureteral strictures, the buccal mucosa graft was placed as a posterior onlay graft wrapped with omentum. In another case, there were distal and

proximal ureteral strictures with concern that transection of multiple sites of the ureter would lead to ischemia of the intervening segment. A psoas hitch was performed with anterior onlay graft of the proximal ureter wrapped with perirenal fat. In an additional case, a dense UPJ stricture was present, and a tension-free anastomosis was not possible. The posterior anastomosis was carried out, and a buccal mucosa graft was used as anterior onlay graft, which was covered with omentum. Grafts were sutured to the ureter as well as omentum or perirenal fat to encourage a good blood supply. Ureteroscopy was performed immediately after the reconstruction to ensure ureteral patency, and ureteral stents were placed retrograde. Mean operative time was 298 min, length of stay was 2–3 days, and there was 100% success at a mean follow-up of 15.5 months. There were no complications.

Appendiceal onlay flaps may also be used for robotic ureteral reconstruction. Only the laparoscopic technique has been reported to date, but the technique can be translated to a robotic approach. Appendiceal onlay flaps were performed in a series of six patients via laparoscopic technique [29]. After retrograde pyelography and ureteral stent placement, patients were placed in a modified flank position. The ureter was identified and dissected proximal and distal to the diseased segment. An anterior ureterotomy was then performed along the length of the stricture. A GIA stapler was used to divide appendix at its base while preserving the mesentery. The tip of the appendix was transected and discarded, and the appendix was incised along its antimesenteric end. 4-0 polyglactin suture was used to anastomose the onlay flap to the ureter. Mean stricture length was 2.5 cm. Mean operative time was 244 min, length of stay was 3.2 days, and there was 100% success. No complications were noted.

Conclusion

Robotic ureteral reconstruction provides an excellent minimally invasive alternative to open surgery. Multiple case series have demonstrated the feasibility, safety, and effectiveness of various applications of robotic surgery to ureteral reconstruction, and new techniques and technologies have the potential to further improve patient outcomes.

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49 Outcomes and Complications of Robotic Kidney Surgery

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Abstract

From its first developments, robot-assisted surgery had a rapid and wide diffusion into the field of urology and its indications have been expanded to several urological procedures and, as experience increased in the last years, even to challenging and complex cases with an acceptably low complication rate in the hands of high-volume surgeons. Robot-assisted radical prostatectomy (RARP) is currently the most common treatment modality for surgical management of clinically localized prostate cancer in the US. The consequence of the widespread adoption of RARP was the use of the robotic platform to treat other urological malignancies as well as benign conditions.

Keywords

Robotic surgery · Radical nephrectomy · Robotic pyeloplasty · Partial nephrectomy · Robot-assisted partial nephrectomy · Robot-assisted radical nephrectomy · Robot-assisted pyeloplasty · Robot-assisted laparoscopic partial nephrectomy · Renal surgery · Nephron sparing surgery

Introduction

The history of robot-assisted renal surgery begins in 2002 in the US with the first pyeloplasty [1], followed by the first partial nephrectomy (PN) a few years later [2]. The experience with robotic assistance in renal surgery continued with radical nephroureterectomy, first reported by Rose et al. [3], but the need to undock the robotic system to remove the bladder cuff has limited its acceptance.

In this chapter we describe outcomes and complications of three commonly performed robot-assisted renal procedures, namely radical nephrectomy (RN), pyeloplasty and PN, with a particular focus on the last one, which is attracting most research and interest from the urological community.

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Radical Nephrectomy

The indications of robot-assisted RN are the same as conventional laparoscopic and open approaches. In 2009 Hemal et al. compared two groups of patients treated with either robot-assisted or laparoscopic RN [4]. There were no significant differences in terms of intra- and postoperative complication rate or estimated blood loss. The authors concluded that robot-assisted RN is a safe, feasible and effective option to treat localized kidney tumors. In addition, Rogers et al. evaluated 42 patients that underwent robot-assisted RN between 2004 and 2008. No conversion to open surgery was required and the overall complication rate was low at 2.6% [5].

However, the use of the robotic platform for RN has been virtually abandoned due to the high costs and the absence of evident advantages over standard approach. It is only in the last years that robot-assisted RN has been reappraised to manage selected complex cases, such as tumors with inferior vena cava thrombi. The first study was published by Abaza et al. in 2011. The authors reported on five such cases treated robotically with no postoperative complications recorded [6]. Recently, Wang et al. reported a series of 17 patients with renal tumor and inferior vena cava thrombus treated with robotic assistance. There were no conversion to open surgery, one grade IV postoperative complication (i.e., bleeding from tributaries of vena cava, which was treated with intraoperative endoscopic suture) and one grade II postoperative complication (i.e. lymphatic leakage with hypoproteinemia) [7].

Pyeloplasty

Robot-assisted pyeloplasty is currently the most common approach for the treatment of ureteropelvic junction obstruction in the US, accounting for 45.1% of all cases [8]. This trend is sustained by the advantages and low complication rate of robot-assisted reconstructive surgery. In 2014 Autorino et al. published a systematic review of the literature with meta-analysis demonstrating that robot-assisted pyeloplasty has a low conversion rate (roughly 3%) and a low postoperative complication rate (2–18%) [9]. On meta-analysis, robot-assisted pyeloplasty showed no statistically significant difference in complication rate compared to laparoscopic approach.

The so-called redo robot-assisted pyeloplasty is recognized as a more challenging procedure because of the fibrosis that can be present around the renal pelvis due to previous surgery. Complication rates of the included studies varied from 0% to 27%. Unfortunately, complications were not categorized according Clavien-Dindo system. The authors concluded that robotic pyeloplasty is likely to emerge as the new minimally invasive standard of care for ureteropelvic junction obstruction [10].

The experience gained in adults allowed to extend the indication of robot-assisted pyeloplasty to children. Recently, Dangle et al. reported on a multicenter experience of urological robotic surgery in children [10]. In this series, 407 pyeloplasty were performed with an overall complication rate of 13.8%, 2/3 of which were minor.

Table 49.1 details complication rates reported by recent most representative case series of robot-assisted pyeloplasty [11–20].

Partial Nephrectomy

PN is currently recommended by most authoritative guidelines as standard treatment of clinical T1a tumors and as an alternative treatment to RN for clinical T1b tumors [21].

Robot-assisted PN (RAPN) has rapidly evolved as an attractive minimally invasive modality for nephron-sparing surgery because of technical advantages of the robotic platform, including stereoscopic vision, improved articulation of instruments and fine movements, and shortened learning curve compared to laparoscopic PN, with comparable functional and oncological outcomes compared to open and laparoscopic approach.

Overall Complications

Tables 49.2 and 49.3 details complications reported in recent most representative case series

Table 49.1 Complication rate and hospital stay in most representative case series of robot-assisted pyeloplasty

Author	Year	Cases	Conversion rate (%)	Complication rate (%)	Hospital stay (days)
Patel [11]	2005	50	0	2	1.1
Olsen et al. [12]	2007	65	1.5	17.9	2
Schewentner et al. [13]	2007	92	0	NR	4.6
Mufarrij et al. [14]	2008	140	0	10	2.1
Cestari et al. [15]	2010	55	0	1.8	3.6
Gupta et al. [16]	2010	86	2.3	9.3	2.5
Etafy et al. [17]	2011	61	0	11.4	2.0
Minnillo et al. [18]	2011	155	0	11	1.9
Singh et al. [19]	2012	34	0	8.8	2.5
Sivaraman et al. [20]	2012	168	0	6.6	1.5

NR not reported

Table 49.2 Complications reported in recent most representative case series of robot-assisted partial nephrectomy

Author	Year	Cases	Conversion to lap/open	Conversion to radical	Intraop	Overall postop	Clavien 1–2	Clavien 3–4
Long et al. [22]	2012	199	0/199 (0%)	2/199 (1%)	NR	64/199 (32.1%)	53/199 (26.6%)	11/199 (5.5%)
Petros et al. [23]	2012	445	4/445 (0.9%)	3/445 (0.7%)	NR	19/445 (4.3%)	NR	NR
Tanagho et al. [24]	2013	886	3/886 (0.34%)	4/886 (0.45%)	23/886 (2.6%)	139/886 (15.7%)	107/886 (12.1%)	32/886 (3.6%)
Eyraud et al. [25]	2013	364	6/364 (1.6%)	2/364 (0.5%)	NR	89/364 (24.4%)	75/364 (20.6%)	14/364 (3.8%)
Brandao et al. [26]	2014	412	4/412 (1%)	0/412 (0%)	11/412 (2.7%)	65/412 (15.8%)	54/412 (13.1%)	11/412 (2.7%)
Zargar et al. [27]	2014	1185	2/1185 (0.2%)	2/1185 (0.2%)	NR	175/1185 (14.8%)	136/1185 (11.5%)	39/1185 (3.3%)
Lista et al. [28]	2015	339	3/339 (0.9%)	0/339 (0%)	NR	49/339 (14.4%)	36/339 (10.6%)	13/339 (3.8%)
Raheem et al. [29]	2016	174	0/174 (0%)	1/174 (0.6%)	6/174 (3.4%)	33/174 (19%)	23/174 (13.2%)	10/174 (5.7%)

NR not reported

Table 49.3 Complications reported in recent most representative case series of robot-assisted partial nephrectomy for "complex" cases (tumors >4 cm or with high nephrometry score)

Author	Year	Cases	Conversion to lap/open	Conversion to radical	Intraop	Overall postop	Clavien 1–2	Clavien 3–4
Ficarra et al. [30]	2012	49	0/49 (0%)	0/49 (0%)	2/49 (4.1%)	13/49 (26.5%)	9/49 (18.4%)	4/49 (8.2%)
Brandao et al. [26]	2014	29	0/29 (0%)	0/29 (0%)	2/29 (6.9%)	11/29 (37.9%)	9/29 (31%)	2/29 (6.9%)
Volpe et al. [31]	2014	44	0/44 (0%)	0/44 (0%)	2/44 (4.5%)	10/44 (22.7%)	6/44 (13.6%)	4/44 (9.1%)
Wang et al. [32]	2016	81	0/81 (0%)	2/81 (2.5%)	4/81 (5%)	14/81 (17.3%)	11/81 (13.6%)	3/81 (3.7%)
Raheem et al. [29]	2016	121	0/121 (0%)	7/121 (5.8%)	4/121 (3.3%)	26/121 (21.5%)	20/121 (16.5%)	6/121 (5%)
Janda et al. [33]	2016	64	0/64 (0%)	5/64 (7.8%)	0/64 (0%)	25/64 (39%)	16/64 (25%)	9/64 (14%)

of RAPN. Intraoperative complication rates range from 2.6% to 5% and are mainly observed in case of complex lesions. Clavien grade 1–2 postoperative complication rates range from 11.5% to 26.6%, and Clavien grade 3–4 postoperative complication rates range from 2.7% to 14% [22–33].

Intraoperative Complications

Intraoperative complications of RAPN include vascular and visceral injury due to laparoscopic access as well as bleeding and injury to adjacent structures (renal vein, vena cava, spleen, liver, pleura) performed during kidney isolation, which may require conversion to laparoscopic or open PN, or to RN.

An updated meta-analysis of 28 randomized control trials with 4860 patients evaluating the various methods of laparoscopic access showed no advantage of any technique in preventing major complications. An open-entry technique did reduce the incidence of failed entry, extraperitoneal insufflation and omental injury, but did not demonstrate lower vascular or visceral injury rate [34].

In a multicenter series of 347 patients published by Ficarra et al. in 2012, intraoperative complications occurred in 12 cases (3.46%). Specifically the authors reported 6 cases of renal vein injury, 1 case of vena cava injury, 1 case of splenic injury, 1 hepatic injury and 1 case of pleural lesion. All cases of vascular injury were robotically repaired. They reported no conversion to open PN or to RN for any injury type. Two cases of conversion to RN were required due to perinephric scarring and to limited mobility of the robotic arms because of the patient body habitus [35].

In case of vascular injury, the use of the fourth robotic arm seems to be very helpful to manage the bleeding vessel that has to be sutured. Most cases of hepatic or splenic lesions can be conservatively treated with bed coagulation with bipolar and application of hemostatic agents.

Postoperative Complications

Several of the postoperative complications following RAPN are not specifically related to kidney surgery or robotic/laparoscopic approach. Postoperative complications are generally categorized in life-threatening and non-life-threatening, and graded according to the Clavien-Dindo classification [36].

Bleeding represents the most common postoperative complication following RAPN, ranging from 0.7% to 12.3% of cases [37], and can lead to significant morbidity, even posing life threat. Postoperative bleeding complications include perirenal hematoma, arteriovenous fistula and renal artery pseudoaneurysm, and their occurrence can be immediate or delayed, the latter defined as occurring >7 days after surgery.

Arteriovenous fistula and pseudoaneurysm are thought to arise from partial transection of a segmental artery during tumor resection and/or renorrhaphy. Drainage of high-pressure flow into a low-pressure system can result in an arteriovenous fistula (leakage into an adjacent vein) or renal artery pseudoaneurysm (leak into renal parenchyma or hilar areolar tissue). Patients typically present with delayed gross hematuria, although they can experience a range of symptoms (e.g., flank pain, dizziness, fever). Bleeding severity varies, although patients can progress rapidly to hemodynamic instability. Diagnosis is made with CT angiography. Management ranges from observation to selective arterial embolization and, in rare cases, nephrectomy, depending on the severity of the clinical picture. In this context, a tertiary referral center with the availability of interventional radiologists is paramount. Meticulous haemostatic renorrhaphy and careful reinspection of the surgical site after vessel unclamping and deflation of pneumoperitoneum are mandatory. Use of adjunct hemostatic agents does not apparently reduce the risk of vascular injuries [38].

Urinary leakage occurs as a result of collecting system lesion during tumor excision and may present as ileus, electrolyte derangement or increased surgical drain output. Reported rates of urinary leakage following RAPN range from 0.6% to 2.0% [37]. An analysis of 1791 RAPN collected from five US centers showed 14 cases of urinary leakage (0.78%). There were no significant differences in terms of nephrometry

score between patients experiencing urinary leakage and those with no leakage, although the analysis was underpowered. These cases were treated with retrograde ureteral catheterization until the leakage resolution [39].

Acute kidney failure is a further potential complication. Although standardized definitions of postoperative acute kidney failure based on objective parameters, such as serum creatinine, estimated glomerular filtration rate or change in urine output, are lacking, reported rates of clinically significant acute kidney failure requiring hemodialysis are low, ranging from 0% to 0.8%. This complication is more threatening in patients with tumors in solitary (anatomic or functional) kidney or with bilateral tumors [37].

See Figs. 49.1 and 49.2.

Oncological Outcomes

Few data are available on long-term follow-up after RAPN due to the relatively recent introduction of this approach worldwide. In 2013 Khalifeh reported a 3-year overall survival and cancer-free survival of 97.01% and 98.92%, respectively, in a series of 134 patients treated with RAPN and with a minimum follow-up of 2 years [40]. An update of this data was recently published by Andrade et al. [41]. After a median follow-up of 61.9 months (IQR 50.9–71.4) overall survival, cancer-free survival and cancer-specific survival were 91.1%, 97.8% and 97.8%, respectively.

The oncological assessment of PN is obtained also by measuring the rate of positive surgical margins. In a multicenter experience of skilled surgeon published by Ficarra et al. the rate of positive surgical margins was 3.6% [35]. Slightly inferior results were reported by Masson-Lecomte et al. in 2013, with an 8% positive surgical margins rate after RAPN in a multicenter French study [42]. Moreover, in a series of 44 RAPN performed for complex lesions (PADUA score $\geq$ 10) positive surgical margins rate was 4.5% [31]. Recently Tabayoyong et al. analyzed the data of 11,587 patients treated with PN with three different approaches: open, laparoscopic and robot-assisted. Laparoscopic and robot-assisted PN were associated with higher positive surgical margin rates compared to open PN for cT1a RCC (8.1% vs 8.7% vs 4.9%, respectively) [43].

Functional Outcomes

Preservation of renal function is the main prerogative of PN when compared to RN. The theoretical advantage of RAPN versus laparoscopic PN is represented by the easier and faster renorrhaphy. Warm ischemia time (WIT) is one of the factors that principally influences the recovery of renal function after PN and published data demonstrate that the learning curve of RAPN is relatively short and WIT rapidly decreases below 20 min [44, 45].

In 2012 Aboumarzouk et al. published the data of a systematic review including studies between 2000 and 2012 that compared RAPN and LPN for a total of 717 patients. The meta-

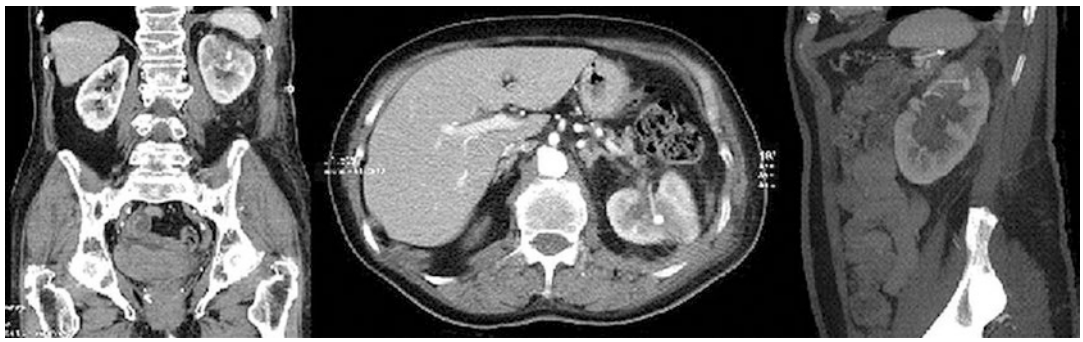

Fig. 49.1 CT scan showing pseudoaneurysm on upper pole of left kidney after PN

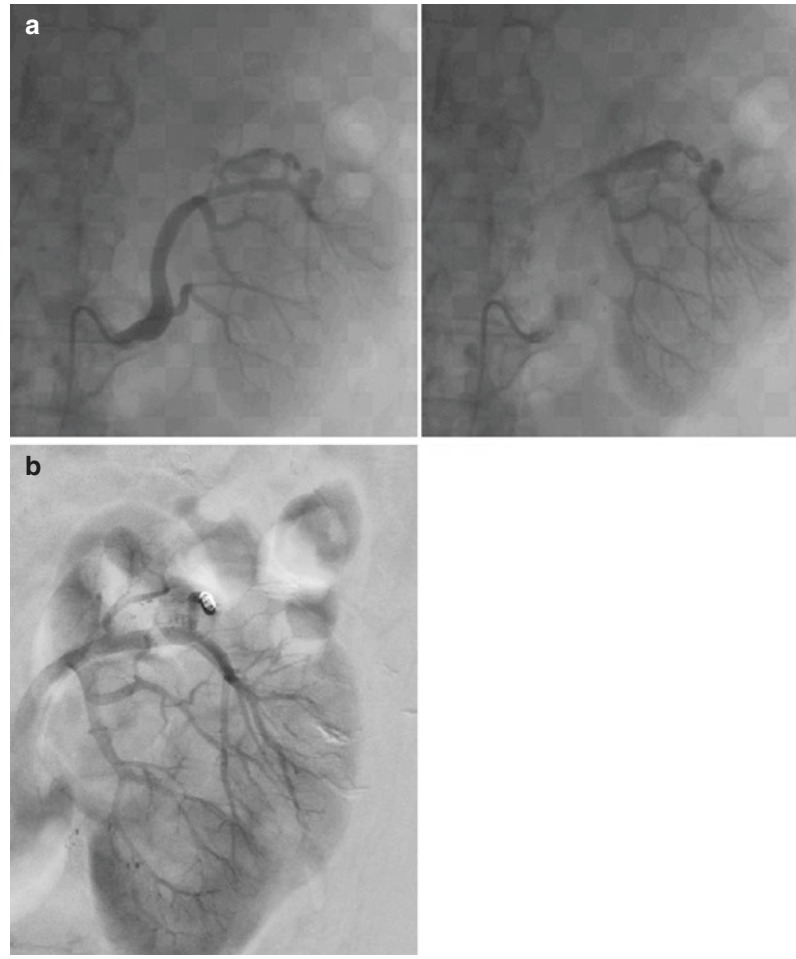

Fig. 49.2 (**a**) Angiography showing pseudoaneurysm on upper pole and concomitant arteriovenous fistula. (**b**) Angiography image after selective embolization of peripheral artery branch

analysis showed a statistically significant difference for WIT in favor of robot-assisted approach (p = 0.0008) [46]. A subsequent systematic review of the literature with meta-analysis including six comparative studies of robot-assisted versus laparoscopic PN for a total of 256 patients showed no differences in terms of WIT between the two approaches [47]. Notably, the two meta-analyses did not include the same studies, and both included studies with cases performed during the learning curve of the surgeons.

Recently, the authors of a further systematic review including 2240 patients treated with robot-assisted or laparoscopic PN found that the RAPN group had a significantly shorter WIT and smaller change in estimated glomerular filtration rate (eGFR) [48].

Most studies evaluate the renal function after RAPN using eGFR [49, 50]. In 2013, Khalifeh et al. reported the functional outcomes in a series of 427 RAPNs. Postoperative eGFR was calculated at 3 and 6 months. The authors reported a mean eGFR decline of 8% (7.4 ml/min) after RAPN. On multivariable analysis, only preoperative eGFR had a significant positive correlation with decline in postoperative eGFR [40].

Recently, Zargar et al. used mercaptoacetyltriglycine renal scan to assess postoperative renal function in 99 patients undergoing RAPN, and calculated also the amount of healthy rim of renal parenchyma removed with the tumor using a mathematical model. They reported a total eGFR preservation of 83.83% and an ipsilateral renal function preservation of 72%. On multivariable analysis, volume of healthy rim of renal parenchyma removed

in addition to WIT (>30 min), body mass index and preoperative ipsilateral eGFR were predictive of ipsilateral renal function preservation. The authors concluded that total eGFR tends to overestimate the degree of renal function preservation after RAPN compared to renal scan [51].

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50 Robot-Assisted Partial Nephrectomy in Hereditary and Multifocal Kidney Cancer

Mark W. Ball, Lernik O. Namagerdi, and Adam R. Metwalli

Abstract

Hereditary and multifocal kidney cancer presents a unique challenge for the urologic surgeon, as patients are often at risk for multiple, bilateral renal surgeries. Maximizing oncologic efficacy while minimizing renal compromise is paramount in treating these patients. Nephron sparing surgery has been the standard of care, and the addition of a robotic approach in select cases can minimize perioperative morbidity. We review the role of robotic partial nephrectomy in patients with hereditary and multifocal kidney cancer.

Keywords

Inherited kidney cancer · Birt Hogg Dube · Hereditary leiomymatosis renal cancer · Hereditary papillary renal cell carcinoma · Von Hippel Lindau · Clear renal cell cancer

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Introduction

Kidney cancer or renal cell carcinoma (RCC) is a heterogeneous group of diseases, consisting of several cancers that are genetically and morphologically distinct [1]. While the majority of kidney cancers are sporadic (non-hereditary), 5% of cases are associated with known hereditary cancer syndromes and up to 25% of cases have multifocal tumor involvement [2, 3]. In fact, the true incidence of hereditary kidney cancer may be underestimated, due in part to limitations in understanding the role of cancer susceptibility genes in RCC. A multi-generational study of Icelandic people indicated that 58% of RCC cases thought to be sporadic occur in patients with 1 or more family members with RCC, supporting the notion that far more cases of seemingly sporadic RCC are actually hereditary in origin [4].

Multifocality occurs in both hereditary and sporadic cases. Multifocality refers to having more than one tumor in a single kidney (Fig. 50.1a), while bilaterality refers to at least 1 tumor in each kidney (see Fig. 50.1b). Multifocality and bilaterality are commonly encountered together with nearly 9 of 10 patients with multifocal RCC also having bilateral tumors [5]. Over half of patients with bilateral tumors will also have multifocal disease [6]. Bilateral, multifocal (BMF) patients, whether hereditary or sporadic, pose challenges to the treating surgeon,

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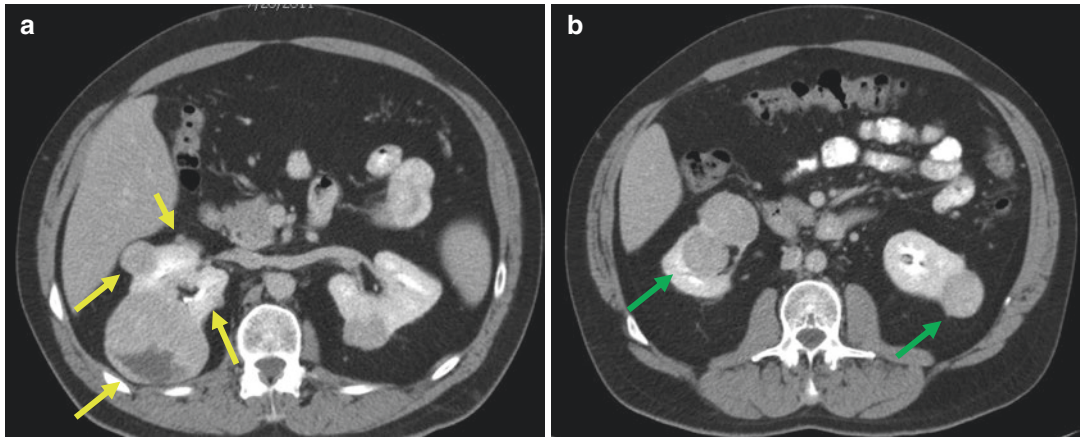

Fig. 50.1 CT images of a patient with both bilateral RCC and multifocal RCC. (**a**) Yellow arrows demonstrate multifocality multiple tumors in a single kidney. (**b**) Green arrows demonstrate bilateral tumors at least one tumor in each kidney

as these patients are often at increased risk of requiring multiple interventions over a lifetime in order to definitively treat their condition. This may involve simultaneous or staged bilateral renal interventions or may require repeat ipsilateral renal intervention. For example, in some cases such as hereditary kidney cancer, there is a high rate of ipsilateral tumor recurrence over time due to the presence of incipient microscopic tumors throughout the renal parenchyma and subsequent development of *de novo* tumors [7, 8]. Even in predominantly sporadic RCC series, multifocality by itself increases the likelihood of ipsilateral tumor [9]. Repeat renal surgeries pose the risk of increased complications and perioperative morbidity and blood loss [10–15].

Currently, up to 14 different hereditary conditions have been identified with increased lifetime risk of developing renal tumors [16]. The genetic basis of these tumors may influence treatment planning including surgical approach [17]; consequently, urologists need to be familiar with the associated signs of hereditary kidney cancer syndromes as well as the different surgical management approaches to these conditions (Table 50.1). Hereditary and multifocal kidney cancer present unique surgical challenges that may require different standard surgical techniques depending on the tumor biology; varying surgical techniques is also true for robotic approaches for these patients. Herein, we review the biology and clinical manifestations of heredity kidney cancer syndromes, as well as surgical approach in treating them.

Hereditary Renal Cell Carcinoma Syndromes

Von Hippel-Lindau

Von Hippel-Lindau (VHL) is an autosomal dominant, inherited syndrome with an incidence of 1:35,000. It is associated with development of tumors of the kidneys, adrenal glands, central nervous system, pancreas, retina and epididymis. VHL patients are at risk for the development of early onset, BMF clear cell kidney cancer and renal cysts, and approximately 25% to 60% develop RCC. While reports have demonstrated development of up to 70 clinically detectable tumors in VHL patients [18], incipient microscopic tumors can number up to 600 per kidney [19]. The VHL gene is located on the short arm of chromosome 3. VHL patients inherit one mutated VHL allele, and often develop loss of 3p in the 2nd allele. The VHL protein forms a complex with several other proteins which targets hypoxia inducible factor (HIF) for ubiquitin-mediated degradation. Under normoxic conditions, HIF-α is hydroxylated which facilitates VHL binding

Table 50.1 Hereditary kidney cancer syndromes

Name	Gene	Tumor Suppressor/ Oncogene	RCC histology	Non-Renal manifestations	Surgical approach
Von Hippel-Lindau	*VHL* (3p25)	Tumor suppressor	Clear cell RCC, cystic RCC	CNS Hemangioblastomas, retinal angiomas, Pheochromocytoma	Enucleation
Hereditary papillary RCC	c-*MET* proto-oncogene (7q34)	Oncogene	Type 1 papillary RCC	None	Enucleation
Familial leiomyomatosis and RCC	Fumarate hydratase (1q42)	Tumor suppressor	Type 2 papillary RCC	Cutaneous leiomyomas Uterine leiomyomas	Wide margin excision
Birt-Hogg-Dube	*BHD1* gene/Folliculin (chromosome 17p11.2)	Tumor suppressor	Chromophobe RCC, Oncocytoma, hybrid oncocytic tumors	Cutaneous fibrofolliculomas, lung cysts, spontaneous pneumothorax	Enucleation
Tuberous sclerosis complex (TSC)	*TSC1* gene/Hamartin (9q34) *TSC2* gene /Tuberin (16p13)	Tumor suppressor		AML, renal cysts, RCC. Facial angiofibromas, ungual/ periungual fibroma, shagreen patch, retinal hamartomas, subependymal nodule, cortical hamartoma	Enucleation
SDH	*SDHB (1p36), SDHC (1q21) or SDHD (11q23)*	Tumor suppressor	SDHB: Oncocytic RCC SDHC/D: Clear cell RCC	Pheochromocytomas, paragangliomas, gastrointestinal stromal tumors	Wide margin excision

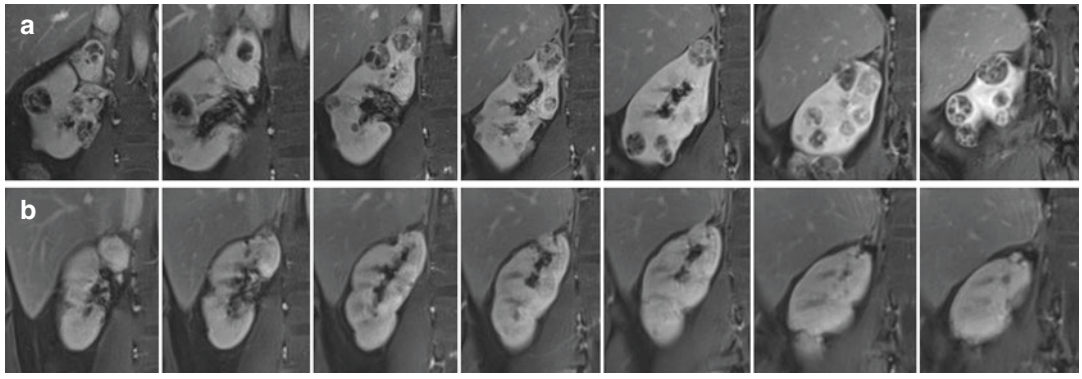

Fig. 50.2 MRI images of VHL kidney pre- and postoperatively after robotic multiplex partial nephrectomy (RMxPNx). (**a**) T1 weighted gadolinium-enhanced coronal MRI abdomen of right kidney pre-operatively on showing numerous multifocal renal tumors throughout the kidney; RMxPNx performed: 31 tumors excised, 2500 cc EBL, 0 min ischemia. (**b**) Right kidney 12 months post-operatively on T1 weighted gadolinium-enhanced MRI showing no residual or *denovo* renal tumors and minimal post-operative distortion of renal parenchyma

and subsequent degradation. However, under hypoxic conditions, hydroxylation of HIF-α does not occur, preventing degradation and leading to HIF accumulation. HIF mediates transcription of several downstream genes thought to be important in RCC carcinogenesis including transforming growth factor alpha (*TGFA*), platelet-derived growth factor (*PDGF*), and vascular endothelial growth factor (*VEGF*).

The first step on managing a VHL ccRCC patient centers around meticulous screening guidelines and accurate diagnosis. Surgical management of these patients focuses on active surveillance, preventing further metastasis while preserving the renal function. Only when the largest solid enhancing component reach 3 cm, surgical intervention is indicated with the aim to prevent the development of metastasis, delay the need for dialysis and preserve native renal function [20]. Considering the numerous multiple small tumors (Fig. 50.2a) and the need to preserve normal renal parenchyma, enucleation of the tumors is used and has been demonstrated to be a safe surgical technique (described below) [7]. In general, the over-arching goal of the surgeon is to "reset the clock" meaning removed as many lesions as possible in one surgery in an attempt to prolong the interval between ipsilateral renal surgeries. Toward that end, all solid and complex lesions are removed with frequent intraoperative ultrasound being utilized to localize and ensure complete removal of all tumors (see Fig. 50.2b). In VHL, renal cysts can become increasingly complex over time and may eventually become solid tumors. In addition, renal cysts are extremely common in VHL affected kidneys which often results in needing to remove numerous cysts in order to better approach more solid lesions. Consequently, enucleation of cysts is commonly performed in conjunction with tumor enucleation. Some are removed as "collateral damage" so to speak in the process of excising tumors; but some complex/mixed cystic lesions are specifically targeted for excision due to the high likelihood of filling in with tumor overtime to become totally solid tumors requiring reoperation.

Birt-Hogg-Dube

Birt-Hogg-Dube (BHD) is an autosomal dominant inherited syndrome with an incidence of 1:200,000. It is caused by a mutation in folliculin (*FLCN*), a tumor suppressor gene on the short arm of chromosome 17(17p11.2.). It is characterized by multiple cutaneous fibrofolliculomas, RCC, pulmonary cysts and spontaneous pneumothoraces. Fibrofoliculomas are an essential component of BHD present in around 90% of patients.

These benign tumors of the hair follicle occur most frequently on the face and upper torso and appear as pale bumps. Renal tumors develop in 18% of BHD patients, with the majority (67%) being hybrid oncocytic kidney tumors or chromophobe RCC (23%). Clear cell RCC develops in 7% of patients, while 3% develop pure oncocytoma [21].

While BHD patients can have BMF kidney lesions, unifocal tumors are not a rare finding in BHD patients. After diagnosing BHD-related renal tumors, a nephron-sparing surgery is indicated. As with VHL, the "3 cm rule" applies to this disease as well, saving surgery until the largest tumor is 3 cm.

Hereditary Papillary Renal Carcinoma

Hereditary papillary renal cell cancers (HPRC) is an autosomal dominant, highly penetrant syndrome with over 70% of carrier developing type 1 papillary RCC. No other manifestations of the disease have been reported. The mean age of tumor occurrence is 50, which is older than other kidney cancer syndromes. HPRC is caused by activating mutations or amplification in *MET*, an oncogene on 7q [22]. The MET protein is a receptor kinase that binds hepatocyte growth factor (HGF).

The 3 cm rule is applied to patients with HPRC, and enucleation is the again the preferred resection technique. However, caution should be used since HPRC tumor and papillary RCC in general does not have a well-defined capsule, posing a higher technical challenge as they may be fractured. Therefore, a very small margin of normal parenchyma can be taken with the tumor to minimize the risk of spillage.

Hereditary Leiomyomatosis and Renal Cell Cancer

Hereditary leiomyomatosis and renal cell cancer (HLRCC) is an autosomal dominant syndrome caused by a germline mutation in gene encoding for the citric acid cycle enzyme Fumarate hydratase (*FH*). The reported incidence of kidney cancer is in the range of 20–30% in affected patients. The disease is also characterized by uterine leiomyomas affecting 90% of women suffering from the disease. In women with symptomatic uterine fibroids, hysterectomy by minimally invasive techniques is recommended at early age in order to avoid morbidity related to disease. Affected patients are at risk of developing cutaneous leiomyomas. These benign nodules are skin colored or red-brown. The size ranges from 0.2 to 2.0 cm. The nodules are distributed over the trunk and limbs with a firm consistency. Dermal leiomyomas may exhibit sever pain in response to pressure or cold.

HLRCC-related kidney cancer is morphologically categorized as type 2 papillary RCC. These tumors have enlarged nuclei along with rich eosinophilic cytoplasm and perinucleolar clearing. The tumors of collecting duct are not HLRCC-related, these tumors have histologically distinct characteristics and should not be misidentified. Dissimilar to listed hereditary kidney cancer syndromes, HLRCC-related tumors are solitary. However, occasionally multifocal lesions can occur in patients affected by HLRCC. HLRCC papillary type 2 RCCs may have an infiltrating margin not visible on CT and MRI. Furthermore, patients can present with metastasis even from very small tumors thus management of HLRCC patients is markedly different from other forms of hereditary kidney cancers. Unfortunately, few patients experience long-term survival following diagnosis of metastatic disease. Urgent surgical intervention is indicated upon diagnosis of HLRCC-related renal cancer. Due to aggressive behavior of these tumors, strong consideration should be given to open tumor excisions. Furthermore, HLRCC tumors are commonly found within complex and nodular cysts, so minimally invasive approaches are not preferred due to the inherent lack of haptic feedback which increases the likelihood of cyst rupture and tumor spillage. This typically leads to tumor dissemination and ultimately death from metastatic disease due to the aggressive biology of these tumors.

SDH Deficient RCC

Mutations in the succinate dehydrogenase (SDH) enzyme have been associated with hereditary pheochromocytoma and paraganglioma, as well as gastrointestinal stromal tumors. More recently, kidney cancer in families with germline SDH alterations has been described at our institution [23]. The SDH enzyme is made up of four subunits: SDHA, SDHB, SDHC, and SDHD, and germline mutation of SDHB, SDHC, and SDHD have been identified in patients with RCC. SDHB associated tumors can have a variety of histology, but most have oncocytic features. Despite the oncocytic phenotype, the biology can be quite aggressive and these tumors can be associated with metastatic disease. SDHC have classic clear cell RCC which also has been associated with the development of metastatic disease. SDHD mutations are rare, with one patient described from a family with history of carotid body tumors. The histology in this case was clear cell, and the patient eventually developed metastatic disease. Overall, SDH associated RCC can be aggressive and should be managed early with wide excision.

Translocation RCC

Translocation kidney cancer is associated with translocation of transcription factor E3 (TFE3) located at Xp11.2 or transcription factor EB (TFEB) on chromosome 6 [24, 25]. While this type of tumor can present at any age, they frequently present in children and young adults. Often they can be highly aggressive, with up to 50% of patients presenting with node positive or metastatic disease. In localized cases, however, partial nephrectomy can safely be used [26].

Tuberous Sclerosis Complex

Tuberous Sclerosis Complex (TSC) is an autosomal dominant syndrome, caused by mutations in *TSC1* (*9q34*) which codes for hamartin and *TSC2* (16p13.3) which codes for tuberin. TSC is characterize by development of tumors of the kidney, including angiomopliomas (AMLs), cysts and clear cell RCC, as well as harmartomas of the CNS, and a variety of cutaneous manifestations, including adenoma sebaceum. Many AMLs can be managed with observation or embolization, but occasionally require surgical resection. Some TSC variants have been associated with clear cell RCC with an aggressive phenotype. Distinguishing fat-poor AMLs from malignant tumors is an ongoing challenge in the management of patients with TSC.

Surgical Techniques

Surgical Planning

For patients with hereditary and multifocal kidney cancer, surgical planning must focus both on the current surgery and planning for future surgeries. Planning should include decisions on when to operate, order of operations, and strategies for maximizing renal preservation. For synchronous, bilateral tumors, option include simultaneous bilateral partial nephrectomy and staged partial nephrectomy. For staged partial nephrectomies, it is often preferable to perform the less complex side first, in case the more complex side requires radical nephrectomy, as this sequence may avoid temporary dialysis [17].

As mentioned above, our institution protocol for VHL, HPRC, and BHD is to perform active surveillance on renal lesions until the largest lesion reaches 3 cm [27]. At that time, enucleative partial nephrectomy is performed on all solid lesions or mixed solid-cystic lesions. For patient with HLRCC and SDH-deficient RCC, neither active surveillance nor enucleation is employed, as these tumors have an aggressive phenotype that can metastasize at a small size and can be locally infiltrative.

Repeat surgery, or surgery after ablative therapies are other challenges often faced in this population. These surgeries are associated with increased operative time, blood loss, and perioperative morbidity [11, 12, 28, 29]. As such, treatment of these patients mandates that not only the

operating surgeon inform the patient but also the entire surgical team as anesthesia must be aware of the high likelihood of increased blood loss and need for transfusion. Previously published series of both open and minimally invasive surgery for predominantly multifocal and reoperative RCC cases report increases in both transfusion rates and estimated blood losses [10–13, 30].

Patient Position and Port Placement

After induction of general anesthesia and placement of a Foley catheter, the patient is placed in the flank or modified flank position with the operative kidney facing up, and the patient is secured to the table. All pressures points are carefully padded with a combination of pillows and foam, and the patient is secured to the surgical table with tape. For the Xi robot, standard renal surgery port placement along the lateral edge of the rectus muscle is used, with a four port configuration and 2 assistant ports. For the Si robot, three robotic trocars are used and two to three assistant trocars are placed. The trocars for the robotic arms are placed in a curvilinear arrangement with the A 15-mm trocar is placed in the peri-umbilical area and a 5 mm trocar is placed in the subxiphoid region. Pneumoperitoneum is initiated with a Veress needle, all anatomical landmarks are marked with a marking pen, the trocars are placed in the usual fashion. Laparoscopic mobilization of the colon below the lower pole is generally performed prior to docking the robot.

Renal Exposure and Hilar Dissection

The peritoneum is incised along the white line of Toldt, medializing the colon and exposing the psoas muscle and Gerota's fascia. Given the likelihood of future ipsilateral operations, only minimal dissection of the hilum is performed to minimize scarring and increasing difficulty of future operations. Gerota's fascia is then opened in a clam-shell fashion from cephalad to caudad, and the entire kidney is completely mobilized within Gerota's fascia dissecting in the avascular plane between the renal capsule and Gerota's fat. The surface of the kidney is inspected carefully and thorough intraoperative ultrasound is performed. At this point, the surgeon must determine surgical approach to determine the order of lesions to be removed and the potential need for renal hilar occlusion.

Enucleation Technique

When enucleation is employed in appropriate cases, most lesions can be enucleated without renal hilar clamping. First, the renal capsule is incised circumferentially around the tumor, and the renal parenchyma is gently separated bluntly with robotic scissors with the tips closed. Peeling away normal parenchyma from the tumor capsule is often done using a Penfield dissector in open surgery, and the closed-tip scissors approximates this instrument very effectively. Once identified, the tumor capsule is followed typically with blunt dissection. The closed scissors in combination with gentle fenestrated bipolar are used to bluntly peel the tumor from the surround parenchyma. The assistant is critical during this portion to ensure visualization of the junction between the tumor capsule and the normal renal parenchyma. Placement of the suction catheter against the normal parenchyma with intermittent suction, with gentle downward retraction away from the tumor, while the surgeon gently retracts against the tumor creates an operating space in which the surgeon can identify the plane of dissection. While blunt dissection is usually sufficient to separate the tumor from the surrounding compressed renal parenchyma, perforating vessels are sometimes encountered. These can be controlled with bipolar cautery, point monopolar cautery, small clips or can be cut sharply and later oversewn.

If the true enucleation plane is identified, then the surrounding parenchyma that is peeled away tends to have been compressed by the tumor growth. As such, it does not bleed as briskly as cutting into normal, non-compressed renal parenchyma. Once the tumor is completed removed from its defect, the base in inspected. If the true

enucleation plane is followed throughout the dissection, the likelihood of entry into the collecting system and significant renal vasculature is minimal. Consequently, complex renorrhaphy involving collecting system and major vasculature repair are often unnecessary. Generally, any pulsatile bleeding can be controlled with figure of eight sutures with a 3-0 vicryl suture using an Rb needle. Sutures can be secured with hand-tied knots or LapraTys based on surgeon preference. The defect is then filled with hemostatic agent and SurgiCel. Given the numerous tumors throughout the kidney, defects are not closed immediately because closed renal defects are difficult to image with ultrasound after the capsule is re-approximated. In addition, the ultrasound probe can be placed into the defect once hemostasis is achieved which may allow for better imaging of and access to deeper lesions adjacent to the renal sinus fat and collecting system. Periodic intraoperative ultrasound is performed throughout the partial nephrectomy to ensure maximum removal of all clinically significant tumors. Repeated use of the ultrasound is critical because multi-tumor partial nephrectomy results in substantial distortion of the kidney which may make finding target tumors more difficult. Serial use of the ultrasound allows the surgeon to keep real-time spatial relationships among tumors and intra-renal landmarks thereby facilitating complete excision of all targeted and clinically relevant lesions. Smaller tumors are removed immediately using laparoscopic spoon forceps, larger lesions are set aside all in one safe area. On the right side, larger tumors are set over the liver to be placed in an endocatch bag when the renorraphy is complete. On the left, tumors are set by the spleen or in the pelvis. It is imperative that the surgeon, scrub tech and circulating nurse each keep an up to date record of the number of tumors left in those locations to ensure complete removal of all tumors at the end of the case. It is also critical to ensure that accurate information is relayed during OR staff shift changes and breaks to avoid inaccurate accounting of tumors excised but left in the body. This can be quite challenging when total number of tumors excised routinely is in double digits. After renorraphy and closure of Gerota's fascia, the tumors should be recounted by all members of the surgical team as they are placed in the laparoscopic endocatch bag. Typically multiple tumors are placed in each bag, however, many operations result in so many tumors removed that multiple bags are needed (Fig. 50.3).

Wide Excision

In cases where a margin or normal parenchyma is needed, as in HLRCC or SDH deficient kidney tumors, wide excision is performed. Our institution practice is to avoid robotic surgery in known HLRCC cases, as tumor spillage due to lack of haptic feedback can occur. For other cases, a robotic approach can be utilized. Because normal parenchyma is transected, bleeding is more substantial than in enucleation; consequently, renal hilar occlusion is employed more frequently in

Fig. 50.3 Multiple EndoCatch laparoscopic specimen bags extracted from peri-umbilical incision after RMxPNx. If there are certain tumors of interest on preoperative imaging the tumor or the bag can be marked with Hem-o-lock clips for later identification

cases requiring wide margin excision. In addition, a preoperative ureteral catheter is placed to enable retrograde injection of methylene blue dye to delineate collecting system entry to optimize water tight renorraphy. Furthermore, post-operative double J ureteral catheter placement is performed in the setting of large collecting system repairs since post-operative large volume urinary extravasation is common when that occurs. Additionally, we perform pathologic analysis with frozen section to confirm a negative margin before completing the renorraphy. Due to the typical time delay associated with waiting for frozen section results to return as well as the greater blood loss associated with these cases, open partial nephrectomy is preferred so that cold ischemia can be used and large blood losses can be more easily managed with less obstruction of visibility.

Post-operative Care

Patient should be monitored carefully in the immediate post-operative setting for hemodynamic stability and need for ongoing resuscitation and/or blood products. Early ambulation if encouraged, and clear liquid diet is initiated on post-operative day 1 and are advanced as patients tolerated. In cases in which stents are placed, these are often left for 3 months if the patient tolerates the stent well. The stent is then removed at the 3 month post-operative follow up. However, if significant stent dysuria is bothersome to the patient, the stent is removed once the JP drain creatinine is the same as the serum creatinine level. Otherwise, the JP drains are removed on postoperative day 4 if there is no clinically apparent urine leak. The index of suspicion for a urine leak should be raised in patients undergoing repeat partial nephrectomy compared to initial partial nephrectomy [31].

Renal functional outcomes are generally very favorable. Although immediate post-operative estimated glomerular filtration rates (eGFR) can be influenced affected by prolonged operative time, high blood losses and occasionally elevated creatine kinase, the effect appears to be transient [32]. Among 54 patients with 3 or more tumors removed treated at our institution, the average eGFR change was found to be a miniscule decrease of 3.01 mL/min, representing a truly negliglible decline despite averaging more than 8 tumors excised per kidney [30].

Conclusion

Treatment of hereditary and BMF RCC requires careful preoperative planning and intraoperative decision making. Robotic surgery can be utilized for the majority of these patients, even in the reoperative setting.

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Part V

Kidney Transplant

Robot-Assisted Kidney Transplantation

51

Akshay Sood, Rajesh Ahlawat, Wooju Jeong, Mahendra Bhandari, and Mani Menon

Abstract

Minimally invasive approaches to conventional kidney transplantation have been recently developed. The rationale for these explorations rests on the successful reduction in morbidity demonstrated across a variety of surgical operations following adoption of minimally invasive surgery, so much so that the minimally invasive counterparts now represent the standard-of-care for such procedures. Here, we describe our technique of robot-assisted kidney transplantation, and also report, for the first time, on the operative, postoperative and short-term survival outcomes.

Keywords

Transplantation · Robotics

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Introduction

Minimally invasive surgery (MIS) is associated with reduced postoperative morbidity and complications – notable advantages include lower blood loss, shorter hospital stay, and reduced incisional pain, surgical site infections and absenteeism after surgery [1–6]. Indeed, today, a minimally invasive approach represents the standard-of-care for several routine surgeries across a variety of surgical disciplines; common examples include appendectomy, cholecystectomy, and prostatectomy, among others [1–6]. The field of transplantation is no exception. The role of MIS in renal donors is well established, and represents the preferred method for living donor nephrectomies [7]. However, its utility for renal recipient surgery is only beginning to be explored [8]. Here, we describe our updated technique of robot-assisted kidney transplantation with regional hypothermia, and initial outcomes.

The Rationale for Robotic Surgery

Surgical procedures can be categorized into three categories based on complexity – excisional, in which a structure is removed (e.g., cholecystectomy), ablative, in which a tissue is destroyed (e.g., cryosurgery of renal tumors) and reconstructive, in which two or more anatomical structures are joined or connected

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together (e.g., urethrovesical anastomosis, vascular anastomoses, orthotopic neobladder). Reconstructive procedures are, in general, the most complicated and morbid of the three. Morbidity of a reconstructive procedure may arise from any of the several steps of the procedure including the surgical incision, the tissue dissection and/or the anastomoses, while the morbidity of ablative and excisional procedures is mainly incisional. A case in point for the latter is the tidal adoption of laparoscopic cholecystectomy [9, 10]. The 'lapcholy' was so rapidly adopted because the morbidity and the need for hospitalization following the procedure was not related to the removal of the gallbladder but rather stemmed from the trauma to the abdominal wall caused by the incision to gain access to the gallbladder – a laparoscopic incision thus made all the difference [11]. With regards to reconstructive procedures however certain limitations of laparoscopic surgery such as the loss of natural hand-eye coordination, depth perception and dexterity render it unsuitable for precise, delicate anastomoses – thus the benefits of its minimally invasive nature are lost to the difficulties encountered during the reconstructive steps. Robotic surgery was developed to overcome these limitations of laparoscopic surgery, while preserving the benefits of its minimally invasive nature [12]. Robot-assisted systems supersede laparoscopy by conferring efficient microsuturing through laparoscopic ports, a 3-D high-definition view, and ergonomic, wristed instruments with seven degrees of freedom that provide improved outcomes as compared to laparoscopy alone [5, 6, 13–17], or even open surgery [18].

These benefits should theoretically be even more pronounced in patients undergoing kidney transplantation (KT) as being chronically ill and immunocompromised, the KT recipients are at a greater risk for developing perioperative complications than an average surgical patient. These complications adversely affect both short-term and long-term graft and patient survival [19–22]. Thus, transplant recipients stand to benefit substantially from MIS.

Patient Selection

Our inclusion criteria has expanded over time – now, we consider all end-stage renal disease patients that are eligible for a conventional KT as candidates for RKT with regional hypothermia as well, given that the patient desires to undergo minimally invasive surgery. The only patients that are still excluded are those undergoing simultaneous multi-organ transplant.

However, during our initial studies we carefully selected patients, according to the IDEAL model of safe surgical innovation (Balliol Collaboration). We recommend that surgeons seeking to start a minimally invasive KT program should also start by selecting ideal candidates for the initial cases (in addition they may consider preclinical studies and/or undergo technical mentoring). Our patient selection criteria for the initial studies were (adapted with permission) [23–25]:

1. Inclusion criteria: irreversible chronic renal disease, defined as end-stage renal disease (ESRD) or anticipated ESRD within the next 1 year (preemptive transplant), and matched living donor.
2. Exclusion criteria: previous major abdominal surgery with high suspicion for intra-abdominal adhesions, significant atherosclerosis of the iliac vessels (>30% blockage), immunologically high-risk, second transplant, and Simultaneous dual or multi-organ transplant.

Operating Room Setup and Patient Positioning

Operating Room (OR) Setup

Ideal OR setup is demonstrated in Fig. 51.1. The OR setup depicted in the illustration helps in promoting sound to-and-fro conversation amongst the console surgeon, the bedside assistant and the anesthesia team, thereby ensuring a collaborative effort.

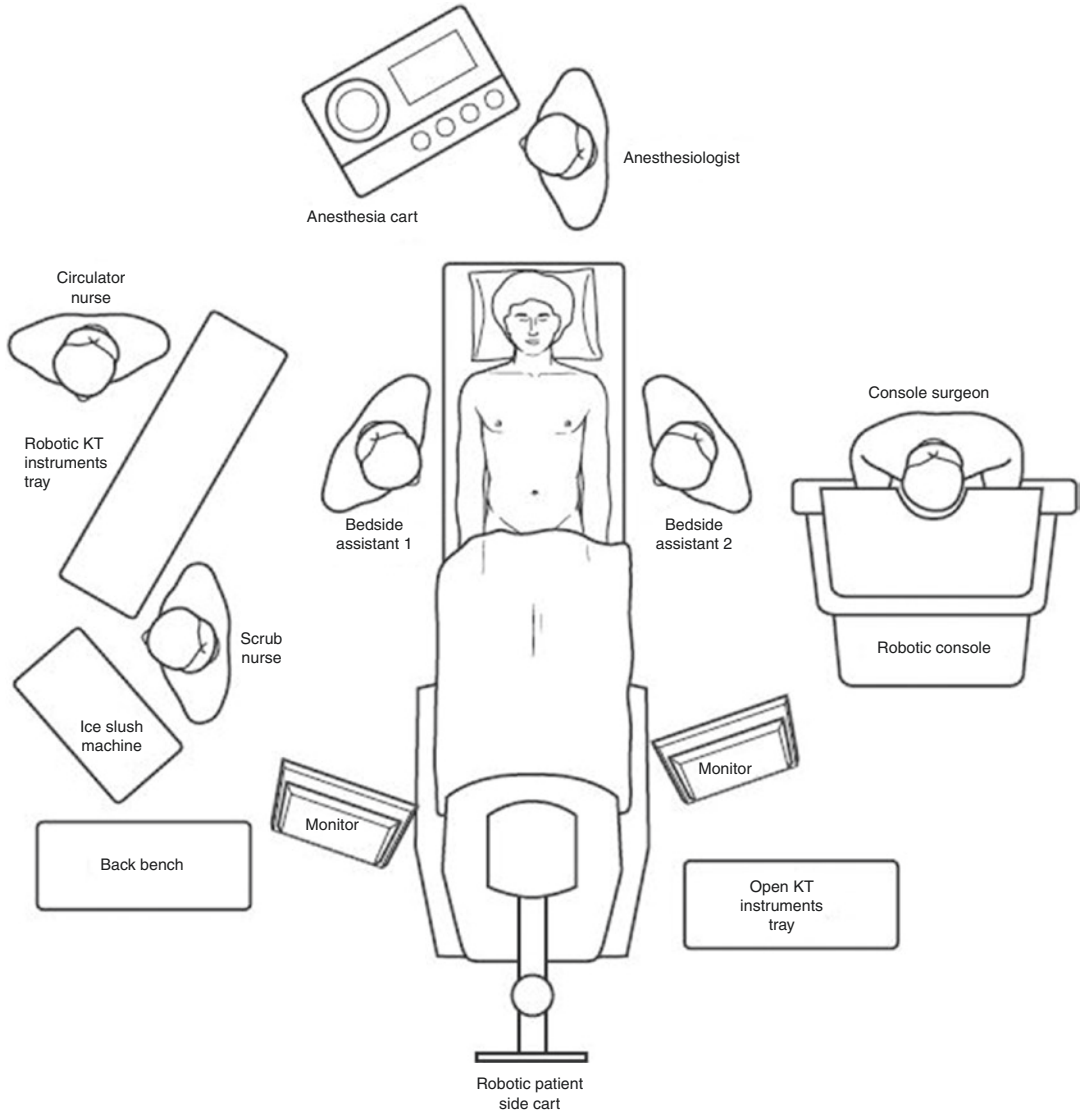


Fig. 51.1 Ideal operating room setup for robotic kidney transplantation with regional hypothermia. Reprinted from Atlas of Laparoscopic Urologic Surgery, 3rd. ed., Minimally invasive renal recipient surgery, Sood A, Jeong W, Bhandari M, et al., 2016, with permission from Elsevier

Patient Position

Patient positioning followed the well-established template used for the Vattikuti Institute prostatectomy technique of robotic radical prostatectomy [26, 27]. Briefly, the patient is placed in steep lithotomy with a 15–20° Trendelenburg tilt (Figs. 51.2 and 51.3). The robot is docked in between the legs. This patient position and robot docking can be utilized independently of the proposed location for the graft (left or. right iliac fossa). However, the right iliac fossa is the preferred location for renal grafting in general, irrespective of the surgical approach (open or MIS), as the iliac vessels are superficial and thus more accessible in that location.

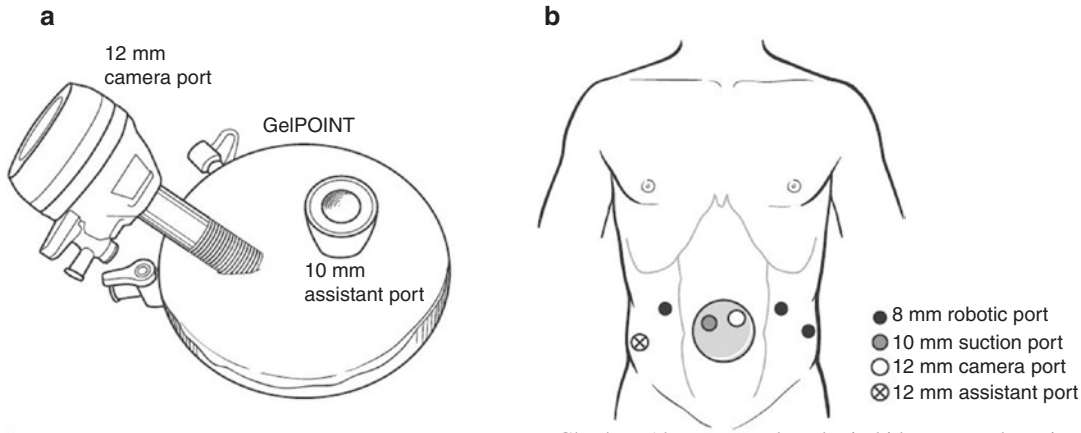


Fig. 51.2 (**a**) GelSeal cap with a 12-mm camera-port (C) and a 10-mm assistant port, for the 5-mm suction (A); (**b**) Diagrammatic illustration of port placement for robotic kidney transplantation with regional hypothermia. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

Instruments

Robotic Instruments and Ports

Robotic 8 mm ports ×3; Robotic Maryland Bipolar Grasper; Robotic Monopolar Curved Scissors (with Cover-tip accessory); Robotic Black Diamond Micro Forceps; Robotic Large Needle Driver; Robotic Hem-o-Loc Applier and Robotic ProGrasp Forceps (on the 4th arm).

Laparoscopic Instruments

Microfrance laparoscopic grasper; Suture passer; Hem-o-Loc applier (5 mm, 10 mm, 12 mm with Weck Clips – 5 mm, 10 mm, 12 mm) and Bulldog Clamps with appliers (Scanlan International, Saint Paul, MN).

Disposables

GelPOINT platform ×1 (Applied Medical Corp, Rancho Santa Margarita, CA); 12 mm camera port × 1 and 12 mm assistant port × 1; 5-F ureteric catheter for flushing and Sutures [5-0 CV-6 ePTFE (Gore-Tex; W. L. Gore & Associates Inc., Flagstaff, AZ) and 4-0 PDS/3-0 V-Loc CV23 6″ (Covidien Inc, New Haven, CT, USA)].

Other

Ice-slush Machine (OR Solutions Model: ORS-1075 H5); Slush Machine drape (OR Solutions Model: ORS-321); Toomey Syringes (modified, nozzle sawed off) and 3.6 mm Aortic Punch (Teleflex-Medical Inc., Research Triangle Park, NC).

Surgical Technique

We have previously described our technique of RKT with regional hypothermia in a detailed step-by-step manner [24] and have also compared it with other approaches of RKT in a tabulated fashion [28]. Here, we recapitulate the major steps of the procedure as below:

Port Placement

Figures 51.2 and 51.3 illustrate the GelPOINT and trocar placement. The GelPOINT device is a hand-access platform, initially devised for single-site laparoscopic surgery that we utilize for easy introduction of ice-slush and the renal graft during RKT with regional hypothermia. The GelPOINT device consists of two components: a GelSeal cap and an access port. A 12-mm camera port and a 5/10-mm suction port are placed into the GelSeal cap ahead of

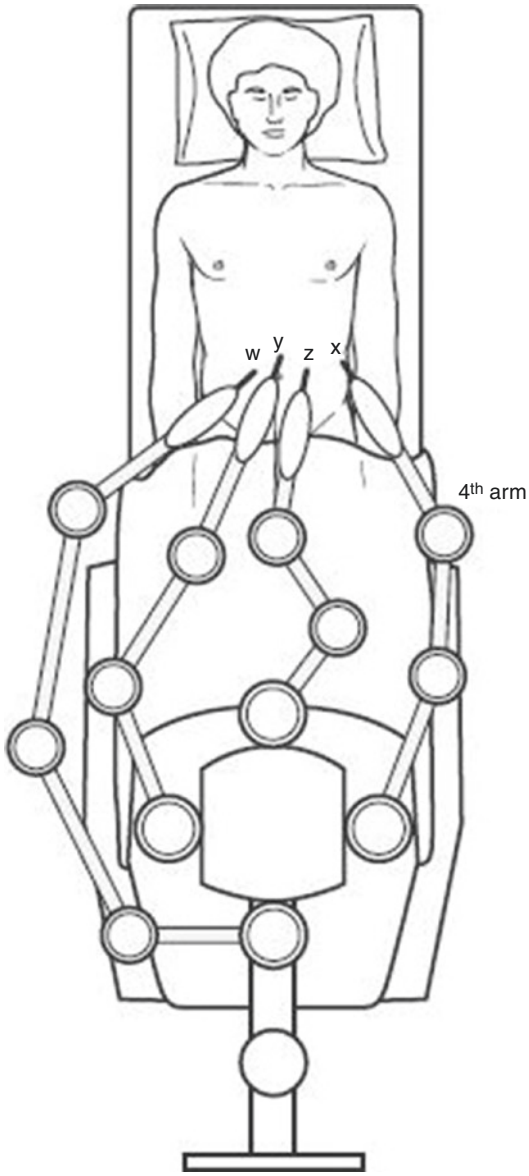


Fig. 51.3 Robot docked in between the legs of the patient, in a manner typical for robotic radical prostatectomy. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

time (Fig. 51.2a). With the patient in lithotomy position, an approximately 5 cm long vertical periumbilical incision is made. The GelPOINT access port is then inserted through this incision and the prepared GelSeal cap is secured on top of the port. After establishing pneumoperitoneum (usually ~15–20 mm Hg), the patient is moved to steep Trendelenburg. Other ports, including three 8-mm robotic ports and one 12-mm assistant port are placed under direct visual guidance at positions as demonstrated in Fig. 51.2b. The 8-mm robotic ports for the left and the right robotic arms are placed along the left and right mid-clavicular lines around the level of the umbilicus, respectively. The third 8-mm port for the 4th robotic arm is placed on the patients' left side near the iliac fossa. The 12-mm assistant port is placed near the iliac fossa on the patients' right side (Fig. 51.2b).

Preparation of Recipient Vascular Bed and Bladder

The surgery starts with identification of external iliac vessels in the pelvis. With the camera lens in 30° up position, the bladder is taken down, in a manner similar to robotic prostatectomy (anterior approach), with monopolar scissors in the dominant hand of the console surgeon and Maryland bipolar forceps in the non-dominant. The camera lens is then switched to 30° down, and the external iliac vessels are skeletonized as shown in Fig. 51.4. Small vascular and lymphatic offshoots are controlled using clips, ties or electrocautery as needed. Next, a transverse incision is made approximately 3 cm distal to the cecum and peritoneal flaps are raised bilaterally over the psoas – these are utilized later for extraperitonealizing the graft (see later).

Then the bladder is distended with 240 ml of normal saline (via Foley catheter) and detrusor flaps are created in preparation for a subsequent modified Lich-Gregoir ureteroneocystostomy (Fig. 51.5). Of note, a surgical video demonstrating the procedure is available at the following hyperlink: http://www.europeanurology.com/surgery-in-motion-video/1127/robotic-kidney-transplantation-with-regional-hypothermia-a-step-by-step-description-of-the-vattikuti-urology-institute-medanta-technique-ideal-phase-2a.

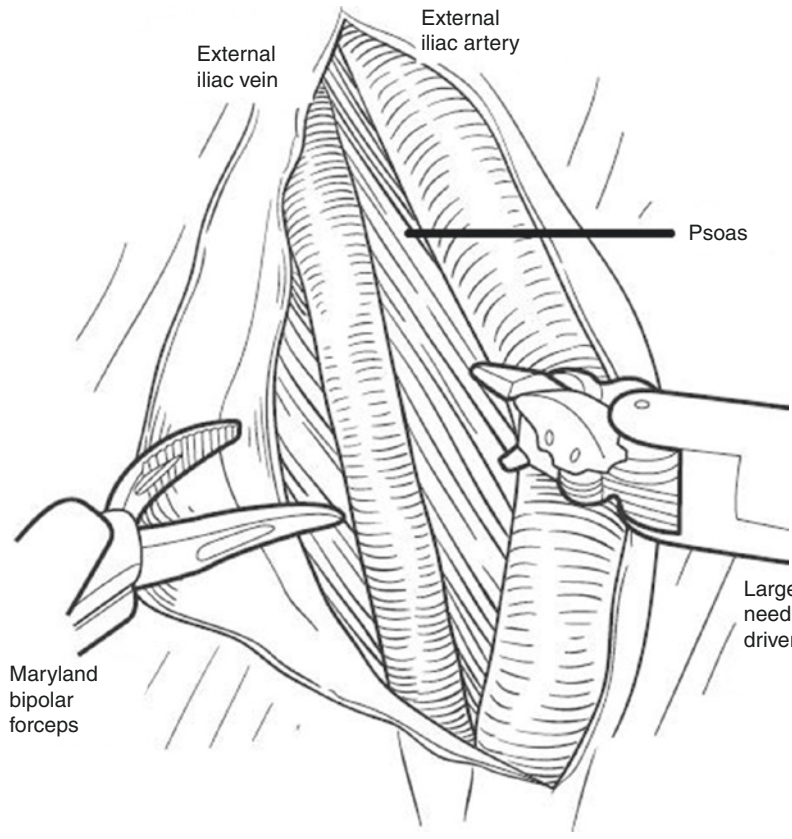


Fig. 51.4 Skeletonization of iliac vessel bed. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

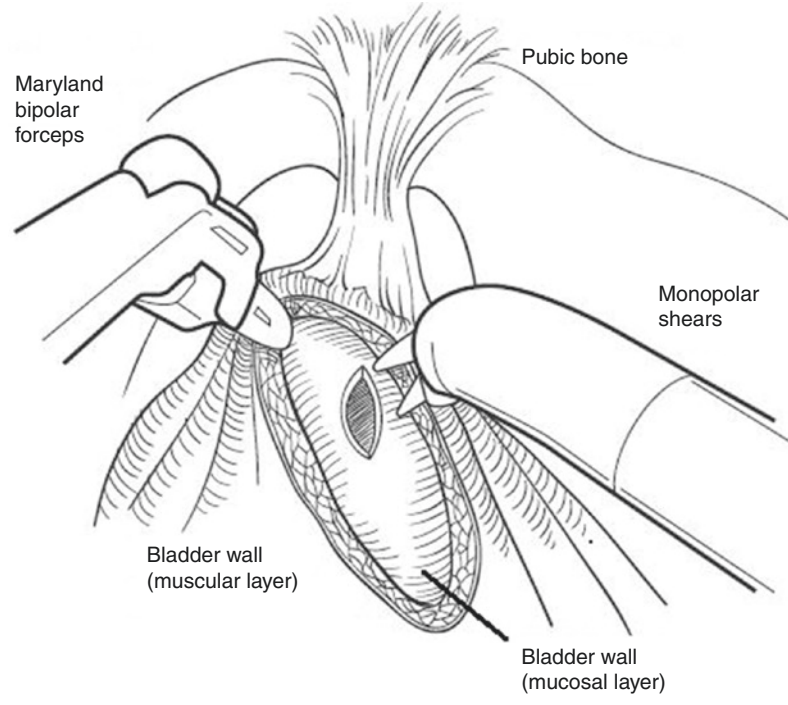


Fig. 51.5 Bladder preparation, detrusor flaps are created for ureteroneocystostomy (modified Lich-Gregoir). Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

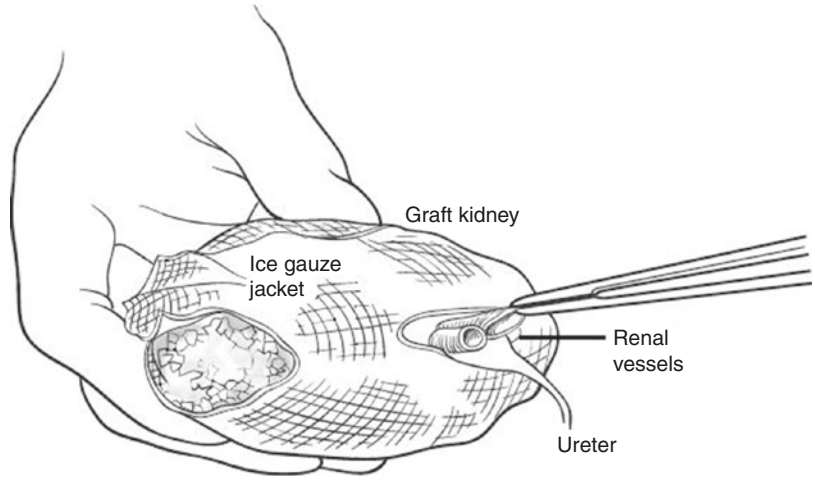


Fig. 51.6 Graft kidney wrapped in a gauze jacket filled with ice-slush. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

Preparation of Donor Graft

Although a routine step at most transplantation centers, it is one of the most critical steps in the initial stages of procedure development – *optimal, efficient* and *timely* preparation of the donor graft helps recipient surgery progress smoothly and reduces overall operative time. It may also impact graft outcome by decreasing warm and cold ischemia times.

Briefly, while the recipient vascular bed and bladder are being prepared, the graft kidney is harvested laparoscopically in an adjacent OR by a donor kidney team working in tandem with the recipient team. The donor organ is prepared in a manner similar to open KT; it is defatted and perfused with cold Ringer's lactate or 0.9% saline. The graft is then wrapped in a gauze jacket filled with ice-slush with an opening to allow access to the hilar structures (the renal vessels and the ureter; Fig. 51.6). The upper pole of the kidney may be tagged with a long silk-tie tail to aid in orientation following graft insertion. The ice/gauze jacket serves two valuable functions: it keeps the graft kidney in a hypothermic milieu, and it also facilitates atraumatic intracorporeal handling of the graft during anastomoses.

Introduction of the Graft and Cooling

The pelvic bed is cooled to 18–20° centigrade with the introduction of approximately 240 ml ice-slush (Fig. 51.7) via modified Toomey syringes (nozzles sawed off; Fig. 51.8). The ice-slush should be delivered approximately 10–15 min prior to introduction of the graft kidney to achieve effective cooling of the pelvic bed. Next, the camera arm and the GelSeal cap are removed and the graft in its ice jacket is introduced without resistance though the access port (Fig. 51.9). Care must be taken to orient the lower pole towards the feet of the patient and the hilum towards the iliac vessels. More ice-slush may be added on top of the graft (Fig. 51.10) to achieve uniform and effective regional hypothermia. We have previously shown that by utilizing local hypothermia, we were able to overcome the delay in graft function recovery that other groups practicing minimally invasive KT noted (see reference [8].

Venous Anastomosis

After the renal graft is stiuated and optimal hypothermia is ensured, the external iliac vein (EIV) is clamped utilizing robotic drop-in bulldog clamps (Fig. 51.11). A venotomy is made using cold monopolar scissors. Then, the scissors are swapped for large needle driver while Black Diamond microforceps are kept in the non-dominant hand. The graft renal vein is anastomosed in a continuous end-to-side manner to the EIV (Fig. 51.12) using Gore-Tex CV-6 suture. The large needle holder is used to pass the stitch

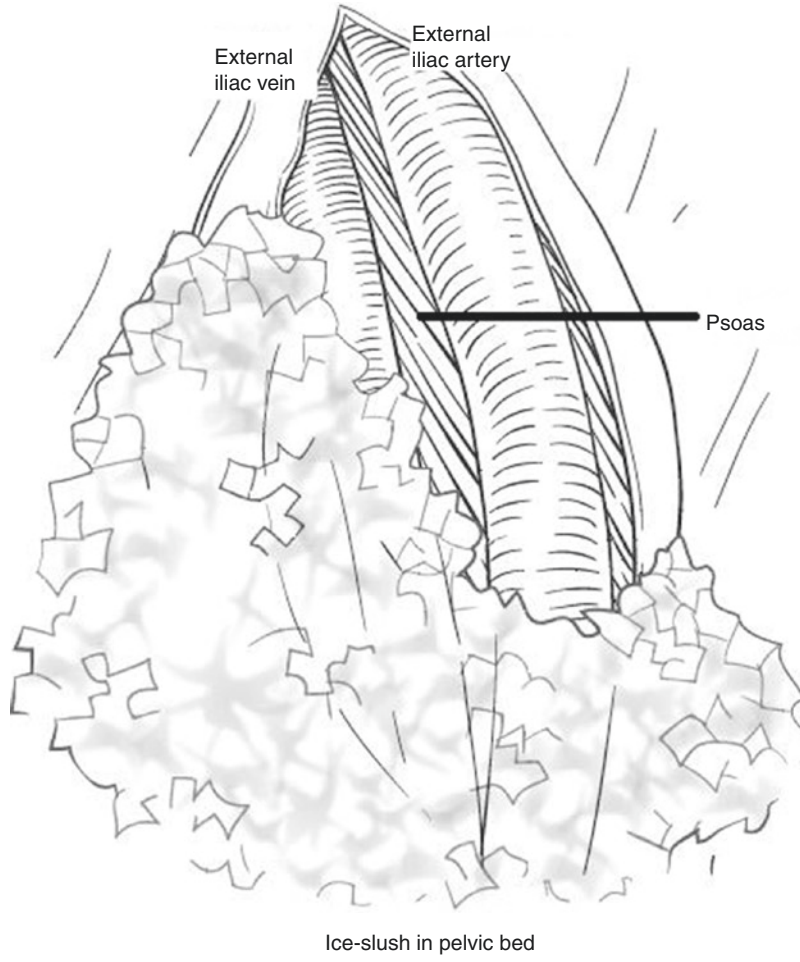


Fig. 51.7 Pelvic bed lined with ice-slush to achieve pelvic-bed cooling before introduction of the graft kidney. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

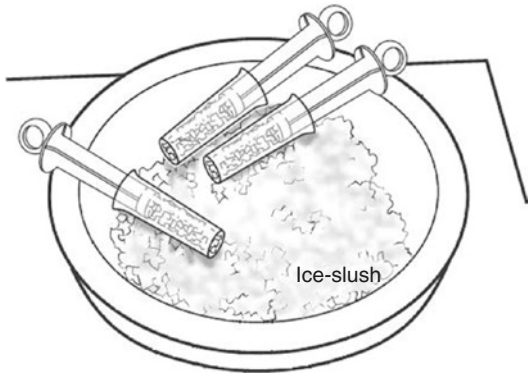


Fig. 51.8 Multiple modified Toomey syringes (nozzles cut off) being readied for rapid delivery of ice slush. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

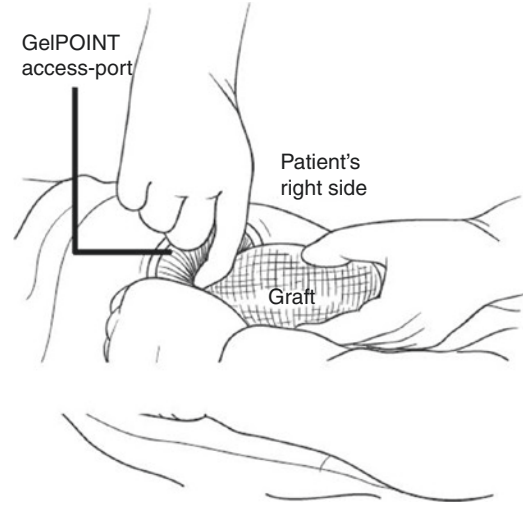


Fig. 51.9 Graft kidney being introduced through the access port (GelSeal cap and the camera arm have been removed). Reprinted from Atlas of Laparoscopic Urologic Surgery, 3rd. ed., Minimally invasive renal recipient surgery, Sood A, Jeong W, Bhandari M, et al., 2016, with permission from Elsevier

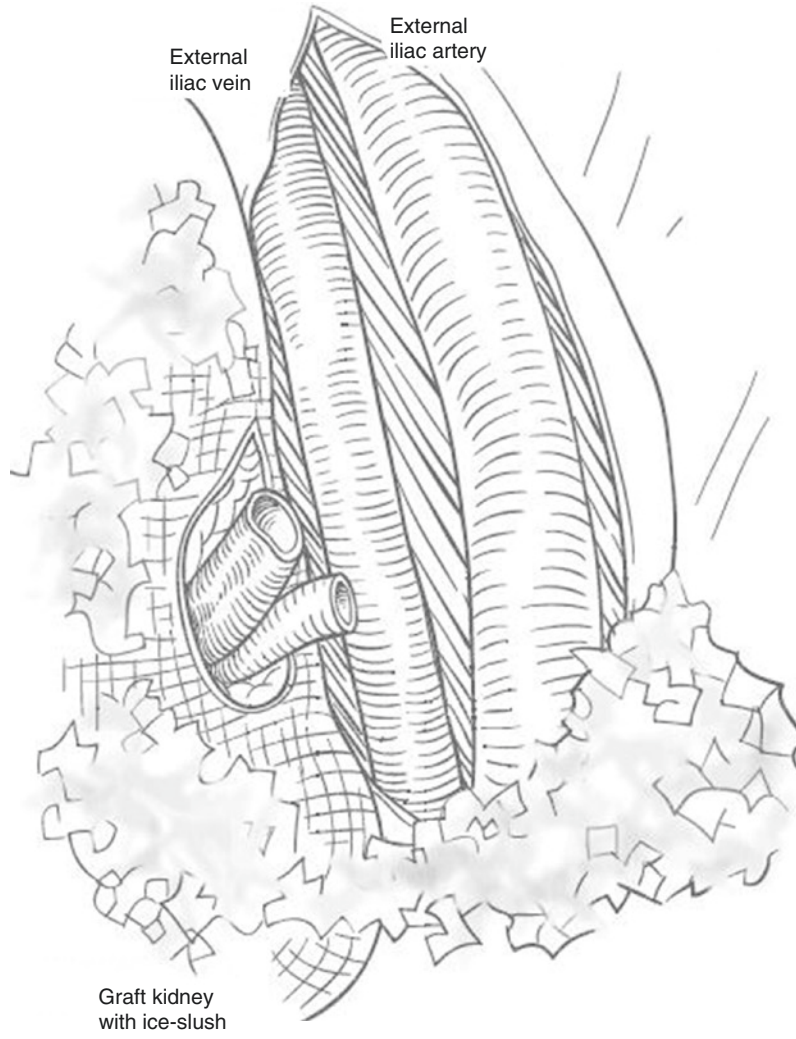


Fig. 51.10 Additional ice slush delivered onto the graft kidney immediately after its introduction, to achieve uniform cooling. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

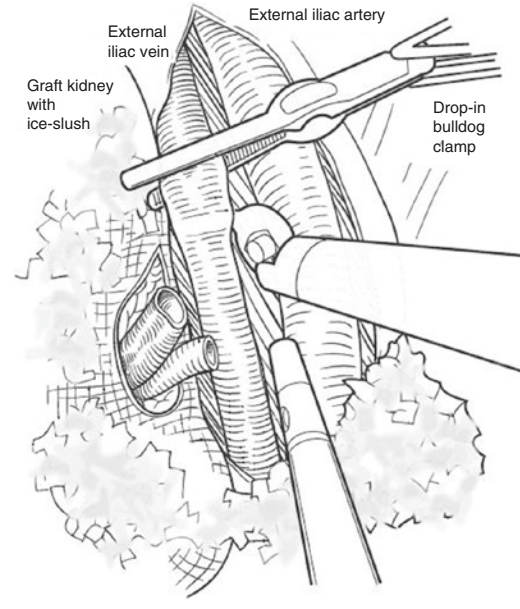


Fig. 51.11 External iliac vein clamped with a robotic bulldog clamp. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

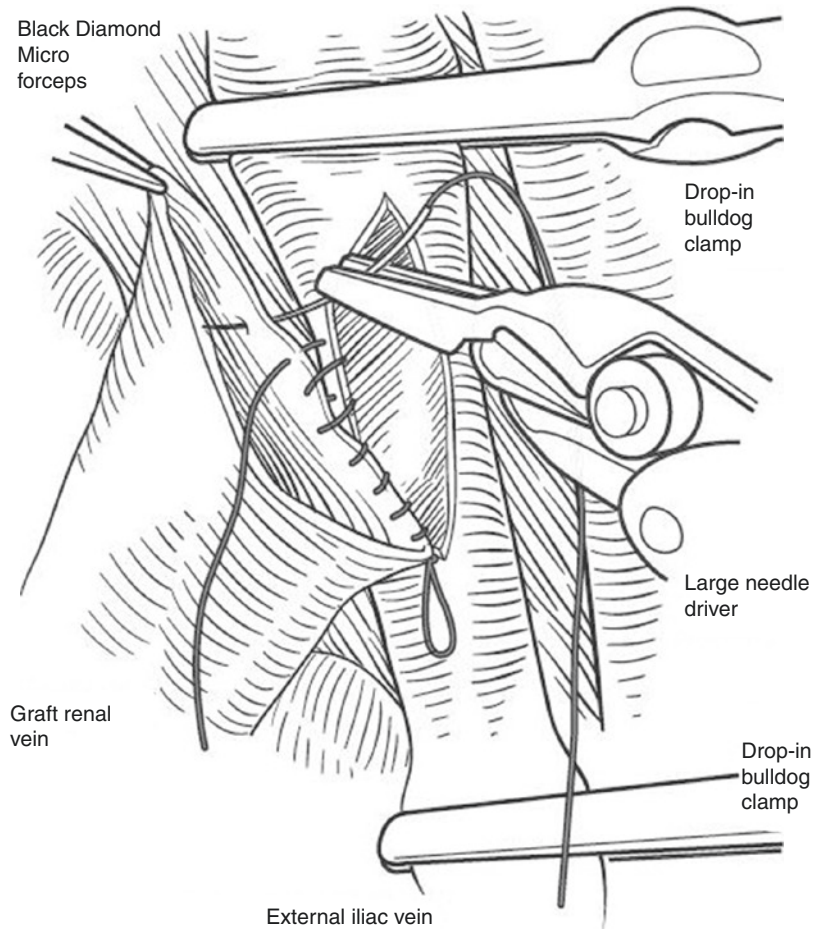


Fig. 51.12 End-to-side continuous venous anastomosis. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

and the Black Diamond micro forceps is utilized to atraumatically hold the vein open and pull the stitch through. Just prior to completing the venous anastomosis, the lumen is flushed with heparinized saline via a 5F ureteric catheter introduced through the 12-mm assistant port. The graft renal vein is occluded using another drop-in bulldog clamp and the EIV is unclamped. Additional ice-slush is introduced as and if required (if the venous anastomosis took ≥20 min to complete).

Arterial Anastomosis

Next, the external iliac artery (EIA) is clamped using the robotic bulldog clamps. A linear arteriotomy is made using the monopolar scissors or the robotic scalpel (scissors work well and are more easily available, so, this is optional). This is converted to a circular arteriotomy (Fig. 51.13) using a 3.6-mm aortic punch introduced through the GelPOINT by the assistant surgeon (see the video at the link provided above for further details). The renal artery is anastomosed in a continuous end-to-side fashion to the EIA using Gore-Tex CV-6 suture (Fig. 51.14). After flushing and testing the anastomotic integrity, the graft renal artery is temporarily clamped and the EIA is unclamped. If the anastomosis appears secure, the renal artery and vein bulldog clamps are removed and the gauze jacket is removed. The graft kidney is visually inspected for color (pink), turgor (taught) and on-table diuresis (grossly visible urine formation). Following unclamping, pneumoperitoneum pressure is dropped to 8 mm Hg and an intravenous bolus of 100 mg furosemide is given.

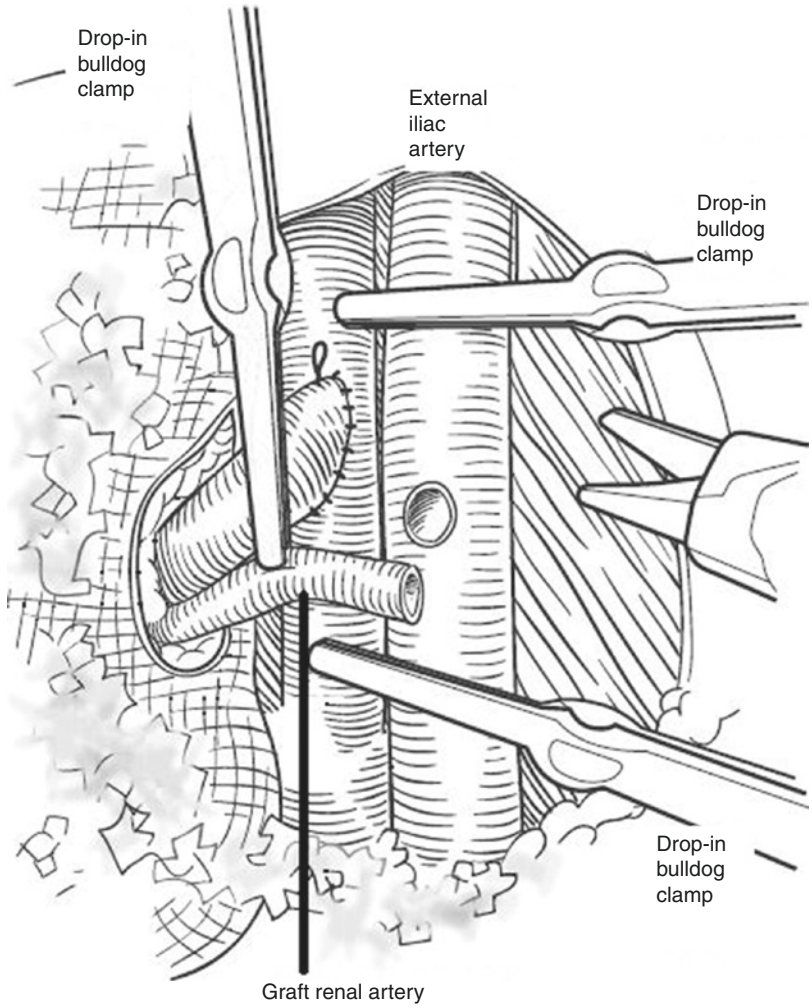


Fig. 51.13 External iliac artery clamped with a robotic bulldog and linear arteriotomy converted to circular arteriotomy using a 3.6-mm aortic punch. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

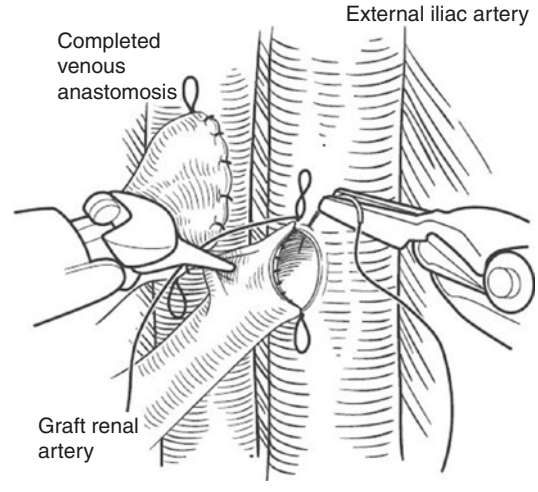


Fig. 51.14 End-to-side continuous arterial anastomosis. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

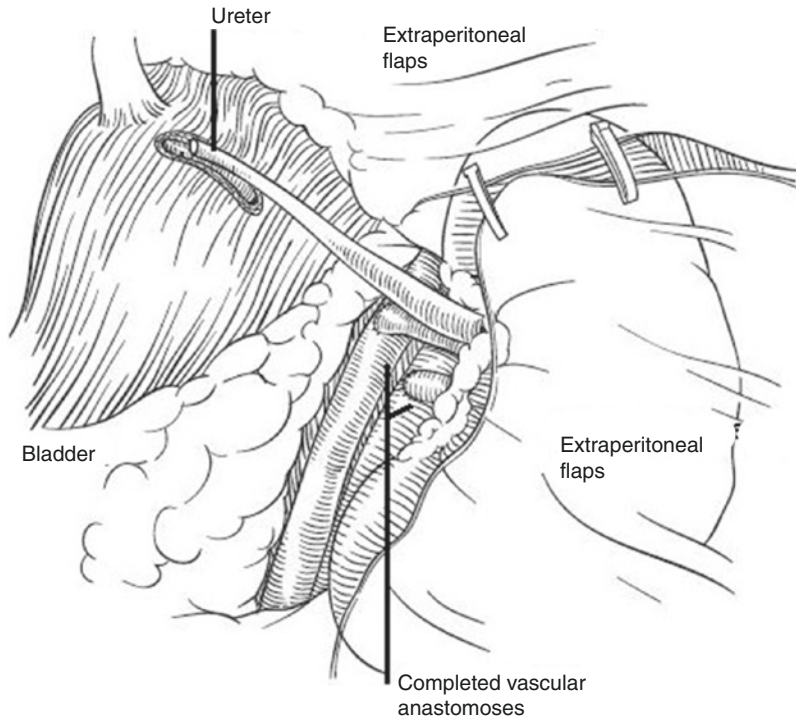


Fig. 51.15 Retroperitonealization of the graft using peritoneal flaps prepared earlier during iliac vessel bed dissection. Reprinted from Atlas of Laparoscopic Urologic Surgery, 3rd. ed., Minimally invasive renal recipient surgery, 2016, Sood A, Jeong W, Bhandari M, et al., with permission from Elsevier

Then the graft kidney is extraperitonealized by approximating the peritoneal flaps prepared earlier (Fig. 51.15). This step insures against graft torsion (vs. leaving the graft intraperitoneal). The importance of this step was demonstrated by Modi et al., when during the initial stages of their pioneering technique of laparoscopic KT they did not routinely extraperitonealized or fixed the kidney and thus noted 2 torsions with graft loss. The subsequently standardized their technique and performed graft fixation in all cases and did not note torsion afterwards [29].

Ureteroneocystostomy

Utilizing the modified Lich-Gregoir technique, the ureter is apposed to the bladder mucosa in a continuous manner (4-0 polydiaxone suture). A double-J stent, introduced through the 12-mm assistant port, is inserted into the ureter after completing the posterior wall of the mucosal ureteroneocystostomy. The detrusor is closed atop in a continuous fashion using the V-Loc suture (Fig. 51.16), creating an antirefluxing mechanism. It is important to note that we perform (and strongly recommend) extraperitonealization prior to ureteroneocystostomy, as it gives time to observe the graft vessels for any potential kinking or compression that might have occurred during extraperitonealization. The muscle, fascia and skin are closed in the standard fashion. At the end of each case, after fascia-muscle and skin closure in the standard manner, we perform a Doppler USG to ensure optimal graft vascularity.

Extra: Accessory Vessels

In six of 79 cases, the graft kidney had an accessory polar artery measuring 1.2–1.6 mm in diameter, perfusing >10% of the parenchyma. These were considered unsuitable for bench reconstruction. Thus, we decided to anastomose the accessory artery to the recipient inferior epigastric artery (IEA). The recipient IEA

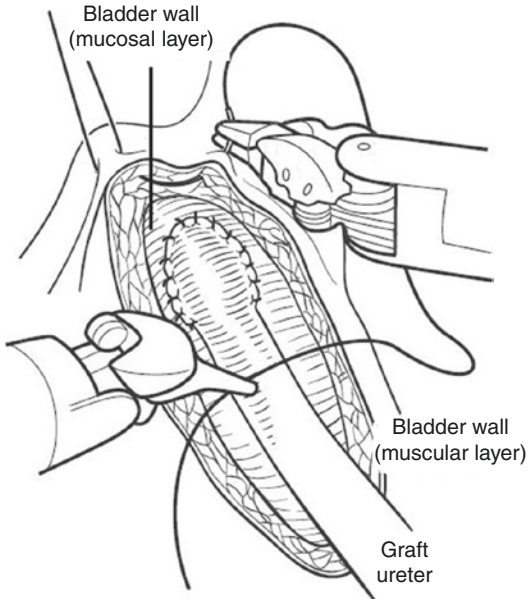


Fig. 51.16 Ureteroneocystostomy (modified Lich-Gregoir). Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

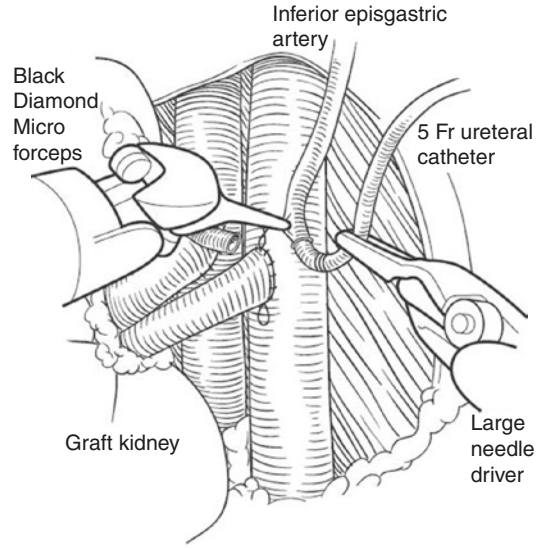


Fig. 51.17 Inferior epigastric artery being flushed with heparinized saline using a 5F ureteric catheter. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

is prepared for anastomosis prior to introduction of the kidney in such cases. A bulldog clamp is used to occlude the stump, and the distal end is secured (Fig. 51.17). The accessory polar artery is anastomosed to the IEA using 7-0 or 6-0 prolene sutures (Fig. 51.18). This step may be technically challenging for surgeons learning the technique, given the small caliber of the vessels. However, the surgeon may take his time as the ischemia clock is not ticking at this moment. We use interrupted sutures for this step.

Early 6-Month Outcomes

Between January 2013 and December 2014, 79 patients underwent RKT and 350 underwent open KT. All patients had a minimum follow-up of 6 months with a median follow-up of 23.1 months for RKT and 18.6 months for open KT.

None of the patients in the RKT suffered delayed graft function while 6 (1.7%) in the OKT group did ($p = 0.477$). Operative times were longer

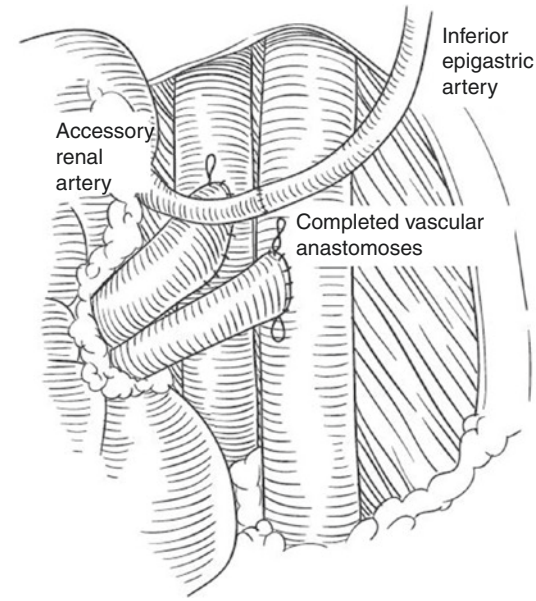
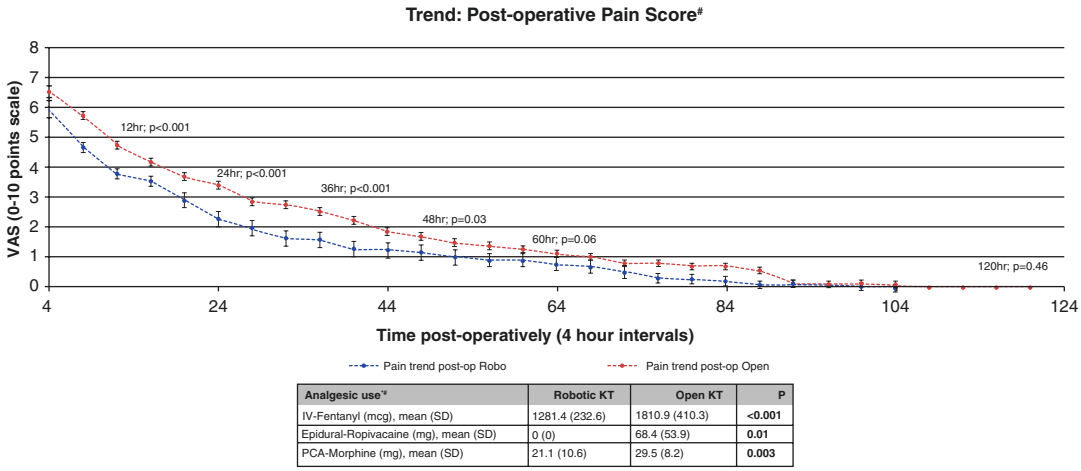


Fig. 51.18 Lower-pole accessory artery anastomosis to the inferior epigastric artery using 6–0 prolene sutures. Reprinted from Menon M, Sood A, Bhandari M, Kher V, Ghosh P, Abaza R, et al. Robotic kidney transplantation with regional hypothermia: a step-by-step description of the Vattikuti Urology Institute-Medanta technique (IDEAL phase 2a). Eur Urol. 2014;65(5):991–1000; with permission from Elsevier

Table 51.1 Operative parameters in patients undergoing robotic and open kidney transplantation (baseline characteristics although not shown here did not differ among the groups)

Operative parameters	Robotic KT	Open KT	P
Operative time (min), mean (SD)	204.1 (39.8)	166.6 (40.1)	**<0.001**
Ischemia times (min), mean (SD)			
Warm	2.4 (1.1)	2.4 (0.7)	0.89
Cold	26.3 (14.1)	19.6 (6.0)	0.009
Re-warming (ice-slush)	42.6 (9.3)	31.7 (5.1)	**<0.001**
Total	71.3 (19.2)	53.7 (8.5)	**<0.001**
Vascular anastomoses times			
Arterial (min), mean (SD)	12.0 (2.6)	13.0 (3.0)	0.23
Venous (min), mean (SD)	12.8 (3.4)	10.6 (1.5)	**0.027**
Blood loss (mL), mean (SD)	151.7 (103.5)	296.8 (183.2)	**<0.001**
Intraop vascular injuries, No. (%)	0 (0)	0 (0)	1.00
Incision length (cm), mean (SD)	6.1 (0.5)	15.6 (1.1)	**<0.001**
Anastomotic revision, No. (%)	0 (0)	0 (0)	1.00
Conversion to open, No. (%)	1 (1.3)	NA	NA



Analgesic use*	Robotic KT	Open KT	P
IV-Fentanyl (mcg), mean (SD)	1281.4 (232.6)	1810.9 (410.3)	**<0.001**
Epidural-Ropivacaine (mg), mean (SD)	0 (0)	68.4 (53.9)	**0.01**
PCA-Morphine (mg), mean (SD)	21.1 (10.6)	29.5 (8.2)	**0.003**

Fig. 51.19 Trends in pain scores using Visual Analog Scale between robotic and open kidney transplantation patients during the initial postoperative period, and analgesic use

in the RKT group – on average it took approximately 204 min for an RKT case to be finished while an open KT case took approximately 166 min ($p < 0.001$). Re-warming time (i.e., the time that the graft kidney spent in the recipient prior to unclamping) was also longer in RKT – 42.6 min versus 31.7 min ($p < 0.001$). Blood loss and incision size were shorter in RKT patients (Table 51.1). One RKT patient needed conversion to open. Pain scores and analgesic use were significantly lower in the RKT patients (Fig. 51.19). Complications were also significantly lower in the RKT population when compared to the open KT patients (Table 51.2). The most remarkable reduction was noted in the occurrence of lymphoceles, 17.8% in

Table 51.2 Clavien-Dindo graded complications in patients undergoing robotic and open kidney transplantation (baseline characteristics although not shown here did not differ among the groups)

Clavien-Dindo Grade	Robotic KT	Open KT	P
	No. (%)	No. (%)	
Grade I	5 (6.3)	44 (12.6)	0.168
Grade II	1 (1.3)	10 (2.9)	0.697
Grade III			
Grade III a	0 (0)	3 (0.8)	0.999
Grade III b	3 (3.8)	21 (6.0)	0.592
Grade IV			
Grade IV a	0 (0)	0 (0)	0.999
Grade IV b	0 (0)	0 (0)	
Grade V	0 (0)	0 (0)	0.999
Total	9 (11.4)	78 (22.3)	**0.030**

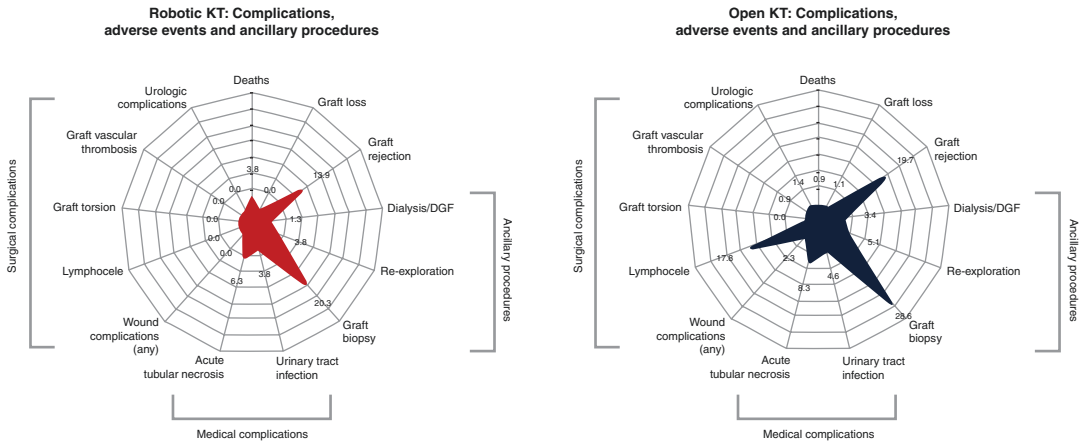


Fig. 51.20 Spider Plots of complications in patients undergoing robotic and open kidney transplantation

the open group versus 0% in the RKT group. Wound complications including surgical site infections and wound dehiscence were also lower in the RKT group (0%) versus 2.3% in the open KT group. Other complications also exhibited also exhibited a favorable profile for RKT as shown in the spider-plots in Fig. 51.20. Table 51.2 provides the Clavien-Dindo breakdown of the complications – overall 22.3% of the patients undergoing open KT suffered a complication while the percentage of patients undergoing RKT that suffered a complication was 11.4% (p-0.030). Creatinine fall trends, Graft and Patient Survival did not exhibit any differences – 1 year graft survival was 98.8 and 99.1 for RKT and open KT, respectively (p = 0.314), and 1 year overall survival was 99.1 and 99.1 for RKT and open KT, respectively (p = 0.100).

Conclusions

RKT with regional hypothermia is technically feasible, safe, and reproducible, and has promising functional outcomes. It appears to reduce postoperative morbidity in the fragile end-stage renal disease patients, and appears to be a safe surgical alternative to the conventional kidney transplant with equivalent graft and overall patient survival outcomes. However the existing data only represent level 3 evidence in support of RKT. Larger multicenter experiences and randomized controlled trials with long-term follow up are needed to establish RKT as a serious contender to open surgery given its higher cost at present.

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Part VI

Bladder

Anatomic Robot-Assisted Radical Cystectomy in Male

52

Taylor C. Peak and Ashok K. Hemal

Abstract

Radical cystectomy with an extended pelvic lymphadenectomy is the gold standard for patients with muscle-invasive bladder cancer and those with recurrent, high-grade noninvasive disease. As in other urologic malignancies, the use of the robotic platform to perform radical cystectomies has revolutionized the treatment of bladder cancer. It is clear from the results of published reports in the literature, as well as from our own experience at Wake Forest in performing over 250 robot-assisted radical cystectomies (RARC), that the clinical and oncologic goals of the radical cystectomy are achieved. Furthermore, in select patient populations it may even be preferred over the open approach. Therefore, in effort to share our experience with the urologic community, we set out to describe a detailed anatomical description of the steps that are involved in performing the RARC.

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Keywords

Anatomic robotic radical cystectomy · Pelvic lymph node dissection · da Vinci robotic system · Techniques of space

Introduction

Radical cystectomy with an extended pelvic lymphadenectomy is the gold standard for patients with muscle-invasive bladder cancer and those with recurrent, high-grade noninvasive disease. Unfortunately, this operation is also one of the most morbid operations in urology due to its complex nature and the potential short and long-term complications that follow. The use of minimally invasive technology, and specifically, the robotic platform, has revolutionized the field of urologic oncology, leading to decreases in mortality and morbidity with associated improvements in the quality of life of patients.

The first series of robotic radical cystectomies was reported in 2003 by Menon et al. [1]. Since its inception, the robot-assisted radical cystectomy (RARC) has continued to gain popularity throughout the urologic community. Although its use is growing fast, it has yet to gain the same level of widespread acceptance as the robotic prostatectomy. This can be attributed to the high level of surgical complexity, the comorbidities of the often frail, elderly patients, as well as the desire from surgeons to indulge in long surgical

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procedures comprising ablative and reconstructive components. Therefore, this chapter describes a detailed anatomical description of the steps that are involved in performing the RARC, in an effort to provide greater appreciation for the complexity of the case. Furthermore, we will highlight some of the more recent clinical studies that have explored the oncologic efficacy of the procedure.

Indications and Contraindications

Candidates for a robot-assisted radical cystectomy (RARC) are similar to those who undergo an open radical cystectomy, and include patients with muscle-invasive bladder cancer, high-grade non-muscle invasive disease at increased risk of invasion, select cases of advanced disease, as palliative therapy, and finally as salvage treatment. Robotic surgery may be particularly advantageous in select cases of locally advanced bladder cancer because the morbidity and mortality is often too high to undergo open radical cystectomy, and yet often leads to adverse pelvic and urinary symptoms in addition to disease progression, significantly decreasing the patient's quality of life [2].

While there are no absolute contraindications, the surgeon should consider patients who are obese, have had prior pelvic radiation, focal ablation to the prostate, extensive prior abdominal surgeries, or bulky disease as relative contraindications for robotic surgery. In particular, the excessive amount of visceral fat of obese patients often distorts the exact surgical dissection planes and leads to longer operation times, larger blood loss, higher postoperative complication rates, and higher conversion rates. In addition, the steep Trendelenburg that patients are placed in can lead to increased risk of complications in those with a history of angle closure glaucoma, intracranial aneurysm, severe mitral valve insufficiency, and severe pulmonary dysfunction.

Pre-operative Workup

All patients should undergo a thorough preoperative workup beginning with an extensive history and physical along with the appropriate lab work, imaging studies, and endoscopic assessment. A basic lab work up should include serum chemistries, liver function tests, and complete blood counts. Patients with adequate renal function and no contrast allergies should be clinically staged with CT of the chest, abdomen, and pelvis. If the patient has impaired renal function, then an MRI is a suitable alternative. An elevated alkaline phosphatase or symptomatic bone pain should prompt a bone scan. The transurethral resection should obtain adequate tumor tissue sampling to establish adequate pathologic diagnosis, and if needed re-TURBT should be employed. In addition, a bimanual exam should be performed prior to and after the resection to further establish the local extent of the disease.

Patient Pre-operative Preparation

As per local requirement or patient's preference, we admit patients the day prior to surgery for preanesthesia check-up, to meet with the enterostomal therapist pre-operatively for marking and urostomy teaching, mechanical bowel preparation, and a clear liquid diet. Preoperative counseling, including teaching of the Enhanced Recovery after Surgery (ERAS) protocol is essential to improving outcomes in this patient population due to the complexity of post-operative care and follow-up. Evidence highlighting the importance of preoperative enterostomy teaching is predominantly based on the colorectal surgery literature. Nevertheless, many of the principles are the same, and as such it is believed that preoperative education improves postoperative outcomes, including factors related to quality of life, stomal skill acquisition, and long-term adjustment to an ostomy [3–5]. If a neobladder diversion is being considered, then clean intermittent catheterization

teaching is also essential because there is the added benefit of improving patients' ability to irrigate mucus if he is not able to empty his neo-bladder.

Given that a radical cystectomy is associated with a 40–60% reduction in functional capacity, it has now become evident that patients should not only be educated prior to surgery, but that they should be advised to physically prepare as well. The reduction in functional capacity for those undergoing cystectomy often manifests as fatigue over the following 8–12 weeks after surgery. Because this is common in all patients undergoing major abdominal surgery, robotic or open, it is now believed that a pre-rehabilitation plan that combines both cardiovascular and resistance exercises should be undertaken by patients in preparation for surgery in order to allow them to return more quickly to baseline.

Bowel Prep

If a mechanical bowel preparation is desired, we recommend Go-lytely. The patient is allowed clear liquids the day before surgery and nothing by mouth after midnight. It should be noted that the advantages of this practice are not well established in the literature. In addition, complications that can arise with such a preparation include preoperative dehydration, electrolyte imbalance, bacterial translocation, and increased susceptibility to enterocolits. There is no evidence to suggest a difference in overall complication rates, gastrointestinal complications, time to discharge, and recovery of bowel function between those patients who received a bowel preparation and those who did not [6].

Positioning

The operation is performed under general endotracheal anesthesia with the patient positioned in the dorsal lithotomy position with sufficient padding around the shoulders, elbows, and sacrum. The patient's arms are tucked at the side of his body with adequate padding in order to prevent compartment syndrome and neuromuscular injuries. Once the patient has been adequately padded and secured, the table is placed in steep Trendelenburg, elevating the pelvis and decreasing its depth for easier surgical access (Fig. 52.1a). As an alternative position, the patient can be left supine while the robot is docked at the side to

Fig. 52.1 (**a**) Steep Trendelenburg position; (**b**) Patient is supine, in 20° Trendelenburg position for side-docking of robot. [Reprinted from Richards et al. [8] with permission from Mary Ann Liebert, Inc. Publishers]

Table 52.1 All required instrumentation for RARC

(a) Non-disposable Instrumentation
1. 4-arm da Vinci Si system (Intuitive Surgical, Inc., Sunnyvale, CA)
2. Plasmakinetic bipolar generator (Gyrus ACMI PK; Gyrus ACMI, Norwalk, OH)
3. Johann Fenestrated 5 mm Grasper (MicroFrance®, Medtronic, Minneapolis, MN)
4. KOH Macro Needle Holder (KARL STORZ GmbH & Co. KG, Tuttlingen, Germany)
5. *Hot Shears*™ (Monopolar Curved Scissors) (Intuitive Surgical, Inc., Sunnyvale, CA)
6. PK® dissecting forceps (Intuitive Surgical, Inc., Sunnyvale, CA)
7. ProGrasp™ forceps (Intuitive Surgical, Inc., Sunnyvale, CA)
8. Large needle driver (Intuitive Surgical, Inc., Sunnyvale, CA)
9. Large SutureCut™ needle driver (Intuitive Surgical, Inc., Sunnyvale, CA)
10. 10 mm Stryker suction tip (Stryker; Kalamazoo, MI)
11. 5 mm long Stryker suction tip (Stryker; Kalamazoo, MI)
12. Large laparoscopic Hem-o-lok® appliers (WECK, Teleflex Inc., Research Triangle Park, NC)
13. Extra-large laparoscopic Hem-o-lok® appliers (WECK, Teleflex Inc., Research Triangle Park, NC)
14. Three 8 mm cannulas with obturator and seals (Intuitive Surgical, Inc., Sunnyvale, CA)
(b) Disposable Instrumentation
1. StrykeFlow 2 suction/irrigation system (Stryker; Kalamazoo, MI)
2. Echelon Flex™ Powered ENDOPATH® Stapler (Ethicon Endo-Surgery, Inc., Cincinnati, OH)
3. Large and extra-large Hem-o-lok® clips (WECK, Teleflex Inc., Research Triangle Park, NC)
4. Veress needle (Ethicon Endo-Surgery, Inc., Cincinnati, OH)
5. One ENDOPATH® XCEL™ 12 mm bladeless bariatric trocar for camera port (Ethicon Endo-Surgery, Inc., Cincinnati, OH)
6. One ENDOPATH® XCEL™ 5 mm bladeless trocar (Ethicon Endo-Surgery, Inc., Cincinnati, OH)
7. One ENDOPATH® XCEL™ 15 mm bladeless trocar (Ethicon Endo-Surgery, Inc., Cincinnati, OH)
8. ENDO CATCH™ II 15 mm Specimen Pouch (Covidien, Norwalk, CT)
9. Two extra-large Hem-o-lok® clips prepared with suture attached (WECK, Teleflex Inc., Research Triangle Park, NC) for clipping and tagging of the ureters
(c) Optional Instrumentation
1. 0-Vicryl on CT-1 needle (Ethicon, Inc., West Somerville, NJ)
2. Echelon ENDOPATH® 45 mm Stapler (Ethicon Endo-Surgery, Inc., Cincinnati, OH)
3. 1–0 V-Loc™ 90 (Glycolic acid-trimethylene carbonate, Covidien, Norwalk, CT) for vaginal reconstruction
4. *Harmonic* ACE® Curved Shears 8 mm (Ultrasonic Energy Instrument, Intuitive Surgical, Inc., Sunnyvale, CA)
5. Large Robotic Clip Applier (Intuitive Surgical, Inc., Sunnyvale, CA)
6. *EndoWrist® One*™ Suction/Irrigator (Intuitive Surgical, Inc., Sunnyvale, CA)
7. *EndoWrist®* Vessel Sealer (Intuitive Surgical, Inc., Sunnyvale, CA)
8. *EndoWrist®* Stapler (Intuitive Surgical, Inc., Sunnyvale, CA)
9. LigaSure Atlas™ (Covidien, Norwalk, CT)
10. Enseal® Tissue Sealing Device (Ethicon Endo-Surgery, Inc., Cincinnati, OH)
11. Silicone vessel loops (Aspen Surgical Products, Caledonia, MI)
12. Endo GIA™ Ultra Universal Stapler (Covidien, Norwalk, CT)
13. Lapro-Clip™ (Covidien, Norwalk, CT)

avoid prolonged Trendelenburg in patients at risk for cardiopulmonary complications (Fig. 52.1b). The patient's abdomen, perineum, and groin are prepped and draped in the usual sterile fashion. An 18 French Foley catheter is then placed on the sterile field.

All required instrumentation for RARC can be found in Table 52.1a–c [7].

Port Placement

For da Vinci S and Si Robotic Systems

After the patient is draped, access to the abdomen is gained with a Veress needle allowing for insufflation to 15 mm Hg. Alternatively, access can be obtained using an open Hassan's technique for

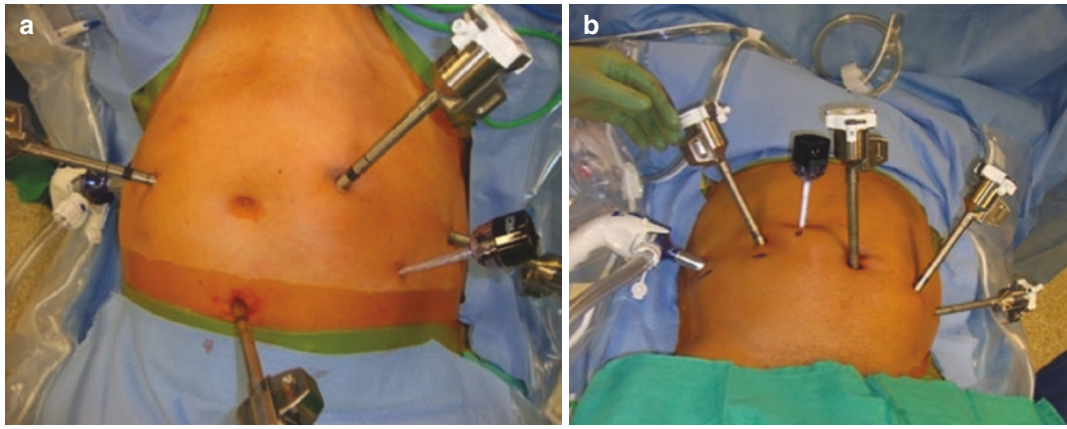

Fig. 52.2 Port placement for the (**a**) da Vinci Si system and (**b**) da Vinci Xi system

camera port placement with subsequent laparoscopic placement of the ports. A12 mm trocar is inserted 5 cm above the umbilicus, allowing for insertion of the camera and inspection of the abdomen and pelvis for access-related injuries, adhesions, and metastatic disease. Under endoscopic guidance, three additional 8 mm robotic ports and two assistant ports are placed (Fig. 52.2a). Two of the 8 mm ports are placed on the right side of the camera port approximately 7–10 cm lateral and at the level of the umbilicus. The third 8 mm port is placed at the level of the umbilicus on left, and an AirSeal trocar is placed in the left lower quadrant of the abdomen approximately 5 cm lateral to the left-sided robotic port and 7 cm superior to the iliac crest. However, in cases where we perform an intracorporeal ileal conduit urinary diversion, the port placement can be reversed. A 15 mm bladeless trocar is placed through the pre-marked stomal site when an ileal conduit is contemplated. A 5 mm port is placed either on the left or the right of the camera port to aid in suction. The robot is then docked between the patient's legs or side-docked. Monopolar Curved Scissors are placed in the right robotic arm, bipolar or plasma kinetic dissecting forceps in the left arm, and the Prograsp™ forces in the third robotic arm. The 30° camera lens can then be used for the majority of the dissection, including the extended pelvic lymph node dissection, in which the 30° lens may be more helpful due to the location deep within the pelvis. The 0° camera lens is helpful when dividing the urethra. Once the ports and instruments are placed, the landmarks of the pelvis must be examined.

For da Vinci Xi Robotic System

With the latest da Vinci Xi system, the six-port transperitoneal approach is utilized, with all working robotic ports placed at the level of umbilicus (Fig. 52.2b). On the Xi system, the 12 mm camera port mentioned previously in the S and Si systems is replaced by a da Vinci 8-mm universal camera-robotic port.

Adhesiolysis

As previously mentioned, one of the relative contraindications for performing a RARC is a prior history of abdominal surgery. This can put the patient at risk for the development of intra-abdominal adhesions, which can lead to bowel injury during entry into the abdomen with the ports and during the procedure itself. However, for those surgeons experienced in robotic surgery, a few principles will serve to prevent such injuries. First, the initial port placement should be away from prior abdominal scars. Furthermore, in difficult cases a 5 mm laparoscope along with laparoscopic tower can be utilized to inspect the intraabdominal cavity for adhesions and possible laparoscopic adhesiolysis. At our center in difficult situations, we

Fig. 52.3 Lysis of adhesions. [Reprinted from Richards et al. [8] with permission from Mary Ann Liebert, Inc. Publishers]

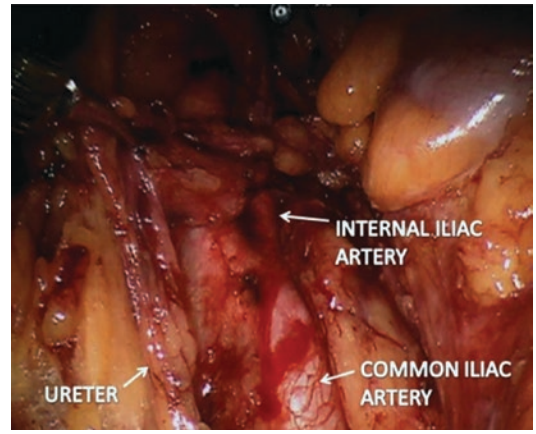

Fig. 52.4 After incising the peritoneum, the ureter can be found at the level of the bifurcation of the common iliac artery. [Reprinted from Richards et al. [8] with permission from Mary Ann Liebert, Inc. Publishers]

perform laparoscopic adhesiolysis prior placing ports and docking the robot.

Once access is obtained, the remaining ports can be safely placed under direct vision away from other adhesions. If the adhesions are extensive, initial lysis can be performed laparoscopically using cold scissors or limited thermal energy (Fig. 52.3). Otherwise, in those who feel more facile with the robot, adhesiolysis can be performed once the robotic camera port and 1–2 robotic ports are placed. Alternatively, as mentioned in above, access can be obtained using an open Hassan's technique for camera port placement with subsequent laparoscopic placement of the other ports.

Our Technique

After gaining substantial experience, we described the technique of the anatomic robotic radical cystectomy in 2012, which we follow routinely [8]. We have continued to make modifications to improve the efficiency of the procedure, and will report our latest technique here.

Dissection of Ureters and Biopsy

The first step is to identify and dissect the ureters after all adhesions in the lower abdomen and pelvis have been lysed. An incision into the posterior peritoneum is performed in order to identify the ureters bilaterally, which are often found at the level of the bifurcation of the common iliac artery (Fig. 52.4). The ureters are isolated proximally along the psoas muscle and distally toward the ureterovesical junction. The course of the lower ureters will be seen as a peritoneal folds that extend from the iliac bifurcation to the posterior bladder wall [9]. The ureter is often encountered running medial and underneath the ipsilateral medial umbilical ligament (superior vesical artery), which can be divided between clips to help provide adequate ureteral length. More distally, the ureter lies just lateral to the seminal vesicles in men, running inferior to the vas deferens before entering the bladder. During the dissection, it is important to avoid excessive skeletonization, leaving a healthy amount of periureteral tissue in order to prevent devascularization and the potential for future ureteral stricture formation. The ureter must be dissected both proximally and distally to the level of the bladder, taking care to avoid unnecessary grasping of the tissue. Distally at the level of ureterovesical junction, the ureter is tagged with colored suture tied Hem-o-lok® clip and divided with the distal margin sent for frozen section analysis. In order to identify the ureters, colored suture tied over Hem-o-lok® clips helps later in the surgery. Similarly, the other ureter is dissected free, tagged, and divided. The left ureter is transposed under the sigmoid mesocolon to the right iliac

fossa for subsequent urinary diversion. Thereafter, both ureters are tucked into the upper abdomen, out of the way for further dissection. It should be noted that some experienced surgeons will perform the right-sided lymph node dissection after dissection of the right ureter. Following this, they will perform a mirror dissection on the left side.

Lymph Node Dissection

The lymph node dissection can be performed prior to the cystectomy or after completion, depending on surgeon preference. We prefer to begin the lymph node dissection at the beginning of the case for several reasons. First of all, given the prognostic significance of accurate staging, it is important that the surgeon is "fresh" during this part of the case. Furthermore, by removing the lymph nodes and clearing away the fibrofatty tissue, you are able to better identify the boundaries of the dissection, as well as major pelvic structures including the ureters, iliac vessels, and obturator nerves. Finally, there is added efficiency by sending the nodes along with the bladder specimen after the case has been completed [8].

The anatomical limits of the dissection include the genitofemoral nerve laterally, the bladder medially, the node of Cloquet inferiorly, and the aortic bifurcation superiorly (Fig. 52.5a). The superior limits of the dissection continue to be extensively discussed among experts, with the previous standard dissection extending only to the bifurcation of the common iliac artery. However, evidence suggests improved survival in those patients with a more extensive lymph node dissection [10, 11]. Moreover, it has been shown

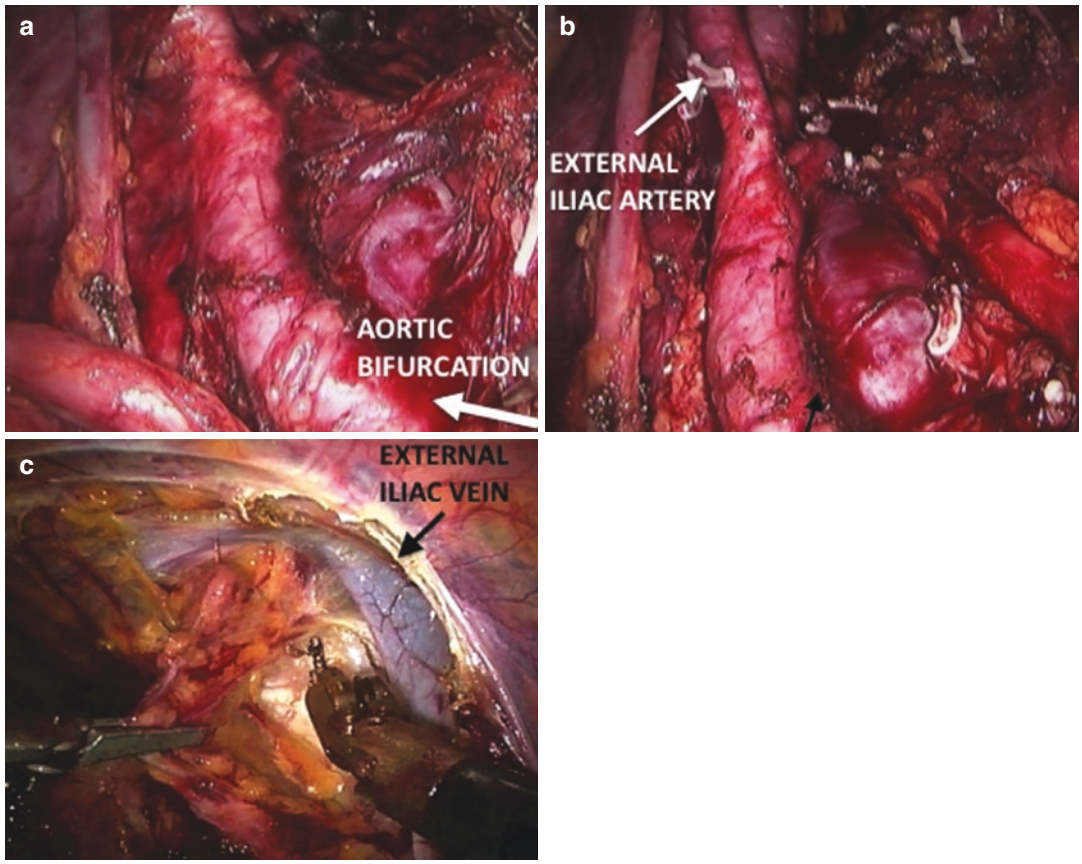

Fig. 52.5 Lymph node dissection. (**a**) Aortic bifurcation as the superior boundary of dissection; (**b**) Visualizing the common iliac artery and external iliac artery pulsating; (**c**) Dissection of the lymph node packet from the obturator fossa. [Reprinted from Richards et al. [8] with permission from Mary Ann Liebert, Inc. Publishers]

that the extent of the dissection during RARC has been associated with both surgeon and institutional case volume [12]. Further randomized controlled trials are under way to better determine the extent of the dissection, and so as of now we believe that the surgeon should at least dissect 2 cm above the common iliac bifurcation. It should be noted that some surgeons dissect all the way up to the inferior mesenteric artery (IMA), in what is considered a high-extended lymph node dissection. This will often depend on the patient's age, comorbidities, and clinical stage but there is no proven advantages.

The lymphatic tissue is dissected using the "split-and-roll" technique. The external iliac artery should first be identified by visualizing pulsations through the tissue (Fig. 52.5b). Just posterior and medial to the artery, the external iliac vein can be found (Fig. 52.5c). It is vital to identify the correct avascular plane of dissection above the artery and vein. These vessels are then isolated using blunt dissection with the suction tip irrigator or closed monopolar scissor tips. The obturator and internal iliac packets are prepared by identifying the medial border of the external iliac vessel. To facilitate this dissection, the bedside assistant can retract the external iliac vein laterally with suction, while the surgeon provides countertraction on the obturator packet medially. The nodal tissue is carefully dissected away from the vein distally to the pubic bone and the node of Cloquet. Care should be taken to avoid injury to the hypogastric nerves that travel along the rectal wall, especially during the nerve-sparing approach where potency is desired. Of note, the circumflex vein and other aberrant vessels of the external iliac or obturator veins can be encountered at the distal-most aspect of this dissection. The veins may be compressed from the pneumoperitoneum, and thus are more susceptible to injury. Compression can be minimized by decreasing the pneumoperitoneum to 10 mmHg. A combination of blunt dissection, release of fibrofatty attachments using monopolar scissors, bipolar or plasma kinetic cauterization of larger vessels and lymphatics, and Hem-o-lok® or Lapro-Clip™ as needed results in a thorough dissection and helps prevention in leakage of lymph. As the obturator packet is peeled back cephalad, it is divided distally. To achieve exposure to the internal iliac packet, the median umbilical ligament should be retracted medially and the external iliac vein should be kept in view. The internal iliac artery does not have the same fibroalveolar sheath as the external iliac artery. This nodal tissue is often more fixed to the artery, and thus may necessitate more sharp dissection and ligation of small blood vessels prior to division of the packet at the level of the bifurcation of the common iliac artery. The robot not only provides certain ergonomic advantages to the surgeon, but also offers multiple imaging modalities that are being evaluated intraoperatively as a means of delineating the extent of the tumor as well as lymph node drainage [13]. In particular, indocyanine green, an infrared fluorophore, has been successfully shown to identify sentinel drainage bilaterally with the use of optical cameras [14, 15]. While still in the early phases of testing, the use of intraoperative optical imaging by way of fluorophores highlights an additional technological advantage of using the robot platform.

Posterior Dissection

The posterior dissection begins with a 6–8 cm inverted, U-shaped incision made in the peritoneum of the cul-de sac above its reflection over the rectum to develop the retrovesical space. The vertical limbs of the U extend to a point approximately 2–3 cm proximal to the bifurcation of the common iliac artery. This begins the process of separating the bladder off of the rectum (Fig. 52.6). Initially, it may help to retract the sigmoid posteriorly and the bladder superiorly. To ensure an adequate surgical margin yet reduce the risk of rectal injury, the surgeon should dissect posterior to Denonvilliers fascia and anterior to the rectal fat. The dissection should continue laterally to connect the incisions that were made during the identification of the ureters. Continuing the dissection posterior, the seminal vesicles and vas deferens are identified. The seminal vesicles, vas, and surrounding small vessels should be dissected free and the vessels around clipped or fulgurated. If a nerve-sparing procedure is being performed, minimal cautery should be used because the thermal energy can severely damage

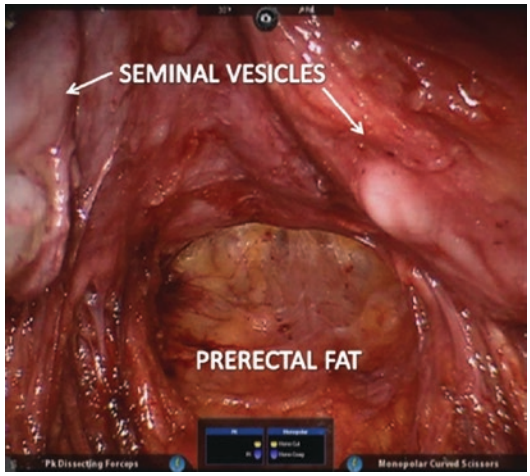

Fig. 52.6 Posterior dissection. [Reprinted from Richards et al. [8] with permission from Mary Ann Liebert, Inc. Publishers]

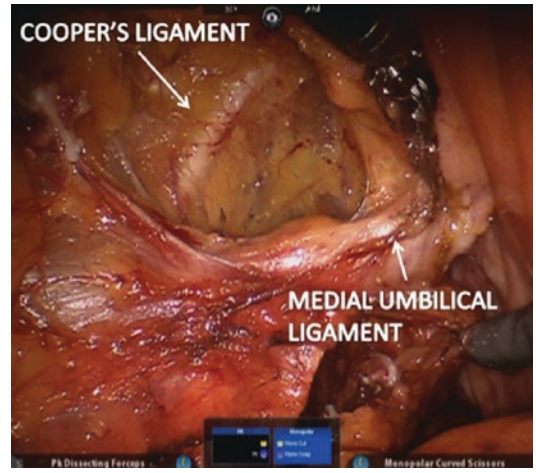

Fig. 52.7 Developing the perivesical space. [Reprinted from Richards et al. [8] with permission from Mary Ann Liebert, Inc. Publishers]

the neurovascular bundles. The third robotic arm can then be used to hold the seminal vesicles upwards in order to establish the plane distally towards the apex of the prostate. As previously mentioned, we have found that it is helpful if a 30° upward-facing lens is used during this part of the dissection because it will allow better visualization at this depth of the pelvis and for posterior dissection of the prostate until the apex of the urethra. This helps in obtaining long length of urethra if you are contemplating neo-bladder.

Creating the Lateral Space and Division of the Lateral and Posterior Pedicles

Once the posterior dissection is complete, attention can be turned towards the lateral dissections in order to develop the perivesical space between the bladder and the pelvic sidewalls (Fig. 52.7). Incisions are made lateral to the medial umbilical ligaments and carried distally to Copper's ligament until the endopelvic fascia is reached using a combination of blunt dissection and cautery. It is important that the umbilical ligaments and urachus are left intact at this point of the dissection, ensuring that the bladder remains attached to the anterior abdominal wall in order to keep it elevated during the ligation of the bladder pedicles. The vas deferens is divided to open the space medial to the external iliac vessels. Using the fourth arm, retract the bladder towards the umbilicus and follow the anterior division of the internal iliac artery. The inferior vesical artery gives off vesical branches and terminates as the prostatic artery. This vessel is dissected until it bifurcates into the urethral artery and capsular artery. The urethral artery is clipped and transected, but the capsular artery, which forms the vascular part of the neurovascular bundle, is preserved. Identification of the capsular artery enables the subsequent preservation of the neurovascular bundles [9]. The umbilical artery and inferior vesical artery are ligated between Hem-o-lok® clips and divided (Fig. 52.8). Small vessels can be controlled using the PK dissecting forceps. In addition, an endovascular stapler can be used to divide the pedicles as another option.

When neurovascular bundle preservation is not needed, the perivesical space between the bladder and lateral pelvic sidewall can be developed bluntly. An incision is made lateral to the medial umbilical ligaments, using blunt dissection and cautery. Dissection is continued medially to the external iliac veins to carefully preserve the obturator nerves and expose the lateral pelvic wall.

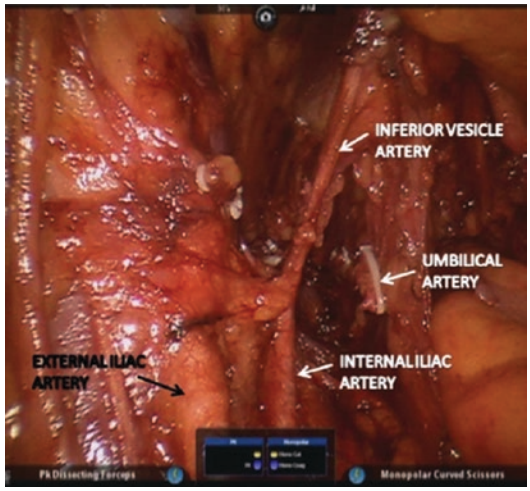

Fig. 52.8 Division of the lateral and posterior pedicles. [Reprinted from Richards et al. [8] with permission from Mary Ann Liebert, Inc. Publishers]

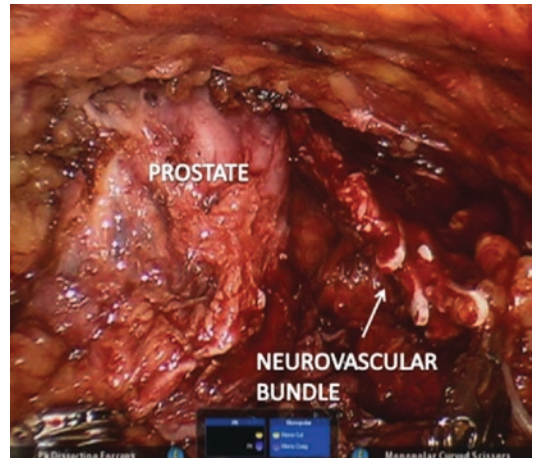

Fig. 52.9 Preservation of the neurovascular bundle using an intrafascial dissection, along with several Hem-o-lok® clips to divide the prostatic pedicle. [Reprinted from Richards et al. [8] with permission from Mary Ann Liebert, Inc. Publishers]

Nerve-Sparing Approach

It is at this point that either a nerve-sparing approach or wide excision can be performed. Examining the prostatectomy data, the nerve-sparing surgery has widely been applied for more than 20 years, becoming the standard in routine clinical care in appropriately selected patients. There has been far less data evaluating the functional and oncologic outcomes with the use of a nerve-sparing approach in radical cystectomy patients, in part due to the different patient population, the lethality of the disease, and the limits of the open procedure. However, with the advent of the robot and the increased dexterity and visualization that it affords the surgeon, more studies are now evaluating its role [1, 16–19].

The dissection can be performed in a similar fashion as for robotic prostatectomy with subtle changes as one should not use thermal energy close to the tip of the seminal vesicles. Furthermore, the hypogastric nerves should be avoided during the lymph node dissection as injury to these nerves can have a negative impact on erectile function. Our approach begins with an incision in the peri-prostatic fascia that is carried distally to the apex of the prostate. The peri-prostatic fascia is swept laterally, avoiding thermal injury or unnecessary traction on the neurovascular bundles. The prostate and bladder are retracted laterally exposing the contralateral prostatic pedicle which is divided between several Hem-o-lok® clips (Fig. 52.9). Alternatively, absorbable Lapro-clip™ can be used with excellent results especially if considering orthotopic neobladder to prevent complications related to erosion of non-absorbable clips. We prefer to perform an intrafascial dissection, as these are not cases of prostate cancer although prostate cancer is quite common in these patients. However, it should be noted that even in experienced hands, the nerve-sparing approach still does not produce the sorts of results seen in patients undergoing radical prostatectomy, with erectile dysfunction affecting up to 80% of men following cystectomy [20]. For this reason, some surgeons have employed a seminal vesicle sparing approach [16]. This approach relies on the ventral surface of prostate showing a triangular area bare of neuronal tissue, known as isosceles triangle. The neurovascular bundle can be detached from lateral prostate-vesicular angle to reach Denonvilliers fascia posteriorly.

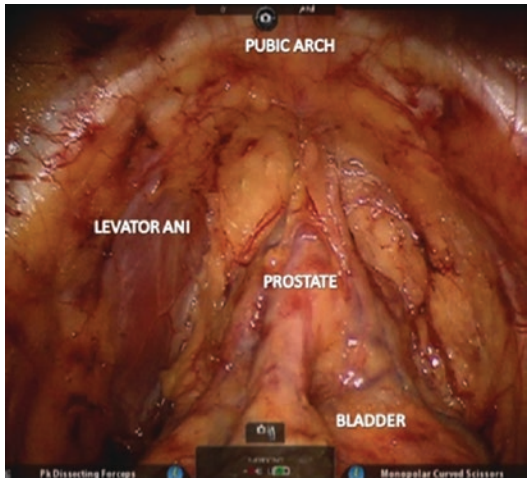

Fig. 52.10 Dropping the bladder to develop the avascular space of Retzius. [Reprinted from Richards et al. [8] with permission from Mary Ann Liebert, Inc. Publishers]

Anterior Dissection and Dropping the Bladder

Now that the pedicles have been divided, the avascular space of Retzius can be developed by dropping the bladder with incisions of the medial umbilical ligaments, joining them in the midline to divide the median umbilical ligament (urachus) (Fig. 52.10). The endopelvic fascia can be incised from the base of the prostate to the puboprostatic ligaments, and the levator ani muscle fibers should carefully be swept away from the prostate and bladder.

Dorsal Vein Complex Control

The dorsal vascular complex (DVC) is ligated by passing a 0-Vicryl on CT-1 needle underneath the vessels, distal to the prostate (Fig. 52.11). Cold cut scissors can then be used to divide the DVC. Needle drivers are not needed as this suture can be applied with the help of PK® dissecting forceps and ProGrasp™ forceps. As an alternative, the DVC can be divided using bipolar energy, a vessel-sealing device, or Echelon ENDOPATH® 45 mm Stapler. Once again, if a nerve-sparing approach is utilized, thermal energy should be avoided.

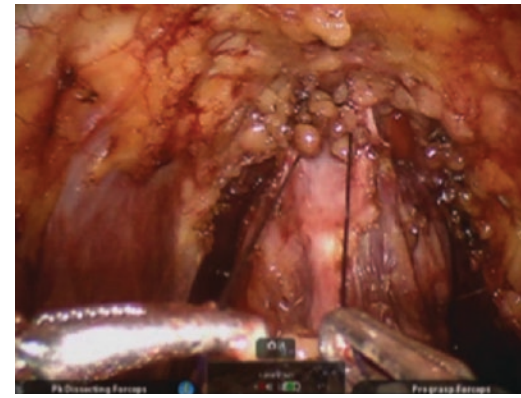

Fig. 52.11 Ligation of the dorsal vascular complex (DVC) with 0-Vicryl on CT-1 needle. [Reprinted from Richards et al. [8] with permission from Mary Ann Liebert, Inc. Publishers]

Apical Dissection and Division of the Urethra

Once the DVC has been controlled, the urethra is divided at the prostatic apex (Fig. 52.12). Maximum sparing of the urethra is performed if orthotopic neobladder (ONB) is being considered. In some cases, we perform intraprostatic dissection to gain additional length thus increasing functional length in patient with an orthotopic neobladder. The Foley catheter is withdrawn and the urethra is divided. A Hem-o-lok® clip is placed on the prostatic apex to avoid urine and tumor spillage. We have previously placed the clip over the Foley catheter with the balloon inflated, acting as ball valve to aid in traction and counter traction and further prevent spillage of bladder contents. After the division of the urethra, the specimen consisting of the bladder, prostate, and seminal vesicles can be removed en bloc and placed in a 15 cm Endo Catch II bag. It is important that the pneumoperitoneum is lowered to 5 mm Hg to reveal any venous bleeding being occluded by the increased intra-abdominal pressure. Once the surgical field is hemostatic, a closed suction drain can be placed through the lateral robotic port into the pelvis. The bag can be retrieved by extending the camera port incision approximately 4 cm.

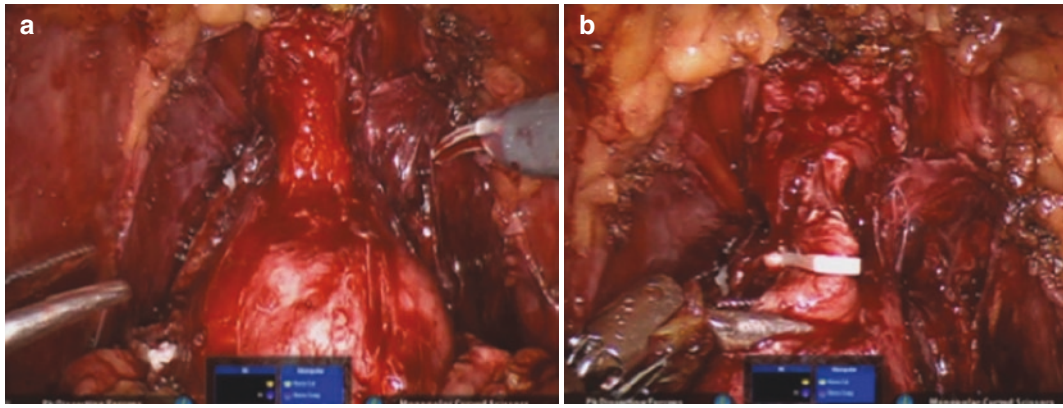

Fig. 52.12 (**a**) Apical dissection of the urethra with maximal sparing of urethra and preservation of the sphincteric complex; (**b**) Division of the urethra with placement of Hem-o-lok® clip to avoid urine and tumor spillage. [Reprinted from Richards et al. [8] with permission from Mary Ann Liebert, Inc. Publishers]

Urinary Diversion

Originally, a hybrid extracorporeal urinary diversion was performed. However, as surgeons have become more familiar with the robot, some are now opting for a totally intracorporeal diversion. Nevertheless, a substantial group of people perform a pure extracorporeal urinary diversion. The details of such a diversion will be covered elsewhere in the book.

Postoperative Care

The postoperative care for all patients after RARC should follow the ERAS protocol. A consensus review has recently been published by the European Robotic Urology Section (ERUS), in order to guide standardized perioperative management of RARC [21]. As part of the postoperative program, the NG tube can be removed shortly after extubation in the recovery unit. Ureteral stents in those patients who receive an ileal conduit can be removed within the first 2 weeks. Orthotopic neobladder patients can have their stents removed within the first 2–4 weeks as well. In order to prevent postoperative ileus, patients can be started on alvimopan. Chewing gum may also promote the return of normal intestinal function. Commonly used promotility drugs such as metoclopramide, serotonin receptor antagonists, and naloxone, have not shown to be effective. Early mobilization is critical, not only in terms of promoting bowel function, but it is associated with improved cardiopulmonary function and independence. While many surgeons will wait for the patient to pass flatus or begin having bowel movements, there is no evidence that fasting supports recovery. A diet can be started as early as the patient can tolerate it. Finally, for discharge, it has been agreed upon by the committee that at a minimum the patient should have adequate pain control, regular diet, normal bowel function, mobilization, and competence in handling their urinary diversion.

Learning Curve

With any new surgical technique, it is important to evaluate the learning curve that is involved with effective implementation. While it is difficult to standardize a learning curve, multiple groups have attempted to evaluate their center's performance using a set of defined outcomes. One group reported on 164 patients' who underwent RARC and found case number was not significantly associated with the frequency of complications, surgical blood loss, positive margins, or survival [22]. However, with experience, the operation time and lymph node yields

improved. Richards et al. evaluated their learning curve in 60 consecutive cases of RARC with PLND and found blood loss, positive margins and lymph node yields were unchanged [23]. However, complication rates and operation times continued to decrease with increasing experience. A more recent study expanded upon these results and found, in addition to decreasing operative time, that an experienced mentor can further improve the learning curve of a new surgeon, resulting in decreased operation times and minimizing complications, as well as the need to convert early in their personal series [24].

Results

The technical feasibility of the RARC in the treatment of bladder cancer has been demonstrated in a number of case series. However, one concern faced by surgeons is whether the RARC adheres to key oncologic principles, thus preventing the development of pelvic, peritoneal and port site recurrences. To this point, a large multi-institutional study found that of almost 1400 patients undergoing RARC, 305 (22%) experienced disease relapse, 220 (16%) distant, 154 (11%) local recurrence, 17 (1%) peritoneal carcinomatosis and 5 (0.4%) port-site recurrences. 71 patients (5%) developed early oncologic failure, defined as disease relapse within 90 days of surgery, a decrease from 10% in 2006. The presence of any complication, ≥pT3 disease, and nodal involvement were the only significant predictors of oncologic failure, suggesting that disease-related factors rather than technical factors play a major role [25].

Complication rates of the RARC have also been reported in large multi-institutional studies [26, 27]. Gastrointestinal complications occur most commonly during the post-operative period, approximately 27% of the time. In addition 30 and 90 day mortality has been reported at 1.3% and 4.2%, respectively. These rates are higher in those patients with T4 disease, relative to those with ≤pT3, with the overall 30- and 90-day mortality rates of 0.4% and 1.8% vs 4.2% and 8.5% vs 0.4% and 1.8%, respectively.

Retrospective evidence supports promising functional outcomes in those patients undergoing the robotic nerve-sparing approach. One study found that 63% of patients who underwent the nerve-sparing RARC were potent with or without the help of PDE-5 inhibitors at 12 months [28]. Another group reported a postoperative 45% rate of erection sufficient for penetration with or without PDE-5 inhibitors [17].

When validating a therapy, it is important to compare it to the current standard of care, which in this case is the open radical cystectomy. Therefore, over the past 5 years there have been a number of series comparing both oncologic and functional outcomes of RARC to ORC. Studies have demonstrated no difference in the short-term, and in some cases intermediate, oncologic outcomes when comparing RARC to open cystectomy [29–48]. The results have been summarized in Table 52.2. There have also been several systematic reviews published evaluating the evidence from these series. Tang et al. examined 13 studies and found that although there was a significant difference in the operating time in favor of ORC, patients having RARC might benefit from fewer total complications, less blood loss, shorter length of hospital stay, lower blood transfusion rate, less transfusion needs, shorter time to regular diet, more lymph node yield, and fewer positive lymph node. There was no significant difference between the RARC and ORC regarding positive surgical margins. The RAZOR trial is currently underway to compare ORC to RARC, pelvic lymph node dissection (PLND), and urinary diversion for oncological outcomes, complications and health-related quality of life measures with a primary endpoint of 2-year progression-free survival. The randomized, prospective design of this trial will hopefully clarify many of the questions that urologist have attempted answering over the past decade through small, single-institution, retrospective studies.

In a systematic review based on a comparison of cost analysis between the two techniques, researchers found that despite an increased materials cost, RARC was less expensive than ORC when the cost of complications was considered. Thus, while the upfront cost is greater for

Table 52.2 Robotic versus open radical cystectomy in the literature

Robotic Versus Open Radical Cystectomy in the Literature										
Author	Year	N	Estimated blood loss (mL)	Operative time (Min)	Lymph node yield	Positive surgical margins	Length of stay (days)	Complication rate		Additional comments
								Total	Major	
Kim et al. [34]	2016	ORC: 150	840	466	15	4%	22	NR	NR	The surgical approach was not associated with tumor recurrence, disease-specific mortality, or all-cause mortality after radical cystectomy regardless of pathologic tumor stage.
		LRC: 22	400	524	19.5	0%	12			
		RARC: 58	500*	501.5*	18*	3.4%	28*			
Sharma et al. [30]	2016	ORC: 407	800	302	15	12%	7	59.7%	19.7%	RARC resulted in similar complication rates as ORC, as well as positive surgical margin rates in high-risk cases with no identifiable difference in oncological control.
		RARC: 65	350*	423*	16	10.8%	6	52.3%	13.8%	
Winters et al. [35]	2016	ORC: 58	641	370	17.2	NR	9	38%	NR	For elderly patients undergoing ORC or RARC, there was no significant difference between in complications or the 90 day readmission rate.
		RARC: 29	257*	413*	22.6		7*	38%		
Atmaca et al. [47]	2015	ORC: 42	1314.3	552	17.2	2.4%	18.8	52%	18%	Better trends were detected in the robotic group concerning daytime continence with no pad use (84.6% vs 75%,)and severe daytime incontinence (8.3% vs 16.6%). No significant differences in post-operative mean IIEF scores between groups
		RARC: 32	412.5*	582	25.4*	6.3%	17.4	33%	8%	
Bochner et al. [36]	2015	ORC: 58	676	456	Extended: 31.9 Standard:19.5	4.8%	8	85%	21%	Three- and 6-mo Quality of Life outcomes were similar between ORC and RARC. Cost analysis demonstrated an advantage to ORC compared with RARC.
		RARC: 60	526*	329*	Extended: 30 Standard: 18.9	3.6%	8	84%	21%	
Aboumohamed et al. [37]	2014	ORC: 100	489	350	NR	NR	7	NR	16%	Postoperative analysis revealed better sexual function in ORC group (P = 0.047), with no significant differences between both the groups in urinary, bowel, and body image domains (P = 0.11, 0.58, and 0.93).
		RARC: 82	444	382*			8		23.2%	
Trentman et al. [38]	2014	ORC: 102	601.8	258.8	NR	NR	9.8	NR	NR	Recovery room opiate consumption was significantly less in RARC group: 9.5 ± 8.9 versus 12.6 ± 9.9 mg (morphine equivalents), p = 0.02.
		RARC: 96	257.7*	372.1*			7.1*			
Maes et al. [39]	2013	ORC: 14	942	256.8	9.5	14%	11.4	78.6%	14%	RARC can be accomplished in a community-based, non-tertiary health care setting without compromising perioperative or pathologic outcomes
		RARC: 14	470*	373.8*	11.9	21%	11.2	57.1%	21%	

Parekh et al. [41]	2013	ORC: 20	800	285.5	23	5%	6	25%	NR	No significant differences between oncologic outcomes. There was a trend toward a decrease in excessive length of stay (65% vs 90%, p = 0.11) in RARC compared to ORC. RARC also trended toward fewer transfusions (40% vs 50%, p = 0.26)
		RARC: 20	400*	300	11	5%	6	25%		
Knox et al. [40]	2013	ORC: 84	1522	396	17.7	8%	10.8	64%	NR	Both age groups in RARC had less early complications than ORC patients (p < 0.014). The older group in RARC had less early complication rate (17%) than the younger group in ORC (59%).
		RARC: 58	276*	468*	21.3	7%	6.3*	43%		
Kader et al. [29]	2013	ORC: 100	986	393	15.7	11%	12.2	57%	22%	There were no significant differences between groups for pathological outcomes, including stage, number of nodes harvested or positive margin rates.
		RARC:100	423*	452*	17.7	12%	7.8*	35%	10%	
Richards et al. [42]	2012	ORC: 20	600	370	15	NR	14.5	85%	35%	RARC is a reasonable option in caring for the elderly patient.
		RARC: 20	275*	461*	17		7	45%*	10%*	
Gondo et al. [48]	2012	ORC: 15	1788.7	363.5	13.8	9.1%	37	73.3%	NR	RARC is a safe technique to perform by surgeons who have had over 60 cases of robot-assisted radical prostatectomy
		RARC: 11	656.9*	408.5	20.7*	13.3%	40.2	54.5%		
Styn et al. [43]	2012	ORC: 100	475	349.1	15.2	22%	10.2	NR	21.3(% of total)	No difference in the final pathologic findings, number of lymph nodes removed, or margin status was identified
		RARC: 50	350*	454.9*	13.3	16%	9.5		28.1(% of total)	
Lee et al. [44]	2011	ORC: 103	NR	NR	NR	NR	NR	NR	NR	Despite a higher cost of materials, RARC was less expensive than ORC for ileal conduit and cutaneous continent diversion, but not for orthotopic neobladder. The largest contributor to cost was length of stay. RARC showed a shorter hospital stay, although this did not offset the higher cost of surgery. Complications materially affected cost performance.
		RARC: 83								
Nix et al. [44]	2010	ORC: 20	575	211.2	18	0%	6	50%	NR	This prospective randomized controlled study with a primary end point of lymph node yield demonstrated noninferiority when comparing RARC to ORC.
		RARC: 21	258*	252*	19	0%	5.1	33%		
Ng et al. [46]	2010	ORC: 104	1172	357	15.7	8.7%	8	58.7%	29.8%	RARC is an independent predictor of fewer overall and major complications.
		RARC: 83	460*	375	17.9	7.2%	5.5*	41%	9.6%*	

* represents < 0.05

RARC, it is not the robot that largely drives cost, but instead the length of stay, operative durations, and daily hospitalizations costs that result. They went further to determine that while RARC was less expensive than ORC for patients receiving an ileal conduit or cutaneous continent diversion, the cost advantage deteriorated for orthotopic neobladder.

Conclusion

The anatomic robot-assisted radical cystectomy is now being performed at centers around the world, especially at those with advanced robotics programs. It is clear from the results of published reports in the literature, as well as from our own experience at Wake Forest in performing over 250 RARCs, that the clinical and oncologic goals of a radical cystectomy are achieved. Furthermore, in select patient populations it may even be preferred over the open approach. We are hopeful that with more clinical trials and maturing data from high-volume institutions, the long-term oncologic outcomes will prove comparable to the current standard of care.

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Robot Assisted Anterior Pelvic Exenteration for Bladder Cancer in Female

53

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Abstract

The standard-of-care management of muscle invasive bladder cancer in females is anterior pelvic exenteration. This involves the surgical excision of the urinary bladder and the female reproductive organs in addition to pelvic lymphadenectomy. Among many factors, performing this procedure robotically requires thorough knowledge of female laparoscopic pelvic anatomy in order to conduct this complex surgery in a safe and efficient manner. However, most urologic surgeons are more familiar with male pelvic anatomy given the prevalence of the more frequently performed robotic prostatectomy. Our technique was developed based on minimal deviation from robotic radical cystectomy in males and this chapter will review its various steps and highlight the main differences.

Keywords

Cystectomy · Female cystectomy · Anterior pelvic exenteration · Robot assisted radical cystectomy in females · Robot assisted radical cystectomy

Introduction

Bladder cancer is the fourth most common cancer and the eighth most common cause of cancer related deaths in the United States. It caused more than 16,000 deaths in the United States in 2016. Although bladder cancer is more common in males compared to females (male to female ratio is 3:1) females usually present with more advanced stage of bladder cancer. Several studies identified female gender as an independent risk factor for death from this disease [1–3]. Similarly, other studies reported higher incidence of prolonged hospital stay, need for intensive care units admission and higher blood loss in female patients when compared to their male counterparts [4, 5].

The initial successful experience in robotic prostate surgery has naturally resulted in exploring the role of the robot in treating bladder cancer. Robot assisted radical cystectomy (RARC) was successfully performed for the first time in a male patient in 2003 [6] and the first RARC in a female patient was reported shortly afterward [7]. The last decade witnessed the publication of

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numerous studies that established the safety and efficacy of RARC in treating muscle invasive bladder cancer [8–11]. However, this procedure is still technically demanding for most urologists especially in females as they are more familiar with male laparoscopic pelvic anatomy.

In order to ensure complete cancer eradication, anterior pelvic exenteration (APE) is considered the gold standard therapy for female patients with muscle invasive bladder cancer. A standard APE for bladder cancer in females should ideally include surgical excision of the urinary bladder, urethra, anterior vaginal wall, uterus, bilateral fallopian tubes and the ovaries. However, a vaginal or urethral sparing procedure can be performed in cases of orthotopic diversions or in sexually active females [if oncologically safe in the absence of bladder neck involvement and the presence of low-stage disease (≤cT2)]. In this chapter, we will describe our stepwise approach for a standard APE and we will highlight the variations of vaginal or urethral sparing procedures.

Preoperative Preparation

The preoperative preparation in female patients is not significantly different from their male counterparts. Women being considered for robot-assisted radical cystectomy (RARC) should undergo complete metastatic and staging evaluation. Particular attention needs to be paid to abdominal and pelvic cross sectional imaging to evaluate local extension of the disease into adjacent female reproductive organs, presence or absence of lymphadenopathy, and anatomic abnormalities. Past surgical and gynecological history such as history of hysterectomy may alter the surgical plan.

Following detailed preoperative anesthesia evaluation, all patients should be strategically marked immediately prior to surgery for the potential urostomy site (even if an orthotopic neobladder is planned). This should be performed in the sitting and standing positions. Education regarding urostomy or neobladder care and maintenance should be initiated preoperatively. Bowel preparation is limited to patients who received preoperative radiation therapy. Several studies demonstrated the lack of benefit of bowel preparation in terms of infectious and anastomotic leakage complications [12–14]. Moreover, certain reports demonstrated higher tendency of prolonged ileus after radical cystectomy when bowel preparation is used [15].

The preoperative initiation of a μ opioid receptor antagonist (Alvimopan) has been shown to decrease the duration of postoperative ileus, postoperative hospital stay and need for parenteral nutrition in cystectomy patients [16, 17]. Currently, this represents a standard part of our perioperative care unless contraindicated.

Broad-spectrum antibiotics covering gram-negative, gram-positive, and anaerobic organisms are administered 60 min prior to skin incision. In order to decrease postoperative thromboembolic complications, mechanical prophylaxis in the form of long sequential compressions and elastic stockings are placed on the lower extremities prior to anesthesia induction as well as pharmacological prophylaxis with low molecular weight heparin. Postoperatively, heparin is continued until independent ambulation is achieved.

Patient Positioning

A nasogastric tube is placed for decompression of the stomach. An arterial line may be inserted for intraoperative monitoring. The urethral catheter is placed after the patient is prepped and positioned in a sterile fashion. The patient is placed in low lithotomy position with arms tucked to the side. Care must be taken to ensure the patient's hands and elbows are adequately padded. The patient will be placed in extreme/maximal Trendelenburg during the case and this must be tested prior to prepping and draping the patient. A chest strap may be employed; however, patients rarely move on the bed with the arms tucked and the legs in low lithotomy stirrups.

Management of the Urethra

The female urethra can be excised one of two ways. One option is to dissect it out robotically and carry the dissection to the introitus from a

cephalad to caudal approach. Another option is to perform the dissection transvaginally before docking the robot. The authors have found that in cases of radical cystourethrectomy, scoring the urethral meatus with cautery and dissection a small portion of the distal urethra can make identification of the limits of the robotic dissection easier. In some cases we carry the dissection between the anterior vaginal wall and posterior bladder wall much like a dissection one would do for an anterior colporrhaphy. We usually infiltrate the space with a saline or lidocaine solution with epinephrine prior to dissection to separate the tissues and enhance vascular control. With the use of the Si da Vinci surgical system, meticulous hemostasis should be performed prior to switching to the robotic portion of the procedure as these tissues are quite vascular and can bleed without notice when the robot is docked between the legs. However, with the newer Xi da Vinci surgical system, the robot can be side docked and the assistant can have a better simultaneous access to the patient introitus during the robotic portion of the procedure.

Positioning of Operating Room Equipment and Personnel

The list of robotic instruments that we use during this procedure is shown in Table 53.1. The robot is docked between the patients legs or from the side (for the Xi da Vinci) with the robotic arms oriented in a cephalad direction. The third robotic arm is positioned on the patient's right side if an intracorporeal diversion is to be performed. If an extracorporeal diversion is to be performed then it can be positioned based on surgeon preference. The bed side assistant stands on the contralateral side in relation to the third robotic arm. The positioning of operating room equipment and personnel is demonstrated in Fig. 53.1.

Port Placement

Access and establishment of the pneumoperitoneum can be performed with a Veress or Hassan technique depending on surgeon preference and likelihood of adhesions. An important point is to resist the temptation to place one of the working port incisions at the conduit site. In general, patients are marked so as the stoma is located through the rectus muscle and a working port in this location would be too medial and result in external collision.

A total of six ports are utilized during the operation. This includes two assistant and four robotic ports. With the da Vinci Si, the camera port is 12-mm and the rest of the robotic ports are 8-mm. With the Xi da Vinci surgical system, all ports are 8 mm in size including the camera port. Our port placement with the Si and Xi is identical.

As mentioned earlier if an intracorporeal diversion is planned, the third arm should be placed on the right. However, if an extracorporeal diversion is planned it can be placed on either side depending on surgeons' preferences. Herein,

Table 53.1 List of robotic and laparoscopic instruments required during the procedure

Surgeon Instrumentation			Assistant instrumentation
Arm 1	Arm 2	Arm 3	• Laparoscopic suction-irrigator • Laparoscopic blunt tip grasper • Laparoscopic needle driver • Laparoscopic scissors • Laparoscopic vessel sealing device (LigaSure™)[c] • Hem-o-lock clip applier • Laparoscopic vascular stapler (Endo-GIA 30–2.5)[c] • Reusable specimen retrieval bag
• Curved monopolar scissors • Needle driver • Robotic vessel sealer[a,b] • Hem-o-lock clip applier[*] • Endowrist stapler[a,b]	• Maryland bipolar grasper or vessel sealer • Needle driver	• Prograsp dissector	

[a]The use of these instruments is optional and can be substituted with assistant held devices
[b]Used with the Si or Xi daVinci surgical system
[c]The use of this instrument is optional

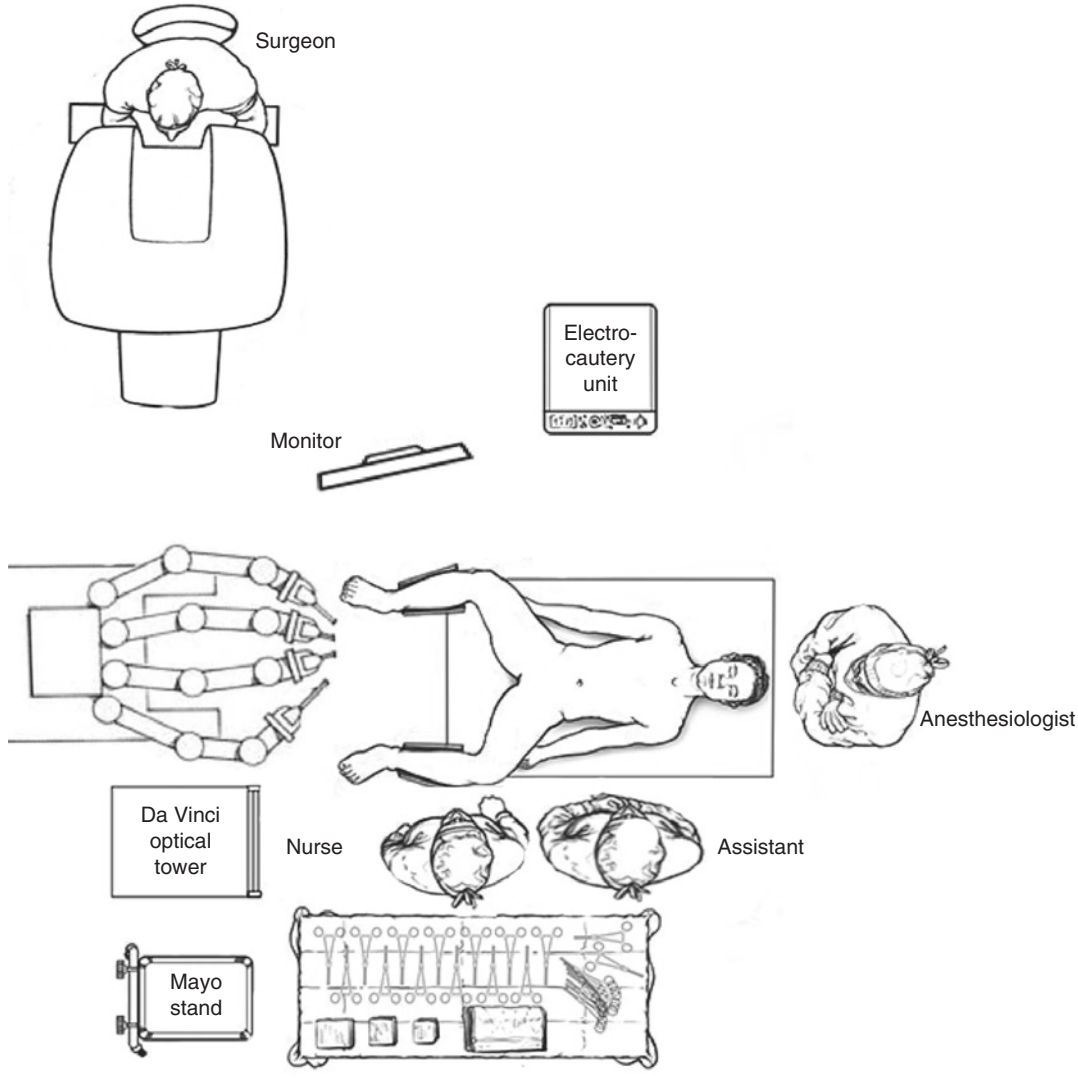

Fig. 53.1 Operative room set up

we will describe the port location as if the third robotic arm is on the ride side of the patient. When the third robotic arm is placed on the left side, the ports should be simply placed in mirrored locations.

In general, the ports are arranged as diagrammed in Fig. 53.2. The camera port is placed in the midline cephalad to the umbilicus. This port is 3–4 c cephalad for ileal conduits and lowered slightly for neobladder diversions. Two 8 mm robotic ports are placed 8–9 cm lateral from the midline and approximately 1 cm above the superior aspect of the umbilicus to allow for proximal ureteral and lymphadenectomy dissection. These will be used for robotic arm number 1 and 2 on the right and left respectively. The third robotic arm port is placed along the same horizontal line and as lateral as possible on the right side. The two assistant ports are placed lateral and caudad to the second robotic port on the left side. The assistant ports should be a 15 mm port and 5 mm port. A 15 mm port is mandatory

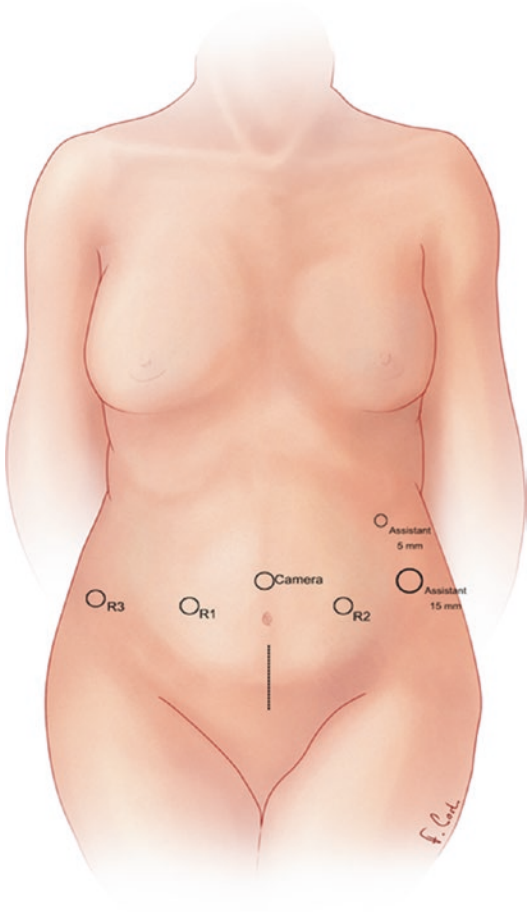

Fig. 53.2 Template of port placement. *R1* first robotic port, *R2* Second robotic port, *R3* Third robotic port

in these cases for easier extraction of the specimen during lymph node dissection. Often, a 12 mm port is used as second assistant port (instead of 5 mm) especially when the pedicle is controlled with a stapler as this gives a better angle to staple it.

Our technique implies starting the procedure with pelvic lymphadenectomy as this will facilitate anatomic dissection of the vascular pedicle.

Division of the Infundibulopelvic Ligament

This is the first step that needs to be performed in a female cystectomy prior to starting the lymphadenectomy and ureteral dissection. Once

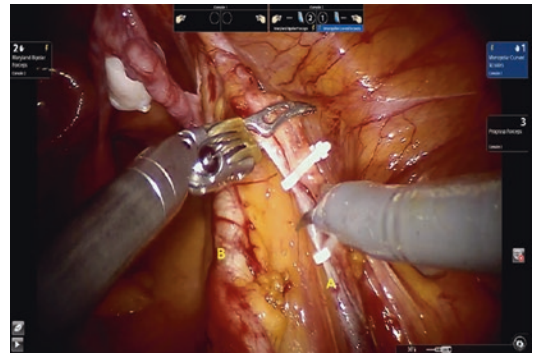

Fig. 53.3 Division of the infundibulopelvic ligament/gonadal vessels. *A* Infundibulopelvic ligament, *B* Right external iliac artery

identified, they can be controlled with locking clips, staplers or suture ligation (Fig. 53.3). The peritoneal incision is extended inferomedially through the broad ligament toward the pelvis just lateral and parallel to the uterus. The round ligament will be encountered and should be divided in a similar manner. Completion of this step will free the uterus and will make it easy to manipulate it to visualize deeper pelvic structures. Once completed, the fallopian tubes can be retracted medially and anterior to the uterus and thus provides good exposure to the ureters and iliac vessels for subsequent ureteral dissection and lymphadenectomy respectively.

Mobilization of the Sigmoid and Left Colon

The left colon and sigmoid colon should be released from the left side wall to allow access to the left iliac vessels and left ureter. This is done along the white line of Toldt where the sigmoid colon is released from the lateral abdominal wall as high as possible and reflected medially and superiorly out of the surgical field. At this point the only remaining bowel that should be visualized is the sigmoid and the rectum.

Development of the Paravesical Spaces

The medial umbilical ligament should be identified and retracted medially with the third arm or the assistant. The peritoneum just lateral to the

Fig. 53.4 Fully developed paravesical space. *A* Right external iliac artery, *B* Right internal iliac artery, *C* Right medial umbilical ligament

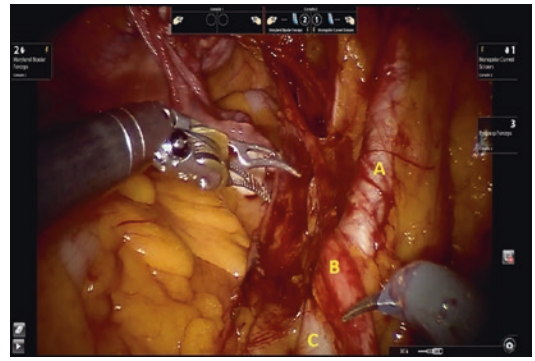

Fig. 53.5 Ureter identified as it is crossing the common iliac artery bifurcation. *A* Right external iliac artery, *B* Right ureter, *C* Right common iliac artery

ligament and medial to the iliac vessels should be incised. The incision extends from the anterior abdominal wall to the bifurcation of the common iliac artery and just parallel to the ligament itself. Care should be taken to make this incision as superficial as possible to avoid injury to underlying vascular structures. Once an incision is made the dissection should be carried caudad to expose the endopelvic fascia. Care should be taken to avoid injury to the epigastric vessels while dissecting close to the anterior abdominal wall. Creation of the paravesical space will subsequently make the lymphadenectomy easier and provide an ample working space (Fig. 53.4). It should be emphasized that the remaining bladder attachments to the anterior abdominal wall should not be disturbed as this will help to maintain anterior retraction.

Identification, Mobilization and Division of the Ureters

The ureter is identified crossing over the iliac vessels at the bifurcation of the common iliac artery (Fig. 53.5). The ureter should be dissected free of its underlying structures while preserving as much periureteric tissue as possible. The distal end can be dissected down to its insertion into the bladder. The umbilical artery or the superior vesical artery should be seen just lateral to the insertion of the ureter into the bladder and can be clipped and divided to allow for greater ureteral length. The ureter can be clipped with a locking clip that has a pre-tied suture to the crotch of the clip (Fig. 53.6). One may use a different color suture for the left and right sided clips. The ureter

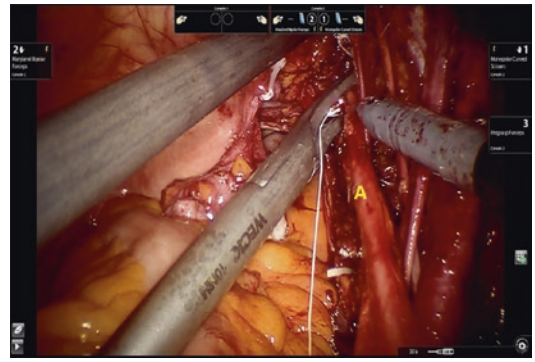

Fig. 53.6 Tagged clip applied to the distal right ureter. *A* Right ureter

is divided and a margin may be sent for frozen section. The ureter should be dissected free of its lateral attachments as far cephalad as possible but preservation of some medial blood supply from the common iliac artery is preferred to maintain good blood supply.

Pelvic Lymphadenectomy

The dissection is begun on the external iliac artery. A "split-and-roll" technique is utilized. Dissection is extended both proximally and distally along the shaft of the external iliac artery. The dissection should be carried proximally along the common iliac artery up to the bifurcation of the aorta. It should be noted that the right common iliac artery crosses over the right common iliac vein. This is important to remember when performing "split-and-roll" along the common right iliac artery as the common iliac vein

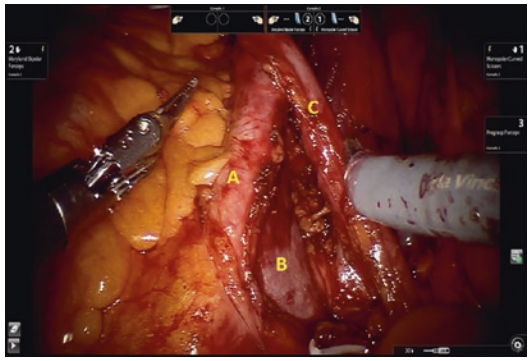

Fig. 53.7 Completed right common iliac lymphadenectomy. *A* Right common iliac artery, *B* Right common iliac vein, *C* Right ureter

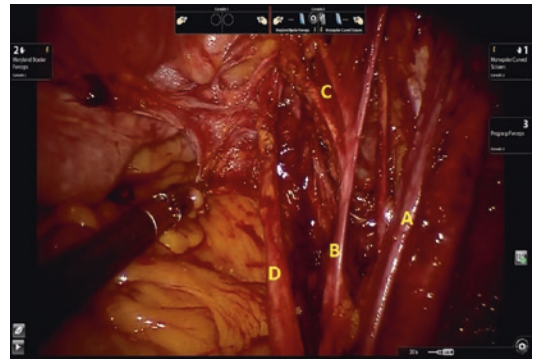

Fig. 53.8 Superior vesical and umbilical arteries. *A* Right external iliac vein, *B* Right umbilical artery, *C* Right superior vesical arteries, *D* Right ureter

will be encountered (Fig. 53.7). A space between the lateral aspect of the external iliac vessels and the medial wall of the psoas muscle is developed. Developing this space and retracting the vessels medially, allows more extensive dissection and ensure early visualization of the obturator nerve. The obturator nerve is easily identified by orienting oneself with the pubic ramus and external iliac vessels. By following a line directly posterior to the point where the external iliac vein crosses the pubic ramus, one can find the obturator nerve and vessels. No blind cutting should be done until adequate visualization of the obturator nerve is achieved. We highly encourage splitting and rolling the nerve as one would do for any vessels to prevent injury. Use of cautery can help identify the nerve when the obturator reflex is triggered. The hypogastric artery can be skeletonized down to the take-off of the umbilical artery. Lymph nodes can be removed in separate packets with 10 mm specimen retrieval bags.

During the lymphadenectomy the umbilical and superior vesical arteries should be clearly seen (Fig. 53.8). These vessels can be clipped with a locking clip or taken with an endovascular staple load. In the most caudal part of the dissection, the uterine vessels can be seen crossing anterior to the ureter "water under the bridge" and can be controlled at that point (Fig. 53.9). This will help minimize the risk of inadvertent injury during later steps of the procedure.

At the end of lymphadenectomy, the left ureter can be transposed behind the sigmoid mesentery with the help of the third robotic arm. The surgeon may opt to place a locking clip onto both ureteral tags to facilitate delivery of the ureters into the abdominal incision. The ileum should be tagged to allow for orientation during extracorporeal work. It is often helpful to mobilize the lateral attachments of the cecum at this point. This will make delivery of the ileum into the abdominal incision easier and make identification of the distal portion of the ileum easier.

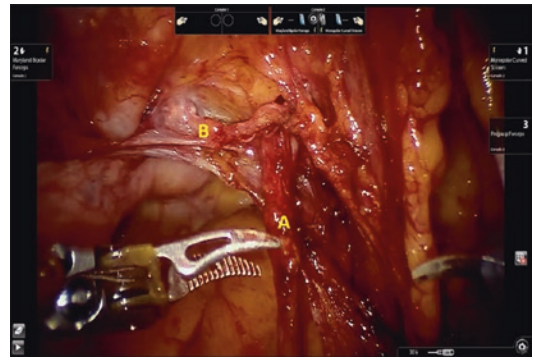

Fig. 53.9 Anatomic relation of the uterine artery and the ureter. *A* Right ureter, *B* Right uterine artery crossing anterior to the ureter

Hysterectomy, Bilateral Salpingoopherectomy, and Vaginal Dissection

Proper retraction of the female reproductive organs is key during this step of the procedure. In general, the uterus should be manipulated by the bedside assistant or third robotic arm in the desired direction. The authors have used a variety of types of uterine manipulators to move the

uterus and "seal" the vaginal cuff. However, we believe that a sponge stick in the vagina is adequate for this part of the procedure.

In a standard APE a horizontal peritoneal incision is made along the posterior fornix while the assistant maintains traction anteriorly. This vaginal incision is extended slightly anteriorly and distally along the anterolateral wall of the vagina so that the anterior wall of the vagina remains attached to the specimen. It is important to preserve as much of the lateral wall of the vagina as it lies in close proximity to the autonomic branches of the pelvic plexus. As the incision of the vaginal wall is extended distally, the vascular pedicles of the bladder will be encountered. The lateral vascular pedicles are intimate with the lateral wall of the vagina and to control these vessels properly they must be separated from the vagina before ligation. These pedicles can be controlled in a variety of ways. As described above, if a meticulous extensive pelvic lymphadenectomy was performed, the uterine vessels should have been identified and divided earlier. While performing the distal portion of the dissection, the surgeon should be cognizant of the location of the arcus tendinous fascia pelvis and avoid its injury in nerve sparing procedures or if a neobladder reconstruction is planned since it may contain autonomic nerves in the pelvis and provide support that prevent pelvic organ prolapse. Once the distal extent of the vaginal wall incisions are reached, attention is turned to dropping the bladder from its anterior attachments, dorsal vein complex and urethral dissection as described below.

Vaginal Sparing Procedures

If a vaginal sparing procedure is intended, the dissection starts along a transverse peritoneal incision between the bladder and the vagina. A space posterior to the bladder is then developed with a combination of blunt and sharp dissection. The dissection should proceed as distal as possible. As mentioned earlier, completing some of the dissection transvaginally can make proper identification of the space anterior to the vaginal wall much easier. This dissection will remain anterior so nerve sparing is already being performed. A combination of lateral and anterior dissection is often used in an alternating fashion to complete the dissection. The vascular pedicles of the bladder will be delineated while the dissection proceeds and will be controlled in the same manner. Once anterior dissection is completed, a circumferential incision along the posterior fornix is extended anteriorly at the level of the cervix. This will detach the uterus and the cervix and surgeon can then proceed with the cystectomy.

Anterior Dissection

The medial and median umbilical ligaments should be divided as proximal as possible with electrocautery (Fig. 53.10). The dissection is carried lateral to the medial umbilical ligaments and caudad over the anterior surface of the bladder toward the symphysis pubis. Completion of this step will free the bladder from all of its attachments. If not already done, the endopelvic fascia should be incised bilaterally at this stage. The apical dissection of the vagina is then started. The pubovaginalis ligaments are analogous to the puboprostatic ligaments and cutting them will provide further access to the dorsal vein complex.

Dissection, Ligation and Division of the Urethra

Dissection of the urethra depends on the type of urinary diversion intended. In case of ileal conduit, the urethra should be traced all the way to the external urethral meatus. This should be

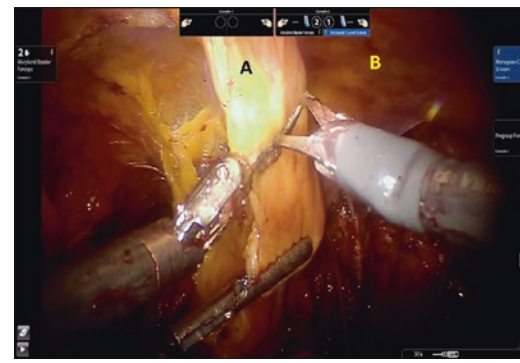

Fig. 53.10 Dividing the median umbilical ligament. *A* Median umbilical ligament, *B* Anterior abdominal wall

performed carefully and meticulous hemostasis to avoid uncontrolled bleeding from the venous plexus that surround the urethra. Once completely dissected, a locking clip is applied to the catheter and the catheter is transected to avoid any spillage of urine into the peritoneal cavity. In case of an orthotopic urinary diversion, the urethra should be circumferentially dissected and the bladder neck area is delineated by gently pulling on the Foley catheter balloon. Careful excision of the bladder neck area should be performed. The middle and lower thirds of the urethra should be preserved to maintain the continence mechanism as this is the area of the rhabdosphincter. A urethral margin should be sent for frozen section and neobladder should not be performed unless a negative margin is ensured.

Specimen Extraction

The entire specimen can be entrapped in a 15-mm specimen retrieval bag. It will be extracted though a 5- to 6-cm infraumbilical or periumbilical incision. Prior to extraction, the tags on the ureters and the ileum should be grasped in a locking grasper to allow delivery of all tags into and through the extraction incision. This will allow for extracorporeal creation of the urinary diversion of the surgeons choice.

Vaginal Reconstruction

It is very important that the closure be performed in a "clamshell" fashion. Avoid rolling the posterior vaginal wall into a tube" in an attempt to preserve length. It has a high likelihood of breakdown or being too narrow for intercourse. We use a barbed suture (1-0) on a CT1 needle to transversely close the vagina in running fashion and then reinforce with three or four interrupted sutures. The integrity of this closure is checked manually and by inserting a vaginal pack to help with visualization. We recommend using one or two permanent sutures such as polypropylene to perform a lateral paravaginal fixation to provide some lateral support. Vaginal prolapse is not uncommon after radical cystourethrectomy since all anterior and superior support has been excised and paravaginal fixation can provide at least some lateral support.

Post-operative Care

Recently there have been many advances in post-operative care of the cystectomy patient. In general, minimizing antibiotics, ambulating the patient quickly and early refeeding have been undertaken. While many of the pathways are subjective and reflect surgeon preference, there are some common themes and key points. First, decreasing IV antibiotics to 24 h of coverage in most patients, barring any extenuating circumstances. Secondly, use of alvimopan has been demonstrated to shorten post-operative opiod associated ileus. Liberal use of peri-operative anticoagulation for deep venous thrombosis prophylaxis. We use subcutaneous heparin or enoxaparin peri-operatively and in some cases up to 1 month post-operatively. A nasogastric tube is not left routinely in robotic or open patients. Early ambulation and aggressive physical therapy is also important to avoid deconditioning. Finally, we monitor electrolytes including sodium, bicarbonate and creatinine every 48 h after discharge for 1 week to identify failure to thrive early. In combination, these measures have allowed us to discharge patients between 4 and 7 days after surgery.

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54 Robotic-Assisted Laparoscopic Extended Pelvic Lymph Node Dissection for Bladder Cancer

A. Karim Kader and Zachary A. Hamilton

Abstract

Bladder cancer affects more than 70,000 people in the U.S. each year, and the standard of care for muscle invasive disease is radical cystectomy with pelvic lymph node dissection. Despite negative preoperative imaging, the rate of node positivity can be up to 25%, highlighting the importance of this dissection. In this chapter, we discuss the robotic-assisted laparoscopic approach to standard and extended pelvic node dissection. Attention is paid to anatomy, robotic set up, dissection, and potential complications.

Keywords

Radical cystectomy · Pelvic lymph node dissection · Robotic surgery · Surgical technique · Surgical complications

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Introduction

In the late 1800s Halstead first described the metastasis of primary tumors through lymphatics to regional lymph nodes [1]. In Urologic Oncology we know too well the dire consequences associated with the malignancies that we treat. We, and particularly our patients, are fortunate that a well-performed lymph node dissection can not only aid in staging but also provide benefits to local control and survival especially in testes and bladder cancer.

In this chapter we will describe the indications, techniques, and outcomes associated with extended pelvic lymph node dissection in the treatment of bladder cancer patients, emphasizing the low morbidity and excellent cancer control of the robotic-assisted laparoscopic approach.

Bladder cancer is the fourth most common cancer in men in the United States with an estimated incidence of 76,960 new cases and 16,390 deaths expected in 2016 [2]. The vast majority of patients, approximately 70%, present with a non-muscle invasive form of the disease for which trans-urethral resection and possible intravesical therapy is usually sufficient. However, the remaining 30% of patients present with a muscle invasive form of the disease which risks metastases and death. In the absence of demonstrable metastases these patients warrant aggressive therapy as 50% of those undergoing definitive treatment die of the disease at 5 years and over 85%

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of those not undergoing therapy for their disease will die within 2 years [3]. Due to the aggressive nature of muscle invasive bladder cancer, some have advocated "early cystectomy" for individuals with high-grade urothelial bladder cancers in the absence of muscle involvement if they do not respond to intravesical therapy [4].

The current widely accepted standard of care for the treatment of this disease is radical cystectomy (cystoprostatectomy in the male patient and anterior exenteration in the female) with pelvic lymphadenectomy. Current guideline statements endorse neoadjuvant and/or adjuvant platinum-based chemotherapy in conjunction with surgery [5–7]. An alternative is the "bladder sparing" approach of platinum-based chemotherapy in conjunction with external beam radiation therapy, which in North America has been typically reserved for individuals who are felt not to be surgical candidates, but has had encouraging results [6, 7].

The standard staging methods for bladder cancer include laboratory investigations, chest X-ray, cross sectional abdominal/pelvic imaging (CT or MRI), and possible bone scan. Surgically, a carefully performed, pelvic lymph node dissection will provide the best possible staging of patients undergoing cystectomy and, as illustrated in this chapter, is likely to provide a therapeutic benefit in those with minimally positive lymph node disease and even in some with grossly positive lymph node disease [8].

Surgery for urologic malignancy has a storied past complicated by significant morbidity and mortality. The perioperative mortality rate for the cystectomy was 20% prior to the 1970s [9]. Thankfully, our understanding of anesthetic care, our appreciation of the anatomy, improved surgical technique, and stage migration have helped to drop this rate down to approximately 2.5% [10, 11]. Despite this, the contemporary complication rate for patients undergoing this surgery is approximately 50%, even at high volume centers [12]. In an ongoing attempt to decrease surgical mortality and morbidity associated with this procedure, robotic-assisted laparoscopic techniques have become adopted in the setting of bladder cancer [13]. Robotic-assisted laparoscopic radical cystectomy was first introduced in 2003, and the past decade has shown increasing experience and utilization of this technique [14].

In this chapter, attention will focus on the lymph node dissection performed at the time of radical cystectomy. Specifics regarding the indications, benefits, boundaries, and complications will be provided which will be applicable to open, laparoscopic, and robot-assisted laparoscopic approaches. We will then go further to discuss the evolution of the minimally invasive technologies for performing this dissection and will provide data to support the use of the robotic-assisted approach for this procedure. Finally, technical points will be provided so that maximal lymph node yields can be achieved while avoiding complications.

Anatomy of Lymphatic Drainage of the Bladder

The seminal paper by Leadbetter and Cooper in the early 1950s summarized our understanding of the lymphatic drainage of the bladder [15]. Smith and Whitmore extended these initial descriptions and found in their series that the common iliac, external iliac, and obturator node packages were positive in 19%, 65%, and 74% of the time, respectively [16].

Leissner and colleagues, who performed a large multicenter analysis of 290 patients undergoing an extended pelvic lymph node dissection at the time of radical cystectomy, described 12 anatomical locations or zones involved in bladder cancer patients. They used the IMA, genitofemoral nerve, and the pelvic floor as the margins of their dissection [17]. The zones include (1) precaval, (2) inter-aorto-caval, (3) pre-aortic to the level of the IMA, (4 and 5) right common and external iliac, (6 and 7) left common and external iliac, (8) pre-sacral, (9) right internal iliac, (10) right perivesical, (11) left internal iliac, and (12) left perivesical. In this series, 30% of patients had lymph node metastases. In those with only one positive node, that node was never present above the level of the bifurcation of the aorta. These nodal zones were divided into three levels: level I below the bifurcation of the iliac vessels, level II

below the bifurcation of the aorta to level I, and level III below the IMA (internal mesenteric artery) to level II. Only 6.6% of positive nodes are seen in level III. Therefore, given the fact that only 30% of the overall patient population had positive nodes, less than 2% of overall patients undergoing cystectomy with extended pelvic lymph node dissections had positive lymph nodes above the aortic bifurcation, and none of those in the single lymph node category (i.e., those individuals who are likely to derive most of the clinical benefit from a node dissection). Thus, we advocate for the aortic bifurcation to be the cephalad extent of nodal dissection.

In present studies, the limits of nodal dissection have become standardized. All nodal dissections include a lateral margin of the genitofemoral nerve, the obturator lymph node package, and the distal margin of Cloquet's node. With regards to the proximal extent of dissection and inclusion of pre-sacral nodes, there are essentially three broad categories [15, 18–20].

1. Modified PLND—Bifurcation of common iliac
2. Standard PLND—2 cm above the common iliac
3. Extended PLND—Aortic Bifurcation with inclusion of the pre-sacral nodes

The following definitions are used in this chapter:

1. IMA—Nodes surrounding the aorta from the aortic bifurcation to the IMA
2. Aortic bifurcation—Nodes surrounding the aortic bifurcation
3. Common Iliac—Nodes surrounding the common iliac artery and vein
4. External Iliac—Nodes surrounding the external iliac artery and vein
5. Internal Iliac—Nodes surrounding the internal iliac artery and vein
6. Obturator—Nodes surrounding the obturator nerve
7. Iliacus—Nodes surrounding the iliacus muscle
8. Pre-sacral—Nodes anterior to the sacrum

Incidence of Lymph Node Metastases Identified at Cystectomy

The incidence of positive lymph nodes at the time of cystectomy for those individuals who are felt to be free of nodal metastases preoperatively is approximately 25% [11, 21]. This relatively high rate of positive lymph nodes at the time of cystectomy points to the rather crude preoperative staging studies that are available for this disease. CT remains the gold standard imaging modality for muscle-invasive bladder cancer, although it is an anatomic rather than functional study and limited to diagnosing lesions above certain size thresholds. Given the poor performance of CT scans at detecting low-volume metastases and a 5-year cancer-specific survival of approximately 35% for patients with positive lymph nodes at cystectomy, neoadjuvant chemotherapy has emerged as the standard of care [11, 22, 23].

MRI has emerged as a potential option for bladder cancer, with a general benefit of improved soft tissue contrast and enhanced anatomical detail, especially of the primary tumor. With regards to pelvic lymph adenopathy, MRI has an overall accuracy of 73–98%, sensitivity of 76–83%, and specificity of 89–98%, as compared to traditional CT with an accuracy of 54–97%, sensitivity of 85%, and specificity of 67–91% [24]. Given the minor improvements in pelvic lymph node detection, MRI has not yet replaced CT as the standard staging modality.

PET imaging has several applications within oncology due to its ability to locate metabolically active tissue enhancement; however, in bladder cancer this role is not completely defined. Furthermore the most commonly used radiotracer for PET, ^{18}F-flurodeoxyglucose (FDG), is excreted in the urine which can hinder visualization of perivesical lymph nodes. In a recent study of 233 patients undergoing cystectomy, the PET/CT pelvic lymph node dissection rate was 87%, compared to 83% for CT. In this same study, only 3% of patients were found to have metastatic disease on PET/CT that was missed on traditional CT [25]. PET provided a small improvement in preoperative imaging for bladder cancer; however, the authors of this study felt the advantage

was not significant enough to justify the increase in cost. Future PET use may be best utilized in highly selected patients.

There is mounting evidence that even standard pathologic analysis misses some occult metastases as noted when careful dissection, RT-PCR, and staining are used [26, 27] or with the improved survival with extended pelvic lymph node dissections in the absence of lymph node metastases read by traditional means [28].

Implications of Bladder Cancer Lymph Node Metastases

There is a dramatic fall in survival rates once bladder cancer has spread to the regional lymph nodes. Stein and colleagues examined outcomes on 1054 patients following cystectomy with median 10-year follow-up, and demonstrated that in the 23% of patients with lymph node positive disease, the 5- and 10-year recurrence-free survival rates were 35% and 34%, respectively. This compares to the node negative patients in whom those with extravesical disease had 5- and 10-year recurrence-free survival rates of 50–60% and those with organ confined disease having rates nearing 85% [11]. Comparable results have been seen by others with 5-year recurrence-free survival rates ranging from 21% to 33% in those bladder cancer patients with nodal metastases noted following radical cystectomy with pelvic lymph node dissection [29–32].

Number of lymph nodes removed has been shown to play a role in prognosis as well. Wright et al. analyzed the Surveillance, Epidemiology, and End Results (SEER) registry for a cohort of 1260 patients undergoing radical cystectomy with at least 1 positive lymph node and no distant metastases, and noted that the number of positive and total lymph nodes removed were independent predictors of survival on multivariate analysis [31]. Removal of >10 lymph nodes was associated with increased overall survival. Additionally, Herr and colleagues reviewed surgical and pathologic reports from 268 patients with muscle invasive bladder cancer undergoing radical cystectomy and showed that >10 lymph nodes removed was associated with improved survival. Fewer than ten nodes removed was also associated with local recurrence on multivariate models [32].

With node positive disease, it is also important to consider lymph node density, calculated by dividing the number of positive lymph nodes by the total number of lymph nodes sampled. Stein et al. demonstrated that those patients with a lymph node density of 20% or less had a 43% 10-year recurrence-free survival compared with only 17% survival at 10 years when lymph node density was greater than 20% ($p < 0.001$) [33]. Kassouf and colleagues obtained comparable results in their cohort of 248 cystectomy patients treated by radical cystoprostatectomy at M.D. Anderson cancer center. In this series, there was a comparable 5-year disease-specific survival of 54.6 and 15.3% in patients with lymph node densities of less than 20% compared to those above 20%. Furthermore, in a multivariate analysis of this population only lymph node density greater than 20% held as a predictor of disease-specific survival in this population [34].

Extracapsular extension is a very powerful predictor of outcome following cystectomy as demonstrated by Fleischmann and colleagues [35]. In this study 507 consecutive cystectomy patients were analyzed for lymph node parameters including number of nodes positive, node density, and the presence of extracapsular extension. Extracapsular extension of disease outside the confines of the lymph node was identified as the most powerful predictor of outcome in the multivariate model. Additionally, recent meta-analyses have confirmed extracapsular extension as a significant predictor of recurrence-free survival and cancer-specific survival [36].

Extent of Lymph Node Dissection at Time of Cystectomy

Since the mid-1900s, surgeons have recognized that pelvic lymph node dissection can decrease local recurrence rates for bladder cancer [37]. Despite an acknowledgement of the importance of the pelvic lymph node dissection at the time of cystectomy, there is a lack of consensus on the extent of dissection needed to provide the maximum benefit.

The concept of extended node dissections to improve outcomes has been evident for over 20 years. In a retrospective analysis looking at 68 patients treated between 1990 and 1993, Poulsen and colleagues compared outcomes in 68 patients undergoing a standard lymph node dissection (the iliac bifurcation to Cloquet's node including the obturator fossa) to 194 patients undergoing an extended lymph node dissection (including common iliac nodes to the aortic bifurcation, presacral nodes, and the obturator fossa). They demonstrated an increased number of nodes in the extended lymph node dissection group consistent with the concept of "seek and you shall find." Furthermore, they demonstrated that the extended node dissections resulted in markedly improved survival for those with organ confined disease (<T3b, 85% vs 64%) and even in those without nodal metastases (<T3b/N0, 90% vs 71%) [38]. As previously mentioned, recent data examining the total number of nodes removed was correlated with improved overall survival [31, 32]. And in a SEER-based analysis of over 1900 cystectomy patients Konety et al. found a lymph node yield of 10–14 nodes to have the greatest impact on survival [39]. Due to confounding variables and potential bias, it is difficult to make a definitive conclusion regarding improved survival associations with extended node dissections. Fortunately, there is an ongoing randomized prospective trial, SWOG 1011, that is designed to compare extended and standard pelvic node dissection, which will answer this question.

Furthermore, there appears to be a benefit to a more extensive node dissection with those patients having nodal yields of more than 10 nodes deriving the most significant benefit. However, it should be noted that nodal yield of more than ten nodes, as determined by the absolute nodal count on final pathology, may simply be a surrogate for a carefully performed nodal dissection. Every attempt should be made to completely clear all of the soft tissue within the boundaries outlined above as lymph node numbers are based on a variety of factors including: boundaries of dissection, inherent anatomical diversity, and diligence of the pathology team. There may also be a benefit when separate nodal packages, corresponding to the nodal areas are sent individually. Bochner and colleagues demonstrated a greater than threefold increase in nodal counts following a conversion from sending en bloc to sending separate nodal packages for analyses [40].

Robotic-Assisted Laparoscopic Radical Cystectomy

Robotic-assisted laparoscopic radical cystectomy is a new, emerging extension of the well-described laparoscopic approach to the management of patients with muscle invasive or superficial bladder cancer refractory to intravesical therapy. Early reports of robotic-assisted laparoscopic cystectomy by Menon et al. invoked excitement for this technique worldwide [41–43]. Review of recent SEER data has shown that the robotic radical cystectomy has equivalent perioperative and intermediate term outcomes, as compared to the open approach [44]. With continued evolution in robotic techniques and increased utilization among centers of excellence, robotic surgery is expected to improve outcomes and quality of patient care [45].

As outlined above a critical component of radical cystectomy is the lymph node dissection. In the next section we will outline our technique and results in performing the robotic-assisted laparoscopic lymph node dissection as well as results of our colleagues. We will then discuss briefly complications and their management.

Technique for the Robotic-Assisted Laparoscopic Extended Lymph Node Dissection at the University of California San Diego

Port Placement

As with any laparoscopic procedure optimal port placement allows for the best possible surgical outcomes. As opposed to prostatectomy the extended lymph node dissection of the radical cystectomy requires a wider surgical field thus requiring more proximal placement of the robotic

ports. Typically, the camera port is placed two finger breadths above the umbilicus, the two robotic ports 17 cm from the pubis, and 10 cm from the camera port. Two further 12 mm assistant ports are placed on the right and the fourth arm or 5 mm assistant port on the left if a third arm robot is being used. In general, care must be taken to place the ports higher, which helps in obtaining more proximal nodal tissue.

In our experience, successful lymph node dissection can be performed with any robotic system (daVinci-S, Si, or Xi).

A 0° or 30° lens is used with the bipolar Maryland or plasma kinetic Maryland in the left hand, curved monopolar scissors in the right hand, and the prograsp in the fourth arm. Note, the suction assistant port is placed between the right robotic port and the camera port, and in some patients can be placed at the location of the pre-marked ileal conduit site.

Nodal Dissection

The first part of the dissection depends on the operating surgeon and school of thought. We will often start with the dissection with the lymph node for several reasons:

1. One is "freshest" at the start of the case.
2. The lymph node dissection "sets-up" the rest of the case through the identification of the boundaries of dissection and important structures namely the genitofemoral and obturator nerves, the ureters, and the iliac vessels.
3. Many of the nodes may be sent along with the bladder specimen reducing the number of cumbersome instrument passages or expensive endocatch bags used in the procedure.

There is, however, controversy as some feel that the lymph node dissection is facilitated by having the bladder "out of the way."

When starting with the lymph node dissection, the initial step involves incision of peritoneum on the left lateral aspect of the sigmoid colon and early identification of the left ureter. This early identification allows for protection of this important structure. A concomitant left ureteral dissection is performed at the time of the nodal dissection. A proximal mobilization of the peritoneum and ureter is taken to the level of the IMA so as to facilitate passage of the left ureter under the sigmoid mesentery. The iliac artery is identified at the level where the ureter crosses. A "split and roll" technique is used to incise the nodal tissue overlying the aorta from the IMA proximally (Fig. 54.1) down the left common (Fig. 54.2) and external iliac arteries (Fig. 54.3) to Cloquet's node distally to the level of the circumflex iliac

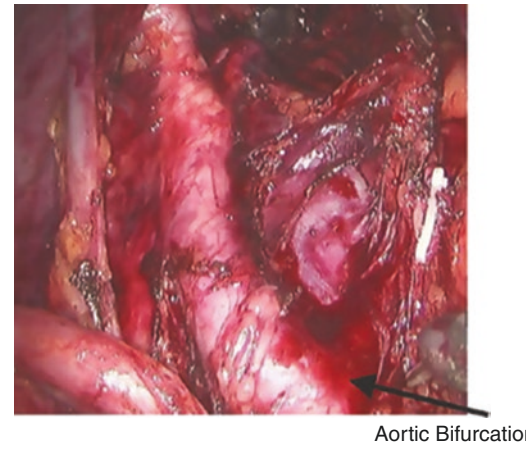

Fig. 54.1 Proximal extent of pelvic lymph node dissection demonstrating the aortic bifurcation. The left ureter can be seen in the *left* lower quadrant of the figure

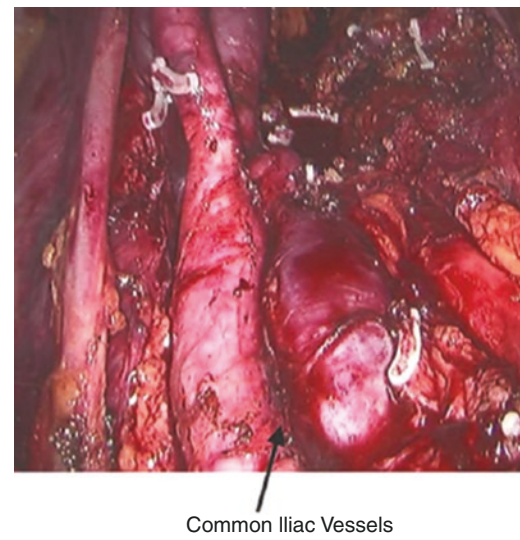

Fig. 54.2 More distal aspect of the dissection demonstrating the left common iliac artery

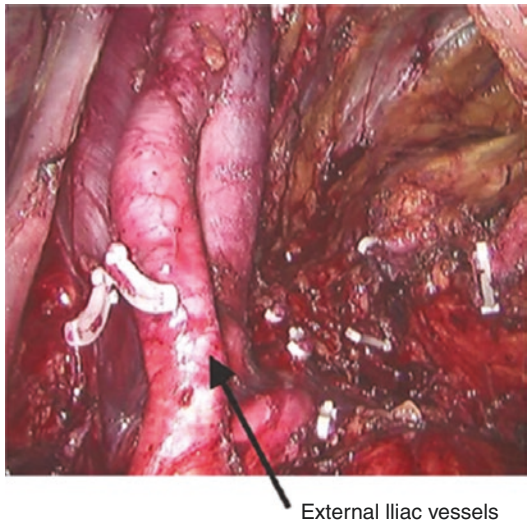

Fig. 54.3 Bifurcation of the left common iliac artery demonstrating the left external iliac artery and vein as well as the left internal iliac artery

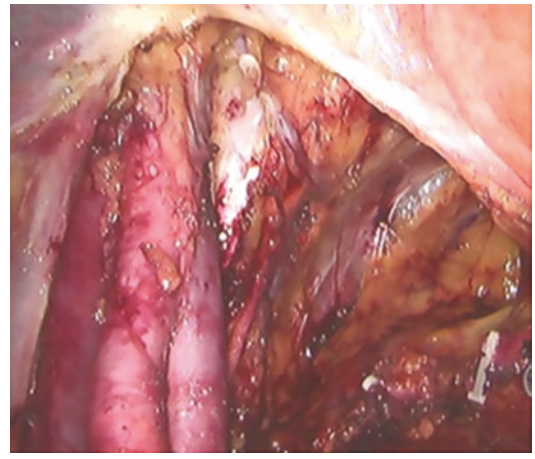

Fig. 54.4 Left obturator nerve just deep to the left external iliac vein. Obturator lymph node packet has already been dissected out

vein. The genitofemoral nerve is identified lateral to the common iliac artery and is preserved. All of the nodal tissue between the genitofemoral nerve and the artery are then harvested. We no longer clip lymphatic vessels at our institution and have not had any increase in symptomatic lymphoceles.

At this point it is critical to initiate a dissection lateral to the artery and medial to the pelvic musculature in the so-called "space of Marseille". Very shortly upon entering this space the iliac vein will become apparent therefore caution and awareness are key to avoid injury to this structure. Further dissection lateral to the vein will further increase nodal yield. Perforating vessels from the pelvic side wall can be dealt with by judicious use of bipolar cautery. Upon deeper dissection, eventually one will come upon the obturator nerve which marks the end of the lateral dissection (Fig. 54.4) and underneath this level, we extend our dissection over the iliacus muscle.

A medial dissection on the artery is carried out and nodal tissue between the artery and vein is then harvested. This will initiate the "split and roll" on the vein which again is carried distally to Cloquet's node and Cooper's ligament.

The obturator nerve is again identified just deep to the pubic bone at which point the external iliac vein crosses it. The obturator package is harvested and dissected proximally to the bifurcation of the iliac arteries. The most proximal obturator tissue is then dissected free from the lateral aspect of the vessels in the "space of Marseille."

A "split and roll" technique is then used to dissect the nodal tissue overlying the left internal iliac artery. Identification and early clipping of the median umbilical and superior vesical arteries are possible during this dissection.

A comparable dissection is performed on the right; however, further dissection is carried out medial to the proximal aspect of the internal iliac artery in order to harvest the pre-sacral lymph nodes.

Specimen Retrieval

Nodal packages are sent off as "right and left pelvic lymph nodes" in two separate packages. Furthermore specimens can be subdivided into "external iliac", "internal iliac", "obturator fossa", and "common iliac" packages to aid the pathologist. An Endocatch bag can work well to assist with LN removal, otherwise nodes can be removed from the abdomen using a microfrance grasper or a laparoscopic scoop under direct vision. Often the seat of the 12 mm port is removed to facilitate extrusion of some of the larger nodal packages.

Results at Our Institution and Others with the Robotic-Assisted Laparoscopic Lymph Node Dissection

Despite a motivated group of experienced pelvic surgeons whose pathologic specimens were being examined as part of a trial, only 73% of surgeons performed a complete dissection of all 12 pre-defined lymphadenectomy fields of the radical cystectomy [17]. It takes experience, a knowledge of the anatomy, effort, and commitment in order to complete a thorough lymph node dissection. This can be said for both the open and robot-assisted laparoscopic approach.

There are several other centers using the robotic-assisted approach to radical cystectomy and as standard of care to perform pelvic lymph node dissections. A comparison of median lymph node yields between some of the largest RARC and ORC series can be seen in Table 54.1. These series represent some of the largest series in the English language literature. As can be seen, there does not appear to be any significant difference in the number of median nodes collected at the time of cystectomy. This leaves little doubt that with typical lymph node dissections performed at leading institutions, there is no difference in absolute lymph node counts.

Table 54.1 Lymph node counts in cystectomy series

Group	Number of patients	Median LN	References
Robot-assisted laparoscopic series			
UNC	100	19	[46]
Cornell	83	17.9	[47]
RPMI	67	18	[48]
WFUBMC	45	16	[49]
Mayo Clinic	27	12.3	[50]
Open cystectomy series			
USC	1349	31	[51]
MSKCC	553	14	[52]
Mansoura	418	17.9	[21]
Vanderbilt	279	7	[52]
U Michigan	210	9	[52]

Complications of Robot-Assisted Lymph Node Dissection for Bladder Cancer

Complications associated with lymph node dissections are low with the open procedure and are limited to nerve-related injury to the genitofemoral or obturator nerves, lymphocele, or vascular injury. In a recent report of surgical complications associated with open and robotic cystectomies, the robotic-assisted cystectomy patients had less overall (41% vs 59%) and less major complications (10% vs 30%) [53].

Damage to obturator and genitofemoral nerves can manifest as neuropraxia or contusion, which are self-limiting injuries that normally resolve within 6 weeks, or axonotmesis, in which neural elements distal to the area of injury degenerate and may take up to 6 months to resolve or complete transection.

The genitofemoral nerve (L1–L3) has both motor and sensory function. It has a genital branch which supplies the scrotal skin, cremasteric muscles, and lower abdominal muscles and a femoral branch which innervates the femoral triangle. Significant clinical sequelae of damage to the nerve are rare but can include paresthesia and pain [54]. Typically the nerve lies just lateral to the iliac artery and can be a fan of nerves rather than a single nerve. It typically represents the lateral dissection margin for the pelvic lymph node dissection for bladder cancer patients.

The obturator nerve (L2–L4) innervates the medial thigh adductor muscles (gracilis, pectineus, adductor longus, brevis, magnus, and obturator externus) and provides sensation to the medial thigh. Clinically this can present as problems with gait however many patients can compensate with supportive muscle groups and suffer minimal disability from injury. Of note, it can affect the capacity to drive as there is decreased ability to shift from the gas pedal to the brake pedal on the affected side. Although the reported rates are low, it is possible that rates are higher due to a lack of reporting or a lack of recognition

of injury, especially in cases without transection. Obturator nerve injury can occur by overstretching, electrofulguration, transection, and/or clip entrapment. This tends to occur more proximally on the nerve, as the nerve can be obscured by the external iliac vein or near the iliac bifurcation. The key to avoidance of this injury includes careful dissection and knowledge of pelvic anatomy [55]. The nerve should be clearly defined in its course before placing clips or using excessive cauterization. Medial retraction of the nodal packets can assist in nerve identification as well. Bipolar cautery is preferred to reduce electrofulguration effects.

For neuropraxic and axonotmetic injuries, time and physical therapy are best due to the self-limiting nature of these injuries. Following transection, complete recovery can reach 90% when primary repair is performed. Primary repair can be performed at the time of transection laparoscopically as well [56].

Most of the literature on symptomatic lymphocele following laparoscopic pelvic lymph node dissection comes from the prostate cancer literature. The incidence is low, approximately 1% given the fact that these procedures are intraperitoneal and the lymphatic fluid can thus be absorbed by the peritoneal cavity [57]. The incidence of asymptomatic lymphoceles is likely higher but is difficult to ascertain as most of these patients are not imaged in the perioperative period. Symptoms relate to the mass effect of the lymphocele and can include pain from pelvic nerve compression, leg swelling from venous compression, hydronephrosis secondary to ureteral obstruction, and compression on surrounding structures. Management can come in the form of aspiration, drainage, sclerotherapy, or laparoscopic/open internal marsupialization. Risk factors associated with the development of lymphoceles include heparin, lack of lymphostasis, metastatic lymph nodes, steroid use, and diuretic use [58].

As discussed earlier in this chapter, there is a growing body of evidence to support an increased node dissection. With an increase in the complexity of this part of the procedure it is fair to assume a chance of increased complication rate. Brössne and colleagues compared 46 patients undergoing an open extended pelvic lymph node dissection at the time of radical cystectomy to a comparable group of 46 patients undergoing the standard dissection. Within a 30-day period there was no difference in complication rate between the two groups; however, the extended lymph node dissection did increased the procedure time by 63 min [59]. This data is applicable to the robot-assisted laparoscopic series as well, as extended node dissections will likely increase operative time.

All in all, complications stemming from pelvic lymph node dissections performed at the time of robotic-assisted laparoscopic cystectomy are rare. Careful attention to surgical technique and gentle dissection close to the genitofemoral and obturator nerves, as well as an understanding of the anatomy result in decreased complication rates. Thanks to the magnified image and dexterity provided by the robot, a further decrease in an already low complication rate may be achievable.

Future Directions

The sentinel lymph node (SLN) is the first draining lymph node from the site of disease and is likely the primary landing zone for metastasis. SLN has been used to guide therapy in other cancer (e.g., breast, melanoma) and can be utilized to enhance lymph node dissection. A recent systematic Pubmed search of SLN in radical cystectomy found seven studies with 156 patients total. The negative predictive value of the SLN to predict metastasis free state was 92%; however, the positive predictive value was only 77% [60]. This is because clinically positive nodes do not always take up pharmaceutical agents used for SLN. All in all, SLN is a novel concept in radical cystectomy with promising results and may help to guide node dissection and reduce operative complications.

Conclusion

Robotic cystectomy is a new, minimally invasive technique which appears to result in less blood loss, shorter hospital stays, and potentially less complications. Furthermore, with careful attention to detail, comparable oncologic results are achievable with this procedure and the open procedure in terms of negative margins and total node counts. Definitive claims regarding oncologic outcomes await long-term follow-up.

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Robot-Assisted Intracorporeal Ileal Conduit Urinary Diversion

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Abstract

Deciding the most appropriate method for urinary diversion is usually individually tailored according to the patient and disease characteristics, and the availability of specially trained staff to assist with perioperative management and patient education. Ileal conduit remains the most popular diversion method in United States. Robot-assisted radical cystectomy has been associated with equivalent oncological efficacy and safety to open radical cystectomy, while providing superior perioperative outcomes and enhanced recovery. In this chapter, we sought to describe a step-by-step approach to intracorporeal ileal conduit using the "Marionette" technique, and to summarize the perioperative preparation and outcomes.

Keywords

Intracorporeal · Urinary diversion · Ileal conduit · Robot-assisted · Robotic · Radical cystectomy

Introduction

Radical cystectomy (RC) remains a complex and highly morbid procedure, with a high rate of complications and 5-year overall survival of 50–70% [1–3]. Attempts have been made to improve outcomes following RC, including deployment of neoadjuvant chemotherapy (NAC), and performing more extensive lymph node dissection [4]. A robot-assisted approach to RC has gained much popularity in the last decade, as it has been associated with less blood loss, transfusion rates and shorter hospital, in addition to improved ergonomics and visualization without jeopardizing oncological outcomes [4].

The choice of urinary diversion after RC is a multifactorial decision that requires careful consideration of oncological safety, patient appropriateness, short and long-term complications, in addition to provision of the best possible quality of life (QoL) [5]. While continent urinary diversion in the form of orthotopic bladder substitutes may represent the new standard of care as it offers the potential for normal voiding without an abdominal stoma, it is not feasible for all patients. An absolute contraindication to continent urinary

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Table 55.1 Absolute and relative contraindications to continent urinary diversion [5, 34]

Contraindications	Oncological control	General condition	Technical considerations	Others
Absolute	Urethral/bladder neck positive margins	Renal compromise Hepatic compromise	Inability to perform ISC Length of mesentery	Unmotivated patient
Relative	Need for adjuvant chemotherapy Extensive local disease with high risk of recurrence	Advanced age Associated comorbidities Bowel disease	Urethral pathology Prior abdominal/ pelvic surgeries Prior pelvic irradiation	Non-Compliance with rehabilitation

CUD continent urinary diversion, *ISC* intermittent self-catheterization

diversion of any type is compromised renal function especially with serum creatinine above 150–200 mmol/l. Severe hepatic and bowel function compromise represent well-known contraindications as well. Urethral stricture disease, impaired intellectual ability and the lack of manual dexterity represent relative contraindications of orthotopic bladder substitutes [6]. Table 55.1 shows different factors that may affect the decision for urinary diversion.

Deciding the most appropriate method is usually individually tailored according to the patient and disease characteristics, and the availability of specially trained staff to assist with perioperative management and patient education [7]. Prior studies have shown that surgeon experience and training have a substantial influence in the presentation of the available options to patients, and therefore significantly affect the decision for urinary diversion [7]. Ileal conduit (IC) remains the most popular diversion method in United States (>80%) [8]. Although the proportion of RCs performed with robot assistance rose dramatically from <1% in 2004 to 13% in 2010, urinary diversion is mostly performed extracorporeally [9]. In this chapter we will discuss and describe a step-by-step approach to intracorporeal IC.

Preoperative Preparation

Patients should be properly counseled and provide an informed consent after fully understanding the risks, benefits and possible complications of the procedure. They should also be counseled about their future lifestyle and management of the stoma. The stoma therapist represents a key figure in the pre and postoperative management of patients.

A complete preoperative anesthesiology assessment including cardiac testing, renal and hepatic function, and correction of modifiable medical diseases should be performed. One of the contraindications of the minimally invasive approach is decreased pulmonary compliance and inability to tolerate the steep Trendelenburg position, especially with prolonged operative duration during intracorporeal diversion. A clear-liquid diet 12 h before surgery has become the standard. The enhanced recovery protocols, or "fast-track", incorporate innovative aspects such limited bowel preparation. Extensive bowel preparation can lead to electrolyte imbalance especially in older patients [10]. Scant evidence supports bowel preparation, and a simple cleaning enema the night before surgery as part of fast track seems to be sufficient [11].

Thrombo-embolic complications after RC are at least twice as likely when compared to nephrectomy and prostatectomy [12]. Further, RC has been shown to be an independent risk factor for thrombo-embolism, which is a strong predictor of mortality and cost of hospitalization [13, 14]. Therefore, perioperative thromboembolic prophylaxis with low molecular weight heparin in addition to mechanical methods as compression stockings and intermittent pneumatic compression devices should be also used [15]. Broad-spectrum intravenous antibiotics are preferably administered up to 1 h before the start of the procedure.

Positioning and Port Placement

The patient is positioned in the Trendelenburg position with the feet higher than the head with around 10–15°. This position allows the intestinal loops to be displaced upwards, giving more space in the pelvis. The abdomen is insufflated using the Veress needle or Hassan technique. After the camera port, all ports are placed under direct vision. Ports should be placed more cephalad to facilitate bowel maneuvering and performing extended pelvic lymph node dissection. A standard 6-port transperitoneal approach is used (three—8-mm robotic trocars, one—15-mm assistant port, and one—5-mm suction port are used). An additional 12-mm short suprapubic port is placed to facilitate bowel anastomosis.

Intracorporeal Ileal Conduit, the "Marionette" Technique

Marionette Stitch and Isolation of the Bowel Segment

The left ureter is crossed to the right side by incising the sigmoid mesentery. A 12-cm ileal segment is identified (15 cm proximal to the ileocecal valve) (Fig. 55.1). A measuring tape can be used to guide harvesting an adequate length of bowel. Any adhesions should be released at this point to facilitate manipulation and mobilization of the bowel loops. A 60-cm silk suture on a Keith needle is passed through the hypogastrium

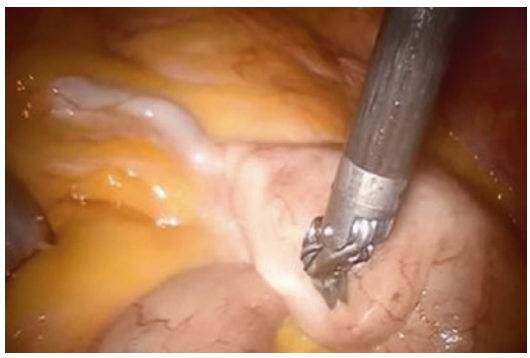

Fig. 55.1 The bowel segment is selected, by identifying the ileocecal junction

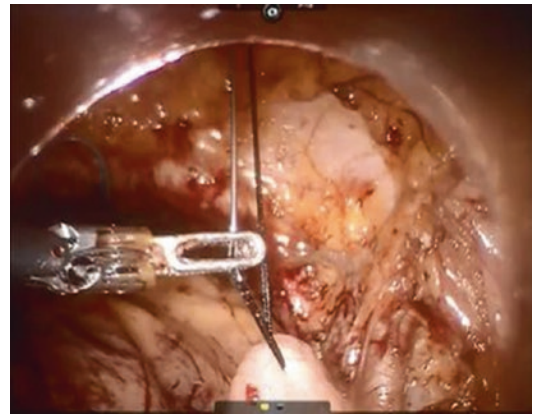

Fig. 55.2 A Keith needle with 60-cm length of 1–0 silk suture is introduced through the hypogastrium and passed into the distal end of the conduit

of the anterior abdominal wall. It is passed through the distal end of the bowel segment and then brought back through the same location on the anterior abdominal wall (Fig. 55.2). The stitch is not tied but held in position with a surgical instrument. This allows raising and lowering of the bowel segment similar to moving a marionette to facilitate bowel manipulation during the creation of the conduit. The proximal segment of bowel is controlled using the fourth arm.

Isolation of the Bowel Segment

Two mesenteric windows are created in the bowel mesentery of the chosen bowel segment. The mesentery is stretched in a fan-like manner (by putting the marionette stitch under tension and by using the fourth arm and a Cobra grasper). The hook cautery is used to incise the stretched mesentery, ensuring adequate width of its base. Mesenteric fat should be incised in a progressive fashion. A deep cut may risk injuring structures posterior to the isolated segment as an adjacent bowel or its mesentery. The mesentery should be gently manipulated to avoid stretch injury, especially with the lack of tactile feedback. The mesenteric vessels can be controlled in different ways, including hook cautery, bipolar grasper, hem-o-lock clips, vascular stapler or Ligasure.

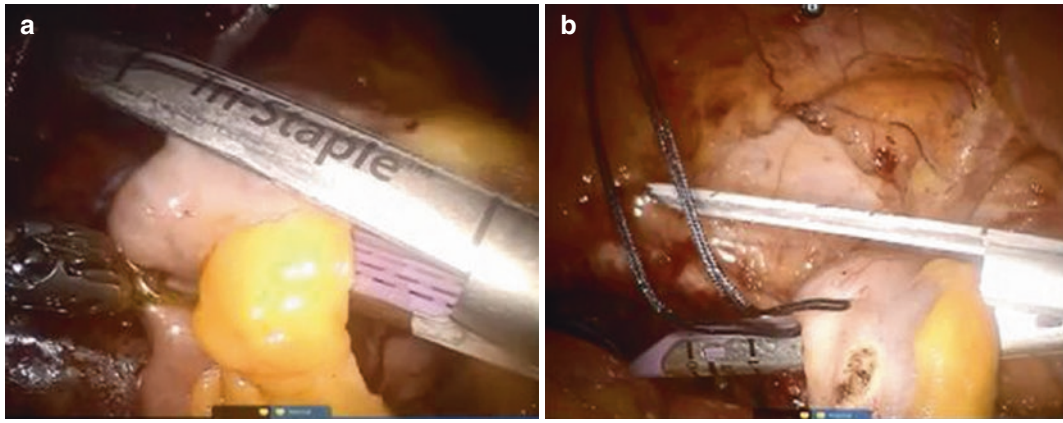

Fig. 55.3 After creating the two mesenteric windows a 45- or 60-mm Endo GIA stapler is passed through the 15-mm assistant port to divide the bowel proximally (**a**) and distally (**b**)

Once the two mesenteric windows are completed, an Endo GIA stapler is passed through the 15-mm assistant port to divide and isolate the bowel segment (Fig. 55.3). Choosing the appropriate length of the Endo GIA stapler is very important when dividing the bowel; 60-mm stapler should be used if the 45-mm one is not big enough to accommodate the whole bowel diameter. The hook cautery is used to create an enterotomy on the distal end of the isolated bowel segment (for introduction of the ureteral stents), and two other enterotomies on either side of the proximal end for the uretero-ileal anastomoses. Bowel continuity is not re-established at this point; instead, the two ends of the bowel are approximated using a single 0-silk suture to ensure proper orientation and avoid malrotation.

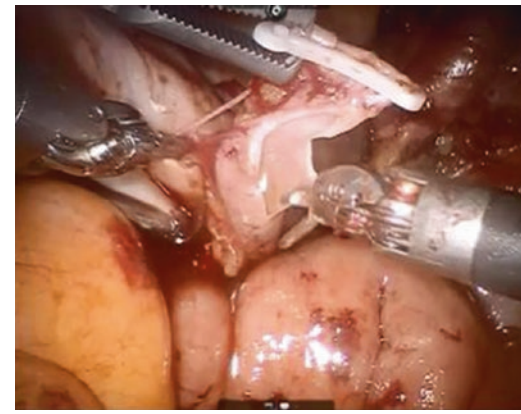

Fig. 55.4 The ureter is partially transected and spatulated using robotic scissors for a wide anastomosis

Uretero-Ileal Anastomosis

The ureters should be anastomosed to the isolated bowel segment in wide, tension-free and watertight manner. Appropriate length of the ureters can be ensured by aligning the ureteric ends with their corresponding enterotomies. The distal ureter should be excised if scarred or if of questionable vascularity, till healthy end is encountered to avoid uretero-ileal narrowing.

The uretero-ileal anastomosis can be performed using the Wallace or the Bricker techniques. During the Wallace anastomosis, the ureters are spatulated and joined at the posterior walls of the ureters. The Wallace plate is sutured to a single eneterotomy on the conduit. In the Bricker anastomosis, the left uretro-ileal anastomosis is performed first. The fourth arm can be used to steadily hold the ureteral end. The ureter is partially transected and spatulated for a wide anastomosis (Fig. 55.4). The marionette stitch is manipulated to align the conduit with the ureter to facilitate the anastomosis. A single armed 4–0 absorbable suture (5 cm long) is used for an interrupted anastomosis. The first anchoring stitch is placed in an "outside-in" manner on the ureter side at the angle of the spatulation, and then "inside out" on the conduit side, perpendicular to the proximal staple line (Fig. 55.5). Then, the

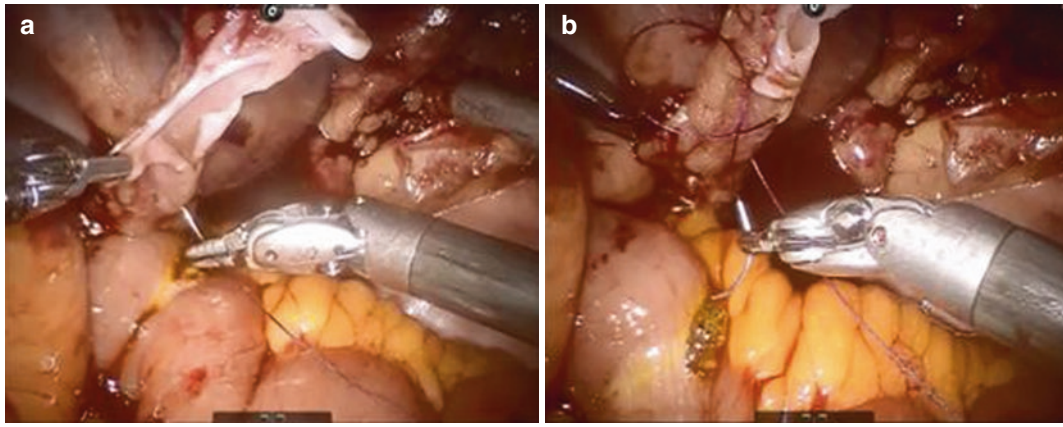

Fig. 55.5 The 1st anchoring stitch should be placed in an "outside-in" manner on the ureter side at the angle of the spatulation (**a**) and "inside out" on the conduit side (**b**), perpendicular to the proximal staple line

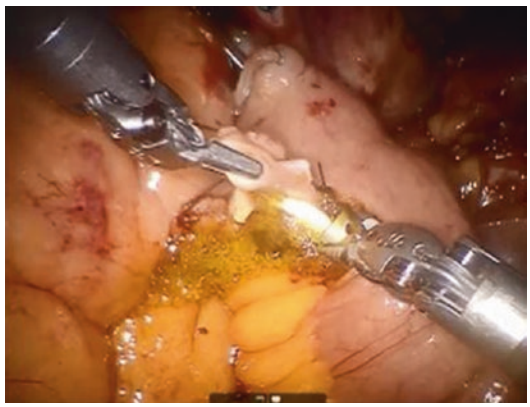

Fig. 55.6 A metal laparoscopic suction tube is gently advanced through the 15-mm assistant port, through the distal opening. The metal suction tip is held in place by the robotic needle driver to allow passage of stent into the ureter, without damaging the anastomosis

fourth arm is used to approximate the ureteral end to the conduit before tying the suture for a tension-free anastomosis. The ureteral mucosal edges should be clearly identified for a proper mucosa- to-mucosa anastomosis. Improper exposure of the mucosal edges can result in luminal obstruction or narrowing.

Once the posterior wall of the anastomosis is completed, the ureteral stent is placed. A metal laparoscopic suction tube is gently advanced through the distal enterotomy up to the anastomosis, guided by the robotic needle driver, to allow passage of stent into the ureter (Fig. 55.6). A 90-cm, 8.5 Fr, single-J ureteral stent with a guidewire is passed through the suction tip and fed into the ureter. Once the stent is pushed all the way, the suction is removed while holding the stent in place. A 3–0 chromic suture on SH needle is used to secure the stent to the conduit to prevent dislodgement. The guide wire is removed and the anterior half of the anastomosis is completed. The anastomosis of the right side is performed in similar fashion. After placement of right stent, the distal ends of both the stents are left in the 15-mm side port.

Restoration of the Bowel Continuity

Continuity of the bowel is restored by performing a side to side anastomosis. An additional 12 mm is placed in the hypogastrium, on the left side just lateral to the midline (Fig. 55.7). In males, the port incision may be extended later for specimen bag retrieval. The anti-mesenteric borders of the two bowel ends are incised just below the staple line to allow the jaws of a 60-mm Endo GIA stapler to pass through. The two bowel segments are aligned and properly oriented along the anti-mesenteric border. The stapler is passed through the hypogastric port and is fired. Another stapler is fired from the right assistant port, to staple the open ends of the either bowel segments. The mesenteric window is closed with interrupted silk sutures.

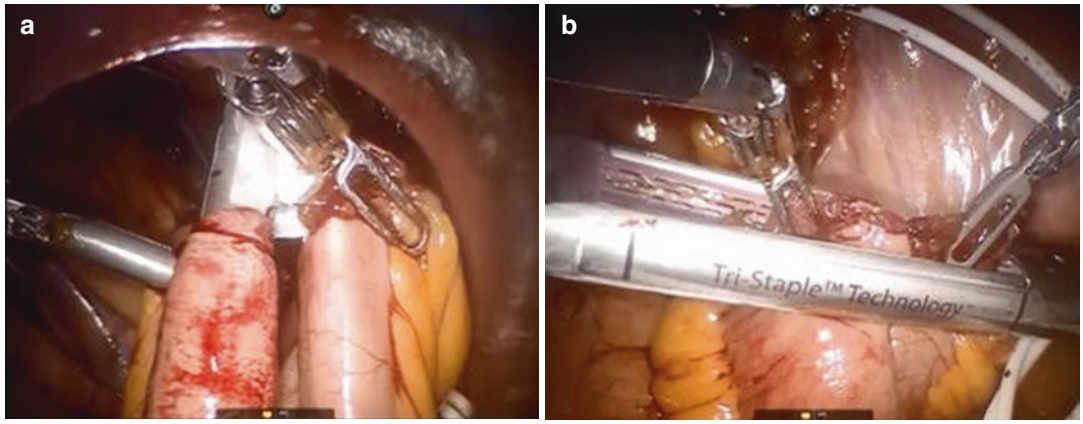

Fig. 55.7 Placement of an additional port in the hypogastrium for stapler insertion to restore continuity of the bowel by performing a side to side anastomosis. The fourth arm Cobra grasper is used to keep the segments aligned, while correct orientation is ensured using the right and left robotic instruments (**a**). Another stapler is fired from the right assistant port, to staple the open ends of the either bowel segments (**b**)

Creation of the Stoma

The specimen bag strings are retrieved from the hypogastric port. The standard approach of stoma creation is performed. A cruciate incision is made in the anterior rectus sheath, and the rectus muscle is split using a long hemostat. Four stay sutures are placed in the sheath to anchor the conduit once it is exteriorized. Under vision, a vascular clamp is introduced through the stoma opening to grasp the marionette suture and the ends of the ureteral stents. These are pulled out through the stoma while avoiding twisting of the conduit.

Outcomes

It has been stated that the major advantage of ileal conduits is the relatively simple surgical technique and the low rate of inherent postoperative complications. On the other hand, a visible stoma, the need for lifelong stoma care, and the related limitations in terms of social relationships, lifestyle, and leisure activities are well-recognized disadvantages of it. The advantages of intracorporeal IC urinary diversion include faster post-operative recovery, early return of bowel function and reduced analgesia requirements which also impact the overall hospital stay.

Studies that compared different urinary diversions had some inherent limitations including non-standardized reporting of short and long-term complications; they are mostly retrospective in nature with non-uniform patient selection and follow up. This may explain that although technically simpler to perform, IC has not been associated with lower complications as patients who undergo ileal conduits are usually older, with multiple comorbidities and unfavorable disease characteristics [16–18].

Uretero-Ileal Complications

Leakage of the uretero-ileal anastomosis occurs in 0.5–7% of cases, and is usually related to poor surgical technique, tension at the anastomosis, devascularization, rotation of the ureters, or defective suture [19, 20]. Meticulous handling and preparation of the distal ureter are essential to minimize the risk of urine leak and postoperative

strictures. Prolonged leakage can result in fibrosis and subsequent stricture formation, which was described in about 7–14% of cases, commonly during the first 2 years after surgery [18, 19]. Endoscopic and percutaneous management procedures may provide prompt and adequate drainage that prevent further deterioration, but may lack durable response. Surgical revision, via an open or recently robot-assisted approach, may provide definitive treatment [19, 21].

Stomal and Abdominal Wall-Related Complications

These complications are extremely frequent and contribute significantly to reduce the overall QoL in IC patients [22, 23]. Skin complications may be attributed to chemical or mechanical injury, and infection [24]. The role of the stoma therapist is vital for prevention and management of these complications.

Parastomal hernia, prolapse, stenosis, and retraction of the stoma have been reported in up to 31% of cases and represent a frequent cause for reoperation after IC [22–24]. Hernias may occur in the wound or adjacent to stomas and may require surgical revision. The true rate of parastomal hernia is unknown because most patients are asymptomatic or prefer not to get treated [24]. Although most parastomal hernias can be managed conservatively, approximately 30% of patients require surgical intervention due to obstruction, pain, and bleeding [25].

Fistulae

Fistulae following RARC and open surgery are rare (<4%) [26–28]. Technical modifications may decrease the incidence of fistula formation: closing the vaginal stump meticulously while embedding the mucosa; covering the vaginal stump with peritoneum in front of the anterior rectal wall; and interposing a generously pedicled omental flap between the closed vaginal stump and the urethro-ileal anastomosis [29].

Bowel-Related Complications

The incidence of bowel obstruction ranges between 0.8% and 11% [17, 30]. It may be related to the type of preoperative bowel preparation, fasting prior to surgery, postoperative pain control, and inadequate surgical technique. Generally, small bowel obstruction maybe treated conservatively with nasogastric tube, intravenous fluids, and bowel rest. Surgical intervention after failure of conservative measures has been less than 3% [19, 26, 27]. Late small bowel obstruction may be caused by stenosis of the ileo-ileal anastomosis, intraperitoneal adhesions, peritoneal carcinomatosis or irradiation. Bowel obstruction secondary to peritoneal carcinomatosis varies widely (3.5–21%) [2, 31]. Intestinal anastomosis leakage is a potentially catastrophic complication if not recognized early and accounts for an increase in the mortality rate [18].

Quality of Life

While continent urinary diversion in the form of orthotopic bladder substitutes may represent the new standard of care as it offers the potential for normal voiding without an abdominal stoma, the literature has failed to demonstrate superiority in terms of QoL. Although most studies were flawed by the retrospective nature and utilization of diverse instruments to assess QoL, overall QoL was generally acceptable for most forms of urinary diversion [32]. Only one study reported better QoL with neobladders compared to IC [33]. Careful patient selection and thorough preoperative discussion and counseling with the patient, relatives and the surgical oncology team are the key steps for satisfactory overall QoL regardless of the urinary diversion chosen.

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56 Robot-Assisted Intracorporeal Neobladder and Ileal Conduit Urinary Diversion: Technique, Current Status, and Outcomes

Justin W. Collins, Abolfazl Hosseini, and N. Peter Wiklund

Abstract

Although open radical cystectomy (ORC) remains the gold standard of care for muscle-invasive bladder cancer, robot-assisted radical cystectomy (RARC) continues to gain wider acceptance. The technique of robot-assisted radical cystectomy (RARC) has evolved significantly since its inception more than 10 years ago. Several high-volume centers have reported standardized techniques with refinements and subsequent oncological and functional outcomes. We summarise published outcomes for totally intracorporeal RARC in the chapter. Totally intracorporeal RARC aims to offer the benefits of a complete minimally invasive approach while replicating the oncologic outcomes of open surgery. In this chapter, we focus on the steps of intracorporeal urinary diversion in RARC, describing our approach, which has been developed over the past 10 years. We have described the Karolinska technique for both intracorporeal ileal conduit formation and neobladder formation. Our structured approach to RARC has enabled us to develop this complex service while maintaining patient outcomes comparable with ORC series. We conclude that the refinement of techniques for RARC and urinary diversion over the past 10 years has made it safe, reproducible, and oncologically sound.

Keywords

Neobladder · Radical cystectomy · Robotic cystectomy · Robot assisted radical cystectomy · Totally intracorporeal · Surgical technique · Intracorporeal orthotopic neobladder · Intracorporeal ileal conduit

Introduction

The creation of the urinary diversion is a challenging surgical part after radical cystectomy and holds a special place in the development of urological practice. Following cystectomy, urine can be diverted either into an incontinent stoma, into a continent urinary reservoir catheterized by the patient or controlled by the anal sphincter, or into an orthotopic bladder substitute so that the patient voids per urethra.

The history of urinary diversion is almost more than one and half centuries old. Simon was the first to describe a urinary diversion, using intestinal segments in 1852 [1]. Ureterocutaneostomy or transuretero-ureterocutaneostomy, the simplest form of urinary diversion, was the first diversion

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which has been tried initially. Strictures and scarring of the ureters were common problems, which later led to the use of intestinal segments of ileum or colon to create conduits.

In the late nineteenth and early twentieth centuries, in the absence of prophylactic antibiotic treatment, urinary diversion using bowel segments carried a high risk for peritonitis. When Coffey in 1911 [2] introduced a new method for ureteric implantation, ureterosigmoidostomy became the most frequently used technique. With increasing concern over secondary colonic malignancy, fewer ureterosigmoidostomies were performed, as it became unpopular because of the high incidence of tumor occurrence at the anastomosis between the ureters and the colon [3].

The ileal conduit, first described by Zaayer in 1911, was established as a standard technique by Bricker in 1950 [4]. At the same time, Ferris and Oedel demonstrated that hyperchloremic metabolic acidosis was common in 80% of the patients treated with ureterosigmoidostomy [5]. Thus the ileal conduit became the preferred form of urinary diversion. Longer follow-up has shown that ileal conduits do have significant physical and psychological morbidity, and this has stimulated the increasing use of continent urinary diversion and orthotopic bladder substitutes.

The first attempts to create a continent urinary diversion were undertaken by Tizzoni and Foggi in 1888 [6]. They replaced the bladder in a female dog by an isoperistaltic ileal segment. Mauclaire, in 1895, used the isolated rectum as a urinary reservoir [7]. Sinaiko was the first to use the stomach for the creation of a urinary reservoir in 1956 [8]. Two findings were essential for the development of modern continent urinary diversion: Kock established the principle of bowel detubularization to create a low-pressure reservoir, and Lapides popularized the use of clean intermittent catheterization [9]. In 1969, Kock published his first results obtained with an ileal continent fecal reservoir in patients after total proctocolectomy [10] and in 1975 he transferred the principle of this technique to urinary diversion [11]. In the 1980s as surgical outcomes of cystectomy continued to improve, emphasis was directed toward improving long-term quality of life. The pioneering work of Nils Kock and Maurice Camey [12] led to a variety of continent urinary reservoirs. The majority of these used either ileal segments, like the Hautmann and Studer neobladder [13, 14], or ileocecal segments, like 'Le Bag' MAINZ II pouch [15] and the modified rectal bladder of Ghoneim [16]. These are only a few examples of continence reservoirs which are still commonly used.

In the 1990s with development of minimally invasive techniques and advances in instrumentation design the interest in laparoscopic urinary diversion following cystectomy increased dramatically. The first simple laparoscopic cystectomy for pyocystis was performed by Parra et al. in 1992 [17]. In 1993 de Badajoz et al. published the first study on laparoscopic radical cystectomy (LRC) for muscle-invasive bladder cancer, wherein the ileal conduit urinary diversion was performed extracorporeally [18].

In 1995 Puppo et al. [19] described five cases of a combined laparoscopic and transvaginal anterior pelvic exenteration for bladder cancer. In 2001 Turk et al. described a completely intracorporeal LRC with a continent urinary diversion (rectal sigmoid pouch) [20]. A completely intracorporeal reconstruction of the entire LRC and urinary diversion procedure was reported by Gill et al., who also performed the first purely laparoscopic ileal conduit urinary diversion and laparoscopic orthotopic Studer neobladder in 2000 and 2002, respectively [21, 22].

During the last 15 years, urologists worldwide have witnessed a tremendous uptake of minimally invasive surgery due to the development of robotassisted surgery in many urological diseases. In parallel the interest in expanding the role of robot-assisted radical cystectomy (RARC) for the management of urinary bladder cancer has risen during the last years and continues to grow. Robotic-assisted laparoscopic techniques have emerged allowing surgeons to more readily overcome the difficult learning curve and shorten operative times in minimally invasive abdominal and pelvic operations [23, 24].

The da Vinci Surgical System® (Intuitive Surgical, Inc., Sunnyvale, CA) was first introduced in 2000 [25]. After the initial report of

robot-assisted radical cystectomy [26], several investigators have described the feasibility of RARC in the management of urinary bladder cancer [27–30].

RARC has been grown steadily during the last decade and has replaced LRC in centers where the robot is available. The neobladder can be formed intracorporeally [26, 31, 32] but operative time may be reduced early in the learning curve if this is done extracorporeally through the same incision used to deliver the cystectomy specimen. It has been shown that operation time is related to surgical experience and can be reduced using a standardized approach to RARC [24].

Raza et al. [33] reported that RARC is a minimally invasive procedure with long-term follow-up which is oncologically equivalent to open radical cystectomy. Novara et al. [34] reported in a review article that minimally invasive techniques, LRC and RARC, were associated with significantly reduced blood loss, hospital stay, marginally higher operative time and similar postoperative complication rates when compared to open radical cystectomy. Yuh et al. [35] reported in a review article that RARC oncological and functional outcomes with early and intermediate follow-up analysis were equivalent to reported outcomes from open surgery. Herein we describe step by step the method used at Karolinska University Hospital for robot-assisted urinary diversion with ileal conduit and orthotopic neobladder by intra- and extracorporeal technique.

Patient Selection

Selecting the correct patient for totally intracorporeal RARC and optimising their peri-operative care is crucial to optimising outcomes. The selection process includes preoperative investigation to ensure fitness for surgery as well as specific counselling about robotic technology. Patients with decreased pulmonary compliance who cannot tolerate prolonged Trendelenburg positioning are not candidates for the robotic-assisted technique. Furthermore, if the patient has a history of previous extensive abdominal surgery, RARC may be contraindicated. Relative contraindications include patients aged >80 years, body mass index (BMI) >30 and those with bulky disease and such cases should be avoided early in the operative learning curve.

Options for urinary diversion (UD) are discussed with the patient. Inclusion criteria for robot-assisted formation of an orthotopic ileal neobladder are the same as for open surgery, with all suitable patients primarily considered for orthotoptic neobladder. If a neobladder is contraindicated or if patients prefer, they will then receive an ileal conduit. The absolute contraindications for neobladder formation are: disease infiltration of the urethra distal to the prostate, impaired renal (serum creatinine >2 mg/dL) and hepatic function, and decreased mental capability and hand dexterity. The relative contraindications include: inflammatory bowel disease (Crohn's disease), non-competent external sphincter with associated urinary incontinence, history of recurrent urethral strictures, previous abdominal or pelvic irradiation and history of severe comorbidities, elderly patients (octogenarians), or morbid obesity (BMI > 30).

Preoperative Preparation

Standard preoperative evaluation includes computed tomography (CT) of the chest, abdomen and pelvis, routine blood tests and anaesthetic review incorporating evaluation of cardiopulmonary reserve. Patients with pT2 + tumours receive preoperative neoadjuvant platinum-based chemotherapy. In RARC with intracorporeal urinary reconstruction, bowel preparation can be avoided [36]. However, irrigation of the bowel segment may be tricky and non-digestible vegetables can be seeded into the peritoneum when the small bowel segment is opened. Thus, vegetables should not be part of the diet the day before surgery. A stoma site is marked the day prior to surgery in all patients and broad spectrum intravenous antibiotics are administrated at the start of the procedure. All patients should follow an enhanced recovery after surgery protocol for their peri-operative care planning [37].

Operative Setup

Patient Position

After induction of general endotracheal anesthesia a naso-gastric tube and an 18 Ch Foley urinary catheter are inserted. The patient is placed in lithotomy position with arms adducted and padded. The legs are also abducted and slightly lowered on spreader bars. The table is placed in 25° Trendelenburg position during the cystectomy and lymph node dissection. For the urinary diversion the Trendelenburg position is decreased to 10–15°.

Equipment

The technique is challenging, requiring conventional laparoscopic infrastructure as well as an assistant with high skills in conventional laparoscopy. Standard laparoscopic surgical equipment with some extra instruments is required (Ligasure® Covidien, surgical endoscopy clip applicators, laparoscopic endo-catch bags, and laparoscopic stapler for intestinal stapling).

Surgical Steps (Table 56.1)

Trocar Configuration

Port placement is critical for successful robotic surgery (Fig. 56.1). A six-port technique is used with the camera port placed 5 cm above the umbilicus in the midline. The camera port is placed by a small mini laparotomy as described by Hasson [38] and the other ports are placed in view of the camera. A pneumoperitoneum pressure of 18 mmHg during the port placement can be helpful in creating additional tension on the abdominal wall. Two robotic ports are placed symmetrically and level with the umbilicus on the left and right side, lateral to the rectus sheath. A third robotic instrument port is placed just above and medial to the left anterior superior iliac spine through a 15-mm port thereby enabling laparoscopic stapling by the assistant when the third robotic port is temporarily disconnected. The

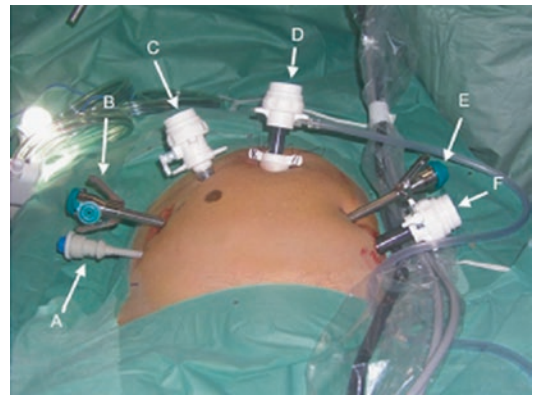

Fig. 56.1 Trocar placement for standard da Vinci system. (*A*) 5 mm trocar. (*B*) 8 mm trocar, *right* robot instrument. (*C*) 12 mm trocar, suction, bowel grasping, LigaSure. (*D*) camera trocar. (*E*) 8 mm trocar, *left* robot instrument. (*F*) 15 mm four robotic arm, specimen retrieval and stapling

Table 56.1 Surgical steps

Surgical step	Lens	Right robotic instrument	Left robotic instrument	Fourth robotic arm	Right assistant port
Anastomosis between urethra and ileum	0°	Needle driver	Cadiere	Cadiere	Bowel grasper
Isolation of 50 cm ileum	0°	Cadiere	Cadiere	Not in use	Endo-GIA 60 mm
Detubularization of ileal segment	0°	Scissors	Cadiere	Not in use	Suction device
Suturing of the posterior wall	0°	Needle driver	Cadiere	Cadiere	Grasper and hook
Folding of the neobladder and suturing the anterior wall	0°	Needle driver	Cadiere	Cadiere	Grasper and hook
Anastomosis between ureters and afferent limb	0°	Needle driver	Cadiere	Cadiere	Suction device
Placement of ureteric stents	0°	Cadiere	Cadiere	Not in use	Not in use
Closing of the neobladder	0°	Needle driver	Cadiere	Cadiere	Hook and suction device

fourth port (5 mm right assistance port) is placed approximately 5 cm above the right anterior superior iliac spine in the mid-axillary line. The fifth (15 mm) port is positioned approximately 5 cm above the left anterior superior iliac spine for the insertion of the fourth robotic arm instrument. During the intracorporeal construction of the urinary diversion the fourth arm port will be removed from the 15-mm port above the left anterior superior iliac spine allowing intestinal stapling through this port. The sixth (12 mm) assistant port is placed midway between the right robotic arm port and the camera port approximately 2 cm above the camera port. The pneumopertioneum can then be reduced to 10–12 mmHg.

Urinary Diversion

Orthotopic Neobladder, Intracorporeal Technique

Anastomosis Between the Urethra and Ileum

After completing the radical cycstectomy and the ePLND the urinary diversion is performed. For the urinary diversion the robot is undocked and the Trendelenburg position is decreased to 10–15° before re-docking, so as to facilitate the bowel dropping into the pelvis.

The first step is to perform an anastomosis between the ileum and the urethra. The 0° lens is used for this initial step. The ileum is sufficiently mobilized in order to reach down to the urethra. This is important for two reasons, first the anastomosis between the neobladder and urethra can be performed without tension, and second the neobladder will be placed correctly in the small pelvis during the whole procedure. This will help during construction of the neobladder by running suture. A 20 Ch opening (Fig. 56.2) is made in the antimesentric site of ileum, using robotic scissor. The anastomosis is performed according to the Van Velthoven technique with a two times 16 cm 2–0 Quill® suture, allowing for 10–12 suture passes (Fig. 56.3). A needle driver and a cadiere are used to establish the anastomosis.

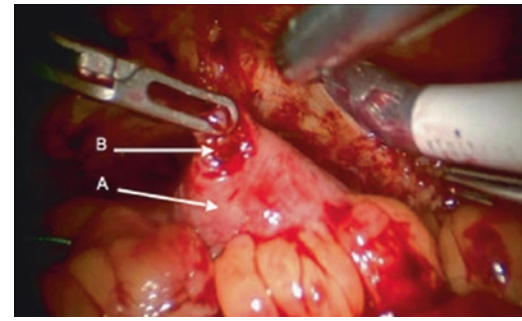

Fig. 56.2 An opening (*B*) in ileum (*A*) is performed to allow the passing of a 20 Ch catheter

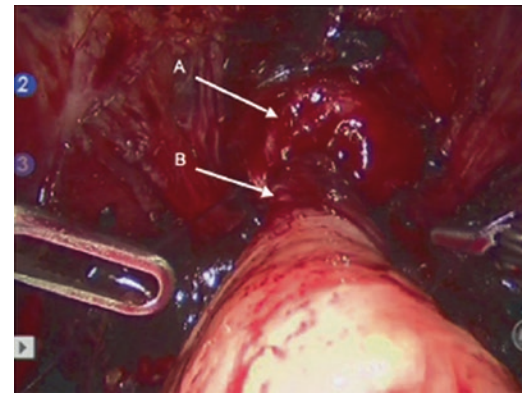

Fig. 56.3 Anastomosis between urethra (*A*) and ileum (*B*)

Isolation of 50 cm Ileum

The orthotopic neobladder is fashioned from a 50 cm segment of terminal ileum. The intestine is isolated using laparoscopic Endo-GIA with a 60 mm intestinal stapler (Fig. 56.4). The staple is inserted by the assisting surgeon, using the 15 mm port on the left side. The ileum is stapled 40 cm proximal to the urethral– ileal anastomosis. The continuity of the small bowel is restored by using Endo-GIA with a 60 mm intestinal stapler, positioning the distal and proximal end of the ileum side to side with the anti-mesentery part facing each other (Fig. 56.5). An additional transverse firing of the Endo-GIA staple is used to close the open ends of the ileal limbs (Fig. 56.6). Stay sutures may be used to attach the intestines before stapling them together.

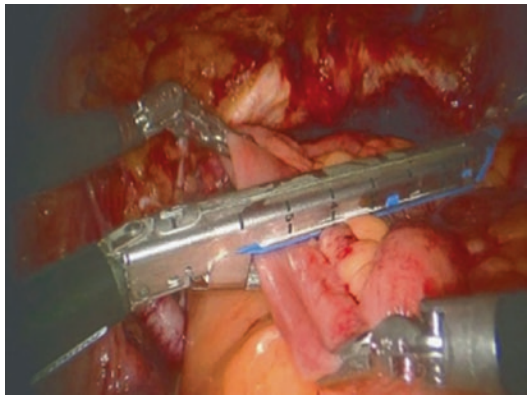

Fig. 56.4 Stapling of ileum using Endo-GIA 60 mm

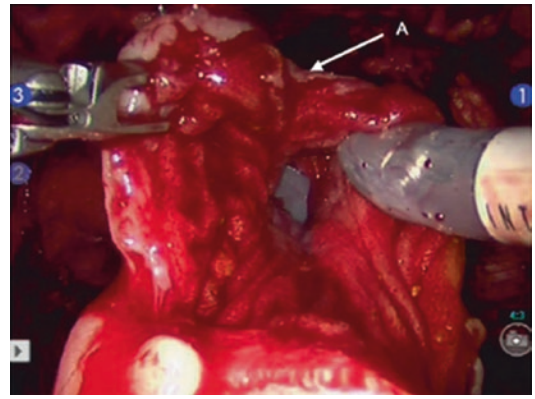

Fig. 56.7 Detubularization of ileum, antimesentricaly (*A*) in order to create the neobladder

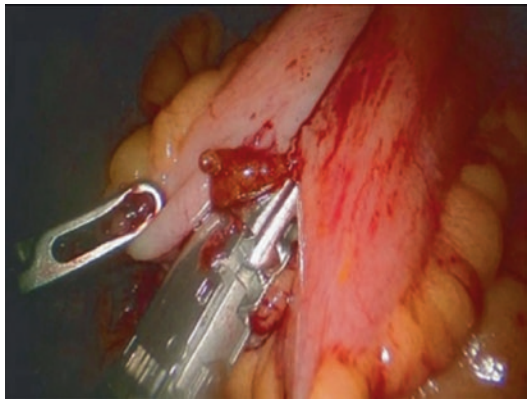

Fig. 56.5 Side-to-side anastomosis of ileum by Endo-GIA 60 mm

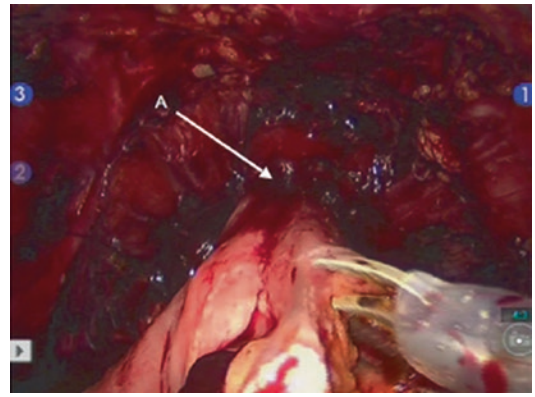

Fig. 56.8 Detubularization close to the ileourethral anastomosis (*A*), special care is taken not to interfere with the anastomotic suture

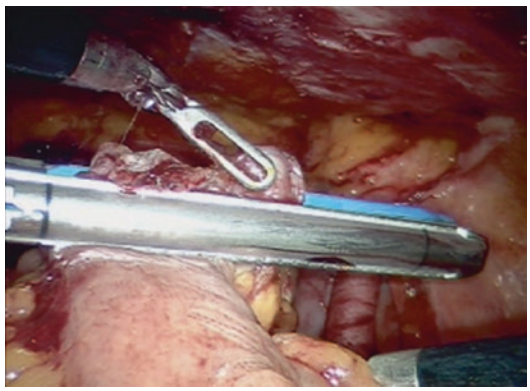

Fig. 56.6 Closing of the open end of ileal limbs using the Endo-GIA staple

Detubularization

The distal 40 cm of the isolated ileal segment is detubularized along its antimesenteric border with cold scissors (Fig. 56.7), leaving a 10 cm intact proximal isoperistaltic afferent limb. Care is taken not to interfere with the sutures used for the anastomosis to the urethra (Fig. 56.8).

Formation of Studer Neobladder

After detubularization, the posterior part of the Studer reservoir is closed using multiple running sutures (15 cm 3–0 V-Loc®) in a seromuscular fashion, avoiding suturing the mucosa. After the

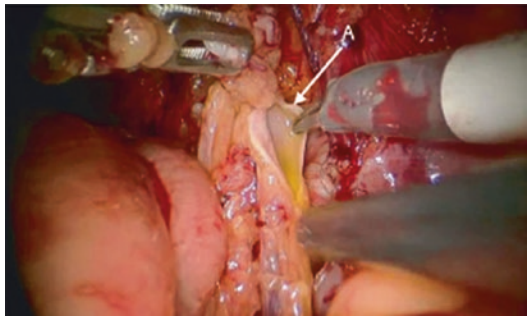

Fig. 56.9 Spatulation of the right ureter (*A*)

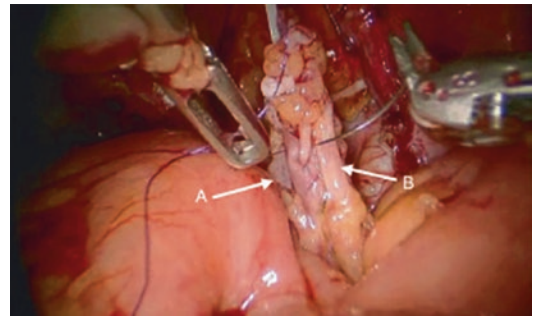

Fig. 56.10 Suture of left (*A*) and right (*B*) ureter side to side, according to the Wallace technique

posterior part is sutured, the distal half of the anterior part of the reservoir is sutured, using the same suture. The 0° or 30° lens can be useful for this part of procedure. The proximal half of the anterior part of the reservoir is left open and is closed in the last part of the procedure.

Ureteric Entero-Anastomosis

The anastomosis between the ureters and the afferent limb is performed using the Wallace technique [39]. Using the fourth arm the ureters are aligned holding the ties attached to the Hem-o-lok clips. The ureters are then incised and spatulated for 2 cm (Fig. 56.9). The posterior walls of the ureters are sutured side-to-side, using a 15 cm running 4–0 Biosyn suture (Fig. 56.10). Before the anastomosis between the ureters and the intestinal loop is made, two single-J 40 cm ureteric stents are introduced with the Seldinger technique [40] through two separate 4-mm incisions at the lower part of abdominal wall (Fig. 56.11). Using the Cadiere forceps the stents are pulled through the afferent limb and pushed up into the ureters on each side (Fig. 56.12). The ureters are then sutured to the afferent limb of the Studer pouch, using a two-times 16 cm 3–0 Quill suture with a needle on each end (Fig. 56.13). After the entero-ureteric anastomoses are completed the stents are sutured and fixed to the skin.

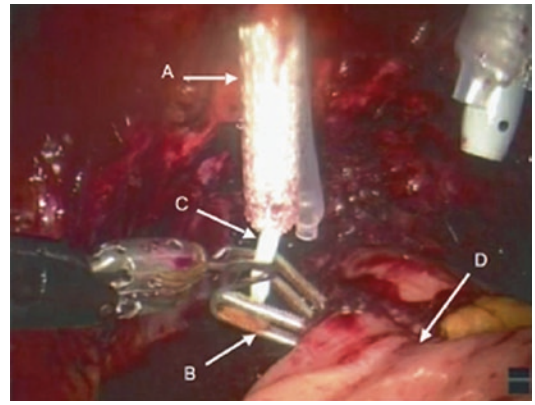

Fig. 56.11 Placement of uretric stent through a 3 mm port (*A*). *Right* robotic instrument (*B*) grasps the tip of the stent (*C*) and pulls in upward through the afferent limb of Studer reservoir (*D*)

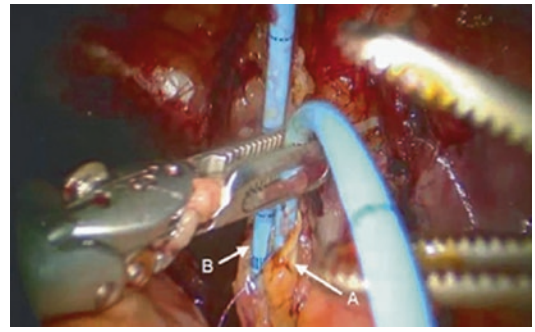

Fig. 56.12 Placement of stent up through the right ureter (*A*). The *left* uretric stent is already in place (*B*)

Closure of the Studer Reservoir

The remaining part of the neobladder is then closed with a running 3–0 V-Loc suture. The balloon of the indwelling catheter is filled with 10 mL sterile water. The neobladder is then filled with 50 mL of saline to check for leakage (Fig. 56.14). Extra suturing to secure a watertight reservoir and anastomosis is fundamental to

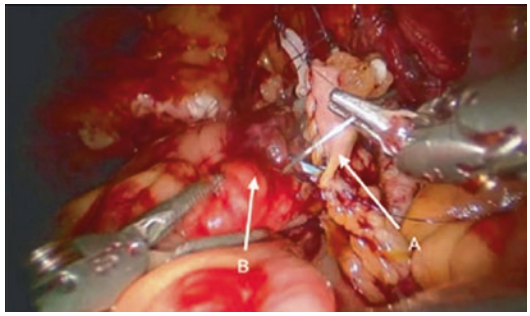

Fig. 56.13 Anastomosis between Wallace plate (*A*) and afferent limb (*B*) of the Studer reservoir, using seromucosal suturing technique

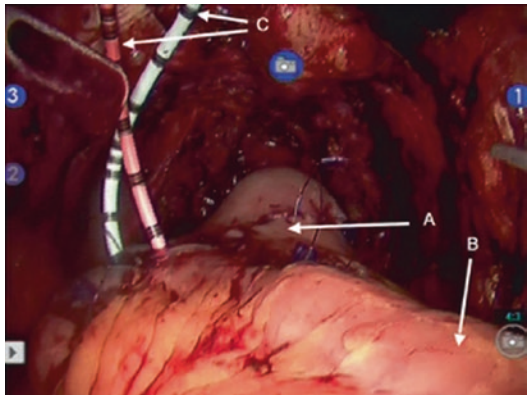

Fig. 56.14 After the neobladder (*A*) is completed it is filled with 50 cc saline to check for leakage. The anastomosis between ureters and afferent limb (*B*) is also checked for leakage. The uretric stents (*C*) are placed separately in the Studer reservoir

decreasing post-operative complications. A 21F passive drain is introduced and placed in the small pelvis. Drain fluid is sent for biochemical analysis the morning after surgery and if there is no indication of urine leakage the drain is removed on day 1 post-operatively [36]. The urethral catheter is removed after 21 days. We do not place a suprapubic catheter.

Ileal Conduit, Intracorporeal Technique

Twenty centimeter intestine is isolated from the terminal ileum, using Endo-GIA with a 60 mm intestinal stapler. The continuity of the small bowel is restored as described above. The distal end of the conduit is fashioned as a stoma by surgical assistant at a previously marked site on the abdominal wall. The left ureter is tunneled under the sigmoid mesentery to the right side. The ureters are then incised and spatulated 2 cm. The Wallace technique is used here as described above. Single-J 40 cm ureteric stents are then introduced through the isolated ileal segment (ileal conduit), using a suction tube for a protective channel avoiding intestinal perforation. The stents are then pushed up into the ureters on each side and the ureteroenteric anastomosis is completed, using a two-times 16 cm 3–0 Quill® suture which has a needle on each end.

Special Consideration

Patient Position

Care should be taken for using a pneumatic leg compression system due to risk of decreased vascular perfusion during the procedure [37]. To avoid cardiovascular complications the patient is started on anticoagulant treatment with low molecular weight heparin according to his body weight the evening before surgery until the patient is fully mobilized. It is feasible to perform the urinary diversion with 10–15° Trendelenburg, since higher degree of Trendelenburg is to be avoided in order to minimize the risk for cardiopulmonary complications.

Port Position

It is always important to make sure that the fourth arm port and the left robotic arm port are not in a same superior-inferior alignment to avoid clashing of robotic arms.

Urethral-Neobladder Anastomosis

The anastomosis between the urethra and the ileum (see Fig. 56.2) should be the first step in the formation of an intracorporeal orthotopic neobladder. This is a critical step because the anastomosis can be performed without tension, and the neobladder will be placed correctly in the small pelvis during the whole procedure.

Steps to Avoid Complication

Shoulder pads should be avoided due to the high risk of plexus damage. Care should be taken during the tunnelling of the left ureter behind the

colon sigmoid and during the extended lymph node dissection to avoid damaging any vascular structures. It is important to check for leakage after the neobladder has been created. Extra suturing to secure a watertight reservoir and anastomosis is fundamental to decrease postoperative complications.

Current Status and Outcomes

Construction of the urinary diversion after RARC is probably the most challenging part of the procedure, especially if using a totally intracorporeal approach. Since the first robot-assisted radical cystectomy (RARC) by Beecken et al. in 2003 [26] RARC has been gradually adopted as a surgical alternative to open cystectomy. As recently as 2010 the number of centres performing this surgery appeared limited, with only ~500 cases being reported in the worldwide literature [41], but by 2012 this had increased to ~1000 cases [42]. Results from more than 2000 RARC cases worldwide have now been published [34]. The first papers publishing long-term oncological outcomes show results that are comparable to published open series [33] and reviews have concluded that functional outcomes and complication rates are also comparable [34, 35]. The operative time used for the reconstruction, early in the surgeons learning curve, is one of the important factors in the decision between performing the diversion extra- or intracorporeally. Currently the vast majority of RARC in the United States are completed with an extracorporeal approach to the urinary diversion by extending the mini-incision used for removal of the specimen [26, 43–45]. In a recent multi-institutional report from the USA only 3% of patients had a totally intracorporeal approach [46]. Robot-assisted intracorporeal ileal conduit and orthotopic neobladder have been described in the literature [26, 47–49]. There is a growing body of evidence that intracorporeal urinary diversion is becoming increasingly utilised and that there are potential advantages to the patient if they undergo a totally intracorporeal approach to RARC [50].

Table 56.2 presents data from case series of intracorporeally performed urinary diversions performed at single institutions.

Currently, there is a limited amount of data on functional outcomes. Whereas in robot-assisted radical prostatectomy (RARP) surgery there is a potential trade-off between oncological and functional outcomes, in RARC functional outcomes are dependent on various factors and surgical choices, e.g., continent vs non-continent diversion, with additional variables such as natural voiding vs required intermittent self-catheterization. Although continence rates after RARC are directly related to the surgical approach, they are influenced by multiple factors including patient age and mental status, an intact and innervated urethral sphincter, urethral length, low-pressure/large-capacity reservoir (>300 mL), absence of bacteriuria, and completeness of voiding. Continence after orthotopic bladder substitution continues to improve up to 12 months after surgery. It is therefore preferable to assess continence stratified by daytime and night-time continence and by gender [51, 54]. Similar conclusions were reached in the 2012 EAU International Consultation on Bladder Cancer [55] which reviewed the data published on urinary diversion between 1970 and 2012 and found that in patients with open radical cystectomy and orthotopic bladder substitution, day- and night-time continence is achieved in 85–90% and 60–80%, respectively. If we consider totally intracorporeal continent urinary diversion, in most published series a Studer neobladder has been created [31, 48, 49, 51] and, although current cohorts are small, functional outcomes reported are encouraging. Tyritzis et al. [51], in a series of 70 patients, reported daytime continence of 88.2% in male patients who had undergone nerve-sparing surgery, whilst night-time continence reached 73.5% at 12 months. Similar rates were achieved for males who had undergone non-nerve-sparing surgery at 12 months (83.3% and 88.9%, respectively). Of female patients, 66.7% were found to be continent during the day and 66.7% at night at 12 months. All continence rates showed significant improvement at 12 months compared with the

Table 56.2 Robotic-assisted radical cystectomy with intracorporeal urinary diversion

Authors (ref.)	Institution	Number of patients	Type of intracorporeal uninary diversion (number)	Mean operative time (min)	Mean perioperative blood loss (mL)	Mean postoperative hospital stay (days)	Erectile function and continence
Collins et al. [30]	Karolinska Institutet	113	Ileal conduit (43)	292 (conduit)	200 (conduit)	9 (conduit)	NR
			Orthotopic neobladder (70)	420 (neobladder)	500 (neobladder)	9 (neobladder)	
Tyritzis et al. [51]	Karolinska Institutet	70	Orthotopic neobladder (70)	420	500	9	88% continent during daytime and 72% at night. 58% of men were potent with or without PDE5I
Goh et al. [48]	Keck School of medicine, University of Southern California, Los Angeles	15	Ileal conduit (7)	450	225	8	Neobladder patients 75% continent during the daytime. Night-time continence and erectile function NR.
			Orthotopic neobladder (8)				
Kang et al. [52]	Korea University School of Medicine	4	Ileal conduit (3)	510 (conduit)	400 (conduit)	14	NR
			Orthotopic neobladder (1)	585 (neobladder)	500 (neobladder)		
Canda et al. [48]	AnkaravAtaturk Training and Research Hospital	27	Ileal conduit (2)	594	430	10.5	64.7% daytime continence and 17.6% night-time continence. Erectile function NR.
			Orthotopic neobladder (25)				
Pruthi et al. [53]	University Hospital of North Carolina	12	Ileal conduit (9)	318	221	4.5 (conduit)	NR
			Orthotopic neobladder (3)			5 (neobladder)	
Sala et al. [31]	UCI Medical Centre, University of California, Irvine	1	Orthotopic neobladder	720	100	5	Continent daytime
Balaji et al. [32]	University of Nebraska Medical Center, Omaha, Nebraska	2	Ileal conduit	600	435	6	NR
Beecken et al. [2, 6]	J.W. Goethe University, Frankfurt	1	Orthotopic neobladder	510	200	10	NR

NR not reported

6-month follow-up. A total of 81.2% of male patients were potent with or without phosphodiesterase type 5 inhibitor medication at 12 months. In that series, all eight female patients received a nerve-sparing procedure by preserving the autonomic nerves on the anterior vaginal wall. Of the evaluated male nerve-sparing, male non-nerving-sparing and female patient groups 84.4, 23.8% and 66.7% of patients, respectively, were sexually active postoperatively. Goh et al. [48] reported daytime continence in six out of eight patients at a mean (range) follow-up of 3.1 (3–21) months. Canda et al. [49] reported daytime continence in 11 out of 17 patients at a mean (range) follow-up of 6.4 (2–12) months, four had mild and two had severe daytime incontinence. In sexual functionality in females, important outcome measures after the reconstruction of the vagina include both the ability to have sexual intercourse and the absence of dyspareunia (see Table 56.2).

RARC surgery is complex surgery with several important outcome measures. It is crucial to optimize both oncological and functional outcomes whilst minimizing complications. With time and increased experience, operative times, functional and oncological outcomes will continue to improve [24]. Totally intracorporeal RARC has potential advantages with the literature showing consistent advantages, such as blood loss and length of stay, compared with open radical cystectomy [34]. However, the outcomes of prospective randomized controlled trials comparing RARC with intracorporeal and extracorporeal urinary diversion and/or standard open radical cycsteectomy are awaited to confirm the current findings. Measures of optimum outcome should include, negative surgical margins, cancer specific survival at 3 and 5 years, absence of major complications in the 30- and 31–90-day periods, daytime and night-time continence at 12 months, sexual activity, plus measures of length of hospital stay and time to return to normal activities. Comparative studies should also include quality-of-life or overall satisfaction scores [50].

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Robotic Radical Cystectomy and Urinary Diversions: Complications and Outcomes

57

Jennifer A. Linehan, Michael Tyler, and Timothy G. Wilson

Abstract

It is incumbent upon urological surgeons who perform robotic assisted radical cystectomy and urinary diversion to critically analyze the complications, functional outcomes and oncological outcomes in order to confirm that it offers no decrease in benefit over traditional open surgery. The surgery can have significant morbidity, so minimizing these complications is and always has been an undisputed goal. Reports from the Pasadena Consensus Panel and the International Robotic Cystectomy Consortium have helped to analyze the literature, review the submitted data, and focus on current issues. This information allowed surgeons from around the world to combine their data to provide optimal care to those patients with invasive urothelial carcinoma. This chapter is a summary of those systematic reviews and recommendations.

Keywords

Robotic-cystectomy · Genitourinary complications · Urinary diversion · Urothelial carcinoma · Pasadena consensus International Robotic Cystectomy Consortium

Introduction

There is significant morbidity in treating bladder cancer with robotic-assisted radical cystectomy (RARC) and urinary diversion (UC). Understanding the balance of oncological outcomes against the complications of surgery has always been a significant task. Approximately 7000 radical cystectomies were performed in the United States from 2001 to 2010 [1]. The number of robotic-assisted procedures has increased from 0.6% to 12.8% from 2004 to 2010 [2].

With proper treatment, 66% of patients are recurrence-free 10 years after surgery. The addition of neoadjuvant chemotherapy has also improved overall survival in addition to surgery [3, 4]. Currently, oncologic outcomes include positive surgical margins, lymph node yield, and survival data. Many reported outcomes come from institutions early in the learning curve for RARC which makes the data more difficult to

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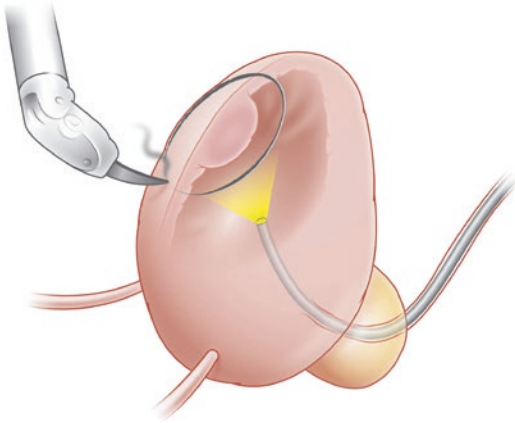

Fig. 57.1

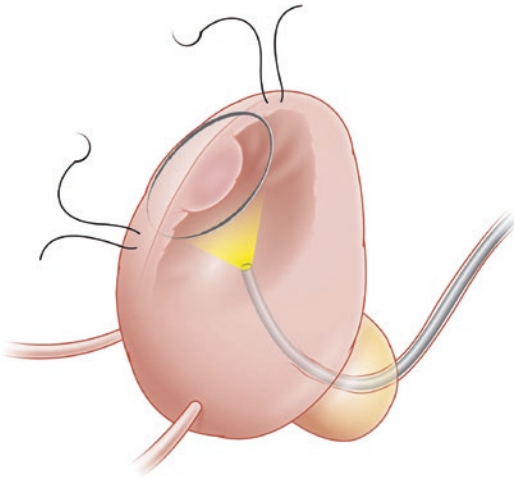

Fig. 57.2

assess [5]. The same is true for functional outcomes which include recovery of continence and potency. Much of the data comes from smaller studies with inadequate follow-up or limited discussion of nerve sparing techniques (Figs. 57.1, 57.2, and 57.3).

Complications both 30 and 90 day after RARC range from 30% to 65% which warrant the imperative desire to improve technique and

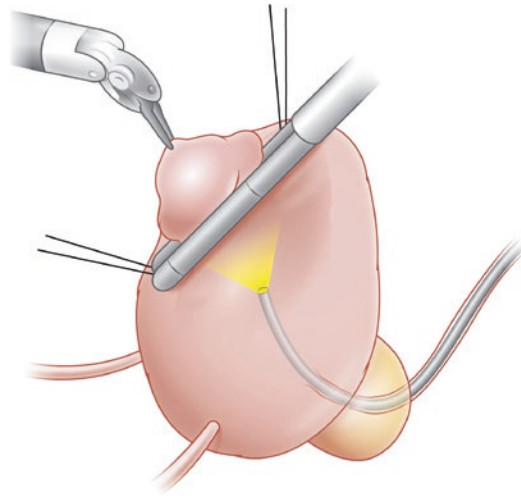

Fig. 57.3

lessen risk [6, 7]. See Table 57.1 Classification of complications within the Clavien system is increasingly important in data standardization and the rates of these reported complications further support the need for referrals to high-volume centers [8]. Additional parameters such as hospital readmission and 90-day mortality provide valuable information on the risk factors for complications. The goal of the consensus groups has been to identify risk factors for complications as well as standardize its reporting [9].

This chapter is a systematic review from recent publications on robotic cystectomy of both oncologic outcomes as well as complications. Both The Pasadena Consensus Panel and the International Robotic Cystectomy Consortium (IRCC) which are composed of experts on robotics and cystectomy have helped to fast track data collection and interpretation. These groups have provided a systematic approach to assessing surgical complications of RARC and providing standards to measure the oncologic and functional outcomes.

Table 57.1

Author (institution)	Approach	Diversion	Patients (n)	Follow-up (months)	Blood loss (mL)	OR time (min)	pT stage ≥ pT3 (%)	Lymph node yield (mean/ median)	Node positivity (pN+) (%)	Positive surgical margin (%)
Peri-operative (follow up less than 3 months)										
Smith 2012 [12]	Extracorporeal	Neobladder	227	1	256	330	15	18	20	2.2
		Ileal Conduit								
Azzouni 2012 [47]	Intracorporeal	Ileal Conduit	100	3	300	352	65 (≥pT2)	24	17	4
Bochner 2015 [29]	Extracorporeal	Neobladder	60	3	500	464	33	n/a	18	3.6
		Ileal Conduit								
Kader 2013 [48]	Extracorporeal	Neobladder	100	3	423	451	42	18	30	12
		Ileal Conduit								
		Continent cutaneous								
Yuh 2012 [37]	Extracorporeal	Neobladder	241	3	400	432	29	28	28	4.1
		Ileal conduit								
		Continent cutaneous								
Intermediate (follow up equal to or less than 2 years)										
Knox 2013 [32]	Extracorporeal	Neobladder	58	7.5	276	468	20	21	2	4
		Ileal conduit								
Styn 2012 [34]	Extracorporeal	Neobladder	50	8	350	455	40	14	24	4
		Ileal conduit								
Niegisch 2014 [49]	Extracorporeal	Neobladder	64	9.1	300	360	42	20	20	6.4
		Ileal conduit								
		Continent cutaneous								
Pruthi 2010 [30]	Extracorporeal	Neobladder	100	21	271	276	13	19	20	0
		Ileal conduit								
Desai 2014 [50]	Intracorporeal	Neobladder	132	25	430	456	16	29	17	0.8
Collins 2013 [51]	Intracorporeal	Neobladder	113	25	350	390	24	21	19	5.3
		Ileal conduit								

(continued)

Table 57.1 (continued)

Author (institution)	Approach	Diversion	Patients (n)	Follow-up (months)	Blood loss (mL)	OR time (min)	pT stage ≥ pT3 (%)	Lymph node yield (mean/ median)	Node positivity (pN+) (%)	Positive surgical margin (%)
Long term (follow up greater than 2 years)										
Tan 2106 [52]	Intracorporeal	Neobladder	90	33.8	n/a	n/a	30	15	14	8.2
		Ileal conduit								
Xylinas 2013 [35]	Extracorporeal	Neobladder	175	37	400	360	35	19	22	5
		Ileal conduit								
		Continent cutaneous								
Schwentner 2015 [53]	Intracorporeal	Neobladder	62	37.3	385	477	39	22.9	24	7.1
Snow-Lisy 2014 [54]	Extracorporeal (robotic + lap)	Neobladder	121	66	400	450	39	14	20	6.6
		Ileal conduit								
Raza 2015 [14]	Extracorporeal	Neobladder	743	67	400	438	38	16	21	8
		Ileal conduit								

Outcomes

Pathologic Outcomes

Surgical Margins

While surgical margins are related to the local extent of the tumor, some may infer that surgical margin positivity is an assessment of surgical skill. Despite this theoretical relationship, many have documented that case number or surgical volume shows limited correlation to surgical proficiency. Richards et al. [10] and Schumacher et al. [11] could not demonstrate a directly proportional relationship between surgical margin rate and number of cases, as data has shown that >pT2 disease is the biggest contributing factor to positive surgical margin status [12]. Acceptable positive margins per T stage are reported to be <3% for pT2, <10% for pT3, <25% for pT4, and <7% overall [13], while the reported rate was 9% from >900 cases within the IRCC [14]. In all of the RARC series, the average reported rate was 5.6% with a range from 0 to 26% [5].

Lymph Node Yields

The lymph node dissection during cystectomy should include all nodes along the common iliac vessels, lateral to the genital femoral nerve, as well as the nodes along the pelvic sidewall and distal to the femoral canal. All obturator and presacral nodes should be removed. Nodes up to the aortic bifurcation are also included. The Pasadena Consensus agreed with this extended dissection [15]. Centers performing >100 robotic cases were 3.5 times more likely to implement an extended pelvic lymph node dissection [16]. Some studies did show that operative times were longer with robotic extended lymphadenectomy (eLND) [17]. The mean lymph node yield combined for all series was 19 (range of 3–55) [5] and as centers increased adoption of extended lymph node dissection, the mean changed to 37.5 with a lymph node positivity rate of 22% [18].

Oncologic Outcomes

Survival Rates

Recurrence-free survival rates for RARC were comparable to open, ranging from 74% to 96% at 1 year, decreasing to 39% to 74% at 5 years [15]. For studies reporting between 6 and 84 months follow-up, the 1-, 2-, 3-, and 5-year disease-free survival was 79–96%, 67–81%, 67–76%, and 53–74%, respectively [5] see Table 57.1. In the series with the longest follow-up, Khan et al. described only 14 patients with greater than 5 years of follow-up, showing a disease-free survival (DFS) of 50%, a cancer-specific survival (CSS) rate of 75%, and overall survival (OS) rate of 64% [19]. Lymph node density which is defined as the number of positive lymph nodes divided by total lymph node count had an effect on DFS, cancer-specific survival, and overall survival. Patients who had lymph node density of 1–10% had 34% DFS, 49% CSS and 31% OS. With lymph node density greater than 10%, patients had reduced survival rates of 30%, 30% and 20%, respectively [5]. In patients with positive lymph nodes at the time of pelvic lymph node dissection, the median time to recurrence was 10 months after surgery [20]. Raza et al. described that for 99 patients with follow-up greater than 5 years, pathologic stage and lymph node positivity were independent predictors of DFS, CSS, and OS, whereas positive margin status and the Charleston comorbidity index predicted worse LS and CSS [21].

Functional Outcomes

Continence

Continence outcomes are under reported to some degree as the definition of continence varies widely among studies [5]. Furthermore, only three of the known published robotic series have used a specific definition of continence as 0 or 1 safety pad per day. The type of urinary diversion also has a distinct role in continence reporting. At

present, there are only nine reports with less than 200 patients that evaluate continence after orthotopic bladder substitution. One early study with a 3.5 month follow-up reported a continence rate of 86% [22]. In more recently published series, the follow-up for continence outcomes range from 6 to 25 months. Daytime continence rates are reported from 48% to 100%, whereas and nighttime continence rates are reported to be 11–100% [5]. Nerve sparing is also important when assessing continence. Daytime continence was 83% in patients without nerve sparing and 94% in patients with nerve sparing; for nighttime continence, it was 59% versus 75% in the same respective groups [23].

Potency Recovery

Potency data within the robotic literature is limited by inadequate documentation of both follow-up and nerve sparing technique. The distinct definition of potency is debated. Furthermore, it is unclear whether or not phosphodiesterase type 5 inhibitor (PDE5-i) treatment to achieve erectile function suitable for penetration defines post-surgical complication. Yuh et al. reported on seven studies, but only three actually defined potency. Sample size for most studies is less than 70 patients [5]. Data recording using the Erectile Function (IIEF) score is imperative in order to standardize the return of function after radical cystectomy. Five studies used the IIEF. In two of the studies, the IIEF was greater than 18 in only one patient from the entire series [24, 25]. Whether the intracorporeal or extracorporeal approach to neobladder formation plays a role in potency is uncertain, but the Karolinska Institute along with several other series showed that 63% of men were potent with or without PDE5-i treatment after 12 months following intracorporeal diversion [26]. In a recent study from 2016, the mean preoperative IIEF score was 24.4 [27]. 77.5% patients returned to normal erectile function (IIEF > 17) within 3 months while 72.5% patients returned to their preoperative IIEF score within 12 months [26, 27].

Hospital Stay, Operative Times and Bowel Function

Overall mean operative times have been longer for robotic cystectomy with urinary diversion (78.3 min for ORC versus 107.9 min for RARC). This is directly related to surgeon experience and number of procedures [28]. Length of hospital stay (LOS) has largely been debated as a measure of benefit from robotic surgery compared to open. Data can be difficult to interpret because it is usually a reflection of institutional policy versus patient morbidity. The average hospital stay was 1.2 days shorter after RARC [15]. In 23 studies which examined the difference between open and robotic radical cystectomy, in-hospital stay was decreased in robotic series [28]. In many of these series, the mean time to bowel function was not reported and therefore was not used as a surrogate to length of hospital stay. Bochner et al. found that the length of stay was 8 days for both open and robotic cystectomy, showing no significant difference [29].

Bowel function can be measured in mean time to flatus as well as mean time to bowel movement. Three different studies which evaluated RARC compared with ORC showed time to flatus 2.1 days vs 2.9 days [30]; 2.3 days vs 3.2 days [31]; and 4.3 days vs 5.9 days [32]. Time to bowel movement was demonstrated in RARC compared with ORC 2.8 days vs. 3.8 days [30]; 3.2 days vs 4.3 days [31]; and 2.3 days for both [33].

Complications

Invasive urothelial carcinoma requires radical cystectomy which has the potential to result in significant patient morbidity. The multi-institutional database from IRCC (Table 57.2) which includes 939 patients reports complication rates of 41% at 30 days and 48% at 90 days [9]. Twenty-nine percent of the complications were Clavien grade 1–2 and 19% were grade 3–5. Bochner et al. had a recent prospective randomized controlled trial that

Table 57.2 Summary of robotic cystectomy complication[a]

	All (%)	Extracorporeal (%)	Intracorporeal (%)	p Value
Complication category				
Gastrointestinal	161 (20)	142 (23)	19 (10)	<0.001
Infection	136 (17)	114 (18)	22 (12)	0.035
Genitourinary	77 (9)	58 (9)	19 (10)	0.776
General	30 (4)	27 (4)	3 (2)	0.119
Wound/skin	42 (5)	35 (6)	7 (4)	0.353
Hematologic/vascular	75 (9)	56 (9)	19 (10)	0.667
Pulmonary	24 (3)	21 (3)	3 (2)	0.324
Metabolic	8 (1)	8 (1)	0	0.209
Endocrine	3 (0.4)	2 (0.3)	1 (0.5)	0.546
Head/Neck	4 (0.5)	3 (0.5)	1 (0.5)	1
Post-op outcomes				
LOS, median	9	8	9	0.086
30-day complications	336 (41)	269 (43)	67 (35)	0.07
90-day complications	387 (47)	309 (49)	78 (41)	0.055
30-day readmission	105 (13)	95 (15)	10 (5)	<0.001
90-day readmission	143 (18)	121 (19)	22 (12)	0.016

[a]Adapted from Ahmed et al. [39]

enrolled patient to ORC versus RARC with extracorporeal diversion. In 118 randomized patients, 90-day complication rates were 66% for ORC and 62% for RARC (p = 0.7). The authors documented that in RARC, EBL was decreased, operative time was longer, and LOS was unchanged with similar pathologic outcomes such as seen in ORC. The study failed to demonstrate the benefit of robotic assistance [29].

Mortality

Mortality rates have varied among studies. Styn et al. demonstrated that 90-day mortality was 3% for ORC and 0% for RARC [34]. In other study of over 175 patients, the perioperative (30 days) mortality was reported at 2.8% for RARC with extracorporeal diversion [35]. Open series have reported mortality from 0.3% to 3.9% [36]. The Pasadena Consensus Panel found over 6 comparative studies that in 248 RARC cases there were two deaths compared to nine deaths in 313 ORC cases (p = 0.23) [15]. While mortality rates were comparable, there was substantial difference among both low-grade and high-grade complications.

Procedural

Procedural complications include urethral or ureteral anastomotic leak, wound breakdown, or intraoperative injury. Intraoperative complications can range from vascular injuries to bowel injuries. The Pasadena Consensus Panel found no statistically significant difference between RARC and ORC. Using four comparative studies, two complications were recorded in 116 ORC cases and six complications documented over 235 RARC cases (p = 0.65) [28]; 10.3% of the complications were procedural in the City of Hope series reported by Yuh et al. While urethral anastomotic leak was mostly a minor complication (Clavien grade 1–2), ureteral leak was largely considered a major complication requiring a secondary procedure [37]. When comparing procedural complications by diversion type, 11.9% were during ileal conduit (IC), 11.8% during Indiana Pouch (IP), and 29.7% during neobladder [38].

Genitourinary

The multi-institutional data from the IRSS found that 17% of the complications were genitourinary [9]. Yuh et al. reported that of all complications, 6.7% were urinary tract obstruction, renal failure, and urinary fistula [37]. In comparing diversion types, IC, IP and neobladder complications were 13.4%, 17.6% and 9.9% respectively [38]. Genitourinary complications ranged from 9% of all complications to 9% in the extracorporeal group and 10% in the intracorporeal group which was not statistically significant (see Table 57.2) [39]. The overall ureteral anastomotic stricture rate was 6.2% with no difference noted among diversion types. A urethral anastomotic leak developed in 25.3% with neobladder [38].

Gastrointestinal

Gastrointestinal complications have often been credited to poor bowel preparation. Recent data has shown that bowel prep prior to surgery can actually increase complications. One study showed bowel preparation was associated with *Clostridium difficile* infection [40]. The Cochrane review plus another randomized trial showed no difference in outcomes when there was no bowel preparation including ileus, sepsis, or wound infections [41, 42]. Yuh et al. documented 14% of the complications in the series were gastrointestinal [37]. When compared by diversion types, IC had 20.9% gastrointestinal complications compared with that of 39.2% for IP and 28.6% neobladder [38]. Bowel injury, bowel leak, and bowel obstruction were the most common reasons to return to the operating room within 30 days [9]. Ileus was defined as the inability to tolerate oral intake by postoperative day 10, need for a nasogastric tube, or start of parenteral nutrition. There was 23% incidence of ileus or small bowel obstruction in the City of Hope series [37]. This was comparable to the ORC series [43, 44].

Vascular

Blood loss and transfusion rates have been compared between ORC and RARC. Of 14 nonrandomized studies, (see Table 57.3) there was higher incidence of transfusion with 428 events among 775 cases for ORC and 126 events among 654 cases of RARC. Additionally, blood loss was less in RARC than ORC, as the weighted mean difference (WMD) was 568 ml ($p < 0.00001$) [28]. Yuh et al. reported that of 196 patients 43.9% required blood transfusions, but those who had transfusions had lower preoperative hematocrits and higher pathologic stage. Transfusions were associated with a significantly length of stay (9 days compared 11.5 days $p < 0.01$) [37]. Within that same group, 8.4% of the patients had a vascular complication including deep vein thrombosis or lymphocele; seven events of the 40 vascular complications were Clavien grade 3–5 [37]. A study comparing 768 patients with extracorporeal and 167 with intracorporeal diversions showed 9% and 10% experienced vascular complications respectively [39]. In a series with greater than 20 RARCs, reports of vascular injuries were rare, and Lymphocele rates were 0–9% [5]. The incidence of deep vein thrombosis (DVT) after cystectomy was estimated at 5% to 8% [38, 45, 46],however the Pasadena consensus panel noted that because of potentially delayed presentation of DVT, the true incidence is underestimated [15].

Infections

Urinary tract infection (UTI) is by far the common complication and cause for hospital readmission within 90 days [9], accounting for 16.2% of complications in one RARC series [37] and 23% of the complications from the IRSS multi-institutional study [9]. By diversion type, patients with Indiana pouch had a 41.2% infection rate, 16.4% of IC, and 25.3% of neobladder cases, of which most were UTIs. Patients with IP experienced more UTIs than those with IC and neo-

Table 57.3 Selected series of robotic cystectomy complication

	Diversion (type)	Author	Patient (n)	OR (min)	Blood loss (mL)	Transfusion rate (%)	Hospital stay (days)	Overall complication rate (%)	Clavien I–II (%)	Clavien III–IV (%)
Extracorporeal	Conduit	Smith 2012 [12]	227	330	256	n/a	5	30	23	7
		Kader 2013 [48]	100	451	423	15	7.8	35	24	10
		Nazmy 2014 [38]	67	360	300	24	9.5	n/a	n/a	n/a
		Knox –2013 [32]	58	468	276	5	6.3	43	17	26
	Neobladder	Xylinas 2013 [35]	175	360	400	17	7	42	30	12
		Nazmy 2014 [38]	91	424	400	15	9	n/a	n/a	n/a
	Continent cutaneous	Nazmy 2014 [38]	51	480	400	26	10	n/a	n/a	n/a
Intracorporeal	Conduit	Azzouni 2012 [47]	100	352	300	10	9	79	66	15
	Neobladder	Collins 2013 [51]	113	390	400	n/a	n/a	65	16	33
		Desai 2014 [50]	132	456	430	2	11	47	32	15
		Schwentner 2015	62	477	385	n/a	16.7	50	24	26

bladder (**see** Table 57.3). On multivariate analysis IP urinary diversion was linked with an increased chance of UTI (OR 7.30, p = 0.0009) [38]. Patients with extracorporeal vs. intracorporeal diversion showed 18% and 12% infectious complication rates respectively (p = 0.035) [39]. Wound infection and pelvic abscess were associated as early (<30 days) complications with rate of 6–10% and 2–4%, respectively [35, 37].

Metabolic

Dehydration, electrolyte imbalance, and acidosis are the most common independent of urinary diversion type. Nazmy et al. showed that patients with IC, IP, and neobladder had metabolic complications of 14.9%, 15.7%, and 15.4%, respectively, showing no statistical difference [38]. Only 1% of complications were documented as metabolic in the IRCC analysis [9]. Dehydration defined as need for intravenous bolus fluids was the most common minor metabolic complication [37].

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Robot-Assisted Partial Cystectomy

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Abstract

Radical cystectomy is the standard of care for localized muscle-invasive bladder cancer as well as refractory high grade, nonmuscle invasive urothelial cell carcinoma or carcinoma in situ. However, it is a highly morbid procedure that adversely impacts both urinary and sexual functions. To minimize these side effects without compromising oncological efficacy, bladder sparing strategies such as trimodal therapy and partial cystectomy have evolved. In carefully selected patients, many contemporary series have reported comparable oncologic outcomes and decreased morbidity compared to radical cystectomy. In this chapter, we present the indications and techniques of robot-assisted laparoscopic partial cystectomy for bladder cancer.

Keywords

Muscle invasive bladder cancer · Partial cystectomy · Radical cystectomy · Bladder sparing · Robot-assisted

Introduction

According to American Cancer Society statistics, there will be an estimated 76,960 newly diagnosed cases and 16,390 deaths attributed to bladder cancer in 2016 [1]. Approximately 15–30% of all bladder cancer patients are found to have muscle invasive disease. Radical cystectomy with pelvic lymph node dissection remains the gold standard in the treatment of these patients, as well as in patients with high risk nonmuscle invasive disease [2]. However, the 30-day mortality rates following radical cystectomy range from 1–3%, and up to 75% of patients will have perioperative complications following surgery [3, 4]. To minimize the morbidity of radical cystectomy, bladder sparing strategies offer an appealing alternative in appropriately selected patients. Such therapies include trimodal therapy involving an aggressive transurethral resection (TUR) followed by combination chemo- and radiotherapy, radical TUR or partial cystectomy with or without chemotherapy [5, 6].

Partial cystectomy offers the advantage of a less morbid procedure without the need for uri-

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nary diversion, thus preserving urinary and sexual function. It also allows for complete pathologic staging of the primary tumor and pelvic lymph nodes. In carefully selected patients with muscle invasive tumors, partial cystectomy can achieve comparable survival outcomes to radical cystectomy. Additionally, partial cystectomy can be curative in certain tumor types including squamous cell carcinoma and adenocarcinoma.

In a retrospective series from Memorial Sloan Kettering Cancer Center [7] of 58 patients undergoing partial cystectomy for urothelial cell carcinoma, the overall predicted 5-year survival rate was 69%. With a mean follow up of 33 months, 67% were disease-free with preserved bladders. Risk factors for superficial recurrence on univariate analysis were multifocality and the presence of carcinoma in situ (CIS). Whereas predictors of advanced disease recurrence on multivariate analysis were concomitant CIS and lymph node involvement. In a series from MD Anderson Cancer Center [8], 37 patients who underwent partial cystectomy for muscle invasive urothelial carcinoma were reviewed. The 5-year overall and recurrence free survival rates were 67% and 39%, respectively. On univariate and multivariate analyses, higher pathologic stage was the only variable associated with shorter overall recurrence free survival, but not associated with overall survival. Collectively, in the appropriate patient, these findings establish partial cystectomy as a viable alternative to radical cystectomy for muscle invasive disease.

Indications

Proper patient selection is the single most important factor in performing an efficacious partial cystectomy. The indications for partial cystectomy in the setting of muscle invasive disease are patients with a solitary tumor situated away from the bladder base, with negative random bladder biopsies, and a resection amenable to obtaining negative margins while maintaining an adequate functional bladder capacity. It may be considered after a focal recurrence at the site of the prior tumor, however patients with a prior history of urothelial cell carcinoma are at an increased for disease recurrence and progression [8, 9]. Large tumor size has been associated with increased risk of recurrence and progression [8, 10], likely due to the difficulty in obtaining a negative margin. Partial cystectomy may also be considered for tumors that cannot be completely resected via transurethral resection due to location or size. Urothelial tumors with a diverticulum and urachal adenocarcinoma represent two distinct scenarios where partial cystectomy may be indicated. When properly applying these criteria, partial cystectomy remains an option in approximately 5–10% of patients with muscle invasive disease.

Preoperative Considerations

The primary objective of a preoperative evaluation is to ensure proper bladder tumor staging. All patients should undergo a complete staging workup consisting of the following: (1) a bimanual examination to assess for bladder mobility and the potential presence of clinical T3 disease; (2) random bladder biopsies to exclude multifocal disease and/or the presence of CIS, in addition to prostatic urethral biopsies in the male patient; and (3) a metastatic workup that includes a chest X-ray and cross-sectional imaging of the abdomen and pelvis.

Surgical Technique

The objectives of robot-assisted laparoscopic partial cystectomy are the same as for the open technique, consisting of the following: (1) complete mobilization of the bladder; (2) resection of the entire tumor bed with negative margins; (3) avoidance of tumor spillage; and (4) watertight bladder closure in two layers.

After prepping and positioning the patient in low lithotomy position, initial endoscopic evaluation of the bladder is performed. For complicated cases, circumferential delineation of the tumor can be performed with a Collins' knife initially to allow for precise tumor delineation

(Cook Medical, Bloomington, IN), however this is rarely necessary. A flexible cystoscope can be left in the patient's bladder, which allows for a continuous image of the mucosa surface of the bladder using the tile pro feature on the da Vinci Si system™ (Intuitive Surgical, Sunnyvale, CA).

Next, the steps of port placement, establishment of pneumo-peritoneum, and bladder takedown are as would be performed during a standard robot-assisted laparoscopic radical cystectomy case and are described in detail in other chapters of this book. One important point that should be emphasized is that the bladder should be widely mobilized anteriorly and laterally to allow for at least a 2 cm resection margin and closure without tension. This requires division of obliterated umbilical ligaments and the urachus to completely free the bladder dome of all of its attachments. Once completely mobilized, the bladder is expanded with fluid to help identify the area of the tumor. The fat that lies directly over the tumor should be removed and sent with the specimen.

With endoscopic guidance from a flexible cystoscope and the bladder fully distended, robot-assisted laparoscopic circumscription of the tumor is performed with cautery marking with at least a 2 cm margin around the tumor (Fig. 58.1). Trans-illumination of the affected portion of the bladder by the cystoscope light facilitates this and the light can easily be seen when the robotic light source is decreased in intensity. Cautery is used to demarcate the area of resection using the cystoscope light as a guide. Initially cautery is superficial until four 2–0 vicryl stay sutures have been placed lateral to the proposed resection area (Fig. 58.2).

The bladder is then drained and if possible (e.g., favorable anatomy, lobulated bladder, or bladder diverticulum), a 60-mm Echelon Endopath stapler (Ethicon, Cincinnati, OH) is brought in through either the left or right 12 mm ports and used to divide the bladder at the proposed lines of resection (Fig. 58.3). If not amenable to the use of a stapler, scissors are used instead to cut sharply along the marked lines of resection with care not to spill bladder fluid/urine into the peritoneum. Pulling up on the stay sutures will facilitate the resection and decrease the risk of fluid spillage into the peritoneal cavity. Multiple specimens are also sent for intraoperative frozen section analysis to ensure negative margins have been achieved. Once negative margins have been confirmed, the specimen is then placed in an Endo-catch bag (Medtronic Minimally Invasive Therapies, New Haven, CT) and removed through an extended port incision at the end of the case.

If the stapler has been used, the remaining suture line on the native bladder is excised while tension is maintained on the stay sutures to prevent any urine spillage and contamination of the

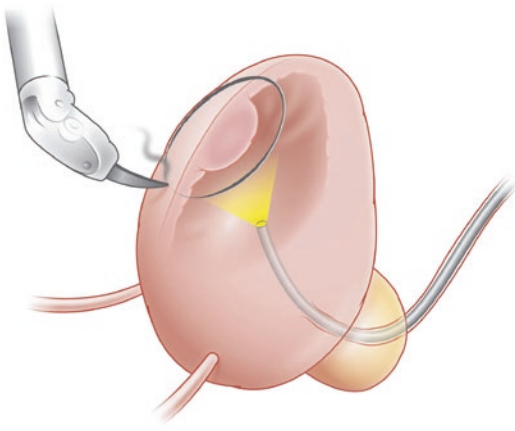

Fig. 58.1 Laparoscopic circumscription of the tumor under endoscopic guidance

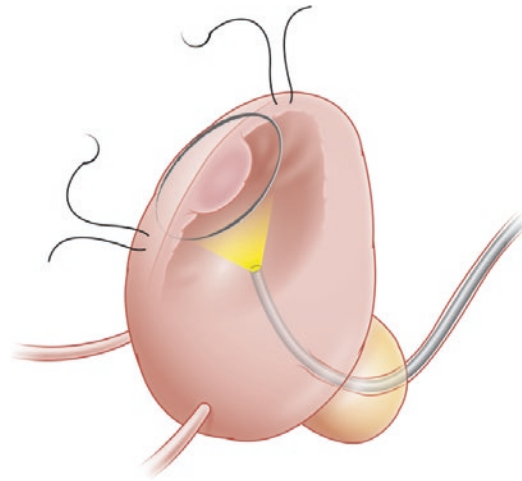

Fig. 58.2 Placement of stay sutures

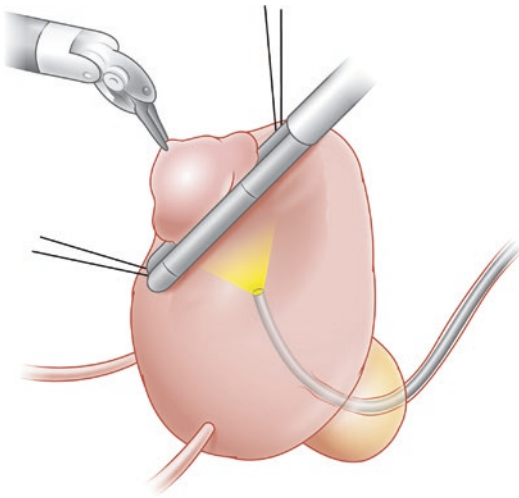

Fig. 58.3 Laparoscopic view of bladder resection using Endo-GIA staplers

peritoneal cavity. This maneuver removes the staples in the suture line that could potentially serve as a nidus for stone formation if left in place. The bladder is emptied completely prior to the resection. Once resected, it is sent for histopathological analysis as the final margin. The bladder is then closed in two watertight layers in a running fashion using 3–0 monocryl/vicryl for the mucosal layer and 2–0 monocryl/vicryl for the outer layer.

A foley catheter is then placed. The bladder is tested for a leak by instilling 250 mL of normal saline while being monitored laparoscopically. A JP drain is also placed via the 5 mm port following assurance that the bladder closure is watertight.

Finally, a bilateral pelvic lymph node dissection should be performed as described in another chapter of this book.

Postoperative Management

The nasogastric tube is removed immediately postoperatively. Patients are allowed then to chew gum and have ice chips, and started on a clear liquid diet on postoperative day one. Intravenous antibiotic prophylaxis is maintained for the first 24 h after surgery while DVT prophylaxis with subcutaneous heparin is continued after surgery and for the duration of the hospitalization.

Additionally, patients are encouraged to ambulate starting on postoperative day one. Pain control is initially achieved with ketorolac and intravenous Tylenol to decrease narcotic use, and quickly converted to oral medications once the patient is tolerating a diet. JP drain is typically removed after output is minimal and the fluid creatinine level is consistent with serum creatinine. The urethral foley catheter is removed in 7–10 days after a cystogram shows no urinary extravasation.

Long-term follow-up with cystoscopy and cytology is crucial as bladder recurrences have been described more than 10 years following partial cystectomy [8]. Cystoscopic evaluation with cytology should be performed every 3 months for the first two years, and then intervals consistent with bladder cancer patients who have been managed endoscopically.

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59 Robot-Assisted Radical Cystectomy Versus Open Radical Cystectomy

Vivek Venkatramani and Dipen J. Parekh

Abstract

Radical cystectomy is suited to a minimally invasive approach, and robotic surgery holds the potential for improving perioperative morbidity compared with open surgery, without a compromise of oncological efficacy. Recent meta-analyses have shown that minimally invasive cystectomy is associated with lower morbidity, shorter length of stay, reduced blood loss and transfusion rates, less post-operative ileus and a reduced need for analgesics. The short and medium term oncological efficacy of robotic cystectomy has been shown to be equivalent to open surgery. However, larger studies with longer follow-up are needed in order to obtain higher levels of evidence.

Keywords

Radical cystectomy · Minimally invasive · Robotic surgery · Complications · Surgical margins · Lymphadenectomy · Oncological outcomes · Quality of life · Functional outcomes · Recurrence patterns

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Introduction

An estimated 72,570 new cases of bladder cancer (BCa) were diagnosed in 2013 and 15,210 patients died from the disease. Open radical cystectomy (ORC) remains the current standard of care for muscle invasive bladder cancer (MIBC) and for selected cases with high-grade non-muscle invasive disease (NMIBC) [1]. It has proven efficacy vis-à-vis local control and long-term cancer specific survival, however it can be associated with perioperative complication rates as high as 25–62% [2].

Minimally invasive approaches using the surgical robot have had widespread adoption in urologic oncology. Studies have shown that radical cystectomy is suited to a minimally invasive approach. Recent meta-analyses have shown that minimally invasive cystectomy is associated with lower morbidity, shorter length of stay (LOS), reduced blood loss and transfusion rates, less post-operative ileus and a reduced need for analgesics [3–5]. The short- and medium-term oncological efficacy of minimally invasive cystectomy has been shown to be equivalent to ORC [4, 6]. Recent small studies have also shown equivalent longer term survival outcomes between open and robotic cystectomy [7, 8]. However there are only three small randomized trials between ORC and robot-assisted radical cystectomy (RARC) till date, and larger studies are needed to confirm these findings [9–11].

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Laparoscopic cystectomy was the initial minimally invasive approach used and was developed in order to reduce the complications of ORC [12–14]. However, laparoscopic cystectomy is a complicated procedure, has an extremely steep learning curve and was never widely adopted. With the development of the robotic system and its attendant advantages over traditional laparoscopy, a true minimally invasive alternative to ORC has emerged. RARC has been performed for more than a decade with several technical modifications [15–17].

Brief Overview of the Procedure

RARC is performed in the steep Trendelenburg position taking care to pad all pressure points. The camera is placed 2–3 cm above the umbilicus. Three robotic ports are placed, two in the right lower abdomen and one on the left. Two 12 mm assistant ports are placed lateral to the camera port on each side. Generally, monopolar scissors and Prograsp forceps are placed on the right and the bipolar Maryland forceps on the left. Initially the ureters are carefully dissected and divided as distally as possible. The posterior peritoneum between the bladder and rectum is incised laterally up to the ureteral stumps. Denonvilliers fascia is pierced and the dissection is carried to the apex of the prostate. The vas is divided at the internal ring and mobilized to the prostate. The bladder pedicles are then isolated and divided with a vascular stapler. Following this the bladder is dropped. The anterior surface of the prostate is exposed similar to radical prostatectomy and the prostatic pedicles divided. The apical dissection is completed, the dorsal venous complex is over sewn and the urethra divided to free the specimen. Lymphadenectomy is then performed and finally a window can be created in the sigmoid mesentery to pass the left ureter to the right side. Subsequent steps depend on the diversion and whether it is performed intra- or extracorporeal.

There are several proposed advantages of the robotic approach for RC. Pneumoperitoneum assists in reducing blood loss. Insensible loss of fluid and fluid shifts are avoided as the abdomen remains closed. Cosmetically, patients are more satisfied with the incisions and the reduced use of major retraction results in reduced postoperative pain and early ambulation. Bowel handling is a bare minimum allowing early bowel recovery. All these factors combine to potentially allow faster discharge from the hospital.

Reviewing the literature, it becomes apparent that as any novel technique emerges, favorable patients are selected to prove the safety and efficacy of the procedure. RARC is no different and early series tended to select patients with less advanced, non-bulky disease. Presence of large lymph nodes, locally advanced disease and morbid obesity were traditionally considered contraindications to any RARC. Extensive intra-abdominal surgery or past radiation increase the risk of bowel injury and other complications. The steep Trendelenburg position required for RARC may not be possible in patients with cardio-respiratory ailments. However, with increasing experience surgeons are beginning to attempt more complex cases using the robotic approach.

Comparison Between RARC and ORC

Minimally invasive cystectomy was developed with the promise of reducing the complications of traditional ORC without compromising oncologic principles. We will compare each of these domains between RARC and ORC. A summary of the comparison between RARC and ORC can be found in Table 59.1.

Table 59.1 Summary of comparison of outcomes between ORC and RARC

Category	Outcome	Summary of comparison
Perioperative outcomes	Estimated blood loss and transfusion rates	Prospective and retrospective studies show a reduction in blood loss and transfusion rates with RARC
	OR time	Most studies show longer OR times with RARC which tend to be overcome after crossing the learning curve Intracorporeal diversions are likely to have an impact
	Analgesic use	Small studies show reduction in opiate requirement. Needs further elucidation
	Recovery of bowel function	Possible improvement with reduced need of TPN in RARC. Needs further studies
	Length of stay	Conflicting evidence at present
	Complication rates	Population based studies and meta-analyses show a trend to lower complications in RARC, however all the prospective trials so far have shown no difference
Pathological outcomes	Surgical margins	Meta-analyses show no significant difference. However, possibility of increasing positive margins in RARC patients with locally advanced disease needs further study
	Lymphadenectomy	RARC has shown equivalence to ORC as long as traditional templates are followed
Oncological outcomes	Survival outcomes	Short- and intermediate-term outcomes demonstrate equivalence between ORC and RARC. More mature data are needed to draw conclusions on long term survival outcomes
	Patterns of recurrence	Possible increase in extrapelvic LN recurrences and peritoneal carcinomatosis needs further study
Others	Functional outcomes	Data on continence and potency rates after RARC is insufficient to draw any conclusions at present
	Quality of life (QOL)	No significant difference between RARC and ORC based on available data
	Cost	Procedural costs higher with RARC

Comparison of Perioperative Outcomes Between RARC and ORC

Estimated Blood Loss (EBL) and Transfusion Rates

Many studies have shown reduced blood loss and transfusion rates in RARC [18]. Parekh et al. in their pilot prospective randomized trial showed significantly lower EBL in the RARC arm (400 ml vs 800 ml, p = 0.003) with a trend towards reduced transfusion rates (p = 0.26) [9]. Similar results with respect to EBL were obtained in the other randomized trials by Nix et al. and Bochner et al. [10, 11] In an analysis of a large group of patients from the United States National Inpatient Sample, Yu et al also showed a trend toward lower transfusion rates in patients undergoing RARC (p = 0.075) [19]. Cumulative analyses and systematic reviews have confirmed these findings [3–5]. Possible reasons contributing to this include the magnified 3-dimensional view of the robot allowing better identification and control of vascular structures, along with the effect of pneumoperitoneum [4].

Operating Room (OR) Time

In general, OR times are increased in RARC versus ORC across many studies and meta-analyses [18, 20]. Hayn et al. used data from International

Robotic Cystectomy Consortium (IRCC) to demonstrate that about 20 cases are required to overcome the learning curve, similar to what had been demonstrated by Pruthi et al in an earlier study [21, 22]. Once the learning curve is crossed the OR time becomes similar. The randomized trials by Nix and Bochner demonstrated a longer operative time for RARC, however the trial by Parekh demonstrated equivalent OR times demonstrating that robotic cystectomy can be done efficiently [9–11]. The vast majority of studies to date involve extracorporeal diversions. The potentially increasing use of intracorporeal diversions will be a significant factor in comparing the duration of surgery, especially for intracorporeal neobladder [3].

Analgesic Use

Guru et al. demonstrated reduced opiate use among patients undergoing RARC in a small retrospective study [23]. Nix et al. demonstrated significantly less use of analgesia (measured in morphine equivalents) in patients undergoing RARC versus ORC (89 mg vs 147 mg, $p = 0.019$) [11]. However other studies have not reported on this outcome and larger studies are required to confirm this finding.

Post-operative Ileus and Recovery of Bowel Function

It is assumed that the minimally invasive approach is associated with reduced bowel handling, desiccation and bowel fluid shifts, which together with earlier ambulation and reduced narcotic use could contribute to a quicker recovery of bowel function [11, 18]. Results of studies comparing RARC and ORC seem to bear out this hypothesis. In the randomized trial by Nix et al., RARC was associated with a shorter median time for return of flatus (2.3 days versus 3.2 days, $p = 0.0013$) and passing a bowel movement (3.2 days versus 4.3 days, $p = 0.0008$) [11]. Parekh et al. also found a quicker time to return to oral diet in the RARC arm, however this was not statistically significant [9]. Two large database studies further showed a significant reduction in the use of parenteral nutrition in patients undergoing RARC versus ORC [19, 24].

Length of Hospital Stay (LOS)

The difference in LOS between RARC and ORC shows conflicting evidence. Smaller retrospective studies and overall meta-analyses show a reduced LOS for the RARC arm [3, 5]. A large study of the Premier Perspective Database, an all-payer hospital discharge database, showed a significantly reduced LOS for RARC (10.2 days versus 11.8 days, $p = 0.008$) [24]. Conversely a study from the National Inpatient Sample failed to show any difference in LOS [19]. In the randomized trial by Parekh et al., there was no significant difference in the median LOS, however they found a significantly lower percentage of patients in the RARC arm had an LOS > 5 days [9]. Other randomized trials also failed to show any significant difference in LOS [10, 11].

Clearly, larger prospective studies and a higher quality of evidence are required to definitively reach a conclusion regarding LOS.

Complication Rates

Novara et al. performed a systematic review and cumulative analysis for complication rates following RARC. The overall complication rate differed by diversion type but generally the complication rates for RARC ranged from 20% to 70%. The cumulative analysis was significantly in favor of RARC for any grade of complication at 90 days and Clavien grade 3 complications at 90 days. In contrast, complications at 30 days, high-grade complications at 90 days and mortality at both 30 and 90 days were similar between both arms [3]. The meta-analysis by Xia et al. observed significantly lower overall and major complication rates at both 30 and 90 days in patients undergoing RARC, but no difference in mortality [5]. In a meta-analysis by Ishii et al. there was a significant reduction in

major complications in the RARC arm but no difference in overall complication rate, minor complications or mortality [25]. The study on the Nationwide Inpatient Sample by Yu et al demonstrated a lower rate of complications in the RARC arm (49% versus 64%) as well as perioperative mortality (0% versus 2.5%) [19]. The study using the Premier Perspective Database demonstrated reduced odds for minor complications (primarily due to a reduced need for blood transfusions and parenteral nutrition) but no difference among major complications or mortality [24]. However, these results need to be treated with caution as none of the three randomized trials have demonstrated any difference in the complication rates between RARC and ORC [9–11]. The reasons for these differences are unclear however they could be related to the limited accuracy of population-based studies and probable difference in baseline characteristics of patients in the two arms. The lack of high-quality data at present prevents us from drawing concrete conclusions until better randomized studies are available.

Comparison of Pathological Outcomes Between RARC and ORC

Surgical Margins

Positive surgical margins (PSM) are rare following RC but have been associated with lower recurrence free (RFS) and cancer specific survival (CSS) [18]. None of the randomized trials showed any difference in the rate of positive margins between RARC and ORC [9–11]. Available meta-analyses have shown similar results [5, 20, 26]. It is possible that selection bias plays a role in these results as the meta-analysis by Tang et al. showed that there was a trend to more organ confined disease in patients undergoing RARC versus ORC [26]. This is especially relevant as a large study from the IRCC group reported a positive margin rate of 1.5% for <pT2, 8.8% for pT3 and 39% for pT4 [27]. A possible mechanism for this is the difficulty in treating bulkier and locally advanced tumors with RARC because of the lack of haptic feedback. A recent cumulative analysis by Yuh et al. showed no significant difference in the margin rate between ORC and RARC (7% versus 5% respectively), but the margin rate for RARC varied with the pathological stage, ranging from 1–1.5% for pT2 disease, to 0–25% for patients with disease pT3 and higher [6]. In contrast, the trial by Parekh et al demonstrated no difference in positive margins despite having >50% cases that were pT3 and higher [9]. A high variability in the margin positive rate exists in RARC literature (0–26%) and could point to significant heterogeneity in tumor and patient characteristics, along with surgical experience [6]. Overall, this data suggests that caution may need to be exercised when performing RARC for more advanced disease and larger trials are needed to determine whether any difference exists between RARC and ORC as regards margin status.

Studies of RARC have also shown no difference in surgical margin status with increasing case volume. This could be due to the small number of events, the high learning curve for RARC of the fact that with increasing experience surgeons may tackle more locally advanced disease robotically which could predispose to more positive margins [6].

Lymphadenectomy

Initial concerns regarding RARC included the ability to perform a complete lymph node (LN) dissection using this approach as the older robotic systems lacked the flexibility required. Studies have proven that present RARC can achieve equivalent LN yields when compared to ORC. Nearly all studies of RARC report nodal yields >15 for patients undergoing extended LN dissection. The randomized trial performed by Nix et al. was powered based on non-inferiority of LN yield as the primary outcome, and showed no difference between the two approaches [11]. In the trial by Parekh et al the median number of LN was lower in RARC arm however this was not statistically significant. They attributed to this difference to the fact that during RARC, LN are not submitted as discrete anatomical packets but rather as complete right or left pelvic LN, a fact

that is known to affect LN yields [9]. Bochner et al. also demonstrated no difference in LN yield in their trial after comparing both standard and extended dissections [10]. Two meta-analyses showed increased LN count in patients undergoing RARC versus ORC indicating that RARC can certainly mirror ORC as long as standard dissection templates are followed [5, 26].

In a study analyzing data from the IRCC, Hellenthal showed a median of 17 LN removed and demonstrated that lymphadenectomy was more likely to be performed by surgeons with increasing experience in RARC (>20cases) [27]. However, studies have not shown an increase in LN yield with increasing case number [6].

Comparison of Oncological Outcomes Between RARC and ORC

Oncological control is assessed using cancer specific survival (CSS), disease free survival (DFS) and recurrence or progression rates, i.e., recurrence free survival (RFS) and progression free survival (PFS). This requires a long-term follow-up of a large group of patients. Such data is clear for ORC, but RARC, being a relatively new procedure, lacks mature long term data from large population-based cohorts [6, 18]. Recently studies with 5- and 10-year survival outcomes have become available but these include institutions early in their learning curves and have an inherent selection bias in patients being selected for the robotic technique. In addition, data remains limited for assessing patterns of recurrence, predictors of survival and the role of adjuvant treatments [6].

Survival Outcomes

In large open series, 10-year CSS and OS rates of 60–67% and 40–45% are traditionally quoted and these remain the standard against which RARC is compared [18]. Several series reported intermediate survival data for RARC, but only a handful report a mean follow-up >36 months. In these studies, DFS was 67–76% and 53–74% respectively, CSS was 68–83% and 66–80% respectively, and overall survival (OS) was 61–80% and 39–66%, respectively, at 3 and 5 years [28–36]. In the series with the longest follow-up among these, a DFS of 50%, CSS of 75% and OS of 64% was demonstrated in 14 patients with >5-years of follow-up [28].

In a non-randomized comparison between ORC and RARC, Khan et al. showed a CSS of 69% in the ORC arm versus 79% in the RARC arm at a follow-up of 38 months [37]. Another series showed similar estimated 2-year DFS, CSS and OS but patients were not matched and the median follow-up was only 12 months [38]. In a retrospective European study of 155 patients from a high-volume center, Gandaglia et al. reported 5-year RFS, CSS and OS rates of 53.7%, 73.5%, and 65.2%, respectively. On multivariable analysis they found pathological stage and nodal status to be independent predictors of CSS and RFS [39]. The IRCC recently reported 5-year oncological data from 702 patients in 11 institutions with a median follow-up of 67 months. The 5-year RFS, CSS and OS were 67%, 75% and 50% respectively. Non-organ confined disease and PSM were associated with poorer survival outcomes on multivariable analysis. In their analysis, age predicted poorer CSS and OS while adjuvant chemotherapy and PSM were predictors of RFS. This study demonstrates oncological data comparable to ORC however, this remains a retrospective analysis lacking a comparison group [7]. Snow-Lisy et al. reported on long term oncological outcomes in a cohort of 121 patients undergoing RARC or laparoscopic RC from the Cleveland Clinic. The median follow-up was 5.5 years with 10-year actuarial OS, CSS and RFS rates of 35%, 63% and 54%, respectively. The positive margin rate was 6.6%. The OS and CSS were worse with increasing disease stage [8]. This demonstrates that it is possible to achieve similar outcomes to ORC, however it is clear that more mature data with a direct comparison between ORC and RARC are necessary.

Patterns of Recurrence

Local control of disease after RARC appears to be adequate with the majority of recurrence being extra-pelvic or distant [6]. A potentially concerning observation was raised by Nguyen et al. in a retrospective comparison of recurrences between ORC and RARC. The median time to recurrence, number and distribution of local recurrences and number of distant recurrence were not significantly different between the two arms. However, they noticed that extrapelvic LN recurrences (23% versus 15%) and peritoneal carcinomatosis (21% versus 8%) were more frequent in RARC. In addition, peritoneal carcinomatosis was the sole site of recurrence in >50% of the cases. They suggest that pneumoperitoneum and tumor spillage with urinary extravasation during RARC could contribute to this and advise further study of this phenomenon [40]. In an elegant animal study, Ost et al. described an inhibition of tumor necrosis alpha secondary to the use of carbon dioxide for pneumoperitoneum and suggest this as a possible mechanism for port sites metastases in urothelial carcinoma cases [41]. Contrary to this, Gandaglia et al. reported only 4% patients with peritoneal recurrence in their cohort and suggest adequate local control with RARC [39]. However, the possibility of unusual patterns of recurrence after RARC remains one that urologists need to keep in mind till larger studies are available.

Functional Outcomes, Quality of Life (QOL) and Cost

Functional Outcomes

Data on continence after RARC is extremely limited with <200 patients evaluated for continence after orthotopic neobladder. Recent series show 48–100% daytime continence rates and 11–100% nighttime continence at 6 months after RARC. They further show daytime continence rates at 12 months of 83–100% in men and 67% in women, and nighttime continence of 66–76% [6]. For the Indiana pouch, Torrey et al. reported 97% daytime and nighttime continence in a series of 34 patients at a mean follow-up of 20 months [42].

Potency data is similarly poorly described after RARC with few series providing a clear definition of potency. The sample size in these studies is extremely small making it difficult to draw any objective conclusions. In a Swedish series, 63% of men (n = 41) who underwent nerve-sparing RARC were potent at 12 months, while Canda et al. found IIEF scores of >18 in only one of 11 men who were preoperatively potent at 6 months from surgery [43, 44]. Nerve-sparing procedures are described in about 20–100% of men undergoing RARC across various series [6]. Functional outcomes are significantly influenced by patient selection, surgeon experience, methodology of reporting and definitions used, as well as the use of rehabilitation programs and inconsistencies in follow-up which make comparison among different series difficult. At present there exist no head-to-head comparisons between ORC and RARC regarding functional outcomes and this represents a large opportunity for future research.

Quality of Life

Radical cystectomy is well documented to be a life-changing operation with significant potential impact on QOL. However, QOL remains difficult to measure in this population due to patient heterogeneity and poor design of studies. As part of a pilot randomized trial between RARC and ORC, Messer et al. administered the Functional Assessment of Cancer Therapy—Vanderbilt Cystectomy Index questionnaire to these patients preoperatively, and then every 3 months following surgery for 1 year. They found no differences between the ORC and RARC arm, with a return to baseline QOL at 3 months post-operatively in both arms. There was a slightly higher physical well-being score in the RARC group at 6 months

which was not statistically significant [45]. A multicenter retrospective study was carried out by Aboumohamed et al. using the Bladder Cancer Index (BCI) and European Organizations for Research and Treatment of Cancer (EORTC) Body Image Scale (BIS). They found better sexual function in the ORC group with no significant difference between urinary, bowel and body image domains. The QOL outcomes were not different between the groups and were further not affected by the diversion type [46]. Based on the available data it seems that QOL is not significantly different between the two approaches.

Cost

With a need to control the ever burgeoning healthcare costs worldwide an analysis of the cost-effectiveness of any new technology is essential. In a small retrospective analysis of 20 cases, RARC was shown to have a higher cost of about $1640 in operating room (OR) fixed and variable costs, while ORC had higher hospital costs due to blood transfusion [47]. On the other hand a study by Martin et al. showed that RARC was 38% more cost efficient because of increased hospitalization in ORC. However, it was 16% more expensive when comparing direct OR costs, and also became more expensive if OR time exceeded 361 min, LOS exceeded 6.6 days or robotic OR supply costs exceeded $5853 [48]. In a large analysis from the NSQIP database, Yu et al found RARC to be $3797 more costly than ORC [19]. In the analysis of the Premier Perspective Database, Loew et al found RARC to have a $4326 higher adjusted 90-day median direct cost than ORC, with the significant contribution being from the increased cost of supplies ($2403). They further determined that despite RARC having a shorter LOS than ORC (10.2 days versus 11.8 days), there was no significant difference in room and board cost. The cost difference at high volume academic centers tended to be less pronounced suggesting that crossing the learning curve and implementing a streamlined postoperative care pathway can help mitigate some cost concerns. Furthermore, the economic impact of decreased convalescence and earlier return to work are difficult to measure. They performed further analysis which suggested that to make RARC cost-competitive with ORC a significant reduction in LOS or OR time are required, and the authors suggest that such complex robotic surgery be best centralized and performed only at high-volume centers [24].

Intracorporeal and Extracorporeal Urinary Diversion

The primary determinant of morbidity with any radical cystectomy is related to the urinary diversion. Further improvement in perioperative and functional outcomes with RARC could depend on the ability to refine the urinary diversion. At present the use of intracorporeal urinary diversion (ICUD) is predominantly restricted to a handful of academic centers and more than 95% of diversions are performed by the extracorporeal approach (ECUD) [49]. The evolution of ICUD is based on theoretical advantages of avoidance of a mini-laparotomy, reduced bowel handling with quicker return of bowel function and less intraoperative blood loss [50, 51]. Another possible advantage relates to the reduced mobilization of the ureters during ICUD as the anastomosis is performed within the abdominal cavity with a theoretical risk in reducing ischemic strictures [43, 51]. In the largest series of intracorporeal neobladders (70 patients), Tyritzis et al. demonstrated a stricture rate of <3% with encouraging functional outcomes [43].

However, ICUD has many challenges including increased operative times, involvement of multiple teams and being an inherently complicated procedure with a very steep learning curve [50]. The learning curve for RARC alone has been traditionally about 20 cases and the use of ICUD could significantly increase that. Given the

fact that radical cystectomy is not performed very commonly in the community, it may take surgeons a very long time to overcome the learning curve required for ICUD [51].

At present there is a paucity of data directly comparing ICUD and ECUD. An analysis from the IRCC retrospectively compared 167 patients who underwent ICUD with 768 patients who had an ECUD. The baseline variables were comparable between both arms. In this study the operative time was equivalent between both groups but majority of the patients underwent ileal conduit. Patients undergoing ICUD tended to have a longer LOS (9 days versus 8 days, $p = 0.086$) and there was no difference in the reoperation rate at 30 days. Patients undergoing ICUD had a significantly lower readmission rate at 30 and 90 days and also a lower mortality rate at 90 days. There was no significant difference in 30- and 90-day complication rates in both arms although they tended to be less in patients undergoing ICUD. Gastrointestinal and infectious complications were significantly lower in the ICUD arm [52]. This study represents the largest available comparison between ICUD and ECUD however given its retrospective nature and possible selection bias it has inherent limitations. Pyun et al. recently reported a comparison from a cohort consisting of 38 ECUD patients and 26 ICUD patients, all surgeries being performed by a single surgeon at a Korean university. The operative time was significantly longer in the ICUD arm but EBL was significantly lower. There were no significant differences with respect to LOS and time to oral intake. All and minor complications at 90-days were significantly more in the ECUD arm, predominantly related to an increased rate of blood transfusion. There were no significant differences in major complications [53].

The procedure of ECUD also continues to evolve, with some centers using a hybrid procedure where the robot is re-docked after completing the bowel work to perform the uretero-intestinal and neobladder-urethral anastomoses [54]. Until better studies are conducted the advantages of ICUD over ECUD remain hypothetical at this time. In the future it is possible that the incremental benefit, if any, may not be enough to justify the cost and learning curve of ICUD.

Conclusion

RARC is a minimally invasive alternative to a traditionally formidable open surgery. It holds the potential for improving perioperative morbidity compared with ORC without a compromise of oncological efficacy. At present, high levels of clinical evidence for the benefits of RARC are absent, and current experiences represent case series or small, single-institution randomized trials. More mature long-term data and direct comparisons between ORC and RARC are needed to draw definitive conclusions.

RAZOR (Randomized Open Versus Robotic Cystectomy) Trial

Comparative results of RARC versus ORC need validation in larger, multi-centric, randomized, prospective clinical trials and this is the main aim of the RAZOR trial. This multi-institutional, non-inferiority phase III trial aimed to enroll at least 320 patients (160 in each arm) at 15 participating institutions. The study aims to determine whether RARC provides non-inferior oncological control versus ORC with the primary endpoint of the study being 2-year progression free survival (PFS). Participating surgeons must have performed >10 ORC and RARC each over the 1 year prior to approval as a site. This will presumably minimize institutional and surgeon biases. All the diversions are to be performed extra-corporeally with level of lymph node dissection left to the discretion of the surgeon. A number of secondary endpoints including perioperative complications, pathological data and QOL issues will also be analyzed. Accrual was completed in 2014 and the results are expected in 2016–2017 [55].

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Part VII

Testis

60

Robot-Assisted Laparoscopic Retroperitoneal Lymph Node Dissection in Testicular Tumor

James R. Porter

Abstract

The treatment of stage I non-seminomatous germ cell (NSGCT) tumor includes retroperitoneal lymph node dissection (RPLND) for patients with high-risk tumor characteristics and for those patients with residual masses after primary chemotherapy. Laparoscopic RPLND (L-RPLND) was initially performed to reduce the morbidity associated with open RPLND (O-RPLND) and at the same time maintain the staging and therapeutic benefits of lymph node removal. However, L-RPLND is a challenging procedure and requires extensive experience with laparoscopic techniques including laparoscopic control of bleeding. Robotic RPLND (R-RPLND) provides enhanced endoscopic visibility, improved dexterity, and superior control of bleeding over L-RPLND. The robotic platform has allowed for a full bilateral RPLND to be performed in one setting without the need to reposition the patient. The bilateral approach as well as improved vascular control has permitted R-RPLND to be expanded to patients with post chemotherapy masses.

Keywords

Laparoscopy · Laparoscopic surgery · Retroperitoneum · Retroperitoneal lymph node dissection · Non-seminomatous germ cell tumor · Robotic surgery · Robotics · Testicular cancer · Testis cancer · Minimally invasive surgery · Lymphadenectomy

Introduction

The management of patients with clinical stage I non-seminomatous germ cell tumors (NSGCT) of the testis remains controversial. Treatment options include retroperitoneal lymph node dissection (RPLND), surveillance, and primary chemotherapy. Fortunately, the survival rate is in the range of 95–99% with each treatment modality [1–3]. Therefore, the patient's perception of treatment toxicities and quality of life, without compromising cancer control, has become of paramount importance in decision making when choosing therapy.

Open RPLND (O-RPLND) has been the standard of care for the surgical management of clinical stage I NSGCT. The approach provides both diagnostic information on the stage of the tumor and is curative in 75–80% of patients with low volume retroperitoneal disease. With refinements in surgical technique to preserve the postganglionic sympathetic nerves, retrograde

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ejaculation has been minimized [4]. Nevertheless, there can be significant morbidity from O-RPLND, with associated bowel dysfunction, prolonged hospitalization, and delay in resumption of daily activities and work [5, 6].

The National Cancer Comprehensive Network (NCCN) guidelines for the treatment of stage I NSCGT include surveillance, one to two cycles of chemotherapy, or primary RPLND, with surveillance being preferred for low risk patients [7]. In practicality, the role of RPLND as a primary treatment for stage I NSGCT has diminished, and the European Association of Urology Guidelines for NSGCT does not recommend RPLND as a treatment option for even high risk clinical stage I disease [8]. There are probably several factors contributing to the decline in RPLND including the significant morbidity associated with O-RPLND. If a young man with high risk NSGCT (evidence of lymphovascular invasion and >50% embryonal cancer) is given the choice of two cycles of chemotherapy or an O-RPLND, many will choice chemotherapy. In addition, as surveillance becomes more prevalent, many urologists may not feel comfortable performing RPLND and chemotherapy then becomes the natural progression of surveillance.

In an attempt to make RPLND less morbid, several investigators have applied minimally invasive techniques to RPLND [9–12]. The effort initially began with laparoscopic RPLND (L-RPLND) at centers with significant laparoscopic experience due to the challenging nature of the dissection around the great vessels. Early experience with L-RPLND revealed that it was safe and a complete retroperitoneal dissection was possible. There was no evidence of infield recurrences attesting to the completeness of dissection [13]. L-RPLND was initially performed as a staging procedure, but as experience was gained, patients with positive lymph nodes were followed and not given chemotherapy and the therapeutic benefit in patients with low volume retroperitoneal disease was demonstrated [14]. However, because of the technical difficulty with L-RPLND, most notably bleeding, the procedure has been limited to centers with expert urologic laparoscopic surgeons and failed to disseminate beyond centers of excellence.

With the widespread application of the robotic surgical platform to urologic procedures, robotic techniques have been applied to RPLND as an extension of L-RPLND. The advantages of the robot over standard laparoscopy include high definition 3-D vision, improved dexterity with greater degrees of instrument freedom, and enhanced surgeon ergonomics, and these benefits play an important role in the control of bleeding encountered during RPLND. Thus, the early experience with robotic RPLND (R-RPLND) has shown it to be safe and feasible with minimal morbidity for the patient. This review will highlight the current role of R-RPLND in the management of patients with testicular cancer. The goal of this review is to provide the technical framework for urologists to perform R-RPLND, and at the same time maintain the current standard of cancer care while reducing surgical morbidity for these patients.

Initial Experience and Evolution of Robotic RPLND

The initial experience with R-RPLND was an extension of the laparoscopic approach with the goal being lymph node removal for staging of the disease. This was accomplished with a unilateral template dissection with the patient placed in the lateral modified flank position as they would be placed for a L-RPLND. The lymph nodes were removed and sent for frozen section analysis while the patient was still under anesthesia. If the lymph nodes came back positive, the patient had to be repositioned for a bilateral dissection as the contralateral side was very difficult to reach with the patient in the lateral position. The other difficulty with the lateral position was the challenge of removing the entire spermatic cord due to the limitations of reach with the daVinci S and Si. This required the robot to be redocked in front of the patients leg and then the three lower ports were used to access the inguinal canal (Fig. 60.1).

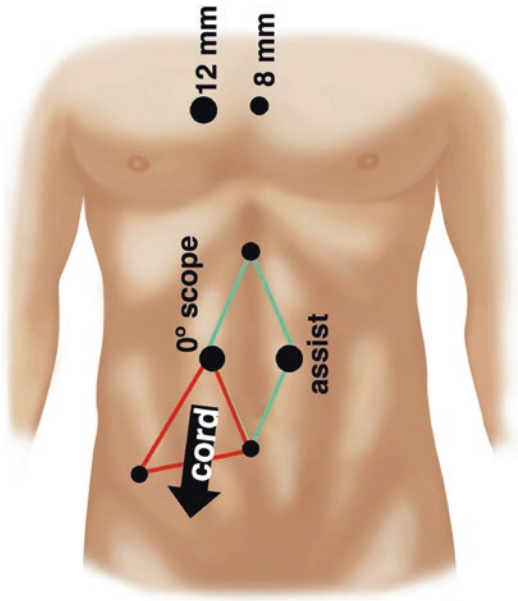

Fig. 60.1 Right lateral robotic RPLND port configuration. After removal of the retroperitoneal lymph nodes, the robot is redocked in front of the patient's leg and the inferior three ports are used to remove the spermatic cord

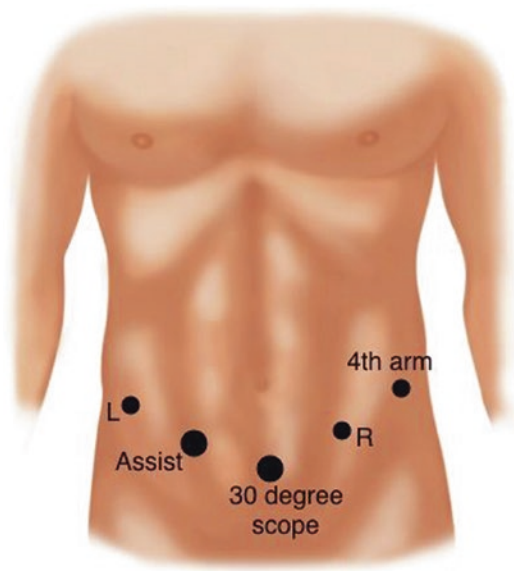

Fig. 60.2 Supine RPLND port configuration for daVinci Si

Given these limitations, and the need for a full bilateral dissection, post chemotherapy RPLND (PC-RPLND) was not performed using the lateral approach.

A novel approach to R-RPLND was developed to address the need for a complete bilateral dissection. This was accomplished by placing the patient in the supine position with the arms padded and tucked at the sides. The ports were placed below the umbilicus and directed up toward the upper abdomen, and the patient was placed in the Trendelberg position to allow the intestines to fall cephalad (Fig. 60.2). The daVinci Si robot was docked over the patient's left shoulder. This approach provided excellent exposure of the entire retroperitoneum and allowed for a full bilateral dissection to be performed without the need to place additional ports. There was still the challenge of removing the spermatic cord and the robot was undocked and redocked along side the ipsilateral leg. The robot was then directed toward the inguinal canal to allow removal the entire cord with cord stump. Credit should be given to Dr. James L'Esperance from the U.S. Naval Hospital in San Diego, CA for sharing these important concepts.

The current state in the evolution of R-RPLND involves the application of the daVinci Xi robot to the supine position. The daVinci Xi is designed to allow multi-quadrant access using one port configuration by reducing external arm conflict. The arms are designed to reach backwards away from the operative field increasing access to more of the abdomen. Because the robotic arms are attached to a rotating boom, the daVinci Xi can be docked from multiple positions over the patient and this simplifies room organization and robot location. These advantages permit full access to the retroperitoneum but also to the pelvis from the same port configuration. This facilitates removal of the retroperitoneal lymph nodes and the entire spermatic cord without the need to redock the robot as discussed with the daVinci Si. The patient is again placed with arms padded and tucked at the sides but the ports are placed in a linear configuration below the umbilicus (Fig. 60.3). The combination of the supine approach and the advantages of the daVinci Xi have permitted the removal of residual masses after chemotherapy for NSGCT.

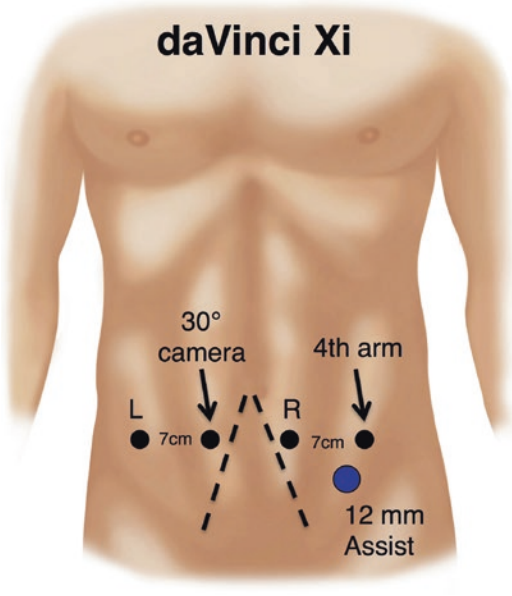

Fig. 60.3 Supine port configuration for bilateral RPLND using daVinci Xi

Indications for Robotic RPLND

The indications for R-RPLND are the same as O-RPLND. Patients with NSGCT found on radical orchiectomy (T1–3) with no evidence of nodal involvement on CT of the abdomen, no signs of lung involvement on CT of the chest, and negative or normalized tumor markers are appropriate candidates for R-RPLND. In select patients with small volume nodal involvement in the abdomen (stage IIa) and predominately teratoma on orchiectomy, R-RPLND can be considered depending on the marker status. Patients are counseled regarding all treatment options for NSGCT including O-RPLND, surveillance and primary chemotherapy. The majority of patients with stage IA and IB NSGCT can be followed closely with surveillance protocols and avoid surgery or chemotherapy. However, if the patient has the potential to be non-compliant with surveillance then he should be counseled to strongly consider R-RPLND. We are inclined to offer R-RPLND to those patients at higher risk of retroperitoneal recurrence such as patients with lymph vascular invasion and greater that 50% embryonal cancer in the orchiectomy specimen.

As experience is gained with R-RPLND, the indications have expanded to patients with residual masses after primary chemotherapy. Masses greater than 1 cm in patients with negative tumor markers may be candidates for R-RPLND with the caveat that larger masses (N3) and tumors involving renal hilum may be better addressed with O-RPLND.

Contraindications to R-RPLND include pure seminoma, patients with elevated tumor markers despite negative nodes on CT scan and patients who have had prior abdominal radiation. Relative contraindications include extreme obesity (BMI > 40), prior episodes of peritonitis and coagulopathy. Patients with prior abdominal surgeries can usually undergo successful R-RPLND after take down of adhesions.

Patient Preparation

Patients being considered for R-RPLND should undergo complete staging of the disease with radiographic imaging of the chest and abdomen, and tumor marker assessment including AFP, B-HCG and LDH. If there is a delay of more than 6 weeks from the initial CT scan of the abdomen to the time of surgery, it is prudent to repeat the CT to look for evidence of nodal enlargement as this may affect the clinical stage of the disease and the operative plan. Patients should be counseled that there is a possibility of conversion to open surgery due to vascular or bowel injury and this should be clearly stated in the informed consent. This is especially important in patients undergoing a post chemotherapy R-RPLND where there can be significant fibrosis and scarring between the tumor and great vessels. The patient should also be informed of the possibility of nephrectomy as this is sometimes necessary due to tumor involvement of the renal hilum. They should be aware of the risk of blood transfusion. We routinely counsel patients that they will be on a low-fat diet (20 g of fat) for two weeks after the procedure to decrease the risk of developing chylous ascites that may require bowel rest with TPN and re-operation if it does not resolve. Finally, we encourage patients to

bank sperm prior to surgery in the event of retrograde ejaculation.

To decrease the size of the intestines and provide more working space for R-RPLND, patients are asked to undergo a modified bowel preparation the day prior to surgery with a clear liquid diet and magnesium citrate orally. We request that patients avoid platelet inhibitors such as aspirin and non-steroidal anti-inflammatory medications for 7 days prior to the procedure. Patients are typed and crossed for blood in the event of acute hemorrhage during the procedure.

Fig. 60.4 Left lateral modified flank position for lateral RPLND

Fig. 60.5 Patient position for supine RPLND with arms padded and tucked at the side

Preoperative Preparation

Anesthesia and Patient Position

Patients undergoing R-RPLND require general endotracheal anesthesia with continuous attention by the anesthesiologist to deep paralysis to maintain adequate pneumoperitoneum. A Foley catheter and orogastric tube are placed prior to positioning the patient to decompress the bladder and stomach and decrease the risk of injury during port placement as well as to provide more room in the peritoneal space for the procedure. Sequential compression stockings are placed on the lower extremities and a cephalosporin antibiotic is administered just prior to making the incision.

For R-RPLND using the lateral approach patients are placed in a 60° modified flank position with the side of prior orchiectomy up (Fig. 60.4). The patients are well padded on a gel pad and the legs are supported with pillows. The arms are placed on an arm board with pillows placed between the arms, although we sometime place the arms in a "prayer" position for patients undergoing R-RPLND. For R-RPLND using the supine approach, patients are placed supine with the arms padded and tucked by the sides and the legs are straight with sequential compression stockings (Fig. 60.5). Because the patient is placed in a slight Trendelenberg position, a full body gel pad is placed between the patient and operating table to prevent patient movement. As with the lateral position, Foley catheter, orogastric tube and pre-incision antibiotics are employed.

Operating Room Set-Up and Equipment

The robotic set up will depend on whether the lateral or supine approach is used or whether the daVinci Si or Xi are employed. For the lateral approach with the daVinci Si the robot is docked over the patient's back on the side of the bed ipsilateral to the orchiectomy (Fig. 60.6). The bedside assist and scrub nurse are on the side opposite the robot and the primary surgeon resides at the surgeon's console. The anesthesia team is located at the patient's head. A second assistant is not routinely used during R-RPLND. For the supine approach using the daVinci Si, the robot is docked over the patient's left shoulder after the patient is placed in a 15–20° Trendelenberg position

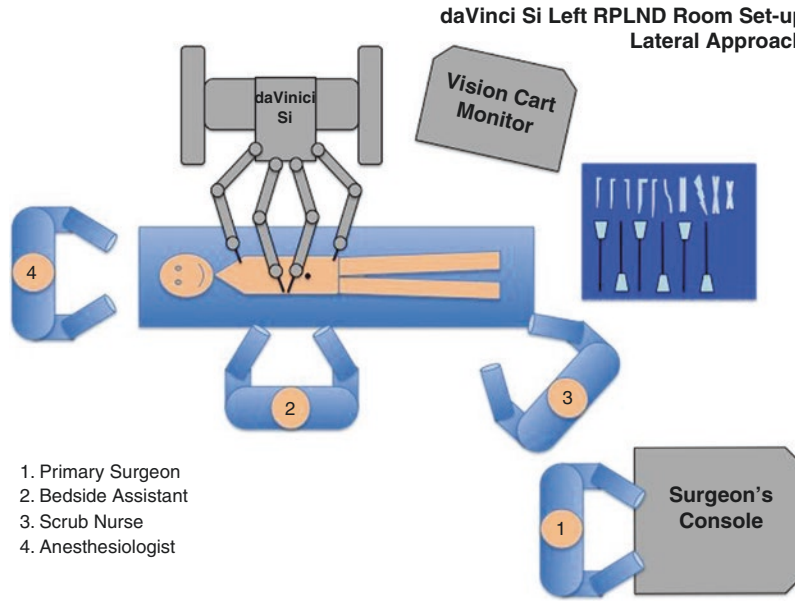

Fig. 60.6 Room configuration for left robotic RPLND with daVinci Si and the lateral approach. Robot is docked over the patient's back

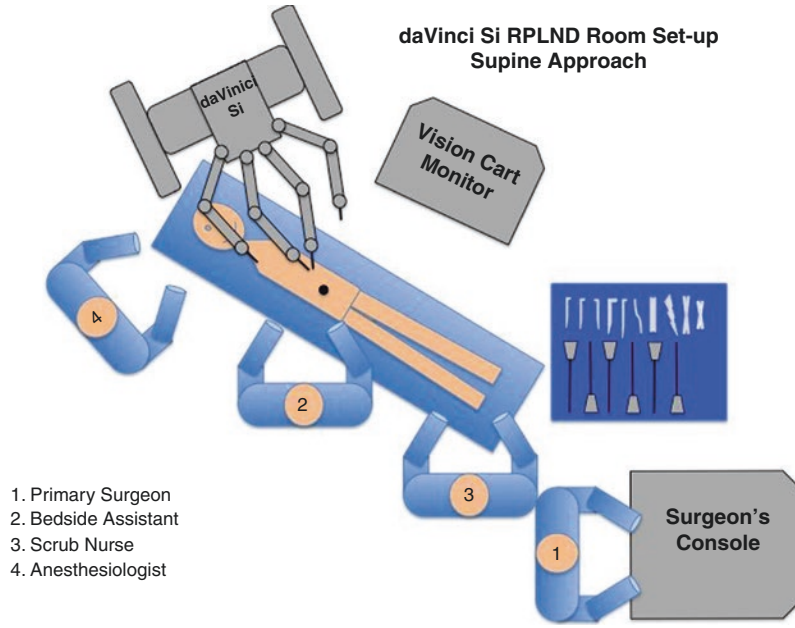

Fig. 60.7 Room configuration for robotic RPLND with daVinci Si in the supine approach. Robot is docked over left shoulder of patient

(Fig. 60.7). The bedside assistant is placed on the patient's right directed toward the head of the patient and the scrub nurse is usually on the same side. The anesthesiologist will be on the right side of the patient's head opposite the robot. The patient side vision cart holds the insufflator, electrosurgical unit, light source, and accessory energy components and can be placed in the optimum position depending on room size and configuration specific to the room.

The daVinci Xi is designed to allow docking from any position due to the presence of a rotating boom. This permits the robot to be brought in from any direction depending on the side of the dissection and thereby simplifies patient position and room configuration. It is also designed to

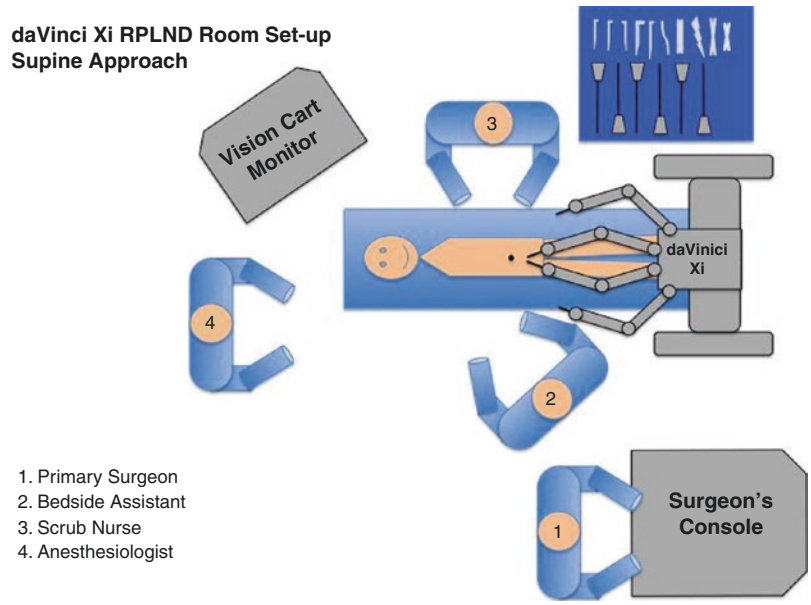

Fig. 60.8 Room configuration for daVinic Xi RPLND using supine approach. Robotic is docked over the patient's foot

allow extended reach of the robotic arms and allows multi-quadrant access in the abdomen and is ideal for RPLND. Given these advantages, the daVinci Xi is our preferred platform for R-RPLND and we have abandoned the lateral position and daVinci Si for R-RPLND.

For a left-sided R-RPLND using the daVinci Xi the patient is placed in the Trendelenberg position and the robot can be brought in on the patient's left side, right side or over the foot of the patient as shown in Fig. 60.8. The bedside assistant is placed on the right side directed up toward the head and the scrub nurse is on the patient's left. The mirror image configuration is used for a right-sided R-RPLND.

The instrumentation used for R-RPLND is the same irrespective of the approach or which model robot is used. Monopolar scissors are used in the right robotic arm, fenestrated bipolar in the left arm, and atraumatic grasper in the fourth robotic arm. For the lateral approach with the daVinci Si, a 0° lens is used in the lateral camera position. For the supine approach with daVinci Si or Xi, a 0° lens is used initially during exposure of the retroperitoneum and then switched to a 30° down lens during dissection of the lymph nodes. Other robotic instruments routinely used during R-RPLND include the robotic needle drivers and the robotic clip applier. The robotic clip applier is an important aid for R-RPLND as it allows clips to be applied in tight spaces and with angles that cannot be accomplished by the bedside assistant. The bedside assistant uses a suction-irrigation device throughout most of the procedure, but may be called upon to apply clips with a laparoscopic clip applier. To control vascular injury, a "rescue stitch" is prepared in advance to allow rapid control of bleeding if this is encountered. A rescue stitch is a 4–0 polypropelene suture on an RB-1 needle cut to 12 cm with a polymer clip on the end of the suture opposite the needle. This allows multiple throws of the needle without the need to tie the suture, although the clip can be removed and the sutured tied once bleeding is controlled if this is the surgeon's preference. Lymph nodes are removed with the aid of an endoscopic retrieval bag decreasing the risk of potential tumor cells coming into contract with the abdominal wall or the extraction port. Hemostatic agents are used at the end of the procedure to aid in the sealing of lymphatic changes that may remain open after lymph node removal. As with any laparoscopic procedure an open laparotomy set is in the room, opened and prepared in the event of rapid conversion to open surgery.

Technique

Access and Port Placement

Once the patient has been sterilely prepped and draped, pneumoperitoneum is established by either on open technique using a Hasson port or a closed technique using a Veress needle. If a Veress needle is used this is usually placed in the midclavicular line below the left costal margin to avoid the midline great vessels.

For a right lateral R-RPLND using the daVinci Si a six port configuration is used with the 12 mm camera port placed midway between the umbilicus and xiphoid in the mid rectus muscle (Fig. 60.9). The camera for lateral R-RPLND is placed lateral to the other robotic ports to decrease external arm collision and allow more room for the bedside assistant. The left and right robotic arms are placed near the midline and the assistant is placed just medial to the line created by these two ports. The fourth robotic arm is placed laterally near the ipsilateral anterior superior iliac spine and is essential for R-RPLND to allow retraction and facilitate dissection behind the great vessels. A 5 mm sub xiphoid port is placed to allow retraction of the liver. The mirror image port configuration for left-sided R-RPLND is performed with the exception of the liver retractor.

For supine R-RPLND the port configuration depends on which model daVinci is being employed. A 5-port fan configuration is utilized for daVinci Si with the 12 mm camera port in the midline approximately 4 cm below the umbilicus (Fig. 60.10). The 8 mm right robotic arm and 4th arm are placed on the patient's left and the 12 mm assistant port is placed between the camera and the 8 mm left robotic port. This port configuration is used for both left- and right-sided supine R-RPLND using the daVinci Si.

The robotic arms on the daVinci Xi are designed to avoid external arm conflict by placing the ports in a linear configuration without the need for port offset as commonly employed

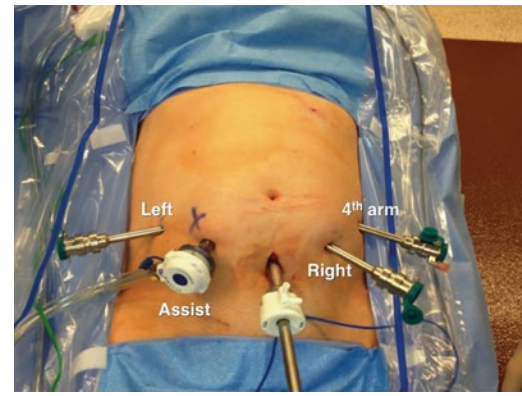

Fig. 60.10 Supine robotic RPLND port configuration with daVinci Si

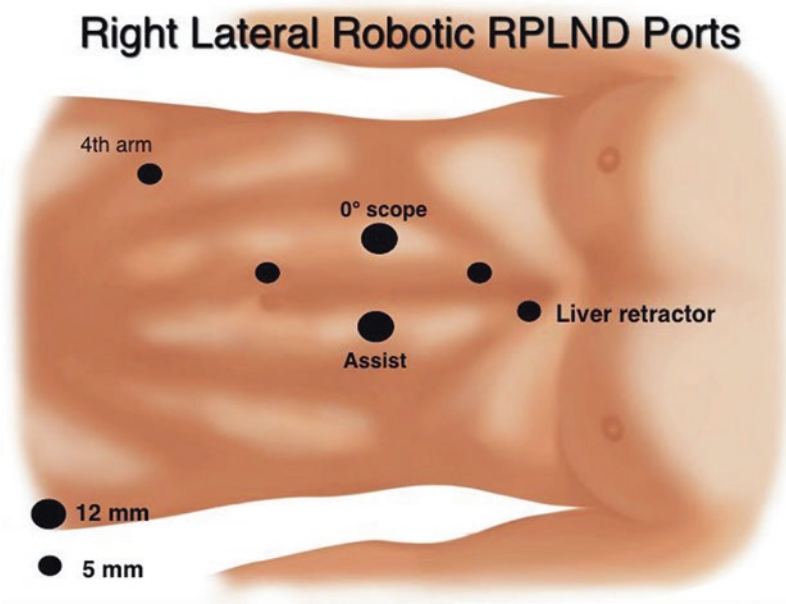

Fig. 60.9 Right robotic RPLND lateral approach port configuration with daVinci Si

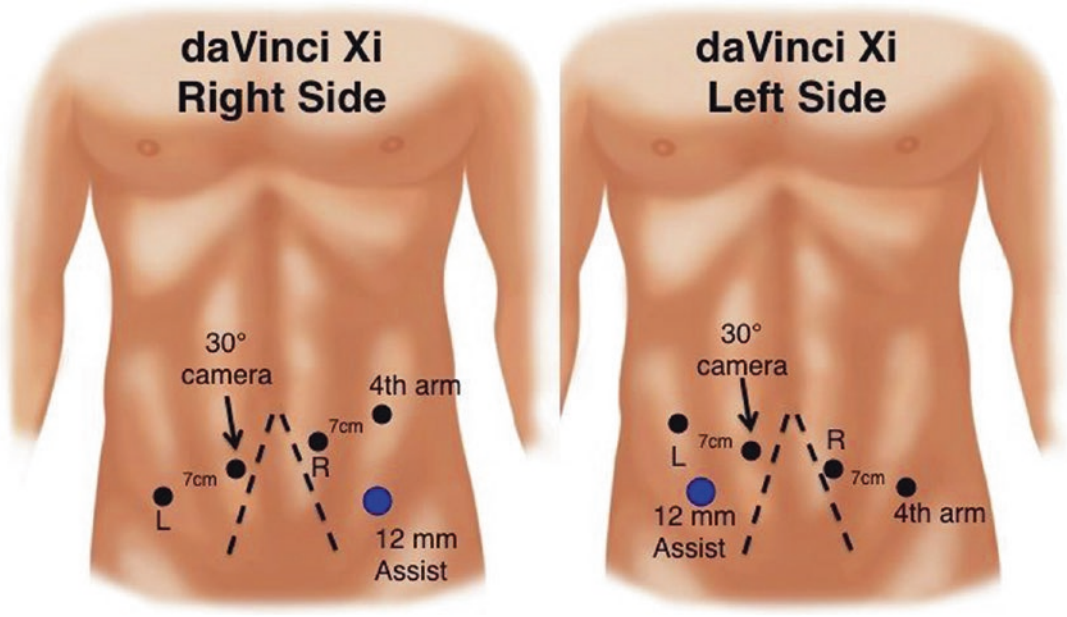

Fig. 60.11 Right and left supine robotic RPLND port configuration with daVinci Xi. For bilateral dissection the linear port array is placed horizontally below umbilicus

with the daVinci Si. The right-sided daVinci Xi port configuration is shown in Fig. 60.11. The ports are placed linear at a slight angle to allow room for the assistant in the left lower quadrant. The camera port and the right robotic arm port are placed on either side of the medial umbilical ligaments. The ports are placed approximately 6–7 cm apart to allow freedom of movement and avoid conflict. The robot is docked from the right side and the 30° lens is used after exposure is created. The left sided daVinci Xi approach is shown in Fig. 60.11 as well. For a full bilateral approach with the daVinci Xi, as in the setting of post-chemotherapy RPLND, the linear port configuration is not angled but placed at a right angle to the midline to allow access to both the right and left distal ureters (see Fig. 60.3).

Boundaries of Dissection

The right-sided template dissection performed during R-RPLND begins with complete mobilization of the right colon and duodenum exposing the retroperitoneum and great vessels. The gonadal vessels are clipped and dissected inferiorly as far as possible but this is limited due to robotic arm restriction. The remainder for the cord is excised after the retroperitoneal lymph nodes have been removed by re-docking the robot in front of the patients legs and using the lower three robotic ports. This permits access to the internal inguinal ring where the entire cord is removed along with cord stump as indicated by retained suture. The renal pedicle establishes the upper limit of dissection while the inferior mesenteric artery is the lower limit of resection medially. The lower limit of dissection laterally is the crossing of the ureter over the right common iliac artery. The modified unilateral template dissection on the right side includes removal of the precaval, paracaval, retrocaval, interaortacaval, and preaortic node packages with extension to the left paraaortic nodes. The post-ganglionic sympathetic nerve fibers are identified coming off the sympathetic chain and are traced under the inferior vena cava on their way to the hypogastric plexus. These fibers are preserved within the template. The split and roll technique is used to remove retrocaval nodal tissue which includes nodal tissue posterior to lumbar vessels. Care is taken to clip all lymphatic channels to prevent lymph leakage especially the lymphatic channels

crossing over the left renal vein. For the left-sided R-RPLND the descending colon is mobilized from the splenic flexure to the iliac vessels and medially to expose the great vessels. The gonadal vessels are once again mobilized and clipped at their proximal origin and dissected down as far as possible and removed completely after re-docking as described for the right side. Dissection of the paraaortic lymph nodes begins at the renal hilum and extends to the where the left ureter crosses over the common iliac artery. The post-ganglionic fibers on the left side are not as large as the right and can be difficult to identify and maintain. The preaortic and interaortacaval nodes are dissected from the renal hilum to the inferior mesenteric artery which is spared.

Excised tissues are removed in organ entrapment bags and sent for immediate frozen section analysis. Patients with positive lymph nodes and stage IIA or stage IIB disease are repositioned for contralateral R-RPLND with nerve sparing. In patients found at surgery to have stage IIC disease, the procedure is terminated after unilateral dissection and the patient is scheduled for post RPLND chemotherapy.

For supine R-RPLND the dissection is the same with the daVinci Si or Xi but is modified depending on the stage of the patient. To begin the dissection the retroperitoneum is exposed by incising the posterior peritoneum medial to the cecum and extending this incision toward the ligament of Trietz. The cut edge of the posterior peritoneum is sutured to the right side of the anterior abdominal wall to provide exposure of the great vessels and retroperitoneum. The left side of the cut edge of the posterior peritoneum is likewise sutured to the left side of the anterior abdominal wall creating a hammock-like barrier preventing the small bowel from falling into the retroperitoneum. The combination of the suspension sutures and the Trendelenberg position provides excellent exposure. While the suspension sutures provide the distal exposure of the retroperitoneum, the fourth robotic arm, using an atraumatic grasper, is used to retract the duodenum proximally and create proximal exposure.

Patients with clinical stage I NSGCT, undergo a unilateral template dissection with nerve sparing. Lymph nodes are sent for frozen section analysis and, if positive, a full bilateral dissection is performed. For patients with post chemotherapy residual masses, a full bilateral dissection with never sparing is performed, including complete removal of the ipsilateral spermatic cord. With the daVinci Si, this is accomplished by repositioning the robot parallel to the ipsilateral leg, providing access to the spermatic cord and internal inguinal ring. Dissection is then carried out caudally, excising the spermatic cord out of the internal inguinal ring until the remnant suture from radical orchiectomy is removed. With the daVinci Xi, the spermatic cord is fully accessible without the need to reposition the robot.

Results

The first report of R-RPLND was presented by Davol, Sumfest, and Rukstalis in 2006 as a single case report of a right sided dissection using four robotic ports and a right lateral approach [15]. One of the lymph nodes that was removed was found to have teratoma and the dissection was extended to the left side using the same right sided port configuration. This initial report demonstrated that R-RPLND was technically feasible and the authors noted that the benefits of the robot facilitated lymphatic removal around the great vessels.

A case series of three patients with stage 1 NSGCT undergoing primary R-RPLND was reported by Williams et al. in 2011 [16]. Patients were placed in the lateral position and the technique described was an extension of the laparoscopic approach using the robot. All three patients underwent unilateral template dissections without positive lymph nodes and there were no complications or transfusions. Each patient was discharged on post operative day number 2. The authors state that the robotic approach offers a minimally invasive alternative to conventional L-RPLND and may allow patients to avoid primary chemotherapy.

A series demonstrating the supine approach for R-RPLND was recently published by Cheney et al. from the Mayo Clinic [17]. They reported on 18 patients, nine with primary testicular cancer, eight with residual masses after chemo-

therapy and one with paratesticular rhabdomyosarcoma. The supine approach was successful in 15 of the 18 patients with open conversion performed for hemorrhage, poor exposure and robotic malfunction in three cases. Mean operative time was 311 min for primary R-RPLND and 369 min for post chemotherapy R-RPLND ($p = 0.03$). Mean estimated blood loss was 100 cc for primary R-RPLND and 313 cc for the post chemotherapy group ($p = 0.13$). Mean length of stay was 2.4 days and there were three minor (Clavien II) complications (17%). Mean lymph node count was 20 and lymph nodes were positive in eight of 18 patients (44%), including five of eight patients with post chemotherapy tumors and three of ten patients undergoing primary R-RPLND. No patient received adjuvant chemotherapy, and at a mean follow-up of 22 months, there were no retroperitoneal recurrences although two patients required salvage chemotherapy for pulmonary recurrence. This study highlighted the utility of the supine approach for R-RPLND and demonstrated that a full bilateral dissection could be performed without the need for reprepping and redraping the patient.

A multi-institutional review of R-RPLND was recently reported by Pearce et al. in European Urology [18]. The authors compiled 47 patients from four academic centers over 5 years. All procedures were primary R-RPLND and 42 patients were clinical stage I with five clinical stage IIa patients. Median operative time was 235 min, estimated blood loss was 50 cc and lymph node count was 26. There were two intraoperative complications: a recognized pancreatic injury that was drained and an aortic injury that failed robotic repair and required open conversion and a blood loss of 1100 ml. There were four early complications including two patients with chylous ascites, one ileus and one body wall hematoma requiring a transfusion. Eight patients had positive nodes (pathologic stage II) and five of those patients received chemotherapy. Of the three patients who were followed, no patient developed a recurrence, although the median follow up for this group was short at 6 months. There were no retroperitoneal recurrences in any patient. The authors concluded that R-RPLND performed by experienced robotic surgeons for low-stage NSGCT appears to be safe with acceptable perioperative morbidity. They noted that longer follow-up is necessary to assess oncologic outcomes.

Our group recently reviewed our experience with R-RPLND using both the lateral and supine approaches [19]. Our initial experience was an extension of our laparoscopic procedure and a major limitation of the lateral approach was the inability to perform a full bilateral dissection in the event of positive nodes or in patients with post chemotherapy residual masses. The supine approach using the daVinci robot addresses this issue and allows a full bilateral dissection without redocking or repositioning the patient. It also permits a superior view of the post-ganglionic sympathetic fibers in those patients undergoing nerve sparing R-RPLND. Our experience includes 19 patients who underwent 20 procedures with 11 clinical stage I, six clinical stage II and three clinical stage III patients. There were 16 primary and four post-chemotherapy procedures with 11 lateral and nine supine approaches. Median operative time for the group was 293 min, but was 259.7 for unilateral dissections and 313 for bilateral procedures. Median estimated blood loss was 50 cc and no patient required transfusion or conversion for bleeding. The median length of stay was 1 day with 14/20 (70%) of patients being discharged in less than 24 h. Median lymph node count was 19.5. Eleven patients had pathologic stage I disease and eight patients had pathologic stage II. One of the eight with retroperitoneal disease had CS I, six had CS II, and one had CS III disease preoperatively. Teratoma was found in three patients: two with CS II disease and one with CS III disease. There has been no evidence of recurrence in these patients. Embryonal carcinoma was found in five patients, four of whom had PS IIA and one PS IIC disease. Two of these five patients received chemotherapy: one with PS IIC disease, and one with PS IIA disease who was followed and found to have a lung recurrence at 4 months after surgery. Three patients with PS IIA disease did not receive chemotherapy and have been followed expectantly; they have not required systemic therapy at follow-up of 46, 47, and 91 months. There has been no evidence of retroperitoneal disease recurrence in any patient in the series at a median follow up of 49 months.

There was one complication in the series. A ureteral transection occurred due to tumor involvement during a left sided R-RPLND in clinical stage II patient. The ureter was repaired over a stent and remains patent after stent removal. Two patients who underwent bilateral R-RPLND suffered ejaculatory dysfunction.

A recent comparative analysis between L-RPLND and R-RPLND was reported by Harris et al. in BJUI in 2015 [20]. They compared 21 L-RPLND to 16 R = RPLND performed by a single surgeon. The series represented a mature experience with L-RPLND as compared to the early learning curve with R-RPLND. Despite this difference in experience, the outcomes for the two MI-RPLND techniques were essentially the same. The R-RPLND operative time was 270 min versus 294 min for L-RPLND representing a difference of 24 min that was not statistically significant. Median estimated blood loss was 125 cc for L-RPLND and 75 cc for R-RPLND ($p = 0.16$). Median lymph node yield was 22 for L-RPLND and 30 for R-RPLND ($p = 0.13$). There were 2 (9.5%) post-operative complications in the L-RPLND group and 1 (6.3%) complication in the R-RPLND cohort. Follow-up for both groups was too short to make any meaningful statements about oncologic outcomes. The authors concluded that R-RPLND appears comparable to L-RPLND but at this stage it is unclear whether R-RPLND offers any tangible benefits over standard laparoscopy.

Conclusions

R-RPLND has undergone an evolution with regard to both technique and intent of the procedure. Initially, it was performed as a staging procedure to direct adjuvant treatment in those patients with positive nodes, but with growing experience the procedure was carried out with therapeutic intent. The application of robotics to RPLND has addressed the major hurdle of L-RPLND that being the control of major vascular bleeding. In addition, the robotic platform has facilitated the development of the bilateral approach to be performed in patients with positive lymph nodes and opened the door for the safe application of minimally invasive surgery to post chemotherapy masses. There will be and should be continued scrutiny of R-RPLND, as the current standards set by O-RPLND need to be adhered and not compromised in the effort to reduce patient morbidity.

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Part VIII

Pediatric Urology

Robotic Surgery of the Kidney in Children

61

Jack S. Elder

Abstract

Robotic-assisted surgery of the kidney in children is a safe minimally invasive in most children with congenital abnormalities of the urinary tract. Robotic nephrectomy, nephroureterectomy, heminephrectomy, pyeloplasty, ureterocalicostomy, and pyelolithotomy have been demonstrated to have equal or favorable outcomes compared with open surgical approaches in children over 6 months of age. Expert surgeon experience and anesthesia and intra-operative bedside assistant support are important for procedural success. Large multi-institutional series have demonstrated safety and surgical success with pyeloplasty and other common robotic renal procedures.

Keywords

Kidney, robotic · Kidney, pediatric · Kidney, duplication, robotic · Nephrectomy, robotic · Pyelolithotomy, robotic · Pyeloplasty, robotic, child

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Introduction

Minimally invasive surgery in pediatric urology has undergone a paradigm shift with the incorporation of the da Vinci surgical system. Following the popularity of robotic radical prostatectomy, many pediatric urological surgeries have been performed successfully with the da Vinci robot, including pyeloplasty, nephrectomy, partial nephrectomy, ureteral reimplantation, pyelolithotomy, bladder diverticulectomy, augmentation cystoplasty, and appendicovesicostomy. Some are in various stages of refinement (pyelolithotomy, augmentation cystoplasty), but many are well established (nephrectomy, nephroureterectomy, pyeloplasty, ureteral reimplantation). Robotics decreases the learning curve for minimally invasive pediatric reconstructive procedures. With the combination of three-dimensional vision, intuitive movements, visual immersion, and magnification, robotic assistance can enable an experienced laparoscopist to expand his/her surgical armamentarium to complex reconstructive procedures and a novice to explore the realm of minimally invasive pediatric urology.

This chapter explores the current status of robotic surgery of the kidney in children. A detailed step-by-step description of technique is provided, including operative setup and positioning, instrumentation, and pearls for preventing complications. The relevant contemporary literature is also reviewed. The transperitoneal

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approach will be described. These operative procedures also can be performed with a retroperitoneal approach, but the space is limited, particularly in small children. In contrast, the working space and visualization with the transperitoneal approach are much greater and easier to develop.

The procedures discussed are grouped into two categories: extirpative—nephrectomy, heminephrectomy, and nephroureterectomy; and reconstructive—pyeloplasty, transposition of vessels for ureteropelvic junction obstruction, ureterocalicostomy, and pyelolithotomy.

Children pose an interesting dilemma regarding robotic instrumentation. An advantage of minimally invasive surgery is that small instruments are used. Although 5 and 8 mm instruments are available, the 5 mm instruments need a much wider range for movement. Consequently, in small infants, 8 mm instruments generally are necessary, whereas in older children 5 mm instruments usually are sufficient.

Extirpative Surgery

Nephrectomy, Heminephrectomy, and Nephroureterectomy

Indications

As congenital anomalies of the urinary tract are commonly diagnosed antenatally or in early childhood, the need for removal of the kidney or part of the kidney with/without the ureter is most common in infants and young children. Common indications for nephrectomy include renal nonfunction resulting from severe ureteropelvic junction (UPJ) obstruction, obstructive megaureter, vesicoureteral reflux, or multicystic dysplastic kidney (MCDK). Removal of the entire ureter is necessary for refluxing or obstructive/refluxing megaureter or posterior urethral valves (PUV) with the VURD ("valves, ureteral reflux, renal dysplasia") syndrome and a nonfunctioning kidney to prevent recurrent infections in the remnant ureteral stump. Less commonly, nephrectomy may also be necessary for Wilms' tumor, although robotic-assisted laparoscopic nephrectomy for Wilms' tumor has not been reported. While laparoscopic nephrectomy generally is straightforward in children, robotic-assisted laparoscopic nephrectomy allows individuals developing a robotic pediatric program to develop their robotic skills and achieve a comfort level, as well as familiarize the robotic team with the unique aspects of robotic surgery in children. However, in situations with previous renal surgery, robotics allows the identification and development of tissue planes around the kidney more accurately than with conventional laparoscopic surgery.

Heminephrectomy is most commonly performed for a nonfunctioning hydronephrotic upper or lower pole moiety of a duplicated system or localized multilocular cystic nephroma. Children with an abnormal duplicated upper urinary tract are ideal candidates for robotic-assisted laparoscopic surgery. The primary conditions include ectopic ureter, ectopic/orthotopic ureterocele, and vesicoureteral reflux. In girls, an ectopic ureter drains into the bladder neck, urethrovaginal septum, or vagina (approximately one-third each). If the ureter drains into the bladder neck, typically the affected ureter is obstructed at rest but refluxes during voiding. If the ureter drains into the distal urethra or vagina, it does not reflux. Most of these ectopic ureters are obstructive and associated with upper pole hydroureteronephrosis. In boys the ectopic ureter typically drains into the prostate, bladder neck, or seminal vesicle. If there is complete upper urinary tract duplication, when the upper ureter drains into the bladder, at times there is vesicoureteral reflux into the lower pole ureter. Management generally is based on the function of the affected moiety. If there is nonfunction, then the moiety is removed, whereas if there is satisfactory function to that portion of the kidney, a ureteroureterostomy may be performed, anastomosing the upper pole ureter to the nonobstructed lower pole ureter, in the case of an ectopic ureter or the refluxing lower pole ureter into the normal upper pole ureter.

Operative Setup

The operative room setup is similar for the three procedures with minor modifications (Fig. 61.1). The surgical assistant helps the surgeon with

Fig. 61.1 Positioning for child undergoing robotic renal procedure. (**a**) Positioning for left renal procedure. Note left arm secured parallel to spine; (**b**) Different patient. Child should be in 15–45° lateral decubitus. Note left arm resting on gel pad. (**c**) da Vinci robot rolled in behind patient. (**d**) Assistant positioned in front of patient between anesthesia equipment (at *head of table*) and robotic equipment (at *foot of table*)

organ retraction, changing instruments, and introducing and cutting sutures. Individual video monitors for the assistant and nurse facilitate smooth progress of the surgical procedure, as everyone involved can monitor the procedure. The lowest electrocautery settings that provide adequate cutting/coagulation should be used. Higher settings may cause the current to dissipate and cause damage to adjacent tissues. The robot is docked from the patient's shoulder along a line from the kidney to the umbilicus.

(a) Patient Positioning

Small children present challenges to positioning, require individual customization, and sometimes use novel techniques to provide optimum position. The patient is placed at 60–90° lateral tilt using a foam or gel wedge or folded blanket to provide posterior support. A rolled-up blanket is placed below the flank to simulate the effect of the kidney bridge to "prop up" the kidney. A Foley catheter is left in place during the procedure. *It is important to bring the patient to the very edge of the table to facilitate movements of the robotic arms and the assistant's instruments.* The child's hips and shoulders need to be secured carefully to the table.

(b) Trocar Configuration

Trocar placement is critical and needs to be individualized to the size of the patient. Neonates and infants have limited surface area externally for port placement. Since it is mandatory to keep a fixed amount of the cannula within the abdomen, the limited space causes two bothersome situations: (1) the camera and instruments may be too close to the target organ to permit efficient movement and (2) the cannulae may fall out of the abdomen causing loss of pneumoperitoneum and interruption of the operation. On the other hand, little patients need

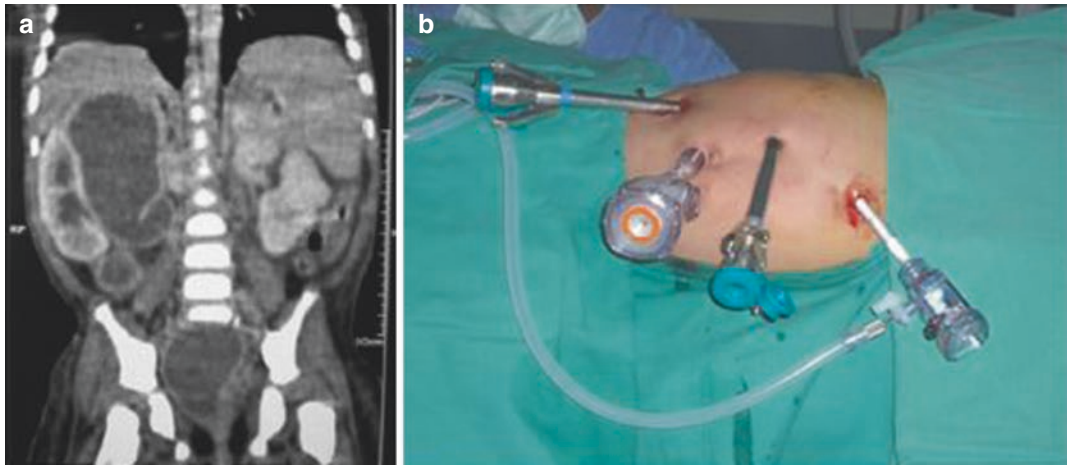

Fig. 61.2 A 16-month-old girl with duplicated right collecting system and hydroureteronephrosis of upper pole system secondary to ectopic ureter. (**a**) CT urogram. (**b**) Port positioning for right upper pole heminephroureterectomy

relatively smaller excursion of the robotic arms to reach from the upper pole to the lower pole of the kidney and the distance to the bladder is shorter than in older children, and these considerations provide some compensation for the challenging port placement. *A prudent principle is to keep the skin incisions for ports as far away from the operative site as possible to give the maximum permissible working space within the body*. This issue is less critical in older children and adolescents.

Generally a four-port template is used (Fig. 61.2); one 8.5 mm camera port at the umbilicus, two 8 mm or 5 mm robotic working ports, and one 5 mm assistant port (for clip application, suction/irrigation, introducing/removing and cutting sutures, and retraction). However, if limited bowel or liver retraction is necessary and there is limited risk of bleeding, the assistant port can be avoided.

Pneumoperitoneum is created using either the Veress needle or the Hassan technique. The initial pressure is raised to 20 mmHg for port placement (the higher pressure provides rigidity to the abdominal wall and facilitates entry of the cannula with minimal indentation of the abdominal wall). Once the ports are placed, the pressure is decreased to 10 to 12 mmHg. The camera port is placed through a midline umbilical incision; this incision heals with no visible scar, as opposed to more traditional incisions along the umbilical fold. In children, given the limited space within the abdomen, it is prudent to place the index finger along the port as a guard to prevent sudden entry and inadvertent damage to intra-abdominal organs. After surveying the abdomen with the 30° up lens, the two robotic working ports are placed such that the three ports are triangulated to the working area. For a nephrectomy or heminephrectomy the ports are centered on the hilum and triangulated to the kidney. Therefore the upper port is placed in the ipsilateral upper quadrant close to the midline and midway between the umbilicus and xiphoid while the lower port is placed in the lower quadrant 2–3 in. medial and superior to the anterior superior iliac spine. For a nephroureterectomy ports are centered on the flank and the lower port is moved more medially and inferiorly to permit access to the pelvis. The assistant port is placed in the midline infraumbilically at a suitable distance from the umbilicus to permit easy access for the assistant. In infants and small children, it is appropriate to place the two working ports in the midline.

In a retrospective series of 858 children from 8 academic institutions undergoing robotic-assisted 68% underwent an open Hassan approach and 32% underwent Veress access for insufflation. None had an access-related complication [1].

(c) Instrumentation List (Table 61.1)

Table 61.1 Instrumentation for robotic extirpative renal surgery

Surgeon instrumentation		
Right arm (yellow)	Left arm (green)	Assistant instrumentation
• Monopolar hook	• Maryland bipolar grasper	• Suction-irrigator
• Needle driver	• Needle driver	• Atraumatic grasping forceps
• Scissors		• Laparoscopic needle driver
		• Laparoscopic scissors

Step-by-Step Technique (Nephrectomy)

(a) Exposure

The steps of nephrectomy are similar to those described for adults with some important differences. A zero degree lens is used for the procedure. The intra-abdominal and perinephric fat are minimal in children and the kidneys are readily visible through the colon. An incision is made along the line of Toldt using the hook and carried inferiorly to the pelvic brim, ensuring the colon is completely reflected medially. On the left it may be necessary to incise the lienorenal ligament and reflect the spleen superiorly, especially while dissecting the superior pole of the kidney. On the right, retraction of the liver may be required in children; a 5 mm port may be placed just below the xiphoid for this purpose. Attention should be directed to the duodenum on the right as it may overlap the renal artery and vein. The lateral aspect of the kidney should not be mobilized at this point, as the fascia holds the kidney against the posterior abdominal wall.

(b) Identification of Ureter

The ureter is readily visible on the iliopsoas after the colon is reflected. It may be identified by noting ureteral peristalsis. Rarely an extremely large megaureter may cause some confusion with bowel and the inferior vena cava on the right. If identification is difficult, it may be necessary to look for it at the pelvic brim overlying the iliac vessels and trace it an upward direction. The gonadal vessels are not as well developed in children as in adults, but may be a source of confusion with the ureter.

(c) Hilar Dissection and Control

The renal vessels are apparent just below the spleen on the left and below the liver on the right. They may also be identified by tracing the ureter up to the hilum. The renal vein is usually apparent first and the artery is situated superiorly to the vein and may be hidden behind the vein. The renal artery is extremely delicate in children and vigorous manipulation (especially during partial nephrectomy) may cause vasospasm of the artery. In infants and small children, both the artery and the vein may be secured with 5 mm metallic clips. In older children it may be necessary to use the endoGIA stapler for the vein. Alternatively, the vessels may be tied off with sutures.

(d) Mobilization of the Kidney

After the renal artery and vein are clipped, the kidney is avascular and can be dissected off the posterior abdominal wall and inferiorly using the hook. The last step is dissection of the superior pole. At this point, care should be taken to identify and protect the adrenal gland. Proceeding with the dissection on the capsule of the kidney is the safest option to protect the adrenal gland. Finally, the ureter is clipped doubly and cut to deliver the specimen. The operative site should be inspected to confirm adequate hemostasis.

(e) Removal of Specimen and Closure of Ports/Skin

The specimen is removed through the umbilical camera port. An endocatch bag may be used in older children; however, it is usually too large for infants. Alternatively, a 5 mm laparoscope is introduced through a robotic port or assistant port and the ureter is held with a grasper introduced through the 8 mm cannula. The endocatch bag is inserted through the umbilical cannula, placed around the specimen, and then removed. If required, the incision in the fascia is extended

under vision. The umbilical incision is closed with a 2-0 polyglycolic acid (PGA) suture with a UR-6 needle. The 5 and 8 mm fascial incisions also are closed with 2-0 or 3-0 PGA. The skin incisions are closed with simple PGA sutures and a cotton ball dressing is placed over each incision and covered with a large transparent film dressing.

(f) Post-operative Care

The patient is admitted for overnight observation with intravenous hydration. Intravenous ketoralac 0.5 mg/kg is administered as the operative procedure is finishing, and 0.25 mg/kg is given intravenously every 6 h, with a maximum of seven post-op doses. A regular diet is resumed as tolerated. Patients are usually discharged on post-operative day 1 or 2. The transparent dressings should be allowed to fall off on their own, often after 2–3 weeks.

Other measures may reduce the need for post-operative analgesia. The port sites may be infiltrated with 0.25% bupivacaine before port insertion or during wound closure. In addition, a small retrospective study of children undergoing pyeloplasty suggested that intraperitoneal aerosolized bupivacaine reduces the need for post-operative narcotic analgesia [2].

Step-by-Step Technique (Partial Nephrectomy)

During heminephrectomy with a duplicated kidney, there are five important clinical considerations:

1. In a child with an ectopic ureter or ureterocele, there is usually upper hydroureteronephrosis, and the dilated ureter is generally easy to identify. However, it is extremely important to maintain the integrity of the normal lower pole ureter, which is adherent to the upper pole ureter. Cystoscopy is recommended at the beginning of the procedure to verify the lower urinary tract anatomy. In addition, a 3 or 4 Fr ureteral catheter may be inserted into the lower pole ureter to facilitate its identification.
2. The hydronephrotic upper pole always has a distinct artery and vein, which may arise from the aorta or the renal artery. Although they may seem atretic, almost always they need to be ligated. When these vessels are clipped, the tissue demarcation between the upper and lower poles usually becomes obvious. On the other hand, if a refluxing lower pole is going to be removed, there is often not a distinct artery and vein.
3. With an ectopic ureter or ureterocele and upper pole hydronephrosis, the upper pole ureter always passes posterior to the renal artery and vein, and these vessels will need to be mobilized to allow the dilated ureter to be passed behind them.
4. With an ectopic ureter or ureterocele and upper pole hydronephrosis, the extent of involvement is quite variable. In some cases, there is a large hydronephrotic moiety with overlying dysplastic parenchyma, whereas in other cases there is simply a dilated upper pole ureter with little overlying parenchyma. The pre-operative imaging studies should be reviewed before the operative procedure to help plan the procedure.
5. If the ureter is refluxing, then the vast majority, if not all, of the ureter should be removed during the partial nephrectomy, and it should be ligated, either with clips or with a suture ligature, or both. On the other hand, if it is non-refluxing, the ureter can be divided just below the pelvic brim and it does not need to be tied off. A caution, however, is the ectopic ureter draining into the bladder neck – these nearly always reflux during voiding – and, consequently, these ureters should be removed in their entirety and tied off.

Port placement and kidney exposure are as described for nephrectomy. The upper pole ureter is medially located at the hilum and passes posteriorly and laterally to the lower pole ureter at the lower pole of the kidney. The vascularity of the normal ureter should be protected. The dilated ureter is dissected proximally to the main renal pedicle. The pedicle is then gently separated from the underlying ureter; the hook is gentle and

helps develop this plane. The kidney should be inspected periodically to be certain that it remains vascularized. The space superior to the pedicle then should be inspected. If there is sufficient room, then the dilated ureter should be transected 2 cm below the level of the lower pole of the kidney and the ureter should be pushed behind the main renal vessels. The surgeon should then grasp the ureter above the renal pedicle. Traction on the ureter helps identify the upper pole artery and vein; until these vessels are transected, the upper pole of the kidney remains relatively fixed. The upper pole vessels are then mobilized and secured with 5 mm metallic clips or suture ligated and divided. The renal parenchyma is incised with electrocautery along the line of demarcation and any bleeding is controlled with electrocautery or suture ligature. The parenchyma generally is very thin and minimal bleeding is the norm. Once the affected pole is removed, the capsule can be approximated over the raw area with mattress sutures of 3-0 PGA and an inlay of fatty tissue can be used. It is unnecessary to drain the operative area.

Removal of the specimen and wound closure is performed as described for nephrectomy.

Step-by-Step Technique (Nephroureterectomy)

The operation proceeds as described in nephrectomy until the kidney is completely mobilized. The ureter is then dissected inferiorly to the pelvic brim. At the pelvic brim there are two structures that are encountered. First, the gonadal vessels cross the ureter from medial to lateral and should be protected. Second, care should be exercised as the iliac vessels are in close proximity to the ureter laterally. Within the pelvis the vas deferens is seen coursing across the ureter from a lateral to medial direction and should be carefully preserved. Dissection is continued until the junction of the ureter and bladder is identified. Superior traction is exerted on the ureter and a transfixation suture is placed at the ureterovesical junction. The ureter is then divided at the ureterovesical junction. At this point the entire kidney and ureter is delivered superiorly and the entire specimen is ready to be extracted.

Extraction of the specimen and closure of the abdomen are as described for nephrectomy.

Results of Heminephrectomy

Lee et al. described nine children who underwent robotic-assisted laparoscopic partial nephrectomy [3]. Mean patient age was 7.2 years. Mean operative time was 275 min. Mean hospitalization was 2.9 days. The authors did not compare their results to an open cohort. Mason et al. retrospectively reviewed 21 patients with a mean age of 4.1 years [4]. Mean operative time was 301 min. and mean hospitalization was 38 hours. At follow-up, 6/21 (29%) had a fluid collection near the upper pole, and these occurred most often when the resection defect was not closed. Most were managed non-operatively. Malik et al. reported 16 children who underwent heminephrectomy with a mean age of 37.5 months [5]. Mean operative time was 135 min and mean length of stay was 2 days. Asymptomatic cyst formation was observed in 25% and a self-limited urinoma was seen in 13%. None lost significant renal function on post-operative imaging. Kapoor and Elder demonstrated the safety of performing bilateral robotic procedures in children with a duplicated collecting system under a single anesthetic [6].

Steps to Avoid Complications

In children there is less operative room and having expert bedside assistance and pediatric anesthesia is critical, particularly in infants.

If port placement seems suboptimal, then the port should be removed and placed in a different site.

Attention should be directed to the location of the bowel, because the tip of the camera is hot and the bowel can be injured easily.

On the right side, an enlarged ureter may be confused as small bowel or the inferior vena cava.

During occlusion of the renal artery or the polar vessels, 5 mm clips may be applied. Two clips each should be placed through an assistant port proximally and distally and then the vessel may be transected. Alternatively, the main renal artery or vein may be tied off with a suture

ligature or a circular tie. In general, pediatric vessels should not be transected with a stapling device and hem-o-lok clips may slide off the vessel.

During a heminephrectomy, the main renal artery may undergo vasospasm during ureteral dissection. Application of topical papaverine along the renal artery through a small spinal needle often causes the vasospasm to subside.

Reconstructive Surgery

Pyeloplasty

Pyeloplasty is an ideal procedure to perform with robotic assistance because the advantages of the robot are most apparent; the magnification helps in visualization of the ureteropelvic junction and upper ureter, the endowristed movements permit accurate suturing of the ureter to the pelvis, and the three-dimensional vision and intuitive movements significantly decrease the degree of difficulty and hence the learning curve for this procedure. As a result, robotic pyeloplasty has become the most commonly performed robotic urologic procedure in the pediatric population [1].

Indications

The indications for robotic-assisted pyeloplasty are similar to those for open pyeloplasty. These include grade 4 (severe) hydronephrosis with reduced function or poor drainage on diuretic renography, worsening hydronephrosis, deterioration of renal function, upper urinary tract infection, and recurrent flank or abdominal pain. Infants generally need to be at least 3-months-old to accommodate the robotic instrumentation.

Operative Setup

The setup of the room is similar to that described for robotic nephrectomy.

(a) Patient Positioning and Trocar Configuration

Principles of patient positioning remain the same as described for robotic nephrectomy. The patient is placed at 60° lateral tilt using a foam wedge, gel roll, or folded blanket to provide posterior support. A rolled up blanket is placed below the flank to simulate the effect of the kidney bridge to "prop up" the kidney. A Foley catheter is inserted at the beginning of the procedure, the bladder is drained, and then the tubing is clamped to distend the bladder for antegrade stent placement during the operative procedure. Cystoscopy and retrograde pyelography rarely are necessary. In addition, insertion of a double-J stent at the beginning of the case is not advised, as it may distort the anatomy of the ureteropelvic junction and make it difficult to identify the exact location and extent of the obstructed segment.

Since the operative steps for robotic pyeloplasty are mostly directed around the renal hilum, trocar placement should be centered to this location. A three-port template is ideal (see Fig. 61.2); an 8.5 mm camera port at the umbilicus and two 5 mm or 8 mm robotic working ports. Assistant ports are unnecessary but facilitate the procedure. The handing and removal of sutures can be accomplished through a robotic working cannula. Pneumoperitoneum is achieved as described above. The ports are centered on the renal hilum and triangulated to the kidney. Therefore, the upper port is placed in the ipsilateral upper quadrant close to the midline and midway between the umbilicus and xiphoid, while the lower port is placed in the lower quadrant 2–3 in. medial and superior to the anterior superior iliac spine. An attempt is made to maintain at least 6 cm distance between the ports. However, this may not always be feasible, especially in infants. This arrangement provides an ideal working environment for both infants and older children. If the renal pelvis is extremely large, ports must be placed further away from the target area to permit smooth movement of the robotic arms.

(b) Instrumentation List (Table 61.2)

Step-by-Step Technique

(c) Exposure

Access to the kidney for pyeloplasty is achieved through a transperitoneal technique. Although retroperitoneal access for laparoscopic pyeloplasty

Table 61.2 Instrumentation for robotic pyeloplasty

Surgeon instrumentation		
Right arm (yellow)	Left arm (green)	Assistant instrumentation
• Monopolar hook	• Maryland bipolar grasper	• Laparoscopic needle driver
• Needle driver	• Needle driver	• Laparoscopic scissors
• Scissors		

is described in children, the authors used 5 mm camera and 3 mm instruments. Given the bulkiness of the robot and the limitation of a larger camera port (8.5 or 12 mm), this approach is not feasible in children with robotic assistance. The ureteropelvic junction may be approached in one of two ways. *On the left side, the renal pelvis may be approached through the mesocolon.* Division of mesocolic vessels should be avoided. Advantages include obviating the need for colonic dissection and possibility of bowel injury; however, the disadvantage may be inadequate exposure for sufficient ureteral dissection to provide a tension-free anastomosis. *On the right side and in older patients with more mesenteric fat it is usually necessary to mobilize the colon by incising along the line of Toldt.*

(d) Identification of Renal Pelvis and Ureter

The dilated renal pelvis is readily visible, although it may be decompressed if a ureteral stent has been placed pre-operatively (Fig. 61.3).

The renal pelvis is dissected and isolated and is carried down to identify the UPJ and the ureter. Attention is directed to the presence/absence of a crossing vessel and these should be carefully preserved. It is often helpful to place a "hitch stitch" percutaneously through the flank using a 4-0 monofilament suture on an SH or RB-1 needle. The needle is straightened to simulate a Keith needle, passed through the flank, grasped by the surgeon, passed through the upper renal pelvis, and then back through the flank, where it is grasped by the assistant. The hitch stitch allows counter-traction for the surgical mobilization of the UPJ and the pyeloplasty. The ureter should be dissected for 2–3 cm to provide for a

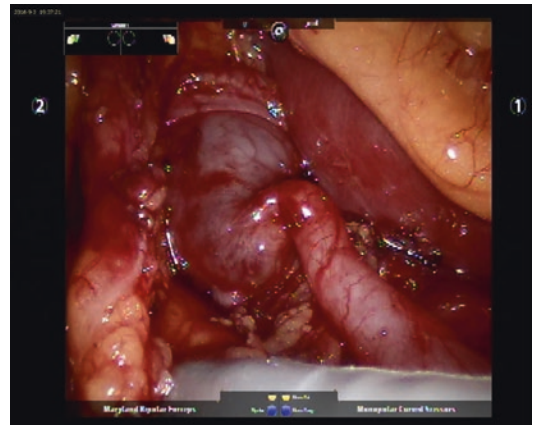

Fig. 61.3 Robotic view of left ureteropelvic junction obstruction without a crossing vessel

tension-free anastomosis. It is preferred to hold the periureteral tissues and not the ureter directly while this dissection proceeds to avoid devascularization of the ureter. After the renal pelvis and ureter are well mobilized one may proceed to the reconstruction.

(e) Excision of Redundant Pelvis and Pelviureteral Anastomosis

Several techniques for pyeloplasty are described and the choice in an individual patient depends on the presence of crossing vessels, configuration, and size of the renal pelvis. Anderson–Hynes dismembered pyeloplasty is preferred because it permits excision of the redundant renal pelvis, excision of the abnormal UPJ segment, and transposition of crossing vessels. The lateral wall of the renal pelvis (which is oriented anteriorly) is divided first at the superior margin and carried downward to the lower border. This maneuver exposes the interior of the pelvis and the lateral wall (which is posteriorly oriented); this can then be divided, leaving the excess renal pelvis attached to the ureter. Leaving the pelvis attached to the ureter has two advantages: it helps to maintain the orientation of the ureter, preventing twisting and spiraling of the ureter and it provides a handle to hold the tissues while placing the first anchoring stitch at the apex of the ureter. If there is significant redundancy to the renal pelvis, trimming is recommended, because leaving a

large renal pelvis may cause the reconstructed UPJ to kink post-operatively. The ureter is then spatulated until normal ureteral mucosa is identified (usually 2–3 cm).

(f) Pelviureteral Anastomosis and Stent Placement

The anastomosis should be performed with a monofilament suture. The anchoring stitch is placed first; a 5-0 or 6-0 PDS on an RB-1 needle is used to approximate the apex of the spatulated ureter to the most dependent part of the dismembered pelvis. The needle travels from outside in on the pelvis and then from inside out in on the ureter thereby placing the knot on the outside. *Care must be exercised at this step to ensure that the ureteral mucosa has been included in the stitch and that the back wall of the ureter has not been inadvertently included*. At this point the redundant renal pelvis and abnormal segment of ureteropelvic junction and ureter are excised. The medial wall of the renal pelvis is first approximated to the medial wall of the ureter and the suture tied to itself.

The ureteral stent is placed in an antegrade fashion prior to approximation of the lateral wall. A 14 G angiocath is introduced through the abdominal wall in the region of the upper quadrant and a 0.028″/0.035″ guide wire is threaded through the angiocath into the peritoneal cavity. The surgeon threads the guide wire through the anastomosis into the bladder and an appropriate stent is threaded over the guide wire. The appropriate stent length in centimeters generally is 10+ age in years (i.e., in a 4 years old, the stent should be 14 cm). The guide wire should be marked at this level, so that the surgeon can determine when the appropriate length of wire has been inserted. Next, the stent is passed over the guide wire, with the aid of the pusher. The Foley catheter in the bladder should have been clamped at the beginning of the case, and the surgeon should visualize urine coming back into the operative field. Injection of methylene blue into the bladder makes it obvious that urine is coming back, implying that the tip of the stent is in the bladder, but this is not a critical step. Intraoperative sonography has been described to image the stent within the bladder [7]. Another 5-0 PDS suture is then used to approximate the lateral wall of the ipsilateral pelvis to the lateral wall of the ureter. Any remaining renal pelvis is then sutured together. Drains are not recommended routinely, because of the stent and the fact that the pyeloplasty is transperitoneal.

(g) Closure of Ports

The excised segment of renal pelvis and UPJ are removed and may be sent for histopathological examination and the cannulae removed. The fascia of the 8.5 mm camera incision is closed with a 2-0 PGA figure-of-eight stitch, the fascia for the operative ports is closed with 3-0 PGA. The skin incisions are closed with simple PGA sutures and a cotton ball dressing is placed over each incision and covered with a large transparent film dressing.

(h) Post-operative Care

This is similar to that described for nephrectomy. The ureteral stent is removed 4–6 weeks later.

Results

Robotic-assisted pyeloplasty has a favorable success rate compared with open pyeloplasty. Sukumar et al. showed that the utilization of robotic pyeloplasty began to increase in 2007; minimally invasive pyeloplasty accounted for 17% of cases from 2008 to 2010 [8]. No difference in perioperative complications was noted, but length of stay was less with robotic versus open pyeloplasty. In a retrospective series of 33 children undergoing robotic-assisted pyeloplasty compared with open pyeloplasty, with a mean age of 7.8 years, operative time was 38 min less for open pyeloplasty, but analgesic requirements and length of stay were less in the robotic group, and success rate was similar in both groups [9]. Franco et al. compared a robotic-assisted pyeloplasty to a laparoscopic anastomosis and found no significant differences in operative time or outcomes in 29 patients [10]. In a comparative analysis, children undergoing robotic pyeloplasty

had a faster resolution rate of hydonephrosis compared with open pyeloplasty, and the overall success rate was similar between the two approaches [11]. In a comparison of robotic and laparoscopic pyeloplasty from 15 academic centers, Silay et al. reported that the success rates were similar, but the post-operative complication rates were higher for laparoscopic pyeloplasty [12].

Transposition of Lower Pole Crossing Vessel ("Vascular Hitch")

One of the most controversial procedures involving the upper urinary tract involves UPJ obstruction with a crossing vessel. There is evidence that in selected pediatric (as well as adult) patients with a UPJ obstruction and a crossing vessel, mobilizing the UPJ and separating it from the vessel, and then hitching the vessel to the renal pelvis, can be curative. The pathology is that the UPJ is draped over the lower pole vessel; at rest, there is normal urine transport through the UPJ, but during diuresis, the renal pelvis may become overdistended and become kinked over the vessel, creating virtually complete upper urinary tract obstruction. Traditional teaching is that these patients have both a crossing vessel and ureteropelvic narrowing. However, in a recent series of children who underwent the vascular hitch procedure and not a concurrent pyeloplasty, there was a 95% success rate [13].

Indications

Typical patients include those with intermittent severe flank or abdominal pain. Typically these children have severe hydronephrosis during a symptomatic attack, but when asymptomatic have mild to moderate hydronephrosis with thick renal parenchyma. A diuretic renogram usually demonstrates good renal function in the involved kidney, and there may be satisfactory drainage following the administration of furosemide, although it is slower than the normal kidney. Infants or patients with antenatally diagnosed hydronephrosis rarely have this finding. Intraoperatively, if the UPJ appears widely patent and the pelvis is nondistended, then the vascular hitch procedure is appropriate. Consequently, operative setup, patient positioning, instrumentation, and operative approach to the UPJ are identical to that described for pyeloplasty. Pre-operatively it is impossible to determine whether a vascular hitch procedure will be appropriate.

Step-by-Step Technique

The UPJ is typically extrarenal and a crossing vessel is identified going to the lower pole of the kidney; the vessel crosses anterior to the UPJ. Using the hook, the renal pelvis is separated from the crossing vessel. The upper 2 cm of ureter is mobilized. A hitch stitch through the superior aspect of the renal pelvis as described for pyeloplasty may be helpful. If the renal pelvis is decompressed and appears widely patent with magnification, then a vascular hitch procedure may be considered.

The lower pole vessels are mobilized carefully; vasospasm may cause devascularization of the lower pole. The renal pelvis is mobilized and the UPJ is moved away from the vessels. The vessels are then fixed to the midportion of the renal pelvis. Two techniques are appropriate. Three or four 4-0 interrupted PGA sutures can be placed between the adventitia of the vascular complex and the seromuscular layer of the renal pelvis. Alternatively, the midportion of the renal pelvis may be wrapped around the vessels with three or four 4-0 PGA sutures. No ureteral stent is necessary.

(a) Closure of Ports

Port closure is identical to that described for nephrectomy.

(b) Post-operative Care

Post-operative care is identical to that described for nephrectomy.

Results

In a series of 20 patients, Gundeti et al. [13] described their results with robotic-assisted laparoscopic vascular hitch in 20 patients, 7- to

16-years-old (mean 12.5 years); mean operative time was 90 min, and median hospital stay was 1 day. At a mean follow-up of 22 months, 19 of 20 patients were successfully treated. The single failure had recurrent flank pain and was cured by laparoscopic pyeloplasty.

Ureterocalicostomy

Ureterocalicostomy involves excision of the hydronephrotic lower renal pole parenchyma and anastomosis of the dismembered ureter directly to the lower pole calyx, providing urinary drainage. The procedure traditionally has been performed via open surgery through a flank incision or transabdominally, necessitating an extended hospital stay and convalescence. Today, with the availability of robotic assistance minimally invasive alternatives have gained popularity, with experienced centers offering these approaches preferentially as first-line therapy in appropriate patients.

Indications

Ureterocalicostomy is an attractive option for patients with UPJ obstruction *and* significant lower pole caliectasis. It is reserved for patients who have a failed pyeloplasty or those with a predominantly intrarenal pelvis. It is also an attractive option for patients with a long upper ureteral stricture that precludes tension-free anastomosis to the renal pelvis.

Operative Setup

The setup of the room is similar to that described for robotic pyeloplasty. Cystoscopy and placement of a ureteral stent may be helpful in patients with previous failed pyeloplasty.

(a) Patient Positioning and Trocar Configuration

Principles of patient positioning and trocar configuration remain the same as described for robotic pyeloplasty.

(b) Instrumentation List (Table 61.3)

Table 61.3 Instrumentation for robotic ureterocalicostomy

Surgeon instrumentation		
Right arm (yellow)	Left arm (green)	Assistant instrumentation
• Monopolar hook	• Maryland bipolar grasper	• Suction irrigator
• Needle driver	• Needle driver	• Atraumatic grasping forceps
• Monopolar scissors		• Laparoscopic needle driver
		• Laparoscopic scissors

Step-by-Step Technique

(a) Exposure

A transperitoneal approach is used and the renal pelvis and ureter are approached by mobilizing the colon. In children with a failed pyeloplasty, there may be intraperitoneal adhesions and a Hassan technique may be preferred to avoid injury to bowel during establishment of pneumoperitoneum. Also, in those undergoing reoperation the renal anatomy and orientation may be altered and this should be considered when the kidney, UPJ, and ureter are mobilized.

(b) Identification of Renal Pelvis, Ureter, and Lower Pole

The hydronephrotic kidney is readily visible on entry. The renal pelvis is isolated and dissected and the dissection is carried down to identify the fibrotic UPJ and the upper ureter. A long segment of normal ureter should be mobilized to facilitate a completely tension-free anastomosis. If there is significant fibrosis from prior surgery, it may be necessary to identify the virgin segment of ureter at a lower level and trace the same back to the UPJ and pelvis. The lower pole of the kidney is also mobilized circumferentially.

(c) Transection of the Ureter and Lower Pole Segment

The ureter is tied and transected below the region of fibrosis and the normal ureter is widely

spatulated. A segment of the lower pole of the kidney is then excised with monopolar scissors or the hook to expose the dilated lower pole calyx. As for the ureter, a wide opening should be made in the lower pole calyx to provide for a wide anastomosis and prevent stricture formation. In the presence of significant hydronephrosis, the lower pole parenchyma is thin, bleeding is minimal, and bovie coagulation suffices for hemostasis. As described for pyeloplasty, a holding stitch may be placed on the anterior surface of the lower pole to provide retraction and separation of the mucosa during anastomosis.

(d) Ureterocalyceal Anastomosis and Stent Placement

5-0 PDS on a RB needle is used to approximate the apex of the spatulated ureter to the most dependent part of the dismembered lower pole calyx and the knot is placed on the outside as described for robotic pyeloplasty. *Care must be exercised at this step to ensure that the ureteral mucosa has been included in the stitch and that the back wall of the ureter has not been inadvertently included.* The anastomosis is then continued using interrupted stitches approximating the calyx to the lateral wall of the ureter. Once the lateral half of the anastomosis is completed, the ureteral stent is placed in an antegrade fashion as described in the section on robotic pyeloplasty. The remaining portion of the anastomosis is then completed using interrupted stitches. On completion of the anastomosis, a segment of omentum may be used to reinforce the anastomosis. Drains are unnecessary.

(e) Closure of Ports and Post-operative Care

This is similar to that described for robotic pyeloplasty. The ureteral stent is removed 6 weeks later.

Results

Past results with open ureterocalicostomy were fair, approximately 67% success, significantly lower than with pyeloplasty. These results were due in large part to challenging case selection. Casale et al. reported on nine children, 3–15 years old (mean 6.5 years) who underwent robotic-assisted ureterocalicostomy [14]. Of the patients, six had undergone a previous pyeloplasty, while three had an exaggerated intrarenal collecting system not amenable to standard dismembered pyeloplasty. Two of the patients underwent concurrent pyelolithotomy. Mean operative time was 168 min for the ureterocalicostomy portion. Mean post-operative stay was 21 h. Diuretic renography was performed at 6 and 12 months and was satisfactory in all patients.

Robotic Pyelolithotomy

Indications

Although extracorporeal shock wave lithotripsy and ureteroscopic or percutaneous extraction and/or lithotripsy are the gold standard for treatment of renal calculi in children, there are situations in which robotic-assisted laparoscopic pyelolithotomy may be particularly efficacious. Potential indications include obstructive or symptomatic cystine stones, concomitant calculi, and UPJ obstruction, and large renal pelvic calculi deemed not suitable for PCNL, such as the infant kidney [15]. Calyceal calculi can be retrieved using flexible ureteroscopy introduced through the 8 mm cannula and guided using the robotic instruments .

Operative Setup

This setup is identical to that for robotic pyeloplasty.

(a) Patient Positioning and Port Placement

Patient positioning and three-port template used are similar to that described for robotic pyeloplasty.

An additional 5 mm assistant port may be helpful to provide traction/retraction and suction/irrigation, especially in cases with a history of recurrent pyelonephritis. In addition, an assistant port is ideal for extraction of the calculus after the surgeon has removed it from the renal pelvis.

Table 61.4 Instrumentation for robotic pyelolithotomy

Surgeon instrumentation		
Right arm (yellow)	Left arm (green)	Assistant instrumentation
• Monopolar hook	• Maryland bipolar grasper	• Laparoscopic needle driver
• Needle driver	• Needle driver	• Laparoscopic scissors
• Monopolar scissors	• Atraumatic grasper	• Flexible ureteroscope

(b) Instrumentation List (Table 61.4)

Step-by-Step Technique

(a) Exposure

A transperitoneal approach is used as described for pyeloplasty, and the renal pelvis and ureter are approached by mobilizing the colon. On the left side, a transmesenteric approach can be considered.

(b) Identification of Renal Pelvis, Ureter, and Lower Pole

The ureter is identified overlying the psoas muscle and followed superiorly to the renal pelvis. Gerota's fascia is incised to identify the renal pelvis, which is located lateral to the artery and vein and requires careful dissection to separate the overlying fat. The fat may be adherent to the pelvis if there has been prior episodes of pyelonephritis, and some bleeding may be encountered while mobilizing the pelvis.

(c) Pyelotomy and Extraction of Calculi

A traction suture with 4-0 PGA on the superior aspect of the renal pelvis should be considered. A U-shaped incision is made on the renal pelvis extending from the inferior to the superior calyx. The calculus is visualized in the renal pelvis and if necessary gentle probing with the Maryland forceps within the pelvis may be necessary to sound the stone and retrieve it. In patients with multiple calculi a 7.5 Fr flexible ureteroscope is introduced through the assistant port and guided with the help of atraumatic robotic graspers into the renal pelvis. The pelvis and calyces are visualized to confirm that all calculi have been removed and if necessary a stone basket may be utilized to remove small calculi within the calyces. In selected cases an intraoperative x-ray may be considered to confirm that the kidney is stone free. Alternatively, intraoperative sonography may be performed with the hand-held ultrasound probe.

(d) Closure of Pyelotomy

Once complete clearance of calculi is confirmed, the pyelotomy is closed with interrupted sutures of 4-0 or 5-0 PGA on an RB-1 needle. It is not necessary to place a ureteral stent. Gerota's fascia is approximated over the renal pelvis to complete the procedure.

(e) Closure of Ports and Post-operative Care

This step is identical to that described for robotic pyeloplasty.

Results

There are few reports of robotic-assisted pyelolithotomy in children. Lee et al. described five adolescents, mean age 16.6 years, who underwent robotic pyelolithotomy [9]. Of the patients, four had a staghorn cystine stone and one had calcium oxalate calculi and concurrent UPJ obstruction. Mean operative time was 315 min and mean hospital stay was 3.8 days. The calculi were removed by a robotic grasper or by a flexible cystoscope introduced through a robotic port. One patient with a staghorn calculus underwent open conversion. Of the remaining four patients, three were rendered stone free. Ghani et al. reported four children with complex upper urinary tracts who had failed conventional endoscopic procedures or who were not candidates for endoscopic treatment [16]. In these cases, the robotic ultrasound probe was critical in locating all of the renal calculi, and the stones were removed with a combination of pyelolithotomy and nephrolithotomy.

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Robotic Surgery for Vesicoureteral Reflux and Megaureter

62

Craig A. Peters

Abstract

The evolution of minimally invasive surgery in pediatric urology has slowly moved towards reconstructive surgery for vesicoureteral reflux and megaureter surgery. Robotic technology has permitted this to potentially become a key element in the surgical armamentarium, yet the technical procedure remains incompletely defined. This chapter presents the basic surgical techniques, current results as well as a discussion of may limitations in methods that potentially contribute to the variable results reported in the literature to date.

Keywords

Vesicoureteral reflux · Robotic surgery · Children · Megaureter surgery

Introduction

The emergence of robotic technology in pediatric urology has been a steady but relatively slow expansion of capabilities and indications. While robotic pyeloplasty has become well-established, surgery for vesicoureteral reflux has developed more slowly and early results have been more inconsistent. The appeal of using robotic technology for reflux management lies in the reduction in morbidity while at the same time providing the greater certainty of a durable cure than current endoscopic techniques can offer. Nonetheless it will be essential to be able to offer extremely high levels of cure rate if this is to be a useful technology for the future. Significant concern has been expressed due to inconsistent results and higher levels of complications, and this most likely reflects variable technique and nonstandard methodologies.

History

In the early days of conventional laparoscopy as applied to children, a laparoscopic extravesical ureteral reimplantation was described and used to a limited degree clinically [1, 2]. It was found to be technically very challenging and never became widely adopted [3]. Several attempts at intravesical correction of reflux using fairly nonstandard surgical methods endoscopically had limited success as well. Intravesical or pneumovesicum procedures as described by Yeung, however emerged as a possible alternative [4]. With the availability of robotic systems, both intra-and extravesical techniques were explored. Extravesical techniques were patterned after the conventional Lich-Gregoire antireflux operation [5] while

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intravesical methods used a transtrigonal Cohen technique [6]. Early results were encouraging but the technical aspects of intravesical robotic methods have continued to challenge its applicability. In recent years the extravesical technique has been used almost exclusively and several large series have reported excellent results with acceptable complication rates [7–12]. However, a recent multi-institutional study has shown success rates below 80% in terms of reflux cure, which most would consider being unacceptable relative to open surgical success rates [13]. In addition to the technical concerns, surgical management of reflux continues to evolve rapidly and the actual role of surgical correction remains in flux.

Indications

At present, robotic antireflux surgery is offered to patient's considered appropriate for surgical repair, which typically includes those with breakthrough infections despite appropriate medical management, long-term persistence of reflux when the family wants to resolve the reflux, and recurrent reflux after endoscopic or open surgery associated with infections. Individual variations for indications of course are common. We do not place any specific restrictions on utilizing robotic technology however, and patients of all ages, grades of reflux, and anatomic variations are considered candidates. As with any surgical management of reflux, all efforts are made to enhance bladder function prior to surgery and to exhaust any other medical management approaches.

The presence of bilateral reflux is not a contraindication to robotic extravesical techniques [7, 14], although it is discussed that there is a slightly higher chance of transient urinary retention necessitating recatheterization [9]. If this is particularly worrisome to the family then open surgery is offered instead.

Families must recognize that this is still an evolving technology without a large historical base of clinical outcomes. In that regard, voiding cystourethrogram continues to be strongly recommended following surgical repair with robotic technology recognizing that reported success rates have not been as high as with open surgery and to develop as large a clinical base of surgical outcomes.

Patient Preparation

Once a decision has been made to proceed with robotic antireflux surgery, patients are asked to take a liquid diet for the day before surgery and to take a laxative or suppository to debulk the rectum of any stool.

Cystoscopy is not routinely performed prior to the procedure and the patient is positioned in the supine position with the feet at the end of the bed. A rectal catheter is placed and drained into a glove on the table to decompress the rectum. Patients are temporarily frog-legged during skin preparation to allow placement of a Foley catheter in the sterile field to permit filling and emptying of the bladder during the procedure. The legs are then straightened and the abdomen draped.

Initial access to the abdomen is achieved through a curved infraumbilical incision under direct vision with a preplaced fascial box stitch using 3-0 Vicryl on a CT-2 the needle that is curved tightly to resemble a UR 6 needle. For older children, a 2-0 Vicryl on a UR 6 needle may be used. A 30° camera in the down position is initially placed and pneumoperitoneum is achieved. Two working ports are then placed in the midclavicular lines and positioned depending upon patient age. In the older child who is longer, these working ports may be placed at the bikini line to avoid visualization of the scars (Fig. 62.1) but in the infant, these need to be placed at or even slightly above the umbilical level. Each are placed under direct vision with a preplaced fascial stitch that facilitates port placement as well as port site closure. We use both the 5 and 8 mm working ports depending upon patient size and surgeon preference. With the preplaced fascial sutures the cannulas can be held in place with a Tegaderm wrapped around the suture and the cannula. The patient is then placed in the Trendelenburg position to a moderate degree to allow visualization of the retrovesical space and to move the small bowel above the sacral prom-

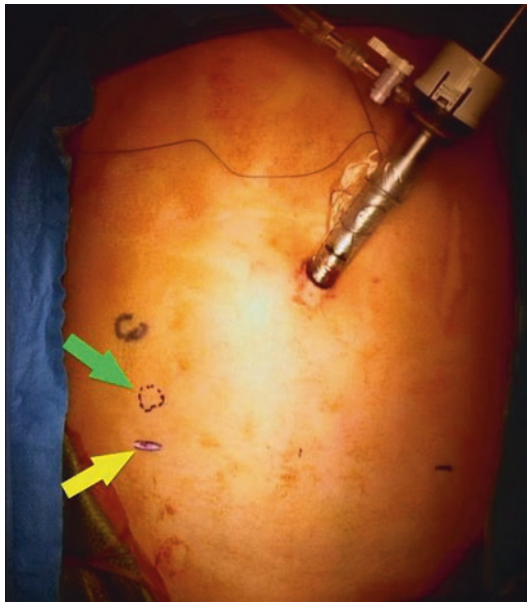

Fig. 62.1 Port placement for robotic reimplant in school age child using the HIDES technique. The skin incisions (*yellow arrow*) are below the actual fascial opening for the trocar (*green arrow*). This keeps the skin incisions minimally visible

ontory. The robot is then engaged from the base of the table. Only in the very tall adolescent would we need to split the legs or to bring the robot in from the side.

Procedural Steps

Antireflux surgery can be broken down into five steps, (1) Ureteral exposure and mobilization, (2) Bladder hitching, (3) Detrusor tunnel creation, (4) Periureteral detrusor closure, (5) Peritoneal closure and completion. Each of the steps involves different technical elements that will be discussed separately.

Ureteral Exposure and Mobilization (Figs. 62.2, 62.3, and 62.4)

Initial exposure the ureter is achieved with a transverse incision of the peritoneum as it reflects onto the back wall of the bladder. In girls this is adjacent to the uterus and in boys it is just

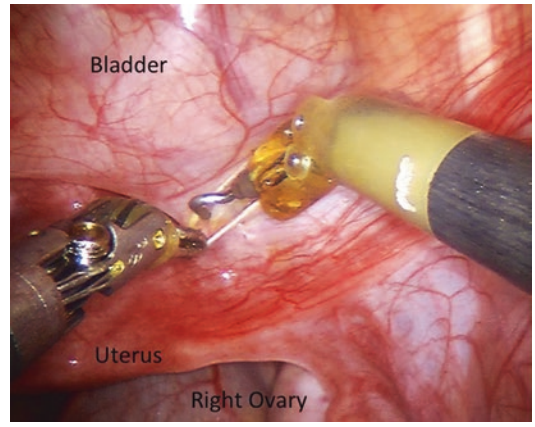

Fig. 62.2 Exposure of ureter between bladder and uterus in a girl after incision of the peritoneal reflection onto the bladder wall. Dissection should remain close to the ureter to avoid injury to nerves presumed to be important for voiding function

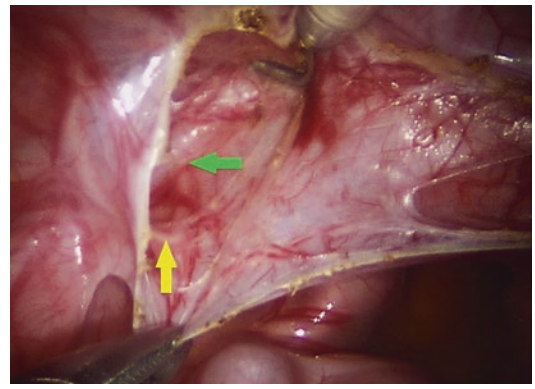

Fig. 62.3 Exposure of the ureter in a boy with the vas deferens (*yellow arrow*) mobilized with the peritoneum to prevent inadvertent injury. The ureter is indicated by the *green arrow*

above the vas deferens. Blunt dissection is then carried down toward the ureter, and its position can be identified by mentally tracing the course of the ureter from the pelvic sidewall exposure. It is useful to do a combination of blunt dissection with the Maryland dissector and hook cautery to first identify the ureter and then lift it upward to complete the mobilization. Care needs to be taken to avoid the uterine vessels, although sometimes these cross directly over the ureter and need to be sacrificed for exposure and creating a tunnel. Extensive dissection away from the ureter should be avoided to limit any nerve

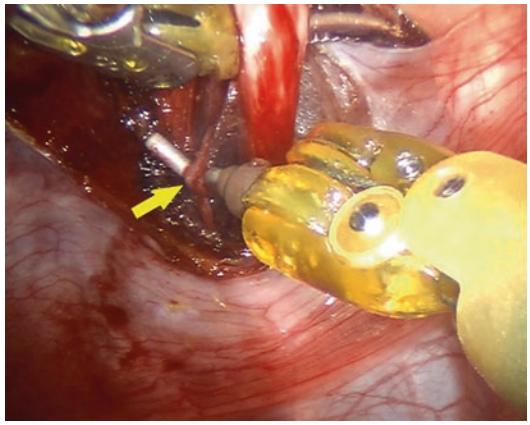

Fig. 62.4 The ureter mobilized to permit inclusion within a submucosal tunnel—about 5–6 cm length. Care is taken to limit dissection too close to the ureter as well as too far away. The *yellow arrow* indicates mobilization and cautery transection of a small vessel from underneath the ureter

injury and subsequent detrusor dysfunction [7]. In boys, the vas is left attached to the peritoneum, which is swept caudally to keep it away from the area of dissection. It should always be monitored during the rest of ureteral mobilization. Initial mobilization of the ureter occurs just proximal to the hiatus and then moves further proximally with a combination of sharp and blunt dissection with the hook cautery. Great care needs to be taken to avoid excessive mobilization into the ureteral adventitia which risks vascular injury or ureteral perforation [15]. The ureter should be free enough to be brought up onto the back wall the bladder for approximately 2-1/2 or 3 cm. There will be some tension but this will be relaxed once the bladder drops back down onto the ureter. The ureter is dissected and freed of attachments down to the level of the hiatus, which is important to facilitate appropriate creation of the detrusor tunnel.

We have not routinely used a ureteral stent although some have described doing this. We do not feel a stent is necessary for identification, mobilization, or postoperative drainage. In the unusual situation of a ureteral reimplantation of a solitary kidney, a double-J stent would be left in place. For tapered megaureters which will be described later, a double-J stent is left in place as well.

Bladder Hitching (Fig. 62.5)

In order to facilitate creation of the detrusor tunnel, we found that the bladder hitch stitch is extremely valuable and easy to place. For both unilateral and bilateral procedures, a two point fixation stitch is used. With the bladder empty a 3–0 Vicryl suture on an SH needle is passed on the right side above the pubis into the peritoneum under direct vision, coming into the peritoneum adjacent to the obliterated umbilical artery. It is then pulled into the abdomen enough to place a stitch and the bladder is grabbed on the right side just above and lateral to where the right tunnel would be placed. The stitch is then wrapped around itself to provide friction and then a second bite is taken on the left side in a comparable position above and lateral to the detrusor tunnel. It is also wrapped around itself and then passed out the abdomen on the left side suprapubically and grasped externally. Both limbs are then lifted simultaneously to lift the back wall of the bladder and pull it laterally. By looping the sutures around themselves, the fixation points do not come together but remain apart. This puts the back wall on tension as well as lifting it upward for better visualization. The camera angle can be changed to a 30° up position and the bladder is partially filled to create wall tension.

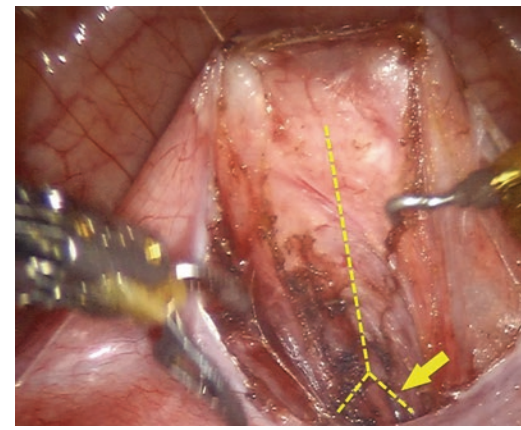

Fig. 62.5 Placement of the hitch stitch to facilitate exposure of the posterior wall of the bladder in creation of the detrusor tunnels (*yellow dashed line*). Two-point fixation permits both vertical and lateral stretching of the bladder wall, which aids in tunnel creation. The ureteral hiatus is indicated by the *yellow arrow*

Detrusor Tunnel Creation (Fig. 62.6)

The detrusor tunnel can be marked out prior to lifting the hitch to allow it to be lined up with the mobilized ureter to limit any angulation. Once the hitch stitch is tightened, the detrusor is incised using the hook cautery and the muscle is cut part way to the mucosa. We initially identify the depth of the mucosa at the upper or proximal portion of the tunnel having incised the muscle for about 1 cm in length. This may need to be a little longer in a thicker walled bladder. Using the combination of tension from the Maryland dissector and hook cautery as well as incision with cautery, the muscle fibers are separated until the bluish mucosa is seen. We then carefully dissect between the mucosa and the muscle separating the layers and incising the muscle with cautery. This can be performed with the hot shears but their tips are sharp and can pierce the mucosa more easily. As the dissection moves inferiorly and toward the ureteral hiatus, the muscle is pulled and the mucosa pushed away from it. This then allows us to carefully incise the muscularis. We also develop muscular flaps by pushing the mucosa away from the incised muscle. This can usually be done satisfactorily on one side to provide enough mobility. As the hiatus is approached, the muscle fibers are more adherent to the mucosa but these do need to be incised. The muscle is then incised in an inverted Y pattern around the actual insertion of the ureter. The ureter is usually not encircled although some do choose to do so. Muscle flaps are developed around the hiatus as well to permit closure. Use of laser energy has been described in creating the detrusor tunnel [16].

During creation of the detrusor flaps, the bladder can be decompressed slightly to prevent the mucosa from bulging excessively and possibly being injured. If the mucosa is punctured, bladder fluid will drain and limit further cauterization so the mucosal defect is closed. This is done with a 5–0 chromic suture on a tapered needle with a figure-of-eight stitch. This is usually watertight. Care needs to be taken to avoid tearing the mucosa further with placement of these sutures.

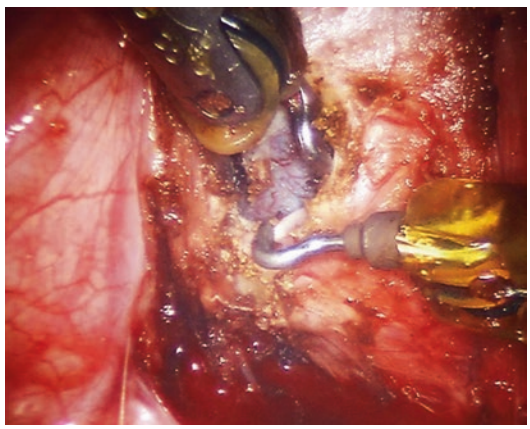

Fig. 62.6 Creation of the detrusor tunnel using cautery and blunt dissection. It is important to maintain tension on the tissues and carefully watch the fibers separate to avoid injury to the mucosa of the bladder

Periureteral Detrusor Closure (Figs. 62.7 and 62.8)

To create the Lich-Gregoire flap valve mechanism, the detrusor muscle flaps are wrapped around the ureter. The author's preference is to do this from the top down which brings the ureter into the tunnel and secured with a single stitch through the muscle at what is the proximal portion of the tunnel [17]. Placing the first stitch can be difficult because of the tension on the ureter. The technique we have found useful

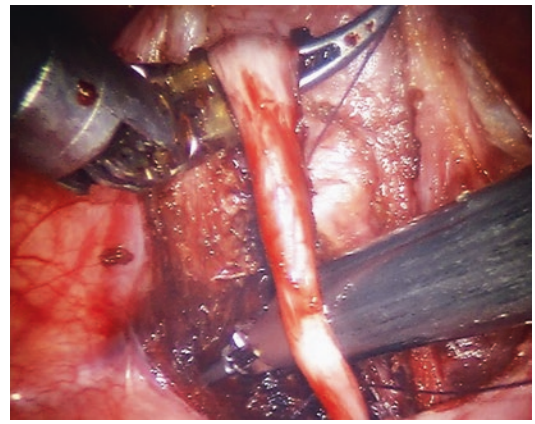

Fig. 62.7 Moving the ureter into the detrusor tunnel and placement of the first stitch to close the tunnel at the superior aspect. This facilitates subsequent suture placement

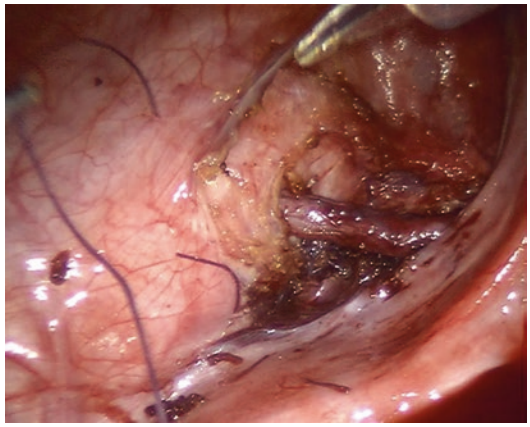

Fig. 62.8 Completion of the tunnel; this typically uses 6–8 interrupted sutures. A running suture is used by some surgeons, yet this seems risky considering the entire repair depends upon this one suture holding in muscle

is to use a 4–0 Vicryl suture on an RB-2 needle passed through the muscle flap at the upper portion of the tunnel leaving enough room for the ureter to pass through, and then to the opposite muscle flap. It is then brought back underneath the ureter and the left-handed instrument with the Maryland dissector lifts the ureter up into the tunnel and holds it in place while the right-handed needle driver creates the knot by looping around the Maryland which then grasps the tail of the suture. The knot is tied tightly by pulling down on the suture with the right hand and lifting upward with the left which keeps the ureter in the tunnel and closes the tunnel with a surgeon's knot. The left hand is then brought out from under the ureter and the knot is completed. Vicryl with a surgeon's knot usually does not slip. Interrupted sutures are used to close the tunnel since these are muscular sutures and not fascial sutures. Failure of one of the knots in a running suture could mean failure of the entire tunnel. We typically use 6–7 sutures which spans 2.5–3.5 cm in most children. With the ureter already within the tunnel, all of the sutures can be placed from one side of the ureter avoiding the need to pass the needle underneath and below the ureter. We close the muscularis over the hiatus to ensure integrity of the tunnel. A fixation or advancing stitch is not routinely used although some do describe this.

For bilateral procedures, each detrusor tunnel is created and then the two ureters are brought into the tunnels. After completion of closure the tunnels, the bladder is filled to make sure that the ureters are not angulated.

Peritoneal Closure and Completion

Although optional, the peritoneum is usually closed with a running 4–0 Vicryl suture with the bladder partially full. If there has been leakage of urine then this is aspirated and the pelvis irrigated. Following a brief inspection of the peritoneum to identify any inadvertent injuries, the working ports are removed and the preplaced fascial sutures are closed. The pneumoperitoneum is evacuated through the umbilicus and that port site is closed similarly. Subcutaneous tissues are closed with Vicryl and the skin is closed with subcuticular Monocryl suture and a dry sterile dressing applied.

For routine unilateral cases, a bladder catheter is not left in place postoperatively but for bilateral procedures, a bladder catheter is left in place overnight.

Postoperative Management

Patients are allowed to resume oral intake immediately after the procedure and are encouraged to be out of bed on the day of surgery. Analgesia is provided through a combination of ketorolac and narcotics as needed for breakthrough pain. Oral acetaminophen or ibuprofen are then used for the next one to 4 days. If a bladder catheter was left in position than it would be removed the following morning and once the patient is managing self-hydration, voiding and comfortable, they may be discharged home. We limit vigorous activity for 1 week and then encourage a gradual return to activity over the second week.

Follow-up imaging includes a renal ultrasound in 4–6 weeks to confirm satisfactory drainage of the affected kidney and a voiding cystourethrogram or radionuclide cystogram is obtained in 3–4 months to confirm reflux resolu-

tion. Some authors have suggested that this is not necessary [18], however given the immaturity of this technology, as well as relatively inconsistent recent results, we still recommend the studies. Further follow-up would be similar to open surgery for reflux.

Megaureter Repair

Robotic repair of obstructed or refluxing megaureters is a novel application of this technology with only anecdotal experience to date [19]. As with open surgery, our preference is to perform an excisional tapering of the ureter to provide for a more normal caliber ureter for reimplantation. The imbricating or plication techniques have not been performed robotically by the author.

Surgical setup for a megaureter repair is identical to that for ureteral reimplantation however the port sites should be placed somewhat higher to allow for ureteral mobilization at least up to the level of the iliac vessels. The ureter is exposed more widely by incising the peritoneum but only mobilizing the distal portion to avoid devascularization.

After exposure of the ureter, the bladder is hitched in a similar fashion for reimplantation and a detrusor tunnel is developed in the same manner. The ureteral hiatus is dissected circumferentially and will eventually be excised. Detrusor flaps are developed on both sides of the tunnel to be able to encompass the larger than normal, albeit tapered ureter.

At this point the exposed ureter is tapered. A preplaced 6 or 7 Fr double-J stent is used to guide the degree of excisional tapering. The ureter is incised longitudinally from the iliac vessels to the hiatus on the anteromedial aspect. The segment of ureter to be excised was determined by approximating the amount of ureter to remain and another longitudinal incision is made from proximal to distal, leaving a segment of ureter to be tapered. The segment to be excised is not removed but is used to provide traction through a ureteral hitch stitch. The ureteral hitch stitch passed through the anterior abdominal wall just suprapubically on the opposite side of the ureter and then passed through the distal base of the segment of the ureter to be removed and then back out the abdomen. As shown in the figure, traction on this will straighten and stabilize the remaining ureter for tapering.

The ureter then is tapered with a running 5–0 Monocryl suture (Fig. 62.9) after lifting adventitial flaps which are laid over the closure and tacked in place with interrupted or running 6–0 Vicryl suture. The length of the ureter is then determined and the ureter is transected to excise the obstructive segment. The distal segment of the ureter with a traction stitch is then excised from the bladder and the ureter is anastomosed to the mucosa. A mucosa to mucosa interrupted anastomosis is performed with 5–0 Monocryl suture, usually using 6–7. The anastomosis is performed around the stent which is placed back into the bladder under direct vision. The stent will remain in place for postoperative drainage.

The tapered ureter, now anastomosed to the bladder is then mobilized into the tunnel and the tunnel closed over it to create an antireflux mechanism in the same manner as with a routine ureteral reimplantation. The larger tapered ureter with the stent is somewhat stiffer and sometimes the bladder hitch stitch needs to be relaxed to permit sufficient mobilization.

The ureteral stent is left in place with an extraction string to permit removal in the clinic after 7 days. Follow-up with an ultrasound 4 weeks after stent removal is necessary to assess

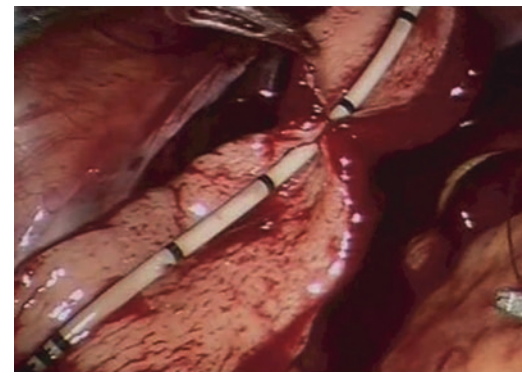

Fig. 62.9 Repair of a megaureter. The excess ureteral wall has been excised and the ureter is being tapered over a ureteral stent in two layers

drainage and a diuretic renogram is used depending on clinical indications. A voiding cystourethrogram is also obtained 3–4 months following surgery to confirm the absence of reflux.

Complications

The principal complications specifically associated with robotic reimplantation relate to ureteral injury or devascularization, as well as bleeding and failure to resolve the reflux. The reported incidence of these complications has been variable, but in some series seems much higher than with open surgery [13]. This is particularly so with regard to reflux persistence. Several cases of ureteral perforation and necrosis have been reported, which is most likely due to overly aggressive mobilization of the ureter. It is critically important to constantly be thinking about the degree of mobilization and potential devascularization as the ureter is being exposed. Any obvious or suspected thermal injury is best managed by placement of a double-J stent immediately after the procedure or even directly during the procedure. Postoperatively having a low threshold for evaluation of possible obstruction or urine leak is wise. Management of these problems is similar to any distal ureteral injury, including retrograde stent placement if possible, and proximal diversion if necessary. Even with proximal diversion, antegrade stent placement should be attempted in order to avoid a possible stricture.

Persistent reflux has been described in up to 23% of reported cases [13], but it remains unclear why the procedure has failed. The likely possibilities include a short detrusor tunnel, failure of the tunnel closure, or unrecognized severe voiding dysfunction. It is possible that ultimate success will be achieved with time and maintaining adequate voiding.

Other complications can include bladder urine leak to perforation during dissection, and this is best managed with an indwelling bladder catheter. Inadvertent injury to intra-abdominal contents is a complication associated with any intra-abdominal robotic procedure, and is described elsewhere. While working in the pelvis for reimplantation surgery, keeping the rectum decompressed with a rectal tube and always maintaining visualization of the instruments are important preventive elements.

Clinical Outcomes

Early reports of extravesical ureteral reimplantation surgery performed robotically were expectedly positive. In the few comparative series, patients appeared to recover more quickly and have less post-operative morbidity, with equivalent surgical outcomes [9, 18, 20]. Clinical applications slowly increased but subsequent reports from several centers have shown less encouraging results in terms of reflux resolution, and a higher incidence of complications, particularly ureteral injuries. Several recent publications have raised the question as to the true efficacy of the approach. It is difficult to reconcile the variability in outcomes as reported, although some authors are not performing routine post-operative voiding cystourethrograms to assess clinical outcomes relative to reflux, but relying on the absence of urinary infections. It is therefore difficult to truly assess the surgical results in contrast to the overall clinical ones. It needs to be borne in mind that the occurrence of postoperative urinary infections is a surrogate outcome marker of limited value, given the variability of indications for actually performing the corrective surgery. At this point in time we continue to perform routine voiding cystourethrograms after all extravesical reimplantation surgery with rare exceptions based on strong family preference. Indeed if the family is hesitant to perform a voiding cystourethrogram, we would recommend that she/he undergo open surgery with an intravesical technique. Nonetheless as shown in Table 62.1, reported clinical outcomes are rather variable and this raises a significant question as to the consistency of the technical performance of the procedure.

Having observed several surgeons performing extravesical robotic reimplantations, significant variation has been noted in terms of the method

Table 62.1 Ureteral reimplantation—extravesical

Author	Study type	Patients	Age range (years)	Success	Comment
Casale [7]	Case series[a]	41	1.3–7	97.6%	Bilateral; no retention
Marchini [8]	Case-control	20 EV/19 IV/17 open EV/20 open IV	EV mean: 8.6 Rob/6.1 open; IV mean: 9.9 rob/8.8 open	92.2% Rob/93.2% Open IV; 100% rob/94.2% Open	Multiple sub-groups, including intravesical reimplants
Smith [9]	Case-control	25 EV/25 Open EV	0.25–12	97% Rob/100% Open	3 transient retention in robotic group
Chalmers [22]	Case series	17 (6 bilat)	6.25 mean	90.9%	No retention
Kasturi [10]	Case series[a]	150	2.25–9.3	99.3%	Bilateral; no voiding dysfunction
Akhavan [11]	Case series	50 (28 bilat)	1.9–18	92.3%	1 transient retention
Dangle [12]	Case series[a]	29	3–10	80%	Grade III–V
Schomburg [18]	Case-control	20 REV/20 open EV		90% no UTI/95% no VUR	VCUG only if UTI post-op
Grimsby [13]	Case series/ multi-institutional	61 (32 bilateral)	0.6–18	72% (pts)	Nine reoperations, 10% complications
Gundeti [23]	Case series	58 (25 bilateral)	>5	67%—73%—87%	Increasing success with new technical modifications in three groups

[a]Some of the same patients included in later report

and thoroughness of ureteral mobilization, development of the detrusor tunnel, management of the ureteral hiatus, and technique for tunnel closure. In specific there is sometimes a very aggressive mobilization of the ureter that raises concern for devascularization or direct injury. In the creation of the detrusor tunnel, some surgeons have been less aggressive about incising to the depth of the mucosa and in developing flaps of the detrusor to cover the ureter. Whether this has a direct impact on the effectiveness of the transmural tunnel is unclear but it would seem preferable to dissect completely to the mucosa as is done with open surgery. Our practice has been to clear all muscle fibers from the mucosa along the entire tunnel and in an inverted V fashion around the hiatus. Some authors have described circumferential mobilization of the hiatus and then placement of a fixation or advancing stitch as previously described by Zaontz et al. [21]. We have not done this as this was not part of our routine practice with open Lich-Gregoire procedures, nor was it the practice in the large European series from past decades. When the detrusor tunnel was closed, some have used a running suture for efficiency but we have used interrupted sutures to avoid possible tunnel dehiscence. The degree of impact of any of these technical elements is uncertain but it is clear that there is inconsistency in the technical execution of this procedure and this may have a bearing on the variability in clinical outcomes.

There is too little experience with megaureter repair to be able to make any reasonable assessment of its clinical efficacy at this point, but hopefully as its use expands, some degree of consistency in execution and assessment will be present to permit an adequate judgment of its value.

Future Horizons

While the clinical indications for antireflux surgery will continue to evolve, when it is felt to be appropriate, it is likely that robotic procedures will play a substantial and increasing role. The advantage of reduced morbidity with comparable efficacy to open surgery is an appealing target. It will be necessary to achieve better standardization of the technical performance is well as postoperative assessment so that comparable results

and consistency relative to open surgery may be achieved. It is uncertain whether the reduction in morbidity can justify any reduction in efficacy. More effective promulgation and adoption of surgical paradigms will be needed to achieve this goal.

Instrumentation improvement would facilitate some aspects of this procedure. More delicate instruments with a finer ability to incise the detrusor without injury to the mucosa will make this element of the procedure more efficient. A method to hold the ureter in the tunnel during placement of the first sutures would also add to efficiency. While suturing with the da Vinci robotic system is very smooth, effective stapling devices for the detrusor tunnel could also be developed to improve technical efficiency.

While robotic intravesical antireflux procedures have not been focused on, for complex reconstructive procedures this may be a valuable option. Technical improvements are needed in terms of achievement and maintenance of intravesical access. Smaller instruments with comparable articulation to the 8 mm instruments would be of value. The potential for transvesical reconstruction of the trigone and bladder neck, particularly with complex ureteroceles, ectopic ureters or even exstrophy has significant appeal. At present however the technical limitations of the system challenge even the experienced operator.

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Robotic Surgery for Neuropathic Bladder

63

Andrew J. Cohen and Mohan S. Gundeti

Abstract

The cutting age application of robotic techniques is arguably intracorporeal pediatric bladder augmentation. While high volume centers are beginning to gain experience in intracorporeal bladder surgery in adults for oncologic applications, pediatric surgeons must apply these techniques in extremely small working spaces and in patients with complex anatomy or surgical history. Long-term results have yet to be reported, but with 5–8 year follow-up, the technique appears to have similar results to traditional open techniques. Larger, multi-center studies are required to confirm safety and effectiveness prior to widespread adoption of this complex technique. Bladder augmentation is often performed with catheterizable channels, bladder neck reconstructions and antegrade colonic enema surgery; as such a brief discussion of these topics is also pertinent to this discussion.

Keywords

Robotic augmentation · Robotic technique · Intracorporeal reconstruction · Intestinal substitution

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Introduction

The first documented case of bladder substitution with bowel was likely a child with bladder extrophy who underwent ureterosigmoigdostomy in 1852 [1]. Since then, the procedure has been refined and addended through time. Detubularized small intestine may have first been applied by Yeates [2]. Early series had very high rates of urinary retention which hindered success and widespread adoption. The concept of clean intermittent catheterization (CIC) changed all of that, and the use of augmentation increased in popularity via native urethra catheterization or continent diversions [3]. Dr. Mundy reported extremely high success rates using clam ileocystoplasty in the 1980s cementing it as the mainstay of treatment.

Shortly thereafter, laparoscopy quickly became popular in adult and pediatric surgery of all kinds [4]. Conventional laparoscopic bladder augmentation evolved allowing laparoscopic bowel mobilization and harvesting coupled with extracorporeal bowel reconstruction [5]. Conventional laparoscopic bladder augmentation is possible but not practical because of difficulties with suturing and the steep learning curve. Moreover, given many performed the bowel reconstruction in an extracorporeal manner, critics noted it was not truly a minimally invasive approach. While some experts certainly thrived, this technique did not gain traction in the general urology community [6, 7]. Over the previous

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decade, advancing experience with robotics have allowed for groups to successfully perform the procedure in a completely intracorporeal manner [8]. While follow-up data is evolving at present, robotic bladder augmentation holds promise for shorter operative times, quicker recovery, and less morbidity for patients. With the advent of intravesical botulinum toxin there is hope patients may avoid major abdominal reconstruction altogether, but data suggests symptoms revert without continued treatment [9]. As such, it is vital physicians remain up-to-date on emerging techniques for bladder augmentation which offer the chance of lifelong cure.

While laparoscopic assisted robotic augmentation cystoplasty is suitable for both adult and pediatric cases, a greater proportion of these cases are performed in the pediatric realm. Even in adults, the reasons for surgery overlap with those for pediatric patients; patients included in published series are 32 years old on average [10]. Given the paucity of data on adults, this chapter will focus mostly on patient selection, technique, post-operative management, and post-operative complications in the pediatric patient.

Common candidates for augmentation cystoplasty includes those suffering from severe neurogenic bladder. This population of patients often have underlying pathological conditions including body deformity and multiple other medical problems. Indeed most often, the cause is neurospinal dysraphism [11]. Often, they have need for multiple operative interventions to achieve social continence of urine and stool and protect the upper urinary tracts. A high degree of societal cost is associated with supporting these patients. Partially via surgical operations, it is hoped patients can ultimately care for themselves independently. Because of the high health care burden for these patients, minimally invasive surgery may be of particular benefit. Given sometimes inherent poor cardiovascular reserve, or multiple previous operations leading to adhesions and associated intestinal obstruction; any steps which may lead to decreased patient risk are advisable. Given minimally invasive approaches may lead to quicker recovery and less morbidity when compared to repeated open procedures, if proven safe and effective these approaches should become standard of care.

Patient Selection for Robotic Augmentation Surgery in Children

Patients with neurogenic bladder should ideally be tried on conservative therapy. This may include anticholinergics, intravesical botulinum toxin, and intermittent catheterization. Nonetheless, in severe cases in which surgery is being considered these efforts are unlikely to correct the problem. Patients with both low bladder capacity and high pressure characteristics are appropriate for bladder augmentation, because they have the risk of urinary tract infection and upper tract deterioration.

Preoperative evaluation should likely involve urodynamics to assess detrussor leak point pressure (DLPP). A pressure tracing indicating DLPP 40 cm H_20 or above has been associated with upper tract deterioration [12]. Moreover urodynamics will provide information regarding bladder capacity, and potentially inform the surgeon of issues that can be addressed concomitantly such as bladder neck closure or appendicovesicostomy. Renal ultrasound may demonstrates signs of hydronephrosis, which in this context may reflect reflux, upper tract deterioration, or presence of a duplex system all of which should be fully evaluated prior to any procedure. In longstanding bladder issues, often upper tract changes are secondary and may correct with treating the primary issue. By affixing additional volume to the bladder via bowel augmentation the resting capacity of the bladder is increased. Most importantly, this lowers the storage pressures of the poorly compliant bladder, protecting the upper tracts from further deterioration.

Various methods to increase bladder capacity exist, but ileum remains the most commonly used bowel segment for bladder augmentation. Depending on the expected segment, vital portions of medical history or further diagnostic testing might be prudent. Some groups have suggested autoaugmentation is suitable but long term results are inferior to bowel [13].

Historically stomach was used, but this has fallen out of favor due to concerns over hematuria-dysuria syndrome, electrolyte imbalances, and bone deminerlziation [14]. Nonetheless, for those patients at risk for short bowel syndrome it still could be considered. Indeed, this technique has been performed in a laparoscopic manner previously and likely could be approached using robotic assistance [15]. Patients must not have crohn's disease if ileum is to be used. If a history of GI maladies is suspected, gastrointestinal consultation may be advised prior to operative planning. Novel work involving demuscolizing ileum and applying an urothelial cell lining may revolutionize this field in the future, but such technologies are not available for widespread use and remain experimental [16]. Moreover, due to concerns regarding increased inherent complications via using colon its use has fallen out of favor.

General Technique of Robotic Augmentation Surgery in Children

Preparation

Setting expectations with the family is key for satisfaction. Augmentation cystoplasty, robotic or otherwise, is a major abdominal surgery with prolonged operative time and potential for 6–10 day post-operative stay with longer recovery continuing at home. Keeping the family informed during the operation at regular, preplanned intervals will assuage anxiety and strengthen the doctor-family relationship [17]. Moreover, the family must be given adequate pre-operative information to allow for parental scheduling of sibling's schooling and work responsibilities. Depending on child age, social services may be invaluable in the preoperative area to distract the patient and provide comfort. The importance of learning CIC before undergoing surgery of this type cannot be overstated [3]. Patients and their families must be capable and willing to maintain adequate and timely drainage of the reconstructed bladder to help prevent stone formation or urinary leakage, reduce patient discomfort, and maintain renal function.

There are a number of series suggesting that bowel preparation is unnecessary for children undergoing cystoplasty [18]. In terms of antibiotic coverage, perioperative antibiotics should be given within one hour of incision and preferably before. Typically, coverage of both skin pathogens and possible gram negative pathogens from bowel flora should be the primary goal. In our experience, cefazolin and gentamicin is suitable unless the patient has particular allergies. Issues related to ventriculoperitoneal shunts (VPS) have also been recently addressed and typically broadening the regimen is a logical step [19]. Moreover, some controversy exists regarding need to externalize VPS, but in most clean-contaminated operations there is minimal risk for VPS infection [20].

Once in the operating room, care should be taken to adequately position and pad the patient prior to draping. The authors experience follows, but certainly any variation which safely secures the patient to the bed and protects from robot arm collisions would be suitable [21]. The patient should be brought to the edge of the bed so the perineum is almost hanging off, to allow the robotic arms to easily reach the torso. The semi-lithotomy position may be used but the knees must be low enough to prevent contact with robotic arms. Egg-crate foam may be useful to pad the feet and allow little room for motion if using stirrups, which are often imprecisely sized for pediatric patients (Fig. 63.1).

The patient's arms should be tucked to each side, with foam below. IV's may be protected with boards, but it is best to ensure no plastic tabs will put undue pressure on the skin. Additional egg-crate can be wrapped around hands, palms facing up. Sleds, with additional foam inside, may be used to secure arms or if this causes robotic collisions a pillow case tucked under the patient and around the arms on each side may be used. Wide egg-crate securely across the chest allowing for adequate respiration may be secured to the bed to prevent the patient from sliding on the table. To protect the head one may used a mayo stand or foam. In our experience, a mayo stand hinders camera movement and we have moved away from such practice. Once secure we

lower the table to a comfortable ergonomic position for the assistant and place in Trendelenburg of 25° from horizontal.

Robotic Bladder Augmentation (Ileocystoplasty) Technique

After positioning of the patient, cystoscopy can considered with placement of open-ended ureteral catheters or stents to aid in the intraoperative identification of ureters. A Foley catheter should be placed sterilely to allow for bladder irrigation after augmentation and to help aid cystotomy. Ports should be carefully placed in the usual fashion and triangulated toward the pelvis. A 12-mm camera port is first placed using Hassan's technique through the umbilicus. We typically use a 12-mm balloon port for this purpose (Fig. 63.2). Pneumoperitonum of 12 mmHg is generally recommended. Diagnostic peritoneoscopy should be performed early to ensure ileum appears healthy of appropriate caliper, as well to ascertain the presence of appendix if concomitant mitrofanoff is planned.

In terms of additional ports, two 8-mm robotic ports are placed lateral from midline. We preferentially use 8- over 5-mm robotic instruments given differences in wrist motion and required space for such manipulation inside the body. A 12 and 5 mm assistant port for sutures and suction/retraction are placed further lateral from the robotic arms on each side (see Fig. 63.1). Prior to commencing dissection, the lower end of VP shunts could be placed in an Endopouch Retriever specimen retrieval bag (Johnson & Johnson Medical Ltd, Livingston, West Lothian, UK) to avoid contamination [22]. If this is done, it is imperative to remove the shunt from the bag once the case is complete, but before ports are removed.

For the augmentation itself, a 20-cm ileal segment must be identified approximately 15 cm proxmal to the ilealcecal valve. Premarked umbilical tape or silk can function as a measurement device, if needed. Judicious use of stay sutures, using a straight Keith needle introduced through the abdominal wall, may aid in ileal

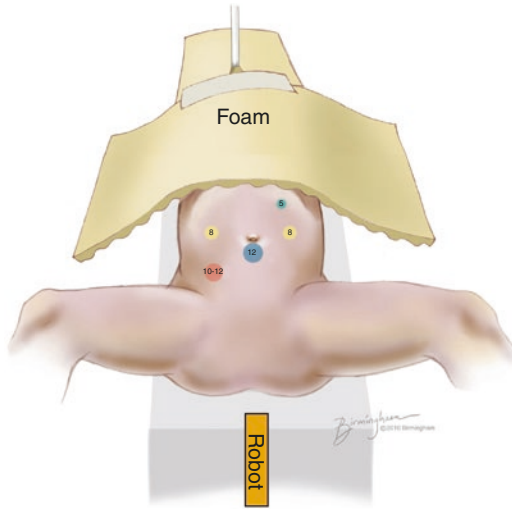

Fig. 63.1 Patient position and port placement. Reprinted from Journal of Urology, 185, Wille MA, Zagaja GP, Shalhav AL, Gundeti MS, Continence outcomes in patients undergoing robotic assisted laparoscopic mitrofanoff appendicovesicostomy, 1438–1443, Copyright 2011, with permission from Elsevier

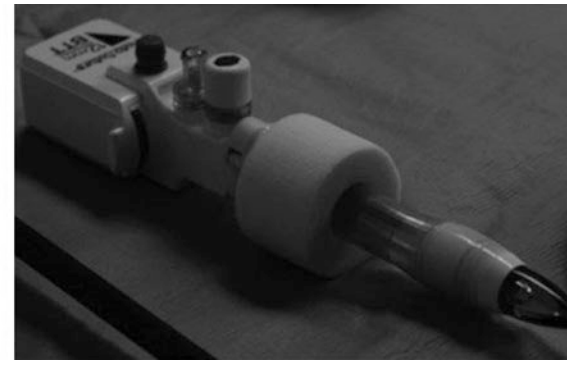

Fig. 63.2 12-mm balloon port. Adapted from Gundeti MS. Pediatric robotic and reconstructive urology a comprehensive guide. Chapter 26. Hoboken, NJ: Wiley-Blackwell; 2012: 169 with permission from John Wiley and Sons

retraction. Adequate mesentery length down to the pelvis should be ensured prior to any bowel division. An endoscopic stapler devise, which is introduced through a laparoscopic assistant port, may be useful for isolation of ileum. In our experience, we typically perform a hand-sewn anastomosis in an end-to-end fashion using running 3–0 absorbable suture in two layers and avoid the stapler device. By balancing the ileal segment on the yankauer sucker, the primary surgeon may easily detubularize. Similarly, in this fashion it may be irrigated in a copious fashion with sterile saline.

Typically, the native bladder is opened near the dome using cautery in the coronal plane from right to left ureteral orifice. To aid in the cystotomy, the bladder may be filled somewhat using Foley catheter irrigation. The ileum then can be affixed using a simple patch or U-shaped configuration using intracorporeal 4–0 absorbable running suture. It is pivotal to avoid the twisting of the ileal mesentery as the ileal segment is brought down to the bladder. If an appendicovesicostomy is needed, the appendix is anastomosed to the posterior wall of the native bladder in an extravesical fashion. A suprapubic catheter usually is placed as well as pelvic drain arranged near bladder anastamosis. A water-tight anastomosis is confirmed by irrigation with sterile saline through the Foley catheter. Open-ended ureteral catheters, if placed, can be removed after surgery.

In cases in which the patient's primary problem does not include neurogenic bladder we will perform appendicovesicostomy alone. Reasons for appendicovesicostomy include noncompliance or difficulty with urethral catheterization despite extensive counseling, patient disability, or urethral stricture disease. It is important laparoscopy proceeds significant dissection to ensure visualization of the appendix and adequate length of 5–6 cm is available. After mobilization and separation from the cecum, a 4–0 polyglactin purse string suture is used to close the cecal defect. The appendix is typically affixed to the anterior wall of the bladder in an extravesical fashion if no cystoplasty takes place. The distal tip is removed, and appendix is spatulated. With the bladder partially filled with liquid, a detrusorotomy is made to create a submucosal tunnel. The anastamosis is completed over an 8 Fr catheter with running 5–0 absorbable suture. Stay sutures can be placed to prevent twisting of mesentery as the appendix is matured to the skin.

At times it may be indicated to perform concomitant bladder neck reconstruction to for a patient with an incompetent urinary sphincter mechanism. This has recently been demonstrated in a robotically assisted fashion. As described by Gargollo et al., a combined Leadbetter/Mitchell repair with sling has demonstrated excellent results in small numbers of patients but requires advanced robotic skills [23]. Our group, in contrast, has had excellent experience with bladder neck closure. The robotic approach offers excellent visualization to allow transection of the bladder neck and closure. Ideally, some form of tissue interposition may improve the adequacy of closure.

Often these patients are suitable candidates for antegrade colonic enema procedure. This too can successfully be performed robotically. This can be performed using a typical cecal flap. At times if the appendix appears 7–10 cm in length with healthy blood supply a split appendix technique could be attempted which eliminates further dissection of the cecum [24]. In this situation, the proximal end of the appendix is kept in continuity with cecum to create an in situ channel. The distal end of the appendix can be used for appendicovesicostomy; importantly, asymmetric division of appendix may be required for both channels to have adequate length. These steps can be accomplished with the robotic approach with the assistance of stay sutures to prevent the twisting of mesentery.

Post-operative Care

Patients may benefit from a streamlined or a protocolized recovery pathway. In this manner, nurses, family, and physician extenders understand the general steps needed to advance a patient towards discharge. Enhanced recovery pathways have been applied successfully in colorectal surgery leading to reduce length of stay and complication [25]. While there is no

direct evidence of the benefit in this context, at the very least it helps ease communication between care providers if everyone understands the general expectations of post-operative events.

Regular use of nasograstric suctioning has fallen out of favor and we avoid it [26]. We encourage early ambulation and advancement of diet. Ketoralac has been utilized for over a decade in the pediatric population and reduces need for narcotic pain medication [27]. Typically in terms of management of bladder drainage, a suprapubic catheter remains in place for 1 month and urethral foley for 1 week. If appendicovesicostomy was performed, an 8–12 Fr feeding tube remains for 1 month prior to CIC teaching at an outpatient. To prevent sluggish flowing catheters from clots, debris or mucous gentle irrigation can be performed. All patients receive follow up renal ultrasounds during outpatient follow-up. Bladder capacity it regularly accessed via catheterization. Urodynamics are not routinely performed unless the patient presents with recurrent or new incontinence.

Immediate Post-operative Considerations

In the days following surgery, high drain output may be indicative of post-operative urine leak. If suspected the drain fluid should be sent for fluid creatinine. Drainage of the bladder should be maximized with continued supra-pubic tube and Foley drainage to gravity. Gentle irrigation of tubes to ensure patency can be helpful. The drain can also be placed onto gravity, in case suction itself perpetuates the leak. If this results in incomplete drainage of urine; however, abscess can form. CT or X-ray cystogram can be used to confirm resolution in 5–10 days.

Fevers, elevated white blood cell count, or severe pain at a single incision site may be the sign of delayed bowel injury. High vigilance is required, and CT with PO contrast can diagnose any potential bowel leak or injury. Often in these rare circumstances, re-exploration is required. Like with other major abdominal surgery, herniation, post-operative ileus, wound infection, and urinary tract infection are some of the more common complications that may be encountered during the post-operative period.

Long-Term Considerations

Long-term effects of surgery include propensity for bladder stones. If needed, irrigation of the catheter may prevent or reduce the incidence of such occurrences which may be related to stasis. Once present, stones may be managed percutanously or endoscopically depending on size. Of note, given the remote possibility of cancer development and the young age of these patients, regular cystoscopy should be considered starting about 5 years after augmentation, although there is extremely limited data on this topic [28]. As with any surgery involving the terminal ileum, B12 deficiency is a concern [29]. Deficiency may result in peripheral neuropathy, loss of position and vibration sense, and dementia and prophylactic supplementation or close monitoring is advised. Finally, the dreaded complication of delayed spontaneous bladder perforation should be suspected when a patient presents with signs of sepsis, abdominal pain, and lack of urine output [30].

For patients with catheterizable channels, stomal complications may be encountered. In open series with up to 10 years follow-up data, 8.3% of appendicovesicostomies and 16.7% Monti channels ultimately required subfascial revision [31]. Keloid formation, may drive the need for stomal dilations [32]. Mild stenosis can be managed with serial dilation or leaving a catheter superficial to the fascia at night. Leaks, if encountered, should be evaluated first to ensure the family or patient is performing CIC at appropriate intervals. Anti-cholinergics can reduce bladder spasm, but repeat urodynamics should be considered to ascertain filling pressures. If required, dextranomer/hyaluronic acid injection (Deflux; Salix Pharmaceuticals Inc., Raleigh, NC, USA) could be attempted as a submucosal injection to reduce stomal leakage. This methodology has been shown to be a successful minimally-invasive treatment with dry rates up to 79% after one or two injections [33].

Once reaching reproductive age, female patients can be reassured that a safe pregnancy is possible. Recent reports have indicated uncomplicated vaginal delivery is possible status post augmentation and even appendicovesicostomy [34]. If a caesarean section is considered, it is imperative an adult urologist be present. Fetal ultrasound may be challenging due to the position of appendicovesicostomy or ACE in relationship to the uterus, and vaginal ultrasound may improve visualization. Because of the altered anatomy, hydronephrosis of pregnancy may be more likely to cause clinical symptoms and should be monitored closely [35]. Of note, commercially available pregnancy tests may not be accurate due to mucous after augmentation, in one small study a 57% false positive was noted [36]. In summary, obstetrician and urologist should avoid emergency caesarean section, closely monitor the patient, and both be present during delivery.

Clinical Results

Evidence of the effectiveness of robotic bladder augmentation in children is growing. Because of the typical neurologic and genitourinary complexity of these children, typically augmentation is not performed alone. As such, many case series present data for children undergoing concomitant robotic appendicovesicostomy, bladder neck closure, and/or Antegrade Colic Enema (ACE) procedure. Therefore, data presented is often heterogeneous and at present the isolated peri-operative risk for robotic augmentation itself may be difficult to accurately ascertain. Nonetheless, the best available evidence is summarized.

A single surgeon series of robotic augmentation in children revealed decreased epidural use and decreased hospital length of stay when compared to patients undergoing open surgery [37]. Bladder capacity, complication rates, and patient urinary leakage were not significantly different between the open and robotic groups. This procedure has been accomplished robotically by other groups with increased bladder capacity of over 100% and physiologic detrussor pressures with follow-up urodynamic testing [38]. In a separate robotic series of adult patients, stomal stenosis occurred in 13.3% and persistent incontinence in 6.7%, with unique quality of life data suggesting only 13% of patients had mild treatment regret with mean follow up of 22 months [10]. Pure laparoscopic augmentation is still being explored by some. Indeed, a recent study followed 36 patients in China for a median of 16.5 months and found significantly increased bladder capacity, decreased pressures and serum creatinine in follow up [39]. Particularly in this complex population with likely past procedures and need for future surgeries, the robotic approach may be associated with fewer adhesions [40].

One of the largest series comprised of 91 patients who underwent open augmentation secondary to bladder extrophy and related epispadius [41]. With mean follow-up of 6 years, 26% suffered from bladder stones and 23% stomal stenosis. Bladder capacity, post-operatively increased 524% on average for these patients. Only 7% of patients had difficulty with incontinence. Earlier series suggested a rate of bladder stones of approximately 50% but noted uncomplicated endoscopic management was possible when stones were present in the lower tract only [42]. There is some evidence irrigation may reduce risk of stone formation and should be encouraged [43]. New data suggests the age of the child undergoing augmentation may not impact the number of subsequent re-operations or stone formation events [44].

In a unique study, Herschorn et al. questioned patients a median of 76 months after augmentation at which time patients were a mean 31 years old [45]. While all patients underwent open surgery in this cohort, it is telling almost all was very satisfied with their urologic care despite 40.6% overall complication rate and 59% requiring daily medications to manage bladder or bowel dysfunction. Clearly, there is room to optimize the procedure to hopefully reduce complications and reoperations. Patients, once adults, recognize the value of this surgery and it certainly should be considered for patients with severe neurogenic bladder.

We urge caution given outcome data is limited and self-reported by single surgeons to this point. There are no ongoing randomized trials regarding open vs. robotic augmentation and given the incidence of surgery of this type, such a trial would likely never take place due to difficulty with accrual and cost. Patients undergoing this type of surgery are heterogeneous and often have many concomitant procedures. Nonetheless, the preliminary evidence suggests robotic augmentation is safe and causes no increased harm to patients. Functional outcomes appear to match those of open contemporary series. Moreover, there is some evidence of decreased length of stay and pain management with less narcotics and epidurals. Given the high rates of complications from this major surgery, any attempts to reduce complication such as different techniques may be beneficial.

Conclusion

Despite the success of intravesical botulinum toxin and CIC, some patients will undoubtedly require bladder augmentation. High-volume centers have begun to demonstrate the ability to perform this surgery in a completely intracorporeal fashion using robotic assistance. With the promise of decreased morbidity, length of stay, shorter recovery once at home, and improved cosmesis more centers may investigate this method. Hopefully, collaboration will provide high quality evidence regarding long-term outcome and improved patient satisfaction [46, 47].

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Part IX

Female Urology and Infertility

64 Robotic-Assisted Sacrocolpopexy and Surgery for Stress Urinary Incontinence in Females

Catherine A. Matthews

Abstract

Sacrocolpopexy remains the "gold-standard" procedure for management of post-hysterectomy vaginal vault prolapse with improved anatomic outcomes compared to native tissue vaginal repair. It is increasingly being offered to women as a primary treatment intervention for uterine prolapse particularly since vaginal mesh procedures have fallen out of favor. Robotic-assisted technology is well suited to pelvic floor reconstruction given the need for deep pelvic dissection with extensive suturing and knot-tying. While reoperation rates remain low, recurrent prolapse and vaginal mesh exposure appear to increase over time. The potential morbidity associated with sacrocolpopexy is higher than for native tissue vaginal repair with complications including sacral hemorrhage, discitis, small bowel obstruction, port-site herniation, and mesh erosion. Use of ultra-lightweight polypropylene mesh and vaginal mesh attachment with delayed absorbable suture may reduce the risks of vaginal mesh exposure.

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Keywords

Sacrocolpopexy · Robotic-assisted · Vaginal vault prolapse · Uterine prolapse · Colposuspension · Burch · Complications

Introduction

Symptomatic pelvic organ prolapse is common and 13% [1] to 19% [2] of women will undergo surgical repair in their lifetimes. In recent years, there has been a growing recognition that adequate support of the vaginal apex is the most essential component of a durable surgical repair for pelvic organ prolapse. Sacrocolpopexy (SCP) is considered to be the most durable procedure for management of post-hysterectomy vaginal vault prolapse with improved anatomic outcomes compared to native tissue vaginal repair [3]. This operation is increasingly being offered as a primary surgical option for women who present with uterovaginal prolapse in an attempt to improve longer-term surgical outcomes [4]. Minimally-invasive techniques of SCP, with and without robotic-assistance, are associated with improved recovery times and less total cost than abdominal SCP without a demonstrable difference in efficacy [5–7]. A recent comparative trial of laparoscopic versus robotic SCP found no overall difference in cost between the two minimally-invasive techniques [8].

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While a small number of surgeons are able to accomplish SCP using standard laparoscopy, prior to the introduction of the da Vinci® robot, the majority were performed via laparotomy because of challenges encountered with extensive suturing and knot-tying. With the introduction of wristed instrumentation and three-dimensional visualization, the feasibility of more surgeons performing this operation through a minimally-invasive technique greatly expanded. The learning curve of robotic SCP appears to be significantly shorter than for standard laparoscopy [9, 10]. Robotic technology also enables one to perform a concomitant retropubic colposuspension and paravaginal repair for management of stress urinary incontinence for Level II anterior vaginal wall support defects.

This chapter will detail appropriate pre-operative case selection for women with both post-hysterectomy vaginal vault and primary uterine prolapse and will then outline a step-by-step robotic technique of SCP that is exactly modeled after the open procedure. In addition, steps for performance of a robotic Burch colposuspension will be described. Finally, a review of surgical outcomes and complications will be presented.

Pre-operative Case Selection

Given the increased risk of serious complications, SCP should be reserved for women with post-hysterectomy vaginal vault prolapse and for women with advanced stage uterine prolapse with known risk factors for surgical failure. Surgeons performing robotic SCP should also be able to offer patients native tissue vaginal repair. The most commonly identified risk factors for surgical failure include Stage III or IV multi-compartment prolapse [11, 12], young age at the time of index prolapse surgery (<60) [11] and wide genital hiatus that is a proxy for underlying levator ani muscle injury [13]. Women considering this procedure for primary uterine prolapse management should be carefully counseled about the potential negative effect of concomitant total hysterectomy on vaginal mesh exposure rates. While obesity is identified as a risk factor for surgical failure, it has also been identified as a significant risk factor for serious intraoperative complications with minimally-invasive SCP [14].

As prolapse is a quality of life condition, it is important to always consider a patient's medical reserve and ability to tolerate a surgical complication when choosing the most appropriate route of prolapse repair. Sacrocolpopexy is associated with a higher rate of serious surgical complications than native tissue vaginal repair [3]. Therefore, patients who are frail and medically infirm may preferentially benefit from a vaginal approach. In addition, women at high risk for significant intraperitoneal adhesive disease, for example a history of sigmoid diverticular abscess, may be better served by an extra-peritoneal vaginal procedure.

Impact of Surgical Technique on Prolapse Recurrence

No consistent surgical technique during SCP currently exists [15]. In a survey of 189 members of the American Urogynecology Society and the International Urogynecology Society, there was no consensus on length of vaginal dissection; number, type, or location of sutures used for vaginal mesh attachment; or intra-operative complication management. Fifty-seven percent of respondents reported using permanent suture for vaginal mesh attachment and 75% used permanent sutures for sacral fixation. All responders except 1 used Type-1 polypropylene mesh.

Quality evidence regarding specific surgical techniques in SCP is lacking. With open SCP, permanent suture was traditionally used to reduce the risk of vaginal graft avulsion. More recently, some have switched to delayed-absorbable monofilament suture in an attempt to reduce vaginal mesh exposure rates [16]. A few retrospective studies have demonstrated a favorable impact of absorbable suture on mesh exposure with no adverse effect on anatomic outcomes. For example, a study comparing braided permanent suture to delayed absorbable monofilament suture found a reduced rate of mesh exposure in the absorbable

suture group (3.7% vs 0%), with no associated POP recurrence [17]. Similarly, when delayed absorbable monofilament suture was used for SCP mesh attachment in 67 women undergoing total abdominal hysterectomy and SCP, no mesh exposures were noted at a median follow up of 27 months [18].

The length of the vaginal graft likely has a greater impact on prolapse recurrence than the type of suture used for graft attachment. Again, there is wide variability reported in the literature. Most European studies detail dissection of the anterior vagina to the level of the trigone and posteriorly to the levator ani [19]. As is the case in the randomized trial of robotic compared to laparoscopic SCP, however, many authors do not detail how this technical step is performed [8]. At present, no study has compared outcomes based on length of anterior and posterior vaginal graft attachment. In my surgical experience, differential dissection of the anterior and posterior compartments is required for varied presentations of prolapse. For example, in a patient with a large enterocele, minimal anterior and extensive posterior dissection may be required. In contrast, a large anterior wall prolapse typically requires dissection of the anterior wall to the trigone. Paravaginal repair is frequently necessary in these cases as well [20].

While anterior and apical recurrence is significantly less common after SCP than native tissue vaginal repair [3], leaving the cervix in situ in women with primary uterine prolapse may adversely affect outcomes in these compartments. In a retrospective cohort study of 83 women who underwent total versus supracervical hysterectomy with concomitant SCP, the rate of recurrent prolapse ≥ stage II was significantly higher for women in the supracervical group (41.9% vs 20.0%, p = 0.03; OR 2.8, 95% CI, 1.07–7.7). Similarly, in a retrospective review of 40 women undergoing supracervical hysterectomy and SCP, 27% demonstrated recurrent anterior vaginal wall prolapse to the hymen within one year [21]. In women with large prolapse of the anterior compartment, consideration should be given to vertical plication of the anterior vaginal wall prior to mesh attachment. In women with a uterus, removal of the cervix potentially allows for greater reduction of the anterior compartment. Finally, using a separate anterior and posterior vaginal mesh graft instead of a pre-formed y-mesh in these cases permits differential elevation of one compartment over the other.

Surgical Preparation and Set-Up

Patients are no longer required to complete a preoperative bowel preparation. While mechanical bowel cleansing has not been shown to decrease operative morbidity, in obese women, it may improve the ease of sigmoid manipulation and retraction may be facilitated. Perioperative antibiotics are administered 30 min prior to the procedure and sequential compression devices are used for thromboprophylaxis. Patients are placed in the dorsal lithotomy position with the buttocks extending one inch over the end of an operating Table. I position patients directly onto egg-crate foam to prevent slippage. Another device designed to stabilize positioning and provide sufficient padding for robot-assisted surgery in steep Trendelenburg is the Bean Bag Positioner (AliMed Inc., Dedham, MA). The gel mattress is fastened to the surgical table and conforms to the shape of a patient's upper body and shoulders when desufflated to stabilize her. Potential drawbacks are a longer setup time, unnoticed deflation during the case, and need for disinfection. Arms are tucked and we either strap a piece of foam across the chest and tightly secure it to the table using silk tape or place shoulder blocks to decrease the chance of movement in Trendelenburg position. Shoulder blocks are associated with a higher risk of brachial plexus injury and care should be taken when employing this method. I recommend testing patients in the steepest Trendelenburg position prior to draping to ensure that no movement exits.

After the patient is prepped and draped, a Foley catheter is placed into the bladder and a vaginal manipulator is placed into the vagina. Several choices exist: A lucite stent, large EEA sizer, Briesky-Navratil retractor, or Colpassist™ Vaginal Positioning Device (Boston Scientific,

Marlborough, MA). An experienced surgical assistant is seated between the legs to provide adequate vaginal and rectal manipulation during the case. With the absence of haptic feedback, the necessity of good vaginal manipulation is imperative to accessing the correct surgical planes and facilitating easy suturing of the graft.

To maximize one's ability to evaluate mesh tensioning at the end of the procedure, I strongly advise side-docking. This is made easier by angling the foot of the bed away from the robot prior to locking the bed in order to bring in the system from a 45° angle.

Surgical Technique

Appropriate Port Placement and Docking the Robot

1. Pneumoperitoneum is obtained with a Veress needle technique through the umbilicus. In the event of prior abdominal surgery around the umbilicus, liberal use of Palmer's point for peritoneal access is advised. An opening pressure of less than 10 mmHg is a reliable indicator of correct intraperitoneal placement. In women with prior abdominal surgery, a Hassan entry technique away from site of prior surgery is another option. This can be challenging in obese women.
2. Careful port placement (Fig. 64.1) is integral to the success of this procedure to avoid robotic arm interference, permit visualization of the sacral promontory, and adequately mobilize the sigmoid colon. We have found that ports arranged in an arc around the umbilicus works best, with the assistant port in the right lower quadrant below and lateral to the camera to facilitate easy visualization of this port during needle retrieval. When evaluating the abdomen prior to trocar insertion, we have determined that at least 15 cm is required between the pubic bone and the umbilicus to rely on this landmark for the 12-mm camera port. If this distance is shorter, as it is in many obese women, then insertion above the umbilicus is necessary. We use the robotic camera through the central trocar to permit safe placement of the remaining ports. Robotic arm 1 is placed 10 cm lateral to the camera and this is used for monopolar scissors and a suture-cut needle driver. An 8 mm accessory re-usable robotic port is placed in the right lower quadrant 10 cm lateral to the accessory port and approximately 3 cm above the anterior superior iliac spine (ASIS) for introduction of sutures and the mesh graft. On the left side of the abdomen, the third and fourth robotic arms are placed 10 cm apart, with the fourth arm typically as far lateral as possible and at least 3 cm above the left ASIS to prevent injury to the iliohypogastric nerve.
3. After placing the patient in steep Trendelenburg position, the robot is docked from the patient's left side at a 45° angle to the bed. Care should be taken to ensure that the spine of the robot is not positioned too high on the bed as this will

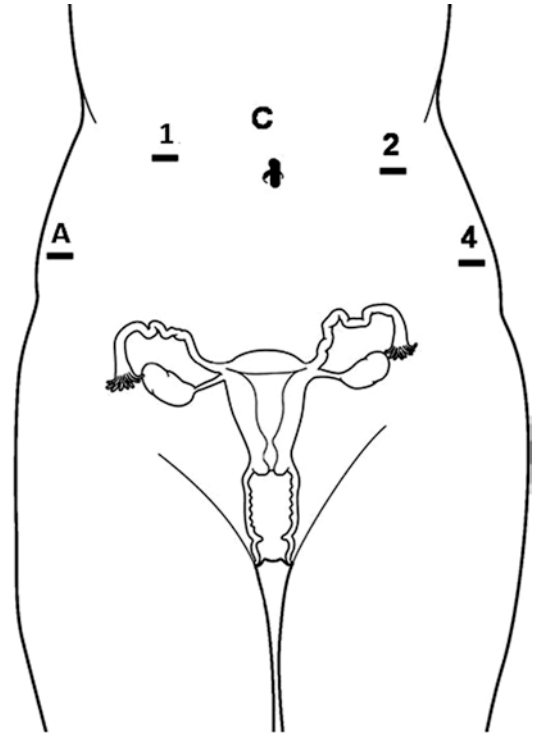

Fig. 64.1 Robotic port placement. C = 12 mm Camera Port; A = 8 mm Accessory Port; 1 = Right arm (monopolar shears); 2 = Left arm (PK Dissector or Bipolar Maryland) 4 = Fourth Arm (Cadiere Bowel Retractor)

interfere with movement of arm 4. A good landmark is for the robot spine to sit at the level of the patient's knees.

4. Necessary instruments include monopolar scissors that are introduced through the right arm, a bipolar PK™ dissector through the left arm, and an atraumatic bowel grasper such as a cadiere™ that is placed through the fourth arm. A prograsp retractor is NOT recommended for bowel manipulation. The bedside assistant sits on the right side of the patient with access to a long maryland dissector and a suction and irrigation device.

Technique of Sacrocolpopexy Procedure

Employing a standard technique during each SCP procedure can increase efficiency. As in all procedures, restoration of normal anatomy through sharp lysis of any bowel adhesions to the vaginal cuff and full mobilization of the small bowel out of the pelvis is necessary to proceed safely. Retraction of the sigmoid colon to the left lower-quadrant should adequately expose the sacral promontory.

Step 1: Exposure of Sacral Promontory

With the use of a 0° scope, the sigmoid colon is retracted laterally using the cadiere™ forceps and the right ureter is identified. The sacral promontory can always be identified 3 cm medial to where the right ureter crosses the right common iliac vessels (Fig. 64.2). This is an important landmark particularly in obese women. The peritoneum overlying the sacral promontory is elevated and opened using monopolar cautery. Great care should be taken to start this dissection lower, as opposed to higher on the promontory to avoid risk of injury to the left common iliac vein. Air is allowed to enter into the retro-rectal space. Lifting the entire fat pad off the sacrum preserves the important hypogastric nerves [22] and allows

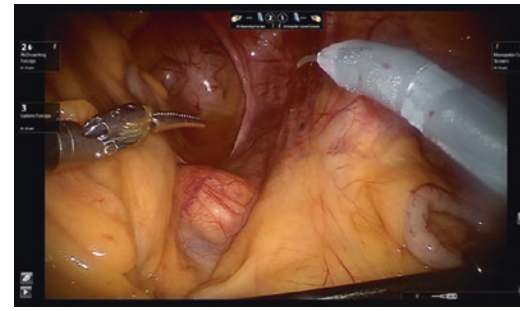

Fig. 64.2 Exposure of sacral promontory. The left common iliac vein presents the greatest risk of hemorrhage at the sacral promontory

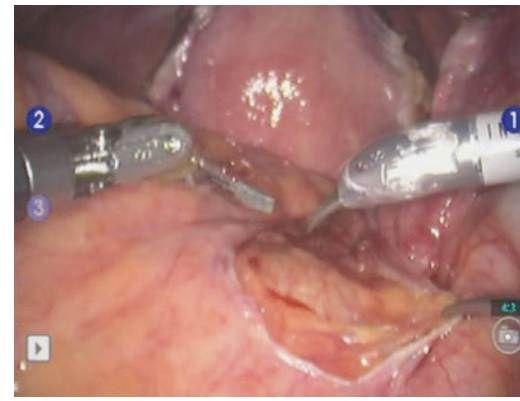

Fig. 64.3 Exposure of anterior longitudinal ligament. Peritoneum opened at sacral promontory and fat pad dissected to reveal the anterior longitudinal ligament

for easier identification of the anterior longitudinal ligament (Fig. 64.3). The middle sacral artery is frequently visualized and can be coagulated using the PK™ dissector if necessary. The vessel that presents the greatest risk at this site, however, is the left common iliac vein. The peritoneum is then opened from the promontory to the rectovaginal peritoneal reflection. Alternatively, one can make a retroperitoneal tunnel- creation of this tunnel allows the sacral arm of the mesh to lie flat and decreases the time at the end of the case to extraperitonealize the mesh. Care must be taken to keep this tunnel just beneath the peritoneum as bleeding can be encountered in the deeper fat plane. It is imperative to maintain orientation in the midline and not deviate into the right ureter or into the sigmoid mesentery.

Step 2: Development of Rectovaginal and Vesicovaginal Spaces

With the vagina deviated anteriorly using a vaginal stent, the rectovaginal space is normally easily identified. The peritoneal incision is started where the rectovaginal peritoneal reflection appears most "mobile" when retracted towards the sacrum. This peritoneal incision is extended transversely and the avascular space is entered. This is gently dissected using a lateral spreading motion to expose the posterior vaginal wall (Fig. 64.4). If any bleeding is encountered, one is not in the correct surgical plane. Ligating the uterosacral ligaments can increase visualization of the posterior compartment. If indicated, the rectovaginal space can be dissected all the way down to the perineal body.

The vagina is then deviated posteriorly to facilitate dissection of the bladder from the anterior vaginal wall using monopolar cautery. If significant scarring between the bladder and vagina is encountered, the bladder can be retrograde filled with 300 ml of saline to help identify the surgical plane. Depending on the degree of anterior vaginal wall prolapse, approximately 6 cm of anterior vaginal wall needs to be exposed. If a large anterior wall prolapse is present, additional dissection to the bladder neck is advised. An attempt is made to leave the peritoneum intact at the apex of the vagina to reduce the chance of mesh erosion.

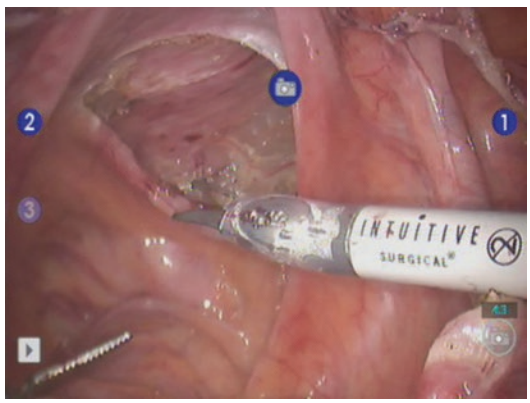

Fig. 64.4 Posterior dissection. Peritoneal incision is extended along the cul-de-sac to the posterior vaginal wall in a T-shaped configuration to access the rectovaginal space. When performing a cervicosacropexy, it is easiest to develop this surgical plane prior to amputation of the cervix

Step 3: Vaginal Graft Attachment

A pre-formed y-mesh or two separate pieces of mesh can be used to suspend the anterior and posterior vaginal walls. My preference is to use a y-mesh but in cases where there is dramatically more prolapse in one compartment than the other, two separate meshes that are variably tensioned to the sacral promontory is preferred. After measuring the respective lengths of the exposed anterior and posterior vaginal walls, a correctly sized ultra-lightweight polypropylene graft is introduced into the abdomen. Several y-mesh options exist including Upsylon™ (Boston Scientific, Marlborough, MA), Restorelle™ (Coloplast, Minneapolis, MN), and Alyte™ (Bard, Murray Hill, NJ). Significant variability in the relative dimensions of the anterior and posterior segments of mesh can exist hence the recommendation to trim the selected graft after completing the dissection. The mesh graft is introduced through the 8 mm accessory port after exchanging the scissors and PK dissector for a suture cut and a large needle driver. I find it personally helpful to attach the anterior mesh first. The bladder is retracted using the fourth arm, and the anterior mesh arm is placed over the anterior vaginal wall and is sutured in place using either 2–0 Gore-Tex® sutures on CT-2 needles or 2–0 PDS™ that are each cut to 6–8 inches long. The choice of suture material depends on the relative risk of vaginal mesh exposure in any individual woman-in those with thin vaginal tissue, it is possible that delayed absorbable monofilament suture may reduce the risk of mesh exposure. It is most efficient to anchor the two distal corners first (Fig. 64.5), and then place a series of interrupted stitches towards the vaginal apex. Knots are tied using two surgeon's knots, followed by two half-hitches. An attempt is made to achieve healthy bites through the vaginal muscularis without perforating the epithelium. A suture device called Stitchkit™ (Origami Surgical, Madison NJ) now

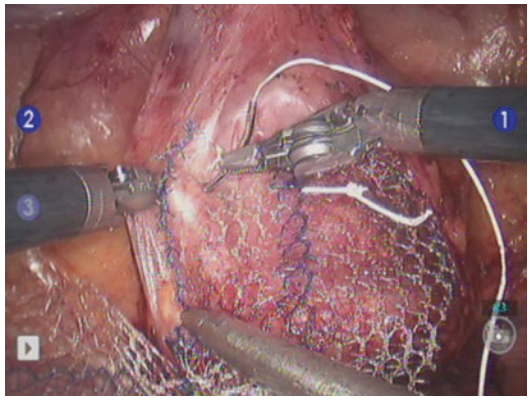

Fig. 64.5 Anterior mesh attachment. The y-shaped polypropylene mesh graft is first sutured to the anterior vaginal wall, starting at the distal corners. The bladder is retracted cephalad by the fourth arm

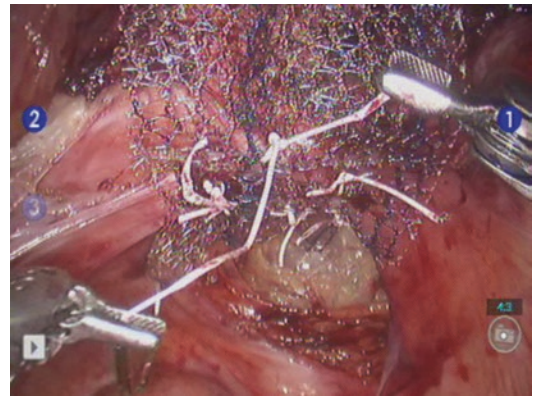

Fig. 64.7 Posterior mesh attachment. Attachment of posterior arm of mesh. Upward traction on the sacral portion of the mesh graft is provided by fourth arm

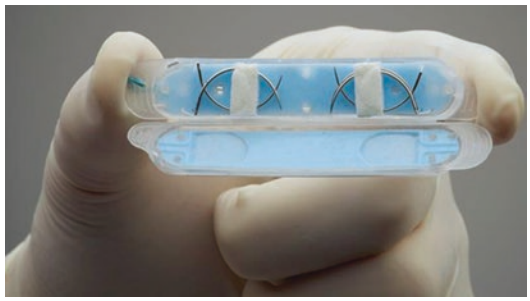

Fig. 64.6 Stitchkit™ that contains six sutures. Once a needle is used, it is deposited back into the lower part of the case and then the bullet is retrieved through the 12 mm camera port at the end of the procedure

exists that contains six sutures within a capsule that is introduced through the 12 mm umbilical port (Fig. 64.6). This kit provides sutures on one side and then a repository for used needles on the other. The kit promotes surgical efficiency, autonomy, and safety—there is no chance of a needle popping off during retrieval through an accessory port.

After adequately securing the anterior mesh arm, the vagina is deviated anteriorly and the posterior mesh arm is draped over the posterior vaginal wall with the assistance of the fourth robotic arm that can hold upward traction on the sacral end of the mesh graft. Starting at the vaginal apex, 6–8 interrupted sutures are placed to secure the mesh to the posterior vaginal wall (Fig. 64.7). If necessary, the 0° scope can be exchanged for a 30° up-scope to fully visualize the rectovaginal space.

Step 4: Sacral Mesh Attachment

The surgical goal is to attach the sacral arm of the mesh to the anterior longitudinal ligament at the level of S-1 with adequate vaginal support but no undue tension on the mesh. To achieve this, the vaginal manipulator is retracted back to allow retrieval of the sacral arm of the mesh through the retroperitoneal tunnel. The vagina is then deviated towards the sacrum, and ensuring that no excessive tension exits, the sacral portion of the mesh graft is sutured to the anterior longitudinal ligament at the promontory using two or three interrupted sutures (Fig. 64.8). Before attaching the sacral arm of the mesh, palpation of the vaginal apex is recommended to ensure no excessive tension exists. New evidence has emerged that the L5-S1 disc is the most prominent structure that one can see at the promontory and that one must suture just over the edge of the promontory to ensure no entry into this disc space. Good et al. determined that in the supine position, the most prominent structure in the presacral space is the L5-S1 disc, which sits approximately 1.5 cm cephalad to the actual promontory [23]. The average angle of descent between L-5 and S-1 was 60°. When patients are placed in steep

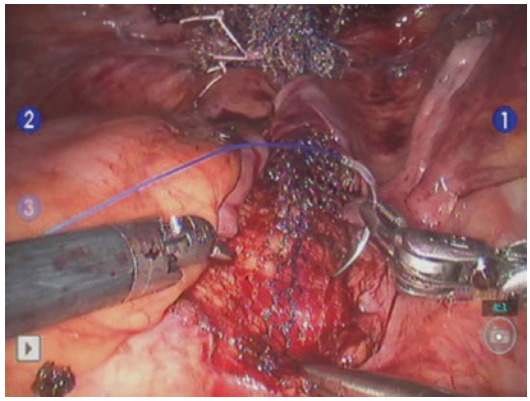

Fig. 64.8 Sacral mesh attachment. Mesh is directly sutured to the anterior longitudinal ligament using two or three stitches, secured with slip-knots. Care is taken to avoid undue tension on the mesh graft

Trendelenburg position during minimally-invasive SCP, the disc assumes an even more prominent position. The "true" sacral promontory lies just beyond the angle of descent and may be difficult to visualize with a 0° camera lens.

When placing the needle during this critical juncture, it is important to rotate through the ligament along the curvature of the needle as opposed to driving the needle forward and potentially exiting further laterally than expected. Because of slight traction that exists on the mesh, a slip-knot is preferred over a surgeon's knot. Care is taken to visualize the middle sacral artery and either suture around, or cauterize it. Suturing below the promontory can increase risk of bleeding from the sacral venous plexus. If bleeding is encountered in this space, a ray-tec sponge can be introduced through the accessory port for manual compression. If bleeding continues, the use of floseal™ is recommended for controlling hemostasis.

Step 5: Closing the Peritoneum Over the Mesh

In an attempt to decrease the chance of postoperative bowel obstruction, the mesh is extraperitonealized using a 2–0 PDS™ suture cut to 8 in. It is easiest to accomplish this task by starting at the vaginal apex with a purse-string like suture from the right anterior peritoneum to the right side of the cul-de-sac, coming over the mesh to pick up the left side of the incised peritoneum and then coming back through the left side of the bladder flap. After tying the knot down, the vaginal apex is covered. The smaller sacral peritoneal window is easily sutured over the mesh with a running stitch towards the sacral promontory. The right ureter can become kinked during this step and therefore, routine cystoscopy is recommended for all cases.

Modifications for Women with Uterine Prolapse

When a woman with primary uterine prolapse is considered for SCP, one has to decide whether to remove the uterus and if so, whether to perform a total or sub-total hysterectomy. Hysteropexy is recommended for women who have not completed childbearing or in those with a cultural or personal preference. A full discussion of this topic is beyond the scope of this chapter.

The decision to remove or preserve the cervix rests on the relative risk of compromised anterior wall support versus vaginal mesh exposure rates. One also has to consider the size of the remaining cervical stump and if there is evidence of cervical elongation or other cervical pathology such as dysplasia. In these circumstances, total hysterectomy is advised. While anterior and apical recurrence is significantly less common after SCP than native tissue vaginal repair [3], leaving the cervix in situ may adversely affect outcomes in these compartments. In a retrospective cohort study of 83 women who underwent total versus supracervical hysterectomy with concomitant SCP, the rate of recurrent prolapse ≥ stage II was significantly higher for women in the supracervical group (41.9% vs 20.0%, p = 0.03; OR 2.8, 95% CI, 1.07–7.7). In women with large prolapse of the anterior compartment, consideration should be given to vertical plication of the anterior vaginal wall prior to mesh attachment. In women with a uterus, removal of the cervix potentially allows for greater reduction of the anterior compartment. As stated previously, using a separate anterior and posterior vaginal mesh graft instead of a preformed y-mesh in these cases permits differential elevation of one compartment over the other.

Vaginal mesh exposure is higher in women undergoing total as compared to supracervical hysterectomy with SCP. Akyol et al. demonstrated a two-fold increased risk (12%) [24] and Bensinger et al. a sevenfold increased risk (8.2%) [25] of mesh exposure with concomitant total hysterectomy. In contrast, four retrospective studies in which Type1 polypropylene mesh was used revealed no increased risk of mesh erosion with concomitant total hysterectomy [26–29]. These widely discrepant rates of mesh exposure may be related to surgical technique, graft material and/or suture materials used for mesh attachment. Based on this evidence, it seems reasonable to avoid colpotomy in women at increased risk for mesh exposure (i.e., smokers) and aggressively treat pre- and post-operative vaginal atrophy with topical estrogen cream. In addition, one should avoid suturing the vaginal graft directly onto the suture line for vaginal cuff closure in women undergoing a concomitant total hysterectomy.

It is easiest to fully dissect the anterior and posterior vaginal walls prior to cervical amputation as the upward traction on the uterine corpus improves visualization of the surgical planes. Once the cervix is amputated, effective vaginal manipulation can present a surgical challenge. Some surgeons use a tenaculum attached to the fourth arm to apply traction on the cervix but this then eliminates this arm for other necessary tasks. Maleable or Breisky-Navratil retractors can be used to delineate the anterior and posterior vaginal fornices but are not always satisfactory, especially if an assistant is not seated between the legs. A useful and inexpensive instrument is the Colpo-Probe™ vaginal fornix delineator (Apple Medical, Marlborough MA) that not only assists in dissection of the vagina from the bladder and rectum but also provides a stable surface during mesh attachment.

Robotic Burch Colposuspension

When performing robotic SCP, access to the retropubic space is readily available and concomitant colposuspension and paravaginal repair can easily be performed. As demonstrated in the CARE trial, Burch colposuspension significantly reduces the rate of occult stress incontinence following SCP [30]. With some women expressing reservations regarding mid-urethral sling placement, robotic surgeons should learn the technique of Burch colposuspension.

To avoid inadvertent cystotomy at the bladder dome, the bladder is backfilled through the Foley catheter with 300 ml of saline. This delineates the superior borders of the bladder dome. Monopolar scissors are used to incise the peritoneum approximately 1 cm above the edge of the bladder between the medial umbilical ligaments. The avascular space of Retzius is developed through blunt and sharp dissection until the pubic symphysis is visualized and the bladder is dropped down. Cooper's ligament is exposed, and adipose tissue is cleared from the vaginal wall immediately lateral to the mid-urethra and urethral–vesical junction. Care must be taken to avoid lacerating one of the many venous plexuses in this space. A vaginal manipulator is placed to provide a stable surface on which to suture. One can use either be a lucite stent or a Briesky-Navratil retractor. Two sutures are then placed on each side of the urethra, the first approximately 2 cm lateral to the urethra at the level of the mid-urethra and the second at the level of the bladder neck. I recommend using a permanent, non-braided suture such as 2–0 Gore-Tex® sutures on CT-2 needles. Each suture is passed through the ipsilateral Cooper's ligament and a slip-knot is used to tie the sutures down with appropriate tension. This tension can be assessed by the operating surgeon or by a trained vaginal assistant to minimize additional tension when tying. Cystoscopy is then performed to confirm ureteral patency and ensure that no sutures have been placed into the bladder. The peritoneum is then closed with an absorbable suture.

SCP and Complications

Most studies conclude that SCP is associated with a "low" rate of complications and that it is a "safe" procedure [10, 31, 32]. A retrospective review of peri-operative adverse events from women undergoing minimally-invasive SCP at the Cleveland Clinic, however, docu-

ments a 26% rate of grade III complications according to the Clavien-Dindo grading system [33]. Furthermore, when comparing SCP to native tissue vaginal repair, serious adverse events such as ileus or small bowel obstruction (2.7% compared with 0.2%, p = 0.01), mesh or suture complications (4.2% compared with 0.4%, p = 0.01) and thromboembolic phenomena are significantly more common (0.6% compared with 0.1%, p = 0.03) [3]. The systematic review and meta-analysis conducted by the Society of Gynecologic Surgeons Systematic Review Group highlights the fact that improved anatomic durability with mesh SCP comes at the cost of increased serious surgical morbidity. Infrequent but very serious complications also include iliac veinotomy and discitis. A high index of suspicion for this complication is required for any patient who presents with post-operative back pain or symptoms of general malaise and/or fever. There may be a significant delay in onset for several months after the index procedure. Typically, management consists of intravenous antibiotic treatment and removal of the sacral mesh. In refractory cases, however, extensive tissue debridement and spinal surgery may be necessary [34]. Diagnosis is evident on either computer axial tomography or magnetic resonance imaging.

Complications are also significantly more common early in a surgeon's learning curve. In a comparative review of peri-operative complications of robotic versus open SCP at the Mayo clinic, Anand et al. reported on the outcomes of two surgeons who had performed 37 and the other 13 SCP procedures [35]. Overall, 38% of patients in the open group versus 46% in the robotic group had at least one complication (p = 0.36). Of these, there were five cystotomies, four bowel injuries, one vascular injury, two port-site herniations, one case of sepsis, and one pulmonary embolism. This computes into a 28% rate of serious complications.

The medical consequences of each of the above complications can be very serious. Surgeons performing SCP need to be aware that any woman who presents with post-operative abdominal pain could have an unrecognized bowel injury and/or small bowel obstruction. Immediate medical evaluation and early abdominal computerized axial tomography imaging with oral and intravenous contrast is recommended for comprehensive evaluation of the gastrointestinal and urinary tracts.

Surgical steps to decrease the rate of post-operative small bowel obstruction include careful surgical closure of any port site that is larger than 5 mm and peritoneal closure over the mesh. When performing reperitonealization, it is imperative not to leave small openings in the peritoneum that can cause internal herniation and incarceration of the small bowel.

Post-operative Mesh Erosion

Irritative voiding symptoms, microscopic hematuria, recurrent urinary tract infections, dyspareunia and pelvic pain may all be symptoms of bladder mesh or suture erosion. Liberal use of cystoscopy in the evaluation of patients who have previously undergone SCP and have any of these symptoms is imperative. The use of permanent sutures for vaginal mesh attachment is associated with a higher rate of postoperative suture erosion into the bladder, particularly with rigid prolene material [36]. The rate of intraoperative bladder injury varies from 0.4 [33]—10% [35] and is higher in trainees [10] and those early in the robotic learning curve [37]. Intraoperative cystotomy may be associated with higher rates of postoperative mesh erosion. Bladder mesh erosion can be managed via a trans-vaginal or laparoscopic approach [38].

Mesh erosion into the rectum or colon is very rare. Mickelson et al. recently described a case of delayed mesh erosion [39]. Four years after a robotic supracervical hysterectomy and cervicosacropexy, the patient was found to have mesh extrusion through the cervical as well as mesh erosion into the sigmoid colon with a connecting enterocervical fistula. This was repaired laparoscopically. Pain with bowel movements or rectal bleeding should prompt endoscopic evaluation in any women with a history of SCP.

Conclusions

Sacrocolpopexy remains the "gold-standard" procedure for management of post-hysterectomy vaginal vault prolapse with improved anatomic outcomes compared to native tissue vaginal repair. Outcomes for uterine prolapse have not yet been proven in prospective trials. Robotic-assisted SCP has equivalent outcomes compared to open and laparoscopic SCP and may allow more surgeons to perform the procedure through a minimally-invasive approach. Surgeons early on the robotic learning curve, however, must be aware that serious complications may be increased. In addition, the complications of SCP can be far more severe than native tissue vaginal repair including injury to the left iliac vein, discitis, small bowel obstruction, port-site herniation, and mesh erosion. Full knowledge of the relevant anatomy is critical as significant morbidity can be encountered during the operation if incorrect surgical planes are created. Key points that must be considered during the procedure include the availability of two proficient bedside assistants (typically positioned between the legs and on the right side of the patient), use of steep Trendelenburg position to remove the bowels from the operative field, adequate spacing of the robotic ports to avoid arm interference, left side-docking, correct identification of the sacral promontory and not the L-5/S-1 disc, individually fashioned y-shaped grafts, and closure of the peritoneum from the vaginal apex towards the sacral promontory.

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Robotic Repair of Urinary Fistulae

65

Joan C. Delto, Ashok K. Hemal, and Akshay Bhandari

Abstract

This chapter provides a brief overview of the various types of urinary tract fistulas including vesicovaginal, ureterovaginal, vesicouterine, and vesicoenteric fistulas. The robotic assisted laparoscopic approach has recently been utilized for many urinary tract fistulas, after demonstration of safety, efficacy, and expeditious convalescence.

This chapter emphasizes safety, efficiency, and economy for robotic repair. Adherence to the principles of fistula repair is key. Principles include adequate separation of organs, non-overlapping suture lines, multiple layer closure, tension free anastomosis, adequate hemostasis, well-vascularized healthy tissues, watertight closure, use of a vascular interposition flap, and adequate postoperative drainage.

Keywords

Robotic repair · Vesicovaginal fistula · Ureterovaginal fistula · Vesicouterine fistula · Enterovesical fistula · Rectovesical fistula · Laparoscopic

Vesicovaginal Fistula

Introduction

Vesicovaginal fistula (VVF) is a distressing condition that involves communication between the bladder and the vagina resulting in continuous urinary incontinence. In the underdeveloped world, obstetric trauma is the most common etiology, where prolonged labor results in bladder ischemia and subsequent fistula [1, 2]. However, in the developed world, iatrogenic injury during gynecologic and abdominopelvic surgeries is the usual culprit, with hysterectomy being the most common [3]. Other causes of VVF include malignancy (i.e., cervical, vaginal, endometrial), pelvic radiation, foreign body erosion, infection, and trauma. Similarly, ureterovaginal fistulas (UVF) can result after iatrogenic ureteral injury.

Careful physical examination, testing with dye (i.e., methylene blue), the double dye test (pyridium and methylene blue), and cystourethroscopy can aid in the diagnosis of a fistula. A cystogram or voiding cystourethrogram (VCUG) may diagnosis and localize the fistula, however it

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may fail to demonstrate this in the case of small fistulous tract. Upper tract imaging (i.e., CT urogram) should be obtained to evaluate for UVF.

Timing of VVF repair, whether expeditious or delayed (months), is still controversial. There are various approaches to VVF repair including transvaginal or transabdominal via an open or laparoscopic approach [4]. Notably, surgeon experience with a particular approach has been associated with surgical success [5]. For most VVFs, the transvaginal approach is preferred given success rates and early recovery [6]. The abdominal approach is generally reserved for complex cases where prior transvaginal surgery has failed, there is a need for ureteral reimplantation, or if there is a concomitant abdominal procedure that will be performed [6]. Success rates for both transvaginal and transabdominal repair are comparable 87% and 87.5%, respectively [7]. A recent retrospective review reported a 100% success rate transvaginally and 90% transabdominally [7]. However, traditionally the open transabdominal route is associated with prolonged hospitalization, recovery, and greater blood loss. Thus, minimally invasive surgery is an appealing alternative.

Robotic assisted laparoscopic repair of VVF was first described in 2005 [8]. It is becoming more frequently performed and techniques have been described [4, 8–12]. A recent case series of ten patients, of which majority failed prior VVF repair, reported a 100% cure of incontinence at a mean follow-up of 23.6 months [11]. A comparative analysis of open and robotic VVF repair in patients with unsuccessful previous surgery revealed 90% and 100% success rates ($p > 0.05$), respectively [13]. There was significant decrease in blood loss and length of hospital stay with the robotic approach. The transvesical technique (as first described by O'Conor) has been the most common type of repair, however, recently the extravesical approach has been described and shown to be safe [14–16].

Surgical Room Setup

The anesthesiologist is located at the cranial aspect of the patient. The robot is located at the caudal aspect and is docked between the legs of the patient. The bedside assistant is to the right of the patient, while the scrub technician is on the left side. Some authors have described a "side docking" approach to enable the assistant easy access to the vagina. The robot is docked from the caudal aspect but parallel to the patient from the side. While this approach could restrict the mobility of the robotic arms, the da Vinci Xi overcomes these restrictions.

Patient Positioning

As the operation takes place in the deep pelvis, the patient is positioned similar to that of a prostatectomy procedure. The patient is placed supine with legs in low dorsal lithotomy with arms tucked alongside the body and padding placed to pressure points. This facilitates efficiency of single positioning for both cystoscopy with stent placement, followed by the robotic segment of the operation. The patient is strapped securely along the chest prior to placing her in steep Trendelenberg positioning after performing the cystoscopy. Alternatively, a Trendelenberg O.R. table pad (Prime Medical) can be used to prevent patient slipping while in steep Trendelenberg position. This anti-skid pad obviates the need for strapping the patient and is particularly helpful in obese patients. Moreover, this pad prevents avoids strapping which could minimize brachial plexus injuries and facilitate chest ventilation secondary to restriction from tape. This positioning is also adequate in the case of UVF where ureteral reimplantation must be performed.

Trocar Configuration

Trocar configuration is similar to that of a prostatectomy with minor modifications, using the standard five or six port transperitoneal approach. The camera port is placed in the midline several millimeters superior to the umbilicus. Two 8 mm robotic trocars are placed laterally to the camera along the pararectus line, at the level of the umbilicus. Another 8 mm robotic trocar is placed in the left lateral position, at the level of the

umbilicus and above the iliac crest. A 12 mm assistant port is placed laterally on the right, at the level of the umbilicus, almost mirroring the left most lateral trocar. If needed, a 5 mm assistant port can be placed superiorly between the camera and one of the main robotic ports.

Instrumentation List

In attempts to minimize robotic surgical costs and increase efficiency, we utilize minimal robotic instruments when safe and feasible [17]. A Hot Shears™ (monopolar curved scissors, Intuitive Surgical) is placed in the right arm (first arm), a fenestrated bipolar forceps is placed in the left medial arm (second arm), and a ProGrasp™ forceps is placed in the lateral left arm (third arm). We replace the scissors with a needle driver when suturing. The bipolar grasper doubles up as a needle driver on the left. A 3–0 monocryl V-loc (Covidien) suture on an RB1 needle is used for bladder, vaginal, and multiple layer closures. The V-loc suture is equipped with an end loop, which avoids knot tying. Moreover, the barbed nature of the suture prevents tissue from slipping after each throw. Thus, we typically forgo the use of a second needle driver, thereby minimizing costs and time spent for knot tying and instrument changes [17, 18]. The assistant uses a suction irrigator and grasper. A 15Fr round Jackson Pratt drain is used at the end of the procedure through one of the 8 mm ports. The fascial layers for the 12 mm port are closed with 2–0 vicryl on a UR6 needle. Skin can be closed with subcuticular stitching with 4–0 monocryl. A 20 Fr foley catheter is left at the end of the procedure.

Technique

Cystoscopy and Ureteral Stent Placement

We have found it helpful to perform a vaginoscopy and cystourethroscopy prior to the robotic portion of the procedure. A sponge stick in the vagina may tamponade the fistula and allows for proper bladder distention during cystoscopy. For small fistulas, a ureteral catheter may be placed through the fistula for easy identification. If the patient has not undergone upper tract imaging to rule out UVF, bilateral retrograde pyelograms can be performed at this time. Bilateral 5F open-ended ureteral catheters could be placed for easy identification of the ureteral orifices during the robotic transvesical procedure. After the cystoscopy, a 20 Fr foley catheter should be placed.

A sponge stick should be placed per vagina to aid in the identification of the vagina relative to the bladder and to maintain pneumoperitoneum during the robotic procedure. If the defect is large, a foley catheter can be placed in the vagina with the balloon insufflated to tamponade the defect.

Adhesiolysis

Adhesiolysis with gentle and sharp dissection should be performed to facilitate safe trocar placement. Then, the colon must be reflected cranially to adequately expose the deep pelvis. Steep Trendelenberg positioning also facilitates this. Release of bowel adhesions also avoids inadvertent bowel injury during the procedure and reduces tension on the bladder or vagina, promoting a tension free anastomosis. Vaginal adhesions in the pouch of Douglas should be lysed for adequate exposure of the vagina and bladder.

Robotic Dissection of VVF

Transvesical Approach

The bladder can be identified with the aid of the foley catheter balloon. Gentle intravaginal pressure with the sponge stick can delineate the vagina from the bladder (Fig. 65.1). A vertical, midline cystotomy can expose the VVF. The location of this incision minimizes the risk of ureteral injury (Fig. 65.2). Although the O'Conor technique describes bi-valving the bladder, a smaller, but adequate cystotomy can be safely created [14, 15]. The fourth arm can lift the bladder for adequate exposure and provide counter traction. Bilateral ureteral orifices are easily identified with the ureteral stents. Creation of bladder flaps will allow for later tension-free closure.

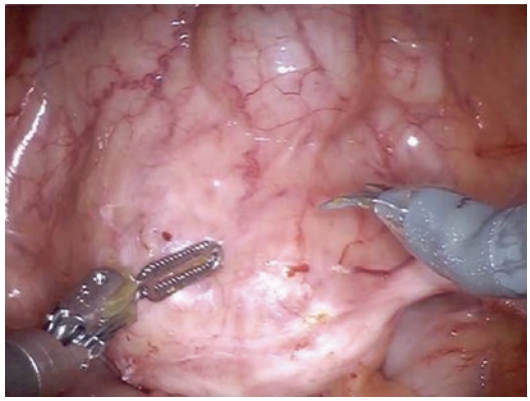

Fig. 65.1 Foley catheter balloon delineates bladder from vagina with sponge stick

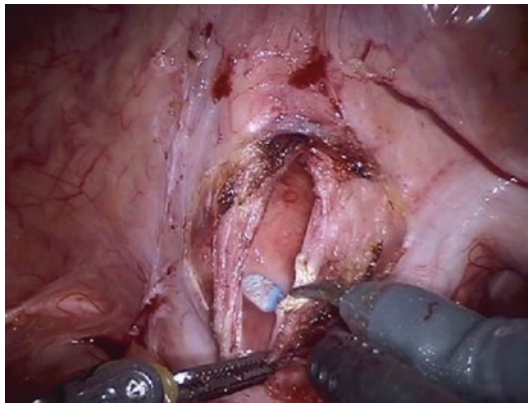

Fig. 65.2 Midline vertical cystotomy with fistula seen. The fourth arm is used to elevate the bladder

Fistulous tract excision without electrocautery should be considered if the edges of the fistula do not appear healthy or well-vascularized or if they appear inflamed or malignant. The bladder and vagina should be separated with meticulous dissection. Adequate hemostasis should be achieved while preserving an intact blood supply to the tissue and preventing necrosis.

Extravesical Approach

The extravesical VVF repair was recently described robotically [16]. In the extravesical approach, a cystotomy is not created, instead, careful dissection is carried out to expose the area of repair of both the bladder and vagina. The remainder of the surgery continues similar to the transvesical approach and follows the same principles of fistula repair.

Fistula Repair

Repair should be performed in multiple layers. The foley catheter balloon should be deflated and cleared from the working area. The vaginal defect can be closed with a 3–0 V-loc suture in a running fashion in the transverse plane (Fig. 65.3). The same stitch can be used in a running fashion to create a second layer closure with peritoneum.

Next, the bladder can be closed with a running 3–0 V-loc in the direction that is perpendicular to the vaginal suture line (Fig. 65.4). Attention should be given towards the ureteral orifices as to not to injure or to inadvertently incorporate them into the repair. To ensure proper bladder closure, mucosa should be obtained with each stitch, ensuring mucosa to mucosa approximation. If possible, an additional

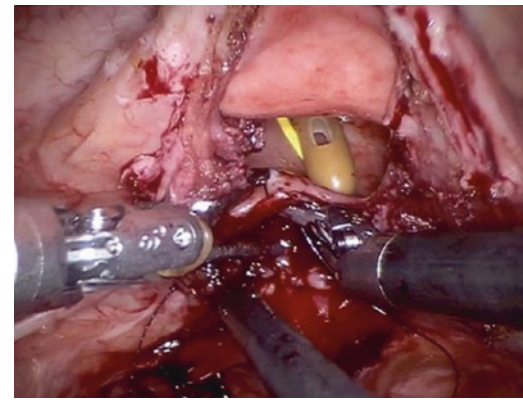

Fig. 65.3 Vaginal closure in a horizontal orientation with 3–0 v-loc suture. Ureteral catheter and deflated foley seen in the bladder

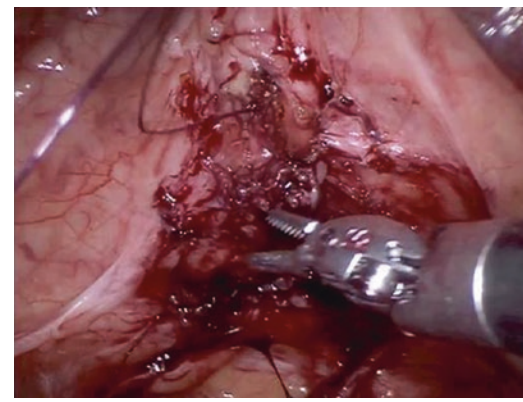

Fig. 65.4 Bladder is closed in a vertical fashion, perpendicular to the horizontal vaginal incision line closure

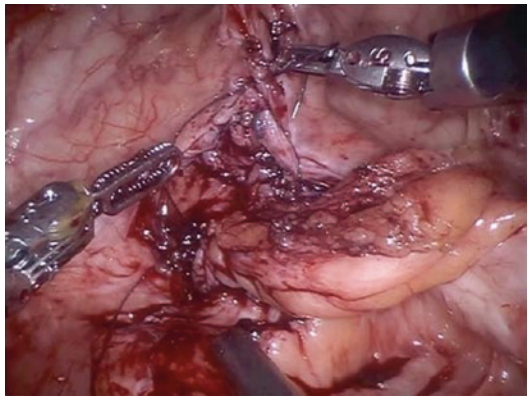

Fig. 65.5 Vascular interposition flap utilizing peritoneum

layer closure can be created with 3–0 V-loc, placing peritoneum over the bladder suture line. Moreover, water tight bladder closure should be confirmed by instilling 200 ml of sterile saline through the urethral foley catheter.

Vascular Interposition Flap

A vascular flap interposition should be highly considered. Options for flaps include omentum, peritoneum, bladder peritoneum, or sigmoid epiploic appendices. The flap should have a wide base to ensure an adequate vascular pedicle. More recently, an amniotic allograft had been described as an alternative to a vascular flap to aid in tissue repair and healing [19]. In our experience, the peritoneum immediately over the bladder provides a long and well-vascularized flap that is easy to mobilize (Fig. 65.5).

Postoperative Drainage

An abdominal drain should be placed in the rectovaginal pouch through an existing port site. If ureteral catheters are used for intraoperative delineation of the ureters, they should be removed. A large foley catheter should remain in the bladder to ensure proper drainage for 7–14 days.

Principles of Fistula Repair

The basic surgical principles of fistula repair should be adhered to strictly: (1) excision unhealthy, devitalized tissues (2) tension free anastomosis (3) water tight closure (4) multiple layered closure (5) non-overlapping suture lines (6) adequate hemostasis (7) vascular flap (8) adequate bladder drainage (9) adequate separation of tissues (10) prevention or treatment of infection (11) removal of foreign body [5, 6, 10, 12, 20].

Ureterovaginal Fistula

Introduction

Ureterovaginal fistulas (UVF) are a rare occurrence, with a 5% incidence in the developed world [21]. Risk factors include radiation therapy, pelvic malignancy, endometriosis, pelvic inflammatory disease, and obesity. The most common etiology is iatrogenic injury during gynecologic, colorectal, or vascular surgery secondary to laceration and ligation. Patients typically present with unilateral flank pain and vaginal leakage of urine up to 4 weeks after a pelvic surgery. However, in the developing world, the incidence of UVF is 68–80%, secondary to obstetric causes [1]. Rarely, UVF and VVF might both be present simultaneously and one should be careful to diagnose both during initial work up.

Diagnostic investigations include the double dye test, CT urogram, and cystoscopy with retrograde pyelogram. Partial injury may be amenable to stent placement, which can possibly avoid transabdominal repair. In 2005, the first laparoscopic technique was performed [22] and recently, robotic assisted repair have been described and deemed to be both feasible and safe [21, 23].

Positioning, Trocar Placement and Instrumentation

A foley catheter should be place preoperatively. The patient is placed in dorsal lithotomy with approximately 30° of Trendelenberg position. After pneumoperitoneum is achieved, a standard five or six port approach can be used (as described in the VVF section). Various techniques of repair can be performed based on the level and extent of the injury (i.e., ureteroureterostomy, ureteroneocystotomy). Since finer sutures are used for ureteral repairs, one may use the micro needle drivers.

Robotic Repair

If an omental interposition flap will be used, it should be dissected and tagged at this point, as it may regress cranially. Planes between the ureter and vagina should be carefully created. Ureterolysis is carried down distally, and is separated from the bladder. The fistulous tract should be excised. The vagina can be closed in two layers using either vicryl or V-Loc suture in a running fashion. A ureteroneocystotomy (UNC) can be performed for distal ureteral injuries, if the distal ureteral tissue does not appear healthy, or if a tension free ureteroureteral anastomosis is not feasible. A psoas hitch with or without Boari flap can be considered. After repair, an omental interposition flap should be placed around the ureter and to separate it from the vagina. A JP drain and foley catheter should be utilized [23].

Ureteroneocystotomy

Gellhaus et al. described a standard extravesical implant through the robotic approach [23]. Adhesiolysis and colon mobilization is performed to identify the healthy ureter, which is dissected to the area of ureteral injury. Care is taken to preserve the adventia—which carries the blood supply to the ureter. Just proximal to the area of injury, the ureter should be transected and spatulated posteriorly. Meanwhile, the bladder should be dissected from its anterior and lateral attachments in preparation for adequate mobilization for the psoas hitch. Two 3–0 monocryl sutures are used in a running fashion to create a tension free anastomosis. Prior to complete closure of the anastomosis, a JJ stent should be placed. A JP drain should be inserted through an 8 mm port site. A foley catheter should be kept in place.

Ureteroureterostomy

When there is adequate distal ureteral length and tension free anastomosis can be achieved, a ureteroureterostomy (UU) may be considered. After exposure and mobilization of the ureter, the area of injury is excised. Both healthy segments of ureter are widely spatulated and closed in a standard end-to-end running fashion with 4–0 monocryl. A JJ stent is placed prior to complete closure of anastomosis. A JP drain should be placed [23].

Vesicouterine Fistula

Introduction

Vesicouterine fistula (VUF) is the most rare of the urogenital fistulas, accounting for 1–4% of urogenital fistulas [24]. Patients typically present with amenorrhea and menouria. The most common etiology is iatrogenic injury during cesarean section, when concomitant injury to the bladder and uterus may occur. Diagnosis can be made with a tampon test and oral pyridium or intravesical instillation of dye (i.e., methylene blue) and monitoring the cervical os. Endoscopic investigations may include hysteroscopy or cystoscopy. Alternatively, cystogram or hysterosalpingogram can demonstrate filling of both organs. CT or MR urogram can also aid in diagnosis.

Surgical management of VUF is accomplished through a transabdominal approach, whether through a laparotomy or laparoscopically. There have been few reports of robotic repair demonstrating safety, efficacy, and efficiency [25–27].

Technique

Cystoscopy

The patient is placed in low lithotomy. Cystoscopy is performed. Bilateral 5 Fr open-ended ureteral catheters are placed for ureteral identification. An indwelling foley catheter should be placed. Vaginal packing is not necessary as there should be no loss of peritoneum.

Robotic Repair

The patient is positioned in low lithotomy and in steep Trendelenberg. After pneumoperitoneum is

achieved, a 12 mm camera port should be placed supraumbilically. Two 8 mm ports should be placed 3 cm below the umbilicus and lateral to the rectus muscle on each side. A 10 mm right assistant port should be placed above the iliac crest in the posterior axillary line. A 5 mm assistant port can be placed between the camera and 8 mm port [25]. If a fourth arm is required, another 8 mm trocar can be placed in the left side, approximately 5 cm lateral to the pararectus trocar [27]. Instruments may include monopolar curved scissors, bipolar Maryland forceps, and needle driver.

Adhesiolysis with curved monopolar scissors in the right arm and Maryland bipolar forceps in the left arm exposes the uterus and bladder. If omentum will be used as an interposition flap, it can be dissected and tagged at this point as it may recede and later be difficult to locate [27]. The vesicouterine peritoneal reflection is dissected to the level of the fistula and careful separation of the two organs is carried out. A midline cystotomy is made above the fistula, then towards and around the fistula in an inverted racquet-shaped incision to excise the fistula. Creation of bladder flaps will aid in tension free closure. Tissue that does not appear healthy should be excised and hemostasis obtained. If a hysterectomy is planned, this can be performed at this time.

Bladder Closure

The bladder should be closed in two layers with 2–0 vicryl or 3–0 monocryl. The first layer should be closed in a running fashion to ensure mucosal to mucosal contact. The second layer can be closed with similar suture, however in an interrupted [25] or locked running fashion [27]. Water-tight closure should be demonstrated by filling the catheter with 200 cc of sterile saline. If leakage is noted, 3–0 vicryl and be used to close any remaining defect.

Closure of the Uterus

The uterus is repaired with a single layer closure using 3–0 vicryl with interrupted sutures. Uterine and bladder suture lines should be non-overlapping.

Interposition flap

If possible, an interposition flap (as described previously) should be placed between the bladder and uterus and can be secured with 3–0 vicryl or monocryl.

Drainage

A JP drain can be inserted through a port site. Vaginal packing should be placed and removed the following day. Ureteral catheters should be removed at the end of the procedure. A foley catheter should remain in place for 7–14 days after the surgery. A suprapubic tube is avoided.

Vesicoenteric Fistula

Introduction

Vesicoenteric fistula (VEF) commonly occurs in patients with bowel disease including diverticulitis, cancer (i.e., colorectal, primary bladder), and Crohn's disease. In diverticulitis, the most common etiology, the colon is involved compared to ileum in Crohn's disease. Other causes include radiation, infection, trauma, and iatrogenic injury. Rectovesical fistula may occur after prostatectomy. Patients may complain of pneumaturia, fecaluria, urinary frequency, dysuria, suprapubic pain, and tenesmus.

VEF can be diagnosed on cystoscopy, however, it is less diagnostic on colonoscopy. However, endoscopy should be encouraged to diagnose an underlying malignant etiology. Imaging modalities include CT with oral contrast or barium enema, or MRI. Centrifugation of urine can be evaluated for fecal material. The Bourne test utilizes the first voided urine after barium enema. It is centrifuged and evaluated for radiodense particles. Activated charcoal test involves ingestion of charcoal and evaluation of black particles in the urine within 24 h. Similarly, a patient may ingest 50 mg of poppy seeds and urine should be inspected after 48 h. Rectal installation of methylene blue can later reveal blue-colored urine.

Operative repair of EVF can be difficult, especially in the setting of diverticular disease, which is associated with severe inflammation. Significant complications after EVF repair include persistent urine leakage, recurrence, bowel anastomotic leakage, abscess formation, cutaneous fistula, and intestinal obstruction [28]. The operative role of the urologist takes place long after bowel diversion. Historically, open repair, has been the preferred approach over laparoscopic given significant inflammatory reaction and high conversion to open rates. However, recently, reports have shown that laparoscopic repair of EVF is feasible, safe, and associated with improved recovery time [28, 29]. The conversion rate to open is 15.4% in the setting of diverticular disease [29]. Moreover, in 2008, a successful robotic assisted laparoscopic rectovesical fistula repair was described [30].

Technique [30]

Patient Positioning

The patient is positioned in low lithotomy and steep Trendelenberg.

Cystoscopy and RVF Catheterization

Cystoscopy is performed to canulate the fistula, which aids in intraoperative identification of the fistula. This is done with an open ended ureteral catheter, which is then pulled through the rectum and exited through the anus.

Port Placement

A standard 6-port transperitoneal placement is used, however, is shifted towards the side opposite the colostomy to avoid injury. Adhesiolysis is performed prior to port placement.

Mobilization of Omental Interposition Flap

Further adhesiolysis is performed. An omental flap is created laparoscopically given the difficult retrieval angle once the robot is docked.

Robotic Repair of Fistula

A midline cystotomy is created and is brought down posteriorly to the fistula. The rectum is released from the bladder. The rectum is closed with a 2–0 monocryl on a UR-6 needle in an interrupted fashion. The omentum is grasped through the assistant port. Then, it is robotically placed over the repair, secured with the monocryl suture. The bladder is then closed with a 2–0 monocryl suture in an interrupted fashion. A urethral foley is not placed to avoid tension to the anastomosis, rather a suprapubic tube is used to drain the bladder. A JP drain is placed.

Conclusion

Laparoscopic approach for repair of urinary tract fistulas has been described to offset the morbidity of the ‘open’ abdominal repair. Despite the lesser morbidity allowing quicker convalescence, laparoscopic repair has not gained widespread popularity, possibly due to the technical challenge associated with laparoscopic dissection of the fistula and intracorporeal suturing. The advent of robotic assistance, allowing fatigue-free ergonomic maneuverability of the instruments, accuracy, and magnified three-dimensional vision has helped overcome these technical difficulties [9]. The robotic approach has helped achieve excellent results, limiting the need for extensive dissection, tissue manipulation and placement of suprapubic cystostomy, even in cases of recurrent fistula surgery [31]. Adhering to the basic surgical principles of fistula repair results in excellent outcomes.

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Part X

Future Perspective

66 Telementoring and Telerobotics in Urology and Use of iPad in Robotic Surgery

Rick Catterwell, G. Blecher, Zisis Kratiras, and Prokar Dasgupta

Abstract

The adoption of robotic technology in medicine has provided some of the most exciting advances in surgery in recent times. This robotic revolution in surgery has been provided countless advantages to both patient and surgeon. With the amalgamation of technological communication and surgery, the future is quite exhilarating. From the practical bedside use of common modern technology to give precise "real time" internal anatomy to the utilization of increasing speed and bandwidth to deliver remote mentorship or remote primary operating the possibilities are exciting and endless. Although there remain many questions in its future, one thing is for certain—the incorporation of technology, including telesurgery and telementoring, is only going to increase.

Keywords

Telemedicine · Telementoring · Telesurgery · Telestration · iPad · Surgery in space

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The introduction of robotics to medicine is certainly one of the most exciting surgical advances of recent years. From open surgery, to minimally invasive laparoscopic, to robotics—techniques of both practicing and learning are rapidly changing. With the amalgamation of technological communication and surgery, the future is quite exhilarating. Although there remain many questions in its future, one thing is for certain—the incorporation of technology, including telesurgery and telementoring, is only going to increase. As surgeons, we are therefore obliged to start answering some of these questions now. At present, there are probably many more questions than answers. How far can telerobotics go? Will it be accessible by all surgeons? Will all patients—no matter of geographical location, be able to benefit? What role does a mentor have in the context of telementoring? In order to truly be a coach, how 'close to the action' does one need to be? Who takes ultimate responsibility for the patient? How about safety—any time technology is involved, it is susceptible to glitches, hacking, or failure. Will these issues be the limiting factor in rolling out telerobotics? Ethics has, and always will remain paramount in the service we provide—what conundrums and roadblocks will telehealth bring to the table. The answer is many and they will be complex.

The first question however, is why? Why should we, as surgeons dedicated to the surgical well being and treatment of our patients, be investing in such technology? The response is

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that it makes a difference. In the first randomized control trial of telerobotics, teams at Johns Hopkins (Baltimore MD) and Guy's Hospital (London England) compared human versus robotic placement of percutaneous needle into a validated kidney model. With over 300 'punctures', although slower, the robot (both remotely and locally) proved more accurate [1]. Furthermore, as technology breaks down borders, the world is rapidly becoming a global unit. To exclude surgery from this modernization means remaining isolated from each other, whilst the rest of the world unites. If we can learn from and support each other moreso than ever before, surely that yields opportunity to better treat our patients?

The utilization of emerging technology such as tablet devices has the potential to be augmented with robotic surgery such as the Translucent Medical system. Such imaging systems allow pre-segmented MRI images of the prostate gland to be mapped to the patient in real time by magnetic tracking to fixed points of the pelvis. The Translucent System can aid the robotic surgeon not only in pre-operative planning but also as an intra-operative guide with real-time data.

Telementoring History

The term 'telementoring' is used to describe the guidance of one health-care professional by another in a different location during either a procedure or clinical interaction with a patient. It encompasses varying levels of interaction ranging from verbal guidance to providing visual instruction on a local monitor screen (telestration) or providing remote control of endoscopic or laparoscopic cameras (Fig. 66.1).

Mentoring of surgeons, began as early as the 1950s, whereby a telemedicine support network was established by the University of Nebraska. Thomas Bird initially coined the phrase Telemedicine—meaning to heal from afar [2]. Between Massachusetts General Hospital and a nearby airport, Bird and his group established an audio-visual network to provide medical consultations. At roughly the same time the Space Technology Applied to Rural Papago Advanced Health Care (STARPAHC) project delivered medical direction to a mobile health unit within the Papago Indian Reservation (Tuscon, AZ), from over 100 miles away by means of radio, two-way television and remote telemetry [3].

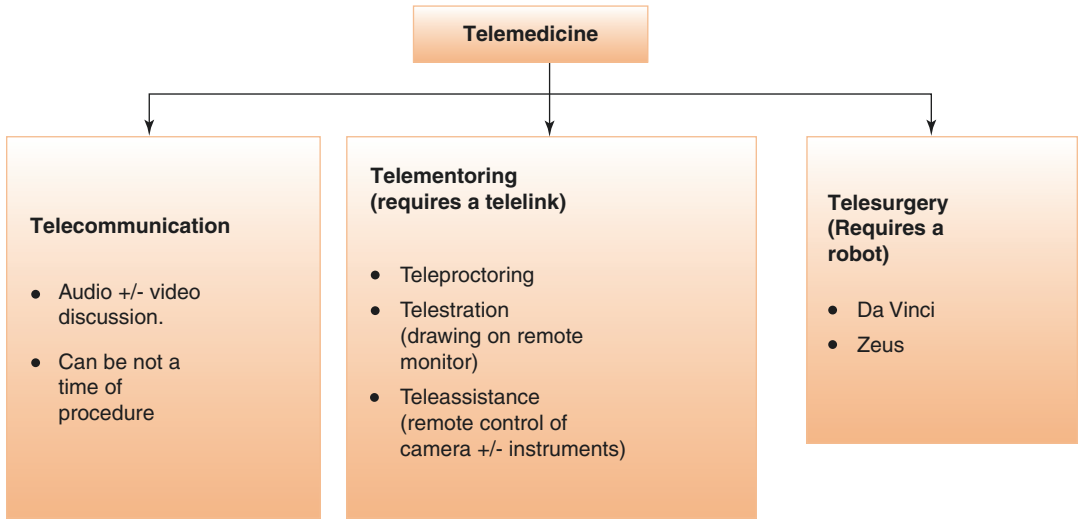

Fig. 66.1 Telemedicine components. Essentially telemedicine involves no specialist equipment. Telementoring utilizes a telelink and software to allow intra-operative audio, visual or instrument assistance. Telesurgery requires a robotic platform to facilitate a remote primary surgeon

In 1999, Rosser et al. set up a mobile operating suite in remote equador—a laparoscopic cholecystectomy was successfully telementored from the department of surgery at Yale University (USA) [4]. An intercontinental telementoring system was utilized for the first time on a naval vessel in 1999 [5]. Video, voice and data systems connected the USS Abraham Lincoln Aircraft Carrier, whilst in the Pacific ocean, to bases in both Maryland and California. Robotic surgical system developers have furthermore been involved—SOCRATES (Computer Motion) is a specific telementoring application, enabling telecollaboration between an operator and another surgeon.

Provision of remote area health care has expanded to such a degree whereby in Australia, Telehealth is an official, Government remunerated process of delivering health care by specialists to rural and remote communities. Due to the large distances involved in the sparsely populated areas of the country telemedicine consultations have proven financially efficient and to patient and physician satisfaction.

Within urology, mentoring of hand-assisted laparoscopic donor nephrectomy took place at Guy's Hospital (London England), with a remote surgeon based in Minnesota (USA) [6]. The surgeons were freely able to communicate with the mentor throughout the case, and the mentor had a view of both laparoscopy, as well as the theatre. No adverse events were noted and the authors conclude that telementoring for this procedure is feasible, effective, and likely to aid independent practice.

Telesurgery

Telesurgery involves the progression from telesurgical telementoring, where the mentor is not the primary surgeon, to procedures where the surgery is entirely controlled by a surgeon at a remote site.

In 1995 the first published example of telesurgery was provided by Rovetta et al. Although not taken up widely due to the costs and complexity, it did provide a starting point for the feasibility of telerobotics. They utilized a SR 8438 Sankyo Scara robot (Adept Technology, Inc., Pleasanton, CA) which simulated physical handling of a TRUS biopsy device.

In 2000, Kavousi et al. performed a series of telerobotic/telementoring procedures [7]. Laparoscopic nephrectomy, ligature of spermatic veins, renal biopsy and percutaneous renal access occurred with the use of AESOP (a robotic device enabling remote control of the endoscope) as well as a second robot (PAKY). The primary operating site was based in Rome (Policlinico Casilino University), with the mentoring site based in the Johns Hopkins Medical Center (Baltimore). Aside from one case where limited space prevented normal robot movement, all five cases were performed successfully and safely.

In 2002 the first randomized control trial of telerobotics was conducted in a collaborative effort between Johns Hopkins University (Baltimore) and Guy's hospital (London). 304 Kellet needles (Rocket Medical, Washington, England) were punctured into a model kidney. Half of them were robotic, whilst the other half were human controlled—although taking slightly longer, the robot was significantly more accurate than the human [8].

Marescaux et al. initially interrogated the effect of time delays on surgery. Over 100 km apart, surgery took place on pigs and time-lapse was artificially increased from standard 20–552 ms. They concluded that the acceptable limit of time-lapse was roughly 330 ms [9]. This project was then pushed further—or farther! The round-trip distance was increased to transoceanic: 14,000 km apart. Six laparoscopic porcine cholecystectomies took place with a mean operative time of 45 min.

In 2002, Marescaux et al. published the Lindbergh operation a transcontinental achievement of performing human telerobotics whereby a robotic laparoscopic cholecystectomy was completed, with a patient in Strasbourg and surgeon in New York (Fig. 66.2)

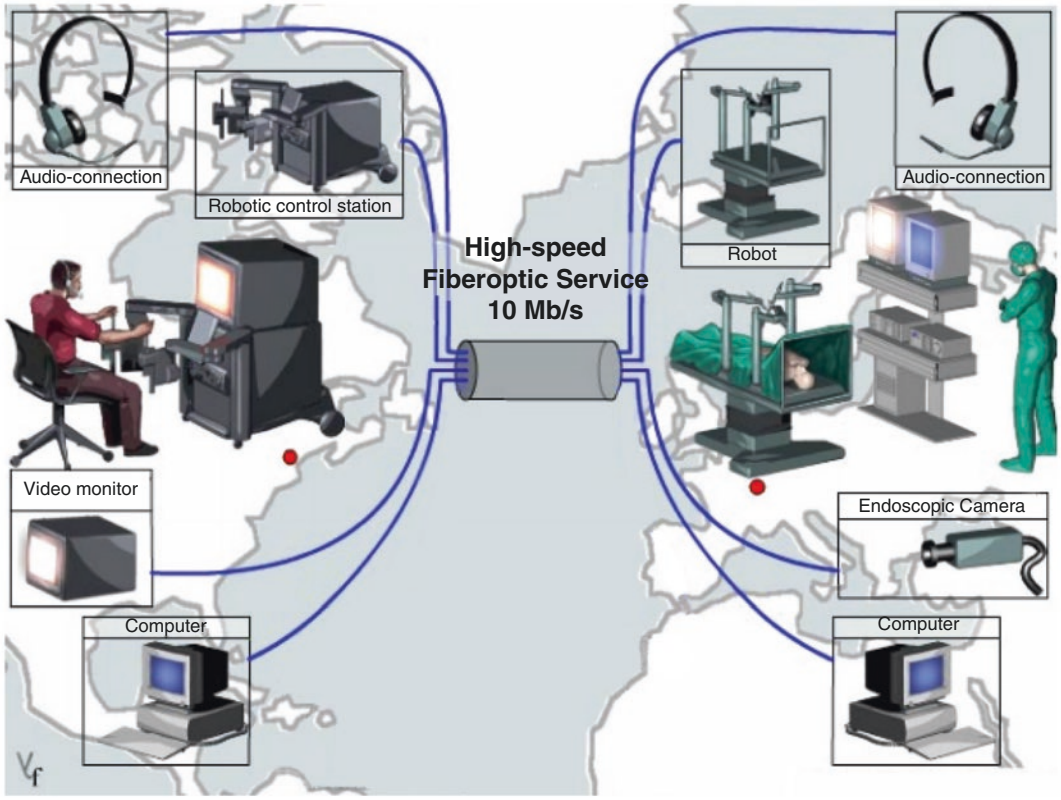

Fig. 66.2 The Lindbergh operation. Diagram of the first transatlantic robot-assisted cholecystectomy in 2001. Marescaux (Institut de Recherche contre les Cancers de L'Appareil Digestif - IRCAD) performed the operation from New York. The patient and the slave robotic arms were in Strasbourg, France, approximately 7,000 km from the surgeon's site. The operation was uneventful

[10]. Utilizing a dedicated asynchronous transfer mode (ATM) fibre-optic link between the two facilities the mean total time delay was 155 ms. The patient was discharged home uneventfully after 48 h.

Variation in Robots

There have been various kinds of robots developed over the years. A supervisor controlled unit enables large amounts of automation—combining radiological registration with surgical planning software, operations can be completed with the surgeon observing and intervening if required. The ROBODOC (Integrated Surgical Systems) is an example of this—developed for orthopaedic hip surgery.

Complete master slave units are the opposite in terms of automation: these systems enable robotic arms to become the extensions of the surgeon. ZEUS (Computer Motion Inc) and DaVinci (Intuitive Surgical) systems are examples.

Robot Development

In 1988 the PUMA 200 was utilised by placing a biopsy needle in the brain with CT guidance [11]. Several years later, Davies et al. performed a TURP using the PUMA 560 which led to the TURP specific designed PROBOT (Imperial College London) [12]. Computer Motion developed the AESOP and ZEUS systems.

So clearly the telerobotics will span further, more reliably and the costs should become less.

But where will it lead? In 2009, a semi-automated trauma surgical system was piloted [13]. It involved deploying a robotic surgeon, nurse and imaging system to a dummy patient, where no other humans were involved. A bowel anastomosis and vascular shunt were performed. It is not inconceivable that human personal may become redundant. Perhaps only a single surgeon coordinator will be required, and these surgeries could be applied from far away: whether it be a battle zone, a hostile third world country, or a highly remote part of the world: surgery could be made available.

Surgical solutions for the next level in remoteness have been considered for several decades—the surgical management of a patient in Space. Surgery in such an extreme environment with additional challenges such as weightlessness may only be possible within the enclosed cavities of the human body. Significant research effort has been invested to develop robotic devices and communication infrastructure facilitating telemedicine to deliver high-quality health care services in space, in orbit and beyond.

Future Hurdles

Before we allow ourselves to become romantic, there exist many major hurdles before such as situation is realized. A number of significant technical and ethical issues are increasingly pertinent with the continued development of technology allowing surgical guidance remote from a patient.

Communication Lag Time

The primary difficulty with teleoperation over large distances or low-quality network infrastructure is the communication lag time. From a technical aspect this concept of operative time delay has been extensively studied. Telementoring requires a secure high speed connection with sufficient bandwidth to provide adequate image, audio transfer and telestration applications. Telesurgery requires additional data exchange to facilitate robotic instrument direction.

Time delay is inherent in any long distance communication. It is a function of the distance between locations as well as the conduit (bandwidth) and hardware over which the signal travels. It has been demonstrated that surgeons providing telementoring can accommodate for latencies up to 700 ms with additional delays increasingly noticeable.

Time delay has more profound effects of telesurgery, especially with increasingly advanced tasks being performed. In 2000, a study designed to interrogate surgical error rate with increasing time lapse delay was performed [14]. Surgical teams were stationed in both Singapore and Baltimore - as time delay increased, so too did the number of operator errors. Researchers also showed that varying latency significantly reduces operator performance with robotic telesurgery; therefore, it is better to use consistent (worst-case) latency to achieve constant performance. For remotely performed complex surgical tasks, such as suturing with a robotic device, a delay of less than 250 ms is ideal although delays up to 500 ms have been shown to be acceptable.

The continued development of the Internet network has resulted in a significant reduction of latencies making this aspect less of an obstacle. Using commercial services, one way delay might be around 85 ms across the USA and anywhere from 20 to 400 ms worldwide. The telerobotic experiment Plugfest 2009 showed 21–112 ms latency for various connections within the USA and 115–305 ms for intercontinental connections. Satellite-based connections can use low to medium Earth orbit satellites, where typical roundtrip delays are 40 ms, but bandwidth is very limited. Geosynchronous satellites provide higher latency due to their 36,000 km altitude; round trip latency is 540–700 ms typically. With continued improvements to the terrestrial internet back bone the problem of operative delay is becoming less of an obstacle.

Ethical Implications

If your surgeon is based on the opposite side of the world what is the most appropriate pre-

operative assessment? How should the consent process be completed? Are there unique issues regarding patient confidentiality? How can technological failures potentially impact on patient safety? Addressing all of these considerations remains vitally important for the safe proliferation of tele-mentoring and tele-surgery.

Using the Lindbergh operation as an example, the primary surgeon assessed the patient and obtained consent locally in Strasbourg, prior to travelling to New York to perform the surgery. As previously mentioned a dedicated fibre-optic link between facilities was utilized with providing improved line security, reliability, transfer speed and available bandwidth. In the event of a communication failure a local surgeon was available to provide assistance.

Telemedical consults may aid in pre-operative assessment but the need for experienced local examination and assessment is still required. As the peri-operative care will require local expert involvement it is acceptable that a local team should have some involvement in the assessment and consent process. Guidelines on the level of involvement of each party, local and remote, need to be created. The interaction between a patient and their surgeon forms a critical component of the delivery of surgical care. The use of a remote surgeon with who the patient has limited contact may impact on patient satisfaction and overall acceptance of telerobotics.

The security of telecommunication links utilized in any telemontored or telerobotic procedure is essential. Modern firewalls and modern encryption minimize the risk of hacking or interruption of a secure connection. Any information that may identify the involved patient may require further attention and specific consent considerations.

The disruption of connection during a critical part of surgery could have disastrous implications. Integrated Services Digital Network (ISDN) and Asynchronous Transfer Mode (ATM) both provide a secure system thus reducing the risk of connection interruption. Both require specific hardware instillation to the point of surgery and therefore significant cost. The expense of the instillation of such connections and the ongoing expenses of line rental may result in such links being financially prohibitive in the very centres with the most to gain from telesurgery—those in smaller, remote locations. Connection over the internet via WAN ('wide area network') connected as a VPN ('virtual private network') offers a cheaper alternative but at the cost of line reliability and security. It remains unregulated what an acceptable level of reliability for such a critical connection should be and measures should be in place in the case of a line failure.

Liability/Credentialing

The involvement of a remote surgeon either as a mentor or telesurgeon carries a degree of liability. Just as intra-operative phone advice is common place in modern surgery and potentially requires clarification of legal liability so would the role of a telementor or telesurgeon. International telerobotic surgery requires a number of arrangements and agreed positions regarding liability of local and remote surgeons both intra-operatively and during post-operative care.

There are aspects of regulation of medical practice that provide significant barriers to long distance telemedicine. Medical qualifications are frequently not recognized across different states and countries. Medical insurance policies are most commonly specific to the country and institutions of the individual surgeon. For worldwide telementoring or telesurgery to become common place a specific international authority, along the lines of the American Telemedicine Agency, may be required to bridge these legal barriers.

Cost

For a system to be adopted as common practice amongst other attributes it needs to be financially viable. As previously discussed the first published example of telesurgery was provided by Rovetta et al. in 1995 with an SR 8438 Sankyo 'Scara' robot controlling a trans-rectal ultrasound device for guided biopsy. In this case the benefits of telesurgery were outweighed by the cost and complexity of the robotic procedure (several thousand dollars, compared to less than US$100 for the manual procedure).

Cost remains another issue to contend with. Currently systems are limited—there is little competition and as such, pricing prohibits the universal rolling out of robotics to all health care institutions. The DaVinci system (Intuitive Surgical Inc) remains the most popular and extensive used in the surgical world. With additions of other surgical robotic systems including ALF-X (TransEnterix), as well as the increasing use by other surgical craft groups, cost-effectiveness will become more commonplace, and less of an issue.

Current Utilization

Although telemedicine provides undoubted potential to benefit both patients and surgeons the field has steadily expanded as opposed to exploding over recent years. The use of remote surgeons and mentors can facilitate complex procedures that would otherwise not be attempted due to lack of available, experienced surgeons.

The use of telementoring platforms providing intra-operative instruction continues to increase in popularity. Driven by a need for improved surgical mentoring the telementoring interface developed by Intuitive Surgical Inc. (CA, USA), called Connect™ used in conjunction with the Da Vinci surgical system has been demonstrated to provide trainee robotic surgeons safe and effective telementoring while performing basic surgical techniques. This software provided the first interface to merge 'telestrations' onto the operating surgeon's view of the surgical field. Using internet connection with either wired or wireless connection—one way video, two-way audio and telestration can integrated. A mentor can provide information from a desktop or laptop without the need for any additional hardware instillation. Shin et al. demonstrated no difference between operative variables or robotic skills assessments for 29 in-room and 26 remote mentored robotic prostatectomy and renal surgery cases. Mentors during this series preferred remote over in-room telestration.

At present telemedicine is ideally suited to developed countries with remote communities. In Australia Telehealth is extensively used to aid in the delivery of health care by specialists to rural and remote communities. Consultations frequently provide a service that reduces the need for either patient or physician to travel potentially thousands of kilometers. Alternatively, medical consultation and assessment can be possible via telemedicine that were previously impossible. Telementoring can facilitate a cardiologist in America to mentor an on-site care worker in Antartica through the performance an echocardiogram or fundoscopy.

Live streaming of surgery has become increasingly common. Workshops, seminars and conferences utilize technology to teach, showcase and promote surgeries, including minimally invasive surgery. It involves positioning cameras live in theatre and broadcasting the surgery—with views provided from the surgical camera, as well as discussion live with the surgical team. Interaction can be facilitated to enable questions from an audience. The WRSE24 is such an example whereby urology units across the globe perform surgery and live studio sessions for conference participants. With increasing online audiences such streaming events allow a worldwide audience of surgeons to observe and discuss difference in approach and technique.

Telerobotic surgery has been applied for several series of patients. Anvari's group from Ontario, Canada, reported on 18 patients who successfully underwent procedures including bowel resection, Nissen fundoplication and splenectomy from a remote distance of 400 km. Using a Zeus robot and telephone lines with bandwidth ranging from 384 Kb/s and 1.2 Mb/s they reported no issues with image quality, time delay or loss of signal.

Use of iPad in Robotic Surgery

Preoperative imaging of patients with prostate cancer, either with MRI or CT, provides anatomical details and data regarding the exact position and the extent of the tumor as well as its proximity with adjacent structures. This remarkably extended information is underutilized in the operating room during the actual interventional procedure. To add complexity, during the operation, shifts and deformations of the prostate and its neighboring structures may alter the anatomical relationships demonstrated on the preoperative imaging.

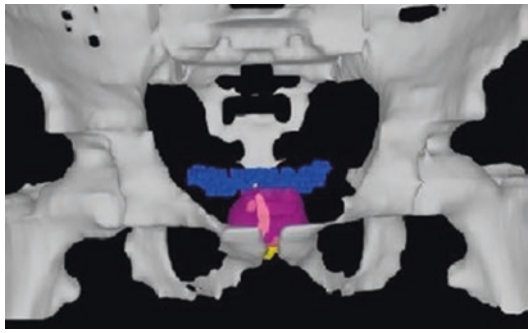

Fig. 66.3 Translucent Medical System intra-operative display. 3D image of prostate and seminal vesicles in alignment with patient's anatomy

The Translucent Medical system is an image-guided surgical system developed specifically for robotic surgery. This advanced image-guided surgical system utilizes preoperative MRI imaging that is mapped to the patient in real time by magnetic tracking to fixed points of the pelvis (Fig. 66.3). Comprised of a tablet computer with a touch screen display, a tracking system housed in a portable cart, a magnetic field generator and position sensors—3D patient images are constructed in alignment with the patient's anatomy. As the tablet computer display is moved, the system software updates image data over 20 times per second to compensate with anatomical alterations during the operation, showing the patient's "real time" internal anatomy in motion on the tablet display. The navigation accuracy that the system provides is $\leq$5 mm. Furthermore, in order to provide a more accurate visualization, the prostate tumors are colour coded.

Future Possibilities

The future possibilities in telementoring and telerobotics are extremely exciting. The potential to provide advice, intra-operative opinion and surgical intervention directed from a remote site will make the world even smaller and the world's most remote corners less remote.

The operating suite of the future should include access to high speed communication links both with in the local hospital network and with an ability to extend connections to regional or international centres. With such links in place surgeons could effective gain the insight of an experienced colleague as quickly as we can now call someone on a mobile phone! The availability of world experts for prompt intra-operative opinion may have significant impact on outcomes and potentially reduce litigation. In a procedure where unexpected intra-operative findings such as complex anatomical variation is encountered a world expert could provide rapid, intra-operative telementoring support or complete the procedure via telesurgery.

The utilization of expert telementoring offers to shorten training periods for new procedures resulting in a reduction of the detrimental impact of surgeon learning curves and a faster reduction in operating times. The worldwide propagation of new techniques could also be advanced in terms of acceptance and patient safety. One can understand such advantages if considered in the context of the adoption of laparoscopic surgery. In the 1990s laparoscopic surgery was adopted with great enthusiasm. Laparoscopic cholecystectomy evolved from the experimental to the gold standard of management with in a decade. With this rapid expansion was an associated alarmingly high rate of common bile duct injury associated with the early experience in laparoscopic cholecystectomy. Many regulatory bodies felt the need to intervene in the regulation of a new procedure for the first time in medical history. The availability of a mentoring network providing intra-operative assessment and advice during the laparoscopic 'revolution' could have significantly impacted on these early uptake problems.

Although presently ideally suited to developed countries with remote communities future massive advantages of telemedicine and telesurgery could lay in the geographically isolated less developed region of this world… or even beyond this world. Telesurgery may make procedures currently impossible due to lack of local expertise possible in less developed areas. Telementoring may allow surgeons in such areas to learn techniques without having to spend extended time away from their areas of need. The complications of surgery in space and increasing communication lag times will require the adoption of multiple models of telementoring and telesurgery (Fig. 66.4). An astronaut

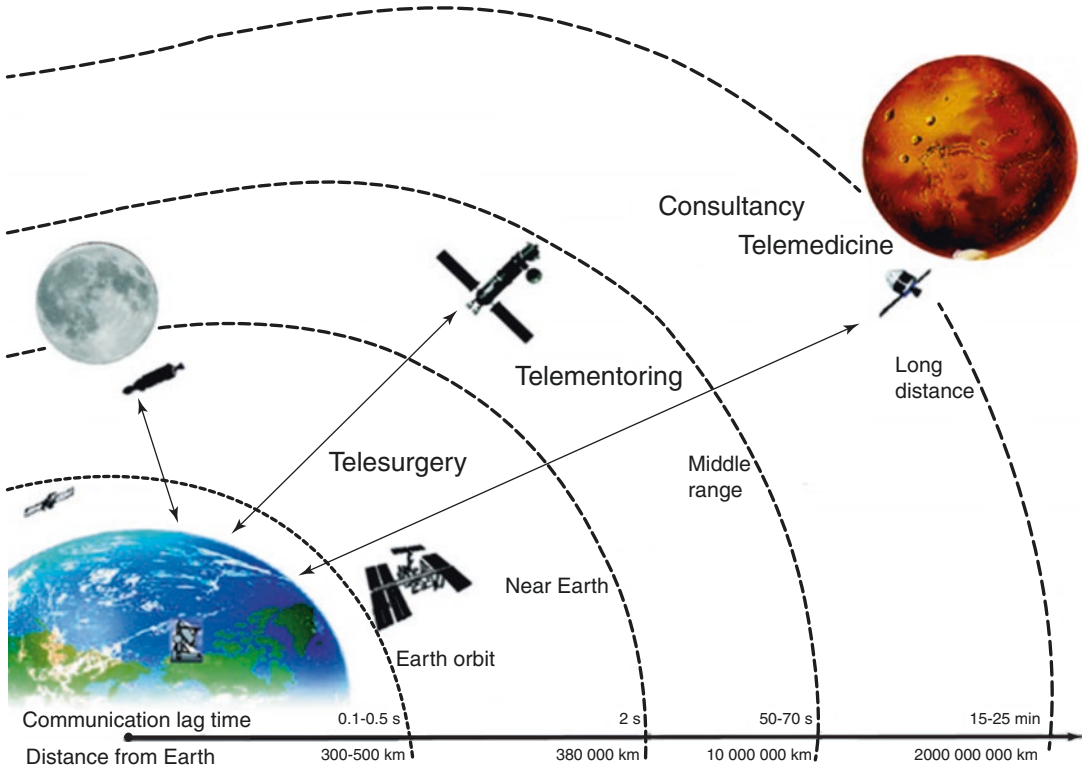

Fig. 66.4 Telemedicine support in space. Distance and communication lag time impact on the method to provide the maximal level of medical care. In close proximity to the Earth a teleoperated surgical robot would be appropriate. With increasing distance telementoring and consultancy telemedicine would be indicated

requiring surgery at a distance from Earth equivalent to the moon would have appropriate lag times for safe tele-surgery. Double that distance from Earth and lag times will go beyond those appropriate for remote operated surgery and telementoring will be provide the best practice. If the distance increases to a point where lag times become greater than one minute then consultancy telemedicine involving pre-operative training via instruction and simulation would be indicated.

Conclusion

The introduction of robotics provides one of the most exciting surgical advances of recent years. Over the past two decades the use of locally controlled robotic assistance has steadily increased and been accepted as a gold standard of surgical delivery in some conditions. Integration of ever improving communication technology with robotic platforms offers the emergence of an exhilarating new era of remotely mentored and performed surgery. Indeed, this new era of surgery has already begun with multiple examples of trans-continental surgeries successfully preformed.

With careful negotiation of the potential hurdles this frontier of surgery provides in the form of financial, technical and ethical issues it has the potential to greatly influence the way medicine and surgery are practiced in the future.

The future of telementoring and telerobotics is to say the least extremely exciting!

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Robotic Systems in Urological Surgery: Current State and Future Directions

67

Wesley W. Ludwig, Shadie Badaan, and Dan Stoianovici

Abstract

Minimally invasive surgery has ushered in an era of popularized robotic-assistance for numerous urological procedures. There continues to be a great deal of interest in improving robotic technologies further. Concomitant robot-assisted laparoscopic radical prostatectomy and trans-rectal ultrasound has been employed to better visualize the neurovascular bundles and other adjacent critical structures during prostatectomy. There have also been attempts to improve prostate biopsy, brachytherapy and percutaneous renal interventions using robot-guidance. A magnetic resonance-safe robot has been designed and safely used to directly biopsy suspicious. Additionally, robot-guided brachytherapy seed placement for prostate cancer treatment has proven feasible and highly accurate. Lastly, robot-guidance for percutaneous renal access has been shown to be accurate and rapid. The evolution of robotic systems may facilitate the development of targeted therapies in urology. The growing emphasis on precision and reproducibility in medicine will likely put robotic technology at the forefront of future urological procedures.

Keywords

Urologic surgery · Urologic oncology · Robotic surgery · Robotic-guidance

Introduction

The advent of minimally-invasive surgery, in the form of laparoscopy, permitted the groundwork for the development and utilization of robotics in the field of urological surgery. Laparoscopy was first used in the beginning of the twentieth century as a means of intra-abdominal inspection for pregnant women [1]. The use of laparoscopy in surgical procedures was popularized in the 1980s and quickly became prevalent throughout a variety of surgical fields [2]. The first laparoscopic nephrectomy was reported by Clayman and laparoscopy was subsequently quickly adopted by urologists [3]. While technically demanding, the opportunity for less blood loss, better pain control and shorter hospital stays made the technology highly attractive [4].

Laparoscopic surgery facilitated the popularization of robot-assisted surgery within the

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field of urology. Robotic-assistance is a "master-slave" system in which a surgeon completely controls a robot from a remotely located console, and was initially pioneered in the 1990s [5]. Klingler described the first robot-assisted laparoscopic radical nephrectomy in 2000 [6]. Currently, robot-assistance is commonplace for a variety of applications, including most extirpative surgeries in urologic oncology and procedures for a number of benign diseases as well.

The main robotic system in use is the Da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA), which has seen widespread proliferation and dissemination within the last two decades [7].

A number of advantages over laparoscopy and open surgery have been professed for robotic surgery, such as; the ability to magnify imaging, tremor filtration, ability to refine movements, wristed instrumentation and three-dimensional (3-D) visualization. The benefits of robotic-assistance compared to open surgery have been well documented, including less blood loss, improved pain scores, shorter hospital stay, less blood loss and possibly fewer intraoperative complications [8]. However, a recent randomized trial comparing robot-assisted prostatectomy to open prostatectomy, showed there were no differences in functional or oncologic outcomes [9]. The balance between cost and patient outcomes will continue to be sought, as robot-assistance finds its place within the urologists armamentarium.

While robot-assistance provides numerous advantages over an open surgical approach, it is still entirely vulnerable to human error. The allure of robotic surgery lies within the ability to eliminate this significant source of error and achieve greater precision and accuracy than is currently available. This chapter will review a variety of robotic system applications in urological surgery, including; augmentation of robot-assisted laparoscopic radical prostatectomy (RALRP), prostate biopsy, brachytherapy seed placement and renal interventions.

Augmentation of Robot-Assisted Laparoscopic Radical Prostatectomy

The DaVinci surgical system is commonly used for RALRP. While there are many advantages of robot-assistance over laparoscopy, there continues to be a drive to improve existing technology further. Enhanced visualization is a frequently cited improvement of robotic-assisted surgery over laparoscopic and even open procedures [10]. Indeed, the surgical field is visualized in 3-D, and the camera allows for previously unavailable magnification. However, erectile function and continence outcomes do not appear to have been improved in RALRP over open retropubic radical prostatectomy [9, 11]. Continued efforts are focused on augmenting current robotic technology to improve functional outcomes after RALRP.

An attempt to better visualize the neurovascular bundles during RALRP has been explored by combining transrectal ultrasound (TRUS) imaging and guidance with the performance of RALRP. In an initial cohort of patients, TRUS was used to concurrently identify the neurovascular bundle, prostatic apex, membranous urethra and the bladder neck. There were multiple instances in which exophytic nodules were noted on ultrasound (US) and contributed to attaining negative surgical margins [12]. Overall positive surgical margin rate using this technique was reportedly 9%, compared to 29% for individuals in which concurrent TRUS was not used [13].

Robotic endocavity ultrasound probe manipulators have been designed and employed in various clinical settings. These robots have remote center of motion kinematics and four degrees-of-freedom, which allows image-based US navigation during RALRP [14]. This novel TRUS robot, as well as 3D reconstruction imaging software were developed and used in conjunction with the Da Vinci surgical system during radical prostatectomy. In a feasibility study, this robotic US guidance was found to be free of complications, and allowed 3D image acquisition of the prostate

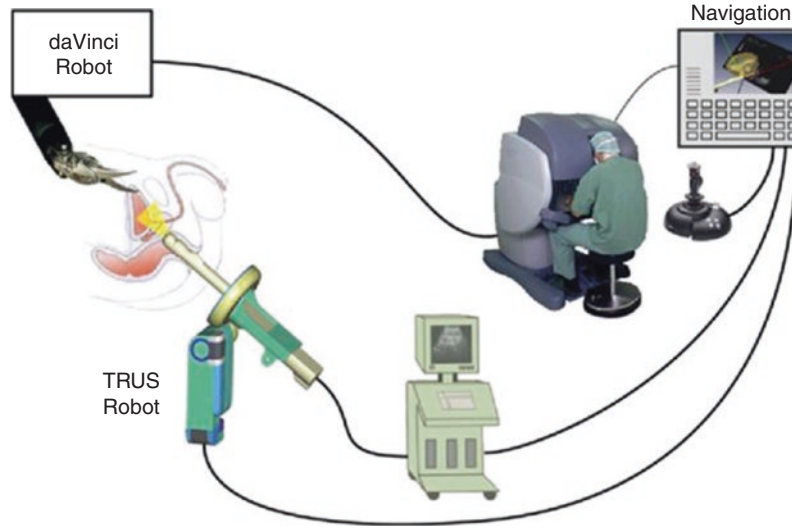

Fig. 67.1 Displays the connectivity and setup of tandem RALP (Reproduced from Han, M, Kim C, Mozer P, Schäfer F, Badaan S, Vigaru B, et al. Tandem-robot assisted laparoscopic radical prostatectomy to improve the neurovascular bundle visualization: A feasibility study. Urology 2011;77, 502–507 (Reference [15], with permission from Elsevier)

and neurovascular bundle during RALRP [15]. Figure 67.1 displays the configuration of this dual robotic system. While feasibility has been determined, the impact of improved imaging on functional outcomes requires further research. Future studies will delineate the value and benefit of this novel approach [15].

An alternative approach to fusing RALRP with real-time US acquired images is overlaying previously acquired images during RALRP. This is commonly referred to as augmented reality and typically utilizes preoperative computed tomography (CT) or magnetic resonance (MRI) images [16, 17]. This is a logical method, as 74%, 97% and 95% of urologists have pre-operative imaging displayed in the operating room during prostatectomy, partial nephrectomy and cystectomy, respectively [18]. This method requires registering previously acquired images to surgical landmarks. Experience with computer-aided image assistance has been reported using real-time US, as well as preoperative CT and MRI. The feasibility of this technique has been demonstrated during laparoscopic partial nephrectomy and prostatectomy [19]. Augmented reality will continue to be an area of interest in improving robotic surgery, as 87% of surveyed urologists believe there is a role for navigation in urologic procedures [18].

Robotic Systems in Prostate Biopsy

Prostate Biopsy: Recent Advancements

Prostate biopsy for the detection of prostate cancer is one of the most commonly performed urologic procedures. Over one million prostate biopsies are performed yearly and are typically done free-hand with ultrasound guidance [20]. Traditional TRUS guided biopsies may miss up to 25% of prostate cancers and may increase the detection of clinically insignificant tumors [21, 22]. Additionally, commonly performed biopsies lack three-dimensionality. The detection of significant and insignificant prostate cancers, as defined by a size cutoff of 0.5 cm^3, was quantified using a novel 3D capsule biopsy model [23]. The geometric distribution of the cores was optimized to maximize detection of clinically significant prostate cancer. The current sextant biopsy was found to miss up to 20% of significant cancers, while a higher number of longer cores improved detection. Importantly, prostate biopsy quality is highly dependent on the individual surgeon performing the biopsy. A study of five urologists performing TRUS prostate biopsies, found that each urologist had a signature clustering of biopsies and

poor accuracy with a mean error of 9.0 mm [24]. However, robot-assisted biopsies in the same study were truly systematic, without clustering and a mean error of 1.0 mm. Robot assistance was associated with better accuracy, precision and detection of prostate cancer. In order to eliminate inherent issues with TRUS guided prostate biopsy, there has been significant interest in the development of robot-guided prostate biopsy.

MRI is an excellent imaging modality for the detection of prostate cancer, and the use of MRI/US fusion-guided biopsy has been increasing greatly in recent years [25]. Studies using MRI/US fusion-guided biopsy have reported both an improved detection of high-risk cancers and minimization of low-risk cancer detection [26]. While fusion technology is an improvement over simple TRUS-guided biopsy, it has a number of drawbacks, including inaccuracy of cross modality image registration, endorectal coil induced tissue deformation and human error [27]. Therefore, there is interest in directly sampling the prostate during MRI using robot-guidance to reduce sampling error.

Development of an MR-Compatible Robot for Prostate Biopsy

One of the major hurdles to prostate biopsy under direct MRI-guidance is the necessity for all instruments to be MR-safe. MR utilizes high-density magnetic fields and any ferromagnetic object near the magnetic field is subjected to elevated magnetic interaction forces. This can cause alterations to the object that can create unsafe patient conditions, and interference with image acquisition. To be MR-safe, all objects must be non-magnetic and non-conducting [28]. Therefore, robots must be composed entirely of glass, rubber or plastic [29]. A group created an MR-compatible device entirely of Ultam plastic, and demonstrated feasibility in a small cohort of patients. The needle guide included MR tracking microcoils for image registration and targeting accuracy was within 1.8 mm [30]. Perhaps the greatest challenge is in selecting a power source for the robot. Most energy utilized in robotics devices is electric, but electric energy generates currents which are not MR-safe. An MR-safe robot was designed at the Johns Hopkins Hospital URobotics Laboratory known as the MrBot, which contains a novel pneumatic step motor and targeting device [31].

The pneumatic step motor, known as the PneuStep motor, avoids the use of eclectic energy. The PneuStep motor utilizes pneumatic actuation and a step motor to collect successive end-to-end motion strokes during the motor's rotary motion. This provides precise pneumatic energy without the need for electric current. The robot-assisted targeting device assists the physician performing the biopsy by orienting the needle guide and fixing the target depth [32]. The endorectal targeting device has three degrees-of-freedom and can be fully automated, as opposed to previously designed devices that require the physician to set the depth [30, 33]. The endorectal portion contains a number of registration markers, thus the needle guide passes through and obtains a robotically determined angle. A specially designed needle spacer corrects for depth [32].

Robot-Assisted MRI-Guided Biopsy

MRI guided in-gantry prostate biopsies have been performed safely and successfully. Comparisons of MR-guided biopsy to TRUS-guided systematic biopsy have found a significantly improved prostate cancer detection rate [34]. In order to achieve more accurate needle placement within MRI detected lesions, robotic-guided needle placement has been actively pursued.

The MrBot was initially tested in a canine model. Following image to robot registration, locations within the canine prostate were selected for biopsy. Thirty targets were chosen and robot-guided biopsy had an average precision of 1.31 mm and accuracy of 1.58 mm. All targets were sampled within 5 mm, which was considered to be the margin of error for detection of clinically significant tumors. Importantly, there were no complications and no issues of note regarding the robots task execution [32]. Following the success of MR-safe robotic targeting in a canine model, an initial trial was performed in a human cohort. Five men were

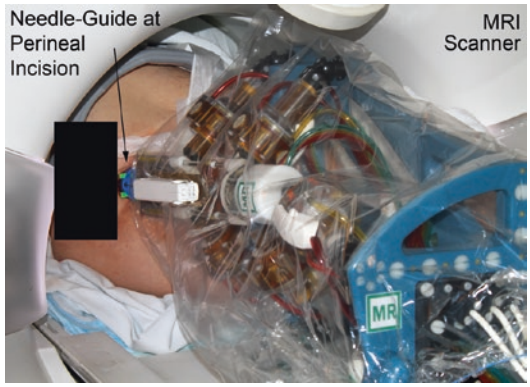

Fig. 67.2 A patient undergoing a transperineal prostate biopsy is seen in left lateral decubitus position within an MRI scanner. The MrBot is placed at the perineum prior to biopsy

selected that had an elevated PSA, presence of a likely cancerous lesion on MRI, and a previous negative TRUS guided biopsy. These five men underwent transperineal direct MRI-guided biopsy utilizing the MrBot. The set-up for this transperineal biopsy can be seen in Fig. 67.2**.** Both targeted biopsies and routine sextant biopsies were performed. There were no complications, however, two men did require catheter placement for urinary retention- which resolved without further issue. In total, there were thirty biopsy sites and clinically significant cancer was detected in two patients (40%). There were no trajectory corrections required and no unsuccessful targeting attempts. Importantly, the targeting accuracy was 2.55 mm [35].

Robot-Guided Brachytherapy Seed Placement

The surgical management of prostate cancer is commonly approached with robot-assistance, as discussed previously. However, there is interest in targeted therapies- such as brachytherapy and cryoablation with robot-guided targeting. This is particularly true in an era where targeted therapy for prostate cancer is gaining traction [36]. Brachytherapy seed placement is an area in which robot-guidance has been actively investigated. Brachytherapy can be performed at a high dose rate or a low dose rate and is typically done under US-guidance with a predesignated treatment map. According to many studies in select patient populations, brachytherapy has similar oncologic outcomes to external beam radiation therapy and radical prostatectomy [37]. Brachytherapy is an appealing modality as it provides a method to apply increasing doses of radiation to higher-risk areas. Robot-assisted MR-guided brachytherapy seed placement may allow even more precise placement of seeds into MRI visible lesions. Optimization of radiation dose would facilitate targeted cancer destruction as well as preservation of the nearby neurovascular bundles. Currently, the use of templates does not permit maximization of seed placement or dosimetric feedback [38, 39].

The feasibility of robot-guided insertion of brachytherapy seeds has been performed with the MrBot. An MR-compatible needle capable of seed injection was developed and was found to be able to perform this task at high speed, thus lessening soft-tissue deflection [40]. Following image to robot registration, the MrBot was highly accurate in motion capability tests, with an error of 0.076 ± 0.035 mm. This system was tested in a tissue mockup and found to have a mean error of only 0.72 ± 0.36 mm [41]. Robot-guided brachytherapy seed placement has great potential for precision prostate cancer therapy and further research will define its role within the treatment armamentarium.

Robotic Systems for Renal Interventions

While a great deal of attention is given to robotic interventions related to prostate cancer, percutaneous renal interventions have been explored as well. The URobotics Laboratory at Johns Hopkins Hospital has developed a robotic system utilizing CT or fluoroscopic guidance to precisely and accurate needle placement various medical interventions [42]. This is a couch-mounted system with a seven degrees-of-freedom passive mounting arm, a remote center of motion and motorized needle insertion device. The accuracy of this device is better than 1 mm [43]. This robotic system has previously been applied

successfully to hepatic lesions, but is translatable to renal masses [44, 45]. CT fluoroscopy is commonly used when performing percutaneous renal tumor ablations, and the ability to perform this remotely with robot-guidance allows for a reduction in possible radiation exposure to the physician and other operating room personnel [46].

A novel robotic system, called "PAKY" (percutaneous access of the kidney) with six degrees-of-freedom was designed for percutaneous needle placement under fluoroscopic guidance. Following skin puncture, this robotic system requires only two degrees of freedom to orient the needle in the correct trajectory. This robotic system has been used successfully to achieve percutaneous access to the collecting system remotely, rapidly and without complications [47]. The PAKY robot was compared to surgeon access for percutaneous renal access in 23 patients, and found that PAKY required a mean of 2.2 attempts and took only 10.4 min [48]. There were no complications, and access was gained in 87% of cases. The PAKY robot setup is depicted in Fig. 67.3. Robotic vs human percutaneous renal access for nephrolithotomy was evaluated in a randomized controlled trial and found that robotic attempts were slightly slower than human attempts, however, the robot provided improved accuracy and fewer overall attempts [49]. Of note, the urologists performing percutaneous nephrolithotomy in this trial were high-volume endourologists, thus robotic results would be expected to be significantly better when compared to urologists that perform percutaneous nephrolithotomy less frequently.

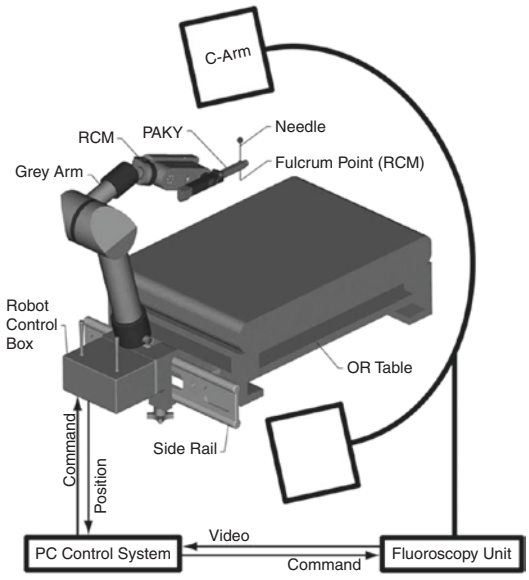

Fig. 67.3 Displays the PAKY robot setup and relationship between PAKY, patient, fluoroscopy unit and computer control system. Reprinted with permission from JOURNAL OF ENDOUROLOGY, 2002, Volume 16, pp. 471–475, published by Mary Ann Liebert, Inc., New Rochelle, NY" (Reference [48])

Conclusions

Urological surgeons have been early adopters of novel surgical technology, particularly in regards to robot-assisted surgery [50]. Many urological surgeries are now commonly performed with the Da Vinci Surgical System, classified as a "master-slave" relationship. However, there is interest in not only improving upon the Da Vinci system, but designing and developing automated surgical tasks to reduce human error. Currently, Da Vinci provides a 3-D visual field and image enhancement, but further improvements are being investigated. To improve visualization of the neurovascular bundles, 3D robot-guided US imaging in conjunction with RALRP may potentially improve imaging of the neurovascular bundle [15]. The impact of this technology on functional and oncologic outcomes will continue to be studied and will determine if this is a viable tool to improve prostatectomy results. Robot-guidance is also being used to improve prostate biopsy and brachytherapy seed placement [35, 41]. Prostate biopsy is most commonly performed via free-hand TRUS or MRI/US fusion-guided biopsy, both of which present unique challenges. MR-guided prostate biopsy using the novel MrBot allows urologists to directly biopsy lesions suspicious on MRI accurately using robotic-guidance [31]. Additionally, the placement of brachytherapy seeds robotically under MR-guidance may permit maximizing radiation dose to high-risk areas and avoidance of nearby critical structures [41]. This may be an important avenue as interest in focal therapy

for prostate cancer increases [51]. Finally, robotic-guidance for percutaneous renal procedures has proven highly accurate and successful [48]. The rapid evolution of robotic systems may facilitate highly-targeted and improved treatments for a variety of urological surgeries. An emphasis on precision and minimizing invasiveness will likely put robotic technology at the forefront of future advancements.

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68 Emerging Molecular, Imaging and Technological Advances in the Field of Robotic Surgery

Smita De, Lara Marie Seltz, and S. Duke Herrell

Abstract

A wide variety of novel technologies are currently under development to augment the existing benefits of robot-assisted surgery. A key concept is the emergence of image-guided robotic surgery, and this includes advanced optical and molecular imaging, such as confocal microscopy, as well as integrated intraoperative imaging with more traditional modalities, such as ultrasound. In addition, advances in robotic technology have not only resulted in the innovation of new intraoperative capabilities and potential competitors to the existing robotic platforms, but may also revolutionize the approach to urologic surgery with novel procedure-specific robots.

Keywords

Surgical robot · Image-guided surgery · Molecular imaging · Confocal microscopy · Fluorescence · Augmented reality

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Introduction

Since its introduction 20 years ago, robot-assisted minimally invasive surgery has become a key component of the Urologic surgeon's practice. Although it is most frequently used for robot-assisted laparoscopic prostatectomies (RALP), urologists have continued to push the envelope to both develop novel techniques and transform traditional open surgeries into minimally invasive procedures using the robotic platform.

The present generation of surgical robots provides excellent stereotactic vision to the surgeon; however, additional image-guidance through the use of intraoperative real-time imaging or incorporation of preoperative images has the potential to increase accuracy, precision, safety and surgeon confidence. For example, limitations from the loss of haptic feedback (touch sensation) may be overcome by image guidance. The majority of research in this area focuses on identification of normal anatomic structures, such as nerves or arteries, and pathologic tissues, such as tumors or lymph nodes. Currently, we stand as a field on the edge of another potential paradigm shift, the incorporation of such advances in imaging technologies, many of which may be combined with innovations in robotic and interventional platforms, to allow for reductions in invasiveness and improvements in outcomes.

Much of the progress and widely adopted use of imaging technologies within robotic urologic

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surgery has occurred in an effort to improve RALPs and robot-assisted partial nephrectomies (RAPN), as focused on in this discussion. The first part of this chapter will focus on advances in image-guided surgery (IGS), which can be divided into two broad categories: molecular-imaging and body-imaging. IGS using body-imaging can be further be divided into real-time intraoperative imaging and augmented reality using preoperative images. The chapter will conclude with comments on recently approved devices and novel technologies still under development.

RALP: Opportunities for Technologic Advancement

Widespread PSA testing has resulted in an increase in detection of both innocuous low-risk prostate cancer and more clinically aggressive high-risk disease. For both low and high-risk, localized prostate cancer, RALP remains the most common treatment option offered by physicians in the United States [1]. First introduced in the early 2000's, RALP using the *da Vinci*® Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) now accounts for more than 80% of all prostatectomies in the United States compared to open radical prostatectomy (ORP) [2, 3]. A recently published study derived from the National Cancer Data Base from 2010 through 2011 with analysis of propensity matched cohorts showed RALP technique reduced the risk of positive surgical margins, use of adjuvant radiation therapy, and 30-day mortality, with oncologic benefits seen primarily in patients with organ confined disease (pT2 pathology) when compared to open surgery [4]. Despite such advances, positive margin rates have been reported to be as high as 22% [5]. Additionally, erectile dysfunction and urinary incontinence remain as potential side effects and affect up to 70% and 21% of patients, respectively [5]. Integration of advanced imaging technologies, such as those discussed in this chapter, will hopefully lead to improved oncologic control through tumor and lymph node identification as well as improved functional outcomes for both continence and erectile function with more precise identification of critical structures, including the neurovascular bundle.

RAPN: Opportunities for Technologic Advancement

The incidence of renal cell carcinoma has increased in the United States steadily between 1975 and 1995 based on data from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program [6]. Per AUA guidelines, partial nephrectomy is considered the standard of care for patient with small renal tumors and with advances in robotic surgery there has been an increasing role of RAPN as an alternative treatment modality to open and laparoscopic partial nephrectomy. Two important outcomes for RAPN include the preservation of renal function and oncologic control of tumors with negative margins. Currently, positive margins during partial nephrectomy range from 2.9% (robotic) to 3.8% (open) per a recently published meta-analysis [7]. The integration of advanced imaging technologies could improve the precision of tumor resection, particularly for endophytic tumors, in order to achieve negative margins while optimizing nephron-sparing. In addition, image guidance can also be used to more easily identify landmarks, including vessels at the renal hilum. Warm ischemia time (WIT) during partial nephrectomy has a long and now controversial potential role in the performance of partial nephrectomy [8–10]. While other factors such as volume preservation are under evaluation, WIT remains an ongoing discussion topic and has even engendered the use of "off clamp" techniques [11, 12].

Molecular-Imaging Systems

Molecular imaging provides the potential for both real-time imaging of microscopic structures as well as targeting specific tissues. Near infrared fluorescence imaging (NIRF) with indocyanine green (ICG) may be familiar to urologists due to the integrated *Firefly*™ (Intuitive Surgical Inc.,

Sunnyvale, CA) system in the *da Vinci*® robotic platform. NIRF in urologic robotic surgery is currently used mainly for delineation of anatomic structures and confirmation of ischemia or perfusion, but many other potential uses are discussed below. Spectroscopy and confocal microscopy are two more investigational techniques that may be of benefit in urologic robotic surgery, and results from recent studies are reviewed here. Several other modalities are in the early stages of development for use in robotic surgery, such as optical coherence tomography, multiphoton microscopy, and photoacoustic imaging, but are beyond the scope of this chapter.

Near Infrared Fluorescence Imaging

NIRF imaging utilizes a fluorophore as a contrast agent to provide real-time visualization of anatomic structures up to a depth of several millimeters. Currently, the most popular non-specific fluorophore used in urologic surgery is ICG. ICG is a water-soluble, nonradioactive, non-nephrotoxic dye that binds to plasma proteins, such as albumin. This fluorophore is excited at a wavelength of about 806 nm and emits light, or fluoresces, maximally at 830 nm (near infrared) in blood. Once injected intravenously, ICG is rapidly circulated throughout the body after which it is metabolized by the liver and excreted in bile. It was first developed for use in hepatic function diagnostics in the 1950s but has since been adopted by multiple medical specialties [13]. While NIRF can be used in open and laparoscopic surgery with specialized systems, use in robotic surgery is increasing due to integration of the NIRF *Firefly*™ system into the *da Vinci*® Si™ and *da Vinci*® Xi™ robots.

Role of NIRF in RAPN

The near infrared spectrum allows for deeper tissue penetration versus white light and may provide enhanced visualization in surgical conditions, such as a bloody field. This feature can be exploited in a partial nephrectomy to aid with tissue and margin differentiation. Bilitranslocase, which is mainly expressed in the liver, kidney and gastric mucosa, transports ICG into the proximal and distal tubules of normal parenchyma but not malignant cells [14]. Thus, during a partial nephrectomy, ICG can both help delineate hilar anatomy as well as identify tumors, which appear hypofluorescent. This has been demonstrated in multiple series of robotic partial nephrectomies with a positive predictive value of 86–87% for malignancy with a hypofluorescent lesion [15, 16]. While there is currently no indication that ICG should replace cross-sectional imaging to predict malignant features in a lesion, NIRF may help decrease positive surgical margin rates while potentially reducing WIT and increasing preservation of normal parenchyma. A recent case-control study demonstrated a lower rate of positive margins with NIRF enhanced RAPN versus the control group (6% vs. 8.5%) though this was not statistically significant [17]. In this same study, there was a small but statistically significant decrease in WIT during NIRF enhanced RPN.

Efforts have been made to reduce not just the duration but also the distribution of WIT in RAPN through the use of selective, rather than main artery, clamping. NIRF can aid in this effort by confirming adequate localized ischemia in that the non-perfused areas after selective clamping will appear hypofluorescent. Multiple matched-pair studies utilizing ICG-based NIRF for selective clamping demonstrated a significant decrease in reduction of GFR with selective clamping (differences ranged from 11 to 13.1 ml/min) [12, 18, 19]. Of note, some recent studies suggest that the differences seen in short-term renal function outcomes with selective clamping outcomes may not persist and that preoperative eGFR and volume of preserved parenchyma may have a greater impact on long-term renal function [11, 20, 21]. In a retrospective study by Desai et al., renal function and CT-based volumetric data were compared in patients who had undergone main artery clamping versus NIRF-guided superselective clamping during RAPN. Patients who underwent superselective clamping had decreased loss of renal function at follow up (11% vs. 17% $p = 0.03$), but more interestingly, they had increased preservation of

normal parenchyma (95% vs. 90% p = 0.07) despite the fact that this cohort had larger tumors (3.4 vs. 2.6 cm p = 0.008) [11]. These studies suggest that the potential benefits of NIRF guidance in partial nephrectomy may be multimodal, although findings should be evaluated with prospective randomized trials as NIRF increases operative costs at a rate of $100,000 per integrated vision system with an approximate cost of $100 per vial of ICG.

Use of NIRF in Other Urologic Procedures and ICG-Based Tissue Targeting

The potential role of ICG-based NIRF has been evaluated in several other procedures including ureteral reconstruction (i.e. pyeloplasty or stricture excision) and identification (i.e. gynecologic procedures, anatomic abnormalities) [22, 23]. Typically in these cases, ICG is not injected intravenously but rather instilled into the ureter using a ureteral catheter or percutaneous access. Other published case reports include NIRF guidance during robotic partial adrenalectomy for tumor identification, robotic radical prostatectomy for sentinel lymph node detection, and robotic cystectomy for tumor marking, mesenteric angiography, and pelvic lymphangiography [24–26].

In addition to its role in imaging, ICG is an ideal molecule for modification and tissue targeting for diagnostics and therapy given its non-toxic nature, small size (1.2 nm), and ability to induce hyperthermia and form reactive oxygen species when excited by specific wavelengths. Limitations of ICG in this capacity include its non-specific bonding to plasma proteins, instability *in vivo*, and rapid clearance. Several techniques have been employed to stabilize and encapsulate the dye into different carriers, such as polymeric nanoparticles, polymeric micelles, liposomes, etcetera, to address these limitations [27]. Many such formulations have included chemotoxic drugs, such as doxorubicin, and some of these have demonstrated a synergistic effect between the cytotoxicity of the chemotherapy and the IGC-induced hyperthermia [28]. To date, studies have mainly demonstrated proof of concept *in vitro* and *in vivo* in rodent models. Potential uses in Urology may include identification of specific structures, both pathologic and non-pathologic, and targeted therapy.

Confocal Laser Endomicroscopy

Confocal Laser Endomicroscopy (CLE) is a form of real-time high resolution microscopic imaging that was initially used in Gastroenterology. CLE is currently being evaluated in several areas of Urology, most notably for imaging of bladder cancer [29]. CLE utilizes a 488 nm laser light source and Fluorescein as a nonspecific contrast agent. Fluorescein is an FDA-approved fluorophore that emits light under excitation. A fiberoptic probe is used to acquire real-time microscopic images once the fluorescein is excited by the laser light source. The emitted light is filtered through a pinhole such that only in-focus light is measured. Larger probes can lead to high resolution and greater depth of tissue penetration.

Role of CLE in RALP

Recently, Liao et al. published a study evaluating the feasibility of using intraoperative CLE during RALPs to identify periprostatic structures as it is generally believed that recognition of these structures intraoperatively is critical to decrease postoperative morbidity [30]. Fifteen patients were imaged *in vivo* during RALP with 2.5 mL of 10% fluorescein administered intravenously 5 min prior to dissection of the neurovascular bundle. 2.6 mm and 0.85 mm tethered CLE probes were placed through the assistant port and manipulated with the robotic instruments. Using the TilePro™ (Intuitive Surgical Inc., Sunnyvale, CA) display in the surgeon console, the prostatic and periprostatic tissues were visualized to a depth of up to 60 μm. Tissues were again visualized *ex vivo* and then sent for pathology, including standard H&E staining as well as immunohistochemistry for S100 protein to help identify the cavernous nerves. Axonal fibers were identified as parallel thin dark lines, both with the *in vivo* and *ex vivo* imaging. The nerves were identified in 11 of 15 patients during i*n vivo* imaging. *Ex vivo* CLE identified the neurovascular bundle in non-nerve

sparing specimens and this was confirmed with immunohistochemistry. In addition, extracapsular extension of one tumor identified on an *ex vivo* specimen was confirmed on pathology. These results suggest that CLE could potentially be integrated into robotic surgery to aid in visualization of microscopic structures including extracapsular extension, which may help decrease positive margin rates.

Spectroscopy

Spectroscopy is a form of real-time imaging based on the interaction of light and other radiation with matter as they travel through tissue and are either scattered, reflected, absorbed, or transmitted. Unique patterns arise from this interaction and are dependent on the wavelength of excitation light or radiation, tissue composition, and the tissue's physiologic state. Spectroscopy systems typically include an optical probe that is used to both deliver light or radiation at variable excitation wavelengths and record the unique signal induced by tissue properties with a compact spectrometer. For example, the WavSTAT ™ optical biopsy system (SpectraScience, San Diego, CA) delivers five 10 ms pulses from a diode laser, allowing the system to take five unique fluorescence spectra from a single location [31]. The induced fluorescence is recorded by a spectrometer preceded by a pass-filter and analyzed by software. Spectroscopy is unique in that it allows clinicians to obtain information on tissue structure and function without cellular disruption. Multiple types of spectroscopy, including autofluorescence, Raman, infrared, and near infrared have shown potential as tools to aid in the diagnosis, staging, and treatment of urologic malignancies.

Spectroscopy for RAPN

Nephron-sparing approaches for management of small renal masses are becoming increasingly common with either extirpative operations, such as RAPN, or ablative techniques, such as cryotherapy. Spectroscopy is a potential real-time intraoperative modality to differentiate between the malignant neoplasm and benign renal parenchyma, thus optimizing oncologic outcomes. In 2005, Parekh et al. reported the initial study on the use of combined fluorescence and diffuse reflectance spectroscopy to differentiate between *ex vivo* malignant and benign renal tissues from radical nephrectomy specimens. Using empirical discrimination algorithms, the authors differentiated between normal parenchyma, clear cell RCC, and papillary RCC with up to 94% sensitivity and 97% specificity [32]. Further work explored spectroscopy as a modality to detect positive margins intraoperatively. Bensalah et al. compared tissues *ex vivo* from radical and partial nephrectomy specimens [33]. In partial nephrectomy specimens, Pearson correlation coefficients demonstrated excellent correlation for optical spectroscopy measurements from the normal parenchyma of negative margins (mean r = 0.94). For the one case with a positive margin (oncocytoma), the optical spectroscopy measurements between the intratumor and positive margin correlated well (mean r = 0.8).

Spectroscopy for RALP

Recent studies have demonstrated that spectroscopy may have multiple clinical applications in the management of prostate cancer, including serving as a modality to identify intrinsic biomarkers of this malignancy. In one of the earlier studies evaluating spectroscopy for prostate cancer, Sharma et al. designed a dual modality system using light reflectance and auto-fluorescence lifetime spectroscopy and obtained spectra over both cancer and control tissue *in vivo* using a rat prostate tumor model [34]. They found that autofluorescence lifetimes at all measured emission wavelengths (532, 562, 632 and 684 nm) differ between control and cancerous tissues with 100% specificity and sensitivity.

New platforms in prostate cancer diagnosis, such as the MRI-transrectal ultrasound fusion–guided prostate biopsy, have focused on differentiating between innocuous low-risk disease and more clinically aggressive high-risk disease. Similarly, spectroscopy may serve as an essential technology to identify and differentiate biologically aggressive intermediate and high-risk disease for targeted therapy and to help identify

positive surgical margins intraoperatively [35, 36]. In a separate study by Sharma et al., a dual modality system with auto-fluorescence lifetime and light reflectance spectroscopy (LRS) was used to differentiate between intermediate and high-grade prostate cancer (Gleason Score (GS) $\geq$ 7) and benign tissue (benign prostate hypertrophy (BPH), normal peripheral zone, or benign extra capsular tissues). The group obtained spectra from fresh *ex vivo* radical prostatectomy specimens and their algorithm demonstrated accuracies of 87.9%, 90.1%, and 85.1% for prostate cancer grades GS 7, 8, and 9, respectively, when compared to BPH and normal peripheral zone tissue [35]. The accuracies improved to 91.1%, 91.9%, and 94.3% for prostate cancer grades GS 7, 8, and 9, respectively, when including benign extra capsular tissues in the algorithm.

Two recent studies have used spectroscopy to assess surgical margins from radical prostatectomy specimens. Baykara et al. evaluated 31 benign samples and 14 malignant samples from 18 *ex vivo* radical prostatectomy specimens with the elastic light singles scattering spectroscopy system [37]. Classification based on the discrimination score derived from principal component and linear discriminant analyses produced a sensitivity and specificity of 86% and 97%, respectively, to differentiate between malignant and benign surgical margins. Morgan et al. found similar results when performing light reflectance spectroscopy on histological positive and negative margins from *ex vivo* prostatectomy specimens in patients with intermediate and high risk disease [38]. Following 5 repeat cross-validation runs, light reflectance spectroscopy predicted positive surgical margins with 86% sensitivity and 85% specificity.

Future Work

Spectroscopy is a novel intraoperative or intraprocedural modality that in the future may aid in diagnosis, staging, and treatment of multiple urologic malignancies. Research to date has demonstrated that spectroscopy has the ability to objectively diagnose and stage malignancies in real-time without tissue or cellular disruption. Future work, including *in vivo* studies, will focus on the development of novel devices and methods utilizing spectroscopy with enhanced diagnostic accuracy and treatment algorithms that can be integrated into clinical practice.

Body-Imaging Systems

Body imaging using CT, ultrasound, and MRI is a standard part of the surgeon's preoperative armamentarium. With image-guided surgery, the hope is to incorporate the critical information from these powerful tools into the operating field. In current practice, a surgeon must create a mental map using these two-dimensional images on an external monitor and then attempt to 'register' the map to a patient's anatomy intraoperatively. Techniques utilizing intraoperative imaging provide a surgeon with the most up-to-date view of the patient's anatomy and pathology (consider that preoperative imaging is often several months old) and in a relevant orientation (flank position during partial nephrectomy versus supine position of CT scan). Alternatively, augmented reality can utilize pre-existing images to provide an intraoperative roadmap. Here we discuss results of recent studies and developments in the field.

Intraoperative Image Guided Surgery: Ultrasound and CT

One of the primary drawbacks of minimally invasive surgery is the loss of tissue discrimination through haptic feedback. Real-time image-guided surgery (IGS) provides enhanced visual information with imaging modalities that are familiar to the surgeon, thus potentially mitigating the loss of haptic sensation during complex urologic surgeries. Various imaging methods have been considered for integration into IGS including ultrasound (US), CT, cone-beam CT, fluoroscopy, and MRI. US and CT imaging are both familiar to urologists, however each has innate limitations for adaptation into IGS. US is inherently limited by its inability to detect isoechoic lesions and a low resolution, two-dimensional imaging format.

While CT provides higher quality images, significant limitations to intraoperative CT include radiation risk to the OR staff and patient, cost, and burdensome workflow.

The adaptation of cone-beam CT shows potential capacity for use with robotic IGS within urologic surgery. Cone-beam CT was first developed for angiography but has now been adapted for use in interventional radiology and implant dentistry and overcomes many of the inherent limitations to traditional CT imaging for IGS. X-rays are directed through the area of interest in a cone shape with a radiation source and detector rotating around a fulcrum, rather than the conventional fan shaped X-ray beam with helical progression. In one rotational sequence, an average of 150–600 sequential planar images of the field of view are obtained [39]. The significant limitations with cone-beam CT include lower quality imaging when compared to conventional CT, cost, and limited availability within operative suites [40]. There has been early experimentation with *ex vivo* renal models using live cone beam CT images with navigation markers (fiducials) to overlay on pre-operative CT images. Teber et al. utilized a porcine renal tumor model to navigate and superimpose the virtually created images with real-time images obtained with cone beam CT and barbed fiducial markers. The error of margin was 0.5 mm (range 0.2–0.7 mm) and image acquisition took only 40 ms [41]. They propose that this system would provide enhanced decision-making guidance immediately prior to tumor resection intraoperatively. Additional translational research is needed to demonstrate cone-beam CT as a feasible modality for IGS within the field of robotic urologic surgery.

US has shown early, practical integration with the *da Vinci*® Surgical System. The TilePro™ function allows for direct visualization of ultrasound images on the console screen in the multi-image display mode, thus allowing for the surgeon to directly manipulate the US probe. Laparoscopic ultrasound (LUS) devices have been developed for use in standard trocars for laparoscopic and robotic surgery and can either be rigid or drop-in with a flexible cord. LUS probes are typically 6–10 mm in diameter and have small linear-array transducers set between 5–10 MHz to optimize image depth and resolution [42]. Flexible drop-in LUS probes provide better tissue contact than traditional rod-type configurations and allow the surgeon to direct the probe. One example is the ProART Robotic Transducer (BK Medical Herlev, Denmark) which has a control-fin at the top of the probe designed to fit the Intuitive Surgical® ProGrasp forceps.

IGS: Ultrasound for Robotic Partial Nephrectomy

For RAPN, intraoperative US use can improve the precision of tumor resection, particularly for endophytic tumors, in order to achieve negative margins while optimize nephron sparing. US image guidance can also be used to accurately identify landmarks, including vessels at the renal hilum. Kaczmarek et al. reported outcomes in 22 patients undergoing RAPN with a drop-in robotic US probe (Hitachi-Aloka, Tokyo, Japan) under console surgeon control to assist with tumor identification. The mean tumor size was 2.7 cm with 21 endophytic tumors (95%) and 6 hilar (27%) tumors [43]. All patients had negative margins intraoperatively and at 13 month follow-up were free of disease recurrence. The study also reported that the robotic US probe could more easily maintain perpendicular contact between the probe and the kidney surface on both the near and far edge of the tumor compared to a rigid laparoscopic probe.

Hyams et al. compared the hilar dissection time for patients undergoing RAPN both with (27 patients) and without (26 patients) intraoperative Doppler US. The authors used a disposable rigid laparoscopic Doppler ultrasound (LDU) probe (Vascular Technology, Inc., Nashua, NH) and demonstrated that the hilar dissection time was significantly less with use of the LDU (7.2 vs 11.0 min, $p < 0.05$) [44]. They also reported that in seven patients (26%), the use of LDU detected accessory vessels that were not seen on preoperative imaging, five of which were accessory renal arteries that required clamping to achieve either selective or global ischemia. Results of these studies indicate that US can be a valuable asset during RAPN.

IGS: Ultrasound for RALP

Similar to RAPN, US has proven to be a promising imaging modality for integration with the *da Vinci® 3D* stereoscopic vision to help better identify critical anatomy during RALP. Specifically, US can be used to visualize structures such as the neurovascular bundles (NVB) and prostate apex, leading to potential improvement in continence and potency functional outcomes as well as further reducing positive surgical margin rates. Recent studies have demonstrated the feasibility of robotic transrectal ultrasound (TRUS) systems for real-time image guidance during RALP. Han et al. demonstrated the safety and improved visualization of the NVB in a small three patient study with a novel, robotic TRUS probe manipulator and three-dimensional reconstruction software used concurrently with the *da Vinci®* robot (T-RALP) [45]. Long et al. also created an integrated TRUS system with a modified ViKY® endoscope holder (ENDOCONTROL; La Tronche, France) that was used during RALP in five patients, again to demonstrate the feasibility and safety of an integrated system for improved visualization during NVB, bladder neck, and apical dissections [46]. More recently, Mohareri et al. published a Phase I-II clinical trial with 20 patients that used a TRUS guidance system that was calibrated to the *da Vinci®* Surgical System. The TRUS images were controlled by the registered coordinate system directly within the surgeon console, rather than requiring custom devices or manual readjustments as early systems required. The set-up and use added 7 min (range 5–14 min) to the surgery [47]. Qualitative feedback was obtained from the surgeons who felt the integrated TRUS system helped to visualize the urethra while placing the dorsal venous complex (DVC) stitch, identify the seminal vesicles and prostate boundaries at the bladder neck and apex, and recognize the location of the prostate relative to rectal wall.

In addition to TRUS, studies have also demonstrated the use of drop-in US probes for real-time image guidance and audible Doppler interpretation during RALP. Shoji et al. demonstrated the feasibility of a 9-mm drop-in probe controlled by the console surgeon with images shown in the TilePro™ display. Notable findings include intraoperative localization of four of four biopsy-proven cancerous hypoechoic lesions in patients with clinical T2 disease [48]. All patients (10/10) had negative surgical margins, despite five of ten patients having extraprostatic (pT3) disease. Badani et al. published work on an audible Laparoscopic Doppler ultrasound (LDU) technology that was used to preserve arterial flow within the NVB during a RALP. In a study on patients with normal preoperative potency, LDU was used to measure arterial flow at six periprostatic locations with the plane of the NVB dissection being altered by the measurements in five of nine patients (56%) on the left and in four of nine patients (44%) on the right [49]. At 8 month follow-up seven of nine (78%) of patients had recovery of erections, defined as erections subjectively "suitable for sexual intercourse." Though not commonly used like in RAPN, these studies suggest a potential clinical benefit to intraoperative ultrasound during RALP.

Augmented Reality

While integrated imaging with CT or US shows promise in robotic surgery, an alternative method for image guidance that takes advantage of pre-existing images and does not require additional expensive hardware is augmented reality. Augmented reality image-guided procedures via registration and segmentation of preoperative images has long been used in the fields such as neurosurgery and radiation oncology. Challenges of incorporating this type of methodology in abdominal and pelvic procedures include soft tissue deformation, changes in perfusion, and lack of rigid structures available for registration. Work being done to address these limitations can be better understood by focusing on four major principles of augmented reality: registration, tracking, deformation, and display.

At a basic level, registration is the process of mapping a patient's three-dimensional anatomy to his or her three-dimensional image space such

that corresponding points are optimally matched in a single coordinate system. Multiple methods have been proposed for registration including manual, fiducial-based, 3D-CT stereoscopic image-based, and surface-based [50]. Manual mapping requires a surgeon to use innate knowledge of anatomy to align an image with the operative field. A few small series using manual registration have demonstrated feasibility of this method. In one study by Ukimura et al., five key anatomic structures were reconstructed from TRUS and/or MRI images into a 3D model, which was then displayed during RALP using TilePro™. The model was manually registered (i.e., oriented) by a second surgeon during the procedure to allow the console surgeon to identify nerves and facilitate dissection near index lesions [51]. Limitations of manual registration include a lack of accuracy and capability for real-time registration during tissue manipulation. Fiducial-based registration generally utilizes intraoperative imaging such as cone-beam CT (described above) as fiducials cannot typically be placed preoperatively in the abdominal cavity. 3D-CT stereoscopic image registration takes advantage of the disparity in perspective between two cameras to localize objects, though one 'camera' in this case is a segmented preoperative 3D image. This system requires no external trackers and can quickly generate accurate images (< 1 mm target registration error) [52] but requires a stereoscopic camera and an ability to quickly process large volumes of data. Finally, in surface-based registration, computer algorithms are used to match the surface of intraoperative anatomy, determined via topography-defining stylus or laser scanner, with the surface of segmented reconstructed preoperative images. Of note, several of these techniques have cross-over and may require an initial manual registration before automated algorithms can take over.

Currently, surface-based registration is thought to have excellent potential for use in partial nephrectomy. The registration process requires tracking of a tool over the surface of the target anatomy. Once an image has been registered, constant tracking is then needed to update the augmented reality image during camera movement or tissue deformation. Options for tracking include line-of-sight optical tracking, which utilizes a specialized camera system and has submillimeter accuracy, and electromagnetic tracking, which requires a magnetic field sensor and trackers within the tissues of interest. As magnetic tracking has been noted to have larger errors (3–5 mm) and is susceptible to distortion from surrounding ferromagnetic objects, it is generally not considered to be ideal for procedures such as partial nephrectomy [50]. Herrell et al. and Kwartowitz et al. proposed a hybrid scheme that utilized internal tracking through the kinematic chain of the robot joints and an external optical tracker and demonstrated errors <2 mm [53]. Validation of this system with *ex vivo* phantom tumors demonstrated faster resection times with increased preservation of normal 'tissue' [54].

A significant obstacle in achieving accurate real-time augmented reality is the ability to account for tissue deformation, which can occur from a variety of sources including but not limited to changes in perfusion (i.e. hilar clamping), surgical manipulation, pneumoperitoneum, and cardiopulmonary variation. Furthermore, prediction of deformation is difficult due to a lack of *in vivo* data on viscoelastic tissue material properties. To date, only small series of *ex vivo* and *in vivo* studies have been performed attempting to address this issue. For augmented reality to be effective, robust methods for addressing tissue deformation must be developed to ensure accuracy and minimal error.

Additional challenges in augmented reality include the intraoperative display itself, which must provide seven dimensional information (x, y, z, yaw, pitch, roll, and time) on a 2D display. This needs to be done in an unobtrusive but meaningful manner in a potentially stressful environment. Possible options include image-in-image or side-by-side displays, such as in 3D image overlays, or multiplane views (i.e. sagittal, axial, and/or transverse views). User interface studies will need to be done to determine optimal configuration of the display.

Novel Devices

Intuitive Surgical: *da Vinci*® Xi™, Integrated Table Motion, Single-Site Surgery

At the most basic level, a surgical robot is a device that acts as an extension of human capabilities and has the ability to scale, filter, and translate human hand motions into precise movements of surgical instruments. The *da Vinci*® surgical robot is currently the only commercially available surgical robot in the United States for abdominal and thoracic surgery, making it the predominant surgical robot assistant used in urologic surgery at this time. The *da Vinci*® surgical platform is designed as a master-slave architecture telepresence robotic system and includes three major parts: the patient side cart, the surgeon console, and the vision tower. The patient side cart (or slave component) consists of a motorized base and four robot arm manipulators which contain passively-positioned hinged joints that support and allow alignment and triangulation of the true 'robot' end effectors. Each arm can manipulate either an endoscopic camera or one of a wide variety of cable-driven, seven-degree-of-freedom wristed surgical tools, all of which are proprietary to Intuitive Surgical. While the previous iterations of the *da Vinci*® robot required the camera to be installed in a specific central arm, the newer *da Vinci*® Xi™ allows for the camera and tools to be interchangeable between all arms. Also new to the *da Vinci*® Xi™ is a boom-mounted system that allows for increased flexibility of robot placement as well as multi-quadrant access in the patient.

The surgeon console (or master component) has several capabilities, including 3D vision, that have played a role in the wide-spread adoption of the *da Vinci*® technology. Perhaps most important is the hand-machine interface that allows for extremely intuitive control of the robot tools such that even novices can quickly master complex manipulations (i.e., knot tying) that can be very challenging with the traditional laparoscopic platform. The general placement of the vision and hand control systems is meant to mimic the familiar triangulation of both open and laparoscopic surgery. However, the adjustable console allows for a seated and potentially more ergonomic position for the surgeon compared to laparoscopy [55, 56], a concept that is being highlighted more often in the current literature. Foot pedals on the console provide control of the camera, electrocautery, bipolar energy, and other specialized instruments (i.e., vessel sealer, stapler). Also available is integration of NIRF imaging (*Firefly*™—see above) and multi-input display of additional imaging sources through TilePro™. In Urology, TilePro™ is most commonly being used to incorporate images from real-time intraoperative US during partial nephrectomies with a robot-controlled drop-in US probe or assistant-controlled laparoscopic US instrument (see above). The *da Vinci*® Si™ and Xi™ also allow for dual console configuration such that two surgeons can operate simultaneously and seamlessly exchange control of instruments.

Though not used as commonly in Urology, there is a single site configuration that is available with the *da Vinci*® Si™. This requires use of a 3-cm multichannel access GelPort that can hold four cannulae and an insufflation port. Two 5-mm curved cannulae are used for proprietary 5-mm semi-rigid instruments while one straight 5-mm cannula acts as an assistant port and one straight 8.5-mm port holds the camera. Though triangulation of the instruments is achieved by crossing of the two curved cannulae, the instruments are mapped such that the each hand controls the instrument on the ipsilateral side of the screen. This provides an advantage over other single port approaches where the instruments are mapped in a crossed manner. One major disadvantage of the single-site configuration is the loss of the 'wrist' in the end-effectors (except the needle driver), which limits the degrees of freedom and makes tissue manipulation more cumbersome compared to the standard wristed *da Vinci*® system.

Until recently, once a *da Vinci*® robot was docked to the patient, the operative table could not be moved as this could cause catastrophic events due to uncoordinated movements between the robot arms and the patient. In

January of 2016, Trumpf Medical's TruSystem® 7000dV (Trumpf Medical, Saalfeld, Germany) operating table was approved by the FDA for integrated table motion with the *da Vinci*® Xi™ platform. This system allows surgical teams to reposition the operating table with the robot arms docked to the patient. Synergistic with the multi-quadrant capabilities of the *da Vinci*® Xi™, integrated table motion allows for optimal anatomic exposure and access to the entire abdominal cavity without redocking. Procedures previously noted to be difficult due to limited access, such as robotic nephroureterectomy, can now potentially be performed with more ease and efficiency. In addition, anesthesiologists gain enhanced abilities to alleviate effects from extreme positioning.

Upcoming Competitors

Currently, the *da Vinci*® Surgical System is the only commercially available, FDA-approved surgical robot for soft tissue manipulations in abdominopelvic surgery. However, there are a number of companies around the world that are in the process of developing, obtaining regulatory clearance for, or launching novel robotic platforms. It remains to be seen which of these, if any, can provide market competition for the current monopoly in the field. Also of note is the emergence of procedure specific-robots that are frequently utilized in other surgical fields such as orthopedics but not in urology until now.

TransEnterix: ALF-X® and Surgibot™

TransEnterix, Inc. is a surgical robotics company based in Morrisville, North Carolina that was founded in 2006. The first device developed by the company was the non-robotic SPIDER® surgical system, which is a single port manually-controlled instrument platform. The SPIDER® consists of an endoscope linked to flexible instruments that allow for more ideal triangulation in a reduced work space for laparoscopic single site surgery. The system, called "flexible laparoscopy" by the company, received FDA approval in 2009 and a CE Mark for use in the European Union in 2010. The device was used for both urologic and general surgery applications [57, 58] but has now been discontinued.

The SPIDER® device was subsequently "roboticized" by the company to create single site robotic prototype that has been named the SurgiBot™. The primary target of this device is outpatient single site surgeries such as cholecystectomies. With the SurgiBot™ system, the end effector instruments are integrated into a suspended "robotic" arm that is attached to the patient side stand. The surgeon remains sterile at the bedside to control the flexible robotic instruments, which function similarly to laparoscopy in that the laparoscopic interface and motions are maintained. This setup permits the surgeon to remain at the patient bedside and allows for multi-quadrant access. Like other robotic platforms, the SurgiBot™ provides camera stabilization, clutching for better ergonomics, and motion scaling, but unlike current commercially available robots, it also provides tactile feedback. The single-site design results in an internal triangulation and a small work volume. The flexible instruments, which come in a variety of standard end effector designs, are capable of tool tip angulation with multiple degrees of freedom despite the lack of a true distal wrist configuration. A 510(k) application was recently denied by the FDA for the Surgibot™, indicating that a premarket approval application will be required to market this device in the US [59].

A major focus of the company at this time is the commercialization of the Telelap ALF-X® surgical robot, which was initially developed by the Italian company SOFAR (Trezzano Rosa (MI), Italy) in collaboration with the European Commission's Joint Research Center of the Institute for the protection and Safety of the Citizen [60]. In 2015, TransEnterix acquired SOFAR and was then granted a CE Mark for the Telelap ALF-X®. The Telelap ALF-X® is intended to be a low-cost surgical robot for use in abdominal and pelvic laparoscopic procedures. The device consists of a surgical cockpit, a connection node, and up to four independent robotic arms. The robot arms, which mimic laparoscopic motion, can attach to any 5 mm instrument or 10 mm endoscope and

are on individual mobile carts that can be arranged in any configuration around the operating table. Due to the unconstrained setup of the arms, there is multi-quadrant access and additional laparoscopic ports can easily be added. Similar to the SurgiBot™, instruments have forces sensors that provide tactile sensation at the surgeon cockpit. While there are a range of instruments available, very few are wristed (i.e. needle driver) resulting in limited degrees of freedom. The surgeon cockpit consists of a three-dimensional high-definition monitor, haptic handles, touchpad, foot pedal, and keyboard. An interesting addition to the Telelap ALF-X® capabilities is infrared eye-tracking that moves the camera in the patient based on the surgeon's eye movement. Unlike the *da Vinci*® console, this surgeon cockpit is open to allow the surgeon easy access and visualization of the patient and operating theater while reportedly providing a more natural seated position for the surgeon.

At this point, the Telelap ALF-X system has been used mainly for gynecological procedures including total hysterectomy and ovarian cyst enucleation [61–63]. More recently, the ALF-X system was used by Bozzini et al. in Lodi, Italy to perform a series of *in vivo* procedures using the porcine model. A report on experiences during seven robot-assisted laparoscopic partial nephrectomies (RAPN) was recently published in European Urology [64]. For these procedures, a total of three robot arms were used. Mean surgical time was 32.4 min with a mean warm ischemia time of 9.4 min and mean blood loss of 48.6 mL. Based on their experience, the authors stated that they "found no limitations in performing RAPN with ALF-X compared with a similar procedure using the da Vinci system." They also noted that the force feedback was helpful, particularly during suturing. At this time, the Telelap ALF-X® is not available in the U.S and it is unclear when the company will submit an application for FDA approval.

Titan Medical: SPORT™

Titan Medical is a publically traded Canadian company based in Toronto, Ontario that is focused on developing surgical robotic technologies that will address limitations of currently available robotic systems. Specifically they state a desire to improve surgical robot versatility, reduce device size, and decrease costs associated with robotic surgery with their new SPORT™ (Single Port Orifice Robotic Technology) system. This platform consists of an open workstation with 3D monitor and a single robot arm mounted on a mobile patient cart with a mast and boom capable of multiple configurations. The robot arm holds a 3D vision system and multi-articulated instruments with disposable tips, thus providing first use quality end-effectors for each patient. Once deployed inside the body through a single 25 mm access port, the snake-like instruments and camera can be configured into a more standard triangulated working configuration. The SPORT™ device was exhibited at the SAGES 2016 annual meeting and is currently undergoing engineering verification. Per their website, Titan is planning to pursue clearance in Europe prior to submitting an FDA application.

Applied Dexterity: Raven™

The Raven™ system is a robotic platform that was initially developed in the BioRobotics Laboratory at the University of Washington. Unlike other devices discussed here, the Raven™ is meant to be a robust tool to foster collaborative research without the proprietary constraints of industry rather than a surgical robot for use in a clinical setting. Currently in its third generation of development, the Raven™ utilizes an open source platform that provides both common software and hardware environments to facilitate sharing and integration of novel work. The device consists of multiple seven-degree-of-freedom robot arm manipulators with interchangeable instruments, PHANTOM Omnis® as the master control device, and a Robotics Operating System open source software environment. Applied Dexterity (Seattle, WA) was established in 2013 to help manage the Raven™ research community. Currently, there are 16 sites around the world that are working with the Raven™ to further research in motion planning, computer vision, machine learning, and tactile sensors for instruments [65].

Medrobotics: Flex® Robotic System

The Medrobotics Flex® Robotic System (Medrobotics Corp., Raynham, MA) is a surgeon-controlled flexible robotic endoscope based on technology from researchers at Carnegie Mellon University that received FDA approval in 2015 for transoral robotic surgery (TORS). The device consists of several components including the Flex® Console with surgeon manipulator and visual display, a reusable Flex® Base that houses the computer controller, a Flex® Cart for transport, and the Flex® Scope. The Flex® Scope is comprised of an inner and outer segment with concentric mechanisms that are capable of both rotation and lateral deviation, allowing for nonlinear maneuverability, and a locking mechanism to provide a stable platform once in the desired workspace. The surgeon controls the distal segment, which is comprised of a digital high-definition camera with lens washer, 3 LED lights, and two external accessory channels through which flexible 3.5 mm instruments can be introduced [66]. The channels can accommodate third party as well as Medrobotics wristed instruments including the Flex® Laser Holder, Flex® Monopolar Scissors, Flex® Needle Driver, and others. Of note, only the endoscope itself is telemanipulated; the instruments are manually operated through the accessory channels without instrument crossing, thus sustaining intuitive and natural control. While currently approved for transoral surgery, this platform could be translated to urologic surgery and provide surgeons with single-site or natural orifice access for robotic-assisted surgery.

Hansen Medical and Auris Surgical

Hansen Medical, Inc. (Mountain View, CA) was founded in 2002 by Dr. Moll and focuses on flexible steerable robotic catheters that are currently being used for cardiovascular applications. Currently there are two major platforms, both of which consist of a remote surgeon control console that is used to telemanipulate a patient-side robotic arm that precisely controls specialized flexible robotic catheters and guidewires. The Sensei® robotic system was initially FDA approved in 2007 for certain electrophysiological cardiac procedures and can integrate data from fluoroscopy, ultrasound, 3D surface maps and EKGs. The system includes Intellisense® Fine Force Technology which provides force feedback to the physician. The newer Magellan™ Robotic catheter system is designed to facilitate navigation and access for a wide variety of peripheral vascular procedures and advertises more efficient and predictable instrument positioning, especially in tortuous anatomy. Notably, the remote workstation allows for reduced radiation exposure and potentially less surgeon fatigue, both of which have become more prominent issues in recent years throughout all surgical specialties [67, 68]. While the current clinical applications are in the cardiovascular arena, the base technology of accurate, efficient, flexible robotic catheters can certainly be modified for use in other specialties. Specifically in Urology, these platforms have been used for prostate artery embolization as well as ureteroscopy for management of nephrolithiasis [69].

In mid-2016, Hansen Medical was acquired by Auris Surgical Robotics, which is also based in Silicon Valley and was co-founded by Dr. Moll. While not publically announced by Auris at the time of this publication, per IEEE Spectrum [70], the company received FDA approval in 2016 for an endoluminal robot dubbed the Auris Robotic Endoscopy System (ARES). Clinical trials have already been completed in Costa Rica using the device, which is remotely controlled with a surgeon work station and utilizes 3D maps generated from 2D scans. In addition, the ARES robot includes an internal 'geo-fence' that aims to prevent accidental injury to tissues during procedures. It is unclear when the company plans to launch the device.

PROCEPT Biorobotics: Aquabeam®

PROCEPT BioRobotics (Redwood Shores, CA) is a medical device company focused on novel technologies for the management of prostate disease. Their first product, the AquaBeam®, is an image-guided robotics system that utilizes Aquablation, a targeted heat-free water jet abla-

tion therapy, for the removal of prostatic tissue in the treatment of BPH. The AquaBeam® system has three components: a surgical console, a robotic hand-piece, and a single-use probe. The hand-piece, which delivers the Aquablation, is placed with the aid of a rigid cystoscope and held in place with an inflatable balloon. The hand-piece is then secured to an articulating arm on the surgical console. A stand-mounted bi-plane transrectal ultrasound probe is inserted to provide real-time integrated imaging for surgical planning and mapping. Once the treatment area is mapped by the surgeon, the Aquablation treatment is initiated and a high-velocity sterile saline stream is delivered orthogonally (at 90°) at flow rates based on the required depth of penetration. The probe is manipulated by the robot-arm based on the mapped treatment plan. Hemostasis is achieved at the end of the procedure using a roller-ball or loop. The device is currently under investigational use in humans.

A Phase I trial including 15 patients treated with the AquaBeam® was recently published [71]. Patients were treated under general anesthesia and had a mean prostate size of 54 mL (range 27–85 mL). Mean treatment time was 8.2 min with a mean procedure time of 48.3 min. All but one patient had their catheters removed within 24 h of the procedure. Eight patients had a Clavien-Dindo grade I–II adverse event, such as re-catheterization, but there were no severe adverse events. At 6 months follow-up, there were no reports of incontinence, retrograde ejaculation, or erectile dysfunction. Functional outcomes demonstrated a statistically significant decrease in mean IPSS (8.6 from 23.1), QoL (2.5 from 5), and PVR (30 mL from 91 mL). Mean Qmax increased significantly from 8.6 to 18.6 mL/s. These data suggest that the AquaBeam® may provide functional results similar to traditional TUR procedures but with shorter surgical duration and without side effects such as retrograde ejaculation. Patients are currently being recruited for the WATER (Waterjet Ablation Therapy for Endoscopic Resection of prostate tissue) study, a Phase III clinical trial comparing standard TURP to the AquaBeam at 20 centers around the world.

VERB Surgical

VERB Surgical™ is an independent start-up that was launched in 2015 as a partnership between Verily (formerly Google Life Sciences) and Ethicon (part of Johnson & Johnson). The company, which is based in Mountain View, CA, aims to develop novel surgical robots that can not only compete with Intuitive Surgical's *da Vinci*® in terms of being smaller and cheaper, but can also provide additional capabilities such as enhanced imaging and advanced analytics. Collaboration with Verily, and thus Alphabet Inc., may provide potential for machine learning, big data, proctoring, and connectivity. Ultimately, VERB™ hopes to lead with a new surgical platform as well as transform the entire operating room environment and work flow. Few details are currently available about the future VERB™ robot but the company hopes to have a prototype by the end of 2016 and a commercial device on the market in four years [72].

Medtronic

Medtronic (Minneapolis, MN) recently announced that they will launch a surgical robot by 2018 or 2019, with the first systems being implemented in India. The company has been working with the German Aerospace Center DLR on its surgical robotic platform for the past three years and is currently on its tenth prototype. Like several of the companies noted above, Medtronic hopes to enter the same space as Intuitive Surgical, Inc. with their target procedures including those in colorectal, thoracic, and bariatric surgery. Prototypes have been revealed and consist of robotic arms, a surgeon console, and surgical tools but additional details were not yet provided. It is likely that Medtronic will submit for FDA approval after they gain initial experience with their expected launch in India. Of note, the company has also joined with Mazor Robotics, which focuses on spine surgery.

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69 Single-Site Robotic Urologic Surgery: Current Applications and Future Technology

Daniel Ramirez, Matthew J. Maurice, and Jihad H. Kaouk

Abstract

Utilization of robotics in urologic surgery has been broadly popularized as it provides substantial advantages over conventional laparoscopic and open approaches, including improved fine dexterity, three-dimensional high-definition magnified optics, and augmented ergonomics. Accordingly, these features have facilitated the espousal of robotics for laparoendoscopic single-site surgery (LESS) to surmount challenges with instrument clashing, intra-corporeal suturing, and intra-abdominal triangulation. Herein we discuss currently available single-site robotic techniques and technology while focusing on specific urology procedures and the future of RLESS.

Keywords

Minimally invasive surgery · Robotic surgery
Singe site surgery

Introduction

Robotics in urology has been widely adopted as a result of the advantages it provides over conventional laparoscopy. These advantages include augmented ergonomics, magnified three-dimensional optics, and enhanced instrument precision and dexterity. These features have ultimately resulted in robotics being applied in single-site surgery to overcome the challenges secondary to the limited working space and poor ergonomics offered by laparoendoscopic single-site (LESS) approach.

The first series of urologic robotic laparoendoscopic single-site surgery (RLESS) was described by Kaouk et al. 2008 and demonstrated that the robotic adjunct improved dissection and suturing as compared to conventional LESS techniques [1]. Since that time, several articles on RLESS have been published, including articles describing enhanced techniques and the application of RLESS to a variety of urologic procedures [2–4]. Some studies have gone on to assess the outcomes between RLESS and other approaches with positive results in regards to pain and cosmesis [5, 6]. Regardless of these advantages offered by RLESS, there still exist real limitations

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inherent to any single-site approach. These obstacles include bulky external profiles resulting in external robotic arm clashing, limited bed-side assistant access, poor maintenance and re-creation of intra-abdominal triangulation, and failure to integrate use of the fourth robotic arm. While several technical modifications have been described to tackle these shortcomings, RLESS continues to be an progressive and changing approach that has not yet become widely adopted [7–9]. The recent engineering of a purpose-built, single-port robotic system designed for RLESS will allow urologist to overcome the current limitations of single-site surgery. In this chapter we will review the evolution of the role of robotics in RLESS and will deliberate how new machinery is creating the way for a new generation of single-site robotic surgery.

When deciding on appropriate candidates for RLESS, patients must be carefully selected as the benefits of RLESS may not outweigh the risks or challenges associated with the technique previously discussed in this review (i.e., Instrument clashing, limited working space, etc.). Pain control, body image and the ability to safely perform the operation, especially in cancer cases, must be taken into consideration and discussed with the patient in detail before an RLESS approach is undertaken. The limitations posed by existing technology may be alleviated with next-generation robotic platforms that are on the horizon. This purpose-built platform will not only allow translation of current open and minimally invasive techniques, but will expand the available approaches for performing transabdominal, retroperitoneal, transoral, perineal and natural orifice surgery.

Current Options for Multiport Access

When discussing access for RLESS procedures, there exists a difference between single-site access and single-port access, determined primary by the number of fascial incisions made for abdominal access. "Single-site" access applies a single incision in the skin through which multiple fascial incisions can be made for insertion of multiple trocars and access points. "Single-port" technique also employs a single skin incision, but only a single fascial incision is made through which numerous channels may be utilized. There exist several distinctive apparatus for use in single-port access, including the GelPort (Applied Medical, Rancho Santa Margarita, CA) and the TriPort (Advanced Surgical Concepts, Bray, Ireland). The umbilicus is the most commonly applied entry point for RLESS as it allows easy access for various areas of the upper abdomen and pelvis and grants enhanced cosmesis by allowing the incision to be hiding within the base of the umbilical fold [10, 11].

Various multichannel ports are available for the RLESS approach, though no studies have been performed to specifically compare outcomes with each. Many studies have assessed the individual application of each depending on the preference of the surgeon, remarking on their particular attributes. In the original RLESS series, Kaouk et al. utilized the R-Port (Advanced Surgical Concepts, Bray, Ireland) [1]. This multichannel port incorporates a cannula for insufflation, a 12-mm lens channel and two 5 mm trocars and accommodates a 12–25 mm fascial incision placed using the Hasson method. Once placed into the wound, the R-Port expands both radially and axially allowing for adjustment to the abdominal wall thickness and to limit loss of insufflation. Stein et al. also described application of the GelPort for upper tract RLESS and reported enhanced assistant access, port placement flexibility, and specimen removal, specifically during nephrectomy [2]. White et al. assessed their RLESS series evaluating the SILS port (Covidien, Minneapolis, MN), GelPoint and R-Port devices, and reported that the SILS port was superior as the trocars are freely exchangeable and allow for placement of various sized trocars, which allow for insertion of larger instruments such as clip appliers and stapling devices [12]. The authors also reported that loss of insufflation was seen with all three multichannel ports secondary to fascial incisions that were made too large or where enlarged during surgery by movement of the trocars. Lee et al. published

the largest case series of RLESS using a multichannel device created by employing a sterile surgical glove and an Alexis retractor (Applied Medical) [13]. The main advantages of this arrangement are widespread availability of components and decreased cost, but with manipulation and higher insufflation pressure, insufflation may be poor.

Current Robotic Systems for Single-Site Surgery

Fine technical differences in docking exist between traditional approaches and RLESS procedures. While only FDA-approved platforms are currently available, the daVinci Si or Xi models are preferred secondary to their augmented optics, enhanced ergonomic control, and, most importantly for RLESS approach, a thinner external profile which minimizes external clashing of the robotic arms. This thinner profile has been greatly improved in the Xi model. A major drawback with current configurations is that only two robotic instrument arms can be used secondary to limited space at the site of access. A new, purpose-build daVinci model will enable use of a accessory third arm, and this system will be discussed later in this chapter.

Alternative methods have been described to reduce exterior clashing of the robotic arms. The "chopstick" technique curtails external clashing of the robotic arms by increasing the distance between the instruments outside the body and crossing the instruments at the level of the fascia in order to create more space between the robotic arms outside of the body [7, 14]. This technique was originally used for LESS but proved to be onerous as crossing of instruments requires "reverse handedness." The advantage of using the robotic system with this technique is that the electronic core design allows for the left and right master controllers to be swapped, thus abolishing "reverse handedness" from the consul. The principle limitation with the "chopstick" method is that the surgeon trades external clashing for increased internal clashing, as the instruments will be in constant contact either at the level of the fascia or intra-abdominally. One must always be sensitive to the orientation of each instrument to prevent counter-springing of the crossed instruments.

Various daVinci apparatuses have been developed for RLESS, including a multichannel access port known as the VeSPA, which is compatible with conventional platforms and includes two curved cannulas, two straight cannulas and a valve for insufflation. Like the "chopstick" scheme, the arms are crossed at the level of the fascia, necessitating electronic exchange of the master controllers. The VeSPA platform was initially utilized for single-site robotic pyeloplasty by Cestari et al. in a series of 9 patients with a mean operative time of 166 min [15]. The authors reported no conversions to conventional open or multi-access site techniques.

RLESS for Prostatic Surgery

Kaouk et al. reported the first series of RLESS prostatectomy in 2008 demonstrating feasibility and proof of concept but still challenging due to the abovementioned limitations [16]. The robot was seen as an invaluable adjunct to LESS prostatectomy, diminishing the learning curve and surmounting technical challenges, especially with intra-corporeal suturing during the vesicourethral anastomosis. Subsequently in 2010, Fareed et al. published their experience with robotic-assisted single-port transvesicle enucleation of the prostate (R-STEP) [17]. The GelPort (Applied Medical) multichannel access port was utilized in all cases in this study and placed through a suprapubic incision, allowing for placement directly into the bladder for performing transvesicle enucleation of the prostatic adenoma. Nine patients were included in this series, and the authors described one conversion to open surgery, two intraoperative blood transfusions and two major post-operative complications. While this study again demonstrated feasibility and proof of concept, R-STEP was ultimately not widely adopted due to a high rate of complications.

Our institution has recently described an RLESS technique for perineal radical prostatec-

tomy [18]. We will focus on the steps of this procedure here in more detail. To begin, a 3–4 cm transverse, curved incision is made in the midline of the perineum between the ischial tuberosities, and the central tendon is divided. A GelPOINT multichannel port (Applied Medical) is placed after the potential space is created by transection of the rectourethralis muscle and the apex of the prostate is identified (Fig. 69.1). We employ a 12-mm camera port, two 8-mm robotic trocars, and a second inferiorly placed 12 mm trocar for the bedside assistant (Fig. 69.2). The patient cart is docked over the patients head after they are placed in high lithotomy position with steep Trendelenberg. The posterior space is developed to expose the levator ani muscles on either side of the posterior aspect of the prostate. The muscle fibers are split beside the lateral prostate and Denonvilliers fascia is opened. This is done in a manner to save the neurovascular bundles on each side, when possible. Once Denonvilliers open, the posterior plane is delineated and followed to the seminal vesicles and vas deferens. Once this is done, bilateral vascular pedicles to

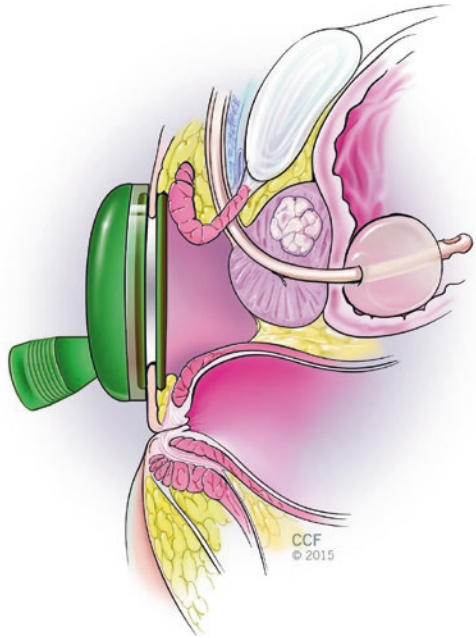

Fig. 69.1 Coronal view of perineal single-port access. Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2015–2016. All Rights Reserved

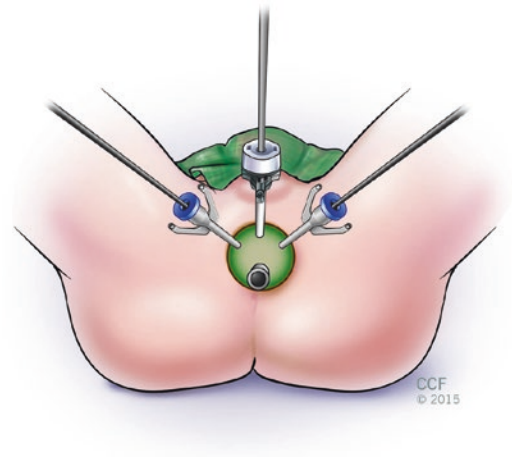

Fig. 69.2 Perineal robotic docking via multi-channel gel port device. Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2015–2016. All Rights Reserved

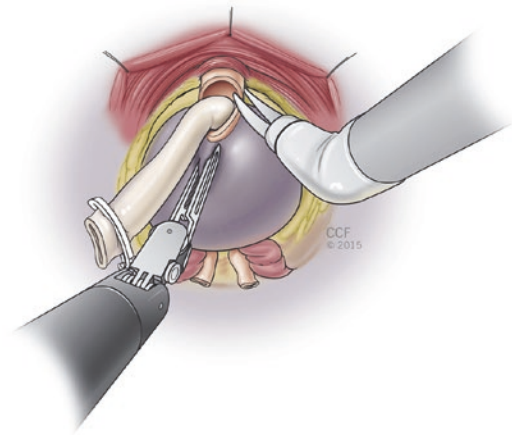

Fig. 69.3 Transection of urethra via the pernieal approach. Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2015–2016. All Rights Reserved

the prostate are identified and ligated. The urethra and prostatic apex are dissected and the urethra is sharply cut (Fig. 69.3). The catheter is clipped to keep the balloon full and is used to place traction on the prostate. The bladder-prostatic junction is identified and opened (Fig. 69.4). Once this is done, the clip on the catheter is removed to empty the balloon and the prostate attachments are completely released.

The anastomosis is performed in a running fashion over a new catheter beginning anteriorly

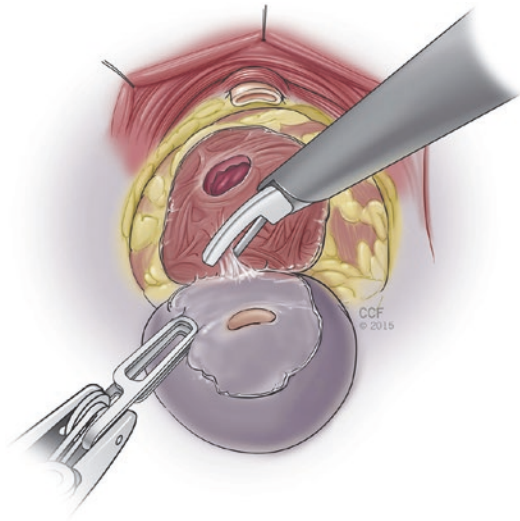

Fig. 69.4 Opening of the bladder neck via the perineal approach. Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2015–2016. All Rights Reserved

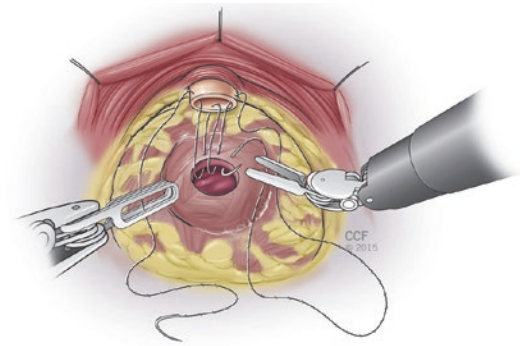

Fig. 69.5 Vesicourethral anastomosis via the perineal approach. Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2015–2016. All Rights Reserved

and completing the anastomosis on the posterior aspect of the urethra (Fig. 69.5). The anastomosis is tested to ensure it is water tight, the robot is undocked and the prostate is removed. We reserved a robotic perineal approach for patients in whom a retropubic or transperitoneal approach is deemed challenging, such as those cases of prior rectal and/or colonic resection and other history of prior pelvic surgery. We have reported this technique reported in two patients with promising results [19], though presently our unpublished series comprises five cases. This technique continues to evolve and maturation of our series is impending.

RLESS for Upper Tract and Renal Surgery

White et al. published a retrospective comparative matched analysis assessing outcomes with traditional laparoscopic nephrectomy and RLESS nephrectomy in 2011 [3]. They demonstrated a decrease in post-operative narcotic requirement (25.3 vs. 37.5 morphine equivalents; $p = 0.05$) and a shorter length of post-operative stay (2.5 vs. 3.0 days; $p = 0.03$) in the patients who underwent RLESS procedures. That same year, Lee et al. reported the largest series of RLESS-PN, which included 51 consecutive cases deploying a custom-made access port [13]. Transfusion was required in 14%. Two patients required conversion to open surgery for hilar bleeding and difficult access. In 2011, Arkoncel et al. also published a comparative analysis of 35 patients match 1:1 to traditional robotic partial nephrectomy (RPN) based on tumor complexity [5]. Analogous to the aforementioned series described by Lee et al., homemade single-site multichannel ports were employed using a surgical glove and Alexis retractor. The authors concluded that RLESS-PN proved to be difficult secondary to the significantly constraining and restrictive nature of the robotic arms. In 2013, Komninos et al. retrospectively compared outcomes in a large series of patients who underwent either conventional RPN or RLESS partial nephrectomy with the primary outcome of achieving a surgical trifecta (warm ischemia time < 20 min, negative surgical margins, and no surgical complications) [9]. They found that the RLESS approach was an independent predictor of failure of achieving trifecta after partial nephrectomy.

Kaouk et al. described RLESS pyeloplasty in the original RLESS series [1]. This technique uses the R-Port multichannel access port, though other multichannel access devices have also been described [2, 6, 14]. Patients with ureteropelvic junction (UPJ) obstruction embody the

optimal candidates for RLESS as they are usually younger, do not have cancer, and require no specimen extraction. The incision does not require extension for specimen extraction thus facilitating its disguise within the umbilicus. Olweny et al. reported a comparative analysis of RLESS and LESS pyeloplasty [6]. They found no significant differences regarding EBL, complications, length of stay or pain. They did report, however, that RLESS was associated with a significantly longer operative time (226 vs. 188 minutes; p = 0.007). In 2012, Cestari et al. described the use of the VeSPA device in nine cases for RLESS pyeloplasty [15]. The features of this platform were discussed in more detail above. No conversions or complications were reported, but the authors expressed that the most significant drawback of the VeSPA system is the lack of articulation as afforded by conventional robotic technology.

Next-Generation Sinle-Port Robotic System

Conjoining LESS with robotic technology has advanced the field by adding stability and articulation for meticulous dissection and suturing. That being said, the original multiport design of the Intuitive Surgical (Sunnyvale, CA) robotic systems were not meant for RLESS and inherent challenges with these techniques still exist. As a result, a purpose-built platform had been constructed specifically for the RLESS approach. This novel daVinci single-port (SP) system employs one 2.5 cm which accommodates a 10 by 12 mm articulating camera and three 6 mm fully articulating robotic instruments (Fig. 69.6). The instruments have been engineered with Endowrist technology at its distal joint and an additional elbow joint which facilitates intracorporeal re-establishment of triangulation without requiring crossing of the instruments. This system is adaptable to the Xi da Vinci robotic platform and is adapted onto a single arm. There is an additional foot pedal outfitted on the surgeon consul which allows for complete control and movement of the robotic arms in unison, which further preserves intra-abdominal triangulation around the surgical field.

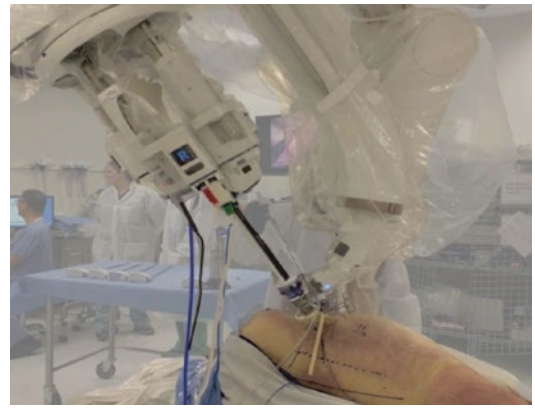

Fig. 69.6 Next-generation single port robotic platform. Reprinted from European Urology, Matthew J. Maurice, Daniel Ramirez, Jihad H. Kaouk, Robotic Laparoendoscopic Single-site Retroperitoneal Renal Surgery: Initial Investigation of a Purpose-built Single-port Surgical System, Copyright July 2016, with permission from Elsevier

Kaouk et al. published the first clinical study using this novel SP system [20]. The first-generation SP machine (previously known as SP999) was utilized in 19 cases, 11 single-site robotic prostatectomy and 8 renal surgeries. The authors reported no conversions, and functional outcomes over a 3-year follow up were comparable to standard techniques. More recently, a next-generation single-port robotic platform (SP1098) has been investigated for performing extra-peritoneal urologic surgery in a cadaveric model in an unpublished series. We performed two retroperitoneal RLESS radical nephrectomies, four R-LESS retroperitoneal partial nephrectomies, and three perineal radical prostatectomy including two perineal pelvic lymph node dissection using this SP platform and have found its application to be feasible in extraperitoneal approaches for abdominal and pelvic surgery. Further clinical trials will be needed in order to better define its role in minimally invasive surgery.

Conclusion

The evolution of RLESS has greatly enhanced the ability to perform single-incision urologic surgery by providing improved optics,

ergonomics, and articulating wrist technology. Nevertheless, universal adoption has been lacking secondary to elemental limitations with current technology, including clashing, limited access for the surgical assistant and inability to utilize all four robotic arms. A next-general robotic system specifically created for single-port robotic surgery has been developed and effectively removes instrument clashing by achieving intracorporeal triangulation, avoiding bulky external mechanics and removing the need for instrument crossing. This technology will continue to expand the scope of RLESS, and its range will not be restricted to the field of urology.

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Newer Robotic Systems in Horizon for Clinical Use

70

Ibrahim Alabdulaali and Koon Ho Rha

Abstract

Current surgical robots had revolutionized the field of minimal invasive surgery for the last 15 years, but still they are lacking when it comes to artificial intelligence and computer cognition to give more support to the surgeon. Future robots are tackling these issues and aiming also to produce single port platforms, improving the haptic feedback and producing robots used through natural orifices (Natural Orifice Transluminal Endoscopic Surgery—NOTES).

In this chapter, an overview of coming surgical robotic systems is presented.

Keywords

Surgical robotics · Minimally invasive surgery · Telesurgery · Cognitive surgical robotics

Single Port Platforms

One of the directions in MIS development is towards single site surgery aiming to reduce the trauma on patients; however this kind of surgery requires more complex tools and more sophisticated surgical robots. Da Vinci single-site© surgical platform have proven to be valuable assets in single-site surgery, owing to the combination of robot use with the dedicated single-incision [1].

The da Vinci SP (Intuitive Surgical Inc.US), is one of the earliest surgical platforms for single incision surgery, and gained FDA approval in 2014. It's composed of a 3D HD camera, three fully articulated instruments all in a 25 mm port. The fully wristed EndoWrist Sp Instruments have two more degrees of freedom than the da Vinci Single-Site Instruments, which are not wristed and are used in single port surgeries. The surgeon controls the instruments and endoscope while seated at the da Vinci Surgical System console. Intuitive Surgical plans to hold off on releasing it to market until it's been made fully compatible with the latest da Vinci Xi robot. This will require product refinements, supply chain optimization and additional regulatory clearances [2]. The system is designed for urologic minimally-invasive procedures that are already performed via a single incision. Major urologic procedures were successfully completed using the da Vinci SP without conversions [3].

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Fig. 70.1 The patient cart of SPORT system (With permission from Titan medical Inc.)

Fig. 70.2 The surgeon console of SPORT system (With permission from Titan medical Inc.)

The second single port system is called Single Port Orifice Robotic Technology (SPORT, Titan medical Inc. Canada) Figs. 70.1 and 70.2. The system utilizes a 25 mm single access port which contains a 3D high definition vision system and interactive multi-articulating instruments, and a highly ergonomic surgeon workstation that provides the surgeon with an interface to the robotic platform, as well as a 3D endoscopic view inside the patient's body cavity during MIS procedures. It's expected to be commercially available in late (2019). The first targets of the SPORT system are gynecology, GI and urology procedures [4].

In December 2015 they announced the built of the initial SPORT™ Surgical Systems to include both the work station and the patient cart and will undergo extensive testing as a part of Engineering Verification (EV). These two EV systems will be tested to measure performance in relation to design specifications and to measure compliance with regulatory guidelines. These EV systems were precursors of the systems that were made ready in early 2016 for the first in-human trials [4].

Another single port robot is SurgiBot (TransEnterix. US) Fig. 70.3. It enhances laparoscopic surgery through robotic assistance, while allowing the surgeon to remain in the sterile field, at the patient's side. It's composed of an integrated 3D HD camera for high definition images with depth perception and deliver up to three articulating instruments through a single

Fig. 70.3 The SurgiBot hand piece (With permission from TransEnterix)

incision. One of its main advantages is that it gives a Minimal reliance on surgical assistants and staff [5]. The producing company is focused on achieving FDA clearance to start lunching as expected in 2020.

Avicenna roboflex flexible uretroscopy robot (ELMED, Turkey) shown in Fig. 70.4. It consists of a console and a manipulator. The hand piece of the scope is locked to the robotic arm. The surgeon at the console can control two joysticks to manipulate the rotation, deflection and in and out movement of the endoscope. A central wheel enables fine tuning of deflection inside the collection system. The surgeon can rotate robotically 440°. This minimizes the torsion risk of the endoscope. Laser fiber can be remotely moved in and out which is very helpful to provide suitable distance between stone and the tip of the laser fiber. Software prevents firing of the laser shot when the laser tip is very close to the endoscope to prevent the laser damages. The integrated water pump can be also adjusted remotely. By this way, it is possible to treat the stone with minimal flow rate and to provide low pressure lithotripsy [6]. A human trail on 81 patients showed efficacy, safety and significant improvement of ergonomics [7].

The last robot near hitting market and utilizes the single port or (NOTES) is the Flex (Medrobotics Corp. USA). It utilizes a highly articulated multi-linked scope that can be steered along non-linear, circuitous paths in a way that is not possible with traditional, straight scopes. The maneuverability of the scope is derived from its numerous mechanical linkages with concentric mechanisms. This enables surgeons to perform minimally-invasive procedures in places that were previously difficult or impossible, to reach [8].

Surgeons can operate through a single access site and direct the scope to the surgical target. Once positioned, the scope can become rigid, forming a stable surgical platform from which the surgeon can pass two flexible surgical instruments. The system includes on-board HD visualization to give surgeons a clear view of the navigation path and surgical site [8]. They achieved approval in Europe in 2014, and aim for a first limited commercial launch on selected European markets [9].

Multi-port platforms

In Fig. 70.5**,** The ALF-X is shown (developed by Sofar S.p.A, Italy. currently owned by TransEnterix. US) It is a remotely operated robotic system that utilizes a remote control

Fig. 70.4 The patient cart and surgeon console of Avicenna roboflex flexible uretroscopy robot (With permission from ELMED)

Fig. 70.5 The ALF-X (With permission from TransEnterix)

station and robotic arms. Three unique system features include haptic feedback, an eye-tracking system and reusable endoscopic instruments. Haptic feedback that allows the surgeon to "feel" the force employed through the instruments and the natural resistance of the tissues. The eye-tracking system allows the accurate movement of the 3D endoscope. The first targets of the system are gynecology, urology and thoracic surgery procedures. The ALF-X gained CE market approval in 2011 [10].

ALF-X has a comprehensive set of multipurpose tools that can be sterilized, which allows, a significant cost reduction in the field of robotic surgery and making it more accessible. Another feature is that there is no need to dock the robotic arm to trocar which decreases the operative time and facilitate easy patient repositioning intraoperatively. The console handpiece is similar to laparoscopic instruments which facilitates easy familiarization and shorter learning curve.

The system can handle up to four arms and each manipulating arm is carried by its own patient side cart. The tools are introduced throw a standard 5 mm laparoscopy ports, making it possible to maneuver both laparoscopic and robotic instruments simultaneously. Since the beginning of clinical trials in 2013, few studies proved safety and feasibility in the treatment of various gynecological conditions [11–13].

The second multi-port system is also from Italy called Surgenius (Surgica Robotica Sp.A, Italy). The system consisted of 6 DOF arms, equipped with 6 DOF tip-force sensors, providing haptic feedback to the operator. The robotic arms can be positioned freely around the surgical bed, as they are independent of each other. They can be equipped with Surgica Robotica's high dexterity instruments, which allow great precision and wide maneuverability. The surgical system can be configured with the number of robotic arms that is necessary for the intervention, from one single arm to as many arms as they fit around the surgical bed. Surgenius gained CE market approval in 2012 [14].

The Bitrack system by (Rob Surgical Systems S.L. Catalonia) shown in Fig. 70.6. Designed to cover current weakness in laparoscopic surgery,

Fig. 70.6 The Bitrack system, Rob Surgical Systems S.L. (With permission from Rob Surgical Systems)

like for example the systems' lack of flexibility and modularity and set-up time. The prototype for the robot finished in terms of technology in early 2015 and moved into the clinical validation phase in order to gain approval for the European and US markets. Rob Surgical Systems expects to obtain European (CE market) approval in 2018 [15, 16].

The Chinese surgical robotic system (Micro Hand S). Invented by Tianjin University, there is three main technical advantages of 'Micro Hand S' system. The first is to use the design technology of multi-degrees of freedom (DOFs) wire transmission, making MIS instruments with features of no coupled motion, fixation, skid-resistance and anti-looseness more conducive to maintain accuracy. Second is the realization of the reconfigurable layout principle and implementation technology for 'slave hand', making the robot 'arms' lighter and more adapt to the needs of the operation. The third is to use the system with homogeneous control model building technology, realizing hand—eye—instruments motion consistency in the three-dimensional (3D) visual environment. The first clinical trial where done in March 2014 and showed safety and effectiveness of the Micro Hand S in performing robot-assisted minimally invasive surgery [17].

NeuroArm is an MRI-compatible image guided computer-assisted device specifically designed for neurosurgery. In 2008 it made history when the robotic system operated on a human patient at the Faculty of Medicine, University of Calgary. This landmark operation was the first time a robot was used to perform image-guided neurosurgery [18].

End-effectors are equipped with three-dimensional force-sensors, providing the sense of touch. The surgeon seated at the workstation controls the robot using force feedback hand controllers. The workstation recreates the sight and sensation of microsurgery by displaying the surgical site and 3D MRI displays, with superimposed tools. NeuroArm enables remote manipulation of the surgical tools from a control room adjacent to the surgical suite. It was designed to function within the environment of 1.5 and 3.0 T intraoperative MRI systems. As neuroArm is MR-compatible, stereotaxy can be performed inside the bore of the magnet with near real-time image guidance. NeuroArm possesses the dexterity to perform microsurgery, outside of the MRI system.

The DLR Institute of Robotics and Mechatronics in Germany has developed MIRO a second generation of robot arms for surgical applications. With a low weight of 10 kg and dimensions similar to those of the human arm, the MIRO robot can assist the surgeon directly at the operating table where space is sparse. The scope of applications of this robot arm ranges from guiding a laser unit for the precise separation of bone tissue in orthopedics to setting holes for bone screws, robot-assisted endoscope guidance and on to minimal invasive surgery. Arms are smaller in size and can be mounted directly to operating table [19].

The DLR also developed a system called MicroSurge which includes a master console with a 3D-display and two haptic devices as well as a teleoperator consisting of three MIRO robot arms. Usually two MIRO arms carry surgical instruments equipped with miniaturized force/torque sensors to capture reaction forces with manipulated tissue. The third MIRO arm can (automatically) guide a stereo video laparoscope. The stereo video stream as well as the measured forces is displayed to the surgeon at the master console. Therefore the surgeon is not limited to seeing but can via force feedback in the input devices also feel what he is doing [20].

The system is designed to be able to perform complex procedures, e.g., beating heart operations, where the tools and camera are moved synchronously with the heart, to give the surgeon the impression that the heart stands still. The virtual stopping of the heart and lung reduces the trauma to the patient [9].

AVRA Surgical Robotics is developing a surgical robotic system of a modular construction which offers a portable lightweight and maneuverable robotic solution not available in any current available systems; the basic AVRA Surgical Robotics System (ASRS) employs four robotic arms with a weight-payload ratio that is unavailable in the current surgical robotics market [21]. This ratio allows robotic application for a vast range of minimally invasive operation as well as robotic application for potential use in traditional open surgical procedures, as ASRS' intelligence is incorporated within the arms and joints. The system can be configured with four or fewer arms and as such can be used, for example, in a single-arm construct with applications such as in joint orthopedics.

The ASRS arms can be mounted on a patient-side cart, placed next to the operating table or directly mounted to the operating table as well as attached to an overhead structure. The ASRS surgeon's console merges the high-resolution view of the surgical field, the data and information management and action of the robotic system to the biomedical and IT environment in the operating theater. This console will provide a newly developed human-machine-interface ("HMI") for the maneuvering of both the instruments and the camera-head.

Conclusion

Robotic-assisted surgery is a rapidly growing field, helped by continually evolving technology and its use in a wide variety of surgical settings. The near future is packed with a promising number of surgical robotic systems which can give better outcomes. Expects costs

will go down as more competitors offering distinct technologies enter the market.

The first challenge for the near future will be to adapt the conventional treatment forms to the integrated, computer-assisted alternatives. This requires new training plans for the medical staff, and changes in the layout of the hospitals to accommodate the new requirements. Without a team that can exploit these opportunities to the fullest, the gained benefit of technology will stay small.

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