Urodynamics, Neurourology and Pelvic Floor Dysfunctions

Giulio Del Popolo
Donatella Pistolesi
Vincenzo Li Marzi
Editors

Male Stress Urinary Incontinence

Società Italiana di Urodinamica
Continenza Neurourologia Pavimento Pelvico

Springer

Urodynamics, Neurourology and Pelvic Floor Dysfunctions

The aim of the book series is to highlight new knowledge on physiopathology, diagnosis and treatment in the fields of pelvic floor dysfunctions, incontinence and neurourology for specialists (urologists, gynecologists, neurologists, pediatricians, physiatrists), nurses, physiotherapists and institutions such as universities and hospitals.

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Editors
Giulio Del Popolo
Neuro-Urology Department
AOU Careggi University Hospital
Firenze
Italy

Vincenzo Li Marzi
Department Urology
AOU Careggi University Hospital
Firenze
Italy

Donatella Pistolesi
Urology Department
AOU Pisa University Hospital
Pisa
Italy

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Foreword

I am very pleased to introduce this book on male incontinence for three reasons: first and foremost because it is the first of the series *Urodynamics, Neurourology and Pelvic Floor Dysfunctions* originating from a collaboration between Springer and the Italian Society of Urodynamics which aims to treat various topics of functional urology in a straightforward but thoroughgoing way. The second reason is because male incontinence is a much in discussion at present. Until a few years ago, urinary incontinence, especially stress incontinence, was mainly a female problem. In recent years, due to the increasing number of radical prostatectomies as a standard treatment for prostate cancer, the number of men with postoperative stress urinary incontinence has dramatically increased.

According to the conventional World Health Organization definition of incontinence it is a non-intentional and bothersome loss of urine from the urethral meatus, which well describes the problem. The literature on this pathology does not universally reflect this concept because the topic of male incontinence is not well defined. The virtue of this volume is its effort at conceptual organization.

Male incontinence boundaries are not well defined, starting from the great variability of post-prostatectomy incontinence rates (5–45 % at 1-year follow-up) up to the significance of "patient cured." The authors try to outline a complete and updated framework. Early postoperative incontinence has been proven to disappear spontaneously with time and under conservative management in the first postoperative year and even 2 years after radical prostatectomy. Surgical approach should be considered after a period of conservative management for up to 6–12 months. About 6–9 % of patients affected by persistent and/or severe incontinence undergo subsequent surgical treatment.

Surgical solutions were initially limited to artificial sphincters, or less invasive (and much less efficient) bulking agent injection. Recently we have seen the introduction of "sling" procedures and, more recently, some adjustable evolution of these devices. Male sling development was borrowed from mid-urethral slings for the treatment of female SUI.

Male slings are the new option along with artificial sphincters. Slings are thought to restore sphincter function both by repositioning the sphincter in its preoperative position and by supporting it to improve its strength. However, despite the hopes raised by this new technique, so far sling results overall are not as good as hoped.

We need to better understand the way slings work and the causes for their failure, and also to better select patients. We still lack long-term follow-up data.

The artificial sphincter is still considered the gold standard for men with SUI after radical prostatectomy because it has the longest record of safety and efficacy. But artificial sphincter is a rather challenging solution vulnerable to complications and mechanical failure. It is also an expensive treatment and for proper use requires patient ability and motivation.

The third reason why I appreciate this text is the expertise of the editing authors. Each of them represents a high level of ability in their respective field. The result is a well-organized text in which contributions and different points of view come together in a practical and modern multidisciplinary approach to produce an up-to-date addition to the treatment of male stress urinary incontinence.

Giulio Nicita
Chief Department of Urology
AOU Careggi University Hospital
Firenze
Italy

Preface

The Italian Society of Urodynamics (SIUD) has launched a book series on pelvic floor dysfunctions covering topics ranging from pathophysiology to evidence-based clinical practice diagnostic and therapeutic guidelines and new horizons advancing care in the field of urodynamics.

This first book deals with one of the hardest problems for functional urologists – male urinary incontinence. Although the implant of artificial sphincters is still considered a long-term effective solution, several emerging mini-invasive treatments may be offered as an alternative in selected patients.

International specialists face this issue intended in an ample sense, providing a useful tool of knowledge to anybody who wants to study male urinary incontinence in depth.

In closing, special thanks go to all coauthors who contributed to the fulfillment of this project.

Firenze, Italy

Giulio Del Popolo

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Francesco Marson, Paolo Destefanis, Alberto Gurioli, and Bruno Frea

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APA Accessory pudendal arteries
CRL Crown-rump length
LA Laevator ani

1.1 Introduction

When we refer to the term "male urinary incontinence" we implicitly refer to several anatomical structures involved in these complex mechanisms. A relevant part of these structures plays a pivotal role when radical prostatectomy is performed. In this chapter all the structures involved with urinary continence will be analyzed, both from an anatomical and functional point of view. The urinary sphincter and the bladder neck, the puboprostatic ligamentous complex, the rectourethralis muscle, the prostate vascular supply, the laevator ani muscle, the inferior hypogastric plexus (IHP), the Denonvillieres' fascia, and the obturatory fossa will be discussed in order. Most of the anatomical descriptions will be accompanied with a brief embryological contextualization, according to the authors' conviction that anatomical knowledge should be always contextualized with an embryological setting.

F. Marson • P. Destefanis • A. Gurioli • B. Frea (✉)
Department of Urology, CIttà della Salute e della Scienza di Torino Hospital, University of Turin, Turin, Italy
e-mail: bruno.frea@unito.it

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1.2 Urinary Sphincter

1.2.1 Embryology

Urinary sphincter can be divided and analyzed into striated (external) sphincter and smooth (internal) sphincter; as reported by Bourdelat and Tichy, before sexual differentiation is it possible to note undifferentiated mesenchyme anterior to the urethra during the 5th and 6th weeks [1, 2]; this configuration becomes more evident during the 19th–20th weeks as reported by Kokoua: by the 245-mm stage, the smooth and striated muscles become really visible; the prostate grows as an urethral diverticulum, growing into the developing urinary sphincter. There is no fascia between prostate and sphincter [3, 4]. Regarding the internal smooth sphincter, histologically distinct smooth-muscle cells are identifiable in the 112-mm – crown-rump length (CRL) – stage as a prolongation of bladder smooth musculature; differently from the latter, trigonal and urethral musculature seem to have a more consistent component of extracellular matrix [5]. As reported by Fritsch in her studies of transversal sectional planes of the bladder neck, the musculus sphincter vesicae is a ring-shaped muscle coming from the trigone, without any muscle portions arising from the detrusor muscle and with a higher muscle volume in males compared with females [6, 7].

1.2.1.1 Structural Anatomy of the External Sphincter

According to Oehich's findings, adult external sphincter has a horseshoe configuration: this is basically due to prostate growth inside it [4]; it is positioned in the so-called membranous urethra, even if it should be noted that there is nothing membranous about it, and the name is a misnomer (Figs. 1.1 and 1.2). A crucial point regards its nerve supply: for most authors it has got double innervations (pelvic and perineal), while some others admit the existence of a third "autonomic" component [8, 9]. The first components are pelvic nerves, coming from the sacral foramina of S2, S3, and S4, forming a plexus located along the pelvic sidewall and, from here, passing superficially on the laevator ani toward prostate apex; they can be called "cavernous nerves"; it is interesting to note that the cavernous nerve, which was originally thought to form a bundle structure, has been found to be in this formation in only 30 % of patients, whereas 70 % have been shown to have plate formation [10]; the second component is the pudendal nerve, formed by the same sacral roots. The terminal branches of the pudendal nerve enter the sphincteric area from the perineum. They separate shortly after they cross the ischial spine and run further ventromedially. Small branches approach the sphincter after their division from the dorsal nerve of the penis [11].

1.3 Puboprostatic Ligamentous Complex

The puboprostatic ligamentous (Fig 1.3) complex is composed of the fascioligamentous tissue, in the periapical area of prostate, including the puboprostatic ligaments and arcus tendineus; the arcus tendineus represents the lateral condensation

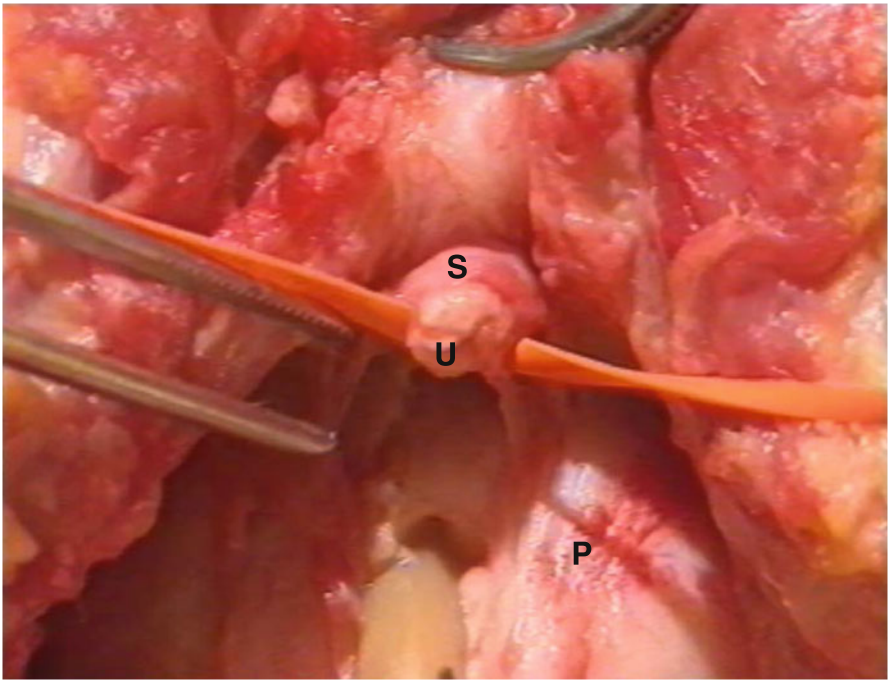

Fig. 1.1 External urinary sphincter (*S*), urethra (*U*), and prostate (*P*). View during perineal prostatectomy

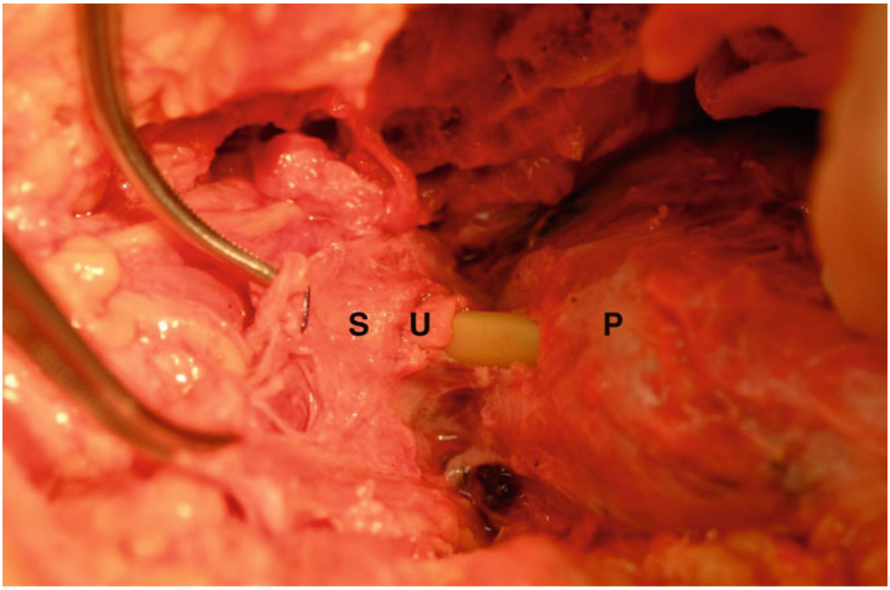

Fig. 1.2 External urinary sphincter (*S*), urethra (*U*), and prostate (*P*). View during a cadaveric dissection after the removal of the pubis bone

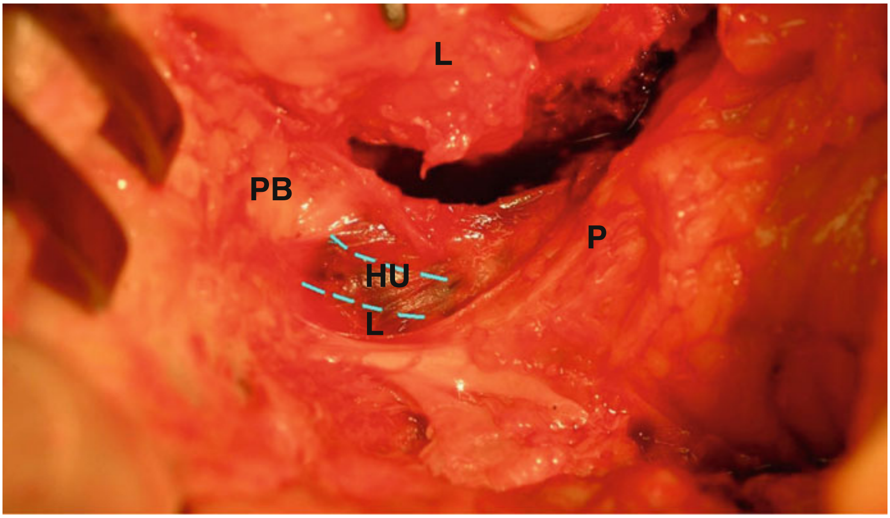

Fig. 1.3 Puboprostatic ligamentous complex (*L*), *P* prostate, *PB* pubic bone, *HU* hiatus urethralis. Side view during cadaveric dissection

of the endopelvic fascia extending from the puboprostatic ligament to the ischial spine [12]; the arcus tendineus of the endopelvic fascia represents one of the thickening of the pelvic fascia that partially constitutes Roggie's star, with the plica ischiadica, the sacro-spinale ligament, and the arcus tendineus of musculus levatoris ani; all these structures take origin from the ischiatic spine laterally [13]. Puboprostatic ligaments are pyramid shaped and fix bladder, prostate, and membranous urethra to the pubic symphysis. They are composed of a pubourethral component which runs deep from the symphysis pubis and attaches to the membranous urethra, a puboprostatic component which blends with the anterior prostatic capsule, and a thin pubovesical part which travels to the anterior bladder wall. The latter was described by Meyers as the "detrusor apron," an avascular plane that connects the anterior bladder wall with puboprostatic ligaments, which must be considered a major component of McNeal's anterior fibromuscular stroma [14]. Histological evidence for this assertion was provided by Dorschner and colleagues; they showed that smooth muscle extended from the bladder down to the pubis [15]. Despite different definitions, according to Fritsch's studies on human pelvis, puboprostatic ligaments represent the only true pelvic ligaments, while the other so-called ligaments are folds of connective tissue [16].

Some authors recognize a second component of the puboprostatic complex, which is called "puboperineales muscular component": a paired muscle that originates from the pubis, flanks the prostatic-urethral junction, and terminates at the perineal body, the deep part of the external anal sphincter and bulbospongiosus muscles. This structure acts as a muscular hammock supporting the urethra posteriorly [12].

As most of the anatomical structures, puboprostatic ligaments can have anatomical variations. Kim and colleagues developed a classification system based on morphology : parallel (running from the anterior surface of the prostate to the pubic symphysis in line and adjacent to one another), V-shaped (originating at a more medial point on the prostate and diverged laterally before inserting onto the pubic bone and symphysis), inverted V-shape (originating at separate, distinct lateral points on the prostate before travelling medially to insert at a more medial point on the pubic bone), and fused (consisting of left and right ligaments indiscernible from each other and no clearly defined borders between the two ligaments) [17].

1.4 Rectourethralis Muscle

A crucial point that should be analyzed in details is the rectourethralis muscle. Generally it is described in the urological literature as an anterior extension of the outer longitudinal smooth muscle of the rectal wall; it is composed of a few thin fascicles of smooth muscle, and leaves the rectum at the apex of the right angle formed by the junction of the rectum and the anal canal to join Denonvilliers' fascia and the posterior rhabdosphincter in the apex of the perineal body. Different hypotheses about its embryological origins have been postulated: for some authors it is an independent structure located between the caudal rhabdosphincter and the external muscle sheath of the anorectal canal, and corresponds to the rectoperinealis muscle in the adult [18], other authors describe this structure as a part of the smooth muscle of the rectal wall consisting in two lateral arms which fuse in the midline and insert into the perineal body, appearing Y-shaped.

Independently from the embryological origin, the important point that should be stressed regards its surgical approach: at radical retropubic prostatectomy, during the division of the posterior wall of the urethra, a sheet of muscle extending from the apex of the prostate toward the perineal body is clearly visible. For many urologists this represents the rectourethralis muscle, but this is only an extension of the urethral mucosa. On the contrary, the rectourethralis muscle is clearly visible during perineal prostatectomy: in this case it is recognized as a structure ranging from 2 to 10 mm in thickness, and must be divided to have access to the posterior surface of the prostate [19]. Rectourethralis muscle influences the stabilization of membranous urethra. Nerve supply of rectouretralis muscles comes from the cavernous nerves; some authors have postulated that the reconstruction of the dorsal musculofascial plate (Rocco's stitch) could injure these nervous fibers, with possible consequent damage about continence [20, 21].

1.5 Prostate Vascular Supply and Anatomical Variability

1.5.1 Venous Bed and Santorini Plexus

Venous prostate drainage follows a regional pattern; the most relevant prostate drainage is anterior, in the puboprostatic space. In this space, prostate veins join with the dorsal vein of the penis, forming the Santorini's plexus.

When performing radical prostatectomy, Santorini's ligation and management rests one of the crucial steps. This plexus was first described in 1724 by Giovanni

Domenico Santorini in Obervationes Anatomicae [22]. This can have different anatomical variations; in a Myers's work collecting data of 160 radical prostatectomies, a midline vein is the most common finding and regards 60 % of patients; in another 20 % there is a bifurcation with approximately 60 % of these patients having right or left pelvic sidewall branches; then a 20 % of patients have something other than a single midline disposition; finally in the 10 % of cases the vein is completely absent [23]. Santorini's plexus drains into both the pudendal and inferior vesical veins, eventually into the internal iliac vein and the hemorroidal veins. It is authors' opinion that, while treating prostate venous supply, Batson plexus must be remembered for its clinical relevance: it is a plexus investing the sacrum, the spine, and the iliac bones, not infrequently involved in metastatic prostate cancer disease [24].

1.5.2 Prostate Arterial Supply

The first description of the arterial vascular supply of the human prostate comes from cadaveric anatomy; the more recent attempt to treat benign prostate hyperplasia by arterial embolization has lead urologists to improve the knowledge of prostatic arterial anatomy with further cadaveric section and CT scan studies. Actual knowledge shows that prostate arterial vascularization comes from two main arterial pedicles: the superior and the inferior. The superior prostate pedicle supplies both the entire prostatic gland and the inferior bladder with the ejaculatory system; the inferior prostatic pedicle supplies the prostatic apex. The superior prostatic pedicle was found to be single in 77.8 % of cases, while in remnant 22.2 % there were multiple superior arterial feeders. Its most common origin was the anterior trunk of the internal iliac artery (56.5 %), while other origins where showed to be middle rectal artery (17.4 %), internal pudendal artery (4.3 %), and obturatory artery (4.3 %). In one of the first studies by Clegg regarding the arterial supply of the prostate, the superior prostate pedicle was called prostate-vesical artery: this was found to divide into a vesical trunk, the constant large prostatic artery and the "posterior vesicular artery" as called by the author, supplying the posterior aspect of the seminal vesicles. Superior rectal artery was found supplying the prostate gland in 32 % of cases.

The inferior prostatic pedicle is most often a plexus that forms an anastomosis with the lateral branch of the superior prostatic pedicle [25, 26]. In 1937, Flocks described a particular division of the prostatic artery: a more superficial group and a deep one, penetrating urethral group. Flocks studied the intraprostatic arterial anatomy by observing some constant bleeding points during transurethral resection. The urethral group was found to course directly to the bladder neck along the lateral lobes, terminating at the level of the verumontanum. These arteries are constant and nowadays are called "Flocks's arteries," and, during prostate transurethral resection, can be found at hours 1 and 11, while the arteries often found at hours 5 and 7 are called "Badenoch's arteries" [27].

Some clarifications must be done regarding the anatomy of accessory pudendal arteries (APA, Fig. 1.4). They are defined as arteries that originate in the hypogastric

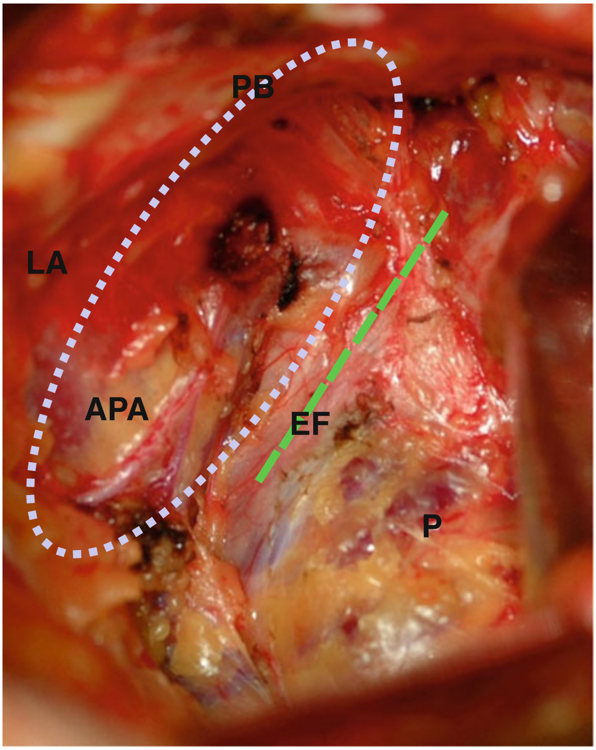

Fig. 1.4 Accessory pudendal arteries (*APA*), *P* prostate, *PB* pubic bone, *LA* levator ani, *EF* endopelvic fascia incised. Side view during cadaveric dissection

artery system, which have a superior path to the levator ani muscle and travel toward the penis infrapubically. Their prevalence is in between 7 and 75 % according to the method of identification (cadaveric dissection, open and laparoscopic/robotic surgery). Two kinds of the APA are generally described: the first is the apical APA, which emerges between the fibers of the levator ani, the second is the lateral APA, which passes above the levator ani. The latter can be further divided into a prostatic type and a pelvic sidewall type. The role of APA is currently under discussion in postprostatectomy erectile dysfunction [28].

1.6 Laevator Ani Muscle

Little is known about the development of the musculus laevator ani (LA). According to Popowsky (1899), the LA developed from the musculus coccygeus by ventral migration of a part of its muscle fibers, while for Power (1948) it is a part of rectus abdominis, separated by ingrowth of the pubic bone. Koch and colleagues studied in details its embryological development, showing that its first appearance is found in embryos with a CRL of 17 mm. In this stage, it is a single muscle at the level of the external anal sphincter complex, attached to the deep part of the musculus sphincter ani externus; at 22 mm CRL it goes toward the pubis, but it is not attached yet; at 30 mm CRL, the pubic symphysis is formed and the laevator ani results attached to it, creating the hiatus urogenitalis. At 43 mm CRL it has completed its posterior development, reaching the os coccygis, where the attachment is made through the ligamentum anococcygeum. At 50 mm CRL its formation is almost completed: it is attached to the upper aspect of the ramus inferior ossis pubis on the ventral side, while on the lateral side it covers the pelvic outlet completely, following the arcus tendineus laevatoris ani toward the future spina ischiadica.

According to this embryological study, the LA results as a single muscle, with no evidence of an anatomical subdivision in three different muscles [29].

The LA muscle is a striated muscle, as the urethral rabdosphincter; it is the main muscle that constitutes the pelvic diaphragm; it is surrounded by endomysium comprising type IV and other collagens. It has got important connections with surrounding structures: it sandwiches the rabdosphinteric area with its bilateral slings, showing the property to transduce its force to the urethra. Histological studies proved that it is a fascia, containing veins and nerves, which connects the LA with the rabdosphincter; this fascia covers a sort of tendon, which acts as a fulcrum for contractions [30]. All the pelvic musculature is fully covered by the endopelvic fascia. Classically and differently from the previously reported Koch's study, LA muscle is formed by three parts, called iliococcygeal, pubococcygeus, and puborectalis muscles. Detailed anatomy of LA was recently described by Shafik et al., especially from a functional point of view: his description results in a logical comprehension of LA function. It results as a cone-shaped structure with an anterior opening, called laevator hiatus, and a posterior structure called anococcygeal raphe. The laevator plate is made of two bundles: the lateral bundle has a triangular shape with a large base on the side of the obturator internus fascia. The medial bundle forms two strips called crura, and three patterns can be identified: classic pattern, crural overlap, and crural scissor. In the classic pattern the crura arise from the pubic bone without crossing, and the gap between the two crura was occupied by the puboprostatic ligament. In the crural overlap pattern the proximal part of the crura overlaps at its origin from the symphysis pubis, while in the cural scissor pattern the two crura cross at their origin such as that the right crus arises from the left pubic body and vice-versa.

At the level of the hiatus a vertical muscular structure called "suspensory sling" exists which connects the LA with the skin, connected in part with anal and urethral sphincter; finally the LA is connected with the intrahiatal organs by the "hiatal ligament"; this could be considered as an extension of the endopelvic fascia, which histologically consists of elastic fibers intermingled with collagen. The Shafik's model is useful to comprehend the functional anatomy of the LA, showing the connections between the muscle and the endopelvic organs [31].

1.7 Male Inferior Hypogastric Plexus

In the era of the "nerve-sparing" surgery, a perfect anatomical knowledge of the male pelvis nerve supply is crucial. Almost all pelvic nerve supply comes from the superior hypogastric plexus (SHP): this is a structure essentially formed by two neural plates coming from the inferior mesenteric plexus. SHP can be found at the level of the aortic bifurcation, in front of the sacral promontory: it is antero-aortic in 90 % of cases and retro-aortic in 10 % of cases. It divides into two layers called hypogastric nerves, which have an oblique antero-inferior course, lying below and within the internal iliac vessel and running into the inferior hypogastric plexus (IHP) at the intersection between the vas deferens and the ureter. IHP was firstly described by Latarjet and Bonnet and by Delmas and Laux [32, 33]. The other components of IHP are pelvic splanchnic nerves, emerging from sacral foramina. IHP measures 40 × 10 × 3 mm, with four borders and two faces: the posterior border receives from hypogastric nerves while the postero-inferior angle from pelvic splanchnic nerves; the superior border is covered by peritoneum of the rectovescical pouch; the inferior border is in contact with the endopelvic fascia, and the anterior border corresponds to the posterior aspect of the prostate. Its medial face is in contact with the antero-lateral aspect of the rectal fascia. From the antero-inferior border of the IHP emerges the cavernous nerve, running along the postero-lateral face of the prostate along the line of reflection overlying the levator ani: other efferent plexuses are the uretero-vesicle, the vesiculo-deferential, and prostatic one. In a detailed cadaveric dissection, Mauroy et al. found three important anatomical transverse cuts in relation to IHP: the first is at the level of intersection between terminal ureter and vas deferens, recognized as the origin of IHP; the second is at the lateral face of the seminal vesicle; and the third, which is the origin of efferent branches, is through the vesiculo-deferential-prostatic crossroads [34].

Atsushi Takenaka et al studied the anatomical variation of cavernous nerve (Fig. 1.5): they found that in their frontal and sagittal courses, the nerves pass through a narrow space between the rhabdosphincter and the levator ani, without

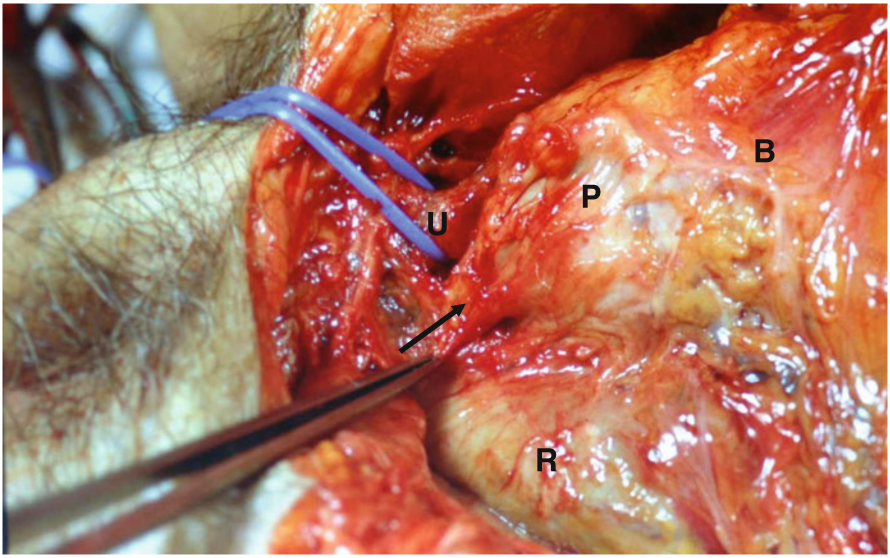

Fig. 1.5 *P* prostate, *B* bladder, *R* rectum, *arrow* pelvic plexus. 4B neurovascular bundle during cadaveric dissection after pubic bone removal. *U* urethra, *arrow* neurovascular bundle

penetrating directly the sphincter, but giving rise to several twigs entering in the sphincteric area; on the contrary, in both frontal and sagittal courses, the nerves appear likely to penetrate the rectourethralis muscle. Considering the relationship between nerve and prostatic apex, no positional changes are observed from a frontal point of view, but in the sagittal course a change of position is evident: they can change from 7–8 o'clock position to 10–11 o'clock position [21].

The last important clarification that must be described in this section regards the innervations of the membranous urethra, studied in details by Song et al. Nerve supply of membranous urethra comes from both IHP plexus, by cavernous nerves, and pudendal nerve; precise course of cavernous nerves is already described. Regarding pudendal nerve, its contribution for membranous urethra comes from both extrapelvic and intrapelvic branches. Before exiting the pudendal canal, the pudendal nerve gives off an intrapelvic branch that traverses the laevator ani muscle to innervate the membranous urethra; on the other side, the extrapelvic branches for the membranous urethra originate from the dorsal nerve of the penis [35].

1.8 Denonvilliers' Fascia

The rectogenital septum (known as Denonvilliers' fascia in the male or rectovaginal septum in the female) forms an incomplete partition between the rectum and the urogenital organs in both sexes.

It is composed of collagenous, elastic fibers and smooth-muscle cells intermingled with nerve fibers emerging from the autonomic inferior hypogastric plexus [36].

Even if this fascia is a surgical landmark for surgeons practicing pelvic surgery, like radical prostatectomy or Miles amputation, there is still no agreement concerning its anatomy and embryological derivation since Charles Pierre Denonvilliers first described the structure in 1836.

He referred to this layer as the "prostatoperitoneal" membranous layer in the male.

The fascia appears to gently fuse laterally with the loose connective tissue surrounding the perivesical plexus. Anteriorly it covers the posterior surface of the prostate, posteriorly it is separated from the rectum by the prerectal loose connective tissue and inferiorly it anchors to the centrum tendineum of perineum.

Anatomically, the fascia is formed by an anterior lamina, further spliced in an anterior and a posterior layer, and a posterior one.

Between the two laminas a virtual space can be developed (retroprostatic space of Proust), while dorsally to the posterior one the space of Hartmann is identifiable [37].

Its embryological origin has been strongly debated along the decades and today it is still a matter of debate.

Cuneo and Veau in 1899 first questioned the embryological origin of this fascia asserting that it arose by the fusion of the embryonic peritoneum of the rectovesical cul-de-sac. They did not find any distinct layers of Denonvilliers' fascia.

On the other hand, Wesson in 1922 contradicted this theory concluding that the aforementioned fascia was the result of the condensation of undifferentiated embryological peritoneum (mesenchyma) caused by rectovesical pouch compression during fetal development; he described the fascia as double layered: an anterior layer dorsal to the bladder and a posterior layer ventral to the rectal canal.

Finally, in 1945, Tobin and Benjamin confirmed the assertion of Wesson that the bladder and rectum were covered by mesenchyme; however, in contrast to him, they found a third tissue layer (mesothelium) between these two mesenchymal ones. This third layer was surrounded by a thin layer of subjacent mesenchyme and the fusion of the layers during fetal development, caused by rectovesical pouch compression, would determine the peritoneal mesothelium recession and disappearance, while the subjacent mesenchyme is left behind and develops into the fascia of Denonvilliers [38].

Even if neurovascular bundles do not pass through Denonvillieres' fascia, Dumonceau and Delmas found that some nerves, derived from the neurovascular pedicle of the inferior hypogastric plexus, cross the rectovesical fascia to innervate the prostate. The same findings were discovered by Kourambas et al in their histological studies. They concluded that, for oncological reasons, this fascia should be systematically removed during radical prostatectomy [39, 40].

1.9 Obturatory Fossa

The obturatory fossa represents an anatomical region of crucial importance for the male incontinence surgery: male slings, often used to cure urinary incontinence, cross obturatory fossa. Its detailed anatomical knowledge proves essential for the surgeon.

The obturatory fossa is the anatomical region formed by the soft tissues surrounding the obturator foramen and the bone structures around it (pubic bone and ipsilateral ischio-pubic ramus). Its further anatomical studies proceed from the most superficial layers to the deeper.

After incision of the skin and the subcutaneous tissue, a muscular plane is found. It is composed of four muscles progressively identified in the dissection: m. gracilis, m. abductor lungus, m. abductor brevis, and m obturator externus [41].

Only the last one completely belongs to the region: it is in a deeper plane with respect to Scarpa's Triangle. It origins by the pubic horizontal and ischio-pubic rami; its fibers run downward and laterally to the trocanteric fossa.

Under the obturator externus muscle a skeletal plane appears, it is composed by the obturator foramen, the obturatoria, and the external obturatory membranes.

The obturator foramen, in the male, has an oval shape. The obturator foramen is closed by the obturatory membrane in its inferior part while only its superior part, with the obturator sulcus, is open.

The external obturatory membrane anteriorly reinforces the obturatory membrane and inferiorly delimits the obturator canal with its superior free edge.

The obturator canal puts in communication the pelvic cavity with the antero-medial part of the thigh, it is 2.5 cm long. Its posterior (pelvic) orifice (15 × 10 mm) is delimited by the obturator sulcus and the fibrous insertion of the musculus obturator internus. Its anterior (femoral) orifice (15 × 8 mm) is delimited by the obturator sulcus, the external obturatoria membrane, and m. obturator externus.

The floor of the obturator canal is composed mediolaterally by the superior edge of m. obturator internus, obturatoria membrane, external obturatoria membrane, and m. obturator externus.

A precise knowledge of the nerves and blood vessels of the region is of paramount importance when performing sling procedures in this area.

Obturator nerve, artery, and vein are disposed lateromedially in the obturator canal.

The obturator nerve is located above the artery and origins three to four branches just outside the obturator foramen. It innervates the obturator internus and externus muscles and the hip muscle group.

The obturator artery originates by the internal iliac artery in most cases, by the external iliac artery in a few cases, and by an anastomotic ramus, between internal and external iliac artery, rarely [42].

It bifurcates just inside the obturator canal and the medial and lateral rami externally surround the obturator foramen and anastomosis.

Each terminal ramus of the obturator artery is followed by two satellite veins, a venous plexus is formed anteriorly by the m. obturator externus and it is in communication with the femoral vein.

The danger of a blind dissection along the iliopectineal line for fear of lacerating the "corona mortis" is known worldwide. This "anomalous" structure is formed by one or more vessels (artery and/or vein) crossing over the pelvic rim and coursing inferiorly to enter the obturator foramen [43].

Gilroy and colleagues studied the pathway of the obturator artery and vein in 105 cadaveric hemipelvis showing that only 18–30 % of the sample population showed no variant vessel.

In literature, three branching patterns have been described regarding the origin of obturator artery: (1) the internal iliac (normal, 62–67 % of cases), (2) the inferior epigastric/external iliac (variant, 33–38 % of cases), and (3) both the positions.

The most common (57–73 %) drainage pattern of obturator veins was a combination of the normal vein draining into the internal iliac vein, and an additional vein coursing over the pelvic brim to the inferior epigastric vein, so variations in venous pattern are much higher than arterials [42].

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2 Continence Physiology and Male Stress Incontinence Pathophysiology

Roberto Migliari, Donatella Pistolesi, Andrea Buffardi, and Giovanni Muto

2.1 Introduction

Neurophysiologic function of the continence mechanism in the male has been largely focused on voiding difficulties and directed to explore the obstruction instead of incontinence. Compared with these conditions, the symptom of stress incontinence was a minor problem that was easily overlooked.

The pathophysiology of male stress urinary incontinence (SUI) is not completely understood; no consensus exists on the mechanisms underlying SUI following radical prostatectomy and whether there are any preoperative risk factors [1]; the relationship between the pelvic viscera, prostate, sphincteric complex, and urethra does not show a radical change as a function of age but a combination of neuropathic changes, and muscle, fascial, or connective tissue damage is most likely responsible for the development of male urinary stress incontinence.

The precise mechanism remains controversial. Our understanding of the pathophysiology of male stress urinary incontinence (SUI) seems to follow the evolution

R. Migliari (✉)
U.O.C. Urologia, Umberto I Hospital, A.O. Ordine Mauriziano di Torino, Turin, Italy
e-mail: r.migliari@tin.it

D. Pistolesi
U.O. Urologia 1, Azienda Ospedaliero Universitaria Pisana, Pisa, Italy

A. Buffardi
U.O.C. Urologia, Ospedale Umberto I, A.O. Ordine Mauriziano di Torino, Turin, Italy

G. Muto
Department of Urological, Universita' Campus Biomedico, Rome, Italy

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of the theories on the etiology of SUI in female patients [2]. However, even though history of female SUI might help to understand and probably reduce the time necessary to investigate male counterpart of SUI, some anatomic differences may render the translation of this knowledge difficult and complicated.

An example of the similarities between etiological male and female SUI historical evolution is the Kelly's report, which attributed female SUI to "vesical neck funneling." It was caused, according to his hypothesis, by loss of elasticity or normal tone of the urethral and vesical sphincter [3]. Kelly's description of vesical neck funneling was the predecessor of future functional theories of SUI pathophysiology. And we know that open bladder neck after radical prostatectomy has been described and indicated as one of the leading cause of male SUI [3].

A full decade after Kelly, Bonney, in 1923, sought to explain the etiology of female SUI in terms of failure of anatomic support: "Incontinence appears to be due to laxity of the front part of the pubo-cervical muscle-sheet, so that it yields under sudden pressure and allows the bladder to slip down behind the symphysis pubis and the urethra to carry downwards and forwards by wheeling round the sub-pubic angle" [4]. Again, surgery of postradical prostatectomy incontinence with different slings suggests that downward dislocation of the sphincter complex may be responsible for suboptimal closure mechanism although definitive proof of the concept is still lacking.

Kennedy [5], another pioneer in female SUI, hypotesized that a peripartum cicatricial lesion of the fibers of the levator ani (LA) which joins a median raphe beneath the urethra, together with damage of innervation of voluntary sphincter, distorted the normally circular shape of the sphincter causing "the folds of the urethral mucosa [to] no longer completely fill the urethral canal." Again we know the importance to respect the integrity of male urethral sphincter especially during prostate apex preparation.

The pressure transmission theory of female SUI was dominant during the 1960s and 1970s, until researchers like Enhorning began to apply the diagnostic capabilities of neurophysiologic testing to the pelvic floor postulating a neurogenic etiology to SUI [6, 7]. Smith and colleagues corroborated these findings by comparing women with urodynamic stress incontinence with continent controls and demonstrating denervation injury to both the striated urethral muscle and the pelvic floor musculature in the stress-incontinent cohort [8].

The innervation of the external sphincter of the male urethra, which is essential for urinary continence, was for many years the subject of numerous conflicting studies. Knowledge of a mixed innervation controlling the continence and having narrow anatomical reports with the lateral faces of the prostate are of major importance in the prevention of incontinence following surgical operations of the prostate and bladder [9–11]. The surgical implications of the unidentified sphincteric nerve fibers are considerable in term of continence, as well as in terms of technical failure after surgery for incontinence [12, 13].

However, sphincteric deficiency can coexist with poor urethral support; most patients with SUI have a combination of loss of urethral support and compromised sphincteric dysfunction. The increasing recognition of the limitations of a dichotomous etiology of SUI set the stage for a theory that combined loss of urethral support and sphincteric dysfunction. In 1994, DeLancey [14–16] proposed a consolidated theory of SUI for female patients. Using anatomic research, he hypothesized that the pubocervical fascia provides hammock-like support for the vesical neck and thereby creates a backboard for compression of the proximal urethra during increased intra-abdominal pressure. Loss of this support would compromise equal transmission of intra-abdominal pressure. This part of DeLancey's theory combines the theories of Bonney and Enhörning. However, his theory also accounts for neuromuscular dysfunction. DeLancey's anatomic observations showed a connection of the pubocervical fascia with the insertion of the levator ani muscles at the symphysis pubis. He hypothesized that this connection with the levator ani muscles permits active elevation of the vesical neck during contraction of the levator ani muscles. In an attempt to harmonize sphincter dysfunction and deficiency of urethral support, Petros and Ulmsten [17, 18] proposed the integral theory of urinary incontinence. This theory attempts to account for the interplay of the structures involved in female urinary continence, as well as the effects of age, hormones, and iatrogenically induced scar tissue. One of the main innovations of this holistic theory was the tentative to demonstrate that ligaments and other connective tissue structures have a key role in pelvic floor dysfunction and especially urinary incontinence. Put simplistically, muscles pull against the ligaments to close or open the urethra. Therefore, loose ligaments may weaken the muscle contraction to cause problems with closure (incontinence).

We do not know whether in man the prostate removal may be responsible for a structural dysfunction that favors SUI by altering the transmission of the muscle movements involved in bladder neck function and/or modifying the vectorial forces that develop during the different activities (micturition, urinary continence, anal continence, etc.), but some reports seem to suggest it [19].

2.2 Male Pelvic Floor Functional Anatomy

The male pelvic floor is an understudied region of the body from a biomechanical perspective. On a daily basis, its anatomic structures must prevent urine and fecal incontinence during the elevations in abdominal pressure and motions associated with daily physical activities. Yet they must also permit waste to be eliminated through urination, and defecation and sexual activity with antegrade ejaculation must be integrated in this complex mechanism. Urethral closure pressure must be greater than bladder pressure, both at rest and during increases in abdominal pressure to retain urine in the bladder. The resting tone of the urethral muscles maintains a favorable pressure relative to the bladder when urethral pressure exceeds bladder pressure. During activities, such as coughing, when bladder pressure increases several times higher than urethral pressure, a dynamic process increases urethral closure pressure to enhance urethral closure and maintain continence that is referred to as "pressure transmission" [20, 21]. Both the magnitude of the resting pressure in the urethra and the increase in pressure generated during a cough determine the pressure at which leakage of urine occurs [22].

Although analyzing the degree of resting closure pressure and pressure transmission provides useful theoretical insights, it does not show how specific injuries to individual component structures affect the passive or active aspects of male urethral closure.

2.3 The Continence Mechanism

The dynamic voiding and storage function of the male urethra, like the female urethra, is dependent on its multiple constituents. The average length of the male urethra is 22.3 cm [23] but the most important part for the continence mechanism is the membranous and prostatic part, which are 3–4 cm in length (like in female); the rest of male anterior urethra, as well as the distal third of female urethra, may be considered as a sort of passive tube which transports the urine directing its flow.

Generally, apart from nonmuscular component, which includes the vascular plexus and mucosal coaptation, two integrated urethral sphincteric mechanisms are advocated to maintain male continence: internal and external urethral sphincter action.

2.4 Internal Urethral Sphincter

The internal urethral sphincter (IUS) has been simplistically described to lay at the junction of the urethra with the urinary bladder and to be a continuation of the detrusor muscle.

In males, the proximal fibers of the IUS were drawn as a bundle lying between the base of the bladder and the superior border of the prostate [24], forming a horseshoe-like arrangement that is continuous with the smooth muscle fibers of the bladder [25]. Classically it has been presumed that IUS muscle controls the flow of urine by contracting around the internal urethral orifice and the sympathetic nervous system has the role to maintain its tonic contractions [26] while the parasympathetic nervous system relaxes the internal sphincter muscle during micturition [25]. The IUS is surrounded circumferentially by layers of striated muscle [27, 28] referred to as the external urethral sphincter. Thus, the combination of the smooth muscle of the IUS and these striated muscles surrounding the IUS acts to control the removal of fluids from the body. Actually, even if the importance of the integrity of this component in the whole process of male urinary continence has not been questioned, there has been a revision of the functional anatomy of the internal urethral sphincter.

2.5 External Urethral Sphincter

The dominant element in the urethral sphincter has been the *striated urogenital sphincter muscle* or *external urethral sphincter* (*EUS*). It is an integral part of the male urethra, is situated at the level of the membranous urethra [29–31], and represents the thickest muscular structure of the male urethra. The gender difference in the morphology of the rhabdosphincter is well known, being omega-shaped in males and having a semicircular configuration in females [32–34]. In early fetuses, the female rhabdosphincter is unable to extend infero-posteriorly because of the developing vestibule close to the sphincter [35]. The anteriorly restricted female rhabdosphincter may require a static ligament-dependent lateral support (i.e., the perineal membrane), in contrast to the dynamic muscle-dependent support in males.

The structure of the striated urethral sphincter, the so-called rhabdosphincter, remains the subject of controversy. There are two main concepts regarding its structure: either it is a part of the urogenital diaphragm, or it extends from the base of the bladder up to the urogenital diaphragm and is an integral part of the urethra. It is also uncertain whether it possesses a somatic innervation or a mixed innervation (i.e., autonomic and somatic).

It possesses one smooth muscle component and one striated muscle component, their respective muscle fibers intermingling on the lateral face of the urethra [36]. There is histomorphological evidence that the external sphincter consists of a striated (musculus sphincter urethrae transversostriatus) and smooth muscle (musculus sphincter urethrae glaber) component. The striated muscles are shaped like incomplete circles on the anterior and lateral faces, and they run parallel to the striated musculature of the prostatic capsule [37]. Morphological investigation of the urethral musculature revealed a striated muscle structure going from the bladder neck to the proximal bulbar urethra and closely associated with the smooth muscle structure. The dissociation of the striated muscle fibers, which form incomplete rings on the lateral and posterior faces of the urethra, represents a space through which the unmyelinated nerve fibers can pass on their way to the smooth muscle layer and submucosa. This phenomenon may explain the presence of unmyelinated nerve fibers in the deep part of the striated muscles [38–40]. They are heading toward the smooth muscular fibers, but they can be found on 2-D images as they pass.

The striated part of the sphincter is the only mechanism of continence after prostatectomy where the smooth muscles will be divided and muscular vesico-prostatic-urethral continuance will be interrupted. Conservation of the sphincter during vesico-prostatic and pelvic surgery is a basic element in avoiding postoperative incontinence [41]. It means that we must minimize trauma during dissection of the prostate, in particular its apex; great attention should be given to the posterior continuation of the striated sphincter and its attachments with the pelvic fascia, and also to the striated muscles on the anterolateral face of the sphincter during the ligature of the dorsal venous complex and during the vesico-urethral anastomosis [11]. Finally, some remarkable differences in the structure of the rhabdosphincter between young and old men were described. The musculature was significantly thicker and more muscular in young men. Others have also described the rhabdosphincter to have less connective and smooth muscle tissue, and more striated muscle in young men. In agreement with these investigators the distinctive morphology and tissue composition of the rhabdosphincter in old men may partly account for the greater difficulty in recovery of urinary control following radical prostatectomy.

2.6 The Evolution of the Urethral Sphincter Concept

These oversimplified (but inaccurate) explanations, such as the two opposing loops of detrusor muscle or baseplate mechanism of the bladder neck, or even the traditionally upheld concept of proximal and distal urethral mechanisms, are often reported to explain urinary incontinence mechanism. This concept is easier to understand but may be misleading.

The so-called two opposing loops or arches of detrusor muscle at the bladder neck that pull it closed as they contract were first described in 1900 by Toldt [42], confirmed by Heiss [43] in 1915 and in 1920 by Wesson [44], but disputed by later investigators [45].

Actually there seems to be no anatomical evidence for two separate urethral sphincteric mechanisms, which is a proximal one of smooth muscles, and a distal one of mixed smooth and skeletal muscles. Rather, as reported by Koraitim [46], there are two functionally independent components of the urethral sphincter complex, namely an inner (internal) lissosphincter of smooth muscle and an outer (external) rhabdosphincter of skeletal muscle that are responsible for passive and active continence, respectively. The two components form a continuous layer that extends uninterrupted from the perineal membrane up to the vesical orifice.

The presence of more than one sphincter is not peculiar to the bladder and is in line with the duplication of safety mechanism generally found in the structural plan of humans. It is noteworthy that the bladder does not form a sphincter of its own from its musculature. Rather, it is formed exclusively by the urethra. Also, irrespective of all different views about the anatomy of the urethral sphincter complex, there has been complete agreement that it is formed of smooth and skeletal muscle components. Hence, in this anatomical concept, the urethral sphincter is composed of two morphologically related but functionally unrelated components, namely an inner lissosphincter of smooth muscle and an outer rhabdosphincter of skeletal muscle.

As reported by Koraitim [46] the urethral sphincter complex extends in the form of a cylinder around the urethra from the vesical orifice to the distal end of the membranous urethra (Fig. 2.1). The inner component of smooth muscle has its main

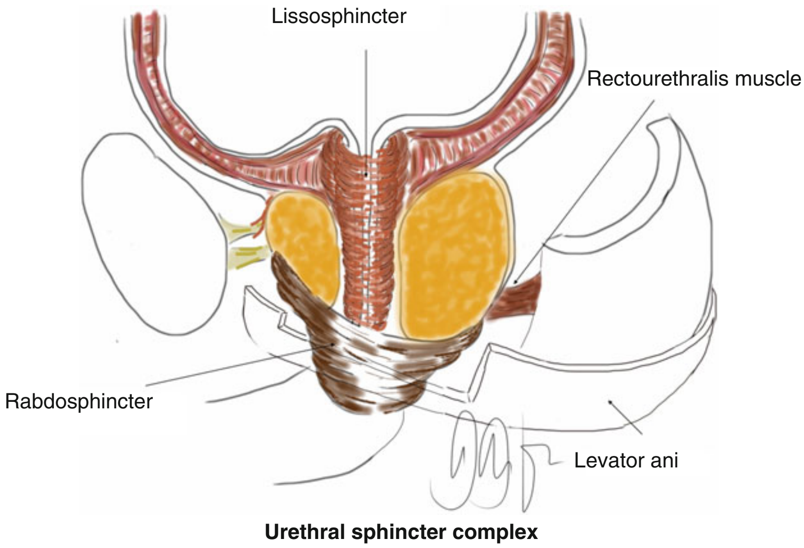

Fig. 2.1 Revised concept of male urethral sphincter complex. The rabdosphincter overlaps ventrally the prostate, is horseshoe shaped, and consists of a smooth muscular part and a striated part. A further smooth muscular part of the urethra (lissosphincter) is evident close to the urethral lumen

part at the vesical orifice and is thinner in its further course in the urethra, while the outer component of skeletal muscle is most marked and thickest around the membranous urethra, and becomes gradually less distinct toward the bladder orifice. Also, whereas the lissosphincter forms a complete cylinder of circular muscle fibers around the urethra, the rhabdosphincter does not. From the perineal membrane to the prostatic apex the skeletal muscle fibers unite behind the urethra in a central fibrous raphe, while more proximal they form a cap on the anterolateral side of the prostate. Furthermore, while after puberty the lissosphincter does not show appreciable change, the rhabdosphincter shows atrophy of its prostatic part, of which the fibers become indistinctly dispersed among the smooth muscles and glands of the prostate.

Passive continence is the involuntary aspect of micturition since no conscious effort is required to achieve continence. There is evidence to show that passive continence is primarily and exclusively a function of the urethral lissosphincter. Maximum closure may be assumed to be at the level of the vesical orifice, where the lissosphincter is most thick, and in the membranous urethra, where the urethra is most narrow. The lissosphincter maintains continence at rest by contraction of its circular muscle fibers, resulting in closure of the vesical orifice and concentric narrowing of the posterior urethra. The presence of the whole length of the lissosphincter is not essential to maintain continence. A minimal length of lissosphincter is crucial for this function, below which incontinence is inevitable. As demonstrated in patients after posterior urethroplasty or prostatectomy, respectively, this function may be accomplished by the proximal or the distal part of the sphincter alone [28, 47, 48].

The urinary and genital roles of the rhabdosphincter are determined by the arrangement of muscle fibers in the caudal and cranial part, respectively. The attachment of the caudal part of the muscle to its posterior median raphe would result in movement of the anterior urethral wall toward the posterior wall with contraction. Compression of the pliable anterior urethral wall against Denonvilliers' fascia and the rectourethralis muscle, which together form a relatively rigid posterior plate, produces a transversely flattened urethral lumen [49] (Fig. 2.1). Much higher urethral resistance could be achieved by concentric contraction of the lissosphincter due to the larger surface area of coaptation created. This is the principle of active continence induced by forceful occlusion of the urethra such as that which occurs during events of increased intra-abdominal pressure or during voluntary interruption of micturition.

Occlusion of the urethra during these events occurs in the region of the membranous urethra, as evidenced by the increase in maximum urethral pressure during urethral pressure profilometry. The rhabdosphincter does not seem to be a purely slow-twitch muscle only, as originally described by Gosling et al. [29], but rather a mixed slow- and fast-twitch striated muscle with fast-twitch fibers more predominant in the caudal part of the sphincter [37, 50]. This relatively recent finding endorses the view that this part of the rhabdosphincter around the membranous urethra is especially concerned with the rapid and forceful closure of the urethra during active continence. Contraction of the skeletal urethral muscle is vigorous but capable of only briefly sustained activity lasting only a few seconds [51]. The arrangement of the muscle fibers of the prostatic rhabdosphincter, whether as a distinct muscle cap in children or as indistinctly scattered fibers in adults, would prohibit it from having a significant role in urinary continence. Contraction of this part of the rhabdosphincter would only produce side-to-side compression of the prostatic urethra, which is not sufficient to produce continence but could result in antegrade propulsion of semen in the presence of a closed vesical orifice. Accordingly, the prostatic rhabdosphincter could have essentially a sexual function [52].

Apart from urethral sphincter, ligaments, muscles (levator ani), prostate gland, and fascias surrounding the urogenital sphincter seem also to play a role either to maintain the proper position and function of the urethral sphincter complex or to perform a sort of auxiliary function in male urinary incontinence. However, their real role must be fully investigated.

2.7 The Levator Ani Muscle

The levator ani (LA) muscle action in the male remains an understudied function particularly from a biomechanical perspective if compared to the female pelvic floor muscle (PFM) dynamic [53]. Several randomized controlled trials have demonstrated that PFM strength training in women with SUI is more effective than no treatment or treatment involving other modalities [54–58]. Nevertheless, although strength training is effective, the strength of a PFM contraction does not always correlate with an individual's level of functional continence [59–61]. However, other properties of PFM function, such as the timing and direction of contractions, endurance, the ability of the PFMs to relax, overactivity of the PFMs, pelvic organ support, and coordination with muscles of the abdominopelvic cylinder, are not completely elucidated. Given the multipurpose role of the pelvic floor, the motor control challenge for the PFMs must be immense and the efficiency of these muscles will not only rely upon the anatomical integrity of the pelvic floor, but will also depend on the central nervous system (CNS) response to satisfy the hierarchical demands of function. The CNS must interpret the afferent input and generate a coordinated response so that the activity of the muscles occurs at the right time, with the appropriate level of force.

There are three basic regions of the LA muscle [52]. The first region is iliococcygeal portion that forms a relatively flat, horizontal shelf, which spans the potential gap from one pelvic sidewall to the other. The second portion is the pubovisceral muscle that arises from the pubic bone on either side attaching to the walls of the pelvic organs and perineal body. In males, the pubovisceral muscle itself consists of three subdivisions: the puboperineus (inserting into perineal body), the pubourethralis (less defined inserting into the urethra and prostatic apex), and the puboanalis (inserting into the intersphincteric groove of the anal canal). The third portion of the LA, the puborectal muscle, forms a sling around and behind the rectum just cephalad to the external anal sphincter (Fig. 2.2). The connective tissue covering on both superior and inferior surfaces is called the superior and inferior fascia of the

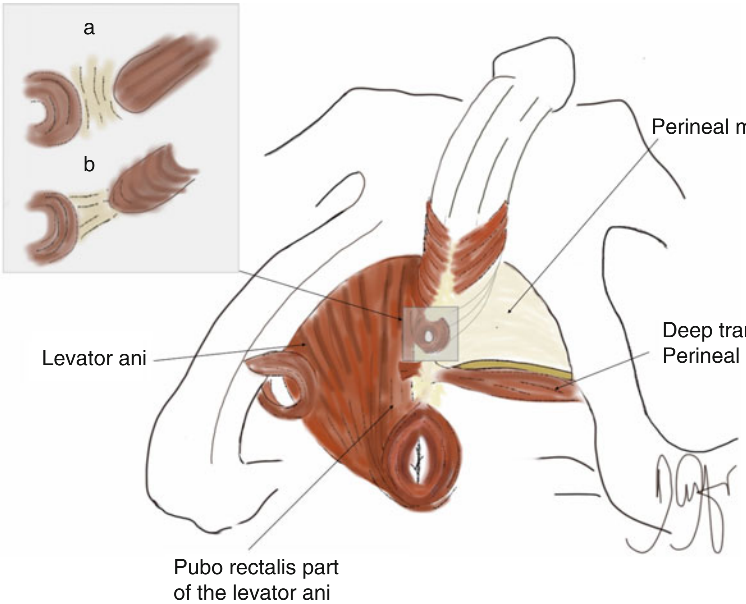

Fig. 2.2 Schematic drawing of the perineal membrane and levator ani muscle in the male seen from below. The *inset* shows *t* at higher magnification, a diagram of interface tissue configurations between the rhabdosphincter and levator ani. The morphology shown in panel (**a**), similar to the configuration between a skeletal muscle and bone when the connecting fibrous tissues are formed by collagenous fibers, is most suitable for upward traction. In panels (**b**) the fasciae along or surrounding the levator and/or the rhabdosphincter area are not suitable for force transduction but for sliding between these two muscles

LA. When these muscles and their associated fascia are considered together, the combined structures make up the pelvic diaphragm.

In females, the normal baseline activity of the LA muscle keeps the urogenital hiatus closed by compressing the vagina, urethra, and rectum against the pubic bone, the pelvic floor, and organs in a cephalic direction [62]. This constant activity of the LA muscle is analogous to that in the postural muscles of the spine and renders any opening within the pelvic floor a virtual one.

We do not know if the same is valid also for the male counterpart even if it may be similar. This continuous contraction of the LA is similar to the continuous activity of the external anal sphincter muscle and should close the lumen of the urethra in a manner similar to that by which the anal sphincter closes the anus. The only known voluntary function of the PFM is a mass contraction best described as an inward lift and squeeze around the urethra and rectum [63]. However, the different muscles have different fiber directions, and if each muscle could contract in isolation, they would all have different functions.

Looking to the female counterpart it might be assumed that a maximal voluntary LA muscle contraction causes the pubovisceral muscles and the puborectalis muscles to further compress the mid urethra and rectum against the pubic bone distally and against abdominal hydrostatic pressure more proximally. Contraction of the bulbocavernosus and the ventral fibers of the iliococcygeus will only marginally augment this compression force developed by the pubovisceral and puborectalis muscles. This is because the former develops little force and the latter is located too far dorsally to have much effect. Finally, maximal contraction of the mid and dorsal ilioccyggeus muscles elevates the central region of the posterior pelvic floor, but likely contributes little to levator strength or pressure because they do not act circumferentially.

The interaction between the pelvic floor muscles and the supportive ligaments is critical in pelvic organ equilibrium. As long as the LA muscles function properly, the ligaments and fascial structures supporting the pelvic organs are under minimal tension.

Actually the male LA seems unsuitable for elevation of the urethra and rhabdosphincter: its action on the urethra might be overemphasized relative to that on the anorectum. The PFM contraction tended to be analyzed as a whole [64] and, thus, LA function on the urethra might not be compared with that on the anorectum.

Moreover, the most striking difference between the LA and other striated muscles lies in the relationship between the direction of muscle action and that of the muscle fibers: in skeletal muscle, the muscle fibers, tendon, and fibrous tissue connecting the two are consistently arranged "in series" along an almost straight line, whereas the LA muscle fibers are parallel (Fig. 2.2). Thus, the term "pubourethralis muscle" (the most anterior part of the LA [65]) may not indicate the function but merely the muscle location near the urethra. Moreover, the rhabdosphincter muscle fibers are not bundled by collagen fibers but by elastic fibers, and hyaluronic acid seems to act as a lubricant between the elastic fibers [66].

2.8 Connection Between the Levator Ani and Rhabdosphincter in Males

Hinata and Murakami [67] clearly demonstrate that, in the male, the bilateral slings of LA sandwich the rhabdosphincter area. This topographical relationship strongly suggests that the LA provides mechanical support. In fact, it has been considered that the function of the LA to rapidly cut off urinary flow is effected via active elevation of the urethra, in contrast to the old concept of slow-twitch nature of the rhabdosphincter [68, 69]. Thus, it seems reasonable to assume that there are specific structures suitable for transduction of force from the LA to the urethral wall, via the rhabdosphincter area. A thick fascial structure has been reported to connect the rhabdosphincter area to the LA [70, 71]. This fascia or interface structure contains abundant elastic fibers and smooth muscles, which are irregularly arrayed. Collagen fibers (type I collagen fibers) possess very little elasticity, whereas elastic fibers absorb tensile stress and recover their length. Tendons of skeletal muscles require a small proportion of elastic fibers in order to recover their length after muscle contraction and they are composed of mostly type I collagen fibers [72, 73]. Instead, fasciae that are exceptionally elastic fiber-rich cover or bundle striated muscle fibers in the extraocular muscles of the eye [74], the intrinsic lingual muscles along the tongue surface [75], and also the LA and external anal sphincter [76, 77]. Notably, all of these muscles are inserted into soft tissues, and not into bones.

In arterial walls, smooth muscles and elastic fibers usually coexist because elastic fibers are necessary for maintaining the three-dimensional configuration of smooth muscle fibers [78]. This kind of elastic interface between a striated muscle and a soft tissue target would seem to minimize any damage or tears resulting from sudden and strong contraction of the LA. In this context, the connecting fascia between the LA and the rhabdosphincter would seem to play a role in (1) stabilizing structures in the event of elevation force and (2) regulating and distributing tensile stress from the LA. This is somewhat reminiscent of the nature of smooth muscle cells or fibers in the walls of arteries, which can act against blood pressure without nerve or hormonal control (i.e., Bayliss effect; increased pressure and subsequent stretch of smooth muscle cause muscle contraction and increased resistance [79–81]). In accordance with Bayliss effect, connective tissue composed of smooth muscle would seem to function as an ideal barrier or protector against mechanical stress because, even without innervation, smooth muscle fibers resist (not absorb) pressure. This function seems to be much stronger than the passive action of elastic fibers.

The "integrated pelvic floor theory" [62] attributed a key role to the longitudinal anal muscle (conjoint longitudinal muscle coat) in the statics and dynamics of the female pelvic viscera, being involved in the closure and opening of the urethra and anal canal. According to Petros [62], the smooth muscles, with their vertical course, create a downward force for bladder neck closure during effort and stretch the outflow tract open during micturition. However, Hinata and Murakami [67] do not think that smooth muscles in male the pelvic floor connective tissue play a strong, monodirectional, and long-term traction role without cooperation of striated muscle function because of their random arrangement and nonexistence of any nerve network such as the myenteric plexus for intestines.

2.9 The Dispute About the External Sphincter and the Urogenital Diaphragm

In males, endopelvic fascia condenses to form three distinct ligaments:

- Pubourethral and puboprostatic ligament – stabilizes the urethra and the prostate
- Urethro-prostate-pelvic ligament – supports the prostate, the bladder neck and the urethra
- Pubocervical fascia – supports the bladder

Their attachments to the side wall of the urethra and pelvic wall (arcuate tendons) form a "hammock" behind the membranous urethra. When intra-abdominal pressure increases (e.g., when coughing, sneezing, and during exercise), the urethra, like in the female, might be forced and closed against the posterior "hammock" [14].

Musculofascial and skeletal structures provide a critical framework for the male urethral sphincteric complex. Burnett and Mostwin confirmed the fixation provided ventrally by the subpubic fascia, as recently described by Steiner who has proposed that the bilateral pubourethral ligaments consist of anterior, intermediate, and posterior divisions comprising a median suspensory mechanism for the urethra beneath the subpubic arch [19, 41].

These structures have been viewed as a unit suspending proximal pendulous urethra and corpus spongiosum distally, and membranous urethra and rhabdosphincter proximally. The fascial components of the urethral sphincteric complex also arise laterally and dorsally. Several descriptions support the role of the dorsal midline fibrous raphe as an anchor for the rhabdosphincter dorsally with Denonvilliers' fascia. Based on their dissections, Burnett and Mostwin [19] reported that this raphe is continuous with a broad musculo-fascial plate, which serves as a backboard for the urethra and extends laterally in continuity with the subpubic fascia and medial fascia of the levator ani. This arrangement of fascial components is an intricate scaffold that suspends and stabilizes the rhabdosphincter.

Hirata et al. [77] reported a gender difference in the fiber architecture of the endopelvic fascia (fascia pelvis parietalis; a fascia lining the superior or inner aspect of the LA): the male endopelvic fascia is multilayered and contains abundant smooth muscle fibers, whereas the female endopelvic fascia is solid, thick, and contains abundant elastic fibers rather than smooth muscle. Such a difference in connective tissue may be the result of the different hormonal backgrounds, as estrogen is known to increase the formation of elastic fibers. Different techniques of radical prostatectomy may partially spare or not the endopelvic fascia and it has been demonstrated that saving the puboprostatic ligaments may be of importance in maintaining or quickly regaining urinary continence even if this is debated. At this moment the importance of male endopelvic fascia in urinary incontinence has not been elucidated properly even if saving the anterior part of this condensed fascia, which starting from the pubic bone spans from the bladder to the urethra, is very important for fast recovery of urinary incontinence after radical prostatectomy [65].

2.10 The Myth of Urogenital Diafragm and the Perineal Membrane

Finally, it is necessary to discuss the concept of the urogenital diaphragm, which is believed to be composed (simply) of the deep transverse perineal muscle. It is said it constricts the membranous urethra and expels the last drops of urine. The latter does not exist in the female.

The "urogenital diaphragm" is a myth. It is formed by the perineal membrane (PM), which is a complex, three-dimensional structure and is an anatomical term for a thick, fibrous, and triangular membrane attached to the bony framework of the pubic arch (Fig. 2.2) [68, 69].

The basis of magnetic resonance imaging studies, the strictest argument against the existence of the urogenital diaphragm was provided by Myers [82], who established a safe treatment for the retropubic veins in radical prostatectomy. He stated that "there is not a hint of what might be called Henle's artifact, his diaphragma urogenitale". In spite of his excellent schemes, which included a membranous structure at the external genitalia, Oelrich [32, 83] also had a negative, rather than positive, opinion, because he did not identify striated muscles but smooth muscles in the membranous structure

The deep transverse perineal muscle has long been considered as a core of the urogenital diaphragm. Nakajima et al. [84] have reported that the deep transverse perineal muscle is attached to Cowper's gland in males and is continuous with the rhabdosphincter. Likewise, a fascia covering the deep transverse perineal muscle may be regarded as the perineal membrane. Actually, because the male rhabdosphincter is continuous with the transverse muscle, the male perineal membrane along the bottom of the rhabdosphincter area is likely to attach to the muscle.

Kato et al. [85] clearly demonstrated that elastic fibers between the rhabdosphincter muscle fibers join together to form the perineal membrane. Thus, an elastic fiber cage for the rhabdosphincter muscle fibers is a common feature in both genders, although the male perineal membrane is solid, collagen fiber-rich, and extends along the inferior margin of the rhabdosphincter area. Mirilas and Skandalakis [86] simply considered the perineal membrane as a structure extending between the bilateral LA slings, but it is similar to a concept of the hiatal ligament by Shafik [87].

Nakajima et al. [84] considered that, because the deep transverse perineal muscle is not sheet-like but a three-dimensional pillar continuous with the rhabdosphincter, previous researchers had found it difficult to identify, especially in histology preparations. The perineal membrane might also be considered a "fascia" of the transverse perineal muscle.

In both men and women, where the urethra passes through the deep pouch, it is surrounded by skeletal muscles called the EUS [71].

During dissection of the urogenital hiatus from the ischiorectal fossa on the anterior side of the rectum and on the lateral side of the urethra, we were able to touch by hand a diaphragm-like structure containing (1) the rhabdosphincter, its extensions, and the elastic interface tissue with the LA; (2) the perineal membrane; (3) the rectourethralis muscle; (4) the deep transverse perineal muscle; and/or (5) parts of the bulbospongiosus and ischiocavernosus muscles. Likewise, for measurement of thickness using clinical imaging, Betschart et al. [88] considered the perineal membrane as en masse that includes striated muscle, smooth muscle, and connective tissues.

2.11 Rectourethralis Muscle

The rectourethralis muscle (smooth muscle mass in males) has been one of major interests in uroanatomy [89, 90], but its topographical relation with the LA was not described well. Some reports using frontal sections clearly demonstrate the rectourethralis muscle occupying the urogenital hiatus [91]. Unlike the descriptions by Walz et al. [92], the rhabdosphincter is unlikely to attach to Denonvilliers' fascia because the rectourethralis muscle, to various degrees among individuals, is consistently interposed between the fascia and the sphincter [91, 93, 94].

In males, Rocco et al. [95] considered that the "tendinous" median dorsal raphe of the rhabdosphincter acts as a fulcrum for contraction. However, it is not tendinous or collagenous but composed of smooth muscle and elastic (not collagen) fibers.

The tendinous nature of the dorsal raphe may have been overestimated through comparison with general morphology in experimental animals such as rats that carry the typical raphe [96]. Actually, a recent big review of the rhabdosphincter physiology was based on the rat anatomy [97]. The median part is continuous with the rectourethralis muscle or, rather, it is a part of the rectourethralis muscle [91]. Because of Bayliss effect, the smooth muscle may resist traction from the rhabdosphincter and urethra. Some urologists believed that the LA contributes to a double-sling mechanism via the median dorsal raphe for closure of the urethra in males [65, 98], but the LA does not extend to the midsagittal area. This theory seems to be an analogy of the triple loop system of rhabdosphincter around the anal canal [99].

On the inferior side of the pelvic floor in males, the rectourethralis muscle is attached to the perineal body [94], whereas in females the superolaterally located perineal membrane is not attached to the perineal body.

2.11.1 Superficial Perineal Muscles

Under perineal membrane, three muscles are found bilaterally in the male; the bulbospongiosus muscle arises from the perineal body and the fibrous raphe on the bulb of the penis and is inserted into the superior aspect of the corpus spongiosum. It aids in expelling urine or semen. The ischiocavernosus arises from the ischial ramus and is inserted on the crus penis. It helps to maintain erection by compressing the veins in the crus. The superficial transverse perineal muscle arises from the ischial ramus and is inserted into the perineal body. All three superficial muscles are supplied by the pudendal nerve. In the female, the bulbospongiosus is separated from the contralateral muscle by the vagina. It arises from the perineal body, passes around the vagina, and is inserted into the clitoris. The ischiocavernosus is inserted on the crus clitoridis. There seems that the role of these muscles, which is important for sexual function, is neglectable on urinary continence.

Conclusions

Over the past 20 years, much has been elucidated about the pathophysiology of male SUI. As improved diagnostic modalities have provided new insight into the function and dysfunction of the urethral continence mechanism, theories have evolved from being purely anatomic to being both functional and anatomic. As our knowledge of the physiopathology of the urethral continence mechanism expands, new opportunities for intervention will become possible, setting the stage for novel innovative prevention and treatment options.

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3 Incontinence: Definition and Classification

Giovanni Bodo and Enrico Ammirati

3.1 Definition

Urinary incontinence (UI) is a "storage symptom." The most recommended definition of incontinence in men, as well as in women, is that of the fifth International Consultation on Incontinence (ICS): "the complaint of any involuntary loss of urine" [1]. This definition is suitable for epidemiological studies of male incontinence, but in clinical practice it must be emphasized that: the loss of urine should be objectively demonstrable, it should happen in socially unaccepted time and place ("social or hygienic problem"), and it should be expelled from an orthotopic anatomically intact urinary system (e.g., urinary leakage from a ureteroileocutaneous urinary diversion is not considered a form of incontinence).

Urinary incontinence is further classified with regard to the specific circumstance in which urinary leakage occurs. Stress urinary incontinence (SUI), in particular, is considered the complaint of involuntary loss of urine on effort or physical exertion (e.g., sporting activities), or on sneezing or coughing. In case the patient complains of involuntary loss of urine on effort or physical exertion, or on sneezing or coughing associated with urgency, it is better to refer as to mixed incontinence with a prevalent stress incontinence component.

Data found in medical literature show that the prevalence of urinary incontinence in men ranges from 1 to 39 % of the population; the wide variability of data can be explained by the heterogeneity in the population studied, by the different definitions

G. Bodo (✉)
Department of Neurourology, Azienda Ospedaliera Universitaria Città della Salute e della Scienza, Torino, Italy
e-mail: giannibodo@libero.it

E. Ammirati
Department of Urology, Azienda Ospedaliera Universitaria Città della Salute e della Scienza, Torino, Italy

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of incontinence and by the different methods of data collection [2]. Urgency incontinence is the prevalent complaint in the male incontinent population with predominant prevalence of 40–80 %, followed by mixed forms of urinary incontinence ranging between 10 and 30 % and stress incontinence <10 % [3]. The higher percentages of urgency and mixed types of incontinence are more significant in studies involving older people. In fact, the increasing prevalence of UI in men with age is largely due to the contribution of urgency incontinence rather than stress incontinence. One study demonstrated an increasing rate of urgency UI from 0.7 % between age 50 and 59 to 2.7 % between 60 and 69 and 3.4 % for 70 years and older population; stress UI was steady at 0.5 %, 0.5 % and 0.1 % for the above groups, respectively [4]. On the other hand, Maral and coworkers reported the increasing prevalence also of SUI with age: from 0.9 % between age 35 and 44 to 1.2 % between 45 and 54, 3.8 % between 55 and 64, and 4.9 % for 65 years and older respondents [5]. Multivariate analysis in several studies has shown that age is an important risk factor for incontinence. Compared to women, however, there seems to be a more steady increase in prevalence of urinary incontinence in men with increasing age [6–10].

3.2 Etiologic Classification

As it was exhaustively explained in the previous chapter, the anatomical and functional integrity of the urinary sphincter is crucial in the maintenance of continence. Any cause that directly injures the urinary sphincter or that reduces its capacity of maintaining adequate resistance may result in stress urinary incontinence [11].

Thus we can classify stress urinary incontinence into three main etiologic categories:

1. Neurologic stress urinary incontinence (neurogenic bladder)
2. Stress urinary incontinence associated with prostate cancer (PC) and BPH treatment
3. Post-traumatic stress urinary incontinence

3.2.1 Neurologic Stress Urinary Incontinence (Neurogenic Bladder)

"Neurogenic bladder" is a generic term as it can be applied to a broad spectrum of clinical conditions. The neurogenic conditions that can provoke stress urinary incontinence are sacral spinal cord lesions (spinal dysraphism, sacral agenesis, anorectal anomalies, conus injuries) and subsacral lesions (sacral dysraphism, familiar dysautonomies, cauda equina injuries, pelvic nerve injuries) (Fig. 3.1).

Spinal cord injury (SCI) can be a dramatic consequence of car accidents, sports injuries, spinal vascular events, violence, infection, disc prolapsed or spinal surgery. The male-to-female ratio is around 4:1 and in a published epidemiological study in 2000–2003, the mean age at the time of the injury was 37 ± 17.5 years [12]. SCI is classified by the neurological level of the motor and sensory function on the American Spinal Injury Association (ASIA) Impairment Scale [13]. Bladder and

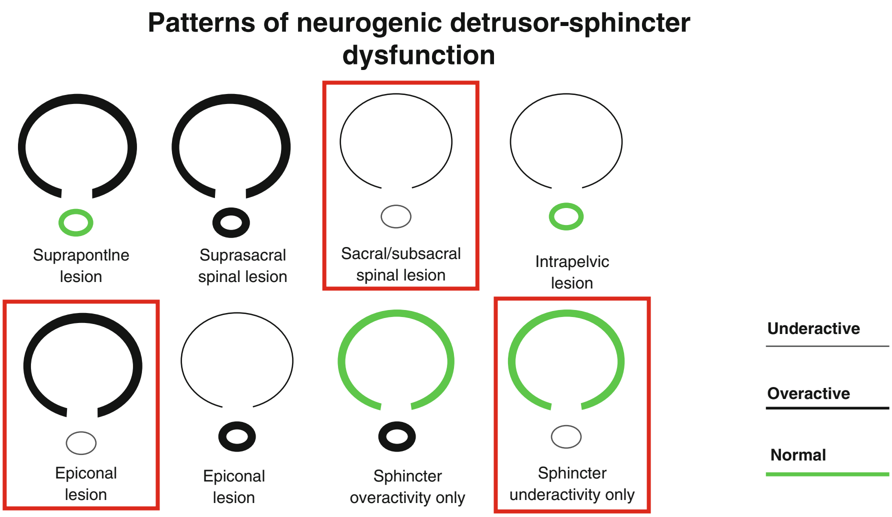

Fig. 3.1 Patterns of neurogenic detrusorsphincter dysfunction (Adapted from The European Association of Urology (EAU)–Madersbacher classification system [14, 15]). *Red squares* – evidence conditions potentially causing SUI

pelvic dysfunction after SCI can be divided into two different phases: acute and chronic. The acute phase, also called "spinal shock," covers the first few weeks or months after the injury and is generally represented by the loss of muscle tone and spinal reflexes caudal to the level of the segmental spinal lesion: detrusor and sphincter are in most cases areflexic; however in this phase, SUI is not typically yet present, surprisingly. SUI is typical of the chronic phase of sacral (conus injuries) and subsacral (cauda equina injuries and pelvic nerve injuries) lesions due to sphincter weakness, sometimes associated also with neurogenic detrusoral overactivity.

3.2.2 Stress Urinary Incontinence Associated with Prostate Cancer and BPH Treatment

Another well-known cause of stress urinary incontinence, and perhaps the most frequent cause of SUI in male, is represented by radical prostatectomy. In a Norwegian survey of elderly men with UI, 28 % of men complaining of UI had undergone prostatectomy [16].

Post-prostatectomy incontinence (PPI) and erectile dysfunction are common problems following surgery for prostate cancer. Open radical prostatectomy (RP) is a common treatment for patients with clinically localized prostate cancer (cT1–cT2) and life expectancy over 10 years, with laparoscopic radical prostatectomy (LRP) and robot-assisted radical prostatectomy (RARP) becoming the most up-to-date techniques. Evaluating the major surgical series coming from referral centers, functional results were overlapping between RP and LRP, with 12-month continence rates ranging from 60 to 93 % after RP and from 66 to 95 % after LRP [17]. Data variability in published studies depends on many factors such as different patient selection, study designs, continence definitions and surgical techniques. A recent systematic review of literature by Ficarra et al. found that the 12-month PPI rates after RARP ranged from 4 to 31 % (mean value 16 %) of cases using a "no pad" definition and from 8 to 11 % (mean value 9 %) when also including as successful for those patients using a safety pad. Age, body mass index, comorbidity index, lower urinary tract symptoms (LUTS) and prostate volume were the most relevant preoperative predictors of urinary incontinence after RARP. A cumulative analysis showed a better 12-month urinary continence recovery after RARP in comparison with RP [18]. Another predictor of urinary incontinence has been identified by Thompson in the surgeon expertise using the RARP technique. Early urinary incontinence scores for RARP surpassed open RP after 182 RARPs, plateauing around 700–800 RARPs [19].

Also another therapeutic option for the treatment of prostate cancer, radiotherapy, is a possible cause of stress urinary incontinence. A recent work compared long-term urinary function after radical prostatectomy or external-beam radiation therapy in a population of 1,665 men with diagnosis of localized PC. Men in the prostatectomy group were significantly more likely than those in the radiotherapy group to report urinary leakage at 2 and 5 years. However, despite absolute differences in the prevalence of urinary incontinence between the two study groups at 15 years (18.3 % and 9.4 %, respectively), they observed no significant difference in the adjusted odds of urinary incontinence (odds ratio, 2.34; 95 % CI, 0.88–6.23) [20].

Surgical treatment for BPH is a rare cause of stress urinary incontinence. Surgical retropubic and soprapubic prostatectomy, in experienced hands, have a low overall rate of morbidity. Stress incontinence and total incontinence are rare often self-limiting, but possible complications [21, 22]. With a precise enucleation of the prostatic adenoma, the risk of injury to the external sphincter mechanism is minimal. Endoscopic treatment is considered a safe procedure with concern to the preservation of the urinary sphincter mechanism. In a large cohort of 3,589 TURP procedures done by a single-surgeon, there were no cases of iatrogenic stress urinary incontinence [23]. Laser technologies are developing and their use is becoming a feasible option to traditional TURP. There are only a few studies analyzing the long-term results of Laser-based procedures for treatment of BPH with small study populations; however, no stress urinary incontinence cases have been yet evidenced [24]. The standard technique of transurethral incision of the prostate (TUIP), if correctly applied, should not be considered a cause of stress urinary incontinence if the operator ends the incision just proximal to the verumontanum. The incidence of urinary incontinence after prostatectomy for benign disease has been reviewed and described in the AHCPR "Benign Prostatic Hyperplasia" Clinical Practice Guidelines [25]. The following percentages for stress incontinence and total incontinence, respectively, were reported: open surgery (retropubic or transvesical prostatectomy): 1.9 and 0.5 %, transurethral incision of the prostate (TUIP): 1.8 and 0.1 % and transurethral resection of the prostate (TURP): 2.2 and 1.0 % [1].

3.2.3 Post-traumatic Stress Urinary Incontinence

The injuries of the urinary tract are the most typical complications of pelvic fractures with disturbance of integrity of the pelvic ring. The close anatomical relationships between the skeletal and connective systems, neurological and vascular structures, and pelvic organs are the predisposing factors for structural and functional damages of the urogenital system. According to the literature, almost 25 % of patients with pelvic ring trauma have any type of urinary tract lesion. Male patients are more susceptible to have urogenital lesions than females: 66 % versus 34 % [26]. The increasing number of injuries to the urogenital tract associated with permanent sequelae is caused by a growing number of pelvic ring fractures as well as, and this is more important, by decreasing mortality in patients with severe trauma to the pelvic ring. The extent of urogenital injury is related to the degree of dislocation of the pelvic skeleton. Injury to the male urethra is the most frequent urogenital trauma because of the male anatomy. It occurs most often in unstable C type fractures when the pelvic ring is disrupted with bone displacement due to shear force at the site of urethra attachment [27]. Incontinence following posterior urethral injuries occurs in 0–20 % of patients and is thought to be due to the extent of injury rather than to the method of management. The data on surgical treatment are mostly retrospective case series and the most commonly published therapy is the artificial urethral sphincter. Bladder neck reconstruction by excising the scar and narrowing the caliber was reported by Iselin and Webster in six patients who had incontinence with an open bladder neck on cistourethrography, following urethroplasty for traumatic strictures [28].

3.3 Severity Classification

Another different way to classify stress urinary incontinence is the evaluation of its severity. Incontinence is an objective manifestation, but it is associated with an important subjective component. The fear of losing even just a few drops of urine in public may condition one's life, so it is not always true that a low-grade incontinence is a minor problem. On the other hand, some patients feel their incontinence as a physiological consequence of aging, accept it and manage to have a normal life even with the existence of a high-grade incontinence. Classification and grading of incontinence, however, is an important and crucial element in clinical evaluation, decision making for treatment and follow-up of patients. There are several ways to indicate the grade and severity of incontinence: the number of pads used per day, the use of pad test, validated questionnaires and the urodynamic evaluation of Valsalva leak point pressure (VLPP).

It is not reliable to define the degree of incontinence evaluating just the number of pads used per day. Every patient may use pads of different brands, having a different absorbing capacity, different size and may change it after a different leakage amount (e.g., some patients may feel discomfort even with a few drops of urine in their pad, and thus change an almost dry pad many times per day). It may be used to evaluate the clinical amelioration or worsening of incontinence in the same patient, but we should be sure that the patient used always the same type of pad and changes the pad always at the same level of leakage. Thus it is better to apply a much more objective method of evaluation: a 1- or 24-h pad test. For the application of the 1-h test, the patient is asked to pass urine 1 h before the beginning of the evaluation and to postpone micturition until the end of the evaluation. During the test, the patient is asked to do some specific activities: (1) drinking 500 mL of water, while sitting for 15 min; (2) walking on a treadmill at a self-determined comfortable speed for 30 min; (3) standing up and sitting down ten times; (4) coughing ten times in a standing position; (5) running on the spot for 1 min; (6) bending down to pick up a coin from the floor five times and (7) washing hands under running water for 1 min [29]. During each activity, the patient is wearing a pre-weighted pad. The values of the exam consist in the sum of the gain of weight of each pad worn by the patient. The reference values may be considered as indicated: <1 g, continent; 1.1–9.9 g, mild incontinence; 10.0–49.9 g, moderate incontinence and >50.0 g, severe incontinence [30]. The 24-h pad test, instead, consists in wearing pre-weighted pads during a 24-h interval, from the morning after passing urine until the morning of the next day. The values of the exam, as in the previous case, consist in the sum of the gain of weight of each pad worn by the patient. The reference values may be considered as indicated: <4 g, continent; 4.1–19.9 g, mild incontinence; 20.0–74.9 g, moderate incontinence and >75.0 g, severe incontinence [31]. The only standardized data available, as those just reported, refer to female population; there is a lack of studies for standardized values for pad test in male. In our experience, for example, we refer to mild SUI in male with 24-h pad test <200 g, moderate male SUI with values between 200 and 400 g and severe SUI in male with values >400 g.

As previously stated, the subjective perception of incontinence by the patients plays a crucial role in the way the disease limits one's life and becomes a problem needed to be treated. Many patients during an office evaluation complain of urinary leakage, their fear of losing urine, the conditions and activities that are mostly associated with leakage and many other relevant clinical elements. This subjective component of incontinence can be measured with the aid of validated questionnaires. They are composed of specific and targeted questions to evaluate specific aspects of incontinence: the different burden of urgency and stress incontinence components, the limitation in everyday life and the implication in modifying one's quality of life. They are easy to be understood by the patient as they have been translated and validated in many languages, and they are repeatable and costless. Even if there are many questionnaires currently available, the ICI committee developed a complete modular questionnaire (ICIQ) to provide a definitive international review and consultative opinion regarding the recommended measures to assess patient-reported outcomes within the area of urinary incontinence and LUTS. The ICIQ modular questionnaire was developed to meet the need for a universally applicable standard guide for the selection of questionnaires for use in clinical practice and clinical research. Fourteen ICIQ modules/questionnaires are currently available for use, with further modules in development. Clinicians or researchers are able to select module(s) to meet the particular requirements of their study or clinical practice [1].

Another way to define the severity of stress incontinence is the urodynamic evaluation of leak point pressure (LPP). The detrusor pressure or the intravesical pressure or the abdominal pressure (pdet or pves or pabd) at which involuntary expulsion of urine from the urethral meatus is observed is the LPP. The rise in bladder pressure causing leakage may originate either from the detrusor (caused for example by the filling of a low-compliance bladder) or from an increase in the abdominal pressure. Thus there are two different leak point pressures – the detrusor LPP (DLPP) and the abdominal LPP (ALPP). The abdominal pressure increase during the latter is produced voluntarily by coughing leak point pressure (CLPP) or by Valsalva maneuver (VLPP). Based on a study of 29 men with incontinence after radical prostatectomy, it was concluded the ALPP is a relatively poor predictor of incontinence severity and, therefore, has limited clinical value in the urodynamic evaluation of post-prostatectomy incontinence. The ALPP can be also measured with the recording of the abdominal pressure only (without simultaneous urethral catheter positioned) and it seems to be more concordant to the clinical severity of incontinence. The urodynamic assessment of these patients should focus on the presence or absence of stress incontinence and on the presence of associated bladder dysfunction [32].

Alternatively the severity of impairment of the urinary sphincter function can be evidenced with a video urodynamic technique for the evaluation of VLPP in men (video-Valsalva leak point pressure/VLPP) [33]. The length of the urethra and the entrapment of urine in the bulbar urethra may render less synchronous measurement of the bladder pressure at the moment of leakage; in our opinion and clinical practice, it may be better to evaluate the bladder pressure at the passage of urine through the proximal urethra seen on fluoroscopy (Fig. 3.2).

LPP, otherwise, can be measured in a retrograde fashion (RLPP). There are two main techniques: (1) by retrograde infusion of the distal urethra while simultaneously recording intraurethral pressure and (2) by the application of a Foley catheter cuffed in the navicular fossa connected to a water infusion system, usually a saline solution bag, dropping into the catheter; the height of the water level in the bag expressed in centimeters at the moment the fluid stops to drop, equals the urethral opening pressure expressed in cmH_2O. Craig et al. demonstrated that RLPP measurements are reproducible and simple to perform and that RLPP correlates significantly with the lowest of multiple ALPP measurements in men with SUI [34].

We need further studies to investigate whether RLPP measurement can definitively replace V-VLPP, especially for keeping sanitary expenses low; on the other hand, video urodynamic testing may allow evaluation of the anatomical integrity of the urethra, thus eliminating the need for further urethrographic scans or urethroscopies.

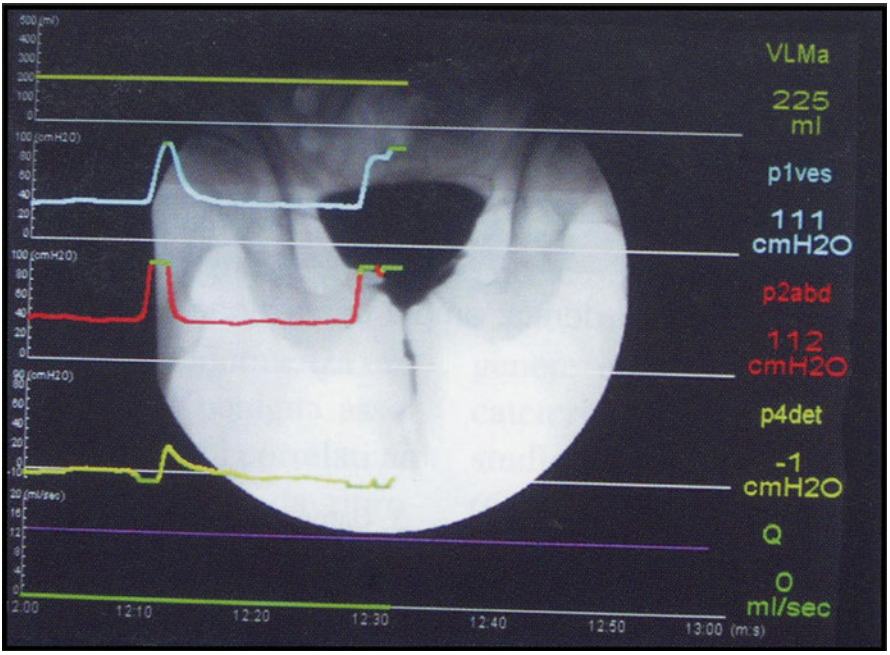

Fig. 3.2 The value of abdominal pressure at the moment of urinary leakage in the posterior urethra at fluoroscopy expresses the video Valsalva leak point pressure. Note that the flowmeter does not record any flow of urine

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4 Male Stress Urinary Incontinence Following Surgical Intervention: Procedures, Technical Modifications, and Patient Considerations

Ryan W. Dobbs, Ervin Kocjancic, and Simone Crivellaro

4.1 Introduction

Stress urinary incontinence has long been associated with urologic surgery. In Millin's initial description of the technique of the radical retropubic prostatectomy (RRP) he notes that one of his reasons for pursuing an improved technique was the "dread sequelae even in hands of the foremost exponents – e.g. incontinence (9 % Hinman, 5–8 % Goldstein), urethrorectal fistulae, persistent perineal fistulae" [1] associated with the perineal prostatectomy as first described by Hugh Hampton Young in 1905 [2]. This interest in postsurgical urinary incontinence has produced a wealth of information from a number of investigators and studies. Between different studies, with varying patient populations, the definitions used to define continence, utilization of different questionnaires, and duration of follow-up, significant variation may exist in reported complication rates. For example, previous studies have reported rates of incontinence following RRP from 2.5 to 87 %, demonstrating the tremendous variability in recording this critical post-operative outcome [3].

Going forward, standardization of definitions for urinary incontinence and the use of validated metrics in evaluating postoperative functional outcomes are of critical importance for designing future research studies to scientifically approach and assess postoperative continence following urologic surgery.

R.W. Dobbs
Urology Resident, Department of Urology, University of Illinois at Chicago, Chicago, IL, USA

E. Kocjancic • S. Crivellaro (✉)
Asst. Professor, Department of Urology, University of Illinois at Chicago, Chicago, IL, USA
e-mail: crivellaro76@hotmail.com

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4.2 Urethral Dilation, Direct Vision Internal Urethrotomy, and Urethroplasty

Urethral dilation and direct vision internal urethrotomy are popular surgical techniques in the treatment of short anterior urethral stricture disease. However, this procedure while technically simple is fraught with potential complications. Large series have reported overall recurrence rates of 68 % and have demonstrated that repeated urethrotomy does not appear to improve success rates [4]. Additionally, urethrotomy has been associated with rates of urinary incontinence ranging from 0.4 % [5] to 5 % [6] in historical series.

Given the risks of complications including rectal perforation [7], erectile dysfunction, and stress urinary incontinence secondary to sphincteric deficiency, some authors have suggested that anastomotic urethroplasty should be a preferred treatment option for these patients. In one series of 168 patients with a median follow-up of 58 months who were treated with anastomotic urethroplasty for bulbar stricture disease, no patients reported clinically significant urinary incontinence following their repair [8]. Similarly, Andrich et al. reported that long-term outcomes of 82 patients with at least 10-year follow-up had no significant urinary incontinence [9]. Urethral disruption following pelvic fractures requiring substitutive urethroplasty represents a more significant clinical challenge as 28 % of patients undergoing this procedure were noted to have post void dribbling although this was attributed to the preexisting injury and not surgical technique [9]. This relatively high percentage provides additional evidence to studies, which have suggested that changes to normal urethral function represent a significant risk factor for post void dribbling stress urinary incontinence following radical prostatectomy [10]. While urethroplasty is a significantly more invasive procedure requiring greater technical expertise, we believe that the superior outcomes for both durable stricture-free patient outcomes as well as a favorable side effect profile for significant complications such as stress urinary incontinence should make urethroplasty the preferred treatment for all but short urethral strictures.

4.3 Transurethral Incision of the Prostate

Transurethral incision of the prostate (TUIP) is a minimally invasive treatment that can be used in the treatment of bladder neck contracture and for prostatic obstruction in men with small volume prostates. Transurethral incision of the prostate can be performed either with a Collings knife or with a laser and has been shown to provide similar effectiveness to transurethral or laser resection of prostate tissue in men with small prostates [11], although the exact size of prostate for which TUIP is most effective varies between individual studies.

A meta-analysis of ten randomized control trials and 795 patients randomized between transurethral resection of the prostate (TURP) and TUIP treatments did not observe a significant difference in postoperative urinary incontinence although only three of the ten trials evaluated postoperative urinary incontinence [12]. This may also reflect a relatively low event rate as Nielsen reported only one case of incontinence following 25 TURP 4 % risk and no cases of incontinence following TUIP [13]. In a larger study of 220 divided equally to TURP or TUIP reported two patients who developed incontinence following TUIP (1.8 %) and four patients who developed incontinence following TURP (3.6 %) [14]. Furthermore, more contemporary studies such as Tkozc & Prasjner reported no new SUI for 100 patients randomized to either TURP or TUIP, which may be reflective of improvements in optical technology and further experience with the procedure [15].

Laser technology has been introduced to the TUIP in an attempt to minimize catheter use and improve operative hemostasis. Comparisons of TUIP versus resection with HoLEP or PVP have demonstrated statistically less stress urinary incontinence for TUIP in small studies with no patients reporting persistent stress urinary incontinence noted in small cohorts of 13 [16] and 47 [17] patients. Preoperative brachytherapy has been suggested as risk factor for the development of stress urinary incontinence [18]; however, available sample sizes are too small to draw definitive conclusions. Overall, these results suggest that for men with small prostates and without existing risk factors, TUIP is a safe and efficacious treatment with a low risk of postoperative urinary incontinence.

4.4 Transurethral Resection of the Prostate (TURP)

Transurethral resection of the prostate represents the most commonly utilized treatment for benign prostate hyperplasia (BPH) and may be a cause of iatrogenic stress urinary incontinence. While early surgical techniques to alleviate urinary obstruction were associated with high rates of incontinence, improvements in surgical instrumentation and technique have significantly improved outcomes for this procedure [19]. Nevertheless, early incontinence is a relatively common phenomenon following TURP and may occur in 30–40 % of patients [20]; however, this is typically an urge incontinence related to inflammation of the resection bed, postoperative urinary tract infection, or detrusor instability due to prolonged BPH. Persistent urinary incontinence is a feared complication but relatively uncommon sequelae of TURP. Zwergel followed 232 patients who were treated with TURP in 1979 and reported an 11.4 % ($n=21$) rate of urinary incontinence for patients in this early cohort [21]. However, upon further urodynamic evaluation, only one patient (0.4 % of entire cohort) was found to have stress urinary incontinence while bladder instability ($n=12$), reduced bladder capacity ($n=10$), and urinary retention ($n=4$) were more common reasons for prolonged urinary incontinence after TURP [21]. Rates of true stress urinary incontinence after TURP are generally accepted to be approximately 0.5 % [20].

Patients who have been previously treated with brachytherapy appear to have an increased risk for stress urinary incontinence following TURP or TUIP. In one case series, seven of ten patients (70 %) who were treated with TURP/TUIP for obstruction due to radiation effect of normal urethral tissue developed some degree of permanent urinary incontinence, with four patients (40 %) who were scored as having severe incontinence [18]. The authors of this case series postulated that radiation treatment may compromise urinary sphincters and predispose patients to being less able to tolerate surgical manipulation without postoperative complications [18]. More contemporary reports have been somewhat more favorable, however still the reports rates are around 18 % (7/38) for the development of stress urinary incontinence for patients being treated with TURP following brachytherapy [22]. Similarly, high rates of patients (23 %) requiring AUS placement following TURP or open prostatectomy were noted to have had prior radiation therapy [23]. Given these risks, surgical intervention following brachytherapy or radiation therapy for obstructive urinary symptoms should be proceeded with only after the exhaustion of medical treatments. Interestingly, patients who are treated with prostate brachytherapy with a history of prior transurethral resection of the prostate appear to have more favorable results with only one patient of a series of 19 patients (6 %) developing mild stress urinary incontinence with a median follow-up of 3 years [24].

While TURP is a safe, effective, and common procedure with an acceptably low risk of true stress urinary incontinence following resection, high rates of postoperative urge incontinence as well as detrusor instability present in men with obstructive prostates may cloud the clinical picture and necessitate a careful evaluation of persistent postoperative urinary incontinence preferentially with urodynamics. If patients do develop urinary incontinence following TURP, AUS placement has been shown to be an efficacious treatment with 90 % of men reporting improved incontinence and 87 % satisfaction in one series [23].

4.5 Alternative Prostate Treatments (TUNA, Greenlight, HoLEP)

4.5.1 TUNA

While the introduction of bipolar TURP technology has reduced the risk of several classical complications of TURP including TUR syndrome [25] a number of other complications persist including the risk for blood transfusion, urethral strictures, bladder neck contracture, sexual dysfunction, and urinary tract infections [20]. Given this complication profile, a number of alternative treatments including transurethral needle ablation (TUNA), potassium-titanyl-phosphate (KTP), photovaporization of the prostate, and holmium laser enucleation of the prostate (HoLEP) are available.

Transurethral needle ablation uses a low level radio frequency energy to produce a high thermal energy state to ablate excess prostatic tissue. Initial studies with a 1-year follow-up period did not report any clinically significant incontinence for 65 patients treated with TUNA [26]. Further follow-up of this cohort reported one patient (1.6 %) developing stress urinary incontinence over a 5-year follow-up period [27]. Interestingly, these studies reported rates of 3.6 and 21.4 % for the TURP arms of this trial over 1- and 5-year follow-up, although the authors note that the questionnaire used to assess for urinary incontinence include urgency or stress incontinence occurring at any time during the study was defined as urinary incontinence, which may have contributed to higher than expected urinary incontinence rates. Systematic reviews have demonstrated that urinary incontinence rates favor TUNA over TURP but do not reach statistical significance but that TUNA was associated with greater reoperation rates than TURP [28]. Clinicians should balance the risks and benefits of the more effective and durable TURP versus TUNA, which may have fewer side effects but require additional treatments for the relief of prostatic obstruction.

4.5.2 KTP Vaporization

KTP laser vaporization (often referred to as Greenlight™ Photovaporization) of the prostate is a promising treatment option for men with prostatic obstruction. KTP photovaporization removes excess tissue via a hemostatic tissue ablation and, thus, can be used with patients that would poorly tolerate fluid absorption from TURP as well as those taking anticoagulants where postoperative hemostasis would be difficult to obtain. One series of 66 men with high risk cardiopulmonary issues and/or those taking oral anticoagulation medications noted postoperative dysuria in 9 % of patients, but no clinically significant incontinence [29].

Long-term results of KTP vaporization with a mean follow-up of 3.5 years demonstrated durable urinary relief with no patients whom were noted to have developed incontinence follow their procedure [30]. Volkan et al. evaluated a larger series of 186 patients and followed them 6 months postoperatively, in this series again no patients were noted to have developed urinary incontinence following KTP vaporization [31]. Conversely, while not differentiated to specific type of incontinence, persistent (greater than 1 year) urge/stress urinary incontinence was seen in 2.1 % of patients in a cohort of 144 patients who underwent greenlight PVP [17].

While most initial studies were performed at 80 W energy level, KTP vaporization has been utilized at the 120 W [32, 33] and 180 W [34, 35] energy levels as well. The goal of utilizing these higher energy levels is to improve efficiency of tissue ablation by delivering greater energy over a shorter period of time. Incontinence rates of 0 % (0 of 60) [32] and 2 % (1 of 50) [33] were reported for the use of the 120 W KTP laser. Temporary urinary incontinence (urge/stress) was noted in 5.3 % (4 of 75) within the first month of discharge and in 5.6 % (4 of 72) patients between 1 and 3 months of discharge with the 180 W energy level [34]. Recent results from a randomized control trial comparing 180 W KTP laser versus TURP reported rates of any urinary leakage of 11.8 % (16 of 136) for patients treated with KTP laser and 4.5 % (6 of 133) for patients in the TURP arm although this difference did not reach statistical significance (Bachmann, 2015). Twelve months following their ongoing procedure self-reported urinary leakage of any kind was noted in 2.9 % and 3.0 % of patients treated with KTP laser and TURP, respectively [35]. Presently, KTP laser represents a durable therapeutic intervention, particularly for those with high risk cardiopulmonary comorbidities or for patients requiring anticoagulation therapy with equivalent urinary incontinence rates post-procedure to TURP. Further follow-up of comparison studies to TURP in addition to well-designed energy level comparison trials will need to be performed to assess if the advantages of higher energy level KTP laser treatment affect postoperative complication rates.

4.5.3 HoLEP

HoLEP utilizes a holmium laser to resect prostate tissue and is a minimally invasive option for the treatment of benign prostate hyperplasia (BPH) that can be an appealing option given its use on large prostates as an alternative to staged TURP or open prostatectomy. Additionally, unlike many ablative procedures such as TUNA or KTP vaporization, HoLEP has the advantage of tissue removal for pathological evaluation. In short-term follow-up, significant rates of urinary incontinence have been observed in clinical trials. One comparison study demonstrated 1-month rates of 44 % and 38.6 % of transient urge incontinence but similarly low rates of 1.7 % and 2.2 % of transient stress urinary incontinence for HoLEP and TURP, respectively [36]. Other studies have reported higher rates of SUI. In a study of 225 patients with symptomatic large (>80 cc) prostates, HoLEP was associated with a 7.1 % risk of stress urinary incontinence postoperatively and a 1.8 % risk of persistent mild stress urinary incontinence [37]. In a large retrospective review of 1,065 HoLEP procedures, stress urinary incontinence was noted in 12.5 % (60 of 477), 3.4 % (13 of 378), 1.8 % (5 of 267) and 4.8 % (4 of 83) for patients who reported outcomes at 1, 6, ≥12, and ≥60 months follow-up, respectively [38]. These results suggest that immediate stress urinary incontinence is not uncommon postoperatively, but acceptably low at greater than 12-month follow-up given that 0.8 % patients reported significant preoperative stress urinary incontinence in this study. The relatively high rates of postoperative stress urinary incontinence may reflect a component of unmasked detrusor instability following the removal of obstructive prostatic tissue. For 7-year follow-up data, no significant difference was noted for urinary incontinence scores in a randomized control trial between HoLEP and TURP, albeit with a relatively small sample sizes of 14 HoLEP and 17 TURP patients [39].

4.6 Cryoablation

Cryoablation of the prostate utilizes cryotherapy needles under ultrasound visualization to freeze prostatic tissue resulting in direct cell trauma and resultant necrosis and apoptosis of the affected tissue. Cryoablation has been proposed as a primary treatment for patients in whom preservation of sexual function is less important or those who may not tolerate more invasive surgical treatment; additionally, it has been used as a salvage treatment following primary external radiotherapy or brachytherapy as well as for those with focal low risk disease. Stress urinary incontinence is a known complication of primary prostate cryoablation. In a retrospective multicenter registry of 1,198 consecutive patients, stress urinary incontinence was reported in 4.8 % of patients, with 2.9 % of patients requiring the use of pads at 1 year [40]. One possible advance is the concept of focal prostate cryoablation to target known areas of tumor and spare benign prostatic tissue and the surrounding support structures. This concept has been proposed for patients with unilateral prostate cancer, low volume, and low Gleason score prostate cancer. In one small pilot study, 31 patients were treated with focal cryoablation with no patients reporting urinary incontinence postoperatively with a mean follow-up of 70 months [41]. Prior radiation treatment has been noted to be a risk factor for increased urinary incontinence following primary cryotherapy for prostate cancer [42]; however, even after primary radiotherapy treatment, salvage focal cryotherapy has been proposed as a treatment option. Registry evaluation of 91 patients treated with biopsy radio-recurrent prostate cancer reported that 5.5 % of patients at 1-year follow-up had urinary incontinence requiring pad use [43]. These results are similar to the 4.4 % stress urinary incontinence rate reported from the same registry for whole gland salvage cryoablation [44] and favorable to the 13 % incontinence rate reported in other salvage cryotherapy datasets [45]. Recent analyses have reported rates of urinary incontinence of 1.6 %, 3.1 % and 12.3 % for focal ($n=507$), whole-gland ($n=2{,}099$), and salvage ($n=299$) patients, respectively [46]. While postoperative functional urinary continence results are generally acceptable following cryotherapy, the relatively high rates of erectile dysfunction have limited the usage of cryotherapy to specific populations. Unfortunately, much of the available research for cryotherapy has been retrospective in nature without specific and defined metrics for evaluating urinary continence. Future research projects should be implemented with stronger experimental designs and validated questionnaires to effectively determining the side effect profile for cryotherapy.

4.7 Prostatectomy

Unlike many of the previously discussed procedures in which stress urinary incontinence represents a potential, but unlikely complication, some degree of stress urinary incontinence following prostatectomy is an often expected outcome of surgical intervention. The exact rate of incontinence following is often debated with reported rates of incontinence following RRP from 2.5 to 87 % [3] This variability represents a significant challenge in directly comparing different studies, despite the seemingly same outcomes.

Reported rates of urinary incontinence following surgical intervention may vary greatly due to variations in patient selection, methods of data collection, differences in the definitions of continence that are utilized, questionnaire or forms administered, duration of follow-up, and surgical technique. Most commonly, urinary continence is defined as achieving urinary control without the use of a pad. However, even within this strict definition of patients who are pad-free there can be considerable variation. One study reported variation in urinary control with 31 % ($n=32$) of patients reporting “perfect” urinary continence and 69 % ($n=74$) of patients reporting pad-free status with occasional leakage or “imperfect” urinary continence [47].

Imperfect urinary continence was noted to be more common in older men with more preoperative urinary symptoms, larger prostates, lower voided volumes postoperatively, and those that took longer to achieve a pad-free status than patients in the perfect urinary continence group [47].

These results are similar to those reported by Krupski et al. [48], which demonstrated that when patients are provided a number of different definitions for continence, including ≥80 on UCLA-Prostate Cancer Index (PCI) score, "leaked urine not at all," "total control," "no pads," "dripping/wetting very small or no problem," and "leakage interfering with sex very small or no problems," there could be substantial discordance between two definitions that could be used for determining postoperative outcomes. For example, only 42 % of patients who described wearing "no pads" also answered that they "leaked urine not at all" [48].

The use of various definitions may also affect postoperative outcome conclusions. Wei et al. [49] noted that a nerve-sparing operative technique was associated with significantly better postoperative functional outcomes when patients were asked "do you have a problem with dripping or leaking urine?" and "On average, how often do you leak or drip urine?" However, when patients were asked "To control your leakage, you most often wear about how many pads per day" or the no-pad definition used by many studies, they did not observe a significant difference in urinary incontinence [49].

This variation in patient responses to different questions, even at the same time, demonstrates the substantial challenge in assessing postoperative urinary continence as well as the difficulty toward comparing different individual studies. Similarly, it has been noted that significant differences are reported when patients self-administer questionnaires as opposed to the results obtained via physician interview [50]. Additionally, while most studies focus on daytime continence, patients may experience incontinence during sexual activity. One study of Swedish men following prostatectomy noted that of 691 sexually active men, 268 (38.8 %) noted some degree of orgasm related incontinence, even though 230 of these 268 were otherwise continent [51].

The ubiquitous nature of postprostatectomy incontinence and significant impact on patient quality of life [52] has produced a plethora of available research on the subject. In this section, we will summarize critical portions of the available evidence relating to urinary incontinence rates following open radical retropubic, perineal, laparoscopic and robot assisted prostatectomy, techniques, and modifications that have studied to attempt to reduce postoperative morbidity and patient risk factors, which may influence the development of postoperative urinary incontinence.

4.7.1 Radical Retropubic Prostatectomy (RRP)

Given the prevalence and favorable prognosis for clinically localized prostate cancer, prostate cancer survivors represent over 40 % of all male cancer survivors and comprise a group of greater than 2.7 million men [53]. Recent population studies have indicated that for men with clinically localized prostate cancer, approximately half will elect to proceed with prostatectomy as their primary treatment modality [54]. While recent surgical trends have favored the use of the robotic assisted radical prostatectomy, as recently as 2007, the majority of prostatectomies in the United States were performed using a radical retropubic technique [55].

Hautmann et al. reported a series of 418 consecutive RRP patients and reported complete urinary continence rates of 14.1 % at 3 months, which increased to 54.5 % at 36-month follow-up [56]. When including occasional nonbothersome spotting (Grade I SUI), the combined rates of continence were 58.8 % and 81.7 % at 3 and 36 months, respectively [56].

A large longitudinal cohort study of 1,291 African American, white, and Hispanic men diagnosed with primary prostate cancer who underwent RRP demonstrated a temporal increase in men reporting total urinary control from 20.5 % at 6 months to 31.9 % at 24 months [57]. At greater than 18-month follow-up after surgery, 40.2 % of patients reported rates of occasional urinary leakage, 6.8 % reported frequent urinary leakage, and 1.6 % reported total incontinence. Postsurgery, patients reported significant lower overall urinary function and 8.7 % of patient described their incontinence as a moderate-to-big problem at 24 months [57].

One encouraging trend that was noted in regard to functional outcomes was a generalized decrease for incontinence rates following radical prostatectomy that were observed for Medicare patients between 1991 and 1998 (20 % and 4 % 3-year incontinence rates, respectively) with improvements in surgical technique as well as better patient selection [58].

While most of the available literature has focused on outcomes within the first 12–24 months following prostatectomy, Glickman et al. followed 731 patients who underwent RRP using a self-administered UCLA PCI questionnaire to determine functional outcomes for patients between 24 and 48 months [59]. For the 449 patients who completed 48 month questionnaires, the majority of patients (73.5 %) reported stable urinary symptoms; however, many patients did report slight (11.1 %), moderate (6.3 %), or marked (6.0 %) improvement in urinary symptoms [59]. Penson et al. [60] noted that at 5-year follow-up, 14 % of 1,288 men postRRP reported frequent urinary leakage or no urinary control and that this rate was actually higher than the 10 % of patients reporting similar symptoms at 2-year follow-up. Recently, maturation of datasets has allowed for evaluation of functional outcomes for even longer time frames. For RRP, 10-year outcomes in a longitudinal study using UCLA-PCI urinary function index has been shown to have declines in urinary function from 2 to 8 years and small but significant declines from 8 to 10 years [61]. These changes may mirror normal changes in urinary function with aging, but have important implications for counseling patients to the expected recovery following surgery and may indicate that recovery of functional results may have a prolonged course that is frequently not captured in shorter-term studies. Additionally these longer-term follow-up studies are of critical importance given that the average prostate cancer patient will survive 14 years following primary treatment of prostate cancer [61].

The gold standard for evaluating postoperative urinary function still remains urodynamics. Majoros et al. performed a prospective analysis of 63 patients treated with RRP with pre- and postoperative urodynamics 2 months following surgery [62]. In this study, 20 patients were noted to have postoperative incontinence and were classified as 60 % ($n=12$) intrinsic sphincter deficiency (ISD) while 10 % ($n=2$) were noted to have pure detrusor instability (DI). The remainder of patients presented with mixed urinary incontinence with 10 % ($n=2$) of patients determined to be combined ISD and DI, while 20 % of the incontinent patients had mixed urinary incontinence with a component of bladder outlet obstruction [62]. This study provides an invaluable confirmation that while sphincter deficiency and dysfunction represents the majority of patients with postoperative urinary incontinence (90 %, 18 of 20), the component of urge incontinence may be prevalent in a substantial subset of patients (40 %, 8 of 20) and that postoperative urodynamics represents a valuable tool for guiding treatment for patients with prolonged urinary incontinence.

4.7.2 Radical Perineal Prostatectomy (RPP)

In the United States, radical perineal prostatectomy (RPP) is a relatively uncommon surgical procedure representing 2.6 % of prostatectomies performed on Medicare patients in 2007 [55]; however, it can be an effective operation in the armamentarium of surgeons familiar with the technique. In a large contemporary single-surgeon case series of 508 patients who underwent RPP, urinary continence rates sequentially increased from 38 % pad-free rates at 1 month to 96 % pad-free at 1-year follow-up [63]. Comparisons of RPP versus RRP reported significantly increased rates of complete continence with the perineal approach (67.6 % versus 49.0 %) and similar severity in urinary incontinence in regard to wearing greater than two pads (22 % versus 22 %), wearing a pad at all times (26 % versus 35 %), leak with minimal effort (13 % vs 18 %), and pads being completely soaked (17 % vs 17 %) for RPP and RRP, respectively [64]. These results suggest that in skilled hands, RPP represents an acceptable surgical treatment in regard to postoperative urinary incontinence as compared to RRP.

4.7.3 Laparoscopic Prostatectomy (LRP)

A laparoscopic approach to radical prostatectomy has been championed by minimally invasive surgeons as offering a number of benefits over the traditional open radical prostatectomy that may help contribute toward improved functional outcomes. The advantages to a minimally invasive approach include improved perioperative outcomes including reduced blood loss and transfusion rates, shorter hospital stays, and improved visualization of the anatomy with the goal for a more precise surgical dissection, particularly during the apical dissection [65]. Guillionneau and Vallancien [66] reported their initial series of 120 patients undergoing laparoscopic radical prostatectomy (LRP) with 71 % of patients reporting complete continence. Of these patients, 58 % had regained complete continence at 1 month. In this study, the continence rate for the first 60 patients was 73.3 % while 15 % of patients were wearing a safety pad and 11.6 % of patients required greater than one pad daily at 6-month follow-up [66]. These initial results were considered to be comparable with open continence rates; however, these outcomes were not assessed in a systematic fashion.

Prospective studies comparing LRP to RRP have produced mixed results. Anastasiadis et al. [67] demonstrated statistically significant improvements for LRP as compared to RRP in diurnal continence 6 months following surgery (59.2 % versus 43.3 %, respectively) and nocturnal continence 1 year after surgery (87.1 % versus 66.7 %) but no significant difference was observed in diurnal continence (89 % versus 77.7 %) or nocturnal continence when including patients who used a safety pad (96 % versus 90 %) at 1-year follow-up based on patient-reported measures [67]. Conversely, Jacobsen et al. [68] enrolled patients treated with either LRP ($n = 57$) and RRP ($n = 148$) and did not observe a significant difference for urinary incontinence rates (LRP 17 %, RRP 13 %) at 12 months utilizing a 24 h pad test as well as no difference in total urinary symptom scores as measured by IPSS. The authors suggest that the use of more objective metrics may have produced different results given that prior studies have reported significant variations between patient-reported outcomes and objective measurements such as the 24 h pad test as patients often will underestimate urinary leakage if assessed by questionnaire only [69]. Overall, LRP likely has similar continence results to RRP with an improved perioperative outcome including hospital stay and blood transfusion rate that along with the availability of robotic technology has led to a sea change toward the usage of minimally invasive techniques for prostatectomy [66].

4.7.4 Robotic Prostatectomy (RARP)

The introduction of the Da Vinci© (Intuitive Surgical Inc., Sunnyvale, CA) robotic surgical platform in 2000 has resulted in a fundamental conversion in the surgical technique utilized for prostatectomy in the United States. While the laparoscopic radical prostatectomy had been previously described in the literature [65], this technique was technically demanding and required a significant learning curve to achieve mastery and had relatively limited utilization in the United States. The minimally invasive robotic technique was technically easier for surgeons to perform and has been widely adopted by urologic surgeons. In 2001, approximately 250 prostatectomies were performed with robotic assistance in the United States [70], by 2009, 63.9 % ($n = 49{,}562$) of cases were performed with this technology [71]. Early reports of the robotic prostatectomy described a number of potential improvements with the robotic approach including three-dimensional visualization, high-powered magnification, wristed instrumentation, and ergonomic surgeon positioning as factors that were postulated to improve surgical technique as well as postoperative surgical outcomes relating to urinary and sexual function [72].

Comparisons of functional outcomes have been performed between retropubic radical prostatectomy (RRP) and robot-assisted radical prostatectomy (RARP) in a number of studies, including retrospective [73], prospective [74], and pooled analysis [75] including meta-analysis [76]. When comparing outcomes of RRP versus LRP or RARP one potential source of bias is that groups of patients being compared may not be contemporary series. Older series of RRP may include patients that were treated prior to the advent of widespread PSA screening and, thus, baseline patient and pathological differences may vary between datasets. These variations of demographics and baseline urinary characteristics can play a significant role in postoperative outcomes for stress urinary incontinence and should be considered when evaluating results.

Many studies of postoperative urinary continence have been limited by single surgeon or single institution design. Ahlering et al. [73] retrospectively evaluated a single fellowship trained surgeon's outcomes for 60 patients undergoing RARP following an initial 45 case learning experience (RARP cases 46–105) as compared to a control of 60 patients undergoing RRP, and reported similar rates of complete continence (0 pads at 3 months) of 76 % and 75 % in the RARP and RRP groups, respectively [73].

Ficarra et al. [74] performed a nonrandomized trial of RALP versus RRP, which demonstrated significantly higher rates of continence at the time of catheter removal (68.9 % versus 41 %) as well as for long-term outcomes at 1 year (97 % versus 88 %). In this study, mean time to continence was also significantly shorter for RARP patients (25 days versus 75 days) compared to RRP. While patient groups were well matched, there was a significant difference in median age between the two cohorts with RARP (61 years) and RRP (65 years) that may have influenced urinary outcomes although this study did use validated questionnaires to assess postoperative functional results and utilized a contemporary comparison arm as opposed to a historical cohort.

Rates of surgical intervention following prostatectomy for urinary incontinence are generally accepted to be low, however, may favor a robotic approach. Carlsson et al. [77] prospectively followed surgical complications from 1,253 RARP and 485 RRP procedures and reported a significant difference in rates of surgical intervention following prostatectomy as only 0.5 % ($n=7$) in the RARP group were surgically treated for incontinence while 2.2 % ($n=11$) patients in the RRP group required operative intervention. Data from Medicare beneficiaries had an overall artificial urinary sphincter (AUS) rates following radical prostatectomy that varied from 3 to 6 % between 1991 and 1998 [58]. Lower AUS rates in more contemporary series likely reflect improved patient selection, improved surgical technique, or some combination of these factors.

More recent studies have utilized more rigorous validated questionnaires to evaluate postoperative outcomes. Novara et al. [78] used an International Consultation on Incontinence Questionnaire for 308 consecutive patients undergoing RARP. At 1-year follow-up, 90 % of patients were continent with no leakage.

In a weighted means analysis of 13 RRP, 9 LRP and 6 RARP studies performed at high-volume centers, weighted mean continence rates at 12 months were determined to be 80 %, 84.8 %, and 92 %, respectively [75]. The authors in this study noted that continence rates between RRP and LRP were similar, the pooled analysis did support that RARP had higher reported continence rates at 1 year. However, they also note that the lack of standardization, use of open interview and lack of validated questionnaires has made true direct comparisons for urinary outcomes difficult to accurately assess and has stalled the use of meta-analysis for outcomes research due to the substantial heterogeneity of prior studies [75].

A recent systematic review and meta-analysis of 51 articles reported 12-month urinary incontinence rates between 4 and 31 % with a 16 % mean value for the no-pad definition [76]. This study was notable for demonstrating an improved 12-month urinary continence recovery for RARP in comparison to RRP (OR: 1.53; $p=0.03$) or LRP (OR: 2.39; $p=0.006$).

4.8 Techniques

While the majority of patients will achieve stable postoperative urinary continence, prolonged postoperative incontinence represents a significant impact on patient's quality of life and has been a challenge that several surgeons have sought to address via modifications of traditional surgical technique. Several techniques and approaches have been described in the literature in an attempt to improve functional urinary outcomes following prostatectomy for open, laparoscopic, and robotic surgical approaches.

4.8.1 Preservation of the Smooth Muscular Internal Sphincter and Proximal Urethra

Surgical intervention with removal of the prostate results in several different anatomical changes to normal mechanisms of continence. Urodynamic evaluation of patients before and after RRP has been shown to result in decreases in mean functional urethral length from 61 to 25.9 mm, decreased maximal urethral pressure from 89.6 to 65.2 cm. water and bladder capacity from 338.7 to 278.8 ml [79]. These changes represent potential anatomical explanations for the development of stress urinary incontinence postoperatively as continent patients were noted to have higher urethral closing pressures (68.1 versus 53.1 cm. water) and increased functional urethral length (27.6 versus 20.5 mm) as compared to incontinent patients [79].

Brunocilla et al. [80] describe their technique of preserving the smooth muscular internal sphincter and proximal urethra by an anterograde approach with incision of the detrusor muscle at the insertion of the ventral surface of the base of the prostate during open RRP. After identification of the sphincteric ring, blunt dissection is performed to separate the sphincter from the prostate to obtain a maximal length of the internal sphincter before incising the urethra and performing a urethral-urethral anastomosis [80]. To ensure oncologic safety, the authors perform circumferential biopsies of the proximal urethra ($n=2$) and of the base of the prostate ($n=4$) prior to performing the anastomosis. In their 55 patient case series of patients with low risk organ confined disease, there were no positive surgical margins and continence rates were 82.5 and 96.5 % as compared to a standard RRP technique case series ($n = 200$) of 77 % and 87 % at 90 and 120 days, respectively. While preservation of the internal smooth muscle sphincter may be an intriguing concept for improving postoperative outcomes, in particular, for rapid recovery, 50 % and 71.7 % of their patients' reports complete urinary continence at 3 and 7 days, respectively. This initial description of this technique does have several weaknesses including a lack of statistical evaluation of their results to assess if the improvements noted in continence are significant, not reporting baseline cohort characteristics, which play a significant factor in postoperative outcomes, and not including oncologic follow-up that would be critical to determine if this technique is a safe and effective approach toward improving surgical outcomes [80].

Membranous urethral length has been investigated in regard to its role in preoperative counseling and patient guidance. While urethral sparing approaches like those described above may improve outcomes, patients will have a natural variation in membranous urethral length, which may also contribute to postoperative outcomes. Prior to RRP, 211 consecutive patients were evaluated with preoperative endorectal magnetic resonance imaging (MRI) and were followed to determine their time to stable postoperative continence (defined as having either achieving complete continence or if urinary incontinence was unchanged for 6 weeks) [81]. In this study, the median time to stable postoperative continence was 76 weeks, which may reflect the need for continued long-term follow-up after surgical intervention to stable urinary function. Notably, while patient age or surgical technique including resection of the neurovascular bundles did not correlate to time to stable urinary function, preoperative membranous urethral length was a significant contributor toward stable continence. At 1-year follow-up, patients with membranous urethras longer than 12 mm had an 11 % risk of partial or complete incontinence, while patients with less than 12 mm membranous urethral length had a 23 % risk of being at least partial incontinence [81]. Similarly, pre- and postoperative membranous urethra length as well as the percentage change in the membranous urethra length as evaluated by endorectal MRI has been observed to be related to recovery time and degree of urinary continence following RP [82]. This variation in membranous urethral length may be helpful as a tool for counseling patients about which primary prostate cancer treatment may be most appropriate given patient preferences for potential treatment related side effects. Given the role of membranous urethral sparing, preservation of the maximal urethral length may be recommended for postoperative outcomes.

4.8.2 Nerve Sparing

Preservation of sexual function with precise surgical dissection and preservation of the neurovascular bundles of the prostate has been a hallmark of surgical technique since the initial proof of concept study in cystoprostatectomy was first reported by Schlegel and Walsh [83]. While the importance of these structures toward postoperative sexual function is unequivocal, their role in postoperative urinary function has been an area of interest and debate.

A prospective study of 536 patients who underwent open RRP was categorized as bilateral, unilateral, or non-nerve-sparing groups [84]. While continent and incontinent patients did not have significant differences in median age, follow-up, preoperative PSA, pathological tumor stage, node status, or Gleason score on logistic regression analysis, they did observe that attempted nerve sparing was associated with an odds ratio of 4.77 and a strong significant relationship with postoperative urinary continence [84]. Divided in nerve-sparing groups, incontinence was found in 13.7 % of patient in the non-nerve-sparing group, 3.4 % in the unilateral nerve-sparing group, and 1.3 % in the bilateral nerve-sparing group [84].

A similarly sized prospective cohort of 602 patients who underwent RARP in a single-surgeon case series were also divided into groups of bilateral, unilateral and non-nerve-sparing technique (in this study, a neurovascular bundle was considered spared if 70 % of the bundle remained in situ) [85]. In this analysis, bilateral nerve-sparing technique was associated with higher urinary function scores at 4, 12 and 24 months as well as significantly higher continence rates for a bilateral nerve-sparing approach (47.2 %) as compared to non-nerve-sparing (26.7 %) at 4 months [85]. Interestingly, while urinary function scores consistently favored a bilateral nerve-sparing approach, no significant difference in urinary continence rates was observed for nerve-sparing (84.6 %, 94.5 %) and non-nerve-sparing approaches (76.9 %, 92.3 %) at 12 or 24 months [85]. Additionally, there were no significant differences in urinary continence between unilateral versus non-nerve sparing at any follow-up time period.

Intraoperative grading of nerve sparing at the time of surgery on a scale from 0 "non-nerve sparing" to 4 "excellent nerve sparing" (intact bundle, significant supportive tissue, no nerve visualized on specimen) has been demonstrated to effect postoperative outcomes. Kaye et al. [86] enrolled a cohort of 102 who were graded at the time of prostatectomy for the quality of the nerve sparing: patients who had excellent bilateral nerve sparing (Nerve Sparing Score =8), those that had unilateral excellent nerve sparing (Nerve Sparing Score 4–7), and those that had at least one bundle spared but neither excellently (Nerve Sparing Score 1–6). In this study, patients who received excellent nerve sparing in one or both neurovascular bundles demonstrated significantly higher EPIC functional and continence at 1 month, which were durable to 1-year follow-up [86]. This study is helpful in confirming that nerve sparing is not an "all or none" phenomenon but that excellent nerve sparing of at least one neurovascular bundle may play a significant role in improved postoperative functional outcomes.

One potential hypothesis for the contribution of the neurovascular bundle to urinary continence may be related to an innervation of the membranous urethra/striated urethral sphincter from an intrapelvic branch of the pudendal nerve. Anatomically, during a radical prostatectomy, the main pudendal nerve is not compromised as it lies posterior to the pubic symphysis and outside the operative field. However, intrapelvic branches of the pudendal nerve may be compromised during surgical dissection. It has been shown that patients after radical prostatectomy have a decreased sensitivity to electrical stimulation at the membranous urethra, which may represent a contributing factor for urethral dysfunction and postvoid dribbling [10].

Radical prostatectomy significantly changes the anatomy and function of the posterior urethra and its surrounding structures, leading to radical changes in the mechanisms required for postoperative continence. Following prostatectomy, the bladder neck (which may require surgical reconstruction) is anastomosed to the membranous urethra and periurethral striated musculature to form a new posterior urethra. Changes to the sensory and functional components of this region after prostatectomy have demonstrated reduced posterior urethral sensitivity and pressure transmission following unilateral nerve-sparing RRP ($n = 8$) or non-nerve-sparing RRP ($n = 31$) on postoperative urodynamics at 6 weeks and 6 months, postoperatively [87]. In this series patients demonstrated a temporal restoration of sensory threshold values between 6 weeks and 6 months which may demonstrate improvement in functional innervation and return to urinary continence [87]. This study helps to characterize the role that disruption of the innervation to the posterior urethra may play in incontinence and how the recovery of this innervation may contribute to regaining postoperative urinary control.

While the role of nerve sparing remains an area of controversy regarding postoperative urinary function, their clear role in postoperative sexual potency represents a critical pillar in the trifecta of oncologic control, urinary continence, and sexual performance, and, thus, unless contraindicated to obtain a satisfactory oncologic outcome, the default approach should include nerve-sparing technique.

4.8.3 Bladder Neck Preservation

Preservation of the natural bladder neck as an important continence mechanism has been evaluated in open [88, 89], laparoscopic [90, 91], and robotic [92] techniques.

For RRP, preservation of the bladder neck has been compared to puboprostatic ligament sparing as well as to a combined bladder neck sparing with puboprostatic ligament-sparing approach. In this study, final continence rates did not vary between the three groups (92 % bladder neck sparing, 92 % puboprostatic ligament sparing, and 94 % combined), however, earlier continence rates were observed for bladder neck sparing (69, 79 %) and combined (68, 80 %) as compared to puboprostatic ligament sparing only (45, 61 %) at 3 and 6 months follow-up [88]. As there was no control group in this evaluation, it is unclear if puboprostatic ligament sparing itself provides any benefit for postoperative urinary outcomes. This faster recovery of urinary function is consistent with previously reported results, which demonstrated higher rates of urinary continence at 1, 3, and 6 months but no significant difference in urinary continence at 1 year suggesting improved short-term but no significant difference in longer-term urinary outcomes [89].

Rates of full continence in laparoscopic patient series with bladder neck sparing have been reported for 75 %, 85 %, and 92 % of patients after 3, 6, and 12 months follow-up, respectively [90]. Retrospective studies on bladder neck preservation have confirmed good functional outcomes, but have also reported high rates (29.2 %) of positive surgical margins in one single center study for bladder neck preserving technique, a concerning finding for acceptable oncological control [91].

For RARP, bladder neck sparing was retrospectively evaluated comparing 791 bladder neck sparing operations to 276 nonsparing surgeries [92]. In this study, bladder neck sparing was associated with a significantly shorter hospital stay and fewer postoperative urine leaks. Additionally, bladder neck sparing was also associated with earlier and better overall recovery of continence as measured on the EPIC quality of life questionnaire. Critically, one of the potential concerns with the bladder neck sparing approach has been that cancer control and oncologic effectiveness may be compromised by dissection in close proximity to the prostate base. In this study, there was no difference in the rates of positive surgical margins for the bladder neck sparing approach as compared to nonsparing approach (1.2 % vs 2.6 %, $p=0.146$) and bladder neck sparing patients and no difference in biochemical recurrence suggesting that bladder neck sparing is a preferred surgical technique for improved perioperative and functional outcomes without sacrificing critical oncologic control [92]. In a single blind randomized study of bladder neck preservation, Nyarangi-Dix et al. [93] found similar results with improved continence at 3, 6, and 12 months with no significant difference in surgical positive margins between the two approaches.

Like nerve sparing, bladder neck preservation has been evaluated in a graded fashion. A retrospective study of 599 patients who underwent RARP were graded between 1 (wide bladder neck dissection requiring reconstruction) and 4 (tight bladder neck dissection) [94]. While at 1 year, there was no significant difference noted between the four different classifications, higher grades of bladder neck preservation were associated as an independent predictor of continence at 3 months, suggesting that bladder neck preservation exists on a spectrum in which more preservation may provide faster recovery [94].

4.8.4 Preservation of the Anterior/Puboprostatic Ligaments

Within normal urethral anatomy, the urethra is fixed anteriorly to the posterior pubis by a suspensory mechanism consisting of puboprostatic ligament as well as fibers from the suspensory ligament of the penis. Preservation of these anterior ligaments has been postulated to improve urinary continence outcomes by providing a natural anterior support for the urethra on the pelvic floor. Lowe [95] compared 51 patients who underwent RRP with anterior urethral ligament sparing to a control group of 70 patients and statistically significant improvements were noted in both total continence as well as the time to continence. Similar small studies with RRP have shown improvement in time to continence with this approach [96].

Given favorable results with preservation of the puboprostatic ligaments this technical modification was assessed for its applicability with LRP [97] and RARP [98] approaches. Stolzenburg et al. [97] noted improved early continence at 2 weeks and 3 months following surgery with the ligament-sparing LRP technique and Tewari and colleagues [98] evaluated this technique in 50 consecutive patients for preservation of the puboprostatic collar (including the muscular collar and arcus tendineus in additional to the puboprostatic ligaments) and observed continence rates of 29 %, 62 %, 88 % and 95 % at 1, 6, 12, and 16 weeks follow-up, respectively.

While there is a relative paucity of high level evidence favoring for sparing the puboprostatic ligaments, anatomical study of these attachments by Steiner [99] provides a reasonable anatomical basis for the role of the ligaments to contributing toward postprostatectomy continence.

4.8.5 Posterior Reconstruction

Reconstruction of the posterior prostatic support and rhabdosphincter has been evaluated in a number of studies. This posterior reconstruction (PR) technique was first described in the RRP by Rocco et al. [100] and is a two-step reconstruction with apposition of the rhabdosphincter to the residual Denonviller's fascia followed by fixation of the Denonviller's fascia median raphe complex to the posterior bladder neck 1–2 cm cranial and dorsal to the new bladder neck. The goal of this reconstruction is to restore the anatomical and functional length of the rhabdosphincter and provide fixation and support for the posterior aspect of the sphincter to attempt to facilitate healing and a more rapid return to normal urinary function. In their initial description of the technique 161 patients undergoing RRP with PR were compared to a historical control group of 50 patients; in this study, patients and controls were well matched for Gleason score, PSA, and age [100]. For early follow-up at 3, 30, and 90 days, patients undergoing RRP with PR demonstrated significantly higher rates of complete continence (72 %, 78.8 %, and 86.3 %, respectively) than their control counterparts (14 %, 30 %, and 46 %) by 1-year follow-up, patients with RRP with PR (95 %) and those undergoing RRP (90 %) had nonsignificant rates in complete continence, but the PR technique demonstrated promise for early continence results [100]. Long-term results from the same group for 250 patients compared to a historical cohort demonstrated significantly better continence rates at discharge (62.4 % versus 14 %), 1-month (74 % versus 30 %), and 3-month follow-up (85.2 % versus 46 %), while long-term continence rates were similar and nonsignificant between the two groups (94 % versus 90 %) [101].

Given the promising results for PR with RRP and similar challenges with prolonged postoperative stress urinary incontinence, there was interest in developing the technique for the RARP. Coelho et al. utilized the PR technique described by Rocco et al. [100, 101] in a prospective single-surgeon study of 803 patients undergoing RARP [102]. In this study, 330 RARP were performed without PR and 473 patients underwent RARP with PR, patients were well matched for age, BMI, PSA, preoperative AUASS, and Gleason score [102]. Patients undergoing RARP with PR demonstrated statistically significant continence rates at 1 week (28.7 % vs 22.7 %) and 4 weeks (51.6 % vs 42.7 %) compared to RARP without PR while outcomes were similar at 12-week (91.1 versus 91.8 %) and 24-week follow-up (97 % versus 96.3 %) [102]. Similar to other published studies, these results may indicate a role of PR in favorable early continence rates although PR does not appear to have a significant impact on long-term continence results. A meta-analysis comparing studies of posterior musculofascial reconstruction with or without anterior reconstruction was associated with a small nonsignificant advantage for urinary continence recovery at 1 month [76].

4.8.6 Combined Anterior/Posterior Reconstruction

In addition to the posterior reconstruction technical modification, an anterior reconstruction utilizing an anterior suspension (AS) stitch anchored to the pubic bone has been investigated for the early return of urinary continence. Anatomically, the AS stitch is thought to provide additional support for the urethra, stabilizing the striated sphincter and urethra and allowing for improvement of urethral length during the apex dissection [103].

RRP with an anterior suspension modification was noted to have earlier return to continence at 1 week, 1 month and 3 months in a small proof of concept trial of 33 patients [104]. Additionally, patients with the AS stitch were noted to have higher abdominal leak point pressures on postoperative urodynamics providing objective evidence of the role of the anterior stitch for reducing urethral hypermobility [104]. Similar to the favorable results for the AS technique in RRP, the technique was translated for use the RARP. In a nonrandomized prospective trial of 94 patients who did not have the AS technique used as compared to 237 who had RARP with AS, continence rates were statistically greater at 3 months for the AS technique (92.8 % versus 83 %) as compared to the standard RARP with a significantly faster median/mean recovery of continence time (6 weeks; mean 7.33 weeks for RARP with AS versus 7 weeks; mean 9.58 weeks for standard RARP) [105].

For most available studies, the anterior stitch has been included with a posterior reconstruction for a combined reconstruction of the periprostatic tissues. In a small randomized control trial of 72 patients, the combined anterior and posterior reconstruction was assessed for 33 patients undergoing a standard RARP and 39 patients who were treated with an RARP with AS and PR. In this study, continence rates at 15 days, 1, 3, and 6 months following surgery were 3.6 %, 7.1 %, 15.4 %, and 57.9 %, respectively, for the RARP group and 5.9 % 26.5 % 45.2 %, and 65.4 %, respectively, for the RARP with AS and PR group. Statistically significant differences were observed for continence rates at 1 and 3 months favoring the combined AS and PR approach [103].

These results are in contrast to a randomized control trial by Menon et al. [106], which evaluated a combined surgical technique, which noted no significant differences in urinary continence rates for early follow-up at 1, 2, 7, and 30 days post surgery. The authors of this study did notice that cystographic leaks were decreased from 10 to 11 % with the standard technique single-layer anastomosis group to 3 % with the anastomosis with periprostatic tissue reconstruction; however, only one of the seven detected leaks was determined to be clinically significant requiring additional catheterization so this difference may not be clinically relevant. Similarly, long-term follow-up of this same patient group at 2-year follow-up with nonsignificant differences in pad-free urinary control with single-layer (80.0 %) and double-layer (82.6 %) pad-free rates [107].

In a meta-analysis, complete reconstruction was associated with a significant advantage in urinary continence 3 months after RARP (odds ratio 0.76; $p = 0.04$) [76] as well as a small but statistically significant difference in favor of total reconstruction at 1 month following RARP [76].

4.9 Patient Factors

As with all surgical interventions, preoperative patient characteristics play a significant role in determining postoperative functional outcomes. A number of factors have been identified as potentially contributing toward clinical outcomes including postoperative stress urinary incontinence. However, several large series have had conflicting results in regard to which, if any, risk factors are predictive of postoperative outcomes. These discrepancies likely reflect variations in methodology, population, and definitions utilized and so these preoperative risk factors represent important clinical questions in which a consensus is still emerging and the debate of which risk factors are significant predictors of postsurgical outcomes is still ongoing.

Given that many factors influencing continence such as pathological stage and neurovascular bundle preservation are interlinked, multivariate analyses should be a favored approach for determining risk factors for postoperative incontinence. In a multivariate analysis of patients undergoing RRP, factors identified with independently regaining continence were decreasing age, anastomotic technique, bilateral neurovascular bundle preservation, and absence of anastomotic stricture [108].

4.9.1 Age

Large population studies have consistently reported increasing rates of urinary incontinence in men as they age. A cross-sectional study of 2,721 Italian men reported a 3 % ($n = 91$) overall rate of urinary incontinence, when this was divided by age, urinary incontinence was reported as 2 % and 7 % in men aged 51–60 and those >70 years old, respectively [109]. Another cross-sectional population study reported rates of overall urinary incontinence in men of 5.4 %, differentiating between stress, urge, and other urinary incontinence with stress urinary incontinence representing 1.2 % of the overall male population [110]. Consistent with other studies, SUI increased with rising age as rates of 0.1 %, 0.6 %, and 1.6 % were reported for the age groups of ≤39, 40–59, and ≥60 years, respectively [110]. Variations in age represent a significant factor to consider when evaluating postoperative outcomes relating to urinary and sexual function.

While age has been demonstrated to a risk factor for postoperative incontinence in a number of studies [49, 79, 108, 111–113], in some studies younger cohorts of patients have failed to demonstrate this finding. In fact, Lepor et al. [114] evaluated a cohort of 500 RRP patients and did not identify any factors that were predictive of early continence at 3 months including age, baseline AUASS, Gleason Score, estimated blood loss, bilateral nerve-sparing technique, or presence or absence of benign prostatic glands on intraoperative biopsy of the apical soft tissue. Additional comorbidities that may accumulate with age may also contribute toward worse outcomes for older patients as increasing Charlson comorbidity score has been shown to be a risk factor predictive of urinary incontinence following surgery independent of age in some studies [78].

4.9.2 Social Support

Multivariate analyses have also demonstrated that postoperative urinary function and urinary bother may be linked to other seemingly unrelated aspects from the urinary system, including marriage. Litwin et al. [115] evaluated a cohort of 415 patients and noted that marital status and general health perception were both significantly associated with urinary bother following prostatectomy suggesting that social support, mood, and attitude toward treatment care may play a role in how patients perceive the severity of their side effects. In fact, the treatment of prostate cancer has been shown to have a demonstrable effect on partner quality of life. Sanda et al. [52] reported that 1 year following prostatectomy, 5 % of partners (99 % female) were bothered by their spouses' urinary incontinence. Educational level has also been noted as a risk factor for postoperative urinary incontinence, hinting at the complex interplay of social factors toward functional results [113].

4.9.3 Obesity

The role of obesity in postoperative urinary function has been evaluated in several studies. The development of obesity is multifactorial and obesity is frequently clinically found in conjunction with a number of other comorbidities including diabetes mellitus, coronary artery disease, dyslipidemia, and hypertension, which may contribute toward postsurgical outcomes. Obese patients may also represent a more technically challenging surgical operation. Due to the complex nature of obesity, it is not surprising that these studies have demonstrated a mixed effect on functional urinary outcomes. In a prospective analysis, obese (Body Mass Index > 30) patients undergoing prostatectomy were reported to have significantly lower rates of complete continence (0 pads) at 6 months as compared to their nonobese counterparts (47 % and 91 %, respectively, $p < 0.001$) as well as significantly increased urinary bother scores on self-reported questionnaires at 3 and 9 months [116]. In this study, similar to the results reported from large population datasets [112], obese patients were noted to have significantly poorer baseline characteristics including preoperative urinary bother, peak urinary flow, increased comorbidities, and a trend toward poorer baseline American Urological Association scores [116]. Thus, in early studies it has been unclear if poorer postoperative urinary continence results lower baseline urinary function or if obesity independently represents a risk factor. Conversely, other studies [113] have failed to observe a difference in postoperative urinary continence levels based on BMI.

4.9.4 Preoperative Urinary Function/LUTS

The evidence for preoperative urinary function as a predictor of postoperative urinary incontinence remains an area in which mixed conclusions have been reached. This may be related to many assessments used to evaluate urinary function including both obstructive and irritative voiding symptoms. It has been suggested by some authors that while patients with irritative voiding symptoms may be worsened by prostatectomy, the removal of the prostate gland may significantly improve obstructive urinary symptoms and, thus, obscure the contribution of preoperative urinary function toward postoperative SUI. Neither obstructive nor irritative voiding symptoms were noted to be a risk factor for postoperative urinary incontinence on multivariate analysis by Eastham et al. [108].

Patients with no prior Lower Urinary Tract Symptoms (LUTS) had a statistically but not significantly higher rates of postoperative continence as compared to those with LUTS (71 % versus 64 %) when patients were evaluated with pre- and postoperative urodynamics [62]. Similarly, Lepor et al. failed to observe a significant relationship between a patient's preoperative AUASS and postoperative incontinence [114].

Conversely, a prospective population study of 228 Canadian men undergoing RRP demonstrated that age greater than 65 (OR 3.35), baseline incontinence (OR 6.20) and prior TURP (OR 14.99) were significantly associated with postoperative incontinence [111]. Intuitively, preoperative urinary incontinence and disruption of the normal anatomical sphincter should represent a significant risk factor for postoperative incontinence, which is confirmed in this analysis.

4.9.5 Preoperative TURP

Prior prostatic surgery, particularly TURP, has been postulated as a potential risk factor for postoperative urinary incontinence due to changes in the bladder neck, impact on innervation of the prostate, and possible development of scar tissue. Similar to many other potential risk factors, the results for preoperative TURP have been mixed in studies. In some studies, preoperative TURP was not associated with increased urinary incontinence in patients undergoing RRP [62, 113]. Conversely, Moore et al. [111] as well as Eastham et al. [108] on a multivariate analysis did find a significant relationship between preoperative TURP and the development of postoperative urinary incontinence.

4.9.6 Surgical Volume and Surgeon Skill

Outside of surgical modality or specific surgical techniques used to reduce postoperative urinary symptoms, variations in surgeon and hospital setting may also play a role in long-term complications. Evaluation of 11,522 patients post RRP using the Surveillance, Epidemiology and End Results (SEER) dataset for long-term incontinence (as defined as the coding symptoms associated with incontinence, corrective surgery, or diagnostic procedures such as urodynamics associated with incontinence) did not demonstrate significant differences in a relationship between hospital or surgeon volume for long-term postoperative urinary incontinence [117]. However, when this study evaluated 159 surgeons with sufficient surgical volumes to allow for surgeon-to-surgeon comparisons, they noted a strongly significant variation between surgeons in postoperative complications, late urinary complications (bladder neck obstruction or urethral strictures), and rates of long-term urinary incontinence [117]. While individual surgeon skill is widely assumed to contribute to the wide variations in clinical outcomes noted in many complex surgical procedures such as prostatectomy, objective evidence that a surgeon's technical proficiency contributes toward postoperative outcomes remains limited. In prostatectomy, the preponderance of single surgeon and observational datasets, particularly in RARP has led investigators to question about different outcomes with different surgical approaches [118]. The validation of outcome data from high volume surgical centers with high volume surgeons and the generalizability of these results to community settings with well-designed methodologically sound studies should be a critical research goal in future studies.

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Part II

Diagnostic Workup

5 Clinical Assessment and Other Instrumental Examinations

Donatella Pistolesi, Chiara Mariani, and Cesare Selli

5.1 Introduction

The aetiology of male stress urinary incontinence (SUI) may be partly associated with demographic factors, for example aging and obesity [1], but it is also linked to the growing common treatment of prostate diseases.

More specifically, the surgical treatment of benign prostatic hyperplasia and of prostate cancer is acknowledged as possible cause of SUI. According to the American Urological Association (AUA) guidelines, the SUI rate after transurethral resection of the prostate (TURP) is rather low (<3 %) [2], and a more recent study has reported the rate to be <0.5 % [3]. Similarly, low rates have been reported after endoscopic procedures such as transurethral prostate incision and laser ablation. On the contrary, radical prostatectomy is connected with considerably higher rates of urinary incontinence: the incidence of early stress incontinence ranges from 0.8 to 87.0 %. This wide array of incontinence rates is in large part likely to depend on the bias of the surgeon dealing with incontinence and on the lack of a standardised definition of the word 'incontinence' [4–7].

External urethral sphincter deficiency [8–14] and bladder dysfunction have been considered responsible for urinary incontinence following radical retropubic prostatectomy (RRP) [15]. The exact aetiology of post-prostatectomy incontinence still needs to be understood, but bladder neck dysfunction and intraoperative damage both of the nerves and the sphincter are known to be responsible for the disease [15, 16]. In this respect, urethral sphincter dysfunction may depend on direct muscle impairment and on neural damage [17]. On the basis of a new concept that is evolving rapidly, incontinence may also depend on sphincter laxity due to surgical procedure, in spite of a good sphincter function [18, 19], and this condition is caused by a disturbance of the male integral system after surgery.

D. Pistolesi • C. Mariani (✉) • C. Selli
Department of Urology, University of Pisa, Pisa, Italy
e-mail: dr.ssamariani@gmail.com; c.selli@med.unipi.it

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Surgical techniques such as bladder neck preservation can improve the early continence rate, but in the long run the outcomes with and without bladder neck preservation are practically identical [20–23]. Furthermore, functional urethral length [24] – with a lower reported limit of 28 mm – is another major element for sphincter function, although no effect of this urodynamic parameter has been identified [13, 25].

It is necessary for a good practice to know the different type of urinary incontinence (urge, overflow and stress urinary incontinence). Urge urinary incontinence and overflow urinary incontinence can be confused with SUI, which is only one type of urinary incontinence.

The specific type of incontinence can be established by a two-step evaluation that comprises early diagnostic work-up, followed by first-line treatment. In case of failure of first-line treatment, specialised clinical evaluation is recommended, according to the guidelines of the European Urological Association (EAU) and the International Continence Society (ICS).

Initial assessment includes history, physical examination, questionnaires, diaries, pad tests, urine analysis, laboratory tests and post-voiding residual volume.

Specialised assessment includes urodynamic testing, endoscopic examination (urethrocystoscopy), imaging (urethrocystography, magnetic resonance imaging and ultrasound) (Fig. 5.1).

During early evaluation, as general research recommendations, we should standardise the nomenclature related to the definition of symptoms and the measurement of symptom frequency, severity and discomfort. Other specific guidelines should be established for the adoption of common scientific terminology related to urgency and other bladder sensory symptoms. Questionnaires should be used as tools to improve the description of the symptoms of the lower urinary tract for a better diagnosis. Accuracy of specific components of the clinical history and physical findings are necessary to perform a careful diagnosis and to start non-invasive conservative or pharmacological treatment. More invasive examinations are necessary to provide a more complex therapeutic intervention.

5.2 Initial Assessment

5.2.1 History

In the clinical process, taking the history of the patient should be the first step to assess male patients with urinary incontinence. The questions addressed should concentrate on the urinary tract, on the family history of prostate diseases (benign prostatic hyperplasia (BPH) and cancer), on the conditions causing bladder dysfunction, on previous surgical or radiation therapy and on bowel and sexual habits. The history of patients who have undergone prostatic surgery should be detailed, by specifying the type of endoscopic procedure (TURP, TUIP, Green Light Laser, Holmium Laser) in case of BPH, or the type of open surgery in case of prostate cancer. The specific approach (whether retropubic, perineal, laparoscopic or

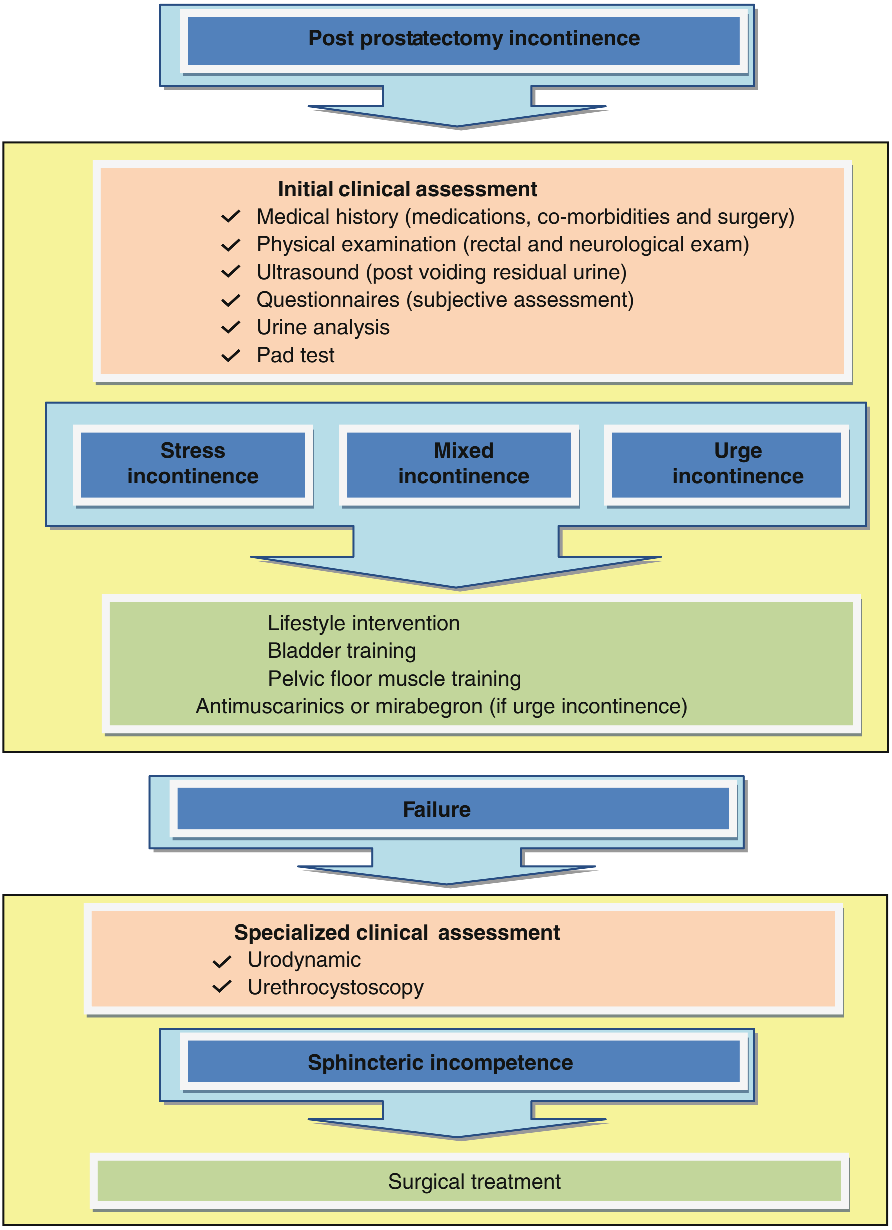

Fig. 5.1 Initial and specialised assessment and management of urinary incontinence in men (Based on European Association of Urology 2014 guidelines)

robotic), the present stage of prostatic cancer and the co-morbid conditions should be evaluated in case of radical prostatectomy. Other important factors to be determined are the type and dosage of radiation therapy, if used.

In addition, specific drugs taken by a patient, such as alpha-adrenergic blockers and agonists, angiotensin-converting enzyme inhibitors, diuretics, anticholinergics, psychotropic drugs and calcium channel blockers, should be critically evaluated to exclude any side effects on the lower urinary tract function [26].

A careful history should thus help classify UI as follows: stress urinary incontinence (SUI), urgency urinary incontinence (UUI) or mixed urinary incontinence (MUI), in order to address the patient for consultation or care.

5.2.2 Physical Examination

This section focuses on general physical examination tests, e.g. digital rectal examination (DRE) and neurological testing of the perineum and lower extremities. These physical examinations include visual assessment of any surgical abdominal scars, of a distended bladder, of bruising of the genital skin secondary to urinary incontinence. Abdominal palpation of the patient is suggested to evaluate bladder distension, with particular regard to incontinent patients following radical prostatectomy, who may be affected by overflow leakage caused by a possible obstruction. The external genitalia should be examined, by evaluating congenital malformations, retractable foreskin and the site of the urethral meatus. The examiner can identify stress incontinence by searching for urethral discharge after abdominal straining (by using the Valsalva manoeuvre) or by the cough stress test with the patient in supine or upright position, as long as the bladder is sufficiently full. The cough stress test is extremely reliable to clinically evaluate and confirm a urinary stress incontinence diagnosis. In particular, the test shows good sensitivity and specificity for stress incontinence compared to more complex and sophisticated multichannel urodynamic examinations. However, in case of uncertain results, further confirmatory urodynamic assessment is required. If the bladder is full (but not close to sudden urination), the patient should be placed in lithotomy position, should relax the pelvic muscles and cough. If the patient is initially placed in supine position and there is no leakage, the test should then be repeated in standing position. The patient should wear a pad, the legs should be wide open over a cloth or sheet placed on the floor to check whether there is any leakage. In presence of urine leak with coughing, and absence of leaking when the coughing stops, the test is positive for stress incontinence.

If there is no leakage nor a delayed leakage (5–15 s), the test is negative so most cases of stress incontinence can be excluded. False negative results may occur if the bladder is empty, if the cough is not strong and if the pelvic floor muscles contract to offset urethral sphincter incompetence. A targeted neurological examination is also fundamental. In cases of suspected neurogenic bladder, the physician should assess perineal sensation, lower extremity neuromuscular function and anal sphincter tone (which is often decreased in neuropathic patients) as well as general, mental and ambulatory status (Table 5.1) [27].

Table 5.1 Neurological examination

	Reflex evocation	Outcome of reflex	Tract of spinal cord involved
Cremasteric reflex	Creeping skin on the proximal inner thigh	Cremaster muscle contraction with lifting of the testis	L1–L2
Bulbo-cavernous reflex	Compression or sensory stimulation of the glans	Contraction of the anal sphincter	S1–S4
Anal reflex	Compression or sensory stimulation of the glans with a wood stick	Contraction of the anal sphincter	S5

5.2.3 Questionnaires

Questionnaires allow the physician to record the patients' symptoms, including severity and impact on quality of life. The responses to the questionnaire are gathered in a standardised way, making it possible to monitor incontinence over time and to verify treatment-related changes. Questionnaires require to be validated in the language used; they can be utilised for result assessment and must report any changes. Other diagnostic tools include scales, indexes, symptom scores, symptom questionnaires, patient-reported outcome measures (PROMS) or health-related quality of life (HRQoL) measures. HRQoL measures can be divided into generic (e.g. SF-36) or condition-specific (e.g. Incontinence Impact Questionnaire, the King's Health Questionnaire, OAB-q). Other questionnaires are the International Prostate Symptom Score (IPSS), the most commonly used, although it does not take into account the symptom of urgency incontinence, the ICS male questionnaire and the ICIQMLUTS. This last questionnaire examines the symptoms of urgency incontinence and can be divided according to voiding and incontinence sub-scores. Many authors have evaluated post-prostatectomy incontinence, showing the lack of reliable symptom scores and emphasising the importance of urodynamic tests [11, 28].

5.2.4 Diaries

A semi-objective method to measure symptoms like urinary incontinence frequency and urgency consists in taking voiding diaries. An important element of male incontinence assessment is the description of the type and severity of incontinence. To evaluate severity, the patient must write down the number of daily episodes, the type of protection (pads, penile clamp, condom catheter) and the effects of incontinence on every day activities. Voiding diaries are also called micturition time charts, frequency/volume charts or bladder diaries. A standardised terminology has been achieved for voiding diaries [29, 30]. Voiding times (for a minimum of 24 continuous hours) are reported in micturition time charts. Voiding volumes and times for 24 h are recorded in frequency volume charts. Voiding diaries provide information on pad usage, incontinence episodes, urgency degree and fluid intake. They can be electronic or paper diaries, and various studies have reported the ways in which they have been evaluated in terms of accuracy and patients' preference, and they have compared shorter (3 or 5 days) and longer durations (7 days) [31, 32]. There is currently no consensus on diary duration and on the way in which diary data correlate with some of the symptoms.

Voiding diaries are useful to assess treatment response and are especially used in clinical trials to measure treatment results.

5.3 PAD Test

Urine leakage in men can be objectively verified by using a pad test. The aim of pad testing is to calculate the volume of urine that has been lost by weighing a perineal pad before and after any kind of leakage provocation. The number and the history of pad usage is not totally reliable, as it can measure only up to 38 %, since patients use pads of different types and sizes and therefore it is difficult to compare the number of pads/day per patient. Moreover, some individuals are disturbed by even small amounts of leakage and change pads frequently, before they are soaked, while the older patients generally have a greater loss in each single pad, as they change it less frequently. Indeed, an important distinction to be made is that of true urinary incontinence and fear of leakage, for which a pad is worn only for safety reasons (security pad). The pad tests can be either short-time (1-h) or long-term tests (usually at home during a 24–48 h period). Groutz et al. have estimated the reliability of the pad test and of the micturition diary and have confirmed that the number and total weight of the pads represent a reliable measure of incontinence at 24, 48 and 72 h. The number of incontinence episodes and total number of emptyings are reliable measurements of 48, 72-h diaries. On the contrary, a longer period of evaluation is usually associated with a loss of compliance on the part of the patients [33]. Patients to be submitted to a standard ICS 1-h pad test are asked to come to the hospital with a full bladder after having drunk 500 ml of water a quarter of an hour before arrival. A preweighed pad is worn when a bladder volume is >200 ml, confirmed by abdominal ultrasound. The patients are told not to contract the pelvic floor muscles to avoid the usual 'leak'. After standard ICS provocation exercises, for example coughing, picking up a heavy object, stepping up and down on a low stool, bending knees, sitting/standing, running or walking on the spot for 1 min and washing hands in cold water for 1 min (each of these exercises performed ten times), the pad is weighed again and urine loss is calculated [34]. A pad weight gain >1 g is considered positive for a 1-h test, and a pad weight gain >4 g is positive for a 24-h test. Each 1 g weight gain is assumed to equal 1 ml of urine loss. In the analysis of 1-hr pad test, an increase of 1–10 g is classified as representing mild incontinence,11–50 g moderate and >50 g severe incontinence. The values for 24-hr pad test are classified as follows: mild (4–20g/24hr), moderate (21–74g/24hr) and severe (>75g/24hr) incontinnece [35]. In another study a 250 ml cut-off value of urine has been proposed to categorise minor from severe leakage [36]. Some authors have reported on the excellent technical feasibility of the 20-min pad test to evaluate post-prostatectomy incontinence [37].

5.3.1 Urinalysis

The guidelines concerning urinary incontinence management recommend that patients use urinalysis in case of high prevalence of urinary tract infection [38, 39].

Dipstick urinalysis performed on a mid-stream specimen is an inexpensive diagnostic test that can identify the presence of urinary tract infection, proteinuria, haematuria and glycosuria, but with a relatively low sensitivity and specificity. For these reasons, microscopy and other tests are necessary to confirm any abnormalities identified on dipstick analysis: complete urinalysis includes physical, chemical and microscopic urine tests.

Urine cytology is also recommended to exclude bladder cancer in male patients with a history of smoking and affected by haematuria and symptoms of urgency.

5.3.2 Laboratory Tests

At present, no laboratory tests are recommended to complete the diagnostic evaluation of incontinent patients. However, there is a tendency to test PSA in men with LUTS and BPH with a life expectancy >10 years, for whom the diagnosis of prostate cancer would considerably change the management.

Renal function screening is not justified in male patients, since epidemiological studies have shown the absence of any association between (BPO/BPE) BPH and chronic kidney disease [40]. The data from the Medical Therapy of Prostatic Symptoms trial (MTOPS) have shown that the risk of developing de novo renal failure in men with LUTS is <1 % [41].

5.3.3 Post-voiding Residual Volume

The post-voiding residual (PVR) volume is the amount of urine left in the bladder after micturition. PVR is often associated with UI symptoms and indicates poor voiding efficiency, which may be secondary to detrusor underactivity or to bladder outlet obstruction. PVR is likely to deteriorate renal function and to be responsible for a dilatation of upper urinary tract.

The best way to measure PVR is by abdominal ultrasound (US) or by catheterisation [42–47].

The International Consultation on BPH [48] has defined the range 50–100 ml as the lowest threshold to define abnormal PVR.

The decision to perform a PVR in male incontinent patients should depend on symptoms or physical findings. A PVR should be carried out in particular for planned treatments aimed at decreasing bladder contractility or increasing outlet resistance in specific sub-groups of incontinent patients, when there is a suspicion of decreased bladder emptying.

5.4 Specialised Assessment: Other Instrumental Exams

5.4.1 Urethrocystoscopy

Cystoscopy introduced by Bozzini in 1805 is an endoscopic procedure performed for the evaluation of lower urinary tract disorders [49]. Urethrocystoscopy has been introduced for the assessment of urinary incontinence (although its routine use is not entirely evidence-based), in order to evaluate the posterior urethra and to identify possible iatrogenic damage of the external sphincter region, anatomic position and presence of vesicourethral anastomotic stricture. The pathophysiology of UI in post-radical prostatectomy patients is still unclear, but the main cause seems to be intrinsic sphincter deficiency. Gozzi and Rehder suggested that post-radical prostatectomy incontinence may also be related to prolapse of the sphincter complex and that its repositioning by a transobturator sling may be successful to achieve continence [50–52].

The function of the sphincter and the mobility of the posterior urethra could be evaluated with dynamic and static urethrocystoscopy, during the pre-operative work-up of candidates to incontinence repair. It is particularly innovative and relevant to perform a dynamic cystoscopic exam while visualising the sphincter region with manual repositioning of the urethra: 'repositioning test' (manual push-up of the central tendon of the perineum) (Figs. 5.2 and 5.3). In case of a persistent good residual sphincter function, even with a mobile posterior urethra, the sphincter closes in an autonomous and concentric manner (Fig. 5.4). Additionally, with perineal elevation, these patients show a much stronger and prolonged sphincter contraction. In case of partial sphincter deficiency, a valid concentric closure may be achieved only by manual perineal elevation. Altogether, these criteria represent positive results of the repositioning test, which is useful to simulate the sling effect prior to surgery, although it has not yet been standardised [53].

Fig. 5.2 Repositioning test: manual push-up of the central tendon of the perineum

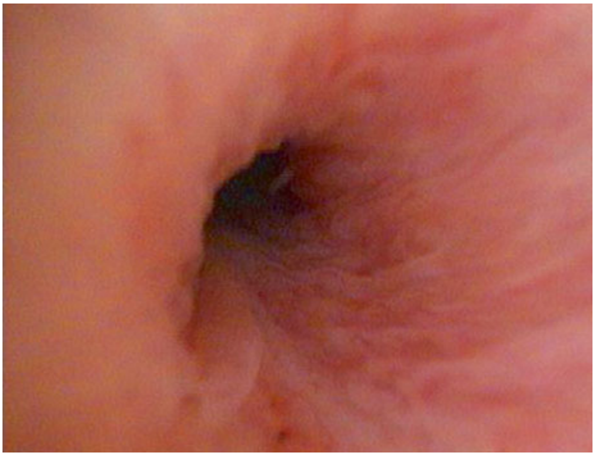

Fig. 5.3 Urethroscopy: open urethral sphincter at rest

Fig. 5.4 Urethroscopy: the sphincter is autonomously closed in concentric manner secondary to manual repositioning

During cystoscopy, it is also suggested to evaluate the intrinsic sphincter function by the retrograde leak point pressure (RLPP) test. During an outpatient cystoscopy, the tip of the instrument is placed in front of the sphincter and a bag of saline is elevated until fluid flows through the drip chamber and into the urethra; RLPP is a pressure value represented by the height of the fluid column above the pubic symphysis at which water dripping stops while cystoscopy shows sphincter closure. 60 cmH_2O was initially chosen as cut-off value based on artificial urinary sphincter (AUS) device data [54, 55] (Fig. 5.5). This test is frequently used during the procedure of sling positioning in order to better graduate the tension of the mesh.

Further research is required to confirm such an interesting pathophysiological explanation of incontinence, and to support the role of endoscopy in the evaluation of these patients.

Fig. 5.5 Retrograde leak point pressure (RLPP) under visual control

5.4.2 Micturition Cystography (MCU)

Cystography is a time-honoured fluoroscopy exam performed in orthostatic and clinostatic position, and provides basic information about the shape of the urethra and the bladder, the presence of ureteral reflux and post-voiding residual urine.

In particular, urethrocystography is an important exam to evaluate the anastomotic stricture a relatively common complication after radical retropubic prostatectomy, with an incidence ranging between 0.48 and 32 % that may cause severe voiding dysfunction.

Provocative manoeuvres performed during this exam can evaluate the morphology and mobility of the bladder neck, as well as the presence of eventual leakage both at rest and under strain [56].

Furthermore, the perineal compression displays the repositioning of the bladder neck and the positive effect on leakage (Fig. 5.6).

5.4.3 Magnetic Resonance Imaging

Imaging studies should be performed to improve our understanding of the anatomical and functional abnormalities that may cause UI. Imaging examinations can also be used to investigate the relationship between lower urinary tract conditions and treatment outcome.

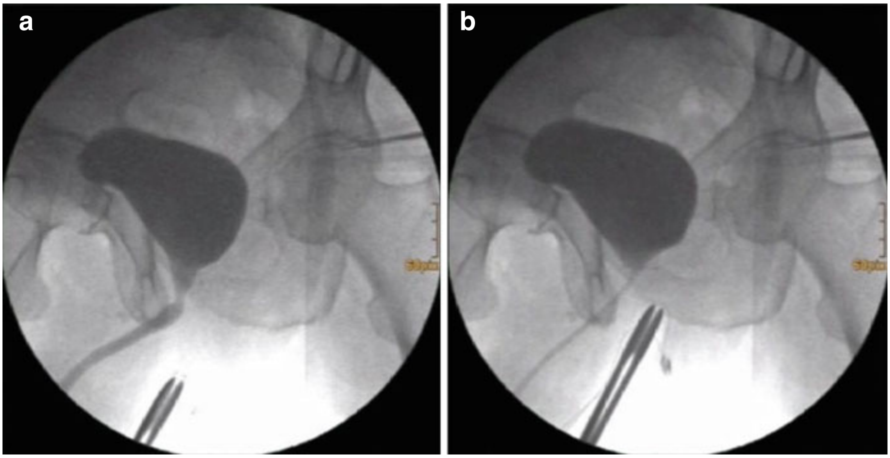

Fig. 5.6 Cystourethrography during Valsalva manoeuvre showing mobile posterior urethra with urine leakage (**a**). Cystography following perineal compression displaying repositioning of the bladder neck and reduction of leakage (**b**)

According to the latest guidelines, ultrasound and magnetic resonance imaging (MRI), especially in women, have replaced X-ray imaging in the evaluation of UI. Both procedures are safer and can provide both qualitative and quantitative data on the kidneys, bladder neck and pelvic floor. Ultrasound is theoretically preferable to MRI owing to its wider availability and to its ability to produce three-dimensional and dynamic images at lower cost, but it is operator-dependent. MRI, performed statically or dynamically, presents a large variation in interpretation between observers [57], and little evidence to support its clinical usefulness in the management of UI.

However, there is a general consensus that MRI provides good global pelvic floor assessment, including POP in females, defecatory function and integrity of the pelvic floor support, particularly after RRP [58]. Static MRI provides an excellent depiction of the pelvic anatomy and is a useful method for identifying single structures of interest pre- and post-operatively, e.g. external sphincter, urethral length or neurovascular bundle [59–61]. Several imaging studies have examined the relationship between sphincter volume and function in women [62] and between sphincter volume and surgery outcome in men and women [63, 64]. MRI can be used to assess male pelvic floor anatomy, in particular the difference between pre- and post-operative length of the membranous urethra, and urethral and periurethral fibrosis [65].

Dynamic MRI studies failed to show statistically significant differences in anatomic measurements of the urethra and bladder neck, regardless of surgical approach, or strong evidence of urethral hypermobility, previously postulated to be a potential cause of post-prostatectomy incontinence [66].

Pistolesi et al. observed after sling positioning on MRI dynamic study (with Valsalva manoeuvre and contraction of the pelvic floor) in 3/5 continent patients, a significant elevation of the bladder neck in comparison with the exams before surgery while in 2/5 no change of the position was appreciable. In the 3 incontinent patients, no modification of the bladder neck position was observed [67].

Soljanik and colleagues at functional MRI after sling suspensions observed significant elevation of the posterior bladder wall, bladder neck and external urinary sphincter; the sling failure was related to the severity of pre- and post-operative periurethral fibrosis more than the anatomic location of these structures [68].

Some authors have studied the use of MRI to assess the positioning of mid-urethral sling insertion for SUI treatment. In one publication, it was suggested that mid-urethral sling placement decreased mobility of the mid-urethra but not bladder neck mobility [69]. Furthermore, the position of mid-urethral slings with respect to the pubis has been associated with the cure of UI [70]. Another study has evaluated the length of the bulbous urethra posterior to transobturator sling in the treatment of post-prostatectomy incontinence using MRI, and has found a positive correlation with the functional results [67] (Fig. 5.7).

Papin et al. evaluated the anatomical relationships between the sling and the urethral sphincter, in patients treated for post-prostatectomy urinary incontinence giving a description of the anatomic findings: the position of the sling was always visible and when correctly positioned, it was retro-urethral [71].

MRI imaging of incontinent patients after sling placement can provide some indications to a further surgical treatment of SUI after radical prostatectomy: if the length of the urethral bulb posterior to the sling is not appropriate, a redo sling can be indicated, while if the length is adequate, repositioning of the urethra is not sufficient to compensate a severe sphincter deficiency. In such case, a compressive solution such as the artificial sphincter must be considered [72].

However, no imaging test has shown to predict the outcomes of UI treatment.

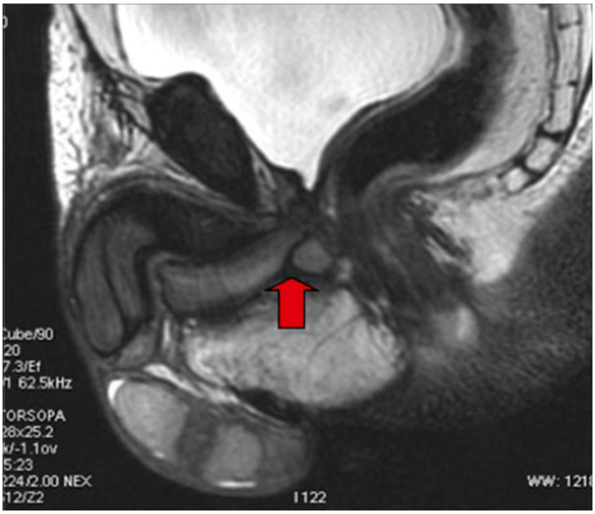

Fig. 5.7 Example of typical MRI findings in continent patients after sling placement on the sagittal T2w CUBE image. In this case, the sling is well visible as linear hypointensity (*arrow*) and the proximal bulb is well represented

5.5 Ultrasonography

Ultrasonography has been used in the evaluation of urinary incontinence since as early as 1980 [73] and is considered the gold standard technique for measuring bladder volume and post-void residual urine. New developments have been used over time, which include contrast medium, colour Doppler, 360° transducers and three- and four-dimensional imaging. These methods have led to a more extensive use of ultrasonography in evaluating the lower urinary tract and pelvic floor disorders.

Different imaging approaches have been used: abdominal, transrectal and perineal. The development of three-dimensional ultrasonographic systems (described for the female urethra in 1999) [74] has brought increased accuracy in the study of endopelvic organs and of the pelvic floor. The bladder, neck and proximal urethra are easily visible in all types of ultrasonography without the need for catheterisation. Measurements are usually taken at rest and during straining (Valsalva manoeuvre).

Perineal ultrasonography as well as clinical and urodynamic testing may be considered useful diagnostic tests in both men and women. Recently, Kirschner-Hermanns has performed ultrasound imaging to investigate the feasibility and interinvestigator reproducibility of perineal ultrasonography in men with and without post-prostatectomy urinary incontinence. The study outcomes clearly show that, in men who have been submitted to radical prostatectomy, it is possible to visualise hypermobility of the proximal urethra and the bladder neck opening, as well as urethral and periurethral fibrosis after surgery and the positioning of a suburethral sling, once it has been placed.

Furthermore, the data gathered using perineal ultrasonography are reproducible and may help to identify risk factors for different surgical procedures [75].

Chan and Tse found that transperineal ultrasound is a good modality of imaging for the assessment of synthetic male suburethral slings and may have a role in the evaluation of patients with a failed sling. Dynamic compression of the urethra by transobturator sling was demonstrated during Valsalva manoeuvre in patients with successful slings, but not observed in failed slings, suggesting that this may be a mechanism of action of male transobturator sling [76]. Ultrasound can produce images at lower cost and wider availability, and for this reason it is preferred to MRI.

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Role of Urodynamic Investigation

6

Giancarlo Vignoli

6.1 Introduction

Postprostatectomy incontinence (PPI) is commonly considered as a specific issue if persisting at least 1 year after radical prostatectomy [1].

In fact, early post-operative PPI has been proven to recover spontaneously with time and under conservative management (involving pelvic floor muscle exercises) in the first post-operative year and even until 2 years after radical prostatectomy [2, 3].

Therefore, initial work-up should be limited to history, physical examination, urinalysis, ultrasound postvoid residual measurement, voiding diary, and pad test [4].

Usually, men complaining of PPI describe stress urinary incontinence (SUI). These symptoms are associated with a significantly decreased quality of life [3, 5].

Some degree of overactive bladder and urge urinary incontinence can also be seen or coexist with stress urinary incontinence.

If one decides to do urodynamic testing after RP, there is some guidance about appropriate timing. Since evidence shows that there is continued recovery of continence up to 24 months post RP (95.2 % at 12 months, 98.5 % at 24 months) [6–8], it is reasonable to perform urodynamics at 1 year from RP [9].

The purpose of urodynamics in the evaluation of postprostatectomy incontinence is to correctly identify the aetiology of urinary leakage and also to assess multiple other parameters which may potentially affect the success rate of future intervention.

> A disease half known is a disease half cured [10]

G. Vignoli
Functional Urology Unit, Casa Madre Fortunata Toniolo, Bologna, Via Toscana 34, Bologna 40141, Italy
e-mail: vignoli.g@tiscali.it

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However, the situation in which urodynamics will change the management and influence clinical decision-making is still unknown.

As has come into use in the recent years, when one speaks of urodynamics is true everything and its opposite.

Urodynamic studies have been recommended until recently to assess the cause of incontinence [11].

However, there are several reports that do not show reliable predictive value of urodynamics regarding PPI surgical treatment outcomes [12–14].

Preoperative use of fewer pads, less severe PPI, and a longer interval between RP and PPI surgery seems to be associated with the successful outcome of anti-incontinence surgery more than preoperative urodynamic dysfunctions [15].

As in other fields, i.e. female stress urinary incontinence, current treatments are so non-specific and non-quantitative that the underlying dysfunction is unimportant: Treatment works equally well and poorly in any case.

6.2 The Mechanisms of Postprostatectomy Incontinence

Incontinence after radical prostatectomy may be secondary to sphincteric dysfunction (ISD), bladder dysfunction, or a combination of both.

While bladder dysfunction (such as detrusor underactivity, overactivity or poor compliance) can also be present, it is rarely the sole cause of incontinence in this setting.

ISD is by far the most common finding as a consequence of a direct injury, or injury to the nerve supply or supporting structures. ISD is found in approximately 90 % of men with PPI. Among men with ISD, however, only 25–50 % have ISD alone without concomitant bladder dysfunction on urodynamics [16–18].

Detrusor overactivity is found in approximately 30–40 %, decreased contractility in 30–40 %, bladder outlet obstruction in 20–25 %, and decreased compliance in 5 % of men undergoing urodynamics for PPI [13, 19, 20]. Approximately 15 % of patients with PPI demonstrate only bladder dysfunction without ISD.

More recently, urethral and bladder neck hypermobility have been suggested as possible causes of postprostatectomy incontinence.

6.3 Urodynamics in PPI: Pearls of Technique

Unlike men with an intact prostate, men after radical prostatectomy can often easily initiate or increase urinary flow by straining.

Valsalva voiding in most cases does not reflect impaired contractility, but is merely a learned response to voiding with less outlet resistance.

When urodynamics is done in standard fashion in men with PPI, a significant number of men with sphincteric insufficiency will not demonstrate urodynamic stress incontinence. Also ALPP may be significantly higher. Finally, urinary flow rates can be grossly atypical. These findings presumably occur because of the presence of a catheter in the urethra [21].

Unintubated urodynamics, utilizing only rectal catheter for the measurement of the abdominal pressure, is probably the preferred approach in PPI patients.

In practice, a second filling phase should be performed to a bladder volume 50–75 % of bladder capacity on the first filling phase. At this point, the vesical catheter is removed. ALPP is assessed in the same manner of standard investigation, with the value determined by the pressure recorded from the rectal catheter (pabd). At the end of filling, a non-invasive uroflow is performed with record of voided volume and free maximum flow rate (free Qmax).

Regardless of the presence of the catheter, the leaked urine may not appear at the external urethral meatus, thus leading to underdiagnosis of SUI and imprecise ALPP measurements.

Videourodynamics may improve detection sensitivity of slight SUI as small volumes of contrast pass the external sphincter into the bulbar urethra.

Furthermore, the video fluoroscopic views of the outlet/anastomosis and the free Qmax may be used to either corroborate the nomogram diagnosis of obstruction or to clinically reclassify these patients into a clinically unobstructed category. More specifically, if the free Qmax remains low and anastomotic stricture is seen on fluoroscopy, then these patients are categorized as clinically obstructed. Conversely, if the free Qmax increases considerably in comparison to the intubated value and the video fluoroscopy shows no obvious narrowing, then these patients are reclassified as clinically unobstructed.

6.4 Quantification of Sphincter Deficiency

6.4.1 Rationale

Current surgical treatment of stress urinary incontinence after radical prostatectomy can be divided into minimally invasive and invasive treatments. Minimally invasive treatment includes injection of urethral bulking agents, male suburethral sling and adjustable continence balloons. Invasive treatment includes artificial urinary sphincter implantation, which is still the gold standard and the most effective treatment of PPI. Theoretically, the degree of sphincteric incompetence should affect the type of treatment recommended for the management of the stress incontinence.

However, the demand for minimally invasive treatment is increasing, and many urologists consider male suburethral slings to be an acceptable treatment for PPI. The male sling is usually recommended for patients with persistent mild or moderate incontinence. Therefore, it seems reasonable that a better knowledge of the degree of sphincter weakness may help surgeon’s choice.

6.4.2 Technique

Several assessment techniques for urethral sphincter function and anatomy have been reported including sphincter electromyography, ALPP, urethral profilometry (UPP), perfusion sphincterotomy and more recently magnetic resonance imaging

(MRI). Sphincter electromyography and perfusion sphincterometry have limited application. ALPP and UPP are the most relevant techniques. MRI and UPP might be also valuable preoperative diagnostic tools in patients waiting for RRP. However, more and larger studies are needed to show the exact role of urodynamics and imaging in the preoperative work-up of patients waiting for RRP and for whom post-operative incontinence may be a big concern [22].

6.4.2.1 ALPP

The abdominal leak point pressure (ALPP) is the urodynamic parameter typically used to assess the presence and magnitude of sphincteric dysfunction [23].

ALPP is the lowest intravesical pressure that causes urinary leakage in the absence of detrusor contraction. This measurement is attained by inserting a urethral catheter (7–10 F in size) and filling the bladder at the rate of 50 ml/min. Once the bladder is filled to 150 ml, the patient is instructed to perform increasingly powerful Valsalva manoeuvres. At least three ALPPs are performed and the lowest accepted. If no stress leakage occurs, testing is repeated at 50 ml increments until leakage or capacity.

In a recent urodynamic evaluation of PPI, mean ALPP in patients with SUI was 59 cmH_2O (range 10–200 cmH_2O) [24].

The presence of urethral catheter significantly affects ALPP. Approximately 35 % of patients leak only when the catheter is removed. Furthermore, in patients who leak in presence or absence of urethral catheter, ALPP is significantly higher with the catheter in place (86 vs 67 cmH_2O $P=0.002$). This finding suggests that the presence of a urethral catheter artificially increases the ALPP by partially obstructing the urethra at the fibrotic anastomotic area [25].

The value of ALPP in management of PPI is debatable [26]. There is evidence that patients with higher ALPP, and, therefore, more preserved sphincteric function tend to respond better to minimally invasive procedures, like periurethral bulking agents, than do patients with a lower ALPP . The proposed cut-off value is 60 cmH_2O [27].

However, while the ALPP appears to correlate with objective incontinence severity in women with stress incontinence, it does not correlate significantly with the 24-h pad test in patients with postprostatectomy stress incontinence [28].

ALPP seems to be a relatively poor predictor of incontinence severity and, therefore, has limited clinical value in the urodynamic evaluation of postprostatectomy incontinence.

Furthermore, low pre-operative ALPP (<30 cmH_2O) seems to have no influence on post-operative outcome of retro-urethral transobturator sling [29].

6.4.2.2 Urethral Pressure Profilometry (UPP)

Urethral pressure profilometry (UPP) is the measure of intraluminal pressure along the length of the urethra obtained by slowly withdrawing a pressure-transducing catheter from within the bladder distally. Maximum urethral closure pressure (MUCP) and functional profile length (FPL) are the two parameters mostly used.

Maximum urethral closure pressure is defined by the maximum difference between urethral pressure and the intravesical pressure, and functional profile length (FPL) is defined by the length of the urethra along which the urethral pressure exceeds intravesical pressure.

Several studies indicate a significant reduction of both FPL and MUCP after radical prostatectomy.

Majoros et al measured pre- and post-operative MUCP noting a significantly higher value in continent vs incontinent groups (56 vs 44 cmH_2O, $P<0.0005$). No differences were seen in MUCP preoperatively [30].

Sub-analysis comparing patients who become continent at 2 months versus 9 months showed significantly increased closure pressure both at rest and during voluntary contraction.

These data might suggest that immediate continence after catheter removal is caused by a good "passive" sphincteric function (high MUCP at rest) whereas continence achieved later may be due to a good "active" sphincteric function that justifies the value of physiotherapy techniques (PFMT with or without biofeedback) in the early post-operative period [31].

MUCP seems more reliable than ALPP in assessing the severity of incontinence.

Minervini et al. [32] reported on the relation between FPL and MUCP and the severity of incontinence. Post-operation, patients were divided in a continent group, a moderately incontinent group and a severely incontinent group. FPL was 3.8, 2.6 and 1.6 cm, respectively. MUCP was 74, 41 and 34 cmH_2O, respectively. Statistically significant difference was found between the continent and the incontinent group for the mean FPL and the MUCP.

6.5 Assessment of Bladder Neck and Urethral Mobility

With the advent of male sling surgery, bladder neck and urethral mobility became a parameter more relevant than sphincter weakness because the mechanism of action of transobturator sling is thought to rely more on repositioning the prolapsed sphincteric urethra than on direct compression of the bulbous urethra.

Urethral and bladder neck hypermobility seems the consequence of the absence of the prostate and its fascial and ligamentous supporting structures.

In fact, the success of sling surgery depends upon the mobility of these structures.

Rehder and colleagues [33] and Bauer and colleagues [34] advocated the repositioning test as a predictor of adequate residual sphincter function and predictor of retroluminal sling success.

Perineal elevation is obtained by gently pushing the preanal midperineum in a cephalad direction avoiding direct compression of the bulbous urethra.

The repositioning test is considered positive when on perineal elevation men with sufficient residual sphincter function demonstrate passive sphincter closure with cystoscopically visible contraction of the striated sphincter. This manoeuvre usually increases the ALPP.

In cases of restricted mobility due to urethral fibrosis, a higher failure rate of the sling is expected and AUS may be the more appropriate solution to resolve the incontinence.

Recently, the role of urethral mobility has been questioned by dynamic MRI images.

Some MRI studies have been conducted to evaluate the mechanisms underlying PPI, and all came to the conclusion that sphincter deficiency by itself is the main responsible of incontinence more than bladder neck and urethral mobility.

Cameron et al. [35] showed that in continent men the visible urethral sphincter was longer, there was less distortion of the sphincteric area and the bladder neck was less funnelled compared to incontinent men on MRI.

In men with PPI, the visible urethral sphincter was 31–35 % shorter and the bladder neck angle was 28.98 more funnelled compared to continent men.

Urodynamically, during a Kegel manoeuvre, continent men were much better at augmenting urethral pressures than their wet counterparts although there were no differences in urethral pressure profiles at rest between groups. All of these findings suggest that the sphincter in men with PPI is both diminutive and poorly functional possibly due to scar.

Soljanik and colleagues [36] evaluated 26 men who underwent transobturator sling suspensions with functional MRI to determine the anatomic changes associated with this procedure. They observed significant elevation of the posterior bladder wall, bladder neck and external urinary sphincter after sling placement, as expected. However, the authors found that sling failure was more likely to be related to the severity of pre- and post-operative periurethral fibrosis than to the anatomic location of these structures.

Suskind et al. [37] found no statistically significant differences in bladder neck and urethral position or mobility on dynamic MRI evaluation between continent and incontinent men status post-radical prostatectomy focusing the attention on sphincteric mechanism by itself.

6.6 Assessment of Detrusor Function

6.6.1 Rationale

Assessment of concomitant bladder dysfunction, like detrusor overactivity, detrusor underactivity and poor bladder compliance, has been shown to have no impact on the outcome of therapeutic strategies particularly if AUS has been selected as treatment of PPI, since the cuff is cycled to an open phase during voiding, relieving urethral occlusion.

Bladder dysfunction may even improve after implantation of an artificial sphincter. Conversely, the assessment of detrusor condition, particularly detrusor contractility has been advocated before sling surgery since the placement of a potentially obstructive male sling in a patient with detrusor underactivity, should at least theoretically increase the risk for post-operative retention .

6.6.2 Detrusor Underactivity

The International Continence Society defines detrusor underactivity as a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal period [38].

The evaluation of detrusor contractility in PPI patients is a technical challenge.

In most urodynamics studies of patients with PPI, detrusor underactivity has been defined using indirect or equivalent measures such as [1] the presence of Valsalva voiding [2], low detrusor pressure at maximum flow (PdetQmax), or, most commonly [3], bladder contractility nomograms developed for men with BPH, derived using both urinary flow rates (Qmax) and PdetQmax with a BCI (bladder contractility index) less than 100 indicative for detrusor underactivity [39].

Bladder contractility nomograms, however, can be inaccurate in men after radical prostatectomy because in consequence of the low outflow resistance state the contractile pressure required to maintain axial flow can approach zero [40].

A more appropriate method of measuring detrusor strength is to directly measure bladder muscle contraction pressure under isovolumetric conditions independent of urinary flow, the so-called *P- iso*.

The easiest way for obtaining *P-iso* measurement is the mechanical stop test [41].

During voiding, the examiner gently occludes the penile urethra, thereby inhibiting urinary flow but not constraining the bladder contraction. The maximum detrusor pressure reached during this manoeuvre is the Piso [42–45].

Piso measurements less than 50 cmH_2O are considered diagnostic of detrusor underactivity [20].

Clinical practice, however, seems to invalidate the theoretical background.

There are few clinical studies on the effects of the male sling in patients with impaired detrusor contractility or those who void by Valsalva and none indicates detrusor underactivity as a risk factor of a poor surgical outcome [13, 46].

It follows that, in a condition of detrusor underactivity, when an artificial sphincter is not desired, the transobturator sling seems to be a viable alternative since its effect relies mostly on a proximal urethral relocation with only minimal compression of the bulbar urethra.

Rehder and colleagues demonstrated no change in Pdet, PVR, or flowrate after surgery, supporting this nonobstructive mechanism of action [47].

6.6.3 Detrusor Overactivity

The rate of detrusor overactivity in men with PPI has been reported in the range of 30–40 % [17, 18, 48].

In 25 % of PPI patients with ISD, there is a secondary diagnosis of detrusor overactivity while it is considered the single or main diagnosis in only 10 % of patients. The rate of de novo detrusor overactivity post-radical prostatectomy is approximately 5 %, often associated to anastomotic or urethral stricture. In 33 % of patients, detrusor overactivity is a condition pre-existent to surgery. With long-term follow-up, the rate of detrusor activity may reduce from 38 % at 8 months to approximately 18 % at 36 months, indicating that the condition, like diminished compliance, is most likely due to poor accommodation associated with a prolonged underfilled state secondary to continual urinary leakage.

If detrusor overactivity is found along with ISD, then it should be taken into consideration during patient counselling for a preventive treatment with antimuscarinics, botulin toxin or tibial nerve stimulation, but is not an absolute contraindication to AUS or sling placement.

Detrusor overactivity does typically improve after AUS implantation and does not adversely affect resolution of SUI [12].

Despite improvement, however, symptoms of overactive bladder may persist post-operatively and patients should be counselled before surgery about this event [49].

Even transobturator sling does not seem to increase voiding pressure or increase the rate of urgency in patients with detrusor overactivity [50].

6.6.4 Reduced Bladder Compliance

The International Continence Society defines bladder compliance as the relationship between change in bladder volume and change in detrusor pressure.

It can be calculated by dividing the change in volume by the change in detrusor pressure during the same time period ($C = DV/DPdet$). The recommended points for this calculation are the start of infusion to the end of filling and at cystometric capacity. Compliance greater than 20 ml/cm is generally accepted as normal. A value less than 12.5 ml/cmH_2O is considered impaired compliance [38].

De novo reduced bladder compliance has been detected in up to 32 % of men after radical prostatectomy, with persistence in 28 % after 36 months [48].

Reduced bladder compliance is not a contraindication to AUS placement. The AUS has been reported to have a predictably high success even in the setting of diminished bladder compliance that may improve after surgery [12].

Conversely, the presence of impaired bladder compliance may be a contraindication to male sling placement due to concerns that the increased voiding pressures may lead to upper tract dilatation.

Small bladder capacity and impaired compliance are independent predictors of unsuccessful clinical outcome of Pro-ACT implantation suggesting that this approach should be considered sooner rather than later after conservative treatment of postprostatectomy incontinence has failed [51].

In radiated patients, impaired compliance may not necessarily resolve after resumption of normal bladder filling and evacuation cycles since there may be a component of intrinsic bladder wall fibrosis secondary to radiation therapy.

In these patients, it is mandatory to continue to monitor upper tract anatomy to assess for the development of hydronephrosis over the time and adopt the necessary measures to protect the kidneys [52].

6.7 Quantification of Obstruction

Anastomotic strictures have been reported at a rate of 2.7–20 % of patients with PPI and are typically diagnosed on cystoscopy [53, 54].

Functionally such strictures may be obstructing or non-obstructing. It is likely that many anastomotic strictures, defined anatomically, may not be urodynamically significant.

Theoretically, a diagnosis of obstruction can be important if one would consider treating it minimally or more aggressively (i.e. dilatation or incision or urethral reconstruction with AUS implant).

Diagnosing obstruction urodynamically in PPI patients can be challenging.

Usually at bladder capacity, the patient voluntarily voids and pressure-flow analysis is performed. Patients are classified into three categories (obstructed, non-obstructed and equivocal) based on the International Continence Society (ICS) nomogram and bladder outlet obstruction index (BOOI) (BOOI = pdet@Qmax/2(Qmax) with >40 being obstructed, 20–40 equivocal and <20 non-obstructed.

In the scarred urethra or anastomotic area that is quite rigid and fibrotic, it is likely that the 7 F urethral catheter creates enough mechanical obstruction by partially occluding the lumen of the non-distensible urethra [21].

In practice, however, most of the patients' results are equivocal for obstruction on ICS nomogram and that makes any decision difficult.

As previously remarked, evaluating the fluoro voiding cystourethrography for narrowing/strictures and combining this information with the free maximum flow rates (free Qmax) is probably the most suitable way to diagnose an obstruction and, in case, reclassify the patients.

The video fluoroscopic views of the outlet/anastomosis and the urethral catheter free Qmax may either corroborate the nomogram diagnosis of obstruction or to clinically reclassify these patients into a clinically unobstructed. Usually, however, the finding of obstruction on urodynamics is not a contraindication to anti-incontinence surgery if the free flow is adequate and post-voiding residual is low. Once again, simple clinical data prevail over the more sophisticated urodynamic traces.

Conclusion

The evaluation of postprostatectomy incontinence is mainly based on clinical features and symptoms assessment. Incontinence after radical prostatectomy is associated with intrinsic sphincter deficiency in the overwhelming majority of patients. The symptom of stress urinary incontinence (leakage under cough) is able to diagnose the urodynamic finding of intrinsic sphincteric deficiency with a positive predictive value of 95 %.

In addition, pad testing may be more useful than ALPP measurement in quantifying the degree of sphincteric deficiency.

The urodynamic work-up of postprostatectomy patients should be focused on [1] demonstrating the presence or absence of stress incontinence and [2] on assessing the presence of concurrent bladder dysfunction or [3] urinary tract obstruction.

The presence of a urethral catheter can have a significant effect on the outcome of the study.

Unintubated urodynamics is probably the preferred approach.

The use of the ALPP as determined with the rectal catheter in the absence of the urethral catheter is probably the most precise urodynamic quantification of sphincter weakness.

Likely, obstruction related to anastomotic strictures is urodynamically best evaluated avoiding catheter and utilizing the combination of voiding cystourethrography and maximum free flow rate.

Bladder dysfunction rarely is an isolated cause. When present on urodynamic tests it may not always be a significant contributor to incontinence.

Furthermore, it does not seem to affect significantly the outcome of the current therapeutic strategies (i.e. transobturator sling, AUS).

For these reasons, in addition to cost and invasiveness, UDS is not routinely done at many institutions to evaluate postprostatectomy incontinence. Because of the high prevalence of sphincteric dysfunction, sphincter closure supports (sling, AUS) are usually considered effective treatment in spite of cure rates almost never above 80 % and other LUT dysfunction that may arise or remain after PPI intervention. Among the non-urodynamicists, this non-negligible event seems more academic than clinically pivotal.

The situation in which urodynamics may influence clinical decision-making is still unknown.

In the absence of comparative trials, whether invasive urodynamic investigation before PPI surgery is only indicated in selected cases or as a routine procedure remains to be established.

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Part III

Conservative and Pharmacological Approach

7 Post-prostatectomy Incontinence and Rehabilitation: Timing, Methods, and Results

Antonella Biroli

Urinary incontinence is a common and feared complication of radical prostatectomy that has a relevant impact on the quality of life and serious psychosocial effects.

Studies show that incontinence affects 2–87 % of patients after radical prostatectomy and 3–40 % of patients complain of persistent post-prostatectomy incontinence (PPI) at 1 year. The wide range of reported incontinence depends on variations in outcome reporting, definition of urinary continence, time from surgery, and patient selection [1].

In the first months after prostatectomy, a total or partial recovery of the function occurs, but it is commonly accepted that the probability to regain continence declines over time, transforming "temporary" incontinence in "persistent" incontinence. The duration needed for PPI to be considered persistent is undefined but 12 months has significant clinical relevance.

When looking at the risk of persistent urinary dysfunction, preoperative sexual dysfunction, older age, and preoperative incontinence are considered predictors of PPI [1].

On the other side, certain technical modifications in surgery are advocated as potential aids to reduce the risk of urinary incontinence, mainly through an earlier return to continence after RRP. These modifications can be divided in preservation, reconstruction, and reinforcement of the anatomic structures in the pelvis, which will make a new supporting system [2].

It is commonly accepted that membranous urethral length is an important factor associated with recovery of urinary continence, therefore confirming the good theoretical basis of some surgical approaches [3].

A. Biroli
Neurological and Autonomic Dysfunctions Rehabilitation Unit,
San Giovanni Bosco Hospital, Turin, Italy
e-mail: biran@virgilio.it

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Nevertheless, the most interesting prognostic factor is continence time trend. Vickers described the prognostic value of prediction models based on current function and time since surgery as strong predictors of recovery [4]. For example, a patient using 1 pad at 6 months has only a 50 % probability of being pad free at 2 years and that drops to 36 % for patients using 2 pads at 6 months. According to this approach that is interesting and useful in clinical practice, all possible predictors, including age, surgical technique, and others, do not importantly add predictive value once current statutes is known ("how you are" is a stronger predictor than "what you are") [3, 4].

When selecting the group of patients to address to rehabilitative intervention, it is important to take into consideration all the elements so far described, as epidemiology of incontinence, rates of spontaneous recovery in the first months, prognostic factors, and prognostic indicators (the current function/time from surgery model).

7.1 Rehabilitation: Premises and Methods

The pelvic floor muscles (PFM) help support and reinforce the sphincteric mechanism. When the internal sphincter mechanism is compromised by surgery and the vesical neck cannot provide a closure function, then the auxiliary external sphincter mechanism is called to play a more important role for the maintenance of continence. Unfortunately, the striated sphincter alone has difficulty in guaranteeing the needed sustained contraction. It can be helped by PFM in order to assure the function of continence through the improvement of the guarding reflex and cough reflex mechanism [5].

It is worthwhile to note that, in the specific field of treatment of male incontinence, the attention is usually focused on reinforcement of the *sphincteric mechanism*, as it is considered the "victim" of surgery.

Conversely, in women, the biological rationale of rehabilitative treatment is that improving pelvic floor strength and tone could involve a better *structural support of the pelvis*, thus preventing perineal descent during increased abdominal pressure. A PF contraction during cough, called the "knack," is also part of the pelvic floor training program in women in order to prevent stress incontinence episodes, contrasting abdominal pressure increases with the effect of pelvic floor contraction on urethral pressure [6].

Actually, the role of a good support of the pelvis is probably relevant in males too, as it could contribute to the efficacy of the sphincteric mechanism. On the other side, many Authors agree about the role of length of membranous urethra as a prognostic factor for recovery of continence after surgery. These two factors could be correlated to each other and this hypothesis is supported by the increase in urethral length observed after sling procedures as bulbourethral composite suspension [7]. Moreover, another type of sling, the retrourethral AdVance one, is described as having a "functional" effect by relocating the membranous urethra with the sphincteric complex proximally. When performing this surgical technique for incontinence that aims to restore membranous urethra position and support, the Authors propose the use of endoscopy in order to confirm sphincter functionality, while using two fingers to elevate the perineum in order to offer support to the sphincter complex (repositioning test) [8]. Interestingly, when PFM was assessed by digital rectal examination and by surface electromyography before retrourethral transobturator sling for incontinence and at 6 months follow-up, weak pelvic floor muscle and greater muscle fatigue were predictors of surgery failure. The concept that this sling relocates the external urethral sphincter and its supporting structure into a pre-prostatectomy position to regain continence is an interesting idea and confirms the double role that rehabilitation should have in regaining both urethral competence and support [9]. A previous work of the same Author in women demonstrated that maximal voluntary contraction strength and resting tone of PF, as measured vaginally and per anus by manometric and electromyographic instruments become higher after reconstructive pelvic floor surgery in women [10], sustaining the concept that "support aids function."

On these bases, indeed, support of the bladder and sphincteric complex could be important for continence, even if not all studies agree about the role of ultrasound or MRI parameters to measure this support and about their value as continence predictors too.

It is also worthwhile to note that, when performing prostatectomy, surgery techniques oriented to early recovery of continence try to reconstruct or reinforce the supporting system of the pelvis.

Rehabilitation aims to ameliorate closure mechanism and to restore this support using pelvic floor muscles [8]. So we can say that rehabilitation and surgery should have the same objectives: to restore both pelvic support and urethral resistance. Pelvic floor exercises should be oriented to reach both these treatment targets.

Training can increase strength, power, endurance of pelvic floor muscles, and neuromuscular facilitation. It was demonstrated in women that, after brief training, voluntary pelvic floor contraction elevates the bladder neck and, after intensive training, bladder neck has been observed to be elevated in functional conditions and also at rest [11, 12].

Rehabilitative approaches show differences in training supervision and training regimes (maximal vs submaximal training, strength and motor relearning training, the use of an adjunct of deep abdominal training, exercises in different positions), but existing evidence is insufficient to make any strong recommendations about the best approach to pelvic floor muscle training in women in terms of strength and duration of contractions, type of training employed, number of contraction, positions, use of ancillary muscles [13]. Similarly, there is no evidence to think that this is not true for rehabilitation in men too.

Training regimes are better described in some studies and just outlined in other works. However, generally the exercise program consists of strength and endurance training in lying, sitting, and standing positions. Moreover, a coordination training, employing the use of pelvic floor contraction in response to a specific situation (usually cough), is often part of the rehabilitative program [6]. In our opinion, the coordination training in men should involve the use of PFM contraction during all activities that are usually associated to leakage, as postural changes like standing up or squatting. Leakages often occur during walking, so the training often involves pelvic floor contraction during this activity; in this case, the use of a low-intensity long duration contraction is important in order to ameliorate the PF tone.

In the absence of any evidence about training regimes, some observations can be done about the rationale that underlies the choice of some therapeutic exercises.

First of all, when teaching how to do a pelvic floor contraction, it is possible to use different cues to instruction. “Close the anal sphincter” is a commonly used instruction, as it is easy to understand and perform, but the patient has a urinary, not an anal continence. So the pelvic floor contraction should be performed in order to elevate and contract the anterior and central compartment (in order to close and support urethra) rather than the posterior one, as shown in Fig. 7.1. Indeed the pelvic floor contraction is an overall movement that involves all pelvic floor fibers, but timing and degree of contraction of different parts of this complex muscular group can be different according to the desired goal of the movement. The brain function is goal oriented and the contraction of the same muscle can be the effect of activation of different cerebral areas, depending on the goal of the action [14].

Therefore, when teaching how to move pelvic floor for training, a greater attention could be paid to its anterior part, even though there is not agreement about this point. When using three different cues to instruction – “squeeze and lift from the front as if stopping the urine flow (anterior contraction),” squeeze and lift from the back as if stopping the escape of wind (posterior contraction),” and “squeeze and lift from the front and the back together” (combined contraction), Crotty et al. [15] found that the posterior or combined cue were more influential on angle of urethral inclination in women. The results of this study should be treated with caution, because an anal contraction could be easier to perform than an anterior contraction in absence of a previous training. On the contrary, a specific training, focusing attention on urethral closure and support rather than on anal squeeze and lifting, could be attractive because urinary continence oriented, but more studies are needed to establish the better movement to train in order to restore urinary continence.

However, there are studies that account for a special interest in exercises that activate the urethral sphincter and the part of the pelvic floor that supports bladder base and urethra, rather than the anal sphincter. In a study, voiding cystourethrography was used before the catheter removal in order to measure the ability to lift the urethra more than 2 mm during a pelvic floor contraction, asking the patient to temporarily stop the urinary flow. Results showed that this ability was correlated with early recovery of urinary control [16].

Additionally, the use of a pre-pubic stretching maneuver to facilitate anterior contraction could improve the urethral closure pressure during a pelvic floor contraction (Kegel pressure) as shown in a little cohort of post-prostatectomy incontinent patients [17]

The existence of a central-anterior and a central-posterior pelvic floor function is also supported by the observation of two types of cough reflex pelvic floor contraction in women: an anorectal lift and an inward clitoral motion that can be differently

Fig. 7.1 Finger position to facilitate pelvic floor contraction to elevate and contract the anterior and central compartment (to close and support urethra).

present or absent. The authors observed that loss of clitoral reflex motion was associated with worse incontinence severity and impact [18].

A recent study supports the use of an "anterior contraction training" by showing that greatest dorsal displacement of the mid-urethra and urinary sphincter activity was achieved with the instruction "shorten the penis." Instruction to "elevate the bladder" induced the greatest increase in abdominal EMG and abdominal pressure. "Tighten around the anus" induced greatest anal sphincter activity [19].

Ultrasounds could also be a good way to teach the right movement. In their study, Patel et al. describe the use of ultrasounds to demonstrate the successful activation for the pelvic floor muscles as 1 cm upward displacement of the bladder base. Then patients were instructed to activate pelvic floor muscles in different functional positions, while carrying out common activities of daily living [20].

When ultrasounds are not available, the use of one or two fingers placed on the perineum between scrotum and anus could be a way to have a feedback about the effectiveness of a pelvic floor contraction in pelvic support.

The need to counterbalance the loss of urethral tone after prostatectomy is a further key point in male rehabilitation. Typically, men complain of leakage during standing and walking. As previously described, exercises based on low intensity, long duration contractions are important to ameliorate the PF tone, as needed during walking. Furthermore, more attention could be paid to the posture that the patient assumes while standing or walking, because it could be linked to a different pelvic floor tone.

Looking at the posture that men assume for micturition, it is possible to observe that hip extension and external rotation, lower abdominal and anterior perineum relaxation, pubis anterior displacement, and center of gravity lowering are all associated with micturition. On the contrary, when stopping urine flow, there is a return to neutral position of the hip, a posterior and superior movement of gravity center that are associated with anterior perineum and transverse abdominis tone recovery.

The idea that more attention should be paid to posture to prevent leakage during standing and walking is supported by the observation that there is higher resting pelvic floor muscles activity in the hypolordotic than in normal and hyperlordotic lumbar position [21]. Another study confirmed that pelvic floor tone is influenced by posture, demonstrating that tall unsupported sitting posture requires greater pelvic floor activity [22].

Little is known about the best type of intervention when comparing PFMT with other treatments. The rehabilitative interventions vary and include PFMT alone, or PFMT plus biofeedback, electrical stimulation with PFMT, and ES, PFMT, and BFB. This variability makes it difficult to have conclusions about the efficacy of rehabilitation and quite impossible to define the role of a single type of intervention versus another. However, according to a recent meta-analysis, based on available evidences, ES-enhanced PFMT does not improve the return to continence more than PFMT in men with post-prostatectomy UI [23].

7.2 Rehabilitation: The Timing

Men's symptoms improve over time in the majority of cases, and the rate of incontinent drops from 80 % at the catheter removal to 10 % or less at 12 months after prostatectomy. So, every approach to post-prostatectomy incontinence should take into account the spontaneous recovery of continence in the majority of men. A cost-benefit point of view is essential when considering incontinence as a sanitary issue that policy should deal with and not only an individual problem.

To this end, three key points become crucial for a correct rehabilitative approach to post-prostatectomy incontinence: effectiveness and timing of rehabilitation (pre- and/or post-surgery treatment) and screening to select patients who could benefit from rehabilitation.

According to a Cochrane review [24], there was no evidence from trials that PFMT with or without BFB was better than control for incontinent men after prostatectomy (*treatment approach*), as the confidence intervals were wide, reflecting uncertainty. The trials differ each other for incontinence definition but overall for number of PFMT sessions (from 1–4 [25] to 24 [26]). The meta-analysis was dominated by the Glazener RP 2011 trial that showed no good evidence to support a one-to one training, in one to four sessions, provided to all men who were incontinent at 6 weeks from the catheter removal, that is to say the large majority or men. We do not know if a more intensive intervention, the use of a more structured training program (using more than two sets of nine contractions for a day and other than only "contract as if holding on to wind") and, finally, a selection of men who most need and could benefit from rehabilitation, could conduct to better results than a population intervention. More researches are needed in this field.

On the contrary, the conservative treatment of all men aimed at *both prevention and treatment* showed a benefit in terms of reduction of UI in two little trials, but the Cochrane review considered the trials of moderate quality [27, 28].

The adjunct of pelvic floor rehabilitation *preoperatively* could reduce the duration and severity of early urinary incontinence within 3 months [20, 29], but this is still under debate, as other authors did not confirmed this benefit [30]. The reason for the discrepancy could be, as underlined by Penson [31], the definition of a good outcome, that was a 0 g urine loss on a 24 h pad test for 3 days [30] or no urinary leakage at bladder diary coupled with an in-office negative stress test [29]. A meta-analysis concludes that additional preoperative PFMT did not improve the rate of re-establishment of continence at 3, 6, or 12 months after surgery, but there are not conclusions regarding the timing to continence or quality of life [32].

A different point of view is offered by a small RCT that analyzed the effect of training sessions for 4 weeks, 30 days before surgery, on histology and function of PF muscles, showing in the treatment group an increase in the cross-sectional area of the muscle fibers of external urethral sphincter and higher pressure contraction of levator ani [33].

Finally, current recommendations by International Consultation on Incontinence conclude that there is suggestion that men undergoing PFMT will achieve continence in a shorter time, but it is uncertain if PFMT can reduce the rate of incontinent men at 12 months or more after surgery. Moreover, evidences about the better timing (after or post-surgery) or number of sessions required are still inconclusive.

It is worthwhile to note that in the majority of trials the rehabilitative intervention is supplied before or in the first months after surgery, while there is a lack of studies about providing rehabilitation to men affected by persistent incontinence, that is to say after 12 months or more from surgery.

According to a Goode et al. study [34], among patients with post-prostatectomy incontinence for at least 1 year, 8 weeks of behavioral therapy, compared with a delayed-treatment control, resulted in fewer incontinence episodes. Mean incontinence episodes decreased from 28 to 13 per week after therapy and the reduction was significantly greater than the reduction from 25 to 21 observed among controls.

A little retrospective study analyzed a population of 51 men suffering from post-prostatectomy incontinence persisting more than 1 year. After an individually tailored rehabilitative training, there was an improvement (at least 50 % reduction in urinary loss at a 72 h pad test) in 57 % of men [35].

The topic of persistent incontinence is very interesting because – while in the first months all men can have a spontaneous recovery (meaning that the risk difference in urinary incontinence rates at 1 year between intervention and control could be low) – incontinence at 1 year is considered stable, so the achievement of positive changes in continence status in men still incontinent is more remarkable. Actually, in the population of persistent incontinent men, it could be easier to appreciate the effectiveness of rehabilitation.

In conclusion, in spite of inconclusive evidences about the effectiveness of conservative treatment in post-prostatectomy incontinence and the better type and timing of intervention, rehabilitation in men is still a hot topic. The reasons for this interest can be found in the high rate of incontinence after surgery, in the impact of incontinence on quality of life in patients who have a good life expectancy, in the opportuneness of waiting for at least 6–12 months before planning surgery for incontinence, quite apart from the fact that many patients refuse surgery. The success of pelvic floor muscle training in incontinent women represents a good example that could be repeated in men. Timing, training regimes, type of intervention, and selection of patients who more need and benefit from rehabilitation should be argument for future research.

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Pharmacologic Therapy

8

Maria Teresa Filocamo

Urinary continence is the result of correct bladder storage and emptying. This mechanism is under the control of the peripheral and central nervous system. In particular, urethral closure comes from innervations of the pudendal nerves, which determine a good functioning of the urethral rhabdosphincter.

Pontine micturition centre (PMC) and pontine storage centre (PSC), while anatomically not interconnected, play with the involvement of the forebrain (anterior cingulate gyrus, preoptic/hypothalamic area and amygdala) and the cerebral cortex (dorsolateral prefrontal cortex), a coordinated central control on both micturition and urinary continence [1].

The excitatory PSC fibres, by glutaminergic neurotransmitters, spread to the sacral motoneurons (nucleus of Onuf) directed to pelvic floor, including both urethral and anal rhabdosphincters, thus resulting in somatic pudendal acetylcholine-releasing nerve/muscle and consequently in a muscle contraction of urethral rhabdosphincter, with increase in urethral pressure (continence circuit).

The PMC activation, instead, via GABA-ergic pathway, projects into the intermediolateral sacral columnae, and where induced, by an inhibitory mechanism, the relaxation of the external urethral sphincter (micturition circuit).

The Onuf's nucleus – placed in the ventral horn of sacral spinal cord (one to three segment) – is a specialized group of motoneurons, resembles a somatic input modality to allow a massive activation of the rhabdosphincter following its fast contraction.

During the storage phase, besides the main action of glutamate on the Onuf's nucleus, the additional contribution of both noradrenaline and serotonin neuromodulators enhances the glutamate-mediated activation of somatic pudendal

M.T. Filocamo
Department of Urology, SS Annunziata Hospital, ASL CN1, Savigliano (CN), Italy
e-mail: mt.fil@libero.it

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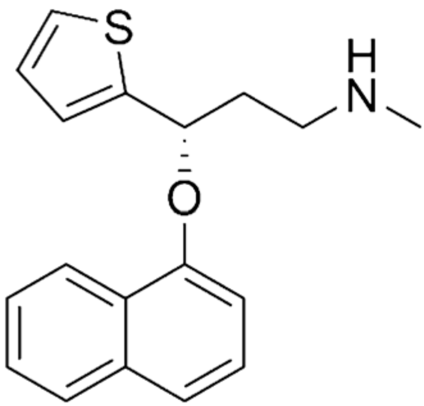
motoneurons that, in turn, induce the acetylcholine-mediated stimulation of the rhabdosphincter receptors, thus allowing a stronger sphincterial response.

The serotonin/noradrenaline reuptake inhibitors (SNRI) at the Onuf's nucleus (presynaptic level of pudendal motoneurons) can cause additional excitatory effect on somatic pudendal motoneurons directed to urethral rhabdosphincter so that the storage reflex is improved particularly in response to sudden increases in bladder pressure (guarding/continence reflex)

The activity of the pudendal nerve is increased by serotoninergic and noradrenergic neurotransmitters in the sacral Onuf nucleus [1].

Duloxetine, a potent serotonine/norepinephrine reuptake inhibitor, has been evaluated in clinical trial programs and proved to be an effective and safe treatment on women with stress urinary incontinence (SUI) [2]. Duloxetine plays a key role in normal urethral sphincter closure increasing rhabdosphincter tone and contraction by stimulating the Onuf nucleus [3].



The efficacy of Duloxetine has been poorly evaluated in the management of male SUI that is most commonly due to iatrogenic insult (after radical prostatectomy or TURP), induced inefficiency of external urethral sphincter.

Urine leakage occurs whenever the urethral resistance, due to rhabdosphincter contraction, is exceeded by an increase of intra-abdominal pressure during physical activities.

In the USA, the Food and Drug Administration has not approved the use of Duloxetine for the treatment of SUI in women because a greater than expected rate of suicide attempts was observed in the open label extensions of controlled studies of Duloxetine for SUI in adult women. Nevertheless, the European Medicines Agency has authorized its use. Currently, there is no pharmacologic treatment approved for SUI in men, either in the USA or in the European Union.

However, an effective drug treatment with acceptable side effects is needed to fill the gap between physical/behavioural therapies and surgical options.

Over the last 9 years many researchers studied the role of Duloxetine in the management of post-prostatectomy SUI.

The first case series date back to 2006, when, for the first time, Schlenker and colleagues tested Duloxetine in 20 patients, 15 after radical prostatectomy and 5 after radical cystectomy and orthotopic ileal neobladder reconstruction, demonstrating a comparable reduction in daily pad use [4].

In the same year, another case series with no control group evaluated the clinical efficacy of 40 mg of Duloxetine daily after radical prostatectomy in 18 patients, with promising results [5].

In 2007, Filocamo et al. conducted the first prospective, randomized controlled study using Duloxetine in combination with pelvic floor muscle training (PFMT) immediately after radical prostatectomy, finding that, after 4 weeks of Duloxetine treatment, 30 % of patients treated with Duloxetine and rehabilitation were dry compared with 11.5 % in the rehabilitation group ($P<0.01$). Nevertheless, after 16 weeks, patients with dual treatment (Duloxetine and pelvic floor muscle training) had a worsening of continence, after suspension of Duloxetine. The authors thought that Duloxetine and rehabilitation had an additional effect with a significant reduction of incontinence episodes with respect to PFMT alone, but at drug suspension the PFMT-only group had a better continence. Probably because patients treated with Duloxetine had less motivation than PFMT-only patients to learn and reproduce an adequate pelvic floor muscle pre-contraction during effort [6].

In 2008, Fink et al. investigated the effect of Duloxetine on men with SUI after prostate surgery; 56 patients were included in this study, 49 after radical prostatectomy and 7 after TURP. All patients were previously treated with pelvic floor exercises. Thereafter 40 mg of Duloxetine was administered twice daily. When taking Duloxetine, the average use of incontinence pads decreased from 3.3 to 1.5 per day, suggesting that Duloxetine is effective in men with SUI after prostate surgery even if standard pelvic floor exercises have failed [7].

In 2011, Collado Serra and colleagues used Duloxetine in a series of patients (68 men) that were affected by stress urinary incontinence 1 year after radical prostatectomy; this choice was made by the authors to avoid interfering with the natural recovery period (established SUI). A significant decrease in the median number of pads used daily by patients after 3 months of treatment was observed ($P<0.001$) [8].

In 2011, Cornu et al. conducted a prospective, randomized, double-blind, controlled trial on 31 patients affected by stress urinary incontinence 1 year after radical prostatectomy. The decrease in incontinence episodes frequency at the end of the study was significantly greater in the Duloxetine group ($P<0.0001$) [9].

Another retrospective study published in 2013 by Neff et al., involving 94 patients after a mean of 19 months from radical prostatectomy, affected by mean to moderate SUI, confirmed the efficacy of Duloxetine (60 mg/day) in reduction of incontinence. Fifty-four percent of the patients reported a >50 % reduction in daily pad usage [10].

Stress urinary incontinence following radical prostatectomy has been described as a major adverse effect reducing quality of life and remains a daily challenge for urologists.

After initial assessment, the first-line treatment is historically non-invasive, based on supervised pelvic floor muscle training. In the case of refractory SUI, more specialized management using invasive options are recommended.

An effective drug treatment with acceptable adverse effect is needed to fill the gap between physical/behavioural therapies and surgical options.

However, even that Duloxetine is a promising medical treatment option for mild to moderate post-prostatectomy incontinence, side effects are common with this drug, and included fatigue, light-headedness, somnolence, insomnia, nausea and dry mouth. Side effects are responsible for 15–31 % of withdrawal [11]. Drug tolerability is an important issue with the use of Duloxetine.

Current literature suggests a potentially valuable tool to add to the limited conservative armamentarium for male patients with post-surgical stress incontinence.

In many studies, Duloxetine showed a facilitative effect on early continence recovery. Moreover, this drug was shown to be complementary to PFMT with a synergic clinical effect demonstrated by a significant reduction of incontinence episodes in post-prostatectomy incontinence, compared with PFMT alone. The studies suggest that combination therapy might increase the percentage of early post-surgery continence and suggest that pharmacologic modulation may improve continence, but its use can be justified in only patients who do not reach an adequate continence with PFMT alone.

So the use of this drug should be considered in the field of post-prostatectomy incontinence management after failure of conservative measures.

Duloxetine could be a pharmacological alternative also when physical or behavioural therapies are insufficient, as well as a useful treatment for patients who want to postpone or delay surgery, especially in cases of mild incontinence. It may besides provide a means to treat patients with incomplete results after minimally invasive therapy, such as sling or balloons.

Nevertheless, the small number of subjects limit the evidence for treatment efficacy, and the interpretation of adverse events.

The present literature, thus, give evidence to introduce a new "pharmacologic" category of efficient management of male SUI after radical prostatectomy.

Because this drug has not been approved for the treatment of stress incontinence in men, and is thus an off-label application at present, the patients must be informed of this fact, and the conversation should be documented in the patient's chart, before any treatment with Duloxetine is begun.

Considering that the therapeutic dose of Duloxetine to treat SUI (40 mg, twice a day) is frequently associated with above-mentioned side effects, it has been shown, in SUI animal models, that the dose may be significantly reduced when such drug is Co-administration could avoid or at least mitigate the Duloxetine-related side effects of Duloxetine on the urethral rhabdosphincter. It follows that, avoiding or at least mitigating the Duloxetine-related side effects [12, 13].

So, efficacious synergistic effects, in SUI animal models, due to co-administration of low-dose Duloxetine and α2-adrenergic blockers, allow to propose such drug combination, as a novel therapeutic measure, to improve the clinical effectiveness of low-dose SNRI in men also for post-prostatectomy SUI Duloxetine depending on intrinsic rhabdosphincter deficiency meanwhile avoiding the Duloxetine side effects [14]. No human experimentation on co-administration of SNRI and *α2-adrenoceptor antagonists* has been carried out for the moment.

In some patients suffering from urge incontinence after radical prostatectomy, anticholinergic treatment is recommended as the first-line treatment for early post-prostatectomy incontinence, within the first 6–12 months.

Lai et al. reported urodynamic findings in a large population of men with incontinence after radical prostatectomy. A total of only 15.8 % of patients had high-pressure bladder dysfunction, such as detrusor overactivity and 17 % had poor compliance, which contributes to the urinary incontinence. Overall treatment demonstrated a significant decrease in pad score for men treated with anticholinergic treatment, and in these patients, the presence of adverse preoperative urodynamic feature does not negatively affect the post-artificial urinary sphincter implantation daily pad use [15].

Duloxetine can improve the urinary continence by inducing, on the one hand, the relaxation of the detrusor muscle, sometimes the association of antimuscarinic drugs or *β*3-adrenoceptor agonist such as mirabegron, when SUI coexists with urge incontinence, and by increasing, on the other hand, the tone of urethral smooth muscle sphincter together with particularly boosting the guarding reflex-related.

Therefore, there is an urgent need for well-designed clinical trials with large series of patients to clarify the role of these new pharmacologic alternatives to manage stress urinary incontinence in men.

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Part IV

Surgical Approach

Functional Devices

9

Jérôme Grall

According to the World Health Organisation definition, incontinence is a non-intentional and bothersome loss of urine from the urethral meatus. As a mostly iatrogenic situation (post-radical prostatectomy in a majority of cases), male incontinence has a significant impact on quality of life [1].

Surgical prostate removal, dealing with very close links between prostate, urinary sphincter and neurovascular bundles, always bears high risks on continence. Disappointingly, open and laparoscopic procedures (including robot assisted), do not make any difference on continence, despite technical accuracy has been much improved over time in the quest for continence preservation.

The great variability of incontinence rates (5–45 % at 1-tear follow-up) might be related to differences in patient evaluation tools, incontinence definitions according to severity, time to follow-up and the actual meaning of "cured patient".

Post-prostatectomy continence improves dramatically over the first 6–12 postoperative months, as the result of natural healing, pharmaceutical treatments or pelvic floor muscles training. Around 5 % of patients eventually seek surgical treatment for their incontinence.

Artificial urinary sphincter, with cure rates ranging from 59 to 91 % [2], is considered as the gold standard. But it is a rather challenging procedure, exposing to complications or reoperations for mechanical dysfunctions. It is also an expensive treatment, requiring patient dexterity and motivation to properly use the device. Despite excellent results, many patients prefer less invasive procedures [3] and among them slings.

Male slings are now the best option beside artificial sphincter. The ideal treatment would be a minimally invasive, outpatient procedure with superior, immediate

J. Grall, MD
Department of Urology, Clinique de FONTAINE, 21121, FONTAINE-LèS-DIJON - France, France
e-mail: grall.j@wanadoo.fr

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and permanent efficacy, no moving parts, no significant voiding obstruction, low cost and minimal morbidity [4]. Research is under way.

But so far overall sling results are not as good as expected; the way slings work and the explanations for failures are not always understood and there is still a need for a better patient selection.

The huge differences in sling results, when comparing incontinence and cure rates, show how difficult it is to have reliable data based on common definitions and how risky it is to compare study results. As a consequence, the reader must be aware of occasional biases when it comes to drawing conclusions from our observations.

9.1 Some History

Back in 1961, Berry made the first surgical attempt to restore continence with a perineal compressive acrylic mesh. Kaufman, in 1972, presented a new design for urethral compression using tetrafluoroethylene mesh and silicone-filled prosthesis in two different techniques, Kaufman I and Kaufman II. Complications (pain, urinary retention, urethral erosion) and poor results made the techniques rather unpopular and led to their end.

Pubourethral slings had their time. They evolved from both old-fashioned female sub-urethral slings and Stamey-like retropubic suspension. Some of these techniques are still used but they have few convincing and significant results [5].

Bone anchored supports subsequently appeared. The Straight-in® bone anchoring system was published in 2001: safe and efficacious at that time (despite short 12.2 months follow-up and non-statistically convincing results) with no perineal pain reported [6]. The most significant was InVance®sling that provided dry rates ranging from 36 to 65 % with 12 % post-void residual urine; but severe complications (perineal pain up to 76 %, infection-related explantations 15 %, bone anchor dislodgments 5 %) drove it off the market to the advantage of transobturator and modern retropubic slings [7].

9.2 From Incontinence Mechanism to Sling Effectiveness

Postoperative incontinence mechanism remains largely unclear. It might have to do with sphincter performance. Urethral dissection and transection during radical prostatectomy, very close to the sphincter muscular and nervous structures, expose to different degrees of sphincter impairment, loss of functional length and drop in closure pressure. But not always urodynamic assessment, prior and after the operation, shows evidence of this mechanism.

Moreover, prostate apical dissection might lead, depending on the technique, to urethra and sphincter mobilisation, resulting in a loss of urethral support and sphincter effectiveness, thus creating stress incontinence.

Slings are thought to restore sphincter function both by repositioning it in its preoperative position and by supporting it to improve its strength. Some urethral compression may also play a part.

As shown by an MRI study of 12 patients before and after sling placement (AdVance®), urethral mobility is not observed in all cases. On cough test, maximum bladder neck movement along the pubococcygeal line ranges from 3 to 7 mm. None of the patients have postoperative urethral mobility, but the lack of preoperative mobility does not appear to be a negative prognostic factor [8]. As a result, urethral and sphincter mobility is not the only incontinence mechanism and therefore urethral repositioning is not the only way slings might act. This study provided interesting images of bulbar support and seemed to rule out any urethral compression.

A quite better continence recovery is observed in patients with urethral length >12 mm (from bladder neck to bulb upper limit) when measured on MRI imaging [9]. But urodynamic evaluation before and after sling insertion (AdVance®) shows no differences but an increase of abdominal leak point pressure (61 ± 14.2 versus 79 ± 20.4 cm of water) [10].

Urethral and periurethral fibrosis, as shown by MRI [9], are among the causes of postoperative incontinence, may be via a limitation of sphincter mobility and elasticity. Surgical dissection of prostatic apex during prostatectomy should preserve urethral stump as much as possible, without taking excessive oncologic risks.

As a conclusion, there is no clinical test nor any precise pathophysiological template on which surgical indication for sling could be based.

9.3 Clinical Evaluation

Incontinence severity in daily practice is measured with a great variety of definitions and tools (questionnaires, pad weight tests, visual analogic scales) making studies rather difficult to compare. Patients are placed in three groups according to incontinence severity: mild, moderate and severe incontinence. But the boundaries of each group are not precisely defined nor commonly shared. Severity is anyway the most important information for selection.

Before sling placement, all the authors agree on checking for urethral or bladder neck stricture, overactive bladder, previous pelvis radiation, infection, that all appear to be total or relative contraindications.

9.4 Is Urodynamic Assessment Useful?

Urodynamics is not routinely performed, out of clinical studies, for stress urinary incontinence assessment before sling placement. Detrusor overactivity is commonly associated with urgency. Intrinsic sphincter deficiency is related to incontinence severity: the weaker the sphincter, the more the incontinence. Dysuria and urethral stenosis are best explored with uroflowmetry and cystoscopy.

All studies on urodynamics are of limited significance because postoperative investigations are uncommon and the collected data are of different kinds and not easy to compare.

It has been written that no adverse preoperative urodynamic parameter is associated with postoperative outcome [10]. The negative prognostic value of incontinence severity on functional result is thus an indication that residual sphincter function (retrograde leak point pressure RLPP or pressure profile) might not be the only explanation for incontinence severity. Data from pre- and postoperative urodynamics [11] indicate modifications in mean urethral closure pressure and functional length, without reaching statistical significance due to the reduced number of patients. Another way to assess sphincter function relies on visible sphincter activity on cystoscopy [2].

Whereas it is a common advice to prefer a good sphincter residual function before sling placement, one cannot find any indication on sphincter pressure threshold for good prognosis. Urethral closure pressure represents the sum of all forces (muscular and elastic) aimed at getting the urethra closed, not only the sphincter.

Patients with bladder impaired contractility for voiding and who void with abdominal straining could benefit from perineal sling without risk of retention if they have preoperative complete emptying [12].

Even taking into account the statistical limitation, when comparing "compressive" slings with AdVance® "repositioning" sling, it appears that the consequences of both slings in terms of sphincteric profile (pression and length) are very similar. Urethral and sphincter repositioning in their normal pre-prostatectomy position, as claimed for AdVance® sling, might not be the only mechanism of action. On the contrary, the efficacy of so-called compressive slings can be obtained without any voiding obstruction and with improved closure pressure and sphincter functional length. Moreover, urinary retention occurs in 15 % of cases after AdVance® insertion indicating that some urethral compression is likely to be associated with the so-called non-compressive slings. I-STOP TOMS® sling, which provides excellent functional results, was never associated with any postoperative urinary retention despite its supposed compressive effect. May be the actual mechanism for explaining these findings is the restoration of pelvic floor in both kinds of slings, driving transobturator compressive and repositioning slings differences back to clinically insignificant philosophical discussions.

The real point is to clearly individualise the preoperative patient's characteristics for prognosis. Patient selection is paramount. Urodynamical findings are only a part of the answer and in many ways not necessary for accurate selection.

9.5 Different Kinds of Slings

9.5.1 Adjustable Slings

Adjustable slings are designed in the same way as retropubic slings. They can be considered an evolution from them with the aim of improving the results by allowing postoperative adjustment. Devices are complex, made of different materials (among them silicone) and they bear a greater risk of complications than the straightforward polypropylene mesh.

They are part of contemporary management of post-prostatectomy incontinence [7].

9.5.1.1 Argus®

(Promedón, Córdoba, Argentina)

Argus® device features a silicone cushion placed underneath the bulbar urethra (Fig. 9.1), two retropubic silicone columns with multiple cone structure and two silicone rings/washers running on the columns and resting on the rectus fascia for tension adjustment [1].

Surgical procedure: In lithotomy position, a perineal incision exposes bulbar urethra. A transverse suprapubic incision exposes enough rectus fascia bilaterally to accommodate silicone rings.

A 90° crochet needle is inserted through perineal membrane between bulbar urethra and ischiopubic bone. The silicone column is pulled upward. The same is done on the other side. The cushion is then positioned around the bulbar urethra.

Cystoscopy checks for bladder integrity.

The tension is adjusted by positioning rings along the columns, as to obtain a RLPP of 45 cm of water (water dripping stops while cystoscopy shows bulbar urethral closure).

Silicone columns are left crosswise deep under suprapubic fat.

Revision for tension adjustment is offered to any patient with persistent stress urinary incontinence. Through suprapubic incision, the rings are pushed over one or two cones along the columns bilaterally to increase RLPP up to 55 cm of water.

Argus® success rate at 27 months follow-up is a hopeful 83 %, including improved and cured patients. Whereas 32 % of patients took advantage of tension adjustment up to 3 times [1], the success rate is higher in case of mild incontinence (92 %) than moderate and severe (67 %). But strict dry rate is only 62 % for mild, 44 % for moderate and 28 % for severe incontinence. The worst prognostic factor appears to be

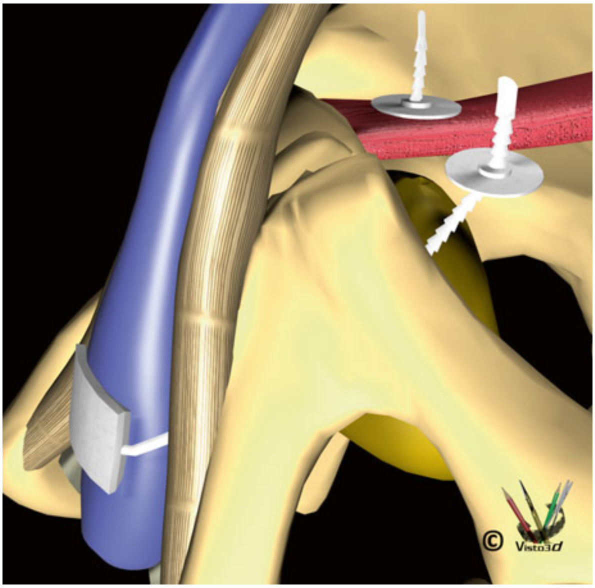

Fig. 9.1 Argus® sling

external radiation for prostate cancer with a poor 15 % success rate [1]. Urethral stricture and bladder neck surgery are also associated with poor prognosis [7].

Complications following Argus placement are as frequent as 55 %, particularly in cases of severe incontinence. They range from urinary retention (16 %), infection, bladder or urethral erosion, to sling rupture, urethral stricture and perineal hypersensitivity and pain, leading to 11 % sling removal.

Argus® experiences are not homogeneous. If some data suggest roughly similar cure rates up to 79 % with 38.6 % readjustment (but 15 % perineal pain and up to 12 % explantations) [7], others are completely different. Some authors consider Argus as highly effective even in radiated patients (54 % dry, 36 % improved). The results raise concerns about the frequent occurrence of postoperative perineal pain (38 %) [13]. Patient selection, learning curve and surgical skills should be taken into consideration when trying to explain such huge differences.

9.5.1.2 Remeex®

(Male Readjustable System® (MRS). Neomedic International, Barcelona, Spain)

Remeex® is an adjustable device featuring monofilament suburethral sling (3 per 4 cm), two retropubic monofilament tension threads and a suprapubic subcutaneous regulation part called "Varitensor" [14]. External manipulator and uncoupler allow for adjustment (Fig. 9.2).

Surgical technique: Vertical perineal incision is made under spinal anaesthesia. Urethra, surrounded by bulbocavernous muscles, is carefully dissected. Urogenital diaphragmatic fascia is sharply penetrated close to the pubic bone and upward dissection is done digitally until reaching rectal muscle fascia and the suprapubic

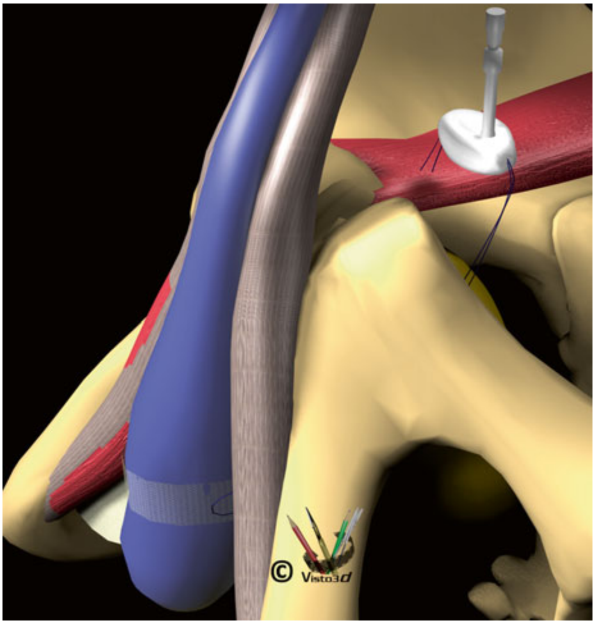

Fig. 9.2 Remeex® sling

transverse incision. The same is done on the other side. Cystoscopy checks for bladder integrity.

The threads are then pulled upward to be secured into the Varitensor. The external manipulator is left connected to the Varitensor via the uncoupler through suprapubic incision.

The morning after tension adjustment is done on the standing patient while performing Valsalva manoeuvre by rotating external manipulator clockwise or counterclockwise. A second adjustment could be done later under local anaesthesia and minimal skin incision [14].

Introduced in the early 2000s, Remeex® provided rather good results in terms of cure rates (64.7 % dry, 19.6 % improved), the majority of patients being submitted to adjustment in the early postoperative period. Among complications are 9.8 % bladder perforation, some device infection leading to explantation of the Variator and perineal pain that resolved under oral medication.

Remeex® and Argus® have comparable results, with necessity of readjustment, 11 % bladder injury and 12 % explantation due to infection [7].

9.5.1.3 ATOMS®

ATOMS® device features an inflatable cushion placed under the bulbar urethra and stabilised with transobturator arms. A subcutaneous abdominal port allows for cushion adjustment by saline injection. So far no reliable data have been found to supporting this technique [15].

One must consider that adjustable sling is an option with acceptable results comparing to artificial sphincter in cases of mild or moderate incontinence but adverse events such as perineal pain and sling removal are likely to occur. Previous radiotherapy should be considered a relative contraindication.

9.5.2 Transobturator Slings

Transobturator slings are currently the most important and used among male perineal slings. Due to its early introduction in the market back in 2005, AdVance® sling, which has been modified into AdVanceXP® in 2010, is by far the most frequently encountered in the literature. This considerable amount of information is of great help when it comes to studying results, mechanisms of action and complications. But, as it has been highlighted for adjustable slings, not all the results are similar, surgical practice is not homogeneous and comparisons are often risky. It is thus impossible to translate particular results from a single study into common rules for comprehensive sling indications and placement. As a recall of the challenging understanding of pathophysiology of incontinence and sling action we bear in mind, the overwhelming presence of AdVance® on the urological scene must not hide the availability of other slings of great interest that might add to our knowledge and help drive surgical practice towards straightforward and safer procedures.

Transobturator sling in men was first published in 2007. The well-known female TOT technique seemed to be interesting even in men, whereas incontinence mechanism is certainly different (sphincter deficiency is a very poor prognostic factor for TOT). In a 20-patient clinical study, it appeared for the first time that supporting the urethra could lead to an increase in urethral closure pressure from 13 to 86 cm of water, and in urethral length from 3 to 17 mm. Despite much less convincing results were to come, sling design was aimed since the very beginning to supporting urethra and sphincter in order to lengthen and strengthen the functional area [16].

9.5.2.1 Advance and Advance XP

(American Medical Systems: Minnetonka, Minnesota, USA)

AdVance® is a polypropylene sling with two transobturator arms protected with Tyvek liners. Its particular retro urethral position around the proximal bulb makes it support and reposition both urethra and sphincter into their pre-prostatectomy position. Intraoperative urethral pressure measurement allows accurate sling tensioning. A profound kinking on proximal urethral bulb with no direct compression on urethra marks good sling placement [17] (Fig. 9.3).

In the first long-term results publication [18], the overall success rate at 3-year follow-up is 75.7 % including dry and improved patients (with no indication of continence definition, but success appreciation is based on daily pad use). Cure rate at 3 years shifts from 58.6 % in case of mild or moderate incontinence to 42.3 % in case of severe incontinence. Failure rate jumps from 18.2 to 32.7 % respectively. At that time, radiotherapy history seemed to have no impact on results.

Complications occur mostly in the early postoperative stage with mainly dysuria (9 % retention) and perineal pain for up to 6 months. Subsequently, results seem to remain stable over time.

The authors stress on the sling mechanism of action: the sling placed retro- and sub-urethrally around the proximal bulb acts as a support to the distal sphincteric urethra, as a hammock, with no direct compression over urethra. Urodynamic data

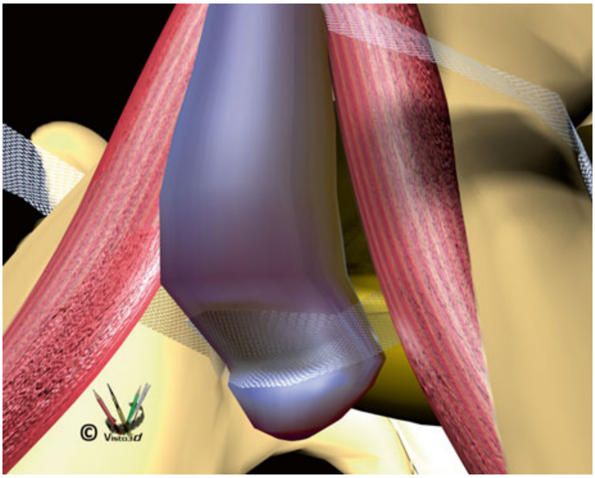

Fig. 9.3 AdVance® sling

show no difference following sling placement neither in urethral pressure nor in uroflow.

Advance® evolved into Advance XP® in late 2010 [19]. Overtensioning of the sling, when removing the Tyvek liners, had been responsible for urinary retention. Modifications were thus designed to secure sling release and anchor it in obturator membrane. The results of a multicentre prospective study at 12 months follow-up show a 67.7 % cure rate and an increase in quality of life. It is a good result, as a matter of fact, but it must be observed that cure rate includes residual urine loss up to 5 g per day, and an incontinence reduction > 50 % was classified as improvement.

In a comparative non-randomized study, AdVance® and AdVanceXP® were evaluated. They provide the same results in terms of success rate with less complications for AdVanceXP® [20, 21].

Efficacy and stability over time were to be associated with AdVance® since the very beginning, spreading the technique all around the world. A number of experiences were subsequently published that show rather different opinions. At an average of 36 months of follow-up after AdVance® implantation, it has been observed a steady decline in cure rate: 40 % cured and 22 % improved [22]. This retrospective review of a prospective database of 102 patients indicates preoperative pad count and detrusor overactivity as negative risk factors. Amazingly 35 % of those patients used more than 5 pads per day, indicating a rather severe incontinence which negatively predicts outcomes [23]. Preoperative selection is of great importance if we want to meet patient expectations.

It is interesting though to observe that, in some single centre experiences, results are not as good as hoped. In a study independent from the originator of the technique, the cure rate at 1 year is only 9 %, with 45 % improved and 36 % with no effect at all or a worsening of incontinence in 14 % of cases [24] putting into question AdVance® ability to cure incontinence.

There is above all a discrepancy between objective and subjective results as exposed by the patients that highlights the dramatic improvement of quality of life whenever postoperative pad use remains rather high with 1–2 pads per day [25]. Patients reporting success a 7 month follow-up experienced an increase of pad use over time (+0.9 at 2 years) without any significant modification of subjective result [26].

It could also be argued that the surgeon must be very careful in respecting the original implantation technique in terms of sling placement and tensioning, but results might indicate that there is a learning curve indeed and that in this kind of functional surgery, outcomes are somewhat surgeon related [24].

Complications

Complications are rare and they occur in the early postoperative period: sling explantation and infection are among the most severe and urinary retention the lightest. Urinary retention is a pretty common complication (up to 46 %) and resolves spontaneously. Data show that retention, despite a bothering postoperative period, could be a positive factor for incontinence cure as 100 % of patients experiencing retention will eventually be cured [27].

Cause of Failure: Slippage

The explanation for delayed failures after an initial dry period might be related to sling slippage as they could occur immediately after an increase of physical activity within a month of sling placement.

Among the reasons for sling failure are most probably inappropriate indication, misplacement or sling “slippage” [28]. MRI, which has been tested as a tool for assessing sling placement, can help to understand the way sling works in restoring continence. T2-weighted sequence with a 3 T MRI is able to differentiate the sling from the hyper-intense urethral bulb. AdVance® accurate placement is associated with deep indentation on proximal bulb, behind membranous urethra, hence displacing upward and forward the urethral and sphincteric complex [28] (Fig. 9.3).

Ultrasound assessment constantly shows sling presence and demonstrates the urethra dynamic compression by AdVance® during Valsalva manoeuvre. Sling is located at the level of inferior border of symphysis pubis in continent patients and more distally in still incontinent patients. Urethral compression is less important with AdVanceXP® and is not observed in incontinent patients [29].

It is likely to be a difference between *technical failure,* in which sling is malpositioned, and *true failure,* in which sling positioning is correct thus indicating a possible sphincter deficiency [17] out of reach for sling action. The normal kinking pattern is not seen in case of technical failure, sling being placed distally in the perineum or proximally and too close to the urethra (possibly as a result of postoperative slippage). Some patients reporting worsened incontinence have a paradoxical opening of the urethra on Valsalva test. Stable sling placement around the bulb with stitches is mandatory.

Recurrent Incontinence

Contrary to prior InVance [30], AdVance® removal is not necessary for artificial sphincter implantation after sling failure. It appears to be a safe procedure [31]. The cuff is placed around the bulbar urethra, distal to the sling. The sling is always left in place. The operation is no more challenging than the primary implantation and results are the same as for naïve patients [32].

9.5.2.2 I Stop TOMS®

(CL Medical, Sainte Foy lès Lyon, France)

I Stop TOMS® is a polypropylene monofilament nonextensible sling with a 2.8 cm central part (22 mm width) placed underneath the bulbo cavernous muscles and bulbar urethra. Two, and subsequently four transobturator arms, bring tension and stabilize the device (Fig. 9.4).

Dissection through perineal incision is minimal and the arms are inserted through an out-in transobturator route [33]. Tension adjustment is achieved by pulling anterior and posterior arms as to obtain a light and homogeneous compression over the bulbocavernous muscles without any string effect. Six stitches secure sling to muscles and corpus cavernous.

This perineal suburethral sling acts as a moderate compressive urethral support [34]. Preliminary report showed encouraging results on mild and moderate incontinence with cure or improvement, but no failure and no urinary retention.

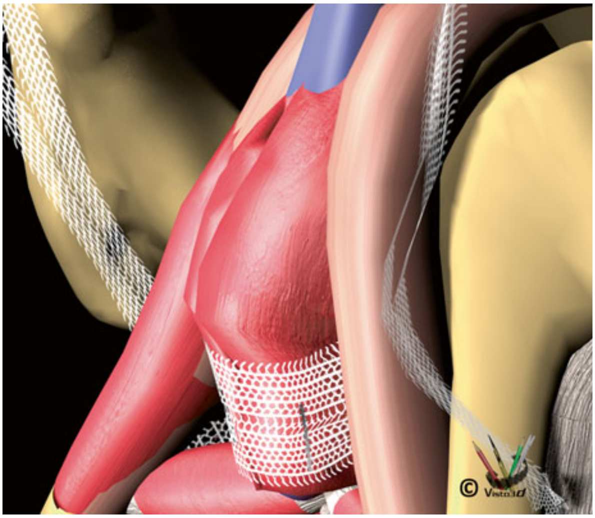

Fig. 9.4 I Stop TOMS® sling

At 1-year follow-up, cure rate (0 pad) is 59.4 % and overall improvement is 87 %; 13 % patients have no improvement. All selected patients have mild or moderate incontinence and no history of radiation. The procedure is safe with very few complications: no urinary retention, no severe perineal pain (mean 2.7 on VAS in early postoperative stage), wound infection is very rare [33]. Interestingly for a "compressive" sling, maximum urinary flow rates are similar before and after surgery. These results are very close to those of AdVance® at 1-year follow-up, with less postoperative complications and show a trend toward superiority when used in difficult cases with urethral damage [35].

Continence rates interpretation in a multicentre study [33] is not straightforward despite homogeneous continence definitions; even with common selection criteria, marked differences in cure rates from one centre to another are observed. This highlights the fact that functional surgery is rather surgeon related.

Continence rate remains stable at 2 year follow-up in a single centre study, 57 % patients being cured and overall 90 % experiencing improvement (0 or 1 pad per day) [36] which compares positively with artificial sphincter.

The promising I-STOP TOMS® achieves adequate suburethral support to obtain good continence without causing obstruction or other adverse events.

9.5.2.3 Transobturator Sling Derived from Gynemesh PS®

(Ethicon, Johnson & Johnson, USA)

A new transobturator male sling is inserted on an inside out basis, with no complication except three suprapubic catheterizations [37]. At 2-year follow-up, 50 % of patients are pad-free and 33 % improved, leading to a subjective satisfaction rate of 72 % [38]. Unfortunately, 25 % failures occur after the first postoperative year. The explanation might be some kind of urethral atrophy or could be related to comorbidities such as previous radiotherapy or bladder neck surgery. In this study, incontinence severity does not seem to be linked to functional result, but obesity is clearly a negative prognostic factor.

9.5.2.4 Quadratic Slings with Four Arms

Transobturator slings currently available are the result of continuous research to simultaneously reach two main goals: high incontinence cure rate and few complications. Combining these targets proves to be rather challenging, as supporting urethra and improving sphincter function is not possible without minimal urethral compression.

Transobturator route is safe and reproducible, as female surgery has been demonstrating since 2001; but male surgery does not leave much degree of liberty to surgeon as perineal anatomy is compelling and the vicinity of complex structures (bulb, urethra, corpus cavernous, vessels and bone) imposes its law. The impossibility to modify transobturator route makes impossible to completely avoid posterior slippage, string effect and compression with the regular 20 mm width sling. Thus, the quest for another design achieving better stability, larger compression area on urethra and no string effect: the four-arm design was born, featuring two additional prepubic arms. Better clinical results remained to be seen in daily practice.

Quadratic Virtue® sling (Coloplast Corporation, Minneapolis, Minnesota, USA) has been presented for the first time in 2011 [39]. The consequence of the new design is an increase of urethral compression which is measured intraoperatively with RLPP. According to published data, mean RLPP jumps from 33 cm of water to 68 cm of water. Overcorrection or excessive urethral compression could increase urinary retention rates: Disappointingly Virtue® studies provide very few information in terms of dysuria and retention.

Considering the poor results in the first trial [40], technique has been modified in order to stabilize tension and prevent postoperative sling loosening. Additional sutures were performed to corpus cavernous and pubic periosteum. After a median

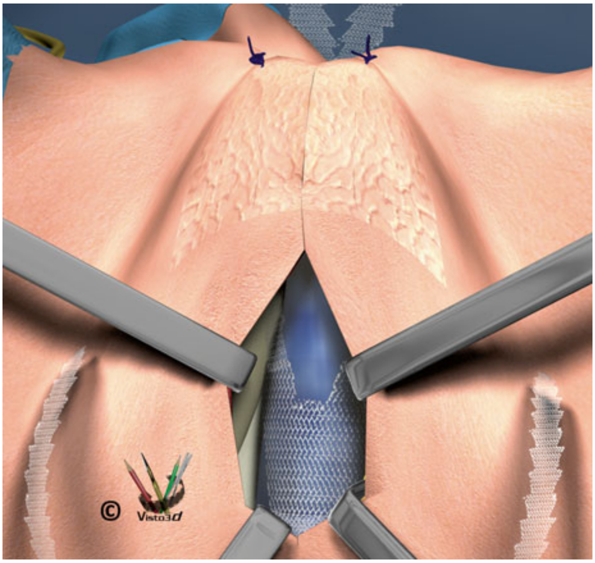

Fig. 9.5 Quadratic Aspide® sling

follow-up of 22 months, continence rate is 45 % with the modified technique (versus 7 % with standard one) while complications are frequent: 63 % postoperative retention and 45 % perineal pain [41].

The same process has been applied to another quadratic sling, Aspide® Male Sling (Aspide Medical, Saint Etienne, France) (Fig. 9.5).

For the time being, quadratic slings have not produced what they were meant to. Follow-up is still short and no conclusion can be drawn from the available data.

9.6 Indications

Sling results could be discouraging if only 45 % of patients reported satisfactory result on their incontinence-related bother [42].

Artificial sphincter is considered as the gold standard. Opposite to it are slings, easier to use, more "friendly", but with less efficacy in some conditions. Identifying such conditions is at the core of selection process: it is not an easy task, considering confusing data exposed above.

Preoperative incontinence severity is among the most significant prognostic factors for success after whatever sling insertion [43]. A patient with a 400 g 24-h pad weight has 80 % lower chance to be cured with AdVance® than another with only 200 g 24-h pad weight. Compared to the overall 51.6 %, the cure rate in case of 24-h pad weight over 200 g is only 28.5 % [44, 45]. Failure rates as high as 78 % could be associated with severe incontinence [46]. Whereas urodynamics is not routinely recommended, urethral pressure of less than 57 cm of water is associated with a sixfold increase in failure risk.

Incontinence severity appears in all the published data as the cornerstone of accurate indication. Severe incontinence is constantly associated with poor efficacy with any sling. Mild and moderate incontinence, with good residual sphincter function, are the best indications for sling. But there is still a lack of standardized and widely accepted definitions. The "repositioning test" could help in clinically selecting those cases; it consists, during flexible cystoscopy, in assessing sphincter closure with or without manual repositioning of the urethra. A wide open urethra, without visible sphincter function, is definitely a bad indication.

Patient expectations are very high as, first of all, they ask to be cured by any technique. But failure rate is related to a variety of criteria that must be carefully examined preoperatively [47, 48]. They could drive medical decision towards different technical options that the patients are not always prepared to accept.

The same could be said about previous radiotherapy. In that case, patients are at risk of failure (60 %) and should be informed and counselled [19]. After radiation, the repositioning effect, as theory states for sling efficacy, might not work [49]. Radiotherapy induced sphincter deficiency, loss of mobility and elasticity are clearly highlighted, not to mention the length of urethral "coaptive" zone. Due to reduced number of patients, there is no statistical validation though. But failure could be associated with a worsening of incontinence which is a very bothering outcome for a patient who has been offered surgery for quality of life. Almost 43 % of radiated patients are actually worse after surgery compared with 3 % of non-radiated patients [50, 51]. Sling use must be very cautious in this indication.

In a retrospective review of medical records after AdVance® placement, two groups were considered [2]:

Ideal patients: Mild to moderate incontinence, less than 4 pads a day or less than 300 g urine loss, intact appearing urinary sphincter on cystoscopy, without segmental defect; no previous history of pelvis radiation or cryotherapy, no previous surgery for incontinence, urethral or bladder neck stricture, no overactive bladder. Volitional detrusor contraction when voiding and post void residual <100 ml.
No ideal patients: Majority of them for severe incontinence.

Results are poorer in the no ideal group than in the former. Despite an improvement of continence after severe preoperative incontinence, patient satisfaction is low (30 %) [2].

Worst prognosis men should be oriented toward artificial sphincter in order to avoid as much as possible two-stage anti-incontinence surgery [52]. But success is not guaranteed when following best indication criteria [31]. On the contrary, sling implantation on a "no ideal" patient is not a guarantee for failure. This inconsistency shows how difficult it is to understand the true reasons for incontinence and how we lack of clinical reliable tests. But it is also a limitation to the advice the patient awaits: Whenever artificial sphincter should be the best indication, it is acceptable to place a sling on a single motivated patient refusing hydraulic device, provided that he has been fully informed about his negative prognostic characteristics.

Patient selection is almost as important as surgical technique in achieving satisfactory result and relief for the patient. Careful patient selection is part of the learning curve. This is the condition to keep slings in the armamentarium for male incontinence surgery.

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10 Constrictive Devices

Vincenzo Li Marzi, Chiara Cini, Sergio Serni,
and Giulio Del Popolo

10.1 Introduction

The normal voiding cycle requires that the urinary bladder and the sphincter work as a coordinated unit. The urinary bladder has two functions: it relaxes to store urine (storage or filling phase) and it contracts to empty bladder (voiding phase). During filling phase, the bladder is a low-pressure reservoir. During voiding, the detrusor contracts and internal and external sphincters relax to void completely the bladder. The urinary sphincter has two functions: it contracts to store urine and it relaxes to eliminate urine. During urinary storage, the urinary sphincter remains closed to prevent urine loss. At the beginning of the voiding phase, the urinary sphincter opens to allow a complete bladder emptying. Intrinsic sphincter dysfunction (ISD) is a serious damage of sphincter function that can cause a stress urinary incontinence (SUI), whereby the urethra remains always open, with a possible continuous urinary leakage. Risk factors for ISD in men include radical prostatectomy (RD), transurethral resection of the prostate (TURP), previous bladder neck or urethral surgeries, pelvic radiation, pelvic trauma, and neurologic disorders. Patients with ISD report the classic history of SUI. The most common complaint of patients is involuntary urine loss when changing their body position, i.e., from sitting to standing position. They experience loss of urine whenever the bladder pressure exceeds that of the urethral pressure, i.e., when coughing, sneezing, or performing the Valsalva maneuver.

Male SUI surgical approach includes three common different solutions. (A) Bulking agents implant: several substances have been used including bovine

V. Li Marzi (✉) • C. Cini • S. Serni
Department of Urology, Careggi University Hospital, Florence, Italy
e-mail: vlimarzi@hotmail.com

G. Del Popolo
Neurourology, Careggi University Hospital, Florence, Italy

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collagen, and silicone macroparticles injected into the urethra which augment the urethral wall, increasing resistance to urinary flow. All agents share similar problems including the need for multiple injections, deterioration of effect over time, and low cure rates. A limit of this procedure is that it may induce bladder outlet obstruction (BOO) with increasing post-micturition residual urine. The short-term duration and low-rate efficacy have led the International Consultation on Incontinence (ICI) in 2009 to exclude bulking agents from male incontinence specialized management algorithm, contrary to what was reported in the previous ICI 2005 edition [1]. (B) The male sling procedure is based on the theory of passive urethral external compression along the ventral surface [2]. In the intermediate term, promising results are reported regarding different types of male slings. The best candidates are patients with mild and moderate degree of incontinence, who have not had previous radiation (see Grall's Chap. 9). (C) The artificial urinary sphincter (AUS) consists of an inflatable cuff around the bulbar urethra attached to a control pump placed inside the scrotum and a silicone pressure–regulating balloon (PRB), allowing for urethral compression and voiding, respectively. A biological urinary sphincter prevents urinary flow via mucosal coaptation, compression, and pressure transmission. An AUS mimics the biological urinary sphincter by providing a competent bladder outlet with closed distal sphincter during urinary storage and an open outlet with a relaxed sphincter during voluntary voiding. In recent years, new devices have been developed in an effort to keep the good success rates and improve some disadvantages of AUS 800 (high cost, complications, and relatively difficult insertion) [3].

The indications to implant a constrictive device in men with SUI include post-prostatectomy incontinence (PPI) after radical prostatectomy, simple prostatectomy, or transurethral resection of the prostate (TURP). SUI post-radical prostatectomy is the most common indication. Constrictive devices implant should be deferred for at least 6 months after prostatectomy; most urologists defer surgery at least 1 year because patients often may improve urinary continence during this time. Other less frequent indications are represented by neurogenic SUI due to underactive sphincter dysfunction and/or bladder neck incompetence, such as in myelomeningocele or patients with spinal cord injury (SCI).

Despite the growing emergence of promising mini-invasive surgical treatments for male SUI such as urethral slings, re-adjustable continence devices, and required future stem cells therapy, AUS is still the "gold standard" treatment for SUI in men over the last 40 years. Different indications mean different problems to take into consideration in neurogenic or in patients who underwent bladder reconstruction (or augmentation); bladder function abnormalities or need of intermittent catheterization must be evaluated carefully to choose the safer and efficacious surgical solution.

10.2 Artificial Urinary Sphincter

Introduced in 1972, the AUS has emerged as the gold standard treatment for male SUI (persistent, moderate, and severe) secondary to ISD [4]. The AUS has demonstrated long-term efficacy and durability [3, 5–7]. During the next 40 years, the design of new devices and new components were introduced (narrow-back cuff in 1987), and surgical approaches changed (transcorporeal and/or transscrotal approaches introduced in the 2000s). It is currently estimated that about 150,000 patients worldwide have been implanted with an AUS [8].

The AUS 800 (AMS800, Minnetonka, MN, USA) (Fig. 10.1) represents the gold standard not only of PPI treatment but also of refractory SUI in general for both sexes. It is composed of a pressure-regulating balloon, an inflatable cuff, and a control pump. The balloon has a double function as a pressure regulator and a fluid reservoir. Balloon reservoirs come in three preset pressures: 51–60, 61–70, and 71–80 cmH_2O. The lowest pressure required to close the urethra is used. Balloon reservoirs are typically placed in the lower abdomen. For uncomplicated bulbar urethral cuffs, the most commonly chosen balloon reservoir is the one with preset pressures of 61–70 cmH_2O. For bladder neck cuffs, the balloon reservoirs with pressures of 61–70 and 71–80 cmH_2O are chosen because higher pressures are necessary to occlude the bladder neck [9]. The inflatable cuff has a variable length that compresses the urethra or the bladder neck circumferentially. Cuff sizes range from 3.5 to 11 cm, in 0.5 cm increments. The cuff is placed around the bulbar urethra in adult males. The cuff size is based on the circumference of the bladder neck or the bulbar urethra. A properly sized cuff for the bulbar urethra ranges from 3.5 to 5.5 cm in length. Most commonly, a 4.0 cm cuff is chosen for adult males. The control

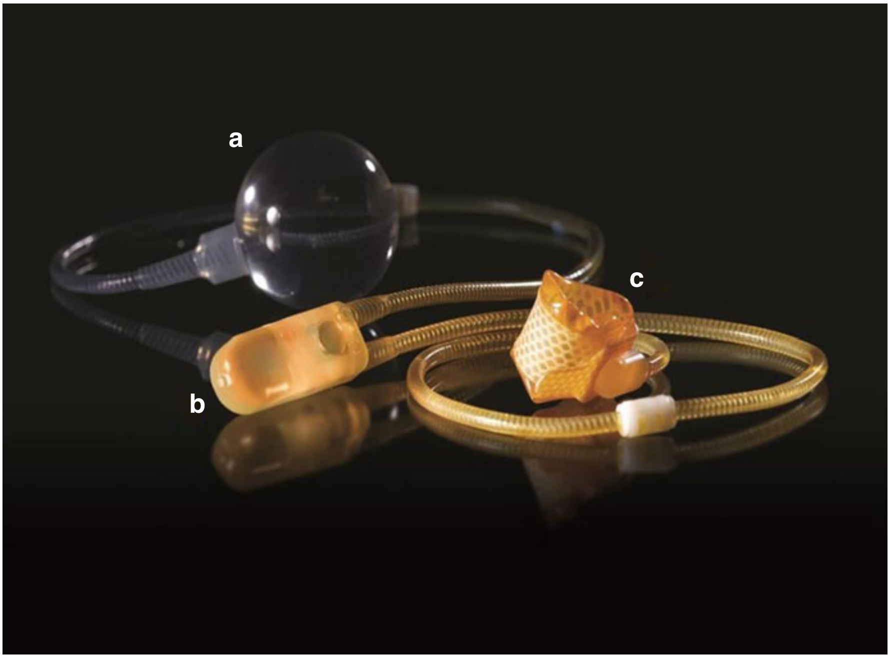

Fig. 10.1 Artificial urinary sphincter AMS 800. (**a**) Pressure-regulating balloon, (**b**) Control pump, (**c**) Inflatable cuff

pump contains unidirectional valves, a delayed-fill resistor, a locking mechanism, and a deflate pump. The control pump is small and easily concealed within a subcutaneous or dartos pouch in the scrotum (or the labia in female). The delayed-fill resistor is responsible for automatic cuff refilling. The cuff inflation takes from 3 to 5 min, although bladder emptying takes less time. A unique feature of this model is the locking mechanism that can keep the cuff deflated for a prolonged period. The locking mechanism is a small button located on the side of the control pump.

The AUS accounts for approximately 12 % of incontinence procedures performed by urologists in the United States, a rate that has been stable in the last 10 years [10]. For severe SUI, the AUS is the only tried and tested device providing consistent results. The first reported objective cure rate was 100 % [2], to date an early satisfactory continence in 95 % of adult patients is described [11]. Efficacy and satisfaction rates are high as long as patients have a working AUS in place [12]. The lack of a uniform definition of incontinence and definition of cure and the reliable use of more objective tools (e.g., standardized pad testing) prevent the estimation of cure rate after AUS implantation from the current literature. In recent systematic review about long-term outcomes after AUS implantation in male patients, dry or improved rates were calculated as 79 % (ranging from 61 to 100 %), while dry rates varied from 4.3 to 85.7 % [13]. While this is an evidence to the quality of the AUS, it raises concerns with regards to patient selection and surgical complications.

10.2.1 Timing of Intervention and Patient Selection

There are no clear data on timing of intervention for the surgical treatment of male SUI, either with benign or malignant disease. A certain period of watchful waiting supplemented with conservative measures, particularly pelvic floor muscle training (PFMT), seems to be a reasonable option. Thus, conservative management may be tried for periods of up to 6–12 months depending on whether there is any progress noted by the patient [14]. Van Kampen et al. have been shown that Kegel's exercises of the pelvic floor muscles are useful to hasten the return to continence [15]. Filocamo et al. in 2005 reported results of a randomized trial that demonstrated improvement of continence with PFMT at 6 months compared to control (94.6 % versus 65 %, $p \leq 0.001$). Although this difference is statistically significant, it decreased in the subsequent year (98.7 % versus 88 %) and was no longer significant [16]. For these reasons, it is important to understand if there was a recovery of continence. Surgery must not be performed until all conservative measures have not been tried and is necessary to establish the degree (number of pads per day and pad weight) and the kind of incontinence (stress and stress-predominant) with a meticulous clinical history and urodynamic assessment.

Before surgical treatment is recommended, basic evaluation including history, physical examination, urinalysis, and post-void residual urine should be performed. Patients should undergo a genitourinary examination and be assessed as to their physical and mental capacity to function an AUS device. It is important to review the etiology and duration of incontinence, prior genitourinary pathology (nephrolithiasis or non muscle-invasive bladder cancer), urinary tract infection, the degree and subjective difficulty of incontinence. A frequency-volume chart or bladder diary (indicating daytime and nighttime frequency of micturition, incontinence episodes, voided volumes, 24 h urinary output, etc.) is also helpful [14]. Blood testing (BUN, creatinine, glucose) is recommended only if compromised renal function is suspected or if polyuria (in the absence of diuretics) is documented by the frequency–volume chart; urine cytology if there is a suspect of urothelial carcinoma [17].

Further evaluation should be adapted to the particular patient. Urethrocystoscopy is useful to verify the integrity of the urethral wall (anterior aspect of the distal sphincteric mechanism in post-transurethral resection of the prostate incontinence, voluntary contraction of the pelvic floor, etc.) and the status of the bladder (trabeculation, stone, diverticula, etc.) [18].

Contrast studies include voiding cystourethrography which may demonstrate an open bladder neck, when bladder denervation is suspected (e.g., following abdomino-perineal resection of the rectum), vesico-ureteral reflux, and bladder diverticula [19]. Grade 2 or higher vesico-ureteral reflux resulted on voiding cystourethrography should be corrected before placement of the artificial urinary sphincter because the sphincter can exacerbate the reflux.

Ultrasound is widely used to evaluate not only the upper urinary tract but also the post-void residual urine. Many studies support the utility of urodynamic testing prior to surgery to detect factors that could limit surgical success even if it is known that the incontinence after RP is secondary to ISD [20]. However, some investigators questioned the value of urodynamics in predicting outcomes after surgery. Thiel et al. analyzed data from 86 patients to determine if urodynamic or clinical parameters can predict AUS outcome in patients who were incontinent after RP [21]. The presence of detrusor overactivity (DO) ($p=0.92$), low first sensation ($p=0.52$), low bladder compliance ($p=0.38$), and bladder capacity less than 300 mL ($p=0.58$) in patients did not predict for AUS failure compared to patients without these findings, but in some cases it could be a risk factor for renal damage after AUS implantation. No clinical parameters were found that demonstrated a statistical association with the number of pads per day. Older patients tended to have decreased perceived improvement. The authors found no clinical or urodynamic parameter that would be a contraindication to AUS placement for post-RP incontinence. Patients with detrusor overactivity (DO) present clinical mixed incontinence. There are controversies about which one should be treated first – DO or ISD. We suggest treating DO first. Otherwise, in a review of post-prostatectomy patients treated with AUS, the authors showed that 29 % of patients with preoperative overactive bladder (OAB) had resolution of their OAB; on the other hand, de novo OAB rate was 23 % [22]. All patients should be treated with concomitant antimuscarinics, in case of persistent DO, sacral neuromodulation or Botulinum toxin intradetrusor injection can be used.

10.2.2 Surgical Technique

During the informed consent, potential complications to placement of the AMS 800 should be discussed. Patients should understand that they will be incontinent during the healing process, until the device is activated (4–8 weeks after surgery). The operating room staff and surgeon should be familiar with the device, the equipment needed, and the surgical steps of the procedure. The surgeon and the operating room staff should observe the prosthesis implantation procedure before surgery. Prophylactic broad-spectrum antibiotics should be administered (usually an aminoglycoside associated to vancomycin). Magera et al. reported that patients who scrubbed preoperatively with 4 % chlorhexidine were four times less likely to experience perineal colonization during surgery [23]. More recently, chlorhexidine-alcohol preparation has been shown to reduce the presence of coagulase-negative Staphylococci from the surgical site better than povidine-iodine in a randomized trial [24].

The standard technique, with the patient placed in the dorsal lithotomy position, comprehends a perineal incision (Fig. 10.2) in order to place the cuff around the bulbar urethra (Figs. 10.3 and 10.4), with a lower abdominal incision to allow the placement of the pressure-regulating balloon and scrotal control pump. To implant the control pump in the scrotum, a subcutaneous or subdartos pouch must be created. The control pump should be placed on the patient's hand-dominant side (Fig. 10.5). A small Foley catheter (14Ch) is recommended for the immediate postoperative period. During the healing process, the cuff must remain locked in an opened position.

Reported variations to this procedure (Table 10.1) include transcorporal placement, transverse scrotal placement, and bladder neck placement [25, 26]. Also a double cuff AMS800 can be implanted instead to a single cuff [27].

Patients with a compromised urethra (prior AUS placement, radiation, urethroplasty, or surgical changes) presenting a higher risk of erosion may benefit from a

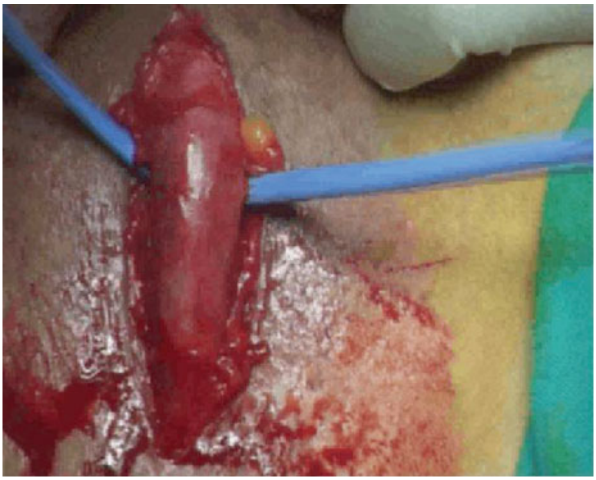

Fig. 10.2 A perineal incision has been made below the scrotum; the bulbar urethra is exposed, and a vessel loop around it is placed

51 to 60 cmH_2O reservoir. In patients with a history of radiation therapy, some authors advocate a transcorporal cuff or double cuff placement (Fig. 10.3) in addition to a lower pressure reservoir [25, 27].

In the transverse scrotal AUS implantation, first described by Wilson et al., a high transverse scrotal incision permits excellent access to the proximal bulbar urethra, retropubic and subdartos spaces. This approach allows the implantation of all the three components through a single incision. In the authors' opinion, this technique affords some advantages over the dual incision perineal approach: it requires only one incision, the implantation can be performed faster than the standard 2- incision approach, and performing the scrotal incision technique with the patient in supine position, the urethra is more mobile to facilitate the posterior dissection [28].

Fig. 10.3 In this case, a 63-year-old man underwent radical prostatectomy and radiotherapy; a double cuff was placed around the bulbar urethra

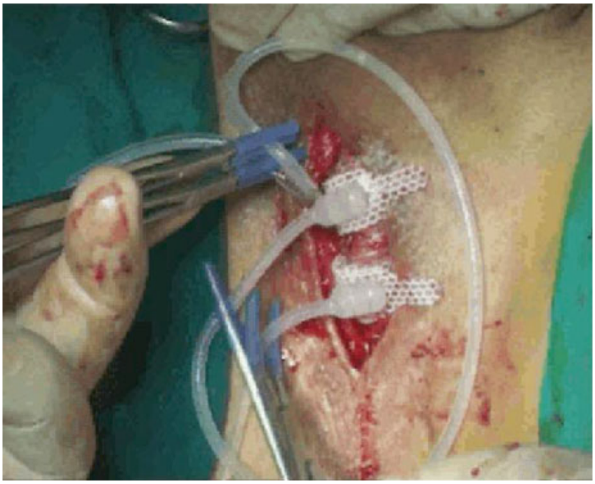

Fig. 10.4 The connections of the cuffs is shown. Afterwards, the tabs of the two cuffs were rotated dorsally

Fig. 10.5 By a perineal incision, a subcutaneous pouch was created to implant the control pump in the scrotum. In this patient with right hand-dominant, the control pump was inserted in the ipsilateral side

Table 10.1 Artificial urinary sphincter implantation techniques: modifications and innovations

Possible approaches	
	Perineal
	Transverse scrotal
	Laparoscopic or robot-assisted[a]
Possible cuff placement	
	Standard (bulbar urethra) single cuff
	Standard (bulbar urethra) double cuff
	Transcorporal
	Bladder neck
Device modifications	
	InhibiZone® (antibiotic-coated AUS)
	Smaller 3.5 cm cuff

[a]In neurogenic male or in female patients

The transcorporal technique consists in augmenting the urethral circumference utilizing a buttress of tunica albuginea from the corpora cavernosa to protect the dorsal urethral wall. First described by Guralnick et al., this technique was employed in patients with a small-caliber urethra or those who have experienced atrophy or fibrosis secondary to previous surgery [25]. In 2008, Aaronson et al. confirmed the safety and the efficacy of the transcorporal approach to AUS placement [29].

Recently, laparoscopic and robot-assisted procedures were introduced; to date, studies are mainly concerning female or neurogenic patients [30–32].

10.2.3 Complications

Complications after AUS placement include infection, erosion, device malfunction, and persistent or recurrent incontinence, which lead to a mean reoperation rate of 26 % (range 14.8–44.8 %) [13].

Device infection is a short-term quite rare complication. It can occur on average 3.7 months after the placement [33]. The clinical features include fever, local tenderness and erythema, and often skin fixation of the AUS components. In this case, it is mandatory to remove the AUS to resolve the infection. A new procedure can be performed only after a period of 3–6 months.

Urethral cuff erosion rates are variable, and the etiology is multifactorial. But lesson learned in time is to implant cuff avoiding a high pressure on the urethra. The patient usually reports voiding difficulty and hematuria. Diagnosis is made by urethrocystoscopy. The management of cuff erosion usually consists of the AUS removal and the placement of a urethral catheter for 3 weeks. A new AUS can be positioned at least 3–6 months after the removal, with a urethrocystoscopy to document the healing of the urethral epithelium [34]. Cystourethrography may be used to demonstrate a fistula, stricture, or urethral diverticulum following healing of the urethral wall erosion caused by the cuff.

Van der Aa et al. identified an average rate of infection and erosion of 8.5 % (range 3.3–27.8 %) after AUS placement [13]. In 2008, an antibiotic-coated version (InhibiZone®, Minocycline, and Rifampin) was introduced to reduce the perioperative infection rate [35]. Otherwise, in a review of 426 consecutive patients, de Cógáin et al. argue that this procedure only adds unnecessary costs [36].

An important cause of urethral erosion is an invasive procedure (also the catheterization). The avoidance of these interventions and a better prior knowledge of the device may reduce this complication. In case of infection, the entire device should be removed and another AUS can be implanted after 3–6 months. In case of erosions, it is necessary to place the urethral catheter for 3 weeks to allow the healing of the urethra [37]. Linder et al. compared the outcomes of primary AUS implantations with those of salvage cases (previous AUS removal). Despite the salvage cases resulted in an increased risk of infection or erosion requiring the device's removal (6.4 % versus 19 %, $p = 0.002$), there was no statistically significant difference in reoperation rate (17.5 % versus 25 %, $p = 0.17$) or 5-year device survival (68 % versus 76 %, $p = 0.38$) [38].

Device malfunction rate range from 2 to 13.8 % and increases with the life of the AUS. Almost 50 % of AUS devices fail after 10 years. This failure mostly occurs 11–68 months after implantation. Device failure generally presents with sudden onset of recurrent urinary incontinence. The management depends on how long the AUS has been in place. It can be necessary to replace the entire AUS if the original is older than 2 years [13]. Urethrocystoscopy should be performed to exclude erosion, anastomotic stricture, or other pathology. Urethral atrophy should also be included in this group of complications. Mechanical failure or recurrent urinary incontinence due to urethral atrophy usually leads to entire device or specific malfunctioning component replacement. This complication affects about 40 % of patients undergoing AUS device's surgical revision. In 2010, a smaller AUS cuff was introduced in order to improve continence in patients with spongiosal atrophy. Simhan et al. in 2014 reported an improved survival rate of 4.0 cm cuff after the introduction of 3.5 cm cuff ($p < 0.05$). In authors' opinion, this suggests that precise cuff sizing appears to be advantageous in men with urethral atrophy [39]. The same author reported that cuff erosion is rare in nonirradiated men (4 %, $p = 0.01$).

Radiation therapy is the only significant risk factor associated with 3.5 cm cuff erosion (OR 6.2, 95 % CI 1.3e29.5) [40]. McGeady et al. reported that AUS placement in patients with a compromised urethra by prior AUS placement, radiation, or urethroplasty is associated with a high risk of failure. In this study, an increased risk of failure was observed after 3.5 cm cuff placement (HR 8.62; 95 % CI 2.82, 26.36) but not with transcorporal placement (HR 1.21; 95 % CI 0.49, 2.99) [41]. The first report about the double cuff AMS 800 placement is the one by Kowalczyk et al. in 1996. They reviewed data of 95 patients with SUI after RP to assess the safety and efficacy of this procedure [42]. DiMarco et al. reported their experience using tandem cuff (double cuff) as a salvage procedure following failed primary sphincter placement with 88 % patient satisfaction and advice tandem cuff in the difficult setting of urethral atrophy or previous radiation therapy [27].

An empty reservoir is a possible cause of device malfunction. An ultrasound scan can be helpful in determining if the reservoir is filled with the correct quantity of fluid. A reservoir empty requires the replacement of the entire device [43]. In the case of a full reservoir cuff downsizing, double cuff placement, transcorporal cuff placement, or a higher pressure reservoir have all been used to improve new onset urinary incontinence. Appropriate component selection, particularly cuff size, is extremely important in preventing residual urinary incontinence and reoperation. These technical elements are related to surgeon experience [44].

Recurrent symptoms can be due to *anastomotic stricture*. This complication can be managed by a transurethral approach with a holmium laser incision of the stricture [45]. Otherwise, the AUS cuff can be dropped and urethrotomy or contracture resection can be performed.

In patients with recurrent symptoms suggestive of *urge incontinence*, pharmacological treatment is indicated. Urge incontinence refractory to antimuscarinic drugs can be managed with injecting Botulinum toxin type A, or with sacral neuromodulation. It is important to be careful during the setting of transurethral injection of Botulinum toxin because of the risk of erosion with endoscopic instrumentation.

Beta 3 agonists have recently been introduced in the market. These drugs could have a role in the treatment of wet overactive bladder (OAB) and also in patients with AUS. Currently, these drugs have demonstrated their efficacy in OAB patients with lower side effects (dry mouth) and lower incidence of post-micturition residual of urine. But, to date, no trials of Mirabregon have been reported in elderly and neurogenic patients with urge incontinence [46].

Surgeon skills play a fundamental role because the technique is easy, but must be accurate and meticulous. Clinical outcomes appear to be very conditioned by surgical experience, with a learning curve of more than 200 cases, which represents a challenge for urologists not working in high-volume institutions [47].

Although a lot of modifications have been made to the AUS to provide better urinary continence and to improve device's safety, nearly a third of the patients with AUS require device revision within 5 years yet [39]. The AUS provides satisfactory long-term functional results for more than 10 years in men with SUI (Table 10.2). As expected, the device needs revision after 5–10 years. However, it is worth noting that more than 70 % of the men remained continent in the long term [47].

Table 10.2 The AMS 800 urinary sphincter feature

Advantages
Long-term data available
Treats all degrees of incontinence
Treats patients with previous radiotherapy
Disadvantages
Infection
Erosion
Device malfunction
Contraindications
Chronic urinary tract infections
Permanent obstructed urinary tract
Refractory detrusor overactivity
Urethral diverticulum at the probable cuff site
Unstable bladder neck contracture

10.2.4 SUI and Erectile Dysfunction

In patients with erectile dysfunction and SUI, the placement of an inflatable penile prosthesis with an AUS in a single procedure has been reported to better restore organ function. Segal et al. retrospectively compared 55 combined placements with 336 single penile prosthesis and 279 single AUS placements. There were no significant differences in rates of infection, erosion, or malfunction, although there was an increase in surgical time [48].

10.2.5 Artificial Urinary Sphincter in Male Neurogenic SUI

Neurogenic stress incontinence is a difficult condition to manage; patients with adequate bladder capacity, compliance, and low sphincteric resistance are ideal candidates for surgical procedures [49]. The AUS device has improved the quality of life of patients with neurogenic bladder dysfunction, mainly those with spina bifida [50, 51].

Fewer data are available in the literature about AUS implantation in traumatic SCI patients. Among patients with neurogenic bladder dysfunction due to spinal cord lesions, dexterity and mobility are frequently impaired, and the management of the AUS mechanical device can be very difficult. The cost of prosthesis and the risk of infection or erosion, resulting in removal, limited the widespread acceptance of the AUS as the gold standard in adult neurogenic patients. The revision rate in this population ranged from 16 to 60 % [49].

In 2009, Bersch et al. reported, in a retrospective study, the success and revision rates of a modified positioning of AUS at the bladder neck using a modified prosthesis comprising an intraperitoneal pressure-regulating balloon and instead of a pump, a port that can be punctured to control the pressure in the system. They analyzed patients with SUI due to neurogenic bladder dysfunction (51 consecutive patients including 37 with spinal cord injury; 37 were male and 14 were female). These patients were evaluated by video-urodynamics before and after the AUS positioning. The mean follow-up was of 95.9 months. A total of 70.6 % of the patients were objectively and subjectively healed. In authors' opinion, the proposed modification proved to be highly successful, reliable, safe, and even more cost-effective compared to the original AMS AUS [52].

Yates et al. describe for the first time the technique of robot-assisted artificial urinary sphincter (R-AUS) insertion in male patients with neurogenic SUI. Since January 2011, six men with neurogenic sphincter weakness incontinence have undergone bladder neck R-AUS (AMS800) placement. A transperitoneal five-port approach was used using a three-arm standard da Vinci® robot (Intuitive Surgical, Sunnyvale, CA, USA) in a 30° reverse Trendelenburg position. The AUS cuff was placed circumferentially around the bladder neck, the reservoir was left intra-abdominally in a lateral bladder space, and the pump was placed in a classic scrotal position. The median operating time was 195 min. The sizes of the cuff were 7.5 and 8 cm. At a median follow up of 13 months, all six patients had a functioning device with complete continence [30]. In terms of AUS insertion, a pure laparoscopic approach is technically challenging and the dissection of Retzius' space, particularly in patients with previous incontinence surgery, is difficult. The inherent attributes of robot-assisted surgery (precise dissection, three-dimensional high-definition vision, maneuverability in tight spaces, and suturing) substantially decreased the complexity of minimally invasive AUS insertion.

In a recent systematic review concerning surgical treatment of neurogenic SUI, 30 studies were identified. Farag et al. analyzed the current evidence of neurogenic SUI treatment using less-invasive surgical modalities. These 30 studies included 849 patients (525 males, 324 females) with a median age of 21 years (range 3–80). The etiology of neurogenic SUI was spinal dysraphism in 578 (69 %) patients, SCI in 191 (22 %) patients, and other causes in 80 (9 %) patients. None of these studies followed a randomized controlled trial design. The surgical procedures considered were AUS device, urethral slings, urethral bulking agents, and ProACT device. AUS was considered more successful than urethral bulking agents (77 ± 15 % versus 27 ± 20 %, $p = 0.002$). Urethral bulking agents reported higher failures than urethral sling procedures (49 ± 16 % versus 21 ± 19 %, $p = 0.016$) and AUS (21 ± 19 % versus 10 ± 11 %, $p < 0.002$). A ProACT device was implanted in 37 cases (13 males, 24 females) and this single study was excluded from final statistics. The analysis revealed an overall success rate of 64 % in a median follow-up of 48 months (range 12–62). This is substantially lower than most series of surgical procedures in non-neurogenic patients. The complication (20 %) and reoperation rates are higher than in non-neurogenic patient groups. In authors' opinion, surgery for neurogenic SUI has relatively high success rates but also high complication rates in this highly heterogeneous population [53].

More studies using modern techniques are required to update our knowledge.

10.3 Adjustable Balloons (ProACT Device)

The adjustable balloon procedure relies on passive compression of the urethra by two balloons located on either side of the urethra. The biomaterial ACT™ (Adjustable Continence Therapy) was originally conceived and developed for female SUI and subsequently was applied to male incontinence. The implantation is performed through a perineal incision with fluoroscopic and urethroscopic guidance. The balloons are filled with 2 ml of isotonic sterile water and contrast medium. At 1 month and thereafter, the balloons are refilled with 1 ml increments of this solution (maximum filling is 8 ml) until continence is achieved. Appropriate candidates are those with mild-to-moderate leakage and no previous radiation.

The introduction of the hand-guided transrectal ultrasound technique by Gregori et al. decreased the intraoperative and early rates of complications as a result of the more precise device placement with ultrasound guidance [54]. Both techniques allow for the identification of generic anatomic landmarks but no measurable and reproducible referral points for the implantation. Crivellaro et al. presented a device called the "stepper," which would enable an easier placement freeing both hands for manipulation of the ProACT trocar during implantation and allow visualization of fixed referral points. This system is based on preoperative ultrasound measurement that reported on the skin and on the instrumentation allowing the operator to plan and perform an extremely precise implantation. They show that the introduction of a geometrical stepper-guided navigation system to implant ProACT under transrectal ultrasound control allowed us to reach the same continence rate as reported in the literature (70 versus 62–67 %) with a lower intraoperative, early (4.7 % compared with 7.8–12.8 %) and late complication rate (4.7 % compared with 11.0–27.4 %). Importantly, a lower mean balloon volume and number of adjustments (3.1 versus 3.2–4.6 ml and 2.6 versus 3.1–4.3) could be achieved using this technique [55]. The benefit of an adjustable system should be weighed against the need for multiple sessions of refilling the balloon, and the reported rate of peri- and postoperative complications. The most common perioperative complications are urethral or bladder perforation. Temporary urinary retention is reported at 5 %, treated by removing fluid from the balloon [56]. Other complications are represented by infection, erosion of balloons, migration, and balloon deflation. Nevertheless, the ProACT device represents an efficacious treatment modality, with acceptable complication rate, improving incontinence and quality of life, for a difficult group of patients [57].

A recent study compares the efficacy of ProACT and bone anchored male sling (BAMS) to assess the effect on urinary leakage and the impact on quality of life. The authors analyzed 80 consecutive, nonrandomized men who had undergone either ProACT ($n = 44$) or BAMS ($n = 36$) for PPI persisting despite conservative measures (pharmacotherapy or Kegel's exercises). The results showed that the overall efficacy of both procedures is satisfactory and comparable (68 % dry in ProACT versus 64 % dry in BAMS, $p > 0.05$). The ProACT has a good efficacy even in the most severe incontinence probably because of adjustability features. After stratification of results between mild (one to two pads) and severe (more than three pads) preoperative incontinence, ProACT results seem to be better for moderate-to-severe incontinence and BAMS for mild incontinence. The operation time of ProACT is shorter (18 versus 45 min, $p < 0.05$) but complication rate was higher (13 % versus 5 %, $p > 0.05$) [58].

The ProACT balloon technique appears to be a feasible procedure in the short-to-medium-term follow-up based on literature reported outcome. Long-term follow-up results are needed.

10.4 FlowSecure TM (RBM_Med)

Currently, the AUS is the only mechanical device that simulates best the function of a biological urinary sphincter. Nevertheless, it has two downsides: it is very expensive and requires activation of the scrotal pump to urinate.

The FlowSecure device is a prosthesis for the management of SUI designed and developed by Craggs M.D. and Mundy A.R. at London's Institute of Urology and Nephrology, in 2006. This new AUS device addresses two major weaknesses of the AMS 800: the inability of the pressure-regulating balloon to adapt to changes in intra-abdominal and bladder pressures and the need for revising surgery after cuff atrophy [59].

The FlowSecure device consists of a single unit, eliminating the need for tubing connections. The patient is able without the need to use his hands to activate the control pump. This one-piece, silicone device comes prefilled with 30 ml of 0.9 % saline and comprises four parts connected together by silicone connecting tubes: a pressure-regulating balloon (PRB), a stress-release balloon, a circular occluding urethral cuff, and a control pump [60]. The stress-release balloon is placed extraperitoneally and transmits intra-abdominal pressure changes to the urethral cuff to increase the occlusion pressure during periods of stress. The PRB creates a basal occlusive pressure. The regulating pressure is adjusted in the range of 0 to 80 cmH_2O and can be changed by the injection or removal of fluid (based on continence status) from the device in situ. This avoids the need to select a specific pressure range before the surgery.

The advantages of the FlowSecure device over AMS 800 are represented by a single-unit system with no connecting tubing for implantation, a lower cuff pressure with pressure adjustment in situ, and a stress-release mechanism that provides a low basal occlusion pressure and a conditional occlusion of the urethra depending on changes in intra-abdominal pressure.

Both perineal and suprapubic access are needed for prosthesis implantation. Pressure-regulating and stress-release reservoirs are lodged in Retzius space through the suprapubic incision. The cuff is placed through the perineal incision around the bulbar urethra as it is designed to transmit direct pressure over the urethra. By blunt dissection, a space is created between the two incisions to pass the tubing, as well as a subcutaneous space in the scrotum where control pump is placed. FlowSecure is accompanied by a plastic trocar and its obturator, which allows transposition of urethral cuff between Retzius space and perineum, and a tube of glue for temporary fixation of the belt over the cuff when adjusting it [61].

The early report on the outcomes of this device was encouraging for the decrease in mean daily leakage volume (770.6–55.1 ml) and an overall improvement in the continence index (54–97 %), but recent publication of larger series showed high mechanical failure (6 %) and infection (5 %) rates, as well as risk of pump assembly perforation (9 %) in the short- to intermediate-term follow-up [62].

However, more time and studies will be needed to define the role of this sphincter in the management of male stress incontinence.

10.5 Periurethral Constrictor (Silimed: Rio de Janeiro, Brazil)

Periurethral constrictor is a minimally invasive, adjustable, low-cost device which consists of two silicone components: a cuff and a self-sealing valve, connected by a tube [63]. The cuff is designed to allow for adjustment around the proximal urethra. A silicone tube links the self-sealing valve to the cuff. The injection of sterile saline solution in the self-sealing valve partially occludes the proximal urethra, increasing the outlet pressure. It is relatively cheap when compared with the artificial sphincter. It is easy to implant and it has been used successfully in the treatment of severe stress incontinence.

The cuff is placed through a mini-perineal incision around the proximal urethra and the valve in the scrotum. Four weeks after the surgical intervention, the valve is filled with 2 ml of sterile saline solution to activate the occlusive mechanism. Introini et al. tested the constrictor in a series of 62 patients with severe incontinence, including difficult cases that were previously submitted to radiotherapy and/or repeated urethrotomy with urethral stent. One year after implantation, continence was relieved in 58/62 (94 %) of the patients. Forty-nine patients (79 %) achieved a complete (dry) daytime and nighttime continence. The procedure failed in eight patients (12 %). Four patients remained incontinent after activation of the cuff and four patients underwent device removal. Even if larger series and longer follow-up are needed to confirm safety and test durability, periurethral constrictor improved continence in most patients [64].

Periurethral constrictor has a low cost, it is easier to implant and allows spontaneous voiding, as well as intermittent catheterization, without the need of pump control. Based on the literature evidences, more studies are needed to assess the long-term safety and efficacy.

10.6 ZSI 375 (ZEPHYR Surgical Implants, Swiss-French)

ZEPHYR Surgical Implants 375 (Mayor Group, Villeurbanne, France) is another one-piece, silicone elastomer urinary continence device developed to facilitate AUS implantation. It is made of two components: a circular urethral cuff available in different diameters (3.75–5 cm) and pressure ranges (60–100 cmH_2O) and a pressure-regulating reservoir placed in the scrotum. The reservoir consists of an activation button, hydraulic circuit, and a compensation pouch. At rest, a piston mechanism under tension exerts pressure on the fluid in the hydraulic chamber. When the activation button is pressed, the piston descends pushing the fluid from the cuff into the hydraulic circuit and compensation chamber, with auto-inflation of the cuff [59].

An interesting feature of the ZSI 375 device is the absence of an abdominal reservoir. This reduces the operating time and allows avoiding abdominal incision and dissection in scarred retroperitoneum. In addition, the risk of air in the tube and of filling fluid leakage into the tube is lower. Staerman et al. retrospectively analyzed 36 consecutive patients who underwent ZSI 375 placement between May 2009 and April 2011 for moderate-to-severe stress urinary incontinence after RP, TURP, or bladder replacement [65]. The implantation procedure was carried out under general anesthesia with the patient in the lithotomy position with a perineal incision for cuff placement and a scrotal incision for pump and tank placement. After setting the closure-pressure range, the pump unit was placed in the scrotal pouch. Pressure could be increased in situ by trans-scrotal injection of saline into the pouch. The mean hospital stay was 3 days and the median follow-up was 15.4 months. The device was activated 8 weeks later by pushing the activation button. At 3 and 6 months after implantation, 28 (78 %) and 26 (73 %) of the 36 patients, respectively, used zero or just one pad per day. Preliminary efficacy results were highly similar to those for the AMS 800. Total continence, as evaluated by pad use, was achieved in three-fourth patients using the ZSI 375 and was stable over 12 months. Continence was improved in further 11 % of patients [66].

The ZSI 375 was designed to simplify artificial sphincter implantation because of the long learning curve needed to manage the procedure and the complications. The complications and the revision rates in ZSI 375 device are similar to those of AMS 800 prosthesis, otherwise the ZSI 375 is still not widely used.

Conclusions

Over decades, the male urinary incontinence has been an unsolved issue in functional urology field. At the end of the second millennium, artificial sphincter was the gold standard treatment and it was the only therapeutic option, as well. In the last decade, we have definitely ruled out the urethral bulking for lack of efficacy in men with SUI. Whereas, new techniques, such as slings and additional constrictive devices, have been developed in the last decade. Today, slings documented a limited evidence in terms of safety and efficacy in selected male patients with no previous radiotherapy and mild or medium stress incontinence (Table 10.3). Newly introduced devices, artificial sphincters, or other constrictors

Table 10.3 AUS versus male sling

	AUS	Sling
Severe SUI		
Mild/moderate SUI	–	
Previous radiotherapy		
Need for recurrent cystoscopy[a]		
Lack of manual ability, dementia, etc.		

 Contra  Pros

[a]For example, urinary stones, non muscle-invasive bladder cancer

need long-term trials to better define their roles in the therapeutic algorithm (Table 10.4). It is worth underlining that neurogenic and iatrogenic SUI are different worlds with the need of different approach and timing of treatment anyway. Recently, in the treatment of neurogenic SUI, changes of AMS 800 as well as variations in the surgical approach were observed. The modified prosthesis, as Bersch's variation, and the changes in the surgical approach, such as the cuff at the bladder neck with laparoscopic approach [30, 52], can represent solutions for an unsolved problem that involves new less-invasive techniques. To date it requires adequate prospective trials to assess the efficacy, safety, and patient tolerance [76].

Three pivots of a successful treatment are the adequate indication, the adequate instrumentation, and adequate surgeon's skills. Moreover, it is extremely important monitoring the results in the medium and long-term to ensure the therapeutic success and the best impact on patient's quality of life.

What we have already known is that artificial sphincter and slings are an effective solution and new surgical options are developing. What we still need to know is whether the new devices might ensure the same or better long-term efficacy and safety as the artificial sphincter. The real future goal is not to regain but to maintain continence.

Table 10.4 Some literature reports about constrictive devices for male SUI

Author (year)	Device	Pts	Severe SUI (%)	Dry (%)	Improved (%)	Infection (%)	Erosion (%)	Device malfunction (%)
Perez (1992) [67]	AMS 800	75	100	52	33	0	5.3	35
Montague (1992) [68]	AMS 800	166	–	75.3	10.8	1	6	0
Litwwiller (1996) [69]	AMS 800	50	90	20	55	–	–	0
Haab (1997) [70]	AMS 800	68	7.5	80	20	0	7.4	44
Mottet (1998) [71]	AMS 800	103	100	89	7	6	6	10
Gomes (2000) [72]	AMS 800	30	–	–	–	3.3	3.3	6.6
Montague (2001) [73]	AMS 800	113	82	32	64	0	0	12
Gousse (2001) [12]	AMS 800	131	25	59	15	1.4	4	0
Gomha (2002) [74]	AMS 800	86	14	63	23	4.8	3.6	3.6
Imamoglu (2005) [6]	AMS 800	45	–	86	10	–	–	0
Lai (2007) [33]	AMS 800	270	62	69	9	5.5	6	6
Gulpinar (2013) [75]	AMS 800	56	100	46	19.2	7.1	8.9	25
Staerman (2012) [65]	ZSI 375 device	36	–	73	–	8.3	2.7	0
Schiavini (2010) [63]	Periurethral constrictor	30	100	73.3	–	10	13	0
Introini (2012) [64]	Periurethral constrictor	66	–	79	15	3	3	0

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Treatment Algorithm and Recommendations

11

Gabriele Gaziev and Enrico Finazzi Agrò

Despite the prevalence of urinary incontinence (UI) and lower urinary tract symptoms (LUTS) in older men, the only group that has received much attention in research is men following prostate surgery.

The primary conservative treatment for males affected by UI remains physical therapies with or without some form of biofeedback (BF). Pelvic floor muscle training (PFMT), along with anal electrical stimulation (EStim), BF or transcutaneous electrical nerve stimulation (TENS), magnetic stimulation (MStim) and even pharmaceuticals have all been utilised and reported as modestly successful in some trials and not in others.

11.1 Evidence and Recommendations for Conservative Treatment

A basic evaluation includes history, pad testing, bladder diary and physical examination; since most of the surgeries apply to patients with incontinence after other operations or trauma, other investigations, such as imaging of the lower urinary tract, cystoscopy and urodynamic studies may provide important information for the treating clinician.

A basic history and physical examination is the cornerstone of the evaluation. The history should focus on the precipitating events (surgery, trauma, etc.) that led to the incontinence, the evolution over time of the leakage symptoms (has there been improvement, etc.), what precipitates the leakage (straining, cough,

G. Gaziev • E. Finazzi Agrò (✉)
Department of Experimental Medicine and Surgery, Tor Vergata University Hospital, Rome, Italy
e-mail:efinazzi@tin.it

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exercise, etc. – suggestive of stress urinary incontinence (SUI) or the sudden onset of urgency, the sense of needing to void immediately, particularly in the absence of any physical activity – suggestive of urgency incontinence) as well as other potential comorbidities (recurrent UTI, previous pelvic radiotherapy) which should be investigated with further instruments. A general sense of the degree of bother of these symptoms, sexual function and pad use is important as well. The physical examination should note any gross urine leakage per meatus with patient straining or coughing as well as general characteristics of the lower abdomen, perineal area and penis and scrotum. Assessment of hand function is important to assess manual dexterity for manipulation of an implanted device. A brief neuro-urological examination (perineal sensation, anal tone, voluntary contraction and relaxation of the anal sphincter, bulbocavernosus reflex) should be performed.

A urinalysis to rule out infection or signs of inflammation or hematuria should be obtained.

A bladder diary (indicating daytime and nighttime frequency of micturition, incontinence episodes, voided volumes, 24 h urinary output, etc.) for at least 7 days is also helpful.

A pad test quantifies the severity of incontinence and may be the most objective measure of the incontinence.

Questionnaires, such as the ICIQ-SF (short form) questionnaire, can be recommended for the assessment of the man's incontinence.

Postvoid residual urine measurement is a good estimation of voiding efficiency. These basic investigations are recommended in incontinent males prior to surgical therapy.

Once the initial assessment is done, the first approach of treatment for male SUI is the conservative treatment which should be performed for at least 6–12 months.

The goals of conservative treatment are lifestyle intervention and physical therapies with PFMT alone or in combination with BF or EStim/MStim.

Overall, the effect of conservative treatment (lifestyle interventions, physical therapies, complementary therapies) for men has received much less research attention compared to women.

11.1.1 Lifestyle Interventions

E. Examples of lifestyle factors that may be associated with incontinence include obesity, smoking, level of physical activity and diet. Most of these factors are associated primarily with female UI, but it is useful to recommend a better lifestyle also to men suffering of UI. Modification of these factors in general may improve UI (*Level of Evidence*: *3–4*) [1].

R. It seems reasonable for health professionals to offer men advice on healthy lifestyle choices that may reduce or delay the onset comorbid conditions that are risk factors for incontinence (*Grade of Recommendation*: *NR*).

11.1.2 Physical Therapies

Different types of physical therapies could be applied to treat male stress UI, starting with PFMT which could be performed alone or in combination with other techniques (biofeedback, electrical stimulation).

11.1.2.1 Pelvic Floor Muscle Training (PFMT)

E. PFMT does not cure UI in men post prostatectomy. There is conflicting evidence as to whether PFMT speeds the recovery of continence following radical prostatectomy but the literature has shown some pre-operative or immediate post-operative instruction in PFMT for men undergoing radical prostatectomy may be helpful (*Level of Evidence*: *1b*) [2].

There is no evidence that pre-operative PFMT prevents UI following radical prostatectomy though it may lead to earlier recovery of continence (*Level of Evidence*: *2*).

R. Offer instruction on PFMT to men undergoing radical prostatectomy to speed recovery of incontinence (*Grade of Recommendation*: *B*).

11.1.2.2 Biofeedback (BF)

E. The addition of biofeedback and pelvic floor electrical stimulation did not result in greater effectiveness. There is conflicting evidence on whether the addition of biofeedback increases the effectiveness of PFMT alone (*Level of Evidence*: *2*) [3, 4].

R. The use of BF to assist PFMT is currently a therapist/patient decision based on economics and preference (*Grade of Recommendation*: *B*).

11.1.2.3 Electrical Stimulation (EStim) and Magnetic Stimulation (MStim)

E. In adults with UI, there is inconsistent evidence whether EStim is effective in improving UI compared to sham treatment or adds any benefit to PFMT alone (*Level of Evidence*: *1*). The same is for MStim. After radical prostatectomy, it is not known if pre- or post-operative EStim or MStim has a role in reducing UI [5, 6].

R. For men with post-prostatectomy incontinence, there does not appear to be any benefit of adding EStim to a PFMT programme (*Grade of Recommendation*: *B*).

11.1.2.4 Other Complementary Therapies

E. Several products, including pads, pants and protectors, help with incontinence but they are not effective as a treatment for UI (*Level of Evidence*: *1b*). Hinge-type penile clamps control SUI in men but an incorrect use may be very uncomfortable and at worst cause damage to the penis and the rest of the urinary system (*Level of Evidence*: *2a*) [7].

R. Suggest use of disposable insert pads for men with light urinary incontinence (*Grade of Recommendation*: *A*).

Adapt the choice of pad to the type and severity of urinary incontinence and the patient's needs (*Grade of Recommendation*: *A*).

Collaboration with other healthcare professionals help adults with moderate/severe urinary incontinence to select the individually best containment regimen considering pads, external devices and catheters, and balancing benefits and harms (*Grade of Recommendation*: *A*).

11.2 Evidence and Recommendations for Surgical Treatment

Surgical treatment of male incontinence is an important aspect of therapy with the changing demographics of society and the continuing large numbers of men undergoing surgery and other treatments for prostate cancer.

Surgical approach should be considered after a period of conservative management, which may vary from 6 to 12 months (*Level of evidence 3–4*; *Grade of recommendation C*).

Approximately 5–25 % of patients will experience incontinence that fails to improve with conservative management, and a substantial minority will ultimately undergo surgical treatment.

If conservative treatment do not achieve satisfactory results for the patient before choosing surgical treatment, further diagnostic assessment such as radiographic imaging of the lower urinary tract, cystoscopy and urodynamic studies should be performed to define the best surgical approach.

Imaging (abdomen X-ray, cystography, cystourethrography, ultrasound) allows to identify any abnormalities of both the high and the lower urinary tract, useful to the surgeon to chose the best surgical approach. Imaging can reliably be used to measure bladder neck and urethral mobility, although there is no evidence of any clinical benefit in patients with UI (*Level of evidence*: *2b*) [8].

A urodynamic evaluation to characterise the underlying physiopathology is important to perform prior to invasive therapy. Preliminary urodynamics can influence the choice of treatment for UI, but does not affect the outcome of conservative therapy or drug therapy for SUI (*Level of evidence*: *1a*) [9]. There is limited evidence for whether preliminary urodynamics predicts the outcomes of treatment for UI in men (*Level of evidence*: *4*) [10]. At last, cystourethroscopy helps to verify the integrity of the urethral wall.

R. Do not routinely carry out imaging of the upper or lower urinary tract as part of the assessment of urinary incontinence (*Grade of recommendation*: *A*).

Do not routinely carry out urodynamics when offering conservative treatment for urinary incontinence (*Grade of recommendation*: *B*).

Perform urodynamics if the findings may change the choice of invasive treatment (*Grade of recommendation*: *B*).

Do not use urethral pressure profilometry or leak point pressures to grade severity of incontinence or predict the outcome of treatment (*Grade of recommendation*: *C*).

At present, most studies on male urinary incontinence refers to incontinence sphincter related, following surgical procedures on the prostate (post-prostatectomy for prostate cancer or for benign disease, endoscopic procedures for BPH). Studies about other causes of surgical sphincter damage after surgery or after traumatic events (after prostato-membanous urethral reconstruction, pelvic floor trauma, unresolved paediatric urologic incontinence, exstrophy and epispadias) are few.

Different types of surgery could be offered to the patient, starting with AUS which is usually the first choice, followed by adjustable balloons, male slings and injectable agents.

11.2.1 Artificial Urinary Sphincter (AUS)

The artificial sphincter is the most studied treatment for men who have stress incontinence after radical prostatectomy with the longest record of safety and efficacy. The AUS has been used extensively for men with moderate to severe incontinence. There is evidence that primary AUS implantation is effective for cure of SUI in men (*Level of evidence*: *2b*). There are some limitations regarding the use of AUS, such as a high long-term failure rate (*Level of evidence*: *3*), mechanical device failure (*Level of evidence*: *3*) and some patients like men who develop cognitive impairment or lose manual dexterity who could have difficulty operating an AUS (*Level of evidence*: *3*) [11, 12].

AUS placement could be tandem cuff or single cuff, without any significant difference in terms of efficacy (*Level of evidence*: *3*). Surgical approach could be penoscrotal or perineal with equivalent outcomes (*Level of evidence*: *3*). Revision and reimplantation of AUS is possible after previous explantation or for mechanical failure (*Level of evidence*: *3*).

R. Offer AUS to men with moderate to severe post-prostatectomy incontinence (*Grade of recommendation*: *C*).

Implantation of AUS for men should only be offered in expert centres (*Grade of recommendation*: *C*).

Warn men receiving AUS that, even in expert centres, there is a high risk of complications, mechanical failure or a need for explantation (*Grade of recommendation*: *C*).

11.2.2 Male Slings

E. Male slings are an alternative approach with intermediate data supporting their safety and efficacy in men with more moderate degrees of post-prostatectomy incontinence. Long-term data are beginning to accumulate. However, the literature contains results on many different kinds of slings. There is no evidence that one type of male sling is better than another (*Level of evidence*: *3*). There is limited short-term evidence that fixed male slings cure or improve post-prostatectomy incontinence and in general SUI in men with mild to moderate incontinence (*Level of evidence*: *3*) [12, 13].

Men with severe incontinence, previous radiotherapy or urethral stricture surgery may have worse results after a male sling placement (*Level of evidence*: *3*) [14, 15].

There is limited evidence that early explantation rates are high (*Level of evidence*: *3*) [12].

There is no evidence that adjustability of the male sling offers additional benefit over other types of sling (*Level of evidence*: *3*) [12].

R. Offer fixed slings to men with mild to moderate post-prostatectomy incontinence (*Grade of recommendation*: *B*).

Warn men that severe incontinence, prior pelvic radiotherapy or urethral stricture surgery, may worsen the outcome of fixed male sling surgery (*Grade of recommendation*: *C*).

Injectable Agents

E. There is no evidence that one injectable (bulking) agent is superior to another (*Level of evidence*: *3*) but there is no evidence these agents cure post-prostatectomy incontinence (*Level of evidence*: *2a*) and there is weak evidence that they can offer temporary, short-term improvement in QoL in men with post-prostatectomy incontinence (*Level of evidence*: *3*) [11, 16].

R. Only offer bulking agents to men with mild post-prostatectomy incontinence who desire temporary relief of incontinence symptoms (*Grade of recommendation*: *C*).

Do not offer bulking agents to men with severe post-prostatectomy incontinence (*Grade of recommendation*: *C*).

Adjustable Balloons

E. Very limited short-term evidence suggests that the non-circumferential compression device (ProACT®) is effective for treatment of post-prostatectomy SUI (*Level of evidence*: *3*) [12].

The non-circumferential compression device (ProACT®) is associated with a high failure and complication rate leading to frequent explantation (*Level of evidence*: *3*) [17].

R. Warn men receiving AUS or ACT that, even in expert centres, there is a high risk of complications, mechanical failure or a need for explantation (*Grade of recommendation*: *C*).

Do not offer non-circumferential compression device (ProACT®) to men who have had pelvic radiotherapy (*Grade of recommendation*: *C*).

More research is needed to find out what are the most important outcomes for men with UI, so such measures can be incorporated as the primary outcome measures in further trials.

In order to get a global and clearer view of the guidelines discussed above, we have created a simple treatment algorithm for the management of male stress urinary incontinence (Fig. 11.1).

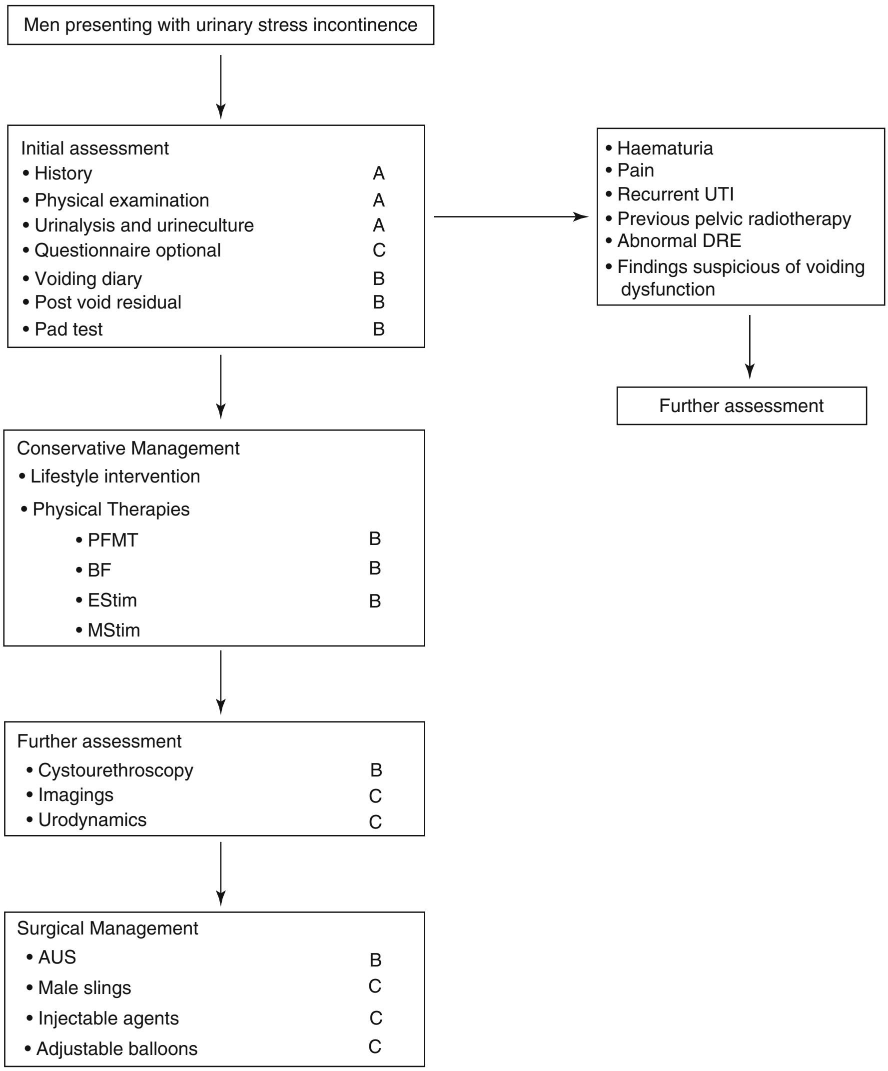

Fig. 11.1 Male stress urinary incontinence treatment algorithm. *PFMT* pelvic floor muscle training, *BF* biofeedback, *EStim* electrical stimulation, *MStim* magnetic stimulation, *AUS* artificial urinary sphincter, *DRE* digital rectal examination

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Surgery Complications and Their Management

12

Christian Gozzi and Donatella Pistolesi

12.1 Introduction

As there are very few data in literature on the resolution of complications post incontinence surgery after prostate surgery, the following treatise is based on experiences of reconstructive surgeons working in this field.

The number of surgical interventions performed for prostate cancer has increased due to the growing age of the population and early cancer detection [1].

Male stress urinary incontinence (SUI) after radical prostatectomy (RP) is not uncommon, the reported rate varies between 1 and 57 %. It is still difficult to determine the exact percentage of SUI, because there are not unique data to determine the extent of incontinence.

The reason for the onset of incontinence after RP has been examined by numerous authors, with the most frequent cited causes being either a combination of urethral sphincter damage, urethral hypermobility, and detrusor instability, or urethral sphincter damage alone. Detrusor instability can be managed medically [2]. In case of urethral sphincter damage, noninvasive therapy, pelvic floor-muscle training, and biofeedback are recommended; pharmacological treatment with duloxetine is especially effective in combination with physiotherapy, where it synergistically improves the continence rate (see Biroli's and Filocamo's Chaps. 7 and 8). If the first line of treatment is not sufficient to restore the urinary continence, a surgical approach is required to adequately address the problem [3].

C. Gozzi (✉) • D. Pistolesi
Department of Urology, Pisa University Hospital, Pisa, Italy
e-mail: christian.gozzi@gmail.com

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There are three popular interventions used for SUI:

1. Artificial urinary sphincter (AUS)
2. Sling procedures
3. Bulking agents

The use of these different procedures depends on several factors, such as the kind of damage and grade of incontinence, the health status, the previous treatment, and age of patients.

Another important factor, which is not to underestimate, is the choice of the surgeon, because not all the centers are equipped with all the instruments necessary and are able to perform every technique offered.

In a study conducted in the United States that included 1,246 patients operated between 2000 and 2001, the reintervention and short- and long-term adverse events associated with the different procedures (AUS 436 pz–Bulk 357 pz–Sling 453 ps) [1] were analyzed.

Overall 346 patients underwent subsequent procedures after their initial treatment, 87 in the AUS group (20 %), 189 in the bulking group (52.9 %), and 70 in the sling group (15.5 %). Patients who received bulking at the initial procedure were also more likely to undergo subsequent intervention with another device (40.1 %), while a smaller proportion of patients who received AUS (2.3 %) and sling (10 %) needed other treatments.

Long-term safety was analyzed throughout the first 5 years after surgery. There was a reduction in infectious and urologic complications observed, with the exception of neurologic complications, likely to be related to advanced age.

With the introduction of effective treatments as transobturator slings, mini-invasiveness and low rates of complications we can have two opposite ethical phenomena. Incontinence incidence rates postprostatectomy are increasing in literature, as is increasing sensitivity of specialists to the problem. A negative factor is that pharmaceutical industry, noticing the big economic potential, introduces different devices into the market every year, without evidences and an adequate education of the surgeons. Because of this most surgeons dealing only part time with incontinence no longer have the competences to use the different surgical options available.

Stress incontinence is in most cases an iatrogenic lesion, and should be solved by reconstructive surgeons who are experts in functional urethra and in incontinence in order to obtain the best results.

12.2 Sling

12.2.1 Adjustable Sling (AS)

The AS provides a soft compression against the bulbar urethra, leading to subvesical obstruction. The slings belonging to this group are as follows.

12.2.1.1 REEMEX®

REEMEX®, a suburethral sling connected to a suprapubic mechanical regulator (“variotensor”)

The first results of this system were published by Sousa-Escandò et al. in 2004.

In a multicenter European study with 51 patients with a mean follow up period of 32 months, 33 patients were cured (64. 7 %). Almost all patients needed at least one readjustment of the sling under local anesthesia. The sling had to be removed in three cases: in one case urethral erosion occurred, and three mild perineal hematomas were seen. Perineal discomfort or pain was very common and was treated with oral pain medication [4].

Considering the various interventions to which patients should be subjected for further adjustments, there is a high risk of infection. The risk of infection is increased by the presence of a foreign body located at subcutaneous level (variotensor) that has to be reached through an incision to obtain a re-tension. To treat this frequent complication, antibiotic therapy is not always sufficient, but in most cases it is necessary to remove the device. This maneuver is made difficult by the incorporation of the network in the subcutaneous tissue that forms a fibrosis around the mesh component and complicates removal.

The infection, associated with the mechanical pressure and the chronic stimulation on the urethra, especially if atrophic, may cause erosion of the urethra itself. This ulceration will give rise to continuous infections with high risk of abscess and, if not treated, erosion. In case of erosion of the urethra, the first treatment must be the removal of the device and the placement of a urinary catheter to facilitate the spontaneous healing of the urethral mucosa, or recut of the wound borders and make a direct suture in more severe cases.

Since Reemex is a treatment that causes an obstruction on the urethra to prevent the leakage of urine, in some cases it can cause urinary urgency. To lessen the problem it is possible to proceed either with the loosening of the cords to reduce the pressure of the network on the urethra, or through conservative treatment with administration of drug therapy (anticholinergics), which could, however, cause an increase in the postvoid bladder residual.

Referred pain in a large percentage of treated patients is due to compression and irritation of the mesh on the superficial perineal nerves. This symptom is often treatable with painkillers and anti-inflammatories, but sometimes leads to the patient's request to remove the device. In case of failure of Reemex, it is possible to implant either a functional sling or an artificial urinary sphincter (AUS). If the residual sphincter function is valid and the membranous urethra shows hypermobility or prolapse, one can choose a functional sling that has to be positioned more cranially than the position of Reemex. In the remaining cases, the gold standard is represented by AUS.

In case of damage of the urethral bulb, the positioning of AUS should be either transcavernous or placed more proximally, where the urethra appears intact.

12.2.1.2 ARGUS®

ARGUS® consists of a silicone cushion attached to two silicone columns, fixed suprapubically on the rectus sheet with a silicone fixation system (“washers”).

In a cohort of 48 patients with a mean follow up of 7.5 months, Romano et al. showed a cure rate of 73 %. Three urethral perforations during surgery were reported, and the sling had to be removed in five patients (10.4 %). Seven patients had acute urinary retention and, except for one patient in whom the sling needed to be loosened, it resolved spontaneously [4].

The Argus implant had several disadvantages, such as a longer admission period resulting from the need of a readjustment operation and increased perineal pain compared with AUS. Nevertheless, Argus surgery is less invasive and has a similar success rate compared with AUS.

Dalpiaz et al. reevaluated 29 male patients who received Argus® and reported a complication rate of 35 %. Overall 24 patients (83 %) experienced a total of 37 complications at a median follow up of 35 months, including 10 (35 %) in acute urinary retention. The sling was removed in 10 patients (35 %) due to urethral erosion [3], infection [2], system dislocation [2], urinary retention [2], and persistent pain [1]. Eight men (27 %) complained of significant perineal pain, necessitating continuous oral analgesics. In one patient ureteral reimplantation was done due to ureteral erosion from a dislocated sling [6].

The urethral perforation is a complication that can occur intraoperatively for the anatomy of the male pelvis, which presents a more acute angle of the lower pubic branches. The acute angle results in a more complicated retropubic passage compared to that of women. In case of drilling, it will be necessary to remove the device, to close the breach and if this treatment is not possible, to place. A catheter has to be placed for spontaneous healing of the bulb.

Subsequently (6 months post intervention), the patient should be reevaluated for a second surgery to correct incontinence. The options are to position a functional transobturator sling in case of residual sphincteric function, or to implant an AUS in the healthy part of the urethra, with trans-scrotal (according to Wilson) or transcavernous (according to Webster) cuff access.

Unlike Reemex, which requires a single incision to re-tension the variotensor, with ARGUS it is necessary to perform two incisions to adjust the tension bilaterally on the two columns, increasing the considerably infection risk considerably.

Infection is an event that can complicate any surgical procedure with implanted devices acting as foreign bodies. Even in this case antibiotics should be administered, and if it is not able to solve the local framework, it is necessary to perform the explant.

As with the other obstructive devices, strong perineal pain may occur caused by compression on the bulb and superficial perineal nerves.

Atrophy can also be present due to chronic pressure on the membranous urethra, eventually leading to erosion of the urethra.

As regards the displacement of the sling the mechanism is due to the retropubic positioning of Argus, which through a continuous tensioning determines the rotation and migration of the device.

In case of failure of Argus, the patient, after removal of the device, should be reevaluated by clinical, endoscopic, and urodynamic workup. According to the evidence obtained with these investigations, treatment of recurrent SUI will possibly take place with the implantation of an artificial sphincter, taking into account the quality of the urethra. In selected cases, in the presence of a moving urethra with residual sphincter function, retrourethral sling may be positioned.

12.2.1.3 ATOMS®

ATOMS®, a transobturator system including an adjustable cushion integrated in a polypropylene mesh that can be filled through a subcutaneous port.

The long-term results (2-year follow up) of the ATOMS® have been described in two prospective cohort studies including 137 patients. Success rate (<50 % reduction in pad use) varies from 72 to 91 %. The most important reasons for sling removal were erosion and infections (47–40 % of cases). Sixty percent of cases present transient pain which disappears within the first 3 months, but in three cases sling removal following persistent serious pain was reported [6].

ATOMS being a combined device there is a high risk of infection due to the silicone parts. There is a great difficulty in removing the transobturator mesh, which, if infected, must in any case be completely removed (Fig. 12.1).

As well as for the other devices that cause obstruction of the urethra, ATOMS can determine atrophy for chronic stimulation and consequent erosion, especially considering the presence of an inflatable cushion placed on the mesh, on which the patient may cause further compression and recumbency, causing a worsening of the local conditions (Fig. 12.2).

Even for ATOMS, in case of erosion, it will be necessary to remove the device and subsequently to implant an AUS distally to the ATOMS site.

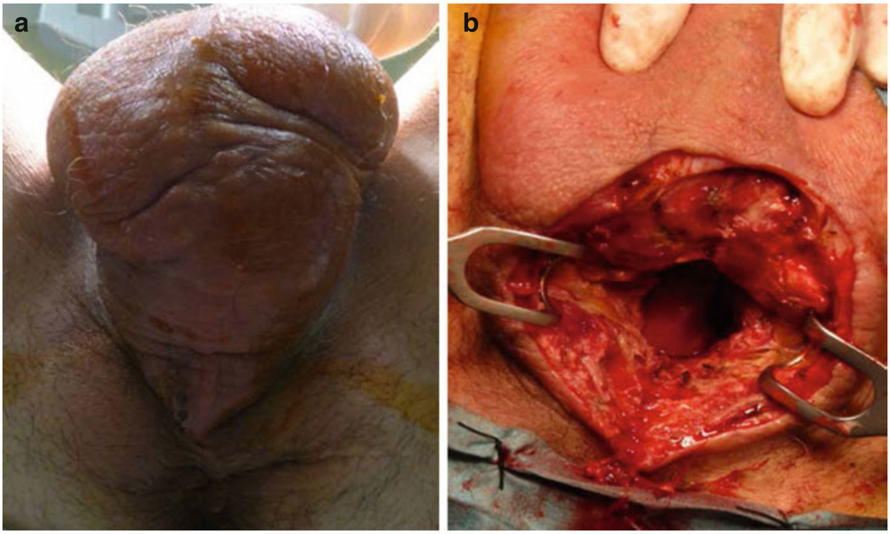

Fig. 12.1 (**a**) Perineal-scrotal abscess after ATOMS implant. (**b**) Post abscess drainage

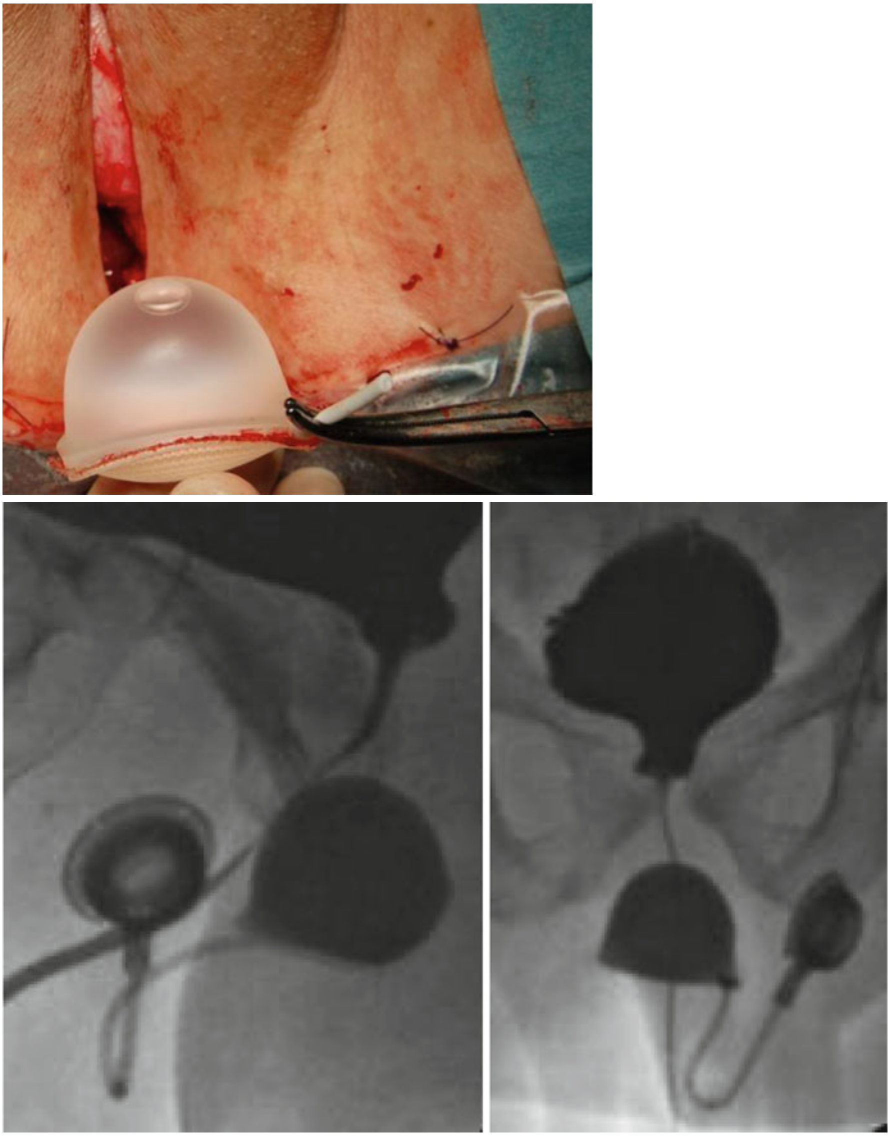

Fig. 12.2 ATOMS device

12.2.2 Retrourethral Transobturator Slings (RTS)

12.2.2.1 (I-STOP) TOMS®

(I-STOP) TOMS®, TOMS is a 2-armed and I – STOP TOMS is a 4-armed sling implanted at the bulbar urethra, working through obstruction of the urethra.

Not many data are available in the literature about this device. In two prospective case series 143 patients were included with 1-year follow up and the reported success rates (>50 % improvement) were excellent [6]. Yiou et al. recently described the prospective results of 40 patients treated with TOMS™ with a 2-year follow up, seven patients required additional treatment between the first and the second year after implantation (five PRO-ACT balloons, two artificial urinary sphincters). No postoperative complications were reported after 12 months [7].

In another work a total of 103 patients were followed up for 12 months. The surgical procedure was considered easy to perform. Treatment satisfaction was >90 %. The postvoid residual urine volume did not increase substantially, and acute urinary retention did not occur. The perineal pain scores were very low at follow up. Wound infection was seen in two patients at the 1-month follow up [8].

One of the complications can be the infection occurring both in the early and late postoperative stages. The problem of postsurgery infection can be attributed to a placement of the sling which is more superficial than other devices. The treatment of the infection consists of antibiotic therapy.

Being positioned more distally and more superficially than the sling Advance, it is possible to treat any failure by positioning Advance correctly, considering that the indications for placement of TOMS are similar to those of Advance (residual sphincter function).

12.2.2.2 Advance/Advance XP

It is a polypropylene monofilament mesh that is placed retrourethrally under the proximal part of the urethral bulb, inside the bulbo-spongious muscle, passing bilaterally through the obturator fossae [9].

In a trial study, 230 consecutive patients treated with the AdVance sling, no severe intraoperative complications such as rectum or bladder perforation or major bleeding were observed, except for one patient in whom the sling had been wrongly placed through the urethra; 21.3 % (49 patients) had acute urinary retention after removal of the catheter. One patient (0.4 %) had urinary infection with fever 10 days after sling implantation and was treated with antibiotics, one patient (0.4 %) showed local wound infection 8 days after surgery and was treated with oral antibiotics. No further treatment was necessary.

One patient (0.4 %) suffered chronical perineal pain and five patients (2.2 %) reported mild perineal discomfort for 4–6 weeks, but these patients needed no pain medication. One patient showed pubic symphysitis 4 months after sling implantation and required explantation during which there were no local signs of inflammation. Further diagnostics revealed the Guillain-Barrè syndrome as the causative pathology [10].

In another study 80 patients were treated with AdVance and AdVance XP (39–41, respectively). No perioperative complications were reported. There were two serious adverse events (AEs) in the AdVance group: one was symphysitis, which occurred at day 54 postimplantation. The patient underwent catheterization and received antibiotics and symptoms resolved at 8 weeks of treatment. The second AE was an infection of tendon adductor longus 41 days postoperative, the event resolved with antibiotic treatment.

In the AdVance XP group there were serious AEs in three patients. One patient who presented urinary urge incontinence received medication with several anticholinergics for 6 months, followed by transection of one arm of the sling, and urgency symptoms disappeared. Two patients with persistent urinary retention underwent transection of one arm of the sling. In both patients, the symptoms were resolved and continence improved. No sling explantation was required in either treatment group [11].

The most frequent complication that occurs after implantation of AdVance is urinary retention. This usually resolves spontaneously few days after surgery, or at most in few weeks.

Therefore, these patients require to be adequately cared for the postoperative period.

If there is a minimum residual of urine the first therapeutic approach will be pharmacological. The association between high-dose anticholinergics and intermittent self-catheterization or derivation by suprapubic or transurethral catheter (4–5 times/day) is recommended in cases of severe residual urine. It is necessary to pay special attention during catheterization; in fact in several patients urethral perforations were found caused by the maneuver itself (Fig. 12.3).

Self-catheterization appears to be difficult to perform; it will be advisable to place a small indwelling catheter or suprapubic derivation for the time necessary to resolution of urinary retention.

Very rarely (<1 %) there could be a retention that persists over time that can be settled by unilateral or bilateral section of the sling under endoscopic surveillance, which should be performed at least after 3–4 months of the device implantation .

In case of failure of Advance, if indications to the implant were correct, an improper placement of the sling has to be considered. The passage too lateral or dorsal of the needles can in fact cause a worsening of incontinence. This condition is due to dorsal traction of the urethra that will keep it pervia, worsening the

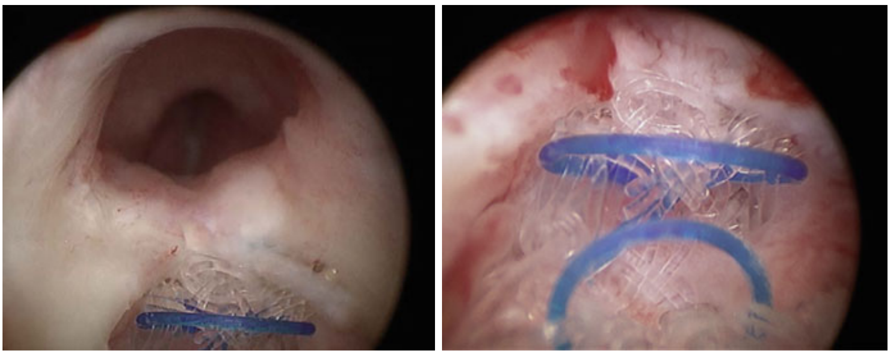

Fig. 12.3 Three months after Advance implant. Radiotreated patient with urethral erosion due to traumatic catheterization for urinary retention

sphincter functionality. In this case, it will be necessary to intervene through the section of the two arms and to implant a new Advance sling in the correct position.

With failure of the sling in radio-treated subjects, a new surgery with Advance is indicated only if it is possible to perform an endoscopic evaluation or a dynamic MRI. However, in case of radio therapy the indication of Advance reimplantation should occur with more restrictive criteria, and if not indicated, it would be necessary to opt for a compression system, such as an artificial sphincter, where the cap adapts itself to the atrophy of the urethral bulb.

12.2.3 PRO-ACT System

It is an adjustable therapy option; it uses the principle of augmenting titration for optimal urethral coaptation. It is composed by two balloons placed bilaterally at the bladder neck and a titanium port placed in the scrotum for volume adjustment.

A study was first published by Huebner and Schlarp in 2005, that included 117 patients with a mean follow up of 13 months. Sixty-seven percent of the patients were dry and in 8 % there was no improvement. The balloons were readjusted a mean of three times. In 32 patients reimplantation was necessary with a success rate of 75 % [6].

Because the effect of the expansion is multidirectional the two balloons do not exercise the power only to the urethra and they will have a tendency to migrate to the place of least resistance. The most frequent complication of the PRO-ACT is, therefore, the displacement to adjacent organs, the space around the membranous urethra being very limited.

With a subsequent reinflate it is possible to reexert a compression which decreases over time and after repeated reinflate, the diameter becomes so large that it has no more space under the symphysis and automatically moves away from the urethra. A globe, like an artificial prostate, can often be palpated by rectal examination.

The balloons, which are placed bilaterally into membranous urethra, exerting a compression, tend to give an atrophy with their expansion, so that the endoscopic appearance can be completely different after the extraction of the balloons with respect to the preimplanted urethra. The atrophy will not allow the placement of a functional sling, because there will not be sufficient tissue of functional sphincter.

Another complication is represented by infection, which is made more likely during device filling and adjustment. In addition, inflammation may develop around the device, with risk of abscess formation and the balloons may form a diverticulum into the membranous urethra (Fig. 12.4), or may even end in bladder or into rectum.

The explantation of the PRO-ACT system after deflation through mini-incision in the site of the port is usually a simple maneuver, although in their pseudo capsule the deflated balloons have a size, which can make the removal problematic, a dilatation of the channel is required.

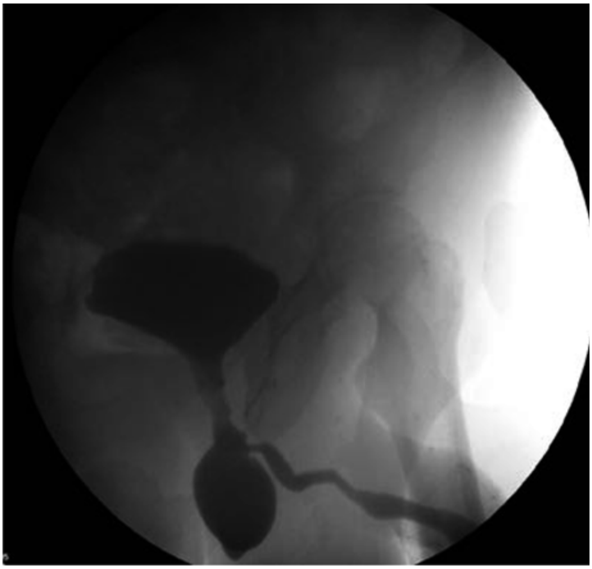

Fig. 12.4 Diverticulum into the membranous urethra

A repositioning is always possible, although in case of moderate to severe incontinence the best therapy is the implantation of an AUS, which can take place immediately after the removal, or at a later time if there are signs of infection or erosion.

12.3 Bulking Agents

Various substances (collagen, teflon, silicone, autologous fat, autologous chondrocytes, dextranomer/hyaluronic acid copolymer) have been used for a long time as bulking agents.

Overall, the short-term effects are good, but long-term success rate is poor because collagen, autologous fat, and chondrocytes are subject to quick migrations. Additionally, periurethral injection in the external sphincter of collagen can cause anaphylactic reaction.

Agents currently used included dextranomer/hyaluronic acid copolymer (deflux), pyrolytic carbon microspheres (durasphere), and polydimethylsiloxane (macroplastique). All these agents show a slower migration without compromising other organs [6].

Early failure rate is about 50 %, and initial success in continence decreases with time. For satisfactory intermediate results reinjection is necessary. However, this may induce inflammatory reactions resulting in an impairment of urethral elasticity and possibly a "frozen urethra."

During surgical procedures in patients undergoing injection of these agents there is often the possibility of finding clusters of substances not only at submucosal level, but also in the periurethral areas, possibly compromising a following implant of functional sling because it causes stiffening and alteration of the membranous urethra.

The "frozen urethra" is characterized by an alteration of the membranous urethra and by subsequent reactions of substances bulking.

The treatment of this complication consists in the installation of an AUS at medio-distal bulbar level, because the urethra will be rigid and devoid of residual functionality.

12.4 Artificial Urinary Sphincter (AUS)

The artificial urethral sphincter consists of an inflatable cuff, which supplies continuous circular compression of the urethra. When squeezing the control pump in the scrotum, fluid is shifted from the cuff to the reservoir balloon, enabling the patient to void, after which the cuff is automatically refilled [6].

Surgical techniques consisted of a perineal incision for cuff placement around the bulbous urethra, a transverse abdominal incision for pressure regulation balloon, and pump placement inside the abdomen and scrotum, respectively. Following the placement of all three parts, the reservoir is filled with ca. 21–24 ml of saline [11].

AUS is the gold standard for surgical treatment of male incontinence (see Li Marzi et al. Chap. 10).

The success rate of AUS is still the best surgical treatment for postprostatectomy incontinence, compared with all the other options available. Even long-term results are very good, with success rates up to 90 %.

However, the intervention is expensive and requires invasive surgery and experienced surgeons. It has a high rate of infection and urethral atrophy owing to the sustained high occlusion pressures on the urethra. In addition, the patient must have the mental and physiological ability to handle the sphincter [4].

The main indication for AUS placement was failure and/or complication of previous anti-incontinence procedures.

In an article by Van der Aa et al., which included 623 patients with 2-year follow up, the mean rate of erosion and infection was 8.5 %, varying from 3.3 to 27.8 %. Mechanical failure rates varied between 2 and 13.8 % and the mean reinterventation rate was 26 % varying from 14.8 to 44.8 %. In those series where urethral atrophy was adequately reported the mean percentage occurrence was 7.9 % [12].

Wiedmann et al. reported a study conducted on 23 patients. In this report no intraoperative complication occurred. Immediate complications included one case of scrotal hematoma next to the pump course, one case of UTI and one case of transient perineal pain. One patient required a reoperation for mechanical dysfunction of the cuff.

Mechanical dysfunction occurred in five patients: four needed a revision for cuff replacement, and one patient had a balloon replacement for fluid leakage. Revision for cuff dysfunction occurred at a median of 10 months, while balloon replacement occurred after 1 year. Three transcorporal AUS devices were explanted because of infection [13].

The most frequent complication after implantation of an artificial sphincter is represented by infection, which can often lead to fever. This usually disappears after drilling with drainage of the material toward the urethra or through the skin. The diagnosis and the clinical examination of infection will be evaluated by ultrasound, radiology, and/or urethroscopy. The initial treatment in case of infection, with or without erosion, has to be executed after sphincter deactivation and consists in the administration of high-dose antibiotic therapy associated with derivation through catheter 10–12 ch and/or suprapubic derivation. In cases promptly diagnosed, where the sphincter was implanted in a few months, it is possible to attempt a rescue of the device, especially in cases of iatrogenic injury as recent catheterization for nonurological intervention without deactivating sphincter. However, infection postimplant of the artificial sphincter leads in most cases to the complete removal of the device. It is necessary to resort to urinary diversion through cystostomy until reaching microbiological negativity. Once the resolution of the infection has been obtained, it is possible to proceed with reimplantation of an artificial urinary sphincter, placing the individual components possibly in a location that is different from that of the previous system.

If urethroscopy or voiding cystography with disabled sphincter confirms the suspicions of erosion–perforation of the urethra, surgical repair of the urethra and sphincter reactivation can occur in selected cases no earlier than 2 months later.

In case of malfunction without other altered clinical parameters, a measurement of the retrograde leak point will be a useful initial approach with a test of repeated activation and deactivation. In the event of a system filled with contrast, in addition to ultrasound, it is useful to perform a direct pelvis X-Rays, by which it is possible to see the filling of the reservoir and the cap, any extravasation and possible kinking of the tube that compromises the patency.

Once the correct filling of the reservoir and the proper function of the individual components have been accertained, it is necessary to think of extrinsic factors such as kinking of a tube or inadequate size of the cap or incorrect filling (osmosis and diffusion in case of hypo- or hyperosmolar of liquid that varies the amount over time).

Another complication that may arise with the use of AUS is the decubitus of the tubes that may cause skin ulcers, often associated with infections. A repair in predecubitus can save the device.

The cap exerts a constant pressure on the urethra spongy body that should be less than that of blood. When the cap is too tight or exerts excessive pressure it is possible to have problems of tropism and in extreme cases, erosion. This leads within a few days to infection of the complete system, which needs to be removed.

Some experts recommend to explant the sphincter and simultaneously place a sovrapubic cystostomy, waiting spontaneous healing of the erosion, although the best solution is to clean the fistula, recut the wound borders, and make a suture with absorbable monofilament 5-0.

The following repositioning of the cap or transcavernous repositioning must take place away from the repaired area, distal or proximal.

To ensure a reservoir pressure that is not too high, it is necessary to implant the balloon intraperitoneally. Especially in patients undergoing radiation therapy, the fibrosis may increase pressure on the urethra that will be added to that of the balloon itself, leading to decubitus.

However, one can also reevaluate the patient after AUS removal in order to implant a functional sling. If a residual sphincter function remains proximally to the area where the cap was placed, if there is an urethra with good response to functional endoscopic tests, with good motility and contractility and good elevating test. And if allowed by the quality of the bulb, it is also possible to implant an adjustable compressive sling.

If the urethra is irreparably destroyed after several implants, especially after radiation therapy, it is not recommended to proceed with new implant of AUS and the only possible option is to perform ileo-cistoplasty and closing of the urethra at membranous level.

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