# 24 Structured Reporting of RARP Complications: Are We Making Measurable Progress?

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## Introduction

Recently, the urologic profession has followed the lead of the general surgeons in defining and quantifying complications with each surgical procedure. At the beginning of the nineteenth century, E. A. Codman introduced the concept of a "end results system" to track hospital outcomes and since then, this has been a central measure in our health care system [1]. Today, the Centers for Medicare & Medicaid Services (CMS) and the Affordable Care Act have further expanded the use of outcomes data through incentive-based reimbursement schemes in an attempt to improve surgical outcomes [2, 3]. Outcomes have previously guided change in surgical techniques. For example, the transition to laparoscopy from open surgical procedures largely followed observations that patients treated with laparoscopic surgery experienced less postoperative pain, improved cosmesis, fewer infections and blood transfusions, and shorter hospital stays [4]. The advent of RAS provided multiple mechanical and ergonomic advantages over standard laparoscopic procedures [5]. The first robot-assisted laparoscopic surgery in humans was performed in 1997 [5]. Since the first robot-assisted radical prostatectomy (RARP) reported in 2000, there has been a prompt increase in utilization, with an almost fourfold surge in robot-assisted prostatectomies between 2005 and 2008 alone, reaching an incidence of 60,000 procedures annually in the United States in 2008 [1, 6–8]. The initial diffusion of robot-assisted surgery has garnered controversy, especially with respect to the appropriate utilization of the technique, procedural costs, reimbursement issues, and complications [5, 7].

Similar to other new surgical procedures, RAS has an initial *learning curve* for most surgical teams. As more procedures are performed over time, operative times decrease, and fewer complications result [9, 10]. Since the first RARP in the year 2000, surgical outcomes and complication rates have seemingly improved; although this conclusion largely results from high-volume single center series [11, 12]. However, initial reports, prior to the publication by Agarwal et al. did not report outcomes from RARP in a standardized fashion [12, 13]. This lack of standardization in reporting early and delayed postoperative complications made it difficult to interpret the safety and efficacy profiles of RARP case series, thereby making it challenging to directly compare outcomes with open radical prostatectomy series. However, many open surgical series also failed to

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categorize complications in a standardized fashion. In the 1990s, numerous attempts in the general surgery literature suggested methods of standardized reporting of surgical adverse events, but generally, these failed to gain wide acceptance [14–17].

Today, several systems of reporting complications currently exist, including the: Clavien–Dindo classification of surgical complications, Memorial Sloan-Kettering Center Classification modification (MSKCC), Accordion, National Surgical Quality Improvement Program (NSQIP), and National Cancer Institute Common Toxicity Criteria (NCT-CTC) [2, 18–22]. In 1992, Clavien introduced *T92*, a grading system that assessed the severity of complications based on the intervention required to alleviate them [23]. In 2002, Martin et al. modified T92 slightly producing a similar classification referred to as the Memorial Sloan-Kettering Cancer Center severity grading system [24]. In 2004, Dindo et al. proposed a modification to T92, increasing the levels of severity available for classification of a complication and specifically identifying if the complication required general anesthesia or admission to intensive care to resolve it, or if it caused organ failure [25].

The Clavien–Dindo classification system offers many advantages over the nonspecific and inconsistent ranking of surgical outcomes data that existed previously. The Clavien–Dindo system avoided previous terms such as minor, moderate, and major, which often were not explicitly defined or uniformly applied to adverse postoperative events [18, 22, 23]. The Clavien–Dindo system ranks the severity of postoperative adverse events according to the therapy or intervention needed to remedy the complication. In its current iteration, it consists of a five-tiered list of complication severity based on the type of therapy needed to treat the complications [18]. By using the medical record to identify the intervention needed to remedy the complication, the opportunity to overlook or downgrade complications is minimized [18]. The system has been widely used in surgery and urology reports and has been evaluated for interobserver variation in categorizing complications across seven centers with an 89 % agreement in identifying and ranking complications [18].

## Complications Associated with RARP

Currently, minimally invasive radical prostatectomy has a lower risk profile than the corresponding open surgical procedures [10]. Previous studies have demonstrated significant improvement in the rates of overall complications as surgeons overcome their individual learning curves [9, 10, 26]. In bariatric surgery, procedure volume correlated with surgical skill, reduced complications, reoperations, readmissions, and emergency room (ER) visits. However, years in bariatric surgical practice, formal fellowship training, and practice in a teaching or nonteaching setting did not correlate with reduced complications, reoperations, readmissions, or ER visits [27]. It is noteworthy that an assessment of surgical skill, obtained from review of a representative video-taped procedure by peer surgeons and blinded to the identity of the operators, correlated closely with surgical skill as assessed by complication rates [27]. How best to expedite the learning curve for RARP remains elusive.

## Preoperative

### Medical/Anesthesia Related

As with all medical and surgical approaches and procedures, proper patient selection is perhaps the most critical initial step. General anesthesia is required for RARP, contributing a relatively well-defined set of anesthetic-associated complications whose frequency and severity are related to the baseline demographics and comorbidities of the patient [28]. It is recognized that even in the hands of an experienced robotic surgeon, certain patient characteristics will dictate increased surgical risks. In patients undergoing RARP, a BMI > 30, prostate gland >70 g or a gland having a large median lobe, previous prostate or other pelvic surgery, and a history of radiation, are associated with higher risks of surgical complications [29]. Armed with this information, urologists and patients can make more educated decisions when weighing the risks and benefits of selected surgery. Present trends

indicate that we may be placing more patients on active surveillance than in previous years [30]. In a large experience, Agarwal et al. reported a correlation of medical and surgical complications of patients undergoing RARP to the patient's baseline characteristics, including the independent prediction of increased medical adverse events in patients with cardiopulmonary comorbidities and increased PSA levels [12]. Additionally, presence of gastric reflux and increasing age or Gleason score were independently associated with surgical complications [12].

### Cardiorespiratory

RARP requires $CO_2$ pneumoperitoneum which may result in hypercarbia, oliguria, subcutaneous emphysema, and organ hypoperfusion [28]. A $CO_2$ pressure of 15 mmHg is commonly used, although 20 mmHg has been shown to be safe, in urologic laparoscopic surgeries [28, 31]. Some surgeons alter the intraoperative $CO_2$ insufflation pressure, depending on their experience and the course of the surgery, as higher pressures may allow for a modest tamponade-like effect on bleeding from venous sinuses, the source of most intraoperative blood loss [32–34]. Rates of cardiac and respiratory complications associated with radical prostatectomy are reported to range between 0.9–4.3 % and 1.2–6.7 % respectively [10].

### Thromboembolic

The majority of patients undergoing radical prostatectomy are considered to be at high risk for venous thrombosis and embolization by the ACCP guidelines [35–37]. Thromboembolic events are potentially lethal medical complications of virtually all types of major surgery and are recognized to be increased in patients with cancer, including prostate cancer (PCa) [38]. As reported by Kim et al. thromboembolic events are increased with longer operative times, which are more frequently associated with more extensive and complicated surgeries [39]. Historically, with ORP, pulmonary embolism (PE) was the most common cause of death, which has now diminished due to thromboprophylaxis such as routine perioperative anticoagulation, early ambulation, compression stockings [36, 37].

The increased use of laparoscopic techniques, compared to open procedures, has reduced thromboembolic complications. Patients undergoing open retropubic prostatectomy (ORP) have a significantly higher risk of thromboembolic events compared to those treated with RARP; in one recent report, thromboembolic risk was increased almost fourfold with the ORP vs. RARP (RR 3.8, 99 % CI 1.42–9.99) [40]. Thromboembolic events and current rates of PE for patients undergoing RARP overall is ~0.2 % [37]. This statistic is informed by the specific mix of patient demographics and comorbidities, which correlate with the incidence of venous thromboembolism (VTE). Specifically, for patients treated with RARP, an increased frequency of VTE is seen in association with: increasing age (>60 years), history of thrombosis, procoagulant states, pT4 disease, Gleason score of ≥8, obesity, personal and family history of PE, venous disease (superficial or deep venous thrombosis), and surgery-related parameters, such as, an RARP lasting more than 60 min, complicated by extensive tissue injury or infection, or combined with lymph node dissection [29, 40]. In a large experience, RARP with lymph node dissection placed patients at an especially high risk. Studying 3544 patients undergoing both open and RARP, the investigators observed almost an eightfold increase in deep venous thrombosis (RR 7.80, 95 % CI 3.51–17.32) and a sixfold increase in pulmonary embolism (RR 6.29, 95 % CI 2.11–18.73) associated with radical prostatectomy that included lymph node dissection [40]. Increased risks associated with lymph node dissection also included wound, respiratory, cardiovascular and neuromuscular events and more than doubled readmission rates (14.6 % vs. 6.3 %) [40].

## Position Related

When a patient is placed in a steep Trendelenburg position for RARP and the patient's arms are tucked, access to the patient's airway and intravenous sites may be limited, thereby compromising the ease of maintaining fluid, medication, and

oxygen administration, and ventilation [28]. Trendelenburg position and maintenance of pneumoperitoneum can increase intracranial and intrathoracic pressure and can cause subcutaneous head and neck swelling, decrease pulmonary compliance, and increase risk of pulmonary edema [41]. These complications, fortunately, are rarely associated with long-term morbidity [41]. While exceedingly sporadic in occurrence, and predominantly associated with spinal surgery, blindness postoperatively with RARP has an incidence of 0.02–0.10 % [42, 43]. It is a devastating event if irreversible and is more likely to occur in long procedures (≥8 h) where the patient remains in steep Trendelenburg [42, 43]. This phenomenon is not completely understood; it may be related to increased intraocular pressures leading to retinal ischemia [42].

Placing the patient in a steep Trendelenburg with adduction of the arms has been associated with other complications including: compressive neuropathies or myopathies (rhabdomyolysis), musculoskeletal pain, edema, and neuropraxia. Neuropathy, resulting from an underlying nerve injury, may occur from positioning, usually the result of excessive external pressure (ischemia) and/or neural stretching [28]. The risk for such injuries increases with stirrups (lithotomy position) and the duration of surgery. Neuropathies attributed to RARP positioning have been reported to include involvement of the brachial, ulnar, femoral, and peroneal nerves. Most neuropathic complications resulting from patient positioning can be avoided by special attention to alleviating the pressure of operative equipment against the patient, intermittent repositioning if feasible, and shorter durations of surgery. Importantly, most neuropathies improve or resolve with time. Analyzing data from 61,656 patients who underwent minimally invasive RP in the National Inpatient Sample database, Wen et al. found that positioning-related complications occurred at a rate of 0.4 % with ophthalmic complications being predominant. These investigators reported that standard laparoscopic procedures were highly associated with the occurrence of positioning injuries (odds ratio [OR] = 2.88, $P < 0.01$), whereas RARP procedures (OR = 0.93, $P > 0.4$) were not, and that positioning injuries increased inpatient costs and extended LOS by almost 400 and 300 %, respectively [44].

## Operative

### Device/Robot Related

Robot malfunction or failure may occur occasionally during surgery [45]. In a survey of 176 surgeons performing RARP, 100 reported having had at least one irrecoverable, intraoperative, robot malfunction; approximately 46 % (80/176) were preoperative and were resolved by rescheduling the intended procedure (58 %) or converting to another type of procedure (19 % were converted to ORP and 15 % to standard laparoscopic prostatectomy) [45]. In only 5 % of cases was another robotic surgical system available for the intended procedure [45]. By far, more problematic from a patient safety standpoint, are malfunctions of the robot *during* active surgery. With respect to intraoperative robot malfunctions, 36 % (63/176) occurred before starting the vesicourethral anastomosis and the remaining 18 % (32/176) occurred before completion of the anastomosis [45–47]. The majority of intraoperative robot malfunctions resulted in conversion to open radical retropubic or standard laparoscopic prostatectomy [45]. Chen et al. reporting on a series of 400 urologic cases, found 14 cases of robot malfunction: four were critical and required conversion to standard laparoscopy and one was noncritical and the procedure was rescheduled [47]. These investigators and others have identified the da Vinci surgical system as highly reliable, with rare critical and irrecoverable malfunctions, ranging from 0.2 to 2.6 %; with even lower rates (0.4 %) being reported from large multiinstitutional studies [10, 45–49]. Since 1993, the U.S. Food and Drug Administration has maintained the Manufacturer And User Facility Device Experience (MAUDE) database which has focused on adverse events associated with robotic surgery, primarily using the Zeus and Da Vinci robotic systems. Note: most information and procedures now relate, almost exclusively, to the Da Vinci system, since, in 2003, manufacturers of the Zeus and Da

Vinci systems merged to produce and promote only the Da Vinci Surgical System (Intuitive Surgical, Sunnydale, CA) [19, 46, 48]. In a report assessing device malfunctions (product use errors and product quality problems) that resulted in patient injury between the years 2000 and 2007, Andonian et al., found a total failure rate of 0.38 %, representing 189 malfunction events [19]. Of the total malfunction events, 4.8 % (9/189) were associated with some degree of patient injury [19]. Notably, between 2003 and 2007, there was a decline in device robot malfunctions that required conversions to open surgical procedures from 94 to 16 % [19]. It should be noted that the MAUDE database, while large, has been criticized for its accuracy. It is an open, voluntary forum that allows patients and healthcare personnel, to post and write about their experiences. There is no requirement to report and no accuracy assurance; hence, it is suspected to be incomplete and perhaps biased.

## Nonprostate Tissue Injury

Injury to the structures and tissues within the operative field may inadvertently occur during RARP. In the era of laparoscopic surgery, bowel, rectal, vascular (especially the aorta, iliac, and gonadal vessels), nervous, and/or genitourinary system injury can occur when trocars or other instruments are placed through the abdominal wall and into the peritoneal cavity. Although uncommon, each of these potential injuries, are complications that have been reported during RARP, and are accepted to be more common in prolonged or more extensive procedures, such as those requiring lymph node dissection. The obturator nerve, for example, a potential target of injury with lymph node dissection, requires special attention during RARP to minimize harm. Precise rates of nonprostate tissue injury are not well defined as current classification schemes do not specifically catalog these problems. In studies reporting uncommon nonprostate tissue injuries, the Martin–Donat criteria has been used to facilitate the comprehensive and accurate reporting of urologic complications and the Clavien–Dindo classification has been used to define severity [50].

The average rate of vascular complications, usually perforation or incision, resulting from RARP is approximately 2.7 % and is recognized to generally decline with increased surgeon/surgical team experience and increased case volumes [9]. Bowel and rectal injury during RARP have been reported at rates ranging from 0.7 to 2.4 % and are not different in frequency from those reported prior to 2004 [51–53]. When these injuries are recognized early and repaired, they often do not have a major impact on the patient's functional recovery. However, delayed surgical correction or unrecognized injury may result in fistulae and local/systemic infections [52]. Ureteral injuries during RARP are reported to occur in 0.05 and 1.6 % of cases [9, 50]. In one reported single institution experience of 6442 consecutive patients undergoing RARP, three ureteral injuries (all transections) occurred, each requiring additional, robot-assisted corrective procedures, with one patient requiring readmission [50].

## Blood Loss

Blood loss and transfusion requirements have not routinely been assessed as a "complication" of surgical procedures prior to the recommendations of Clavien–Dindo, Martin, and Donat [12, 18, 19, 24, 25]. In some series, surgeons performing open prostatectomy plan autologous blood transfusion and have patient's donate 2 units of blood preoperatively [8]. This lack of emphasis on bleeding and transfusion requirements as a complication of prostatectomy is illustrated in the large, comprehensive evaluation of retropubic and laparoscopic prostatectomy reported by Rabbani et al. in which blood transfusion was excluded as a complication [54]. The data in their study supports that laparoscopic prostatectomy is associated with less blood loss than open radical prostatectomy, perhaps reflecting the tamponade effect of pneumoperitoneum on small venous sinuses [12, 54, 55]. Similar to standard laparoscopic prostatectomy, RARP is associated with reduced bleeding and transfusion rates [10]. The Clavien–Dindo classification of surgical complications cites

bleeding and transfusion requirements, as a class 2 complication in the grading system of severity (Fig. 24.1) [18]. The Martin–Donat criteria (Fig. 24.2), specifically addressing complications associated with urologic surgery, require quantitation of bleeding and transfusion rates [12, 18, 56]. A large, consecutive series of 3317 RARP patients reported by Agarwal et al. using Martin–Donat reporting standards and an exhaustive review of multiple datasets, confirmed that RARP was associated with a 1.7 % incidence of postoperative anemia and bleeding, which incidentally was the most common early complication of RARP [12]. This rate is slightly less than the contemporary rate of 2 % for transfusion with RARP reported by others. This includes asymptomatic, reactive transfusions delivered to patients for hematocrit below 30 [10, 12]. The imperative or symptomatic transfusion rate, in the above series of RARP is considerably less at 0.4 % [12]. The prophylactic use of heparin anticoagulant to prevent venous thrombosis and thromboembolism may increase the risk of bleeding which may be further increased, especially, if there is concomitant use of antithrombotic treatments (aspirin and other antiplatelet agents, steroids and NSAIDS, or additional anticoagulants) [28]. The availability and prompt administration of replacement colloid and/or packed red cells may minimize poor outcomes associated with uncompensated blood loss. As mentioned above, patients undergoing prostatectomy for PCa are at increased risk for thromboembolic events, and are often candidates for heparin prophylaxis [36, 37]. Many additional factors have been shown to influence intraoperative blood loss including surgical volume, operative time, and prostate size. Prostate size especially correlates with blood loss during RARP [10]. Contemporary studies reporting blood loss show a mean estimated blood loss with RARP of 166 ml (69–534) and a transfusion rate approximating 2 % (0.5–5 %) [10].

## Conversion

Conversion of RARP to a standard laparoscopic or open procedure may occur for technical or patient-related reasons. Reasons for conversion include: irrevocable/critical robot malfunction, control of intraoperative bleeding, and unexpected adhesions, which may not allow surgery to progress or may compromise the safe creation of adequate pneumoperitoneum. Rarely, an anatomic anomaly or simply excessive adiposity may mandate conversion to gain adequate exposure. As surgical experience increases, the frequency of conversion of RARP to standard laparoscopic or open procedures

APPENDIX A. Classification of Surgical Complications

| Grades | Definition |
|---|---|
| **Grade I:** | Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions.<br>Acceptable therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside. |
| **Grade II:** | Requiring pharmacological treatment with drugs other than such allowed for grade I complications.<br>Blood transfusions and total parenteral nutrition are also included. |
| **Grade III:** | Requiring surgical, endoscopic or radiologica; intervention |
| **Grade III-a:** | intervention not under general anesthesia |
| **Grade III-b:** | intervention under general anesthesia |
| **Grade IV:** | Life-threatening complication (including CNS complication): requiring IC/ICU-management |
| **Grade IV-a:** | single organ dysfunction (including dialysis) |
| **Grade IV-b:** | multi organ dysfunction |
| **Grade V:** | Death of a patient |
| **Suffix 'd':** | If the patient suffers from a complication at the time of dischrge (see examples in Appendix B, http://Links.Lww-com/SLA/A#),\ the suffix "d" (for 'disability') is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication. |

: brain hemorrhage, ischemic stroke, subarrachnoidal bleeding, but excluding transient ischemic attacks (TIA); IC: Intermediate care; ICU: INtensive care unit
**www.surgicalcomplication.info**

**Fig. 24.1** Modified Clavien–Dindo classification system

Table 1
Martin criteria for the evaluation of article reporting complications after surgery

| Criteria | Requirement |
|---|---|
| Method of accruing data defined | Prospective or retrospective accrual of data are indicated. |
| Duration of follow-up indicated | Report clarifies the time period of postoperative accrual of complications, such as 30 d or same hospitalization. |
| Outpatient information included | Study indicates that complications first identified after discharge are included in the analysis. |
| Definitions of complications provided | Article defines at least 1 complication with specific inclusion criteria. |
| Mortality rate and causes of death listed | The number of patients who died in the postoperative period of study are recorded together with cause of death. |
| Morbidity rate and total complications indicated | The number of patients with any complication and the total number of complications are recorded. |
| Procedure-specific complications included | Radical prostatectomy: anastomotic leak, lymphocele, urinary retention, obturator nerve injury, etc. |
| Severity grade used | Any grading system designed to clarify severity of complications, including major and minor, is reported (eg, Clavien and Dindo grading system). |
| Length-of-stay data | Median or mean length of stay is indicated in the study. |
| Risk factors included in the analysis | Evidence of risk stratification and method used is indicated by study. |

**Fig. 24.2** Martin classification system

usually declines, which may be secondary to better patient selection, better surgical skills, or more surgical experience [12]. Previously reported open conversion rates from RARP have ranged from 0 to 5 % with the majority of series reporting 0 % [57]. Modern reports indicate that conversion, of any type, is a rare occurrence in fully trained surgeons, and that RARP has a lower conversion rate than standard laparoscopic radical prostatectomy (LRP), reported to be 1.9 % by Bhayani et al. from multi-institutional data [39, 58]. An analysis of 82,338 patients undergoing RARP, by Weiner et al. using the National Cancer Database between 2010 and 2011, reported an open conversion rate of 0.9 % [59]. Sub-analyses demonstrated that 22.9 % of those conversions occurred at facilities contributing less than 4 % of the total cases for yearly RARP volume, emphasizing the importance of an experienced surgical team in avoiding conversions [59]. Since the potential for conversion always exists, there is continued justification for comprehensive surgical training, in *all* of the approaches to radical prostatectomy for the surgeon performing RARP [12, 57].

## Postoperative

### Ileus

Ileus, defined as an intolerance of solid food for at least three postoperative days (that may be accompanied by nausea, vomiting, bloating, or abdominal distention), is the most frequently reported gastrointestinal medical complication after RARP. Patients undergoing abdominal surgery have ileus rates ranging from 5 to 25 % while patients undergoing RARP have ileus rates ranging from 1.5 to 4.2 % [12, 51, 60]. Ileus may be associated with patient and/or operative factors. In a study of 228 patients having undergone transperitoneal RARP with an overall ileus rate of 2.6 %, diabetes was shown to be an independent risk factor for ileus [60]. Operative factors include visceral manipulation or trauma, anesthetic and/or perioperative analgesic medications (especially opiates), and increasingly complex procedures (e.g., concomitant lymph node dissection). Expectedly, higher rates of ileus are reported with the transperitoneal as opposed to the extraperitoneal approach to RARP [60]. Ileus has also been seen more frequently in the pres-

ence of an abdominal urine leak [10, 48, 61]. Ileus has been reported as the most common cause of readmission or unscheduled visits following an early discharge program post-radical prostatectomy [62].

Infectious complications are most common within the first 30 days following surgery [12]. It may be secondary to a medical complication, such as pneumonia, colitis, or urinary tract infection or the result of a surgical site infection. Most reports comparing complications have not separately commented on the incidence of infection between open and laparoscopic procedures. Earlier reports, reflecting initial RARP experiences reported *all* perioperative complication rates, which incorporated postoperative infections, as similar to those of retropubic prostatectomy [33, 62, 63]. This was not universally observed, however, Ficarra et al. observed significantly higher complication rates with retropubic prostatectomy, compared to RARP and standard LRP, which were similar [61]. Infection in patients undergoing RARP is reported to have an incidence of <1.0 % of patients or 5 % (20/368) of all reported complications in a recent large series [12].

In order to lower infectious complications, preoperative urinalysis with urine culture and sensitivity can easily avoid surgery on patients with infected urine. Furthermore, even if final results are not available at the time of surgery, the culture can expedite appropriate antimicrobial treatment if infection secondary to urinary contamination is causative. Postoperative fluid collections of all types (hematoma, urinoma, lymphocele) increase the risk of infection and should be promptly identified, and appropriately treated.

## Lymphocele

Lymphocele development is the most common delayed complication of RARP, with an occurrence of 0.8 % [10, 12]. Rates of lymphocele and lymphorrhea in other series, have generally been reported at approximately 3.1 % (0–8 %) [10, 64]. Lymphoceles commonly develop after a lymph node dissection and the risk increases with more extensive dissections. Judicious ligation of lymphatic channels with clips may reduce its incidence.

## Anastomosis Complication

Catheter dwell time has been viewed as a meaningful, albeit indirect, measure of the integrity of the urethral bladder anastomosis. In their series of RARP patients, Novara et al. identified a mean catheter duration of 6.3 days (1–6) [10]. Patients with longer catheter durations can result from prolonged urine leaks secondary to RARP performed in a salvage setting, larger prostate volumes, or a history of transurethral resection of the prostate [10, 29].

## Length of Stay

Length of stay (LOS) remains a poor surrogate for overall perioperative complications and outcomes due to the multiple factors that influence it. Similar to the inaccurate and poorly defined terms “minor” and “major” complications, LOS remains a residual metric from the unstandardized reports of surgical complications that precede the Clavien–Dindo classification schema and the Martin–Donat modifications. LOS is still used as a rough estimate of complication severity, and is a parameter followed closely by economists for its correlation with inpatient costs. Keeping the issues with LOS in mind, modern rates of LOS for RARP are estimated to be 1.9 days (1–6) with many high-volume institutions discharging patients within 23 h of surgery by essentially performing RARP as a same day, out-patient procedure with 23 h of observation after surgery [10]. The current safety profile and rapid recovery associated with RARP has made the LOS metric no longer relevant for RARP, allowing current studies and reports to focus on better indices of functional and oncologic outcomes [29].

## Hernia

Incisional hernia is a recognized complication of RARP with a reported incidence of 0.2–4.8 %; however, it is commonly under diagnosed given the limited follow-up in most series [65]. In a series of 577 patients who underwent RARP between 2003 and 2012, Chennamsetty et al. reported a 4 % incidence of incisional hernia repair (almost exclusively umbilical in location) diagnosed within a mean follow-up of 5 years. Similarly, a SEER (surveillance, epidemiology, and end results) database analysis revealed a 5.4 % incisional hernia repair rate following minimally invasive RP within 3.1 years postoperatively [65]. The occurrence of incisional hernia was increased in patients with larger median prostate weights (45 vs. 38 g, $P=0.001$) and was 2–3 times more common in patients having had a prior laparoscopic cholecystectomy (12.5 % vs. 4.6 %, $P=0.033$) [65].

Port site hernia is a complication that also must be addressed and represents a complication of ~1 % of laparoscopic surgeries [66]. Fascial closure is the best method of avoiding port site hernia. It was historically recommended that port sites >10 mm require fascial closure particularly when a cutting trocar was used for port placement [66]. This was difficult due to the small size of the laparoscopic port incision and was more difficult prior to the advent of fascial closure devices. They were also more common prior to the advent of blunt trocars. With blunt trocars, it may only be necessary to close port sites >12 mm [66]. Using this guideline, more modern studies report port site hernias at a rate of ~0.4 % [66].

## Functional Outcomes (Incontinence/ Erectile Dysfunction)

Historically, the earliest, most comprehensive, study addressing incontinence and sexual function following RP for PCa was the Prostate Cancer Outcomes Study (PCOS), conducted by the National Cancer Institute (NCI) between 1994 and 1999 [67]. This study investigated health-related quality of life (HRQOL) outcomes observed nationally in a large heterogenous cohort of patients following the initial community-based treatment of PCa. The findings confirmed important adverse sequelae of RP [67]. At ≥18 months post-RP, 8.4 % of men were incontinent and 59.9 % were impotent. Nerve-sparing procedures were helpful, reducing impotence from 66 to 56 %. However, even bilateral nerve-sparing efforts resulted in an erectile dysfunction (ED) rate of 56 %, a finding more common in older men and black patients [67]. Recognizing that surgical techniques (standard and robot-assisted laparoscopic RP) and other modalities of care are constantly evolving, there is a continual need for ongoing study and standardized reporting of HRQOL outcomes, such as recovery of continence, and erectile function.

Although there is no universally accepted definition or standard objective measurement of urinary continence (UI) and ED after RARP, it is clear that the functional outcomes of UI and ED are of paramount concern to patients. Furthermore, it should be stressed that these are not true complications of surgery and rather, are likely unintended consequences. However, they are also not justified outcomes and every effort needs to be made to prevent their occurrence when oncologically feasible. The incidence of UI and ED are confounded by multiple patient, operative, and reporting variables. Initial reports of UI provided evaluations at diverse postoperative time points and used varying definitions of continence. In other reports, continence is neither defined nor reported, but rather considered an expected result, justified in view of the surgery being performed. Likewise, the reporting of ED has been equally flawed in previous reports. Definitions are unstandardized and/or simply omitted. Several barriers exist to obtaining accurate patient data including: not documenting patient's subjective complaints, variable responses depending upon the type of query made, patient unwillingness to candidly discuss these sensitive and intimate problems,

lack of standardized method of obtaining data (e.g., written or interviewer-elicited, prospective or retrospective), and the wide variation about patients and physicians as to what is considered acceptable or *normal*. These obstacles in gathering accurate information, provides some justification for the wide ranges reported for continence, (52–95 %) and potency (62–97 %) in the early literature following RARP [48, 57, 61, 68–70].

## Incontinence

Stress urinary incontinence is an unfortunately common adverse event associated with RARP and is viewed by most patients as a meaningful reduction in their quality of life. At 1 month post-op from RARP, continence, defined as being free of using any absorbent pads, is estimated to be 56 % [71]. Although previous definitions of continence allowed some pad usage, current definitions of continence do not and the requirement for *any* pads to protect against inadvertent leakage of urine should be considered to be incontinence [70, 71]. Advanced age and significant lower urinary tract symptoms are associated with incontinence, though the strength of the prediction is generally low, while, lower risk disease, young age, and low comorbidities are associated with early continence after RARP [70–73]. Patient and prostate specific factors such as increased BMI and prostate gland size lower the likelihood of early continence [70–73]. Surgical experience also correlates positively with early continence post-RARP. The 1-year incontinence rate post-RARP ranges from 4 to 31 % using a *no pad* definition [73]. New, reliable predictors of early continence are recognizably sparse; a recent report suggests promise for discriminating pad-free continence at 1, 3, and 6 months post-op, with the use of uroflowmetry and a urine flow stop test at the time of urethral catheter removal [74]. This simple, noninvasive maneuver appears to improve the ability to predict early continence post recovery from RARP [74]. RARP series have reported lower rates of incontinence compared to retropubic prostatectomy and laparoscopic prostatectomy; however, large series of experienced open and laparoscopic surgeries show similar rates [73].

Nevertheless, multiple modifications have been proposed to reduce the frequency and extent of UI. Posterior musculofascial reconstruction, with or without anterior reconstruction, has been suggested as offering a slight advantage for urinary continence at 1 month postoperatively [70, 73]. In addition, recent data suggests that pelvic floor muscle training (PFMT) should also be modified. Traditionally, PFMT has focused mostly on repeated Kegel exercises pre- and post-operatively in order to obtain the muscle strength and control to prevent urine leakage during times of increased abdominal pressure. A recent study, however, objectively examined the exact times and activities associated with incontinence in 24 patients post-RARP by a single surgeon [75]. This study found that the majority of men experienced incontinence while sitting or walking at 3 and 6 weeks after RARP. They concluded that sustained functional PFMT should be promoted in order to increase endurance and prevent leakage in the most common situations [75].

## Erectile Dysfunction

Preservation of erectile function is an essential component to HRQOL. However, evaluation and quantification of ED has been variable. In a large meta-analysis of RP studies with ≥1 year follow-up, only 10 % of 212 relevant studies met the minimal requirements for adequate reporting of the effects of surgery on erectile function [76]. Inconsistent definitions, incomplete data acquisition, and heterogeneous patient populations have rendered comparisons implausible between different procedures and even different series on the same procedure [76]. Despite the limitations of such data, Tal et al. found that overall recovery of erectile function was seen in the majority of men (58 %), with single-centers reporting approximately twice the recovery than reported by multicenter series (60 % vs. 33 %, RR = 1.82, $P$ = 0.001). The authors found that patients <60 years achieved greater recovery than older patients (77 % vs. 61 %, RR = 1.26, $P$ = 0.001) and revealed only minimal improvement with follow-up >18 months compared to early post-op evaluations (60 % vs. 56 %, RR = 1.07, $P$ = 0.02). Notably, laparoscopic RP showed similar recovery of erectile function to open RP (58 % vs. 58 %, respectively, pNS); both were

inferior to RARP with regard to recovery of erectile function (73%, $P=0.001$ vs. open and laparoscopic RP) [76]. Despite this finding, they concluded that the superiority of any single surgical procedure was yet to be determined [76].

Nerve-sparing (NS) RARP is the most commonly used technique when attempting to maximize erectile outcomes. NS has also been shown to improve continence rates in men undergoing RARP with rates of continence positively correlated to the degree of neurovascular bundles saved [77]. There are several different levels of NS; pathologic features of the tumor and patient desire to retain potency determine the level. During RARP, the quality of NS is usually classified by laterality (none, unilateral, and bilateral) or degree (none, partial, and full). In one report, the surgeon's subjective assessment of nerve-sparing predicted time to recovery of function post-op [29, 78]. The ideal study to evaluate erectile function post-RP should be prospective, stratified for variability in surgical technique, and controlled for age, baseline erectile function, use of erectogenic therapies, and comorbidities. This type of study is yet to be completed [76].

## Readmission

Readmission rates have been used as a surrogate for surgical complications. Based on this premise, the Centers for Medicare and Medicaid Services (CMS) has recently extended penalties for readmissions to hospitals for all medical conditions from a previous directive which was limited to only three medical conditions [79]. Although readmission rates have been criticized as imprecise and at times arbitrary, an extensive review of 346 hospitals in the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP), for the year 2012 [80], revealed readmissions to be primarily attributable to surgical complications, rather than being reflective of patient and hospital characteristics or socioeconomic factors. Whether readmission rates truly reflect a quality measure in surgery remains debatable [81, 82]. In a large study of 59,273 surgical procedures performed in 112 Veterans Affairs hospitals between 2005 and 2009, Morris et al. found that readmission rates were predicted by patient comorbidities, procedural factors, and the occurrence of postoperative complications. Readmission rates were more reflective of the occurrence of *post-discharge complications*, rather than *pre-discharge* complications. The most common post-discharge complications were surgical site infections [81, 82]. Similar conclusions were drawn by Merkow et al. who assessed unplanned readmission rates for 498,875 operations [80]. Merkow concluded readmission after surgery was associated with new post-discharge complications [80]. Morris et al. suggest that readmission rates are of value for assessing trends in the frequency of surgical complications and for assessing progress in the surgical management of disease; although rates of readmission may depend more on better prevention techniques for surgical site infection than surgical techniques. [80, 82] The refinement of readmission rates, structured within the Clavien–Dindo classification of surgical complications better classifies adverse postoperative events.

## Progress

As described above, improvement in outcomes, as well as more structured reporting has been seen in most new reports detailing the complications of RARP. The reasons for improved general surgery outcomes are complex and reflect more than participation in a program measuring complications, maintaining a database of practitioners and their outcomes, and efforts to mimic best practices [1, 83]. This was shown by the equally successful reduction in risk-adjusted adverse surgical outcomes observed for hospitals that did not participate in the ACS NSQIP. In addition, Osborne et al. determined no significant improvements in outcomes at 1,2, or 3 years after enrollment in the ACS NSQIP compared to the time period before enrollment. These outcomes included risk-adjusted 30-day mortality, serious complications, reoperations, and readmissions [84]. This study used national Medicare data of over 1.2 million patients undergoing general and vascular surgery in 263 participating hospitals [84]. However, there will be significant benefit in

capturing complications by standardized reporting practices. The use of objective, comprehensive techniques of electronic health record data review, so-called *big data*, and dedicated software may allow the ability to capture most major and minor complications from the medical record automatically. This may exclude multiple potential areas of bias that exist with the much more tedious manual abstraction of medical records for adverse postoperative events [85].

Electronic health records (EHR) and large electronic databases have gained broad diffusion over the last several years in both the public and private sector [85]. Anderson & Chang propose automatic retrieval of prospectively identified objective variables from these electronic health records [85]. They performed separate multivariate logistic regression analyses on 745,053 general surgery patients, over a 5 year period beginning in 2005, using the NISQIP database [85]. Using 25 objective measurement variables already routinely collected, they concluded that large data analysis can be utilized in order to provide rigorous, risk-adjusted quality assessment (complication and mortality rates) that avoided time intensive and possibly incomplete or biased data retrieval [85]. These authors suggest that a wider application of their automatic data collection techniques may provide improvements to surgical outcomes and assessments of surgical quality, and may help eliminate subjectivity and bias in data collection. They provide compelling evidence that future outcomes reporting obtained from the use of "big data" show certain promise [85].

As a result many researchers are increasingly using registries to cull cases for review [86, 87]. The American Urological Association (AUA) has recently announced the creation of a specialty-wide national registry for healthcare outcomes and quality, related to the diagnosis and treatment of prostate cancer [88]. Although several university registries exist for prostate cancer care, the AUA Quality registry, (referred to as AQUA), is the first national registry. Launched in 2014, it is expected to be in full operation by July 2015. It will begin with prostate cancer and expand thereafter and will enable practitioners to benchmark their results against national database results and quantitate resource utilization. It will address oncological outcomes, functional outcomes, and complications. It may allow assessment of the course of the disease; variations in treatment, prognosis, and HRQOL resulting from PCa care patterns far in excess of that available through prospective comparative trials [86–88].

## Technique Modifications

Modifications of the RARP technique have been reviewed and found to not significantly influence perioperative outcomes including: surgical approach (transperitoneal vs. extraperitoneal), preservation of the bladder neck, reconstruction of the vesicourethral junction (anterior, posterior, or complete anterior and posterior), anastomotic suture (barbed or standard monofilament suture), interfascial neurovascular dissection, and incision/ligation of the dorsal venous complex. [10, 89–94] Newer robotic platforms have improved the dexterity and adaptability of RARP procedure. At our institution, we have begun to perform the majority of RARP procedures without placing the patient in the lithotomy position, thereby reducing complications that may stem from lithotomy positioning such as nerve injuries. Technical changes will continue to alter the complication profile as time goes on.

## Recommendations

### Complications

Unfortunately, neither the Clavien–Dindo, Martin–Donat criteria, nor the Expanded Accordion Severity Grading System has been universally adopted [18, 20, 22, 95]. Further detracting from progress in this area is the observation that up to 35.3 % of papers published, claiming to have used the Clavien–Dindo classification system, did not use it properly [22]. Standardized reporting of surgical outcomes through the Clavien–Dindo classification allows better understanding of surgical data. The extension of this classification to urologi-

cal surgery by Donat's modifications and the incorporation of the Expanded Accordion Severity Grading System which categorizes outcomes into failures, complications and sequelae, provide the ability to critically evaluate the complications of urologic surgery [95] (Fig. 24.3). Unfortunately, the challenge remains to have all surgeons adopt standardized reporting. We encourage clinical investigators, institutional review committees, and peer-reviewed journals, to request implementation of these standards.

Progress in the comprehensive reporting of postoperative complications has achieved significant milestones in the past two decades (Table 24.1). A summary of information related to the reporting and grading of complications after urological procedures was reported as an ad hoc EAU guidelines panel on the reporting method of complications after urologic procedures [22]. These researchers found that peer-reviewed manuscripts identified by a systematic review of the literature reported complications using standardized criteria in only 35 % of reports. An improvement in quality of the reporting of postoperative adverse events was demonstrated by an increase to 48.3 % of reported complications using standardized criteria, between 2009 and 2010 [22].

In the past, comparisons between ORP, LRP, and RARP have not uniformly documented and reported complications thereby limiting the ability to make comparisons. Rabbani et al. comprehensively reviewed the outcomes of 3458 patients undergoing ORP and 1134 patients who underwent LRP; however, they did not review the postoperative adverse effects of RARP [54].

RARP, the most common surgical approach for organ-confined PCa, was reviewed separately by Novara et al. Coelho et al. and Agarwal et al. [10, 12, 32] Each strived to implement the Martin–Donat criteria in their reports, thereby providing more uniform representation of complications for comparison. Limitations stemming from small patient population, failure to examine comorbidities, and follow-up limited to 6 weeks, compromised two of the studies [10, 12, 32]. The largest study providing a standardized report of complications of RARP was in 3317 consecutive patients by Agarwal et al. [12] The well-substantiated conclusions of these studies, gleaned from exhaustive clinical review and standardized reporting, is that RARP is a safe procedure with a 9.8 % rate of complications, most of which occur within the first 30 days post-op [12].

## Functional Outcomes

In light of the difficulty with qualitative and quantitative characterization of problems, such as incontinence and ED, an equally important task is to standardize reporting of functional outcomes. To accomplish this, we would encourage the routine, prospective use of one comprehensive patient questionnaire in evaluating complications of urologic surgery. The tool for this assessment should be validated and universally accepted; to date, such a tool has yet to be

**Table 1 Accordition classification system with seveity weights**

| Grade | Description | |
|---|---|---|
| 1 | Treatment of complication requires only minor invasive procedures that can be done at the bedside, such as insertion of intraveous lines, urinary catheters, and nasogastric tubes, and drainage of wound infections. Physiotherapy and antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy are permitted. | 0.110 |
| 2 | Complication requires pharmacologic treatment with drugs other than such allowed for minor complications, e.g. antiviotics. Blood transfusions and total parenteral nutrition are also included. | 0.260 |
| 3 | No general anesthesia ie required to treat the complication: requires management b an endoscopic, interventioanal procedure, or reoperation without general anesthesia. | 0.370 |
| 4 | General anesthesia is required to treat complication. Alternately, single-organ failure has developed. | 0.600 |
| 5 | General anesthesia is required to treat complication and single organ failure has developed.Alternately, multisystem organ failure (2 or more organ systems) has developed. | 0.790 |
| 6 | Postoperative death occured. | 1.000 |

**Fig. 24.3** Accordion complication classification system

**Table 24.1** Selected studies of RARP outcomes and complications reporting method employed

| Year | Author (s) | Patients (*n*) | Reporting standard | Complications (%) | Follow up (months) |
|---|---|---|---|---|---|
| 2014 | Jeong et al. [102] | 100 | MCD | 56.8 | 6 |
| 2014 | Pilecki et al. [103] | 4374 | NSQIP | 5.62 | 1 |
| 2013 | Maddox et al. [104] | 575 | MCD | 16.2 | 1 |
| 2013 | Rogers et al. [105] | 69 | CD | 5.8 | 37.7 |
| 2013 | Sagalovich et al. [106] | 82 | None | 2.4 | 6 |
| 2013 | Ou et al. [107] | 148 | MCD | 7.4 | 30.6 |
| 2013 | Yuh et al. [108] | 406 | MCD | 18 | NR |
| 2012 | Ahmed et al. [109] | 1000 | CD | 9.70 | 1 |
| 2012 | Yuh et al. [110] | 30 | CD | 30 | 7 |
| 2012 | Jung et al. [111] | 200 | CD | 3 | 24 |
| 2012 | Van der Poel et al. [112] | 904 | CD | 14.1 | >36 |
| 2012 | Silberstein et al. [113] | 562 | None | 3 | NR |
| 2011 | Patel et al. [100] | 1111 | MCD | 6.6 | 22 |
| 2011 | Agarwal et al. [12] | 3317 | CD | 9.80 | 24.2 (12.4–36.9) |
| 2011 | Jayram et al. [114] | 248 | CD | 4 | 24 |
| 2011 | Davis et al. [115] | 261 | None | 5 | NR |
| 2011 | Lallas et al. [116] | 473 | None | 1.1 | NR |
| 2010 | Novara et al. [117] | 415 | Martin + MCD | 21.70 | NA |
| 2010 | Jeong et al. [118] | 200 | CD | 12 | NR |
| 2010 | Coelho et al. [32] | 2500 | CD | 5.10 | 25 |
| 2010 | Yee et al. [119] | 32 | MCD | 34 | 8.7 |
| 2010 | Katz et al. [120] | 94 | CD | 35.1 | 7.6 |
| 2010 | Cooperberg et al. [121] | 126 | None | 1.1 | NR |
| 2009 | Ham et al. [122] | 121 | None | 8.3 | NR |
| 2009 | Zorn et al. [123] | 1155 | None | 13 | NR |
| 2009 | Feicke et al. [124] | 99 | None | 7 | NR |
| 2009 | Polcari et al. [125] | 60 | None | 4.6 | NR |
| 2008 | Patel et al. [126] | 1500 | None | 4.3 | 53 |

*CD* Clavien–Dindo classification system [23], *MCD* modified Clavien–Dindo classification system [18], *NSQIP* The National Quality Improvement Program Classification System [103], *Martin* Martin classification system [19], *NR* not reported, *NA* not applicable

identified. Incontinence may be evaluated using the International Consultation of Incontinence Questionnaire-Urinary Incontinence (ICIQ-UI) [48, 96] or through the AUA Symptom score. Sexual dysfunction, including ED, may be estimated utilizing the Sexual Health Inventory for Men (SHIM) [48] or the International Index of Erectile Function (IIEF) questionnaires [97]. Once consensus can be achieved, universal questionnaires can be employed at predetermined time points.

## Composite Indices (Combining Oncological, Functional Outcomes, and Complications)

A method to address oncological outcomes, complications, functional outcomes, and other areas of concern, the so-called *trifecta*, was suggested by Patel et al. [98] It was designed to represent a readily communicated index of the surgical outcomes of continence, potency, and cancer-free status. The concept of a trifecta is justified by

Patel et al. in light of the high number of younger patients who seek additional information regarding HRQOL after surgery, especially urinary, and sexual function [98, 99]. A subsequent modification of the trifecta concept has broadened the notion of an easily understood, comprehensive index to that of a "*pentafecta,*" with inclusion of no postoperative complications and negative surgical margins [100, 101]. It must be recognized, however, that a composite index is no more accurate than the accuracy of its individual components. Therefore, the individual components need to be accurately assessed and failure to do so compromises the entire comprehensive index. Consequently, reporting of each of the individual components of any composite index is still required.

## Future

In the future, the parameters stored in the electronic health record may be available for extraction, thereby minimizing the cost and time-intensive process of individual chart review. This process, if routine and merged with a standardized reporting of complications, may be a prompt and objective method of determining accurate frequencies of complications. This would enable comparative effectiveness analyses between institutions, surgical procedures, and other treatment modalities for PCa.

## Conclusion

- Multiple studies have shown that under most circumstances, the repetitive performance of a surgical technique results in decreased operative times and reduced complication rates [9, 27, 56]. In regards to RARP, the following conclusions can be made:
- Urologic surgery is moving toward more standardized reporting of postoperative adverse events by incorporating the classification of surgical complications of Clavien–Dindo and the modifications of Martin–Donat. This trend must be accelerated until it is universally recognized as a requisite for the reporting of complications.
- RARP is a safe procedure with most large series reporting no deaths. Overall, 10 % of patients develop complications. Most (~80 %) of these complications are evident within the first 30 days postoperatively.
- The most common early complications of RARP are postoperative anemia and bleeding requiring transfusion (<2 %).
- The most common delayed complications of RARP are bladder neck contracture (<1 %), and lymphocele formation (<1 %); both are usually treated endoscopically or with percutaneous drainage (Grade 3 by Clavien–Dindo).
- Oncological outcomes, functional outcomes, and complications represent critically important independent aspects of RARP. Each requires its own comprehensive, rational, and readily understandable standardized reporting system in order to allow accurate comparisons across surgeons, institutions, and surgical techniques.
- Functional outcomes including urinary incontinence and ED, considered as "complications" by patients, represent important aspects of RARP and should be qualitatively, and quantitatively assessed in order to accurately describe the true benefits and limitations of RARP.
- To date, a universal comprehensive method of obtaining and reporting functional outcomes is lacking. The level of concern regarding UI and ED postoperatively makes this a priority, for which a standardized reporting system is needed.

In this discussion, complications of RARP have been addressed. The implementation of a standardized urologic surgical reporting system for complications of RARP, and other urologic procedures, is a critical requirement for continued excellence in urologic patient care. Simply having systems and definitions is not enough. Researchers must advance the idea of routinely reporting complications, comprehensively, understandably, accurately, and in a standardized reporting framework. Urologists must demand this information in their investigation of new

techniques, and in comparison with standard and older techniques. In answer to the question posed at the beginning of this chapter, we believe, substantial (measurable) progress, beyond that acknowledged secondary to simply advancing along the learning curve, has indeed been made in robot-assisted radical prostatectomy.

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