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Surgical Complications After Robot-Assisted Laparoscopic Radical Prostatectomy: The Initial 1000 Cases Stratified by the Clavien Classification System

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Abstract

Background and Purpose: Complications after robot-assisted prostatectomy are widely reported and varied. Our goal was to determine the incidence of surgical complications resulting from robot-assisted laparoscopic radical prostatectomy (RALP) during the initial phase of a new robotics program that was developed by two surgeons without laparoscopic or robotic fellowship training. A secondary goal was to see if experience changed the incidence of complications with this technology.

Patients and Methods: A prospectively maintained database was used to evaluate the first 1000 consecutive patients who were treated with RALP from January 2004 to June 2009. The database was reviewed for evidence of complications in the perioperative period. All patients underwent robot-assisted laparoscopic radical prostatectomy by two surgeons. Complications were confirmed and supplemented by retrospectively reviewing the departmental morbidity and mortality reports, as well as the hospital records. The Clavien classification system, a standardized and validated scale for complication reporting, was applied to all events. The complication rate was determined per 100 patients treated and tested with logistic regression for a relationship with surgeon experience.

Results: Ninety-seven (9.7%) patients experienced a total of 116 complications; 81 patients experienced a single complication and 16 patients experienced ≥ 2 complications. The majority of complications (71%) were either grade I or II. The complication rate decreased with experience when the first 500 cases were compared with the latter 500 cases ($P = 0.007$). All the data were reviewed retrospectively. Involvement of residents/fellows increased as primary surgeon experience improved.

Conclusions: Complications after RALP are most commonly minor, requiring expectant or medical management only, even during the initiation of a RALP program. The complication rate improved significantly during the study period.

Introduction

The morbidity of radical prostatectomy for prostate cancer has decreased immensely over the past 25 years. Most recently, robot-assisted laparoscopic radical prostatectomy (RALP) was developed in an effort to perform the procedure in a minimally invasive fashion. The technology has rapidly become the most common approach used to perform a radical prostatectomy. This shift has occurred primarily because of marketing pressures and the perception that the technology provided a swift postoperative recovery, the potential for reduced morbidity, and improved functional outcomes over the gold standard treatment for localized disease, the open radical retropubic prostatectomy (RRP).

Complication rates for RALP range from 0.4% to 37.2% in the published literature.[1–4] Recently, authors have attempted to standardize the reporting of complications using the Clavien classification system.[5] This validated system assigns a grade reflective of the severity of the intervention needed to manage the complication. In our analysis, we graded our perioperative complications using the Clavien classification system. We reviewed the first 1000 consecutive RALP procedures performed by two surgeons with no formal robotic or

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laparoscopic fellowship training before the initiation of our robotics program.

Patients and Methods

Institutional Review Board approval was obtained for the maintenance of a detailed database for all patients undergoing surgery for all urologic malignancies. We examined the first 1000 consecutive patients with prostate cancer who underwent RALP by two surgeons (HAF, JDE). The data were reviewed retrospectively for any complications that occurred within 30 days of the operation. Our cohort had an average age of 59.3 years, average body mass index of 27.8, average Gleason Score 6.5, and an average prostate-specific antigen (PSA) value of 6.4. All patients were clinical stage T_{1c} except for two who were clinical T_3; both of these patients chose to pursue an operation. Patients with a PSA level >20 ng/mL, Gleason score of 8 or higher, or signs of metastasis on preoperative imaging were excluded from the study. These data were verified retrospectively by reviewing the departmental morbidity and mortality reports, and the emergency department and inpatient hospital records. Each complication was graded using a modified Clavien system previously described by Dindo and associates[5] (Table 1). The Clavien score was applied retrospectively by three of the authors (DS, JR, HF). Chi-square testing and logistic regression were used to determine the relationship between complications and experience using SPSS software (SPSS Inc, Chicago, IL).

The first 300 cases were performed by HAF and JDE together as a team. The subsequent cases were performed individually with increasing amounts of urologic fellow and chief resident operative time on the console, as the attending surgeons and the trainees became more comfortable with the operation. Neither surgeon had formal robotic training in his respective residency. The surgeons' training consisted of a 2-day course sponsored by Intuitive Surgical, Inc, which included two live case observations followed by four proctored cases.

Our initial RALP technique followed the description already popularized by Menon.[6] We moved our incision into the lateral prostatic fascia to the 5 and 7 o'clock position, after case 64. We performed the apical dissection described by Ahlering and colleagues,[7] performing a complete apical dissection before ligating the dorsal venous complex with suture ligature. The vesicourethral anastomosis was performed in standard fashion as described by Van Velthoven.[8] Bilateral obturator lymph node dissection was performed for all patients with high-risk features. Bilateral nerve sparing was attempted in all patients. If gross extension or significant fibrosis was encountered, however, a wider plane of dissection was taken. This decision was made intraoperatively.

All patients were treated via a standardized clinical pathway that included preoperative mechanical bowel preparation and a single dose of intravenous antibiotic preoperatively, followed by two postoperative doses. Compressive stockings and pneumatic devices were used in all patients. Deep venous thrombosis prophylaxis, 5000 units of subcutaneous heparin, was used only when the patient had a specific indication, such as drug eluting coronary stents. All patients were advanced to a liquid diet the same evening after the procedure and a regular diet the morning after surgery.

Most of the patients had pelvic drains removed the next day. Pelvic drains were removed when the output was less than 100 mL for 12 hours, or if the fluid creatinine level was normal. The Foley catheter was typically removed within 7 to 8 days after surgery. Cystography was performed only in patients with prolonged Jackson-Pratt drain placement.

Table 1. Clavien Classification System for Surgical Complications*

Grade I	Any deviation from the normal postoperative course, bedside wound debridement, basic pharmacologic therapy, or expectant management required
GradeII	Blood transfusion, total parenteral nutrition, or pharmacologic treatment not listed for grade I complications required
Grade IIIa	Surgical, endoscopic, or radiologic intervention required without general anesthesia
Grade IIIb	Surgical, endoscopic, or radiologic intervention required with general anesthesia
Grade IVa	Life-threatening complication requiring intermediate or ICU admission, single-organ failure
Grade IVb	Life-threatening complication requiring intermediate or ICU admission, multiorgan failure
Grade V	Death

*Adapted with permission from Dindo, et al.[5]

Results

Complication data were available for all 1000 patients from the prospective database. These data were confirmed with the monthly departmental morbidity and mortality reports, and a review of the hospital records. Transfusion and readmission emergency department visit data were reviewed on all 1000 charts.

A total of 97 patients experienced 116 complications, for an overall complication rate of 9.7% (97/1000) (Table 2). No deaths were observed in this series. Eighty-one patients experienced a single complication, 10 experienced two complications, 2 experienced three complications, and 4 experienced four complications. Fifteen (1.5 %) patients needed blood transfusion, and an average of 4.4 units of blood were administered per patient needing blood. The indication for transfusion was based purely on clinical presentation; eg, tachycardia, hypotension except in six patients. In those six patients, the transfusion was because of significant cardiac history to maintain hematocrit >30%. We also identified patients with postoperative bleeds. These patients exhibited symptoms of hypovolemia and a drop >5 in their hematocrit, but they responded to crystalloid fluid boluses alone and did not need blood products. The average hospital stay was 1.2 days, and 79 patients (79/1000, 7.9%) needed either readmission or follow-up examination in the emergency department.

The majority of complications were grade I and II (Table 3). The incidence of complications per 100 patients treated demonstrated a statistically significant reduction with experience ($P = 0.007$) (Fig. 1). We noted a 17% complication rate in the first 100 patients, which decreased to 9% in patients 401 to 500. The complication rate stabilized between 6% and 9% in the next 500 patients. The decrease in the number of complications is depicted in Figure 1. Logistic regression analysis confirmed a reduction in the incidence of complications with experience (Odds ratio 0.998, 95% confidence interval 0.9961, 0.9999).

Table 2. Complications Occurring During the Initial 1000 Procedures

	No.	%	Grade
Urologic complications:	47	4.7	
Clot retention	21	2.1	I
Urine retention (necessitating recatheterization)	15	1.5	IIIa
Urine leakage	7	0.7	
Prolonged Jackson-Pratt drainage	5	0.5	I
Ureteral catheterization	2	0.2	IIIb
Ureteral obstruction	3	0.3	IIIb
Meatal stenosis	1	0.1	II
Bowel complications:	16	1.6	
Rectal injury (recognized intraoperatively)	3	0.3	I
Prolonged ileus	10	1.0	
Expectant management	8	0.8	I
Nasogastric tube needed	2	0.2	II
Bowel injury (unrecognized)	2	0.2	IIIb
Partial small bowel obstruction	1	0.1	II
Intraoperative neurologic complications:	2	0.2	
Foot drop	1	0.1	I
Bilateral thumb parathesia	1	0.1	I
Vascular complications:	26	2.6	
Transfusion	15	1.5	II
Postoperative bleeding (no transfusion needed)	4	0.4	I
Deep vein thrombosis	2	0.2	II
Hemorrhage necessitating reexploration	4	0.4	IIIb
Myocardial infarction	1	0.1	IVa
Infectious complications:	6	0.6	
Clostridium difficile enterocolitis	3	0.3	II
Urinary tract infection	2	0.2	II
Upper respiratory infection	1	0.1	II
Pulmonary complications:	6	0.6	
Bilateral pleural effusions	2	0.2	I
Pulmonary embolus	3	0.3	IVa
Perioperative respiratory compromise	1	0.1	IVa
Other:	13	1.6	
Prolonged Jackson-Pratt drainage, NOS	8	0.8	I
Incisional hernia	2	0.2	IIIb
Corneal abrasion	1	0.1	I
Right groin pain	1	0.1	I
Left lower extremity edema	1	0.1	I

NOS = not otherwise specified.

Table 3. Analysis of Complications by Clavien System Grade

Clavien classification	*N**	*%*
Grade I	56	48.3
Grade II	27	23.3
Grade IIIa	15	12.9
Grade IIIb	13	11.2
Grade IVa	5	4.3
Grade IVb	0	0
Grade V	0	0

**116 total complications.*

Urinary complications were the most common issue encountered, and the most common individual complication was urinary retention (36/1000, 3.6%). Perioperative clot retention necessitating simple Foley catheter irrigation developed in 21 (2.1%) patients, and retention developed in 15 (1.5%) patients after the catheter was removed. Fifteen patients (1.5%) needed prolonged maintenance of the Jackson-Pratt (JP) drain. Conservative management with prolonged maintenance of the JP drain (>1 week) was successful in 13 patients. Seven patients needed prolonged urethral catheterization (>2 weeks), two of whom also needed ureteral stent placement to external drainage. There were no cases of complete ureteral injury. In three separate cases, the ureteral orifice was compressed by the vesicourethral anastomosis necessitating percutaneous placement of an antegrade ureteral stent. The ureteral stents were left in place for 4 to 6 weeks, with resolution of the obstruction in all three cases.

Inadvertent small bowel injury occurred in two patients (2/1000, 0.2%). Both were identified postoperatively, necessitating a second exploration with bowel resection. The first patient had a history of Crohn's disease and multiple previous bowel surgeries. The second patient had previously undergone a colon resection with Hartmann's pouch secondary to diverticulitis. Neither patient needed bowel diversion.

There were three rectal injuries (3/1000, 0.3%). For the first rectal injury, the procedure was converted to an open approach in our early experience, simply because we were not comfortable performing an adequate rectal repair at that time. The two later rectal injuries were repaired using the da Vinci robotic system without any difficulty. All rectal injuries were repaired in two-layer closures. Postoperative management included a course of antibiotic and low-fiber diet in these three patients.

Bladder neck contracture within this series has been reported.[9] A total of five persons (5/1000, 0.5%) presented with bladder neck contractures. Three needed cystoscopy and extraction of eroded Weck™ Hem-o-lok clips into the vesicourethral anastomosis or the bladder. Two patients were successfully treated after single bladder neck dilation. The contractures were not identified or operated on within the first 30 days of surgery, so they are not included in the presented complication data.

There were three patients whose procedures were converted to an open approach—one because of failure to

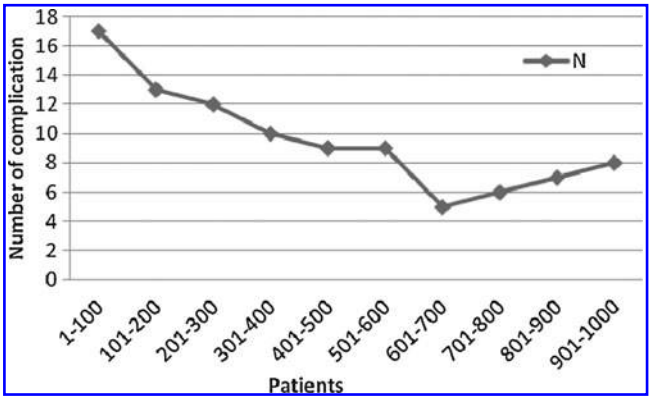

FIG. 1. Number of complications per 100 patients.

progress, the second because of morbid obesity, and the third because of the previously noted rectal injury. All three conversions occurred within the first 30 cases and were not classified as complications.

Discussion

Since RALP was first described, the procedure has rapidly become the most common approach used for the surgical treatment of patients with localized prostate cancer in the United States. The shift to robotic assistance, however, has not been evidenced-based. There are a few proven advantages to RALP over RRP, including a decreased intraoperative blood loss, decreased transfusion rate, and a decreased length of hospital stay.[10,11] Postoperative pain control is frequently reported to be superior after RALP, but a prospective comparative study failed to prove a significant difference in narcotic requirements between RALP and RRP.[12] RALP and laparoscopic prostatectomy (LP) have failed to produce superior functional outcomes (eg, continence and erectile function) over RRP,[11] and oncologic outcomes appear to be related most significantly to surgeon experience.[13]

Another frequently quoted advantage of RALP is fewer associated perioperative complications.[1,11,14] This claim is questionable because of the wide variation in the subjective definition of complication and the reporting of poor outcomes. There has not been a randomized trial that compares complications after RALP and RRP. Such a study is unlikely to be performed. Standardizing adverse outcome reporting is a reasonable approach to comparing the different surgical approaches to radical prostatectomy. The Clavien system is a validated instrument that has gained wide acceptance as a method to standardize complication grading.

Gonzalgo and associates[15] reported on the incidence of complications after their initial 250 LP procedures, finding an overall complication rate of 13.7%.[15] Using the Clavien grading system, the majority of the 34 complications that were classified as grade II or IIIa needed medical or minor surgical intervention only. This study was an important step toward standardizing complication reporting, but it described only patients undergoing LP, a procedure profoundly more difficult to master than RALP. As a result, these data are not comparable to the RALP. Hu and colleagues[16] graded their RALP experience using the Clavien system as well, comparing LP and RALP, finding significantly fewer complications after RALP.[16] All RALP procedures, however, were performed after the surgeons had passed the arduous learning curve associated with LP. Badani and coworkers[17] used the Clavien system to classify a large, purely RALP series, but aside from reporting the number and percentage of each grade, they did not elaborate on the specifics of their complications.

Our investigation found an overall complication rate of 9.7% during the first 1000 consecutive patients who were treated at our institution. The two most common complications were urinary retention and transfusion, affecting 3.6% and 1.5% of patients, respectively. The majority of the complications were low grade, and most were self-limited or needed minor intervention. Our results compare favorably against two of the largest RALP series in the literature. Coelho and colleagues[19] and Agarwal[20] and associates report complication rates of 5.1% and 9.8%, respectively. Lepor and coworkers[21] describe a complication rate of 6.5% in a large single surgeon series of open RRP. Table 4 shows a selection of perioperative complications of the two mentioned RALP series and two large open RRP compared with our data.

The incidence of acute urinary retention from residual blood clots dropped profoundly after we routinely began irrigating the catheter before leaving the operating room and again just before discharge. We found that patient manipulation of the catheter while changing the bags from a large overnight bag to a small leg bag can result in fresh bleeding and subsequent clot retention. Therefore, we advocate using a single large leg bag instead of providing two separate bags at discharge.

In general, we do not consider open conversion a surgical complication and did not include it in our overall complication rate. Although it is true that open conversion is a deviation from the original surgical plan, we consider conversion a prudent clinical decision if it results in a more safe and efficient procedure. Like most other RALP series, conversion occurred early in our experience. All three events occurred within our initial 30 procedures, and it is unlikely that we would have converted to an open procedure with our current level of experience.

Because the two senior surgeons had no formal robotic experience, the first 300 cases were completed together as a team while both surgeons became facile with the complexities of the surgery and the da Vinci technology. The complication rates for the two surgeons as individuals were essentially the same after the initial 300 cases. The data show a significant decrease in number of patients with complications in the first 500 cases *vs* the second 500 cases. We believe it is reasonable to state that with experience, complications in RALP will decrease. The number of complications nadired between 6 and 9 per 100 cases.

At this point, our institution had become a busy tertiary referral center for minimally invasive management of prostate cancer, which means that we are treating a more complex patient population; these patients would not normally be treated

Table 4. Selected Perioperative Complications (Up To 30 Days Postoperatively) of Contemporary Open and Robotic Radical Prostatectomy Series

Reference	*Method*	*Year*	*Number of patients*	*Overall complication rate %*	*Reoperation rate for bleeding %*	*Transfusion rate %*	*Bowel injury rate %*
Catalona[22]	Open	1999	1870	10.5	0	NA (routine autologous blood transfusion)	0.05
Lepor[21]	Open	2001	1000	6.5	0.2	9.7	0.5
Coelho[19]	Robotic	2010	2500	5.1	0.08	0.48	0.08
Agarwal[20]	Robotic	2011	3317	9.8	0.42	1.7	0.27
Current series	Robotic	2011	1000	9.7	0.4	1.5	0.5

by the private urologists in the surrounding community. Being an academic institution, we advocate for ever-increasing console time for both the urology chief resident and endourology fellow, as they became more comfortable with robotic surgery. Both of these factors may explain the leveling of the complication rate during the second group of 500 patients.

The greatest limitation of this study would be the potential for incomplete data collection. Despite our best efforts, it is possible that we are missing data on referred patients who may have experienced complications that were treated by their referring physicians. We believe that this may have produced some inaccuracies because our robotics program matured into a tertiary referral center after 300 cases. Nonetheless, we have made every effort to maintain open communications with all of the referring urologists to ensure that these data are as accurate as possible. Our database was compiled prospectively and supplemented with review of our morbidity and mortality reports and hospital records to confirm, verify, and hopefully maximize the chance that our information would be as complete as possible.

Conclusions

Complications after RALP are most commonly minor, ncessitating either expectant or minor medical intervention, even during the initiation of a RALP program by surgeons without formal robotic training. The complication rate correlated well with surgeon experience on logistic regression, reaffirming the fact that experience does matter when performing robotic surgery.

Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

JP = Jackson-Pratt
LP = laparoscopic prostatectomy
PSA = prostate-specific antigen
RALP = robot-assisted laparoscopic radical prostatectomy
RRP = radical retropubic prostatectomy