

SURGICAL COMPLICATIONS OF ROBOT ASSISTED PROSTATECTOMY IN A CONSECUTIVE SERIES OF THE INITIAL 500 CASES

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ABSTRACT

Purpose: We determined the incidence of surgical complications resulting from robot assisted prostatectomy (RAP) during the initiation phase of a new robotics program by two surgeons without laparoscopic or robotic fellowship training.

Materials and methods: A prospectively kept database was used to examine the first 500 consecutive patients undergoing RAP for evidence of a complication occurring within 30 days of surgery. Transfusion and readmission data was obtained by retrospectively reviewing 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: A total of 60 patients (12%) experienced a total of 77 complications. Fifty patients experienced a single complication and 10 patients experienced ≥ 2 complications. There were 3 conversions to an open approach. A total of 9 patients (2.1%) received a blood transfusion. The average hospital stay was 1.3 days and 13% required either a return visit to the emergency department or readmission. The majority of complications (80.5%) were either grade I or II. Three grade IVa complications occurred, and there were no deaths. The complication rate decreased with experience ($p=0.038$).

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

INTRODUCTION

Complications following a surgical procedure are an unpleasant reality that surgeons and their patients alike must face. The morbidity of radical prostatectomy for prostate cancer has improved immensely over the past 25 years. Most recently, robotic assisted prostatectomy (RAP) was developed in an effort to perform the procedure in a minimally invasive fashion. The technology has rapidly become the most common approach to radical prostatectomy for several reasons, primarily because the technology has been lauded for reduced morbidity, swift postoperative recovery, and improved functional outcomes over the gold standard treatment for localized disease, the open radical retropubic prostatectomy (RRP).

Complication rates for RAP range from 0.4% to 37.2% in the published literature.¹⁻³ Claims regarding reduced procedural morbidity are difficult to verify. This deficiency makes assessing expected adverse outcomes during the initiation of a new RAP program particularly difficult to predict. Recently, authors have attempted to standardize the reporting of complications using the Clavien classification system.⁴ This validated system assigns a grade reflective of the severity of the intervention required to treat the complication.

To our knowledge, the incidence and grade of perioperative complications during the initiation of a RAP program have not been previously published. In this analysis, we report the

complications that occurred during the first 500 consecutive RAP procedures performed by two surgeons with no formal robotic or endoscopic fellowship training prior to the initiation of our program.

METHODS AND MATERIALS

Institutional review board approval was obtained for the maintenance of a detailed prospective database for all patients undergoing surgery for urologic malignancies. We examined the first 500 consecutive prostate cancer patients treated by two surgeons (HAF, JDE) in our database for complications occurring within 30 days of the operation. Transfusion and readmission data were collected retrospectively by searching the hospital records. Each complication was then graded using a modified Clavien system previously described by Dindo et al.⁴ (Table 1) Chi-square testing and logistic regression were used to determine the relationship between complications and experience using SPSS software (SPSS Inc, Chicago, IL).

Our RAP technique initially followed that described by Menon,⁵ although we moved our incision in the lateral prostatic fascia to 5 and 7 o'clock position after case 64. A nerve sparing procedure is attempted in all patients when technically feasible. We perform the apical dissection described by Ahlering et al, performing a complete apical dissection prior to ligating the dorsal venous complex with suture ligature.⁶ The vesicourethral anastomosis is performed in standard fashion as described by Van Velthoven.⁷ Bilateral obturator lymph node sampling is performed for all patients with high risk features.

All patients are treated via a standardized clinical pathway that includes a preoperative mechanical bowel prep, and a single dose of antibiotics preoperatively followed by two postoperative doses. Compressive stockings and pneumatic devices are used in all patients, but

anticoagulation is not used unless there is a specific indication (e.g. drug eluting coronary stents). All patients are given a liquid diet the day of surgery and a regular diet the morning after surgery.

RESULTS

Complication data was available for all 500 patients from the prospective database, and confirmed with the monthly departmental morbidity and mortality reports. Transfusion data was available for 421 patients (84.2%), and readmission/emergency room visit data was available for 426 patients (85.2%).

A total of 60 patients experienced 77 complications, for an overall complication rate of 12% (60/500) (Table 2). No deaths were observed in this series. Fifty patients experienced a single complication, 6 experienced two complications, 1 experienced three complications and 3 experienced four complications. Nine patients required a blood transfusion (9/421, 2.1%), and an average of 5 units of blood were administered per patient. The average hospital stay was 1.3 days, and 55 patients (55/426, 13%) required either re-admission or examination in the emergency department.

The majority of complications were grade I and II (Table 3a). The complication rate (incidence per 100 patients treated) demonstrated a statistically significant reduction with experience ($p=0.038$) (Table 3b). We noted a 16% complication rate in the first 100 patients, which decreased to 9% in patients 401-500. Logistic regression analysis confirmed a reduction in the incidence of complications with experience (OR 0.998, 95% CI 0.9961, 0.9999).

Urinary complications were the most common, and the most common individual complication was urinary retention (20/500, 4%). Eleven patients developed perioperative clot

retention requiring irrigation, and 9 patients went into retention after the catheter was removed. Eleven patients required prolonged maintenance of the Jackson Pratt (JP) drain. Conservative management (prolonged JP drain maintenance, less than 7days) was successful in 8 patients. Three patients required prolonged urethral catheterization, two of which also required ureteral stenting to external drainage. There were no cases of complete ureteral injury. In two separate cases a ureteral orifice was compressed by the vesicourethral anastomosis requiring percutaneous ureteral stenting for 4-6 weeks, with complete resolution.

Inadvertent bowel injury occurred in 2 cases (2/500, 0.4%). Both were identified postoperatively requiring a second exploration with bowel resection. Neither patient required bowel diversion. There were 3 rectal injuries (3/500, 0.6%), all of which were identified at the time of surgery and repaired in two layers without further complication.

Bladder neck contracture within this series has been previously reported.⁸ Since then, one additional patient has developed a contracture, for a total of 5 affected individuals (5/500, 1.0%). Three required cystoscopy and extraction of eroded Weck™ Hem-o-Lok clips into the vesicourethral anastomosis or the bladder. Two patients were successfully managed after a single dilation.

There were 2 patients who were converted to an open approach, one due to failure to progress, and one secondary to patient obesity. Both conversions occurred within the first 26 cases.

DISCUSSION

Since RAP was first described, the procedure has rapidly become the most common approach used for the surgical treatment of localized prostate cancer in the U.S. However, the shift to robotic assistance has not been evidenced-based. There are a few proven advantages to

RAP over RRP, namely intraoperative bleeding and length of hospital stay.⁹⁻¹⁰ Postoperative pain control is frequently reported to be superior after RAP, but a prospective comparative study failed to prove a significant difference in narcotic requirements between RAP and RRP.¹¹ RAP and LP have failed to produce superior functional outcomes (e.g. continence and erectile function) over RRP,¹⁰ and oncologic outcomes appear to be related most significantly to surgeon experience.¹²

Another frequently quoted advantage of RAP is fewer associated perioperative complications.^{10,13} This claim is especially precarious because of the wide variation in the subjective definition of a complication and the reporting of poor outcomes. There has not been a prospective, randomized trial comparing complications following RAP 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.

Gonzalzo et al reported on the incidence of complications following their initial 250 LP procedures, finding an overall complication rate of 13.7%.¹⁴ Using Clavien grading, the majority of the 34 complications were classified as grade II or IIIa, requiring medical or minor surgical intervention only. This study was an important step towards standardizing complication reporting, but it described only patients undergoing LP, a procedure profoundly more difficult to master than RAP. As a result, this data is not comparable to the RAP. Hu et al graded their RAP experience using the Clavien system as well, comparing LP and RAP, finding significantly fewer complications after RAP.¹⁵ However, all RAP procedures were performed after the surgeons had passed the arduous learning curve associated with LP. Badani et al used the Clavien system to classify a large, purely RAP series, but aside from reporting the number and percentage of each Grade, details of how the Clavien system was applied were

not given.¹⁶

Our investigation found an overall complication rate of 12% during the first 500 consecutive patients treated at our institution. The 2 most common complications were urinary retention and transfusion, affecting 4% and 2.1% of patients. Similar to the experience reported by Gonzalzo et al, the majority of the complications were low grade and most were self limited or required minor intervention. Our results compare favorably with published complication rates of RAP¹⁻³ and RRP^{17,18}.

Several caveats must be made when interpreting our results. In our early experience, we applied standard RRP postoperative drain management to our RAP patients. This resulted in 11 patients being discharged with a pelvic drain because of 'high output', however only 3 had confirmed persistent urine extravasation by cystogram. Therefore, it is likely that several of these patients did not have a true urine leak and may not have required persistent drainage. Currently, we remove the pelvic drain as long as output does not exceed 100cc over a 12 hour shift and the fluid creatinine is consistent with serum.

The incidence of acute urinary retention due to residual blood clots dropped profoundly after we routinely began irrigating the catheter prior to leaving the operating room and again just prior to discharge. We also advocate using a single large leg bag instead of providing 2 bags (i.e. a small leg bag and a larger overnight bag) upon discharge. We have found that patient manipulation of the catheter while changing the bags can result in fresh bleeding and subsequent clot retention.

An average of 5 units of blood administered to the 9 patients receiving a transfusion, indicating that the majority of blood transfusions were indicated to treat or avoid shock. However, 3 patients were transfused purely to push their hematocrit above 30% for cardiac protection, which is related to preoperative anemia and not excessive operative hemorrhage.

Bowel injuries occurred in 2 patients, and both required exploratory laparotomy and

bowel resection, significantly prolonging their hospitalization. Both patients had a history of several previous intraperitoneal procedures. The first patient had undergone multiple small bowel resections related to Crohn's disease. The second patient previously underwent a Hartmann pouch diversion for a perforated colonic diverticulum. Since these two events, we have become facile with the peritoneal approach, which took significant practice. We advocate this approach in the setting of significant prior abdominal surgery, but do not use it routinely because of the limited operating space it provides. Three rectal injuries were also identified. The first rectal injury 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 2 more recent rectal injuries have been repaired using the robot, without any difficulty.

In general, we do not consider open conversion a surgical complication, and did not consider it in our overall complication rate. Though 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 RAP series, conversion occurred early in our experience. These 2 events occurred within our first 26 procedures, and it is unlikely we would convert either patient at this time.

Weaknesses of this study include the retrospective collection of the transfusion and readmission data. With missing data on 79 patients, we may be underestimating the transfusion and readmission rates. Grade I complications are likely underreported in any investigation, including our own, because house staff may have failed to consider such a minor event as a complication worthy of documenting in the medical record. Despite our best efforts, it is possible that we are missing data on referred patients that may have experienced complications that were treated by their referring physicians. We believe this to have created minimal inaccuracy because our program did not mature into a tertiary referral center until the very end of the study period. Finally, it is possible that our results are not applicable to surgeons with

laparoscopic or robotic fellowship training starting a new RAP program.

CONCLUSIONS

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

Table 1. Clavien classification system for surgical complications.

Table 2. List of complications occurring during the initial 500 procedures.

Table 3. Analysis of complications by a) Clavien system grade, and b) number of patients treated (by 100s).

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.
Grade II	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, multi-organ failure.
Grade V	Death.

Table 2. List of complications occurring during the initial 500 procedures.

	No.	%	Grade
Urological complications:	31	6.2	
Clot retention	11	2.2	II
Urine retention	9	1.8	II
Bladder neck contracture	5	1	
Dilated	3		II
Incised surgically	2		IIIB
Urine leakage	3	3.9	
Prolonged JP drainage	1		I
Ureteral catheterization	2		IIIB
Ureteral Obstruction	2	0.4	IIIB
Meatal stenosis	1	0.2	II
Bowel complications:	8	1.6	
Rectal injury (recognized intraoperatively)	3	0.6	I
Prolonged ileus	3	6.67	
Expectant management	1		I
NG tube required	2		II
Bowel injury (unrecognized)	2	2.22	IIIB
Intraop neurological complications:	2	2.22	
Foot drop	1	0.2	I
Bilateral thumb parathesia	1	0.2	I
Vascular complications:	16	3.2	
Transfusion	9	2.1	II
Postop bleeding (no transfusion required)	3	0.6	II
Deep vein thrombosis	2	0.4	I
Hemorrhage requiring re-exploration	2	0.4	IIIB
Myocardial infarction	1	0.2	IVA
Infectious complications:	3	0.6	
Clostridium difficile enterocolitis	3	0.6	I
Pulmonary complications:	4	0.8%	
Bilateral pleural effusions	2	0.4	I
Pulmonary embolus	1	0.2	IVA
Perioperative respiratory compromise	1	0.2	IVA
Other:	14	2.8	
Prolonged JP drainage, NOS	8	1.6	I
Intraop open conversion	2	0.4	0
Incisional hernia	1	0.2	II
Corneal abrasion	1	0.2	I

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