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Preventing Perioperative Complications of Robotic-assisted Radical Prostatectomy

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Abstract

OBJECTIVE—To report the change in complication rates after the identification and modification of technique to reduce their incidence during robot-assisted radical prostatectomy (RARP).

METHODS—This study retrospectively reviewed 1000 consecutive patients who underwent RARP from June 2002 to June 2011. A number of technical changes were made after complications were noted and changes in technique were documented. The Fisher exact test and multivariate analysis were used for comparison of techniques, and values of $P < .05$ were considered significant.

RESULTS—The overall rate of major and minor complications was 10.8% (108 of 1000). The complication rates of lymphoceles (0.4%), ileus (0.4%), and wound infection (0.4%) were low and did not require technical changes. There were no significant changes in rates of femoral nerve palsies, rectal injuries, or bladder neck contractures. There was statistically significant change in corneal abrasions ($P = .03$), fossa navicularis strictures ($P = .03$), and camera-site hernias ($P < .001$) after a directed intervention adjusted for age, body mass index, and learning curve. Clavien 3 and 4 complications all significantly decreased to 0.6%, with the most occurring in the first 200 cases.

CONCLUSION—Identification and correction of perioperative complications in patients undergoing robotic prostatectomy has decreased the incidence of major and minor complications adjusted for learning curve. The conscientious monitoring of adverse events can provide targeted change in technique to decrease complications and provide information to those early in learning robotic-assisted radical prostatectomy.

Prostate cancer is one of the most common cancers in men and robotic assisted laparoscopic radical prostatectomy is a common treatment option for localized prostate cancer.¹ Initially, reporting the safety of the robotic approach compared to the laparoscopic or open procedures was of crucial significance for the continuance of the robotic approach.^{2,3}

An overall complication rate of between 2.3% and 18% has been reported for open or laparoscopic/robotic radical prostatectomy, depending on surgeon experience and number of cases.^{3–8} Individual reports and reviews have addressed overcoming some of the

complications and challenges of robotic-assisted radical prostatectomy (RARP).^{9–12} While reporting complications from this procedure are necessary, additional information regarding how to prevent these complications have been limited.

Herein we provide a systematic review of perioperative complication rates in a series of 1,000 RARP's and various ways in which complications are reduced: the learning curve, active correction (deliberate change in technique due to a complication), and passive observation (observation of reduced complications after change in technique for a different intention).

MATERIAL AND METHODS

After Investigational Review Board approval (HS 1998–1984), 1000 consecutive patients who underwent a RARP from June 2002 to June 2011 by a single surgeon (T.A.) were prospectively monitored. All RARPs were performed with the 5- or 6-port transperitoneal approach. A number of technical changes were made after complications were noted, and changes in technique were documented.

Patients were given the Self-care Ability Scale for the Elderly health questionnaires at 1, 2, and 3 months and were additionally assessed by postoperative clinical evaluation or by telephone communication within 3 weeks after RARP and thereafter for a median of 38.7 months (range, 1–113 months). Additional patient follow-up consisted of 1 year (84.5%), 2 years (65.3%), 3 years (52.2%), 5 years (29.7%), and 7 years (7.6%).

Some complications were rare, such as lymphoceles, ileus, and wound infection, and there were no changes in technique. The Clavien classification system was used to grade the severity of complications. The Fisher exact test was used for comparison of complication rates by technique, and a value of $P < .05$ was considered significant. Multivariate logistic regression analysis was used to compare complication rates after changes after adjusting for age, body mass index, and the learning curve.

RESULTS

Patient characteristics are reported in Table 1. There were no deaths. Overall, 108 complications occurred in this RARP group for a rate of 10.8%. Seven complications were identified that were investigated regarding a change in technique to reduce the complication rate.

Table 2 presents the total number of complications by Clavien score over the series of 1000 RARPs divided into groups of 100. Clavien grade 1 complications of corneal abrasion and nerve palsy do not require reoperation but can be painful or very slow to heal, they too decreased appreciably to 0.1% in this study. Clavien 3 and 4 complications of fossa navicularis strictures, incision hernias, and pulmonary embolus/deep venous thrombosis significantly decreased to 0.6%. The reduction of the small incidences of Clavien 3 (bladder neck contractures [BNC] and rectal injury) showed a statistical trend. The complication rates of lymphoceles (0.4%), ileus (0.4%), and wound infection (0.4%) were low and did not require technical changes. There was no statistically significant change in femoral nerve palsies, rectal injuries, or BNC, despite reduced the overall frequency, as listed in Table 1.

The learning curve will be applied to all complications in general, because experience will continue to improve outcomes. Of the 108 RARP-associated complications, 39 (36%) occurred in the first 200 cases for a rate of 18 per 100 cases. This was reduced by 50% after 200 cases, when the rate decreased to 9 per 100 cases ($P = .005$). If we only consider

complications in the first 200 patients compared with the last 800 patients with Clavien grade of 2 (15.5% vs 6.7%) and 3 (12.5% vs 5%), the overall improvement in the complications rate after 200 patients continues to be significant ($P = .0002$ and $P = .0003$, respectively).

Active correction by my modifying technique after a noted complication resulted in statistically significant changes in corneal abrasions ($P = .013$), fossa navicularis strictures ($P < .001$), and camera-site hernias ($P = .007$). We additionally adjusted for age, body mass index, and the learning curve of the surgeon, and these reductions in complications remained significant ($P = .030$, $P = .031$, and $P < .001$, respectively).

COMMENT

The overall reported complication rates among RARP surgeons include minor complications (Clavien 1 and 2) from 5% to 7% and major complications (Clavien 3-5) at approximately 4%.^{7,13} Unfortunately, standardization and under-reporting of complications remain a concern. Reductions in transfusion rates by laparoscopic prostatectomy and RARP have primarily decreased the rate of low-risk Clavien 2 complications.² Mortality rates remain consistently rare, at 0.1% to 0.2%.^{3,7,8} Despite the low complication rate, surgeons and hospitals strive to continually make operations safer as a primary goal, and reporting of these methods are scarce. We discuss 3 mechanisms by which we have attributed to the correction of complications: (1) the “learning curve,” (2) active correction, and (3) passive observation.

Multiple studies have shown that guidance from experienced RARP surgeons may abrogate complication rates of novice surgeons by shortening the learning curve.^{14,15} Because we incorporated RARP early in its inception, guidance from a more experienced robotic surgeon was not possible. Therefore, to display the true effect of a learning curve, our 1000 consecutive patients are shown to fully represent the RARP initial learning experience. Combined intraoperative and early complications were 0.8% high-risk (Clavien 3) and 2.3% low-risk (Clavien 2) for the 1000-patient experience. In this study, half of the intraoperative/early and 25% of the late complications occurred in the first 200 RARP patients from 2002 to 2004.

For example, prevention of deep venous thrombosis or pulmonary embolus, or both, along with nerve traction injuries, may have been improved with familiarity of the surgical team to positioning in the steep Trendelenburg position, improved surgical assisting, and improved efficiency of the surgery.^{12,16} A significant complication is injury to the femoral nerve that can be permanent and has been rarely reported in the urologic literature.¹⁷ Although we did not show a statically significant change in complication rate, prevention of this complication would likely result from decreasing operative time, taking meticulous care to position the patient with attention to hip flexion, and rechecking if the patient was suspected of sliding on the table. The “learning curve” has been shown to have an important effect on complications but is not likely to be the sole difference in reducing complications.

In addition to the learning curve, surgeons will occasionally change technique as a result of a series of complications noted postoperatively that have had a negative affect on the patient and the surgeon. With the use of meticulous of follow-up and documentation of complications, specific complications can be noted and a technical change applied. For example, major side effects (urinary incontinence, erectile dysfunction) and complications (intraoperative bleeding) occurred during the initiation of open retropubic radical prostatectomy. A series of anatomic observations and surgical applications Walsh¹⁸ led to a significant change in the technique used for radical prostatectomy. These observations led to

increased awareness and deliberate change in technique to reduce side effects and complications that merely related to number of cases performed (ie, “learning curve”).^{19,20} Therefore, long-term data collection of patient demographics and outcomes has been essential to identify recurrent complications and provide opportunities to prevent adverse events (Table 3).

We first applied this approach to corneal abrasions by using foam-based safety goggles (SunMed iGuard #9-0210-00) perioperatively, which cost \$5 (U.S. dollars) at full price. Corneal abrasions can cause significant postoperative discomfort and are felt to occur secondary to positional eye edema from the Trendelenburg positioning. Foam-based safety goggles should be placed over the patient’s eyes for the operation and for about 90 minutes in the recovery room, until the patient is fully alert and oriented enough not to rub his eyes. The use of goggles showed a statistically significant difference in this complication and is clinically useful ($P = .03$).

Secondly, reducing the size of the Foley catheter resulted in a statically significant reduction of fossa navicularis strictures ($P = .03$). A 22F catheter was used to prevent inadvertent stapling of the urethra during control of the dorsal venous complex. We found that catheters sized 22F could be associated with nearly a 10% risk of catheter-induced fossa navicularis strictures and consequently reduced the catheter size to virtually eliminate the incidence of strictures in the last 850 cases.¹⁰ Thus, only 16F or 18F Foley catheters are now used perioperatively.

In addition to the previous changes, the number of incisional hernias was noted. After review of the general surgery literature, we found that increased tension may be placed on the vertical fascial incision, and evidence existed regarding changing this incision to a horizontal fascial incision.^{21,22} In response, the incision for the camera port and subsequent removal of the prostate was changed from a vertical to horizontal incision.⁹ The horizontal fascial incision has reduced our hernia rate from 5.4% (40 of 735) to 0.4% (1 of 265; $P < .001$). This result is guarded due to lag time bias because many (50%) incisional hernias present more than 1 year after surgery; therefore, we will continue to monitor this result.²³

Passive observation can be made if a reduction in a complication is noted from a change made with different intentions. We observed that the addition of the Rocco stitch, which reapproximates Denonvilliers fascia before the Van Velthoven anastomosis, may have led to a subsequent reduction of BNCs by relieving tension on the anastomosis.²⁴ Although the intention of the Rocco stitch may have been to reduce incontinence, which has not been convincingly shown, we have seen a trend in reduction of BNCs.²⁵ In the first 600 cases, 6 BNCs (1%) occurred, and since incorporating the Rocco stitch 400 cases ago, there has been only 1 BNC ($P = .052$). Hu et al²⁶ showed a decrease in BNC rate in a series of open compared with robotic radical prostatectomy (14% vs 5.8%, $P < .001$); however, this may be further improved by posterior myofascial reconstruction (Rocco stitch).²⁶ The occurrence of BNC should be further investigated with larger numbers regarding this observation.

We acknowledge limitations of this study, which include an under-reporting of complications due to time lag of presentation and loss of follow-up. Other complications may be asymptomatic and are not recognized by the patient or other physicians not familiar with RARP, and therefore, are not reported. In particular, asymptomatic lymphoceles may be under-reported because postoperative imaging is not routine after RARP at our institution. Despite these limitations, reporting perioperative complication rates for RARP continues to provide information about the safety of this surgery, and providing new solutions may yield continued improvement.

CONCLUSIONS

Identification of complications and proposing insightful working solutions has decreased the incidence in RARP of major and minor complications. Inclusion of these techniques may improve patient outcomes for robotic surgeons in their early experience.

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Table 1

Patient characteristics

Characteristic	Average or %
Age, years	61.2
Body mass index, kg/m ²	26.8
Prostate-specific antigen	5.2
Prostate weight, grams	52.4
Clinical stage	
T1	65.8
T2	29.6
T3	4.0
Gleason biopsy score	
6	55.5
7	34.3
8–10	9.6
Pathologic stage	
PT2	71.9
PT3A	20.5
PT3B	6.7
PT4	0.3
Pathologic Gleason score	
6	34.3
7	54.5
8–10	10.2

List of complications

Table 2

Major Complications	Clavien Score	Occurrence	1000 Patients Grouped by 100										Total
			0-100	101-200	201-300	301-400	401-500	501-600	601-700	701-800	801-900	901-1000	
Corneal abrasion	1	OR	0	4		0	0	0	0	0	0	1	5
Dehiscence	3b	OR	0	2	0	0	0	2	0	0	0	0	4
Rectal Injury	3a	OR	0	1		0	0	0	0	0	0	0	1
Cardiac arrest	4	OR	1	0	0	1	1	0	0	0	0	0	3
Nerve palsy	1	Early	1	0	0	1	2	0	0	0		0	5
Anastomosis leak	ID	Early	0	0	1	0	0	0	0	0	0	0	1
Hematuria with clot retention	1	Early	1-3b	0	1	0	0	0	0	0	0	1	3
Deep vein thrombosis	2	Early	1	0	0	0	0	0	0	0	0	0	1
Transfusion	2	Early	0	1	1	0	0	0	1	1	0	0	4
Post-op bleeding w/o transfusion		Early	0	0	0	2	0	0	0	0	1	0	3
Ileus	2	Early	1	0	0	0	0	0	0	1	2	0	4
Wound infection	2	Early	0	0	0	0	0	0	0	0	0	0	0
Urinary tract infection	2	Early	0	0	0	0	0	0	0	0	0	0	0
Urine leak	1	Early	4	0	0	0	0	2	0	0	0	0	6
Pulmonary embolism	4 a	Early	2	3		0	0	0	0	0	0	0	5
Fossa strictures	3 a	Late	5	5		0	0	0	0	0	0	1	11
Bladder neck contractions	3 a/3 b	Late	0	1	1	2	1	1		0	0	1	7
Lymphocele	3a/3b	Late	0	1	0	0	1	0	0	0	2	0	4
Port-site hernias	3 b	Late	4	2	3	6	5	11	6		1	0	41
Total complications			17	22	6	12	10	16	7		7	3	108

OR, during the operation; w/o, without.

indicates change in technique applied.

Table 3

List of complications and corrections

Complications	Clavien	Old Rate No. (%)	Resolution	New Rate No. (%)	P-Value	
					Unadjusted*	Adjusted†
Learning curve						
Nerve palsy	2	4/800 (0.5)	Avoid hyperextension of the femoral nerve and careful padding	1/200 (0.5)	>.99	.470
Rectal injury	3a	1/150 (0.7)	Meticulous apical/lateral dissection and knowledge of correct surgical planes	0/850 (0)	.870	.419
Pulmonary embolus	4a	5/190 (2.6)	Knee-high to thigh-high pneumatic compression and early/persistent ambulation	0/810 (0)	.858	.863
Active correction						
Corneal abrasion	1	4/200 (2.0)	Foam-based safety goggles	1/800 (0.1)	.013	.030
Fossa strictures	3a	10/165 (6.1)	Avoidance 20F catheters	1/835 (0.1)	<.001	.031
Camera-site hernias	3b	40/735 (5.4)	Transverse midline fascial incision for camera port and prostate extraction	1/265 (0.4)	.007	<.001
Passive observation						
BNC	3a/3b	6/592 (1.0)	Addition of Rocco stitch to the Van Velthoven single-knot anastomosis	1/408 (0.2)	.187	.052

BNC, bladder neck contracture.

* Unadjusted logistic regression.

† Adjusted for age, body mass index, and surgeon learning curve.