Impact of Routine Use of Surgical Drains on Incidence of Complications with Robot-Assisted Radical Prostatectomy

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Abstract

Purpose: To assess the impact of eliminating routine drain placement in patients undergoing robot-assisted laparoscopic prostatectomy (RALP) and pelvic lymph node dissection (PLND) on the risk of postoperative complications.

Patients and Methods: An experienced single surgeon performed RALP on 651 consecutive patients at our institution from 2008 to 2012. Before August 2011, RALP with or without PLND included a routine peritoneal drain placed during surgery. Thereafter, routine intraoperative placement of drains was omitted, except for intraoperatively noted anastomotic leakage. We used multivariable logistic regression to compare complication rates between study periods and the actual drain placement status after adjusting for standard prespecified covariates.

Results: Most patients (92%) did not have $\geq$ grade 2 complications after surgery and only two patients (0.3%) experienced a grade 4 complication. The absolute adjusted risk of a grade 2–5 complication was 0.9% greater among those treated before August 2011 (95% confidence interval [CI] -3.3% – 5.1% ; $p=0.7$), while absolute adjusted risk of a grade 3–5 complication was 2.8% less (-2.8% ; 95% CI -5.3% – 0.1% ; $p=0.061$). Results based on drain status were similar.

Conclusions: Routine peritoneal drain placement following RALP with PLND did not confer a significant advantage in terms of postoperative complications. Further data are necessary to confirm that it is safe to omit drains in most patients.

Introduction

PLACEMENT OF A CLOSED SUCTION DRAIN is considered by many surgeons a standard part of a robot-assisted laparoscopic prostatectomy (RALP). However, there is limited evidence regarding the benefit of routine drain placement. Drain placement has been associated with surgical site infections,¹ pain at the drain site,² bleeding,³ arteriovenous fistulae, pseudoaneurysms,⁴ and retained foreign bodies requiring reoperation.⁵ Moreover, several prospective studies performed with other surgical procedures have failed to show a positive impact of drain placement on rates of complication.^{6–9} It has been our observation that the presence of a drain may be a barrier to early discharge after surgery and may not be necessary in the majority of RALP patients. If drain placement could be safely reserved for cases in which there is a concern for anastomotic integrity, omission of routine drain placement might facilitate discharge on a short-stay pathway in the majority of RALP patients.

This study examines the impact of eliminating routine drain placement in patients undergoing RALP and PLND.

Our primary aim is to determine if the omission of routine postoperative drain placement affects the incidence of complications within 90 days after surgery.

Materials and Methods

Patient population

Following institutional review board approval, we used our institutional database to identify 651 patients who underwent RALP using a 5-port transperitoneal technique performed by a single surgeon (V.P.L.) from September 19, 2008, when he began at MSKCC, to October 15, 2012. Fourteen patients were excluded from the analysis (1 with incomplete charts, 2 who were electively converted to open radical prostatectomy due to adhesions from prior pelvic surgery, and 11 who underwent salvage radical prostatectomy), leaving 637 patients. The standard of care for patients who underwent surgery on or before August 13, 2011, included placing a postoperative drain. There were 34 cases before August 2011 in which a drain was not placed, which represented our first attempts at omitting the drain. After

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August 13, 2011, drains were routinely omitted except in cases of an intraoperatively identified or suspected anastomotic leak ($n=6$).

Patients who underwent surgery before August 13, 2011, were defined as belonging to the first study period and those who underwent surgery after that date were assigned to the second study period. Two patients underwent surgery on August 13, 2011, one who had and one who did not have a postoperative drain placed; they were included in the first and second study periods, respectively. All patients regardless of drain status were managed on a standardized clinical pathway and were included in the analysis.

Demographic and perioperative characteristics were reviewed, as well as complications throughout the postoperative course out to 90 days. All patients are evaluated for complications at each follow-up visit, and complications are prospectively entered into a complications database. Complications identified within 90 days of surgery were graded according to a modified Clavien scale,¹⁰ and reported following the Martin–Donat criteria.^{11,12} All patients underwent transperitoneal RALP with modifications to previously described techniques.¹³ The vesicourethral anastomosis was accomplished using a single-layer, running 2-0 Monocryl suture. When necessary, the bladder neck was reconstructed anteriorly. The integrity of the anastomosis was tested by filling the bladder with 180 mL of saline. PLND was performed in all patients with a 2% or greater risk of lymph node involvement as calculated by the MSKCC nomogram.¹⁴ The boundaries of this dissection included external, obturator, and hypogastric packets.¹⁵ Drains, when placed, were removed if the creatinine level of the fluid was the same as serum, generally on the first or second postoperative day. The urinary catheter was removed by the nursing staff in the clinic at 7–10 days after surgery without cystography. Purposefully, there was no change in the time to catheter removal during both periods.

Statistical analysis

We initially planned to use a previously described method for analyzing modifications to the surgical technique, which adjusts for the surgical learning curve¹⁶ since that can artificially improve the apparent results of a modification. In brief, the method estimates a learning curve based on a model, including patients, before a surgical modification was first implemented and then projects this curve out to predict the results of patients treated with the modification. However, we did not see any clear, consistent, and plausible trends in complication rates over time. This is perhaps unsurprising given that the surgeon was highly experienced (>750 prior RALPs) at the start of this surgical series and would be beyond the learning curve for most complications. Therefore, we did not adjust for a learning curve in our analyses.

Our primary analysis followed the intent-to-treat (ITT) principle with the hypothesis that the study period, in which a patient underwent surgery, would not affect the number of patients with a grade 2–5 or a grade 3–5 complication. This ITT analysis is primary because we would not recommend omitting drains in patients with an indication of a leak. A multivariable logistic regression model was developed, adjusting for the covariates American Society of Anesthesiologists (ASA) score (I/II vs. III/IV), body-mass index, age-adjusted Charlson comorbidity index, number of nodes

removed during surgery, and previous abdominal surgery. These covariates were selected as possible contributors to complications based on the analysis of prior prostatectomy series. The 95% confidence interval (CI) for the risk difference was obtained using bootstrap methods. The 95% CI was calculated based on 2000 bootstrapped samples stratified by drain status and obtained by reporting the 2.5 and 97.5 centile of the 2000 bootstrapped risk differences. There were no assumptions necessary for generating a 95% CI using this bootstrapping technique. As a sensitivity analysis, we repeated the analysis, comparing patients with and without a drain, with the hypothesis that drain placement would not affect the number of patients with a grade 2–5 or a grade 3–5 complication. All analyses were conducted using Stata 12.0 (Stata Corp., College Station, TX).

Results

Patient characteristics are outlined in Table 1. The sample was characteristic of the more advanced prostate cancers treated at academic centers in recent years. Due to the nature of the study, drain status differs by the year of surgery. There were 169 patients (27%) who had a hospital stay longer than 1 day; the proportion of patients with a hospital stay longer than 1 day was significantly greater during the first study period (Fisher's exact test, $p<0.0001$). We did not find sufficient evidence to suggest that lymph node involvement differed by the study period (Wilcoxon rank sum test, $p=0.9$); however, the number of lymph nodes removed during surgery differed significantly by the study period (Wilcoxon rank sum test, $p<0.001$), with fewer nodes removed for patients who underwent surgery in the second study period. Despite this difference in the number of lymph nodes removed, we did not find evidence to suggest an association between the number of lymph nodes removed and the risk of a grade 2–5 complication ($p=0.3$) or a grade 3–5 complication ($p=0.060$). Table 2 presents data on complications, by study period and drain status. Most patients (586, 92%) did not have a grade 2 or higher complication within 90 days after surgery and only two patients (0.3%) experienced a grade 4 complication. Table 3 specifies details of grade 2–5 complications by drain status. Importantly, only 11 (1.7%) patients required interventional radiology (IR) drainage of a fluid collection, with proportions similar regardless of drain placement. Indications for IR drainage included infected lymphocele/abscess in 8, symptomatic lymphocele in two, and urinoma in one patient. In each of these patients, there were no long-term sequelae following the drainage procedure. Asymptomatic or minimally symptomatic fluid collections were observed.

Tables 4 and 5 display the results of the multivariable analyses. Table 4 represents the ITT analysis that investigated the risk of either range of complications by the study period. The adjusted risk of a grade 2–5 and a grade 3–5 complication, respectively, was 8.0% and 2.2% for patients who underwent surgery in the first study period and 7.0% and 4.9% for patients who underwent surgery in the second study period. We did not find sufficient evidence to suggest a difference in the risk of a grade 2–5 complication based on the study period: after adjusting for the previously specified covariates, the adjusted absolute risk difference was 0.9% (95% CI -3.3% – 5.1% ; $p=0.7$). The study period did not reach statistical significance in the case of a grade 3–5

TABLE 1. PATIENT CHARACTERISTICS

Characteristic	Period 1 (n=407)	Period 2 (n=230)	p-Value ^a
Age at surgery (years)	61 (55, 66)	61 (56, 66)	0.6
Age-adjusted Charlson index			
<2	164 (40)	83 (36)	0.6
2–4	219 (54)	133 (58)	
>4	24 (5.9)	14 (6.1)	
ASA			
1 or 2	281 (69)	132 (57)	0.003
3 or 4	126 (31)	98 (43)	
BMI	28 (26, 31)	28 (25, 31)	0.8
Unknown	8 (2.0)	0 (0)	
Preoperative total PSA (ng/mL)	5.0 (3.6, 7.0)	5.2 (3.9, 7.5)	0.2
Gleason score			
6	78 (19)	28 (12)	0.090
7	287 (71)	180 (78)	
8	16 (3.9)	9 (3.9)	
9	18 (4.4)	12 (5.2)	
10	0 (0)	1 (0.4)	
Unknown	8 (2.0)	0 (0)	
Previous abdominal surgery	124 (30)	78 (34)	0.4
Extracapsular extension	136 (33)	88 (38)	0.2
Seminal vesicle invasion	26 (6.4)	20 (8.7)	0.3
Positive surgical margins	61 (15)	39 (17)	0.6
Lymph node invasion	36 (8.8)	20 (8.7)	
Unknown	74 (18)	36 (16)	0.9
Lymph node dissection	333 (82)	194 (84)	0.4
Positive lymph nodes ^b	36 (11)	20 (10)	0.9
Number of lymph nodes removed ^b	16 (12, 21)	13 (10, 17)	<0.0001
Length of hospital stay >1 day	149 (37)	20 (8.7)	<0.0001

Values are displayed as frequency (percentage) or median (interquartile range).

^ap-Values determined by Wilcoxon rank sum test for continuous variables and Fisher's exact test for categorical variables.

^bValues include only those who received a lymph node dissection.

ASA = American Society of Anesthesiologists; BMI = body-mass index.

complication: after adjusting for the previously specified covariates, the adjusted absolute risk difference was -2.8% (95% CI -5.3% – 0.1% ; $p=0.061$).

The results of the sensitivity analysis by drain status are displayed in Table 5. We did not have sufficient evidence to suggest a difference in the risk of a grade 2–5 or a grade 3–5 complication based on drain status after adjusting for the previously specified covariates ($p=0.5$, 0.12 , respectively). The adjusted absolute risk difference for a grade 2–5 complication was 1.3% (95% CI -2.8% – 5.3%) and for a grade 3–5 complication was -2.3% (95% CI -4.7% – 0.5%).

Discussion

Drains are often placed in urologic surgery as a matter of routine or tradition rather than because of evidence-based benefit. Only a few studies have examined the role of drains in

preventing complications in open radical retropubic prostatectomy (RRP),¹⁷ open RRP and RALP,¹⁸ and laparoscopic prostatectomy.¹⁹ The methods used in each of these studies are limited by a clear selection bias, in that, patients who received drains were thought to be at higher risk of developing complications and were compared with patients in whom a drain was omitted. In each of these reports, there were selection criteria for omitting the drain, including bladder neck preservation, hemostasis, and quality of the vesicourethral anastomosis. While the present study also lacks randomization, we report on a consecutive series of RALPs in which a drain was systematically omitted, thereby lessening potential selection bias. Our analysis was performed using the ITT principle, comparing patients treated when a drain was routinely placed with patients treated when the routine placement was omitted.

Our results fail to demonstrate a clear and significant advantage to either drain placement or drain omission. However,

TABLE 2. FREQUENCY (PERCENTAGE) AND GRADE OF COMPLICATIONS BY STUDY PERIOD AND DRAIN STATUS

Maximum complication grade	Period 1 (n=407)	Period 2 (n=230)	With drain (n=379)	Without drain (n=258)
0 or 1	373 (92)	213 (93)	346 (91)	240 (93)
2	23 (5.7)	5 (2.2)	22 (5.8)	6 (2.3)
3	9 (2.2)	12 (5.2)	10 (2.6)	11 (4.3)
4	2 (0.5)	0 (0)	1 (0.3)	1 (0.4)
Grade 2–5 complication	34 (8.4)	17 (7.4)	33 (8.7)	18 (7.0)
Grade 3–5 complication	11 (2.7)	12 (5.2)	11 (2.9)	12 (4.7)

TABLE 3. TYPE AND FREQUENCY OF GRADE 2–5 COMPLICATIONS BY DRAIN STATUS

Complication	With drain (n = 379)	Without drain (n = 258)
Pelvic collection—IR drainage	7 (1.8)	4 (1.6)
Anemia requiring transfusion	6 (1.6)	3 (1.2)
Pulmonary embolus	3 (0.8)	3 (1.2)
Deep venous thrombosis	3 (0.8)	1 (0.4)
Paralytic ileus	2 (0.5)	2 (0.8)
Pelvic collection—observed	3 (0.8)	0
Fever	2 (0.5)	0
Hernia with repair	2 (0.5)	0
Gastrointestinal bleeding	0	1 (0.4)
Renal failure	1 (0.3)	0
Supraventricular tachycardia	1 (0.3)	0
Prolonged intubation	1 (0.3)	0
Cerebral vascular accident	1 (0.3)	0
Urinary tract infection	1 (0.3)	0
Bowel resection	0	1 (0.4)
Stricture with meatotomy	0	1 (0.4)
Diarrhea	0	1 (0.4)
Hydronephrosis	0	1 (0.4)

the 95% CIs allow for a potential difference in grade 2–5 complication rates in either direction of 2%–3% and for an increase in grade 3–5 complication rates of up to 5% in the second study period, differences that could be clinically meaningful. Therefore, we cannot exclude the possibility that drain placement or omission might importantly compromise safety.

It is possible that analyzing all complications could obscure the ability to identify the true impact of drain placement, as most complications are likely unrelated to either omission or placement of a drain. To that end, we performed a sensitivity analysis examining complications that could be potentially drain related, including fluid collections, ileus, infections, abscesses, deep vein thromboses, hematomas, fevers, and pulmonary emboli (results are shown in Supplementary Table S1; Supplementary Data are available online at www.liebertpub.com/end). Similar to the primary analysis, we were unable to identify a significant difference in drain-related complication rates, but are unable to exclude the possibility of a difference.

Although there are limited data in the urological literature, routine placement of drains has been shown to be of limited benefit in other surgical fields. Drain placement has not been shown to prevent complications at the time of elective gas-

TABLE 4. THE ADJUSTED RISK OF A COMPLICATION BY STUDY PERIOD

	ITT analysis	
	Grade 2–5 complication	Grade 3–5 complication
Period 2 risk	7.0%	4.9%
Period 1 risk	8.0%	2.2%
Adjusted risk	0.9%	–2.8%
difference (95% CI)	(–3.3%–5.1%)	(–5.3%–0.1%)

Risk is adjusted for the covariates ASA, BMI, age-adjusted Charlson index, number of nodes removed during surgery, and previous abdominal surgery.

ITT = intent-to-treat.

TABLE 5. THE ADJUSTED RISK OF A COMPLICATION BY USE OF POSTOPERATIVE DRAIN

	Sensitivity analysis	
	Grade 2–5 complication	Grade 3–5 complication
Without-drain risk	6.8%	4.5%
With-drain risk	8.2%	2.3%
Adjusted risk	1.3%	–2.3%
difference (95% CI)	(–2.8%–5.3%)	(–4.7%–0.5%)

Risk is adjusted for the covariates ASA, BMI, age-adjusted Charlson index, number of nodes removed during surgery, and previous abdominal surgery.

trectomy for gastric cancer and is possibly associated with longer operative times, longer postoperative hospital stay, and additional drain-related complications.²⁰ Studies looking at PLND for ovarian, cervical, and endometrial cancers, colon resection, cholecystectomy, elective liver resection, hysterectomy, and spinal fusion have all failed to show any difference in terms of complications as a function of drain placement.^{3,6,8,9,21} These studies failed to demonstrate any difference in the number of complications based on drain placement, which is consistent with our findings.

Surgeons performing PLND are frequently concerned about adequate lymphatic fluid drainage after surgery. Some studies suggest that pelvic drains may be required for extended PLND.²² There are data regarding lymph node dissection (LND) at other surgical sites, which suggest that drains reduce the incidence of seromas, as well as seroma volume and need for aspiration.²³ It is possible that the risk of seroma is related to the extent of LND performed. However, a high percentage of patients (83%) in the present study had LND with a median number of lymph nodes removed, exceeding those of most reported open RRP or RALP series. Moreover, with early drain removal (during the first 1–2 days postsurgery in most of our patients), it appears likely that the surgically placed drain will miss the few patients requiring drainage of lymphatic fluid, as supported by the similar rates of secondary IR drain placement on subsequent follow-up shown in Table 3. Therefore, it is not clear that a drain is beneficial even in this regard.

Limitations of this study include the short-term follow-up data. Late complications could include hernias and late-appearing pelvic abscesses due to secondary infection of a residual pelvic collection. However, it is likely that most complications that might be influenced by drain placement occur within the first few months after surgery. While a prospective randomized study, including surgeons of varying experience with RALP, would be required to confirm the lack of benefit from routine use of surgical drains, our data are consistent with other surgical specialties in demonstrating that a drain may not be necessary in most patients who undergo RALP.

Finally, drains may indeed be useful in select cases. In our series, a drain was utilized in the study group in cases of suspected anastomotic leakage at the time of surgery in 6 cases. While not seen in this series, instances such as a ureteral injury, rectal injury, or inadequate hemostasis may be well served with the addition of a drain. We believe that in the majority of cases, however, any potential benefits of drain

placement may be outweighed by the risks and that omission of drains may have advantages in terms of patient comfort and early hospital discharge.

Conclusions

In conclusion, this large consecutive surgical series failed to demonstrate a clear advantage to routine peritoneal drain placement in terms of postoperative complications following RALP with PLND. However, the potential for a clinically meaningful difference suggests that further study is required to determine the risks and benefits of drain placement. Until such time, on the basis of the current analysis failing to show a significant advantage for drain placement, we have eliminated routine drain use in patients undergoing RALP.

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Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

ASA = American Society of Anesthesiologists
BMI = body-mass index
IR = interventional radiology
ITT = intent-to-treat
LND = lymph node dissection
MSKCC = Memorial Sloan Kettering Cancer Center
PLND = pelvic lymph node dissection
RALP = robot-assisted laparoscopic prostatectomy
RRP = radical retropubic prostatectomy