The addition of robotic surgery to an established laparoscopic radical prostatectomy program: effect on positive surgical margins

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Purpose: *The addition of robotic assistance with the da Vinci surgical system for performing laparoscopic radical prostatectomy has been reported to improve surgical outcomes. In order to evaluate the benefit of robotic assistance to improve cancer control in a center with an established laparoscopic radical prostatectomy program, we evaluated the incidence of positive surgical margins in both transperitoneal laparoscopic (LRP) and robotically assisted laparoscopic radical prostatectomy (RALP).*

Materials and methods: *We performed an Institutional Review Board (IRB) approved, retrospective review of 247 men with clinically localized prostate cancer treated with either a LRP or a RALP from March 2000 to August 2006. Pathology reports were reviewed for both preoperative and postoperative Gleason score as well as clinical and pathological stage. Surgical pathology specimens were evaluated using a whole mount, step section technique. Extracapsular extension, seminal vesicle invasion and positive margins were noted when present in the final surgical pathologic specimens.*

Results: *One hundred ninety seven patients underwent LRP, and 50 patients underwent RALP. Seven of the 197 LRP required open conversion to retropubic radical prostatectomy, and were excluded. None of the RALP were converted. The overall positive surgical margin rate for LRP and RALP was 18% (35/190) and 6% (3/50), respectively (p = 0.032). When examining pathologically organ confined specimens (pT2), the positive surgical margin rate was 12% (20/161) and 4.7% (2/43) for the LRP and RALP cohorts, respectively (p = 0.181). For pathologic disease that has spread outside the capsule (pT3/T4), the positive surgical margin rate was 54% (15/28) and 14% (1/7) for LRP and RALP, respectively (p = 0.062). Patient age, race and prostate volume were not significant factors in the incidence of positive surgical margins.*

Conclusion: *The addition of robotic assistance to an established laparoscopic radical prostatectomy program appears to reduce the incidence of positive surgical margins. Data is maturing to determine whether this will lead to improved functional and oncologic outcomes.*

Key Words: prostatic neoplasms, prostatectomy, robotics, laparoscopy, male

Introduction

Prostate cancer remains the most commonly diagnosed solid organ malignancy in men and the second leading cause of male cancer death in the United States.[1] The stage migration associated with routine PSA screening has led to an increased incidence of localized prostate cancer.[2] As a result, surgical options have become the prominent form of initial therapy in these men. Even with refinements in technique and postoperative care, radical retropubic prostatectomy remains an invasive procedure with associated morbidity.

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Over the past decade laparoscopic prostatectomy (LRP) has gained popularity in the United States. Although initial reports were less than enthusiastic about the benefit of laparoscopy in prostate surgery,[3] perseverance by several groups has led to more favorable results.[4,5] Consequently, patients now benefit from the decreased morbidity and convalescence associated with LRP without compromising oncologic outcomes, measured in the form of positive surgical margins.[6,7]

The major disadvantage of LRP cited by many practicing urologists is the difficult learning curve required before proficiency is achieved with the procedure.[8] This has led to the recent excitement surrounding robotic assisted laparoscopic prostatectomy (RALP). Robotic assistance has been shown to reduce the number of cases required to become adept with laparoscopic prostatectomy and shorten the learning curve, especially in surgeons transitioning from open retropubic prostatectomy (RRP).[9-11] The benefits of RALP are derived from the increased range of motion of the robotic arms, improved three dimensional visualization, motion scaling and superior ergonomics.[12]

There have been several published reports that have shown excellent oncologic outcomes with RALP.[13,14] However, there is limited data on the transition from LRP to RALP within an institution.[15,16] The impact of adding robotics to our established LRP program on the positive surgical margin (PSM) rate is evaluated.

Methods

Patients undergoing LRP and RALP between March 2000 and August 2006 were included in the study population. LRP was performed at our institution between March 2000 and December 2005 while RALP was offered from October 2005 to August 2006. The study protocol was approved by the Institutional Review Board (IRB) of the Thomas Jefferson University Hospital (Philadelphia, PA). The majority of patients were seen in our Multidisciplinary Genitourinary Cancer Clinic, where they elected for radical prostatectomy after being counseled on all treatment options by a urologist and radiation oncologist.[17]

The surgical technique for both LRP and RALP were similar in all cases. An intraperitoneal antegrade approach was used. LRP was performed using the Montsouris technique, using a transperitoneal approach with early dissection of the seminal vesicles and vasa deferentia.[18] RALP, using the da Vinci surgical system (Intuitive Surgical, Sunnyvale, CA), was also performed using an intraperitoneal approach, but the seminal vesicles and vasa deferentia were dissected after division of the posterior bladder neck. The two techniques were otherwise identical.

All pathologic specimens were inked and evaluated using a whole mount step section technique, as previously described.[19] Final Gleason score, as well as pathologic stage, and positive surgical margins were noted when present in the final surgical pathologic specimens. A surgical margin was considered positive if tumor appeared at the inked margin. Prospective review of all positive margins was evaluated in a multidisciplinary pathology conference.

Pelvic lymph node dissection was performed, when indicated, in intermediate and high risk patients. Early in our series, patients were stratified using the D'Amico classification, for whom pelvic lymphadenectomy was omitted in low risk patients.[20] Later in our series, the Kattan preoperative nomogram was used for risk stratification, and pelvic lymphadenectomy was omitted in those patients whose predicted risk of nodal involvement was 1% or less.[21]

Data was collected prospectively for all patients in an IRB approved fashion. Data collected included demographic data, preoperative tumor parameters, perioperative data, and final pathologic data. Demographic and preoperative data included patient age, race, body mass index (BMI), preoperative prostate specific antigen (PSA), biopsy Gleason sum, and clinical stage. Perioperative data included operative time, operative technique, estimated blood loss (EBL), open conversion, final surgical pathology and postoperative complications.

Data analysis was performed using MINITAB statistical software (v14.13). Categorical data was compared using Chi-square analysis while continuous variables were evaluated using the Student's t-test.

Results

Two hundred and forty seven men with clinically localized prostate cancer underwent minimally invasive radical prostatectomy during the study period. One hundred ninety seven patients underwent LRP, and 50 patients underwent RALP. Seven patients in the LRP group required conversion to RRP, and were excluded from analysis. All of the RALP procedures were completed without conversion.

With the exception of body mass index (BMI) the two groups were similar in the demographic and preoperative clinical variables including age, preoperative prostate specific antigen and clinical stage, Table 1.

TABLE 1. **Patient and operative characteristics**

Characteristic	RALP	LRP	p
Number of patients	50	190	
Age (yr)	57.7 (37-70)	58.6 (43-74)	0.441
BMI	28.4 (20.4-36.6)	26.8 (18.8-51.8)	0.036
PSA (ng/ml)	5.5 (1.1-21.1)	6.5 (0.4-46)	0.103
EBL (ml)	287 (50-1500)	370 (50-3200)	0.250
Prostate size (g)	41 (16-102)	43.3 (14-156)	0.506

Most patients had favorable clinical characteristics and were comparable between the two groups, Table 2. Approximately 80% of the patients had no palpable disease on digital rectal examination. Additionally, 72% of the men from each cohort had biopsy Gleason sums of six or less.

The pathologic stage and Gleason score were also similar between the two groups, Table 3. A majority of the men had diseased localized to the prostate with a Gleason sum of six or less. Pelvic lymphadenectomy was performed in 51 (27%) patients in the LRP arm, and in 14 (28%) of the RALP arm (p = NS), indicative that the majority of patients in both arms were low risk. Positive pelvic lymph nodes were found in 0 and 1 patient in the LRP and RALP arms, respectively.

The overall positive surgical margin rate for LRP and RALP was 18% (35/190) and 6% (3/50), respectively (p = 0.032), Table 4. When examining pathologically organ confined specimens (pT2), the positive surgical margin rate was 12% (20/161) and 4.7% (2/43) for the LRP and RALP cohorts, respectively (p = 0.181). For pathologic extracapsular disease (pT3/T4), the positive surgical margin rate was 54% (15/28) and 14% (1/7) for LRP and RALP, respectively (p = 0.062). Patient age, race, Gleason score and prostate volume were not significant factors in the incidence of PSM. The most common location for a positive margin was at the prostatic apex, with 46% and 67% of PSM for LRP and RALP patients, respectively, occurring at this location. Table 4.

TABLE 2. **Preoperative staging criteria**

	RALP	LRP
Clinical stage		
cT1c	41 (82%)	145 (76%)
cT2a	9 (18%)	40 (21%)
Biopsy Gleason		
<=6	36 (72%)	136 (72%)
3+4	8 (16%)	31 (16%)
4+3	4 (8%)	6 (3%)
>=8	2 (4%)	3 (2%)

To investigate the effect that the learning curve may have had on these results, we performed a subset analysis of the final 50 patients in the LRP cohort and compared this to the group undergoing RALP. The overall PSM rate for the final 50 patients undergoing LRP was significantly higher than the first 50 patients who had an RALP (20% versus 6%, p = 0.037).

Discussion

Laparoscopic or robotic radical prostatectomy offer several advantages over open radical prostatectomy. The smaller incisions decrease postoperative pain and recovery times, and have cosmetic benefits. The operative blood loss for LRP and RALP is significantly less than for open RP, likely due to meticulous dissection of small vessels as well as the tamponade afforded by CO_2 pneumoperitoneum. The video

TABLE 3. **Postoperative staging variables**

	RALP	LRP
Pathologic stage		
pT0	0 (0%)	1 (0.5%)
pT2	43 (86%)	161 (85%)
pT2a	12 (24%)	40 (21%)
pT2b	0 (0%)	2 (1%)
pT2c	31 (62%)	119 (62%)
pT3a	5 (10%)	12 (6%)
pT3b	2 (4%)	6 (3%)
pT4	0 (0%)	10 (5%)
Pathologic Gleason		
<=6	33 (66%)	109 (57%)
3+4	12 (24%)	52 (27%)
4+3	3 (6%)	15 (8%)
>=8	2 (4%)	8 (4%)

TABLE 4. **Positive margin status**

	RALP	LRP	p
Stage			
All patients	3 (6%)	35 (18%)	0.032
pT0	0 (0%)	0 (0%)	
pT2	2 (4.7%)	20 (12.4%)	0.144
pT2a	0 (0%)	4 (10%)	
pT2b	0 (0%)	0 (0%)	
pT2c	2 (6.5%)	16 (13.4%)	
pT3/4	1 (14%)	15 (54%)	0.062
pT3a	1 (20%)	7 (58.3%)	
pT3b	0 (0%)	1 (16.7%)	
pT4	0 (0%)	7 (70%)	
Location[a]			
Apex	2 (67%)	16 (46%)	
Base	0 (0%)	12 (34%)	
Other	2 (67%)	12 (34%)	

[a]More than one positive margin location in some patients

magnification associated with laparoscopy improves the detail of fine anatomy allowing meticulous dissection of the apex and neurovascular bundles. These advantages, coupled with patient demand, have fueled rapid implementation of laparoscopic and robotic prostatectomy.

The incidence of PSM in LRP series ranges from 16%-26%.[7,22-25] The Montsouris experience, which has one of the largest experiences with LRP, as reported by Guillonneau and colleagues, reported an overall positive PSM rate of 19.2% in their 1000 cases.[22] Surgical margins status was significantly related to pathologic stage with a PSM rate of 15.5% in those men with organ confined disease (pT2) and higher PSM rates for non-organ confined disease (pT3/4).

Robotic assisted laparoscopic prostatectomy has become an exciting alternative to standard LRP. It shortens the difficult learning curve associated with LRP, and allows both non-fellowship trained urologists and laparoscopically experienced non-robotic surgeons, the ability to offer minimally invasive prostate cancer surgery.[10,11] The robotic assistance provides a three dimensional view of the operative field with similar magnification of detail associated with LRP. The robotic instruments contain a moveable wrist that provides additional degrees of freedom, mimicking natural motion. The dampening of motion and ergonomics of the robot are significant advantages over standard LRP. As a result of these improvements, the difficult learning curve for LRP has decreased dramatically and driven much of the surge surrounding RALP.[26]

The importance of performing an accurate oncologic procedure when treating prostate cancer cannot be overlooked. Positive surgical margin rates have been linked to disease specific survival and PSA recurrence.[27,28] PSM can occur several ways. Inadvertent intrusion into the prostatic capsule, in an otherwise organ-confined cancer (pT2), would be considered iatrogenic and putatively represents a surgical error. A non-iatrogenic margin occurs by dissecting through extraprostatic disease, in the setting of pT3/T4 disease, and is likely unrelated to surgical technique, but more related to patient factors and attempts at nerve sparing. Achieving negative surgical margins, for organ-confined disease, has become a surrogate endpoint of oncologic efficacy in LRP and RALP. Assessment of the surgical margin status for any prostate cancer operation provides an excellent framework on which to analyze the oncologic effectiveness.

Initial oncologic outcomes with RALP have been positive. In their first 200 cases, Menon and associates have shown an overall positive PSM rate of 6%,[13]which decreased from 15% since the initial 100 cases.[29] However, the definition of a PSM at the apex was modified between the two series, significantly lowering the margin positive rate. In the 60 cases following an adequate learning curve, Ahlering and colleagues reported an overall 16.7% PSM rate, with a 4.5% pT2 PSM rate.[14] More recently, Patel et al reported on 500 RALP, with an overall PSM of 9.4%,[30] and other series have reported PSM rates for RALP ranging from 9% to 30%.[31]

The addition of robotic surgery into an established program performing LRP to examine oncologic efficacy has not been well described. The overall PSM rate for RALP in our study was 6%. This compares favorably with the previous reports of RALP. We demonstrated a significant decrease in overall PSM rate when transitioning from LRP to RALP (18% versus 6%). The significance of these findings are increased when considering that all patients were included, even those in the initial LRP learning curve period. In fact, our RALP PSM rate was significantly less than the final 50 LRP performed at our institution. Therefore experience should not account for the difference in PSM. An analysis by Joseph et al, in a similar transition from LRP to RALP, evaluated the final 50 LRP with the first 50 RALP at their institution, and demonstrated similar results for all parameters measured, with comparable frequency of PSM in both cohorts (14% and 12%, respectively).[16] Other reports have demonstrated a decline in PSM for RALP with increased surgeon experience,[26] but improvement in PSM when transitioning from LRP in an experienced center to RALP have not been previously described.

Although not significantly different, the PSM rate for organ-confined disease (pT2) also decreased appreciably between our two cohorts from 12.4% to 4.7% in LRP and RALP respectively, with a trend towards significance. These figures agree with other reported series.[14] In fact, after modifications to their technique Ahlering and associates found a 4.7% pT2 PSM rate.[32] Data from Henry Ford Hospital by Tewari and colleagues, showed a 6% PSM rate in organ confined cancers using the revised criteria for apical margins.[33]

Menon and associates also reported on the comparison of RALP to LRP.[15,34] In the initial comparison of 80 patients, 40 each in the RALP and LRP groups, there was no significant difference found in the incidence of PSM, but the margin rate was relatively high at 25% and 17.5% for LRP and RALP respectively.[34] Follow-up data several years later that included 565 RALP patients and 50 LRP patients showed a similar odds ratio for causing a PSM when compared with RRP.[15] However, when their overall PSM rate for RALP of 6% was compared to published rates for LRP (15%-39%), a large reduction in rates was seen.

Previously from our center, Brown et al demonstrated a similar rate of PSM between open RRP and LRP, with an apical PSM being less likely.[19] The location of PSM in our LRP and RALP do not show a clear trend, and is difficult to interpret with low numbers. Apical PSM are a common site reported in current series on RALP.[26,32]

The reason why the addition of robotic surgery to a center experienced with LRP decreases PSM is unclear. The da Vinci robotic system does offer advantages over traditional laparoscopic instruments, including superior magnification and improved three dimensional visualization, as well as the extra degrees of freedom afforded by the articulating, wristed instruments. Certainly these aspects can explain the dramatic improvement in the difficult learning curve associated with LRP, and these factors could account for the oncologic improvements we have demonstrated. Increased experience and expertise could also account for the improvement we have demonstrated, although in our series, the improvement in PSM remains significant even when compared to the final 50 LRP performed at our institution, which would suggest learning curve alone is not explanatory. Differences in tissue handling between the two procedures, which may create more iatrogenic "false" positive margins, may be another explanation for the differences seen in PSM, although the lack of tactile feedback afforded by robotic surgery would suggest that standard laparoscopy may be favored in this aspect, and may not be explanatory. The surgical technique was nearly identical in our hands between RALP and LRP, which would predict similar rates of PSM and also would not be explanatory. The patient cohort, and tumor parameters in the LRP and RALP arms were very similar, and should not indicate different oncologic outcomes. The advantages offered by robotic surgery are likely the reason for the improvement in PSM that we have seen transitioning from LRP to RALP.

Conclusion

RALP has recently gained significantly popularity in the United States as it provides the benefit of LRP without the long learning curve. Although initial reports of RALP have shown similar oncologic outcomes to RRP and LRP, little data has been published demonstrating the transition from LRP to RALP in a single institution. In the present study, the addition of robotic assistance to an established laparoscopic radical prostatectomy program appears to reduce the incidence of positive surgical margins. Data is maturing to determine whether this will lead to improved functional and long-term oncologic outcomes. □

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