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Robotic Radical Prostatectomy at a Teaching Community Hospital: Outcomes and Safety

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ABSTRACT

Objectives: This study describes the early experience of robotic prostatectomy exclusively at a teaching community hospital.

Methods: This is a retrospective report of 153 consecutive patients on whom 4 physicians were the operating surgeon.

Results: The average hospital stay was 1.5 days, the mean operative time was 175 minutes, and the estimated operative blood loss was <300mL. The perioperative complication rate was 7.8% (12/153). The prostate-specific antigen failure rate was 2% (2/114). Urinary continence was maintained in 98% of patients 9 months after surgery. Postoperative Gleason scores differed significantly from preoperative biopsy results ($P<0.001$). Pathological records reported positive margins in 35% (54/153) of specimens. T3 tumors had positive margins more than twice as often as T2 tumors ($P<0.002$). Surgeon experience correlated with shorter operative times ($P<0.001$), but not with positive margins. Increasing body mass index was associated with increased operating time ($P=0.001$).

Conclusions: Robotic prostatectomy appears to be a safe and successful option for prostate cancer treatment in a teaching community hospital.

Key Words: Prostatic neoplasms, Robotics, Prostatectomy, Hospitals, Community.

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INTRODUCTION

The 5-year survival rate for local and regional stages of prostate cancer is close to 100%, the 10-year rate is 91%, and the 15-year rate is 76%.[1] Treatment options for early-stage disease are dependent on patient age and physical condition. Brachytherapy, external beam radiation, surgery, and observation are all options for managing early stages.[1] Although expectant management of early-stage prostate cancer is an option, caution should be used since treatment provides a higher cure rate than observation. The National Comprehensive Cancer Network (NCCN) recommends no further workup or treatment for asymptomatic prostate cancer patients with comorbidities that portend life expectancy of <5 years *unless* the patient has high-risk cancer, defined as either a bulky stage T3 or T4 tumor or a tumor with a Gleason score ≥8.[2]

Open, laparoscopic, and robotic surgery effect a high cure rate in early-stage disease. Open and robotic surgery report similar rates of positive margins[3] and prostate-specific antigen (PSA) recurrence.[4] Furthermore, in a study comparing laparoscopic and robotic prostatectomies, postoperative PSA levels at 12 months were undetectable in 97.5% and 95% of cases, respectively.[5]

More than half the radical prostatectomies performed in the United States are robot assisted.[6] The advantages of using a robot include reduced surgeon fatigue, greater magnification, and 6 or more degrees of articulating freedom.[6] Elimination of hand tremor improves the precision of dissection.[7] Robotic prostatectomies are associated with decreased blood loss, fewer transfusions, and a faster recovery rate compared to open procedures.[7,8] Robotic operations, however, have a steep learning curve.

Most reports on robotic prostatectomies come from academic university programs. The purpose of this study was to assess the preliminary safety and effectiveness of this procedure exclusively at a teaching community hospital.

MATERIALS AND METHODS

Study Design

This is a retrospective analysis of patients electing robotic radical prostatectomy between January 1, 2007 and September 30, 2007 at a single teaching community institution. Exemption from our institution's institutional review board was obtained for this project. All operations were performed on the da Vinci robot (Intuitive Surgical, Inc., Sunnyvale, CA, USA), which was purchased 1 year before this study. Four surgeons performed 153 radical prostatectomies during the study period.

PSA

PSA results were obtained from patient charts in surgeons' offices. The preoperative value was the test performed closest to the date of surgery; the postoperative values were tests collected closest to 9 months after surgery (±2 months). We chose 9 months because of surveillance practice among our surgeons. PSA failure is defined as ≥0.5ng/mL.[9,10]

Gleason Score

Preoperative Gleason scores were determined from pathology reports in surgeons' offices; these may have come from multiple institutions. The postoperative Gleason score was obtained from the prostatectomy pathology report from our institution. For purposes of assigning risk categories, we used NCCN definitions: low-risk=Gleason score 2 to 6, intermediate-risk=7, high-risk=8 to 10.

Operative Data, Demographics, and Tumor Characteristics

Operative data and patient demographics were collected from the hospital database. Estimated blood loss was obtained from the operative records. Nine cases that recorded blood loss as "minimal" were assigned the value of 50cc, the lowest recorded value of blood loss for all surgeries. Complications during surgery and within 30 postoperative days were identified through International Classification of Diseases, 9th Edition (ICD-9) codes. Tumor stage, tumor margins, prostate weight, and tumor volume were taken from pathology reports. A positive margin was defined as the presence of any cancer cells at the surgical margin, whether unifocal or multifocal. The sites of positive margins were recorded. Close margins were defined as tumor cells within 0.1mm of the surgical margin.

Urinary Continence

Urinary continence at 9 months was determined from physician progress notes. Continence was defined by the need for perineal pads: patients using ≤1 pad per day were classified as continent; those using 2 or more, incontinent.[5,7]

Statistics

Comparisons for numeric variables were done using the *t* test, while Fisher's exact test was used for categorical variables. Linear regression examined the relationship between various factors and operating time. A normal probability plot was used to check whether the residuals conformed to a normal distribution, and differences in beta values (DFBETAs) were examined to evaluate whether a particular observation had a disproportionate influence on parameter estimates. Logistic regression was used to assess relationships among surgeons, surgical margins, and pathological factors. The Hosmer-Lemeshow goodness of fit test assessed whether the model reasonably reflected the observed data. Data were analyzed using SAS version 9.1 (SAS Institute, Inc., Cary, NC).

RESULTS

Table 1 lists the clinicopathological characteristics of the study patients.

Weight Distribution

Twenty-six percent (40/153) of patients had a normal body mass index (BMI<25), 47% (72/153) were overweight (BMI=25 to 30), and 27% (41/153) were obese (BMI>30). Six patients (4%) had a BMI>35.

PSA

The average preoperative PSA was 6.00ng/mL (range, 0.87 to 20.6). Nine months after surgery, all patients with follow-up data (114) had normal PSAs, and 92% (105/114) had undetectable levels (<0.1ng/mL). Of the 9 patients with detectable PSAs, 5 had positive surgical margins, while 4 had negative margins. Only 2 (2%) patients of the 114 had PSA failure (>0.5ng/mL); one had a PSA of 0.5ng/mL, the other 1.61ng/mL. Both patients had negative surgical margins. One patient was lost to follow-up, and the second is undergoing evaluation for recurrence. We did not have data for 39 of the original 153 patients due to patient follow-up with physicians other than the operating surgeons.

Gleason Score

When comparing pre- and postoperative Gleason scores, 40% (61/153) of patients' scores changed (P<0.001), resulting in a shift of risk category in all instances **(Figure 1)**. Five percent (8/153) of patients moved from a low- or intermediate-risk preoperative Gleason score to a high-risk category. Two percent (3/153) of patients had a high-risk preoperative score but an intermediate-risk postoperative score. The pre- and postoperative Gleason scores of both patients with PSA failures were 6.

Operative Time

The average operating time was 175 minutes (range, 105 to 331). Factors examined for an effect on operating time were patient age, BMI, and surgeon. Linear regression showed that patient BMI (P=0.0010) and surgeon (P<0.0001 for surgeons B, C, and D compared to A) were significantly associated with operating time. Operating times were longer by an estimated 38 minutes to 112 minutes for surgeons B, C, and D compared to A, the latter having the highest experience by volume **(Figure 2)**. Controlling for surgeon, operating times increased by approximately 9.5 minutes for each 5-point increase in BMI **(Figure 3)**. Patient age was not significantly associated with operating time (P=0.2829).

Table 1.
Clinicopathological Results. PSA Data Available for 114 Patients and Urinary Continence Data for 126 Patients

Characteristic	Mean (Range) or n (%)
Age (years)	61 (44–81)
BMI[a]	27.7 (19.2–41.6)
Preoperative PSA[a] (ng/mL)	6.0 (0.87–20.6)
<2	4 (2)
2–4.9	67 (44)
5–7.9	54 (36)
8–9.9	14 (9)
>10	13 (9)
Surgical Time (minutes)	175 (105–331)
Estimated Blood Loss (mL)	276 (50–1300)
Aborted Procedures	0
Prostate Weight (g)	46 (23–99)
Prostate Volume (cm^3)	75.2 (26.4–196.6)
Tumor Percentage of Removed Prostate	13% (1–90)
Tumor Volume (cm^3)	8.9 (0.37–109.4)
Postoperative Pathological Stage	
T2	3 (2.0)
T2a	16 (10.5)
T2c	113 (73.9)
T3	2 (1.3)
T3a	16 (10.5)
T3b	3 (2.0)
Preoperative Gleason Score	6.4 (6–9)
Postoperative Gleason Score	6.7 (6–9)
Positive Surgical Margins	54 (35)
T2	40 (30)[b]
T3	14 (67)[c]
Patients With Resected Lymph Nodes	3 (2.0)
Positive Lymph Nodes	0
Positive Seminal Vesicles	3 (2.0)
Complications	12 (7.8%)[d]
Hospital Stay	1.5 (1–10) days
Pad Use at 9 months	
0 Pads	89 (71)
1 Pad	34 (27)
2 Pads	3 (2)
Number of PSA Failures	2 (1)

[a] BMI=Body Mass Index, PSA=Prostate-Specific Antigen.
[b] proportion of T2 tumors with positive margins.
[c] proportion of T3 tumors with positive margins.
[d] see Table 2 for details.

Tumor Stage

Eighty-six percent (132/153) of prostate carcinomas were T2 tumors; 14% (21/153) were T3. Three patients had lymph node dissection; all these were negative for metastasis. In 3 patients (2%) the seminal vesicles were positive for tumor infiltration.

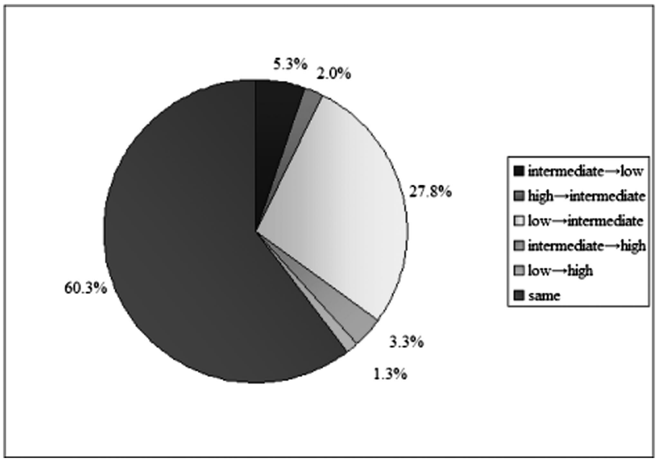

Figure 1. Gleason score risk categories before and after surgery.

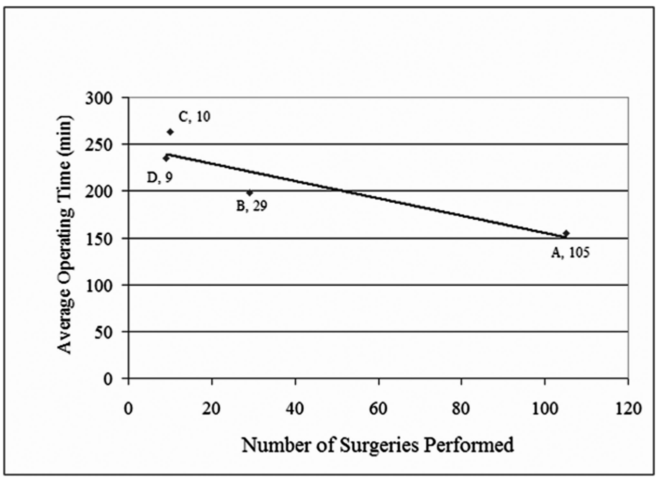

Figure 2. Operating time by surgeon experience.

Margins

Thirty-five percent (54/153) of specimens had positive surgical margins; 4% (6/153) had close margins. Both patients with PSA failure had negative margins. Of the 54 patients with positive tumor margins, 25 (46%) were unifocal. Margin status was significantly related to tumor volume ($P<0.05$) **(Figure 4)**. In a logistic regression, factors independently associated with positive margins were: T3 stage (P=0.0140, odds ratio [OR]=4.0, 95% confidence interval [CI]=1.3 to 12.0), tumors occupying a greater proportion of the prostate (P=0.0382, OR=1.2 for each 5% increase, 95% CI=1.01 to 1.5), and prostate volumes $\leq 90cm^3$ (P=0.0186, OR=3.0, 95% CI=1.2 to 7.6). Margin status was not related to surgeon experience. More than 50% (37/73) of positive margins were in the apical region of the prostate. This was the most common positive margin for both T2 (55%, 29/52) and T3 tumors (37%, 8/21) **(Table 2)**.

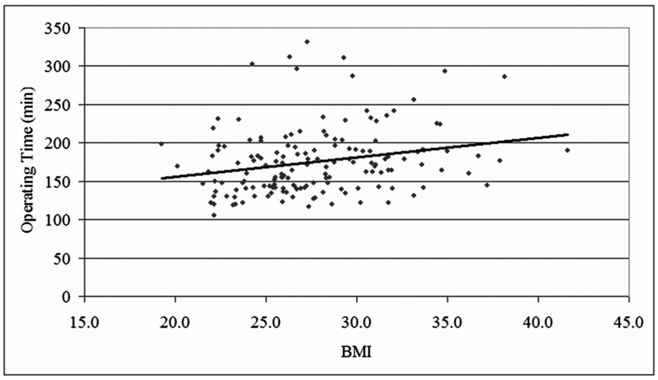

Figure 3. Operating time according to patient BMI ($r^2=0.63$).

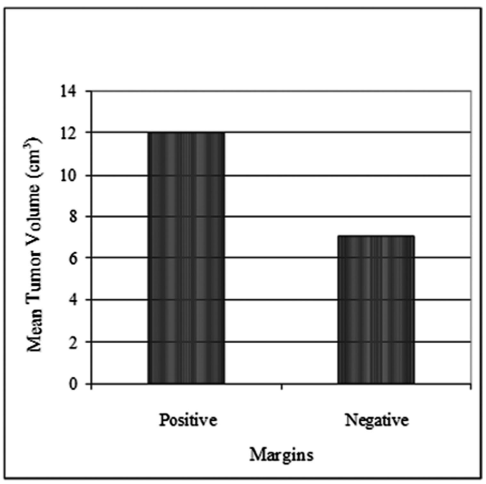

Figure 4. Surgical margins by mean tumor volume ($P<0.05$).

Complications

No robotic operations were converted to laparotomy. Of 153 cases, 12 (7.8%; 95% CI:4.1 to 12.9) sustained perioperative complications **(Table 2)**. BMI did not significantly affect complication rates (P=0.17). Patients with complications had a median BMI of 26.0 (Inter-quartile range [IQR]=24.2 to 33.6), while those without complications had a median BMI of 27.2 (IQR=24.7 to 30.2).

Urinary Continence

Data were available for 126 of the 153 patients (82%). At 9 months, 3 (2.4%, 95% CI:0.0 to 5.0%) of the 126 patients were incontinent, defined as the use of more than one perineal pad per day.

DISCUSSION

Robotic prostatectomy at our teaching community hospital proved to be an effective operation for prostate cancer

Table 2.
Location of Positive Margins and Perioperative Complications

Positive Margins: T2	N (%)
Apical	29 (55)
Anterior	9 (17)
Posterior	6 (12)
Posterolateral	2 (4)
Lateral	4 (8)
Bladder	2 (4)
Positive Margins: T3	
Apical	8 (37)
Anterior	2 (10)
Posterior	5 (24)
Posterolateral	0 (0)
Lateral	5 (24)
Bladder	1 (5)
Perioperative Complications	
Adynamic Ileus	1 (0.7)
Anastomosis Leak	3 (2.0)
Deep Venous Thrombosis	1 (0.7)
Nerve Palsy	1 (0.7)
Obstruction	1 (0.7)
Rectal Laceration	1 (0.7)
Urinary Retention	2 (1.3)
Urinary Tract Infection	2 (1.3)

with good 9-month outcomes. Although the surgeons selected the candidates for robotic operations, the cohort included obese patients and patients with large prostates. Forty-seven percent (72/153) of patients were overweight, and 27% (41/153) were obese. The average prostate volume of 75.2cm^3 is larger than the size reported in other series.[11,12] We found that BMI was significantly related to operative time, as others have reported.[13] Despite the high BMIs and large prostate volumes, the operations were performed successfully with no conversions to open surgery. BMI did not appear to be related to complications, as others found it to be.[14]

While morbidity was low and mortality was zero in this study, there was a significant relationship between surgeon experience and operative time. Robotic prostatectomies have been associated with a steep learning curve. Surgeon technique and experience may also have an impact on margin status, though our study did not find a significant association. This may be due to the relatively low number of cases for some of the surgeons, resulting in insufficient power to detect a difference between surgeons.

Other indicators of robotic prostatectomy safety in this series are the minimal blood loss and the short hospitalization (average 1.5 days). These data are also comparable to data from other series at university medical centers.[7,8,11,15]

The success or effectiveness of radical prostatectomies is commonly measured by postoperative PSA levels. At 9 months, all recorded PSA values (114) were within the normal range. Ninety-two percent (105/114) had undetectable levels (<0.1ng/mL), while 2% (2/114) had PSA failure (defined as >0.5ng/mL). The proportion of patients with an undetectable PSA is comparable to that of other studies.[5,16] We defined a level of 0.5ng/mL as PSA failure based on past studies. Partin et al[10] reported that 81% of patients with PSA levels ≥0.5ng/mL within 12 months following surgery had biopsy-proven local failures and that the majority of patients with bone scans showing distant metastases had PSA levels reach 0.5ng/mL within 12 months. Furthermore, in a series of more than 5,000 patients,[9] no patients with values <0.5ng/mL had evidence of cancer. Our 9-month follow-up may have failed to identify some patients who may have had PSA failure by 12 months. However, we believed that examining the earliest cases performed would give a more critical assessment of the efficacy of this procedure in a teaching community hospital setting. This resulted in a shorter follow-up, because the surgeries took place only 9 months before the start of the study.

The lymph node dissection rate is a reflection of the normal practice patterns in our community, including cases of T3 tumors, and was not associated with the robotic operation itself; it is similar to the rate for open operations.

The prevalence of positive surgical margins in our study was 35% (54/153), which is within the range reported in the literature, 10% to 45.4%.[12,17,18] Prevalence of positive surgical margins is traditionally considered a measure of operative outcome, although their prognostic significance is controversial. Those who believe that positive surgical margins negatively impact patient outcomes report an absolute decrease in progression-free survival of approximately 20% (both 5- and 10-year rates).[19] However, other studies have found that recurrence occurs primarily with nonorgan-confined tumors[20] and that patients with low-risk disease have a favorable long-term outcome regardless of margin status and may even be expectantly managed.[21] A recent multivariate analysis[22] showed that while a positive margin was associated with an increased risk of biochemical recurrence, local recurrence, and salvage treatment, it was not significantly related to systemic progression, cancer-specific death, or overall mortality.

Certain factors examined in this study are consistently related to positive margins in the literature, including T3 stage[15] and a higher proportion of the prostate replaced by tumor.[23] We found similar relationships between these factors and positive margin status (T3 stage OR=4.0, OR=1.2 for each 5% increase in proportion of the prostate occupied by tumor). Fourteen percent (21/153) of the cases in our series were T3 tumors. This proportion is in the middle of the range reported in other studies (0% to 24%).[15,16]

Our data also demonstrate that margin status was related to prostate size <90mL. In another report, smaller prostate size (ie, <40mL) was associated with a larger proportion of prostate replaced by tumor, greater tumor density, and a greater chance of extraprostatic tumor extension, but not with positive surgical margins.[23] However, several other reports[24–27] indicate a relationship between smaller prostate size and positive margin status. We note that "smaller" prostate size is a relative term and is defined differently among the studies that have examined this parameter.[23–27] Furthermore, a review of studies on this subject shows that the same prostate size is associated with a highly variable rate of positive margins.[24–27] Additional exploration of the potential relationship between prostate volume and positive surgical margins is warranted.

In this series, the most common site of positive surgical margins for both T2 and T3 cancers was the apex, which others have reported.[28] Specific features of positive surgical margins appear to affect disease recurrence, including whether they are multifocal and/or extensive, their number, and locale.[29] Of the 54 patients in this study who had positive tumor margins, 25 (46%) were positive at only a single margin. Since only 2 of our patients had PSA failures, both with negative margins, and very few had detectable PSA levels, we could not assess an association between margin status and PSA persistence.

Regardless of the conflicting reports on margin status, due to the possible negative impact of positive surgical margins, surgeons must ensure that their own capability of attaining clear margins is sustained with the adoption of new surgical modalities. Institutions, likewise, should be cautious that the rate of positive surgical margins does not fall outside the normal range reported in the literature after the deployment of robots.

The complication rate in this study was 7.8% (12/153), which is similar to that of other studies.[11,15] Complications varied, but were also comparable to those of other studies.[12,15] There were no conversions to open surgery, and no mortalities.

The Gleason score is the strongest predictor of postoperative recurrence.[23] Of interest was the fact that 40% (61/153) of cancers had different pre- and postoperative Gleason scores, causing these patients to shift to a different risk category. However, only 10 patients had what we would consider a significant shift, that is, in or out of the high-risk class. Other centers have also found differences in pre- and postoperative Gleason scores. The number and length of core biopsies can impact grading error.[30] Both patients with PSA failures had pre- and postoperative Gleason scores of 6. Again, the low PSA failure rate in our study prevents an assessment of an association with Gleason scores.

Urinary continence is an important assessment of patients' quality of life following radical prostatectomy. Our study's continence rate at 9 months, 97% (123/126), compares very favorably to that of other studies.[15] However, assessment of continence 2 years after surgery might be more valuable, because recovery of urinary control may require up to 120 weeks.[15]

CONCLUSION

Our study indicates that robotic prostatectomy can be safely and effectively instituted at a teaching community hospital. Blood loss during surgery was low, no transfusions were necessary, and most patients were in the hospital less than 2 days. Approximately 8% of patients (12/153) had postoperative complications. There were no mortalities. Maintenance of urinary continence was high, and PSA failure was low at 9 months.

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