

Robot-Assisted Radical Prostatectomy: Current Evaluation of Surgical Margins in Clinically Low-, Intermediate-, and High-Risk Prostate Cancer

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Abstract

Purpose: Concern exists over a lack of tactile sensation and positive surgical margins (PSMs) in patients undergoing robot-assisted radical prostatectomy. We report our PSM rates in our most current 500 cases and particularly in clinically high-risk disease.

Materials and Methods: After implementation of our present technique at case #251, we report PSM rates according to pathologic stage and D'Amico's risk stratification: low risk (prostate-specific antigen [PSA] <10, Gleason score [GS] 5–6, cT1-T2A), intermediate risk (PSA 10–20, GS 7, cT2B), and high risk (PSA >20, GS 8–10, cT3). Patients with cT2b/T3 disease or GS 8 to 10 and multiple cores with >30% involvement underwent wide excision of the neurovascular bundle. PSM was defined as ink on tumor.

Results: The overall PSM rate was 7.4%: pT2 = 3.1%, pT3 = 15.9%, and pT4 = 55.6%. PSMs occurred in 13 (4.9%) low, 10 (5.8%) intermediate, and 14 (22.6%) high D'Amico risk patients. Of the 62 high-risk patients, the median PSA was 6.9 (range 2.2–97.9); biopsy GS was 6 to 7 (26%) and 8 to 10 (74%). For preoperatively palpable disease, the PSM rate was 9.9%: cT1 = 6.0%, cT2 = 7.7%, and cT3 = 26.3%. No PSMs occurred along the neurovascular bundle.

Conclusion: Since 2005, 500 men with clinically low-, intermediate-, and high-risk prostate cancer have undergone robot-assisted radical prostatectomy with acceptable surgical margin rates. In patients with high-risk and usually palpable disease, PSM rates were also acceptable despite the lack of tactile sensation with the robot.

Introduction

IN THE UNITED STATES, prostate cancer accounts for nearly 30% of all newly diagnosed cancers in men and is the second most frequent cause of cancer death in men.¹ An estimated 186,000 incident cases will be diagnosed this year with most prostate cancers being localized. For localized prostate cancer, radical retropubic prostatectomy (RP) has been considered the gold standard. The technique for open RP has been refined over the last 25 years with dramatically improved clinical outcomes.² In a recent study from Memorial Sloan-Kettering Cancer Center of 1177 patients undergoing open and laparoscopic radical prostatectomy between 2003 and 2005, Touijer et al.³ reported positive surgical margin (PSM) rates of 11.0% overall with 5.3% in pT2 and 22.0% in pT3 disease for the open group.

In recent years, minimally invasive surgical techniques—particularly, robot-assisted radical prostatectomy (RARP)—have expanded dramatically. Practically speaking, open

surgeons are guided by visual and tactile sensation. Concern exists over lack of intraoperative tactile sensation particularly in high-risk disease in RARP and the danger of having a PSM. We previously published that our PSM rate early in our initial experience (cases #1–50) was 36%. We then described a technique that reduced PSMs (cases #51–250) to 17.6% that was based on visual cues at the apex.^{4,5} Subsequently, we described (cases #251–450) that transecting 2 to 6 mm more distal on the apex further reduced the PSM rate from 17.6% to 7.5% without measurably impacting continence rates.⁵ In the present study of 500 consecutive cases (cases #251–750), we update our RARP experience with PSMs utilizing this apical technique, with a focus on palpable and clinically high-risk disease.

Materials and Methods

In this study, 500 consecutive patients with clinically localized prostate cancer underwent RARP by a single surgeon

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(T.E.A.) between April 2005 and September 2008. PSMs for cases #1 to #250 have been previously described.^{4,6} Our aim was to examine PSM rates in RARP patients using our previously described modification in apical technique.⁵ Patient data (cases #251–750) were collected and entered prospectively into an electronic database. Urinary and functional outcomes were attained by self-administered questionnaires, including the seven-item American Urological Association (AUA) symptom score and the five-item International Index of Erectile Function (IIEF-5). Potency was defined as erections adequate for vaginal penetration with or without oral phosphodiesterase inhibitors. Continence was defined as requiring no pads. Patients were stratified according to D'Amico risk: low risk (prostate-specific antigen [PSA] <10, Gleason score [GS] 5–6, cT1–T2A), intermediate risk (PSA 10–20, GS 7, cT2B), and high risk (PSA >20, GS 8–10, cT3).⁷ The study has been granted full institutional and Institutional Review Board approval.

All the patients underwent a transperitoneal RARP previously described at our institution using the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA).⁸ Our technique for the apical dissection has been previously reported.^{4,5}

Neurovascular bundle-wide excision technique

After the seminal vesicles have been mobilized, Denonvilliers' fascia is incised, and the rectum is freed from the base of the prostate to the apex. At this point, the prostate is still attached by the prostatic vascular pedicles, the neurovascular bundles (NVBs), and the urethra. On the side of wide excision, the vascular pedicle is transected approximately 1 cm from the base of the prostate. The anterior surface of the rectum is then approached by dissecting through the perirectal fat. Once through the perirectal fat the critical landmark of the longitudinal muscle fibers of the rectum is identified, and the dissection is carried laterally to the muscles of the levator ani. This step transects the NVB at the base of the prostate, and the entire NVB is then completely excised down to the apex.

Before the operation, patients were risk stratified based on clinical exam and biopsy characteristics. The New York University nerve sparing algorithm incorporates GS, tumor volume in the prostate biopsy, and perineural invasion for guiding NVB excision given their likelihood of independently predicting extraprostatic extension and PSMs.⁹ Following their general guidelines, we selected when to excise the ipsilateral NVB in preoperatively potent men defined as an IIEF-5 ≥ 21 . For patients with a mild palpable abnormality (i.e., asymmetry, mild induration, or a soft nodule) and moderate biopsy risk factors (GS 4 + 3 to 10 and <30% core involvement), they underwent a partial nerve sparing operation leaving 2 to 3 mm of tissue on the prostate. For those with a palpable nodule involving more than 50% of one lobe or GS 8 to 10 and multiple cores with >30% involvement, they received a wide excision.

All pathologic specimens were inked with four colors and sectioned according to a standard protocol as described by Srigley.¹⁰ After fixation, the distal (apical) segment was transected perpendicular to the axis of the urethra and sliced radially, generating five to eight segments. The basal (bladder neck) portion was also shaved, radially sectioned, and submitted entirely. The remainder of the prostate and attached seminal vesicles was serially sectioned transversely at 3- to

5-mm intervals. For prostates weighing less than 50 g, the entire prostate was submitted, and for larger specimens, the posterolateral portion of each slice and representative sections from the anterior were submitted in order from the apex to the base.

A PSM was defined by the presence of tumor at the inked surface of the specimen. All specimens were reviewed by one uropathologist (N.N.). For cases with positive margins, the location and extent of involvement were identified and mapped. Extraprostatic extension was characterized as either focal (when extraprostatic extension is present in less than one high-power field and no more than two slides) or established (when extraprostatic extension is present in more than one high-power field or more than two slides). All carcinomas were graded using the Gleason system and staged using the American Joint Committee on Cancer/International Union Against Cancer Tumor Node Metastasis sixth edition.

Ten percent of the pathologic specimens were reviewed externally by another uropathologist. The uropathologists achieved 100% concordance in regard to PSMs and 95% concordance in GS and pathological staging.

All statistical analyses were performed with SPSS v.16 (SPSS, Chicago, IL) using the paired *t*-test for comparison of continuous variables. Either Pearson's chi-square or Fisher's exact test was used to compare categorical data when appropriate. All statistical tests were two sided, setting the level of statistical significance at $p < 0.05$.

Results

Patient preoperative characteristics for the overall cohort are reported in Table 1. There were 266 (53%) low, 172 (34%) intermediate, and 62 (12%) high D'Amico risk patients. The 62 patients in the high-risk group were older than the entire cohort with a median age of 66 years (range 48–77). In the high-risk group, the median PSA was 6.9 (range 2.2–97.9); clinical stage was T1 (33%), T2 (36%), and T3 (31%); and biopsy GS was 6 to 7 (26%) and 8 to 10 (74%). For preoperatively

TABLE 1. PREOPERATIVE CHARACTERISTICS OF MEN UNDERGOING ROBOT-ASSISTED RADICAL PROSTATECTOMY

No. of patients	500
Age (years)	61 (41–80)
Body mass index (kg/m ²)	26.5 (19.8–43.8)
PSA (ng/mL)	5.2 (0.0–97.9)
AUA symptom score	7 (0–35)
Urinary bother score	2 (0–6)
IIEF-5 score	23 (0–25)
Clinical stage, <i>n</i> (%)	
T1a/b/c	271 (68)
T2a/b/c	114 (29)
T3	19 (4)
Biopsy Gleason score, <i>n</i> (%)	
≤ 6	285 (57)
7	168 (34)
≥ 8	46 (9)
D'Amico risk, <i>n</i> (%)	
Low risk	266 (53)
Intermediate risk	172 (34)
High risk	62 (12)

Values given as median (range) unless otherwise noted.

PSA = prostate-specific antigen; AUA = American Urological Association; IIEF-5 = five-item International Index of Erectile Function.

palpable disease, the PSM rate was 9.9%: cT1 = 6.0%, cT2 = 7.7%, and cT3 = 26.3%.

Overall, the bilateral nerve sparing rate was 82%, the unilateral nerve sparing 16%, and the bilateral wide excision 2%. In the high-risk group, the bilateral nerve sparing rate was 47%, the unilateral nerve sparing 39%, and bilateral wide excision 10%.

Table 2 describes pathologic features for the overall cohort, including surgical margins according to pathologic stage, D'Amico risk, and location. The overall PSM rate was 7.4% with 37 positive margins over the last 500 cases. PSMs by pathologic stage were pT2 = 3.1%, pT3 = 15.9%, and pT4 = 55.6%. In pT3 cases, PSMs were all found to be established rather than focal extraprostatic extension.

PSMs according to low, intermediate, and high D'Amico risk groups were 4.9%, 5.8%, and 22.6%, respectively. The most common location for a positive margin was at the apex (57%), followed by multifocal, bladder neck, posterior, and base. In the high-risk group, where the majority of clinically and intraoperatively palpable patients present, positive margins were seen predominantly at the apex (64%), followed by multifocal (29%) and bladder neck (7%). There were no PSMs seen laterally along the NVB. PSMs had exposed tumor ranging from 0.2 to 1.4 mm under microscopic measurement.

Continence (pad free) rates at 12 months was 93% overall, 97% in low-risk patients, and 89% in intermediate-risk patients. High-risk patients, who were significantly older, had more urinary symptoms: 84% were pad free, 8% used one pad, and 8% required ≥ 2 pads/day. Mean preoperative AUA

symptom score for the high-risk group was significantly improved from 9 to 3 at 12 months postoperatively ($p < 0.01$). Urinary bother score for high-risk patients also improved from 2 to 1 at 12 months, but was not statistically significant ($p = 0.09$).

In the high-risk group, 19 patients had preoperative IIEF-5 scores ≥ 22 . Twelve had bilateral nerve sparing, six had unilateral wide excision, and one had a bilateral wide excision. Two were excluded because of subsequent adjunctive androgen deprivation therapy. Of the remaining 16, only 3 had follow-up at 12 months with 2 being potent.

Discussion

Prevention of PSMs is a critical goal in radical prostatectomy. A positive margin is well established as an independent predictor for biochemical recurrence.^{11–15} Positive margins may result from iatrogenic error, extraprostatic tumor that extends beyond the limits of resection, or artifact from specimen processing. Men with 10 ng/mL or greater preoperative PSA, biopsy GS 7 or greater, multiple positive biopsies, and clinical stage T2b, T2c, or T3 disease are more likely to have a PSM.¹⁶

Historically, the incidence of positive margins reported in published studies varies widely.^{16,17} In 1998, Wieder and Soloway reviewed the published data of open radical prostatectomy and reported overall margin-positive rates of 0% to 77% (average 28%).¹⁶ During the past decade, contemporary series of open radical prostatectomy from high-volume centers of excellence have reported decreasing overall positive margin rates between 8.0% and 17.7%.^{2,15,18–20} This reduction has been attributed to stage migration with more organ-confined tumors in the PSA screening era, a better understanding of prostatic anatomy, and refinements in surgical technique.¹² In general, comparing margin rates between series is difficult because of the variations in patient populations and pathologic review methodology.

Classically, PSMs occur most commonly at the apex followed by the posterolateral prostate in stage pT2 and pT3 disease. Positive margins occur at the apex for several reasons. The primary reason is that anteriorly there is no capsule and the prostatic apex interdigitates with the striated muscle of the external sphincter. This can be further complicated from obscured vision or access by the pubic bone, anterior prostatic fat, or bleeding from the dorsal venous complex. Insufficient mobilization of the fibromuscular bands that tether the apex also increases positive margins.¹⁶

The lack of intraoperative tactile sensation in RARP is cited as a factor for suffering PSMs inherent with robotics. To evaluate if a lack of intraoperative tactile sensation was likely responsible for PSMs, we analyzed all PSM sites and measured the exposed linear inked surface of tumor. The measured distance of PSMs ranged from 0.2 to 1.4 mm using the micrometer of a high-powered microscope. It is questionable that tactile sensation would distinguish such small surface areas of tumor from normal prostate. Further, we evaluated if absent tactile sensation translated into obvious problems with PSMs laterally along the NVB, particularly in clinically palpable disease.

For patients with palpable disease on rectal examination, the PSM rate was 9.9%: specifically, 7.7% in cT2 and 26.3% in cT3. None of the positive margins occurred along the NVB, apparently as a result of using an established clinical algorithm, similar to that reported by Shah et al.⁹ Similar findings

TABLE 2. PATHOLOGIC FEATURES

Pathologic stage, <i>n</i> (%)	
T0	3 (1)
T2a/b/c	357 (71)
T3a	105 (21)
T3b	27 (5)
T4	9 (2)
Pathologic Gleason score (%)	
6	153 (31)
7	294 (59)
≥ 8	19 (4)
9	29 (6)
Positive margins, <i>n</i> (%)	37 (7.4)
Positive margins, by c-stage, <i>n</i> (%)	
cT1	20 (6.0)
cT2	11 (7.7)
cT3	5 (26.3)
Positive margins, by p-stage, <i>n</i> (%)	
pT2	11 (3.1)
pT3	21 (15.9)
pT4	5 (55.6)
Positive margins, by D'Amico risk, <i>n</i> (%)	
Low risk	13 (4.9)
Intermediate risk	10 (5.8)
High risk	14 (22.6)
Positive margins, by location, <i>n</i> (%)	
Apex	20 (57)
Bladder neck	3 (9)
Anterior	1 (3)
Posterior (rectal)	3 (9)
Base	2 (6)
Lateral	0
Multifocal	7 (23)

along the NVB were reported recently by Smith and associates.²¹ They compared the incidence and location of PSMs associated with RARP and RP in contemporaneous patient groups at a single institution.²¹ They had no PSMs along the NVB in their RARP group of 200 men.

Smith and associates also stratified PSMs by D'Amico classification (low, intermediate, and high) and noted rates of 10.9%, 15.5%, and 53.8% in their RARP groups compared to 26.6%, 37.8%, and 56.3% in their RP patients, respectively. In the 500 patients reported here the PSM rates according to D'Amico classification were 4.9%, 5.8%, and 22.6%, respectively. Hence, in patients with high-risk disease, clinical stratification and anatomic dissection can result in acceptable oncological results.

Concern exists that lower PSMs also come at the expense of increasing incontinence and impotence. We previously reported that more aggressive resection at the apex reduced apical margin rates from 13% to 5.5%, but did not effect time to zero-pad continence.⁵ As noted, the overall pad-free continence rate in our series was 93%. D'Amico high-risk patients had a lower 1-year pad-free continence rate of 84%. The primary cause for this difference can likely be attributable to older age and worse baseline AUA symptom and urinary bother scores in this group. There is not enough follow-up in the high-risk group, however, for an adequate analysis regarding potency.

In this series, our overall PSM rate was 7.4%: pT2 = 3.1%, pT3 = 15.9%, and pT4 = 55.6%. The lower positive margin rate in our last 500 patients compared to the first 250 patients (7.4% vs. 21.2%) was not achieved as a result of excising more NVBs. A significantly greater percent of NVBs were preserved in the later group 90.2% versus 74.0% ($p < 0.01$). Moreover, the proportion of high-risk patients between the first 250 and the last 500 were similar at 11.6% versus 12.4% ($p = 0.75$).

Recent studies have shown that increasing surgeon experience and improved surgical technique from better observation decrease PSM rates in open radical RP.^{15,17,22,23} Our results compare favorably to contemporary series of open, laparoscopic, and robotic operation (Table 3). In Wieder and Soloway's review,¹⁶ average PSM rates according to clinical stage were 17% for T2a, 29% for T2b, and 53% for T3 disease. Most contemporary open radical prostatectomy studies have shown improvement in positive margin rates for both patients with organ-confined disease and extracapsular extension. Han et al¹⁹ reported PSM rates of 9.2% overall, 4% for T2, and 22.7% for T3 disease in an analysis of 4683 patients undergoing open radical prostatectomy from 1997 to 2001. In another recent study of 1389 patients, Swindle and colleagues¹⁵ described PSM rates of 12.9% overall, 6.8% for T2, and 23% for T3 disease.

The selected laparoscopic series with over 2500 patients combined had reported PSM rates of 11.3% to 19.2%.^{3,24-26} In the largest single-center experience, Menon et al²⁷ reported an overall positive margin of 13% in 2652 patients undergoing RARP. In 500 consecutive cases, Patel and coworkers²⁸ reported a PSM rate of 9.4% overall and that for T2, T3a, and T4 disease of 2.5%, 23%, and 53%, respectively.

Weaknesses of this paper include the retrospective analysis of data. A strength of the paper is the outside review of pathological findings in a cohort of patients. Specifically, we had 100% concordance with site and location of PSMs. We also acknowledge the importance of surgeon case volume and overall experience on the rate of positive margins.

TABLE 3. POSITIVE SURGICAL MARGIN RATES IN CONTEMPORARY OPEN, LAPAROSCOPIC, AND ROBOT-ASSISTED RADICAL PROSTATECTOMY SERIES

Author	Technique	No. of patients	% Positive margins
Lepor and Kaci ²	Retropubic	500	8.0
Hull et al ²⁰	Retropubic	1000	12.8
Han et al ¹⁹	Retropubic	4683	9.2
Swindle et al ¹⁵	Retropubic	1389	12.9
Touijer et al ³	Retropubic	692	11.0
	Laparoscopic	485	11.3
Guillonneau et al ²⁴	Laparoscopic	1000	19.2
Rassweiler et al ²⁵	Laparoscopic	450	18.6
Rozet et al ²⁶	Laparoscopic	599	17.7
Menon et al ²⁷	RARP	2652	13.0
Patel et al ²⁸	RARP	500	9.4

RARP = robot-assisted radical prostatectomy.

In conclusion, this study adds to reports that RARP can provide comparable surgical margin results for patients found to have both low- and high-risk disease. Further, lack of tactile sensation can be mitigated with a combination of careful preoperative evaluation, clinical algorithms for excision of the NVB, intraoperative visual clues, and surgeon experience. Until long-term biochemical recurrence and survival data become available, surgical margin rates provide the best surgeon-related surrogate endpoint to predict oncological outcomes after radical prostatectomy.

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Disclosure Statement

Dr. Thomas Ahlering is a meeting participant/lecturer for Intuitive Surgical, Inc. Dr. David Yee has approximately \$5,000 stock ownership in a family trust in Intuitive Surgical, Inc.

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Abbreviations Used

AUA = American Urological Association
 IIEF-5 = five-item International Index of Erectile Function
 NVB = neurovascular bundle
 PSA = prostate-specific antigen
 PSM = positive surgical margin
 RARP = robot-assisted radical prostatectomy
 RP = retropubic prostatectomy