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# Incidence of bladder neck contracture after robot-assisted laparoscopic and open radical prostatectomy

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## OBJECTIVE

To evaluate the incidence and risk factors for bladder neck contracture (BNC) in men treated with robot-assisted laparoscopic radical prostatectomy (RALP) and open radical prostatectomy (ORP), as BNC is a well-described complication of ORP and may be partially attributable to technique.

## PATIENTS AND METHODS

The University of California San Francisco Urologic Oncology Database was queried for patients undergoing RALP or ORP from 2002 to 2008. Patient demographics, prostate cancer-specific information, surgical data, and follow-up were collected. For each surgical approach, multivariate Cox

proportional hazards regression was performed to evaluate associations of demographics and clinical characteristics with BNC. Time to BNC after RP was evaluated using life table and Kaplan–Meier methods.

## RESULTS

From 2002 to 2008, 988 patients underwent RP as primary treatment and had at least 12 months of follow-up. Of these men, 695 underwent ORP and 293 underwent RALP. The mean (SD) age was 59.3 (6.80) years and 91% of men were Caucasian. D'Amico risk groups at diagnosis were low (38%), intermediate (38%), and high (24%). The BNC incidence was 2.2% (22 cases) overall, 1.4% (four) for RALP, and 2.6% (18) for ORP ( $P=0.12$ ). Patients with BNC were diagnosed a median (range) of 4.7 (1–15) months after surgery. At 18 months after surgery, the

BNC-free rate was 97% for ORP and 99% for RALP (log-rank  $P=0.13$ ). The most common presenting complaint was slow stream, followed by urinary retention. In Cox proportional hazards regression analysis, earlier year of surgery, older age at diagnosis and higher PSA level at diagnosis were significantly associated with BNC among ORP patients. In the RALP group, none of the covariates were associated with BNC.

## CONCLUSIONS

The overall incidence of BNC was low in both RALP and ORP groups. Technical factors such as enhanced magnification and a running bladder anastomosis may explain the lower BNC incidence in the RALP group.

## KEYWORDS

bladder neck contracture, prostate cancer, laparoscopic, robotic, prostatectomy

## INTRODUCTION

Radical prostatectomy (RP) is the most common form of treatment for clinically localized prostate cancer [1], either by open (ORP) or laparoscopic techniques (laparoscopic RP, lapRP, or robot-assisted laparoscopic prostatectomy, RALP). There is a growing trend towards the use of RALP [2].

Bladder neck contracture (BNC) is a known complication of RP, occurring in 0.48–17.5% of men after open RP (ORP) [3–6], and 0–3% after lapRP or RALP [4,7,8]. In a review of reported BNC rates, the weighted mean incidence rates of BNC were ORP (5.1%),

lapRP (1.1%) and RALP (1.4%) [4]. Significant morbidity may be associated with the development of BNC, including infection, urinary retention, the need for additional invasive surgery and future incontinence. We sought to examine BNC rates in a single institution cohort of men treated with either ORP or RALP. Our hypothesis was that BNC rates might be lower in the RALP group.

## PATIENTS AND METHODS

Data on men diagnosed with biopsy-confirmed prostate cancer was gathered prospectively in the Institutional Urological Oncology Database (UODB) at the University

of California San Francisco (UCSF). The present analysis was restricted to RPs performed in 2002–2008 with a minimum of 12 months of follow-up. Surgeries were performed by P.R.C. (75%), C.J.K. (8%) and other surgeons (17%). The UODB study protocol and patient consenting process are compliant with and approved by the UCSF Institutional Review Board and Committee on Human Research (protocol #H5664-27042).

The ORP (retropubic) was performed through a 10-cm low, midline incision. After the transversalis fascia was opened, the space of Retzius was developed. A self-retaining retractor was used during dissection. After

extirpation of the prostate, the bladder neck mucosa was everted circumferentially. A single, running suture was placed posteriorly at the bladder neck to create a 22 F opening as needed ('racket handle' closure). Eight interrupted 3–0 monofilament sutures were then placed circumferentially around the urethra. The final Foley catheter was irrigated with saline to confirm a watertight anastomosis. At surgeon discretion, an autologous fascial sling was placed at the end of the procedure in those cases where patients were identified to be at higher risk of postoperative urinary incontinence (i.e. previous radiation, older age, etc.).

RALP was performed using a three-arm da Vinci Robotic System (Intuitive Surgical, Sunnyvale, CA, USA). A transperitoneal approach was used. Based on surgeon preference, the dissection was either started posteriorly by mobilizing the seminal vesicles first or anteriorly by mobilizing the bladder. Bladder neck dissection was performed with cautery and sharp dissection. Nerve sparing was performed when appropriate based on clinical staging. A running vesico-urethral anastomosis was made using two 15 cm 3–0 monofilament sutures previously tied together to create a double-armed suture. This was often preceded by placement of a single suture placed between the lateral edges of the rhabdospincter, the previously incised Denonvilliers' fascia and the bladder neck [9]. The needles (together) used to complete the anastomosis were passed through the urethral and bladder neck  $\approx$ 8–12 times followed by tying the suture ends together at the 12 o'clock position. Rarely were 'racket handle' sutures needed to narrow the bladder neck opening. The bladder was irrigated through the final Foley catheter to confirm a watertight anastomosis.

The Foley catheter was removed after 5–10 days for both procedures. Serum PSA levels were usually measured at the 6-week and 3-, 6-, 12- and 24-month visits. Patients reporting hesitancy, slow stream, frequency, sensation of incomplete emptying or urinary retention underwent urine analysis, flow rate profile, postvoid residual ultrasound testing and cystoscopy depending on the initial evaluation. BNC was diagnosed by direct vision with flexible cystoscopy and the inability to pass the cystoscope into the bladder through a lumen of  $<$ 16 F. After diagnosis, BNCs were treated with balloon dilatation. Further treatment after initial

dilatation was prompted if the presenting symptoms returned. Typically, repeat balloon dilatation or, very rarely, direct vision internal urethrotomy was performed.

Frequencies and means were used to describe patient demographics (age, race), clinical characteristics at diagnosis (PSA level, Gleason grade, T-stage, percentage of cores positive), surgical data (blood loss, operative time), and type of surgical approach. Low, intermediate, and high clinical risk groups were assigned based on PSA level, biopsy Gleason grade, and clinical T-Stage at diagnosis according to the D'Amico risk classification [10].

The outcome of interest was occurrence of balloon dilatation or bladder neck incision for BNC after surgery. BNC procedures before or concurrent with RP were not considered outcome events. Demographic, clinical, and surgical characteristics were compared by surgical approach and by incidence of BNC using chi-square for categorical variables and *t*-test for continuous variables. For each surgical approach, multivariate Cox proportional hazards regression was used to identify factors associated with BNC. Preliminary pairwise correlations between age, clinical, and surgical variables were used to test for collinearity and ultimately select final covariates for the regression model: age at diagnosis, biopsy Gleason grade of  $>$ 6, PSA level at diagnosis, type of surgical procedure, and year of surgery. Disease recurrence was defined as two consecutive increases in serum PSA level  $\geq$ 0.2 ng/mL at least 8 weeks after surgery, or receipt of second treatment (i.e. radiation or androgen deprivation). BNC-free survival at 18 months and recurrence-free survival at 3 years after RP were evaluated using life table and Kaplan–Meier methods. Surgical approaches were compared using the log-rank test;  $P <$  0.05 was considered to indicate statistical significance.

## RESULTS

Of 3166 patients with prostate cancer who gave consent to participate in the UODB research study, 988 had RPs between 2002 and 2008 and had a minimum of 12 months follow-up. In all, 70% (695) of patients underwent ORP and 30% (293) underwent RALP. The patients' characteristics before and after RP are listed in Table 1. The mean (SD) age was 59.3 (6.80) years and 91% of the men were Caucasian. D'Amico risk groups at

diagnosis were low (38%), intermediate (38%), and high (24%). More men with cT2 disease underwent ORP than RALP (64% vs 44%,  $P <$  0.01). One RALP patient ( $<$ 1%) received an autologous transfusion vs 8% (87% autologous and 13% non-autologous) of men undergoing ORP ( $P <$  0.01). Recurrence-free survival at 3 years was 87% for ORP and 81% for RALP patients (log-rank  $P =$  0.02).

The BNC incidence was 2.2% overall (22 patients), 2.6% (18) for ORP and 1.4% (four) for RALP. Patients with BNC were diagnosed a median (range) of 3.25 (1–24) months after RP and at median of 2.5 (1–13.5) months and 6 (3–24) months for ORP and RALP, respectively. The BNC-specific characteristics are listed in Table 2. Of 695 ORP patients, 6% (40 patients) had an intraoperative fascial sling placed. Of the ORP patients who received a fascial sling, 20% (eight) developed a BNC. None of the RALP group had a fascial sling placed. The most common presenting symptom was slow stream. Three patients developed urinary retention, three presented with frequency, one with overflow incontinence and one with straining to void. Most patients' symptoms resolved after one procedure (52%) while the rest required two or more procedures (48%). Of the 10 patients who needed more than one procedure, resolution was achieved in three with one additional balloon dilatation. Two patients underwent balloon dilatation and subsequently required incontinence surgery; one received a male sling and the other an artificial urinary sphincter. One patient underwent a laser transurethral bladder neck incision and had resolution. Two patients were treated with two more balloon dilatations; one resolved and one ultimately required a UroLume® stent (American Medical Systems, MI, USA). One patient was treated with transurethral incision of the bladder neck and now requires self-catheterization. One patient achieved resolution after a laser transurethral incision of his bladder neck followed by a direct vision internal urethrotomy.

Life table analysis showed that the BNC-free rate at 18 months after RP was 97% for ORP and 99% for RALP (log-rank  $P =$  0.13). In Cox proportional hazards regression analysis of ORP patients covarying for year of surgery, age, biopsy Gleason grade, and PSA level at diagnosis, earlier year of surgery (hazard ratio, HR, 0.51, 95% CI 0.34–0.79) and higher PSA

level at diagnosis (HR 1.03, 95% CI 1.01–1.06) were significantly associated with BNC (Table 3). In the RALP group, none of the covariates were significantly associated with BNC (Table 3).

## DISCUSSION

BNC incidence was low after both surgical approaches, with 1.4% in the RALP group and 2.6% in the ORP group. Risk of bladder neck contracture was associated with surgical approach, year of surgery, age, and PSA level. Technical improvements and surgeon experience may explain the role year of surgery has played on BNC outcome. The increased risk that comes with age may be related to comorbidities more common in older patients, such as peripheral vascular disease. Of the BNC in the ORP group, 44% came after fascial slings were placed. If these patients were removed from the series, the incidence of BNC in the ORP group would be 1.4%. Fascial slings therefore may contribute to BNC development during ORP, although those men who underwent this procedure tended to have unique risk factors (i.e. previous radiation, older age, etc.).

While several factors have been associated with the development of BNC, its exact pathophysiology remains poorly defined. Both technical and patient-related factors have been implicated in their development [3,4,6,11,12]. Technical factors thought to increase BNC include low surgeon volume, absence of mucosal eversion, poor vesico-urethral mucosal apposition, urinary extravasation, increased blood loss, ischaemia of the bladder neck/membranous urethra, and excessive narrowing of the urethral anastomosis at the time of the procedure [3,4,6,11,12]. Some surgeons performing ORP have adopted a running anastomosis and achieved low BNC rates [13,14].

Some have proposed patient-related factors may contribute to the development of BNC. Elliott *et al.* [15] reviewed the Cancer of the Prostate Strategic Urological Research Endeavor (CaPSURE) database, a population-based disease registry, and reported the BNC incidence to be 8.4%. In multivariate analysis, body mass index and age were significant predictors of stricture treatment. After surgery, most strictures occurred within the first 6 months and were rare after 24 months.

TABLE 1 Cancer-specific patient characteristics stratified by surgery type\*

Variable	ORP	RALP	P†
<b>At diagnosis</b>			
Mean (SD):			
Age, years	59.2 (6.66)	59.7 (7.11)	0.23
PSA level, ng/mL	7.6 (7.26)	7.1 (5.39)	0.33
Prostate volume, mL	34.3 (19.55)	34.5 (18.34)	0.91
N (%):			
Race/ethnicity:			0.36
Caucasian	602 (92)	254 (90)	
Other	55 (8)	29 (10)	
Biopsy Gleason grade:			0.24
6 (3 + 3)	354 (53)	166 (58)	
7 (3 + 4)	149 (23)	70 (24)	
7 (4 + 3)	84 (13)	29 (10)	
8–10	75 (11)	23 (8)	
cT-Stage:			<0.01
T1	242 (36)	159 (56)	
T2	434 (64)	123 (44)	
T3	4 (1)	0	
Clinical risk group:			0.05
Low	224 (35)	120 (43)	
Intermediate	251 (39)	101 (36)	
High	163 (26)	56 (20)	
<b>Surgery and pathology</b>			
N (%):			
Transfusion:			<0.01
No	641 (92)	291 (100)	
Yes	54 (8)	1 (<1)	
Positive margins:			0.25
No	587 (84)	238 (82)	
Yes	108 (16)	54 (18)	
pT-Stage:			<0.01
T2	478 (69)	242 (83)	
T3	214 (31)	49 (17)	
pN-Stage:			<0.01
NX	380 (55)	231 (79)	
N0	289 (41)	61 (21)	
N1	26 (4)	0	
Gleason grade			0.29
2–6	220 (32)	103 (36)	
7–10	464 (68)	186 (64)	
Neo-adjuvant radiation:			0.26
No	692 (100)	292 (100)	
Yes	3 (<1)	0	
Adjuvant radiation:			0.16
No	675 (97)	288 (99)	
Yes	20 (3)	4 (1)	

\*Categories may not total to 'n' due to missing values; †chi-squared.

In the present series, the overall incidence of BNC in RALP patients was low, consistent with previous reports [4,16–18]. Msezane *et al.* [4] reported a weighted mean BNC incidence of 1.4%. Robotic surgery proponents contend

the approach offers the surgeon a magnified, stereoscopic view of tissue planes, with improved precision, and dexterity [19]. A recent meta-analysis of observational studies directly comparing ORP, lapRP and RALP

Variable	ORP	RALP
<i>N</i>	18	4
Mean (SD) age, years	62.2 (6.3)	63.8 (6.8)
<i>N</i> (%) or <i>n/N</i> :		
Presenting complaint:		
Slow stream	11 (61)	3/4
Urinary retention	3 (16)	0
Frequency	2 (11)	1/4
Incontinence	1 (6)	0
Staining	1 (6)	0
Median (range) time to BNC from surgery, months	2.5 (1–13.5)	6 (3–24)
<i>N</i> (%) or <i>n/N</i> :		
Fascial sling during RP	8 (44)	0
Number of interventions required:		
1	10 (56)	2/4
2	5 (28)	2/4
≥3	3 (16)	0

**TABLE 2**  
*Clinical characteristics of the patients with BNC in the ORP and RALP groups*

**TABLE 3** *Multivariate proportional hazards regression of clinical characteristics of ORP and RALP patients who developed BNC after RP*

Characteristic	ORP		RALP	
	HR (95% CI)	<i>P</i>	HR (95% CI)	<i>P</i>
Age at diagnosis	1.09 (1.01–1.17)	0.03	1.18 (0.95–1.47)	0.14
Year of surgery	0.51 (0.34–0.79)	<0.01	0.52 (0.19–1.44)	0.21
Gleason at diagnosis 2–6 vs 7–10	0.80 (0.31–2.10)	0.66	–	–
PSA level at diagnosis	1.03 (1.01–1.06)	<0.01	0.70 (0.42–1.19)	0.19

found that lapRP and RALP compared with ORP were associated with decreased operative blood loss, decreased transfusion risk and similar risk of positive surgical margins [20]. Taken together, decreased blood loss, improved visualization, and a running anastomosis creating a watertight closure, may lead to the low BNC rates in the RALP population. In contrast, Hu *et al.* [2] recently analysed a large cohort of Medicare beneficiaries undergoing RP and found an increased risk of BNC when minimally invasive RP was used (odds ratio, 1.4, 95% CI 1.04–1.87). The unadjusted incidence of anastomotic stricture was 15.2% and 12.0% for minimally invasive RP and ORP, respectively, *P* = 0.111. Patients treated at high volume centres had fewer BNCs.

Strengths of the present study include the analysis of a reasonably large cohort for analysis and prospectively collected data. One limitation of the study is the infrequency of BNC, which makes it difficult to power comparisons of the two surgical approaches.

Given the large geographical referral pattern of our medical centre, some BNCs could have been treated at outside hospitals.

In conclusion, the overall incidence of BNC after RP was low in both the RALP and ORP groups. Technical factors such as enhanced magnification and a running bladder anastomosis may explain the lower BNC incidence in the RALP group.

**CONFLICT OF INTEREST**

None declared.

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**Abbreviations:** UCSF, University of California San Francisco; (O)(lap)RP, (open) (laparoscopic) radical prostatectomy; RALP, robot-assisted laparoscopic prostatectomy; BNC, bladder neck contracture; UODB, Institutional Urological Oncology Database; HR, hazard ratio.