

Stepwise Description and Outcomes of Bladder Neck Sparing During Robot-Assisted Laparoscopic Radical Prostatectomy

David F. Friedlander, Mehrdad Alemozaffar, Nathanael D. Hevelone, Stuart R. Lipsitz and Jim C. Hu*

From the Harvard School of Public Health (DFF), Division of Urologic Surgery (MA) and Center for Surgery and Public Health (NDH, SRL), Brigham and Women's Hospital, Boston, Massachusetts, and Department of Urology, David Geffen School of Medicine at University of California-Los Angeles (JCH), Los Angeles, California

Abbreviations and Acronyms

PSA = prostate specific antigen

RALP = robot-assisted radical prostatectomy

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* Correspondence: Department of Urology, David Geffen School of Medicine at University of California-Los Angeles, 924 Westwood Blvd., Los Angeles, California 90024 (telephone: 310-794-6168; FAX: 310-794-6789; e-mail: jimhumd@gmail.com).

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Purpose: While bladder neck sparing may improve post-prostatectomy urinary continence, there is concern that it may lead to more positive surgical margins and compromise cancer control. We compared the continence and cancer control outcomes of bladder neck sparing vs nonsparing techniques during robot-assisted laparoscopic radical prostatectomy.

Materials and Methods: Data were prospectively collected on 1,067 robot-assisted laparoscopic radical prostatectomies done from September 2005 through October 2011. We compared the procedures according to bladder neck sparing (791) and nonsparing (276). Continence was defined by zero pad responses on the EPIC (Expanded Prostate Cancer Index) item quantifying daily use. Biochemical recurrence was defined as prostate specific antigen 0.1 ng/ml or greater. Cox regression was performed to assess factors associated with post-prostatectomy continence and biochemical recurrence-free survival.

Results: Median followup for bladder neck sparing vs nonsparing was 25.8 vs 51.7 months. Men treated with bladder neck sparing were more likely to have clinical T1c tumors ($p < 0.001$) and less likely to have biopsy Gleason grade 6 or less disease ($p = 0.023$). They experienced fewer urinary leaks ($p = 0.009$) and shorter length of stay ($p = 0.006$). Regarding cancer control outcomes, there was no difference in bladder neck sparing vs nonsparing base (1.2% vs 2.6%, $p = 0.146$) and overall surgical margin positivity (each 13.8%, $p = 0.985$). On adjusted analyses bladder neck sparing vs nonsparing was associated with better continence (HR 1.69, 95% CI 1.43–1.99) and similar biochemical recurrence-free survival (HR 1.20, 95% CI 0.62–2.31, $p = 0.596$).

Conclusions: Bladder neck sparing is associated with fewer urinary leak complications, shorter hospitalization and better post-prostatectomy continence without compromising cancer control compared to bladder neck nonsparing.

Key Words: prostate, prostatectomy, mortality, prostatic neoplasms, urinary incontinence

RADICAL prostatectomy remains the most popular definitive treatment for localized prostate cancer¹ and more than 75% of radical prostatectomies in the United States are currently performed robotically.² Post-prostatectomy urinary incontinence negatively impacts

quality of life.³ The likelihood of incontinence ranges between 2.5% and 87% depending on the definition of urinary control, collecting outcome methodology and surgical technique.⁴

Recovery of post-prostatectomy urinary function is multifactorial regard-

less of open vs robot-assisted approaches. Patient characteristics associated with better continence include younger age,⁵ better baseline urinary function and longer membranous urethral length.¹ Post-prostatectomy continence may also be improved by surgical technical factors, such as nerve sparing and apical dissection,^{6,7} but the role of bladder neck sparing in urinary control recovery remains controversial.⁸

Opponents of preserving the internal urinary sphincter contend that cancer control may be compromised by dissection in close proximity to the prostate base.⁹ Proponents of bladder neck sparing state that the 3-dimensional 12 \times magnification provided by the robotic surgical system enables differentiation between bladder neck fibers and prostate tissue.² Moreover, comparisons of functional and oncological outcomes between bladder neck sparing and nonsparing may be biased by heterogeneous techniques among surgeons and surgical series.^{10,11}

In this prospective study we compared the perioperative continence and cancer control outcomes of bladder neck sparing vs nonsparing techniques during RALP.

MATERIALS AND METHODS

Surgical Technique

We have refined and streamlined our previously described bladder neck sparing technique.⁹ Before bladder neck dissection we no longer preemptively suture ligate mid prostatic vessels coursing through the detrusor apron and potential back bleeders coursing through the anterior bladder wall proximal to the bladder. The fourth arm ProGraspTM is used to grasp and tent the anterior bladder wall anteriorly to identify the junction of the bladder and prostate. Sharp dissection is performed here in the midline through the connective tissue of the detrusor apron

until reaching bladder fibers. The use of monopolar current may obscure these fibers. Short bursts of bipolar cautery to minimize charring are used for hemostasis. Upon reaching bladder fibers, the curve of the prostate in the sagittal plane is followed proximally to the bladder neck. The incision is extended lateral in arced fashion to avoid vessels that course from the prostate lateral pedicle to the dorsal vascular complex (fig. 1, A).

Blunt dissection is then performed in a caudal direction over the anterior bladder neck to identify the vertical fibers of the prostatic urethra. Blunt dissection is done lateral to the bladder neck on each side by opening the Maryland dissector and pushing the scissors caudal, resulting in a triangular spread bilaterally on the lateral lobes of the prostate and defining the funneled shape of the bladder neck transitioning to the prostatic urethra (fig. 1, B). The bladder neck is opened anterior, the urethral catheter is withdrawn after deflating the balloon and the posterior bladder mucosa is incised with monopolar current (fig. 2). This creates a foothold to grasp the prostatic urethra/base and elevate the prostate. Doing so obviates the need for assistant surgeon catheter manipulation to elevate the prostate. Assistant counter traction is applied on the bladder neck and dissection proceeds posterior to the detrusor apron (fig. 3, A). Dissection then continues laterally to the adipose tissue that defines the lateral border of dissection (fig. 3, B). The detrusor apron is opened as low as possible, revealing the vas deferens (fig. 3, C).

Data

In this institutional review board approved study we prospectively collected data on 1,067 RALPs performed by one of us (JCH) from September 2005 through October 2011. We dichotomized based on bladder neck sparing vs nonsparing. Patients with bladder neck sparing had a bladder neck circumference that approximated the urethral stump before anastomosis, while those with bladder neck nonsparing required bladder neck reconstruction/tapering before anastomosis. Bladder neck sparing was attempted during RALP regardless of prostate cancer

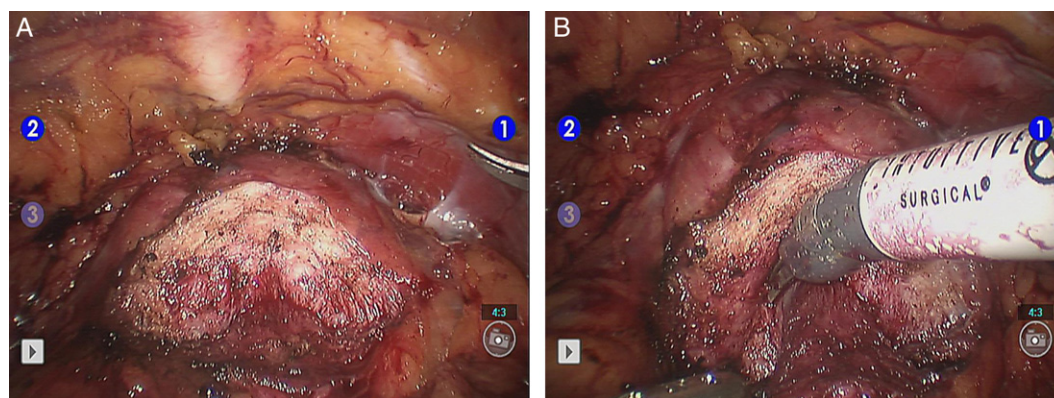


Figure 1. Bladder neck dissection is initiated in midline at prostate mid/base anterior until reaching depth of vertically oriented bladder neck fibers (A). Bladder neck incision is arced cephalad with lateral extension until anterior portion of bladder neck is defined. Blunt dissection is performed anterior, and on right and left (B) of bladder neck to define its funneled contour as it transitions to prostatic urethra.

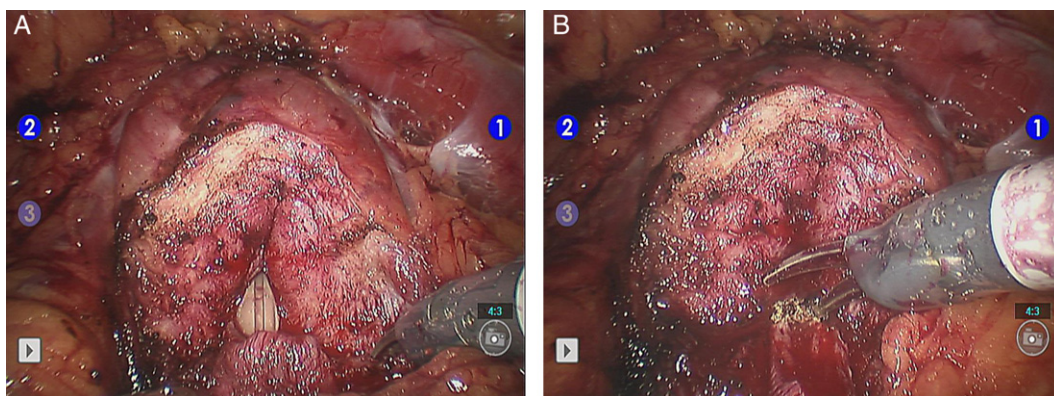


Figure 2. Bladder neck is opened anterior to expose catheter (A), which is withdrawn before scoring posterior bladder neck mucosa with monopolar current (B).

biopsy characteristics. However, the ability to perform bladder neck sparing improved with greater experience and was achieved with greater frequency later in the series.⁹

Men with pathological features such as positive surgical margins, and/or pathological T3a and T3b disease were counseled on the risks and benefits of adjuvant radiotherapy. The 64 men who elected adjuvant therapy were censored from subsequent assessment of continence and biochemical recurrence-free survival, defined as PSA 0.1 ng/ml or greater. The 93 men who experienced biochemical recurrence were counseled on salvage radiotherapy and 59 were censored from continence assessment only after receiving salvage therapy.

Outcomes

Responses to the EPIC³ item that assesses daily pad use were dichotomized to 0 vs 1 or more pads to define continence vs incontinence. Urine leak was defined as 1) high drain output with creatinine greater than serum levels or 2) anastomotic contrast medium extravasation on cystography.

Statistical Analysis

All clinical data and EPIC responses were prospectively collected by research personnel uninvolved with clinical care and entered into Microsoft® Access®. Univariable analyses of continuous and categorical variables were performed with the t and chi-square tests, respectively. Multivariable analysis with Cox regression was performed a priori with covariates associated with continence recovery, such as patient age, baseline urinary function, nerve sparing type (bilateral vs unilateral/non-nerve sparing) and bladder neck sparing vs nonsparing. Similarly, Cox regression analysis was done a priori with covariates associated with biochemical recurrence, such as preoperative PSA, surgical margin status, pathological Gleason grade and stage, and bladder neck sparing vs nonsparing. Statistical analyses were performed with SAS® 9.2.

RESULTS

Median followup for bladder neck sparing in 791 men vs nonsparing in 276 was 25.8 vs 51.7 months.

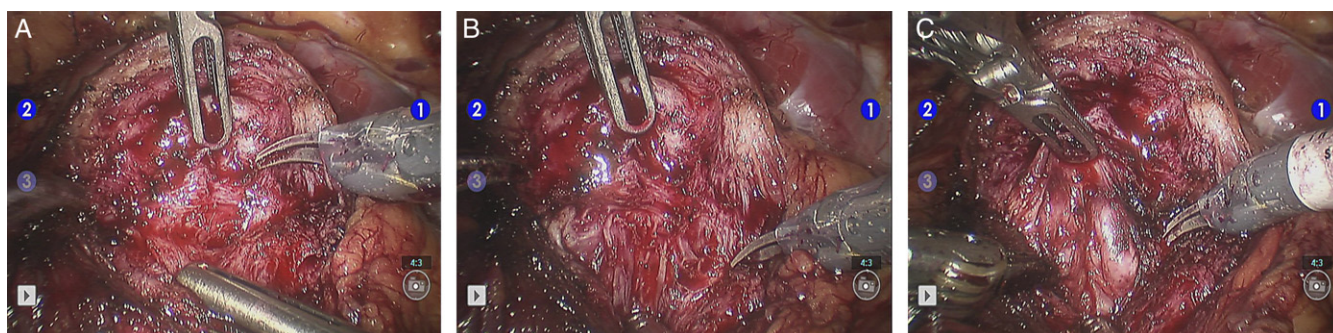


Figure 3. Fourth arm ProGrasp elevates prostate base to create tension for posterior bladder neck dissection (A). Assistant laparoscopic grasper counter traction is applied during posterior bladder neck dissection. Bladder neck dissection proceeds laterally to adipose tissue, which serves as lateral border of dissection bilaterally (B). Downward traction of assistant suction tip aids exposure. Note suction tip on posterior longitudinal detrusor layer. Posterior longitudinal detrusor layer is opened as low as possible, revealing vas deferens (C).

Demographics, tumor biopsy characteristics, intraoperative data, and pathological and perioperative outcomes

	Bladder Neck Sparing	Bladder Neck Nonsparing	p Value
No. pts	791	276	
Mean \pm SD age	58.9 \pm 6.6	58.8 \pm 6.8	0.917
No. race (%):			
White	732 (92.5)	253 (91.7)	
Black	33 (4.2)	12 (4.4)	
Other	26 (3.3)	11 (4.0)	0.852
Mean \pm SD preop urinary function score	96.2 \pm 10.9	95.2 \pm 12.1	0.201
Mean \pm SD PSA (ng/ml)	5.6 \pm 3.4	5.9 \pm 5.2	0.503
No. clinical stage T1c (%)	744 (94.1)	237 (85.9)	<0.001
No. Gleason grade (%):			
6 or Less	437 (55.2)	180 (65.2)	
7	313 (39.6)	83 (30.1)	
8 or Greater	41 (5.2)	13 (4.7)	0.014
No. pathological Gleason grade (%):			
6 or Less	275 (34.8)	131 (47.5)	
7	479 (60.6)	125 (45.3)	
8 or Greater	37 (4.6)	20 (7.2)	<0.001
No. pathological stage (%):			
pT0	4 (0.5)	4 (1.5)	
pT2	669 (84.6)	233 (84.4)	
pT3a	88 (11.1)	29 (10.5)	
pT3b	30 (3.8)	10 (3.6)	0.301
No. pos surgical margins (%):			
Base	9 (1.1)	7 (2.5)	0.146 (Fisher exact test)
Overall	109 (13.8)	38 (13.8)	0.985
No. nerve sparing technique (%):			
None/unilat	148 (18.7)	51 (18.5)	
Bilat	643 (81.3)	225 (81.5)	0.918
Mean \pm SD length of stay (days)	1.1 \pm 0.6	1.3 \pm 1.1	0.006
Mean \pm SD catheterization (days)	7.9 \pm 3.5	8.0 \pm 3.5	0.924
No. urine leak (%)	11 (1.4)	11 (4.0)	0.009

While demographic and biopsy tumor characteristics as well as baseline urinary function were similar (see table), men treated with bladder neck sparing were more likely to have clinical stage T1c tumors (94.2% vs 85.9%, $p < 0.001$) but less likely to have biopsy Gleason grade 3 + 3 = 6 or less disease (55.2% vs 65.2%, $p = 0.023$).

In terms of operative outcomes for bladder neck sparing vs nonsparing (see table), the frequency of the bilateral vs the unilateral/nonnerve sparing technique did not vary by bladder neck sparing vs nonsparing. Men with bladder neck sparing experienced fewer urinary leak complications (1.4% vs 4.0%, $p = 0.009$) and shorter length of stay (1.1 vs 1.3 days, $p = 0.006$). With respect to cancer control outcomes (see table), there was no significant difference in bladder neck sparing vs nonsparing base (1.1% vs 2.5%, $p = 0.146$) or overall (each 13.8%, $p = 0.985$) surgical margin positivity. Similarly, there was no difference in biochemical recurrence-free survival rates for bladder neck sparing vs nonsparing after controlling for pathological stage, grade, baseline PSA and margin status (HR 1.20,

95% CI 0.62–2.31, $p = 0.596$, fig. 4). However, bladder neck sparing vs nonsparing was associated with earlier and better recovery of continence (HR 1.69, 95% CI 1.43–1.99, $p < 0.001$, fig. 5).

DISCUSSION

As knowledge of pelvic anatomy has improved, various surgical technical modifications have emerged that are intended to preserve critical structures, such as the neurovascular bundle and external urethral sphincter muscle. However, controversy exists over whether dissecting the bladder neck vs the nerve sparing plane to preserve the bladder neck/internal sphincter comprises anatomical radical prostatectomy.¹² While RALP has been rapidly adopted and offers several advantages, such as greater magnification and less blood loss, prior research showed that men who undergo RALP are more likely to be diagnosed with incontinence. However, bladder neck sparing was not considered in these studies. Subsequent research revealed that bladder neck sparing vs nonsparing is associated with earlier recovery of continence within a year of RALP.^{4,9}

The absence of tactile feedback may account for bladder neck dissection being regarded as one of the most challenging steps of RALP.¹³ In fact, the inability to palpate during RALP represents one of the most challenging steps for those early in the learning curve.^{14,15} Counterintuitively, while other RALP steps decrease in complexity during the first 50 cases, the requisite time for bladder neck dissection increases.¹⁶ Consequently, bladder neck sparing during RALP may contribute to a greater likelihood of residual prostate tissue and eventual biochemical recurrence.

Our study has several important findings. 1) Bladder neck sparing was associated with quicker return of continence and better long-term continence than nonbladder neck sparing, as evidenced by better bladder neck sparing vs nonsparing continence throughout followup. These results are consistent with those of prior studies demonstrating better early continence for bladder neck sparing during RALP^{4,9} and open radical prostatectomy.^{17–19} In contrast to Freire et al, who found no difference in 24-month continence rates between men with bladder neck sparing and nonsparing,⁹ our study has greater long-term followup for examining long-term continence outcomes.

2) Bladder neck sparing was not associated with worse cancer control, as demonstrated by similar overall and prostate base surgical margin status and biochemical recurrence-free survival between men with bladder neck sparing and nonsparing. Our 1, 3 and 5-year biochemical recurrence-free survival

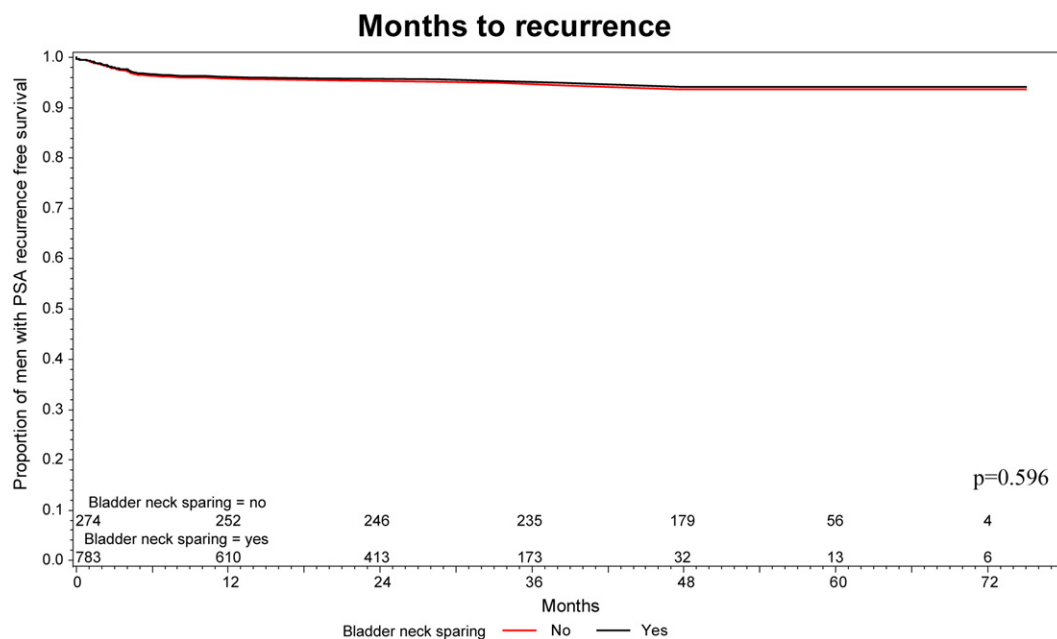


Figure 4. After adjusting for PSA, surgical margin status, and pathological grade and stage, biochemical recurrence-free survival was similar in bladder neck sparing and nonsparing cohorts ($p = 0.596$).

rates are similar to those reported by Menon et al.²⁰ While we noted no difference in surgical margin status for bladder neck sparing vs nonsparing, similar to Shelfo et al,²¹ and Soloway and Neulander,²² this finding contrasts with earlier studies demon-

strating a greater likelihood of positive prostate base margins^{23–25} and worse cancer control⁸ in the setting of bladder neck sparing during open and laparoscopic radical prostatectomy. This may be due to heterogeneity in bladder neck dissection tech-

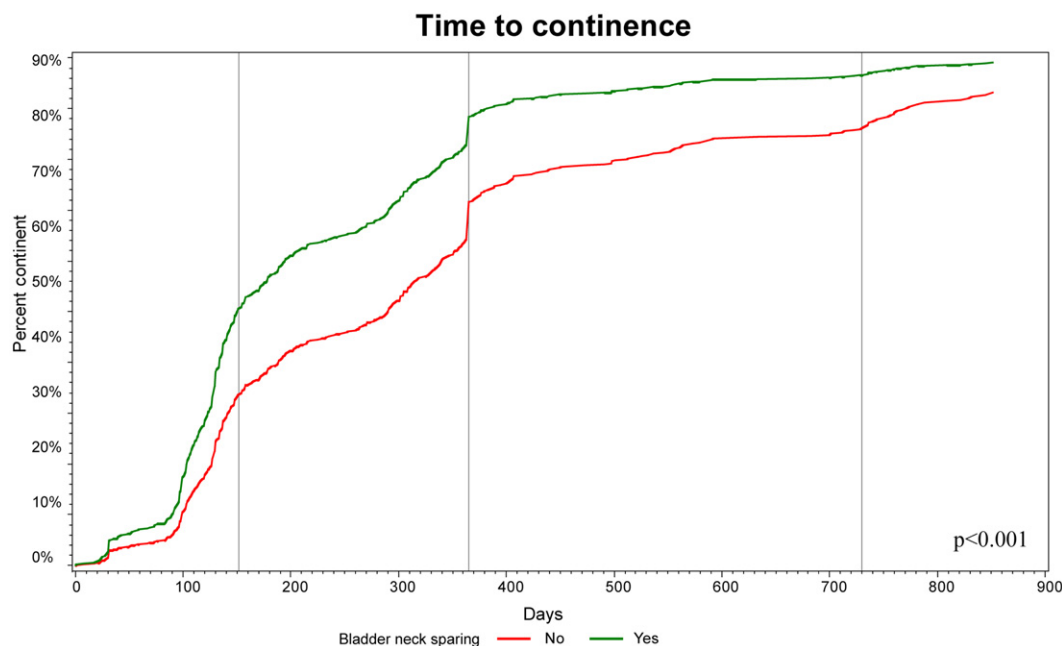


Figure 5. Better urinary continence for bladder neck sparing vs nonsparing (HR 1.69, 1.43–1.99 95% CI). Vertical lines represent 5 (HR 1.43, 1.10–1.85 95% CI, $p = 0.008$), 12 (HR 1.29, 95% CI 1.08–1.55, $p = 0.005$) and 24-month (HR 1.18, 95% CI 1.00–1.40, $p = 0.048$) followup, demonstrating better continence with bladder neck sparing at these followup intervals (p values adjusted for multiple comparisons).

niques coupled with variations in surgical approach, ie robotic vs open.

3) Bladder neck sparing was associated with fewer urinary leak complications and shorter length of stay, consistent with existing RALP literature comparing urinary leak and/or length of stay in bladder neck sparing vs nonsparing cases.^{9,26} The shorter anastomotic suture line associated with bladder neck sparing likely heals more quickly and is less susceptible to urine leak. The greater frequency of urine leaks and accompanying peritonitis, and higher surgical drain output observed with non-bladder neck sparing vs bladder neck sparing may contribute to the greater variation in length of stay. The greater likelihood of urinary leak with bladder neck nonsparing may not be as evident for open radical prostatectomy due to the traditionally longer length of catheterization and the extraperitoneal approach, which precludes ileus and peritonitis secondary to anastomotic urine leak.²⁷

Our findings must be interpreted in the context of the study design. This was a retrospective, observational study, in contrast to a prospective, randomized control trial. Surgeon and patient equipoise is difficult to achieve, particularly if the surgeon is biased toward bladder neck sparing, which obviates

the need for bladder neck reconstruction and leads to shorter operative time. Moreover, bladder neck sparing is a technique that was used with greater frequency later in our surgical experience,⁹ which also corresponded with performing RALP in men with higher biopsy and pathological Gleason grades. However, we adjusted for preoperative PSA, pathological grade and other characteristics when comparing biochemical recurrence-free survival. The definition of continence varies across studies. However, we report continence and pad use from a validated, patient self-reported quality of life instrument with third party data collection, similar to that in other large radical prostatectomy series.^{28,29} Furthermore, any pad use, even for safety or social confidence, was categorized as incontinence. Finally, longer followup is needed to compare biochemical recurrence-free survival for bladder neck sparing vs nonsparing.

CONCLUSIONS

Bladder neck sparing vs nonsparing is associated with earlier and better continence without worsening short-term cancer control. Moreover, bladder neck sparing is associated with fewer urine leaks and shorter RALP hospitalization.

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