

Long-term impact of posterior reconstruction urethrovesical anastomosis during robot-assisted prostatectomy

A secondary analysis of a randomized cohort

Braden Millan¹, Jen Hoogenes², Michael Uy², Raees Cassim², Bobby Shayegan²

¹National Cancer Institute, Urologic Oncology Branch, Bethesda, MD, United States; ²Division of Urology, Department of Surgery, McMaster University, Hamilton, ON, Canada

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ABSTRACT

INTRODUCTION: We aimed to assess early and late continence rates post-robot-assisted radical prostatectomy (RARP), comparing posterior reconstruction (PR) urethrovesical anastomosis (UVA) to conventional urethrovesical anastomosis (C-UVA).

METHODS: Consecutive patients with clinically localized prostate cancer undergoing RARP underwent simple randomization to PR-UVA or C-UVA. Return to continence outcomes were assessed using a validated questionnaire (Expanded Prostate Cancer Index Composite [EPIC] Short Form-26) at baseline, two-, three-, four-, six-, eight-, and 12-month followups. Five-year outcomes were assessed by frequency of undergoing continence-improving procedures.

RESULTS: A total of 163 patients were randomized 1:1 to PR-UVA or C-UVA from April 2014 to July 2015, and 140 patients completed followup. There were no significant clinical or functional differences between groups preoperatively. Using a continence definition of 0–1 pads/day, the continence rates for PR-UVA vs. C-UVA were 39% vs. 38% at two months, respectively ($p=1.0$), and 93% vs. 86%, respectively, at 12 months ($p=0.3$). Frequency of urine leak, quantity of pad use, subjective urinary control, and overall bother improved significantly in all patients during the 12-month study period ($p<0.001$); however, no difference was demonstrated between groups. Five-year results showed no statistically significant difference in the number of patients undergoing a continence-improving procedure (hazard ratio 1.21, 95% confidence interval 0.40–3.65, $p=0.7$).

CONCLUSIONS: PR-UVA failed to show a benefit in short-term return to urinary continence or need for an incontinence-improving procedure five years post-RARP.

INTRODUCTION

Each modality of prostate cancer treatment has the propensity to lead to negative outcomes on quality of life to varying degrees.¹ It is our responsibility to incorporate into our practices the most beneficial treatment regimens that render patients cancer-free while minimizing potential treatment-related adverse outcomes, including incontinence and erectile dysfunction. Urinary incontinence and erectile dysfunction are well-described complications of radical prostatectomy (RP), with observed rates of 4–31% and 25–86%, respectively.^{2–4} Delayed recovery of urinary continence following robot-assisted radical prostatectomy (RARP) is a well-known entity. Numerous contributing factors have been identified for post-prostatectomy incontinence (PPI), including both patient (age, body mass index [BMI], membranous urethral length, prostate volume, pre-existing lower urinary tract symptoms, and oncologic factors) and surgeon characteristics (experience, technique).⁵

In a systematic review and meta-analysis using a no pad or a single safety pad definition, Ficcaro and colleagues showed that the 12-month urinary incontinence rates can range from 8–11%.⁴ As such, several reconstructive options have been incorporated into the contemporary RP to attempt to improve these outcomes. The anatomy of the urethral-sphincteric vesico-prostatic complex is well-described, leading to attempts

KEY MESSAGES

- The study compared posterior reconstruction (PR) urethrovesical anastomosis to conventional urethrovesical anastomosis (C-UVA) during robot-assisted radical prostatectomy in patients with localized prostate cancer.
- No significant differences were found between the groups in early or late urinary continence rates or the need for incontinence-improving procedures at five years.
- Both techniques showed similar improvements in urinary control and bother over 12 months.
- The findings suggest that PR-UVA does not provide a significant advantage over C-UVA in terms of continence outcomes or long-term continence-improving procedural requirements.

to perform reconstruction of the Denonvilliers' musculofascial plate during the urethrovesical anastomosis (UVA) at the time of RP. Performing a posterior reconstruction (PR) of the rhabdosphincter was first reported by Rocco et al in 2006 during open retropubic RP, showing a three-, 30-, and 90-day improvement in urinary continence post-catheter removal.⁶

Posterior reconstruction urethrovesical anastomosis (PR-UVA) has been hypothesized to improve the integrity of the rhabdosphincter and potentially increase the functional urethral length; however, a recent systematic review evaluating the efficacy of PR-UVA showed no statistical improvement in urinary continence at one week, and at three, six, and 12 months.⁷ Conflicting studies within the literature render an environment of clinical equipoise in this specific patient-related outcome. Additionally, despite this, this form of reconstructive UVA is still commonly performed in clinical practice. The objective of this study was to assess the short- and long-term functional outcomes of PR-UVA at the time of RARP.

METHODS

Study population and design

This was a retrospective cohort study involving 163 consecutive patients recruited at a tertiary academic referral center from April 2014 to June 2015. All patients underwent RARP by a single, high-volume surgeon with more than 500 cases experience using both techniques. Study participants were randomly allocated 1:1 to PR-UVA or conventional UVA (C-UVA) using software-generated simple randomization performed by the study coordinator (GraphPad QuickCalcs, San Diego, CA, U.S.).

The inclusion criterion was any patient with localized prostate cancer (cT1–2N0M0) who had elected for surgical management. Study exclusion criteria were those with a history of previous prostatic and/or urethral surgery, a known history of a disease that could affect continence (e.g., insulin-dependent diabetes or urethral stricture disease), and the presence of a urinary catheter preventing preoperative evaluation of continence. The study coordinator informed the surgeon of the allocation immediately before surgery. The study received institutional research ethics board approval, and informed consent was obtained before randomization (Hamilton Integrated Research Ethics Board #15556; NCT05605171).

Surgical technique

In our single-center, single-surgeon study, all RARPs are performed with posterior dissection of the seminal vesicles, without Retzius sparing, and a limited or standard pelvic lymph node dissection. The C-UVA is performed using a continuous running technique that uses two sutures. The sutures are each passed in a hemi-circumferential manner, starting from outside in on the bladder neck at the six o'clock position and inside out on the urethra up toward the 12 o'clock position. The running sutures are snug down after each apposition to ensure there is no slack and are tied together at the 12 o'clock position. PR-UVA comprised of a two-stitch approximation of the free edge of the Denonvilliers' fascia and posterior bladder wall to the posterior aspect of the rhabdosphincter and the posterior median raphe caudally, followed by the above description of the C-UVA.⁸

Data collection

The validated Expanded Prostate Cancer Index Composite Short Form-26 (EPIC-26) was used to measure urinary continence and four health-related

quality of life domains at baseline (before RARP) and at two, three, four, six, eight, and 12 months post-RARP. Patients and outcomes assessors were blinded to the treatment arm.

Additional preoperative variables collected included age, prostate-specific antigen (PSA) level, biopsy Gleason Score, BMI, clinical T-stage, D'Amico risk level, American Society of Anesthesiologists (ASA) physical status classification, and lower urinary tract symptoms. Intraoperative variables included method of urethral reconstruction, nerve-sparing, estimated blood loss, and length of surgery. Postoperative variables included final pathology, length of catheterization, length of hospital stay, need for adjuvant therapy, or undergoing an incontinence-improving procedure post-RARP.

Analysis

The primary outcome measure was urinary continence, defined as either 0 or 0–1 pad use per day, coded as a binary dependent variable. Descriptive statistics were evaluated via counts and percentages. Differences between cohorts were calculated using Fisher's exact test for categorical data, the Student t-test for continuous data, and the analysis of variance for comparing multiple groups. Safety pad use and urinary continence scores were compared using the Chi-squared and Mann-Whitney U test, respectively.

Five-year requirement for incontinence-improving procedures was collected. Mean followup was estimated using the Kaplan-Meier method. Procedure-free survival was estimated using the Cox proportional hazards modeling, controlling for age at surgery, BMI, prostate weight (grams), and receipt of adjuvant/salvage radiotherapy. All analyses were performed with IBM SPSS Statistics v28 (IBM Corporation, Armonk, NY, U.S.), and a p-value of 0.05 was considered statistically significant. No sample size calculation was performed, as this was a convenience sample.

RESULTS

Of the 163 patients recruited, 140 completed the study and were included in the final analysis (Supplementary Figure 1; available at cuaj.ca). A total of 73 patients were allocated to the PR-UVA group and 67 to the C-UVA group. Baseline demographic and clinical data were similar between groups, with no statistically significant differences in age, BMI, PSA, ASA score, or D'Amico risk group (Table 1). The baseline EPIC-26 score was not statistically different between PR-UVA and C-UVA groups ($p=0.9$). Prior to surgery, there was no difference in urinary incontinence between the two groups ($p=0.4$).

Table 1. Baseline characteristics of study participants

Characteristic	PR-UVA n=73	C-UVA n=67	p
Age	64.3 (60.1, 68.7)	64.0 (57.7, 68.0)	0.8
BMI	27.7 (25.2, 30.2)	28.1 (26.0, 30.3)	0.2
PSA	6.8 (4.9, 9.5)	6.3 (4.7, 8.8)	0.8
D'Amico risk group (%)			
Low-risk	7 (9.6)	7 (10.4)	
Intermediate-risk	54 (74.0)	45 (67.2)	
High-risk	12 (16.4)	15 (22.4)	0.6
ASA score			
1	3 (4.1)	4 (6.0)	
2	24 (33.0)	20 (30.0)	
3	41 (56.2)	41 (61.2)	
4	4 (5.5)	2 (3.0)	0.9
Urinary incontinence (%)			
Rarely or never	56 (76.7)	55 (82.1)	
About once a week	13 (17.8)	9 (13.4)	
More than once a week	2 (2.7)	3 (4.5)	
About once a day	2 (2.7)	0 (0.0)	0.3
EPIC-26 score			
Baseline	34.8 (6.6)	34.6 (7.9)	0.9

ASA: American Society of Anesthesiologists; BMI: body mass index; C-UVA: conventional urethrovesical anastomosis; EPIC: Expanded Prostate Cancer Index Composite; PR-UVA: posterior reconstruction urethrovesical anastomosis; PSA: prostate-specific antigen.

Analysis of intraoperative characteristics revealed no difference in total operative time, estimated blood loss, or nerve-sparing, with a median length of hospital stay of two days in both cohorts (all $p>0.05$). No differences were detected in the final grade group, rate of positive surgical margins, number of positive lymph nodes, need for adjuvant therapy, 12-month EPIC-26 scores, or number of patients undergoing an incontinence-improving procedure. Lastly, at five-year followup, 13 patients had undergone an incontinence-improving procedure (all mid-urethral slings), seven (9.6%) who underwent PR-UVA and six (9.0%) who underwent C-UVA ($p=0.9$) (Table 2).

Urinary continence, defined as 0–1 pads/day, did not differ between PR-UVA and C-UVA at two-, three-, four-, six-, and 12-month followup (Table 3). At two months, 28 patients in comparison to 25 patients in the

Table 2. Intraoperative and outcome data for study participants

Outcome	PR-UVA n=73	C-UVA n=67	p
Nerve-sparing			
None	0 (0.0%)	0 (0.0%)	
Unilateral	13 (17.8%)	7 (10.4%)	
Bilateral	60 (82.2%)	60 (89.6%)	0.2
OR time in minutes	178 (167, 192)	174 (165, 186)	0.4
Hospital LOS in days	2 (2, 2)	2 (2, 2)	0.3
EBL in ml	200 (125, 300)	200 (100, 300)	0.4
Prostate weight in grams	50 (40, 64)	48 (39, 46)	0.5
Grade group (missing=1)			
1	1 (1.4%)	3 (4.5%)	
2	52 (71.2%)	40 (59.7%)	
3	11 (15.1%)	17 (25.4%)	
4	6 (8.2%)	3 (4.5%)	
5	3 (4.1%)	3 (4.5%)	0.9
pNI	2 (2.7%)	3 (4.5%)	0.8
RI	12 (16.4%)	14 (20.9%)	0.5
Adjuvant therapy	12 (16.4%)	13 (19.4%)	0.7
Mid-urethral sling	7 (9.6%)	6 (9.0%)	0.9
EPIC-26 score			
12-months post-op	27.9 (8.2)	27.3 (8.8)	0.7

EBL: estimated blood loss; EPIC: Expanded Prostate Cancer Index Composite; LOS: length of stay; OR: operating room.

PR-UVA and C-UVA cohorts, respectively, used none or one pad (p=1.0) (Table 3). No significant differences were observed at any time point when the continence definition was changed to zero pads per day, with 40 patients in each cohort being completely continent at 12 months (Supplementary Table 1; available at *cuaj.ca*). Continence rates among all study patients improved consistently throughout the study period (Table 3). Overall urinary bother scores and associated impact on patient quality of life were not found to be statistically different between groups at each followup point. Mean followup was 94.4 months (95% confidence interval [CI] 89.3–99.5) in the C-UVA cohort, which was similar to the PR-UVA cohort (94.8 months; 95% CI 91.4–98.1, p=0.9). Cox proportional regression modeling using age at time of surgery, BMI, final

Table 3. Comparison of continence (0/1 pad per day) data between PR-UVA and C-UVA up to one-year followup

	PR-UVA n=73	C-UVA n=67	p
Baseline	72 (98.6)	66 (98.5)	1.0
2 months	28 (39.0)	25 (38.0)	1.0
3 months	42 (59.2)	38 (57.6)	0.9
4 months	51 (72.0)	46 (69.7)	0.9
6 months	53 (80.3)	50 (78.1)	0.8
8 months	58 (81.7)	53 (82.8)	1.0
12 months	66 (93.0)	54 (85.7)	0.3
Baseline vs. 12 months			0.7

C-UVA: conventional urethrovesical anastomosis; PR-UVA: posterior reconstruction urethrovesical anastomosis.

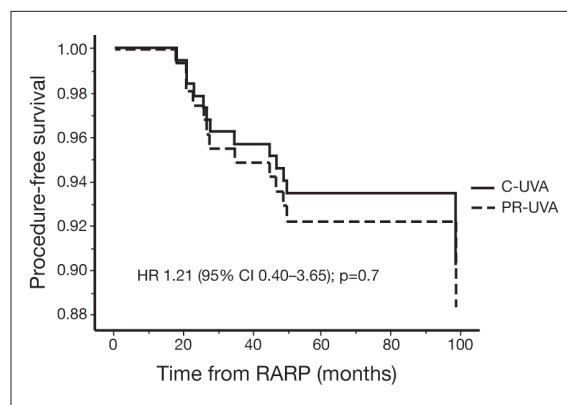


Figure 1. Incontinence procedure-free survival (PFS) post-robot-assisted radical prostatectomy (RARP) comparing those undergoing posterior reconstruction urethrovesical anastomosis (PR-UVA) in comparison to conventional urethrovesical anastomosis (C-UVA) using the Cox proportional hazards model.

prostate weight, or adjuvant therapy showed no difference between groups (hazard ratio [HR] 1.21, 95% CI 0.40–3.65, p=0.7) (Figure 1). Older age was associated with an increased risk of undergoing an incontinence-improving procedure (HR 1.11, 95% CI 1.01–1.22, p=0.03). No patients required insertion of an artificial urinary sphincter. No harm or unintended effects were observed in either cohort.

DISCUSSION

Posterior reconstruction of the Denonvilliers' musculofascial plate is a common technique that was reported to improve early return to continence.⁹ To our knowledge, we are the first to report on long-term outcomes comparing PR-UVA to C-UVA, and

we found no difference between groups for rates of incontinence-improving procedures. There was also no improvement in early (two months) or late (8–12 months) urinary continence between those undergoing PR-UVA and C-UVA. Consistent with previous reports, implementation of PR-UVA did not result in any increase in postoperative complications. A statistically significant difference in mean estimated blood loss was observed favoring PR-UVA, although this is likely of limited clinical relevance.

A recent systematic review and meta-analysis evaluating the efficacy of PR-UVA showed no improvement in urinary continence at one week or at three, six, and 12 months, which includes data from the current study.⁷ In the first described study of this topic, Rocco et al showed an improvement in urinary continence with PR-UVA at 12 months, although not significantly different from historical unmodified Walsh technique controls (95% vs. 90% at 12 months).⁶ A 2012 population-based study showed that five-year artificial urinary sphincter (AUS)/mid-urethral sling procedure rate for PPI was 2.6% (95% CI 2.4–2.8).¹⁰ We observed 13 (9.3%) of our study patients requiring insertion of a mid-urethral sling, with no patients requiring an AUS. It is important to note the difference in the study dates, which may have an impact on the number, availability, and forms of incontinence-improving devices.

The various definitions of urinary incontinence have resulted in differing conclusions in previous studies. Using a strict definition (zero pads), Salazar et al concluded that PR-UVA resulted in improved recovery of urinary continence; however, when the definition included single pad per day use, no significant difference was observed.¹¹ Sutherland et al found no difference in continence at three months (81% controls vs. 63% PR-UVA, $p=0.1$) by either definition, concluding that PR-UVA has no benefit on early return to urinary continence post-RARP.¹²

In another large, observational study (historical control) of 802 patients, no difference in urinary continence (zero pads per day) was observed at six months in comparison to control with PR-UVA; however, 12-month data were not reported.¹³ Our study assessed both definitions of urinary continence up to 12 months to address some of the observed gaps in the current literature. Additionally, to our knowledge, we are the first to report a comparison between PR-UVA and C-UVA on rates of surgery for PPI.

Other surgical techniques that have been investigated in detail in the literature include total anatomical reconstruction (TAR) and Retzius sparing (RS) RARP.

Although not a randomized trial, continence rates following TAR RARP in 1000 patients using a 0/1 pad definition were higher than our observed rates in either cohort, both early and late after catheter removal.¹⁴ RS RARP has also been shown to improve both early and late return to continence; however, there may be an increased risk of positive surgical margins, suspected to be related to the learning curve of this approach.¹⁵ To date, there have been no comparative studies for TAR, RS, or PR-UVA during RARP.

We have described our surgical methodology in detail to ensure consistency with prior literature investigating this technique. The definition of urinary incontinence (0 and 0/1 pads) has been previously debated, and therefore, we assessed both.

Limitations

There are several limitations to our current study. With a small patient population and no sample size calculation, it is possible that our study is underpowered to show a difference between these two interventions. With simple randomization, although it can achieve balance, groups may be generated that are not comparable in terms of important covariates, which may alter the specific outcomes of interest. Additionally, all surgeries were performed by a single, unblinded surgeon, which could result in unmeasured bias in those steps of the surgery before performing the UVA.

CONCLUSIONS

Our study corroborates the findings of previous research evaluating PR-UVA vs. C-UVA, where there is no statistically significant difference in early or late return to urinary continence. Additionally, we observed no difference between groups in the number of patients undergoing continence-improving procedures five years after surgery.

COMPETING INTERESTS: Dr. Shayegan has participated in advisory boards for AbbVie, Astellas, Bayer, Janssen, Knight, Novartis, TerSera, Tolmar, and Verity. The remaining authors do not report any competing personal or financial interests related to this work.

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CORRESPONDENCE: Dr. Bobby Shayegan, McMaster Institute of Urology, Hamilton, ON, Canada; shayeb@mcmaster.ca

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