

A novel method of bladder neck imbrication to improve early urinary continence following robotic-assisted radical prostatectomy

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Abstract Early return of continence forms an important component of quality of life for patients after robotic-assisted radical prostatectomy (RALP). Here we describe the steps of bladder neck imbrication and vesico-urethral anastomosis improving early continence after RALP. Between April 2008 and July 2009, 202 consecutive patients underwent RALP for clinically localised prostate cancer in a tertiary referral centre by a single surgeon. One hundred and thirty-two (65 %) of these patients agreed to participate in the study. Prior to November 2008, 51 patients underwent standard RALP as described by Patel et al. From November 2008, 81 patients underwent a novel

method of bladder neck imbrication. The robotic urethro-vesical anastomosis commences on the posterior wall of the urethra and proceeds anteriorly. In our technique the anastomosis is halted with the suture arms fixed to the anterior abdominal wall. A new suture is used to perform a two-layer repair, anchoring proximally then continuing anteriorly to the level of the urethral stump, where it returns upon itself. The aim is to narrow the urethra to 16 Fr and tighten the second layer to create an imbrication effect. Posterior reconstruction was performed in all patients. Outcome measures were recorded prospectively using the Expanded Prostate Cancer Index Composite tool. Our technique shows significant improvement at all stages of follow-up in urinary summary and incontinence scores. Absolute continence rates increased from 8.2 to 20.5 %, 26.7 to 44.3 %, and 47.7 to 62.3 % at 1.5, 3 and 6 months, respectively. These results support the use of our technique in patients undergoing RALP.

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Introduction

Continence after radical prostatectomy (RP) is a significant area of patient concern, with incontinence having demonstrable impact upon health-related quality of life (HRQOL) [1]. Current evidence suggests that >90 % of patients will return to baseline continence within 12–24 months of surgery [2, 3]. However, there is considerable variation in the rates of early continence between various surgical techniques [3].

Based on pre-procedure tumour characteristics, a subset of patients exists where a wider resection of the base is

often deemed necessary, leading to a size mismatch at the time of urethro-vesical anastomosis. In 2002, Walsh et al. described a technique of bladder neck intussusception for open prostatectomy that was associated with improved early urinary control [4]. Using this concept of buttressing sutures, we developed a technique of bladder neck imbrication when performing robotic-assisted radical prostatectomy (RALP). As RALP does not permit ready access to the posterior bladder, an imbrication anteriorly along the line of bladder neck repair facilitates two-layered closure.

We present here our novel method of two-layered bladder neck imbrication following RALP associated with improvements in short-term continence recovery.

Methods

Quality of life tool

The RALP program commenced at St. Vincent's Hospital, a high-volume tertiary referral centre, in February 2006. From April 2007, all patients undergoing treatment for localised prostate cancer at our centre were invited to participate in an ongoing QOL study utilising the University of Michigan's validated Expanded Prostate Cancer Index Composite (EPIC) questionnaire [5]. RALP forms one arm of this larger prospective study established to compare HRQOL between treatment modalities. The urinary component of the EPIC questionnaire was used to assess outcomes for this study. Ethics approval was obtained as part of our ongoing quality of life study

(St. Vincent's Hospital Human Research Ethics Committee #H07/021) and patient consent was obtained prospectively. Patients who agreed to participate in the study were mailed questionnaires at baseline, 1.5, 3, 6, 12, 24 and 36 months, which were then completed and returned directly to the study coordinators.

Patient selection

Between April 2008 and July 2009, 202 men underwent RALP by a single surgeon (P.S.) for clinically localised prostate cancer. Cognisant of the impact of the learning curve on RALP outcomes [6], those patients prior to April 2008 who comprised the surgeon's initial 100 RALP cases were excluded. One hundred and thirty-two patients consented to participate in the study. Patients were stratified into control and intervention groups, referred to as group 1 and group 2, respectively (Fig. 1). Group 1 comprised 51 patients treated prior to November 2008 who underwent a standard RALP as described by Patel et al. [7, 8]. Group 2 comprised 81 patients treated from November 2008 to July 2009 when our modified surgical technique of bladder neck imbrication was introduced. Patients without complete follow-up for all questionnaires up to 6 months were excluded from the study.

Surgical technique

A standard 6 port transperitoneal RALP was performed. In patients undergoing a nerve-sparing procedure an athermal early retrograde release of the neurovascular bundles was

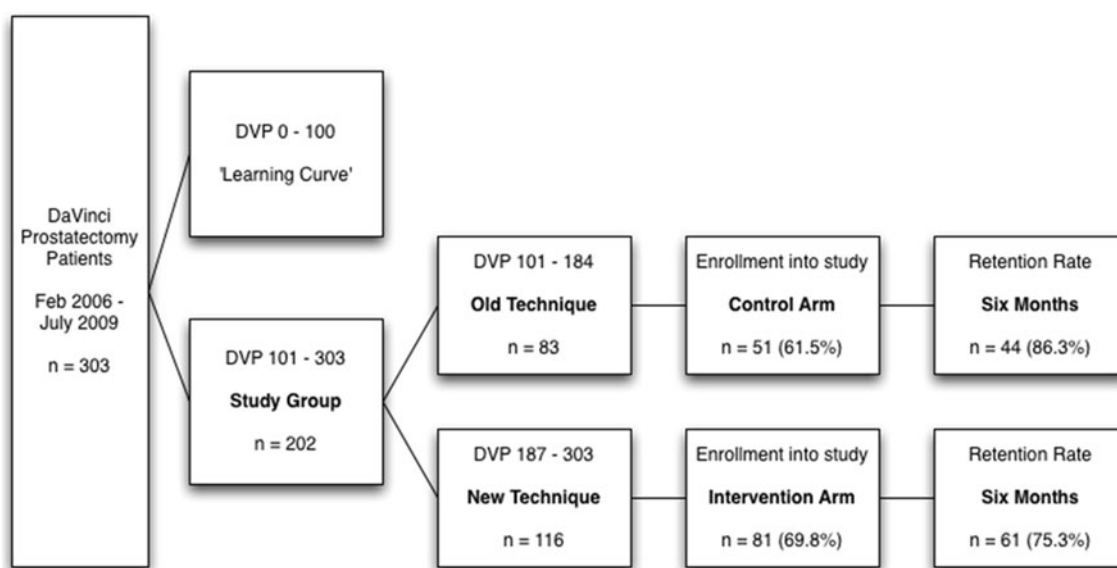


Fig. 1 Study flow diagram. Control arm (group 1) comprises those patients who underwent standard RALP. Intervention arm (group 2) comprises those patients who underwent bladder neck imbrication.

DVP da Vinci prostatectomy sequence number from commencement of RALP program

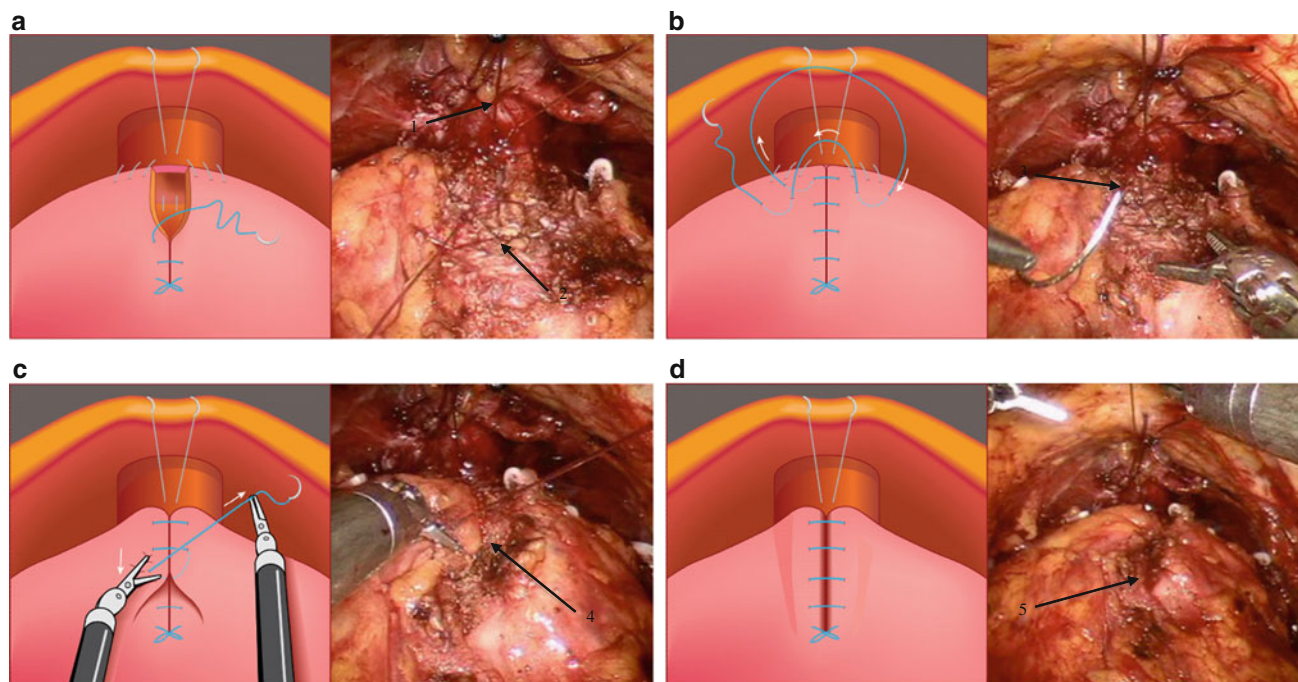


Fig. 2 **a** The urethro-vesical anastomosis is halted, with the two suture arms fixed to the abdominal wall (1). A continuous suture is commenced anchoring proximally to the defect (2). **b** The suture is continued to the level of the urethral stump and tightened over a 16Fr

catheter (3). **c** The suture then returns upon itself through the muscular layer, with continuous tightening creating a rolling in effect (4). **d** At the apex of the wound, the returning suture is tied to the original knot and the anastomosis is then completed

performed from apex to base via an intrafascial approach or by an antegrade technique in an incremental fashion [8–10]. A two-layer posterior Rocco reconstruction [11, 12] and suspension stitch were used in all patients who underwent RALP. The urethro-vesical anastomosis is then completed over a catheter using a continuous synthetic absorbable running suture.

Prior to November 2008, patients underwent a standard repair as described by Patel et al., with a Van Velthoven [13] continuous urethro-vesical anastomosis. When there was a significant mismatch at the bladder neck we used lateral figure-of-8 sutures or a simple anterior racket handle. From November 2008 onwards, we adopted a novel technique of bladder neck imbrication, resembling a tight, two-layered imbricated anterior racket handle technique. All patients after November 2008 underwent this technique, including those with minimal urethro-vesical mismatch where a shorter imbrication was performed.

The anastomosis commences on the posterior wall of the urethra and proceeds anteriorly. In the traditional approach the anastomosis continues until the two arms meet anteriorly in the midline [7]. In our technique it is instead halted, with the two suture arms fixed to the anterior abdominal wall (Fig. 2a). A new suture is used to perform a two-layer repair, anchoring proximally to the bladder neck defect. Using continuous sutures, the repair is continued anteriorly to the level of the urethral stump, tightening to 16 Fr,

whereupon it returns rostrally by taking wider bites (Fig. 2b). On this returning second layer there is continuous tissue opposition creating a rolling in effect (Fig. 2c). After the second layer has returned to the apex the anastomosis can then be completed (Fig. 2d). Upon completion the integrity of the anastomosis is tested by filling the bladder neck with normal saline, thus ensuring no leak intraoperatively.

Post-operative care did not differ between the two groups. A cystogram was performed on day 6, prior to removal of the indwelling catheter.

Statistical analysis

Baseline patient characteristics (Table 1) were tested for differences between group 1 and 2 using the two-sample *t* test for continuous variables (age, prostate-specific antigen [PSA], weight, and baseline urinary summary and urinary incontinence scores). Categorical variables were assessed using Fisher's exact test [14].

Both groups were assessed at three different follow-up times—1.5, 3 and 6 months. This means that each patient was repeatedly asked the same questions three times, and the answers not independent. Continence was defined as rare or no leakage of urine and 0 pad use. This corresponds to a response of 5 to question 8 and 0 to question 12 in the EPIC questionnaire (Table 1).

Table 1 Baseline clinical and pathological characteristics

	Group 1 Mean \pm SD	Group 2 Mean \pm SD	<i>p</i> Value
PSA (ng/mL)	7.9 \pm 5.83	7.2 \pm 3.67	0.47
Prostate size (g)	48.85 \pm 11.62	50.0 \pm 12.94	0.62
Baseline urinary summary score	92.69 \pm 8.9	89.8 \pm 11.94	0.13
Baseline urinary incontinence score	95.34 \pm 9.71	92.33 \pm 17.67	0.21
	Frequency (%)	Frequency (%)	
Age (years)			
<55	7 (13.5)	8 (10.7)	0.86
55–64	27 (51.9)	41 (54.7)	
65+	18 (34.6)	26 (34.7)	
Gleason score			
<7	8 (15.7)	17 (21)	
7	39 (76.5)	55 (67.9)	
>7	4 (7.9)	9 (11.1)	
Margin status			
Extensive	1 (2)	1 (1.2)	1
Focal	8 (15.7)	13 (16)	
Negative	42 (82.4)	67 (82.7)	
P stage			
pt2a	1 (2)	6 (7.4)	1
pt2b	3 (5.9)	4 (4.9)	
pt2c	27 (52.9)	50 (61.7)	
pt3a	16 (31.4)	15 (18.5)	
pt3b	2 (3.9)	6 (7.4)	
pt4	2 (3.9)	0 (0)	
EPIC question 8 ^a			
≤ 4	6	13	1
5	45	68	
EPIC question 12 ^b			
0	51	75	1
≥ 1	0	6	

^a EPIC question 8: Over the past 4 weeks, how often have you leaked urine? 1. More than once a day 2. About once a day 3. More than once a week 4. About once a week 5. Rarely or never

^b EPIC question 12: How many pads or adult diapers per day did you use to control leakage during the last 4 weeks? No pads/1 pad per day/2 pads per day/3 or more pads per day

Repeated measures analysis of variance was used to analyse continence, urinary continence domain and urinary summary domain scores. *p* Values <0.05 were considered significant. All analyses were conducted using R2.12 and the nlme software package [15].

Results

Of the 202 consecutive patients who underwent RALP during the study period, 132 men (65 %) consented to participate in our ongoing quality of life study. Group 1 comprised 51 patients (*n* = 51), and group 2 comprised 81 patients (*n* = 81). Complete follow-up information was available at 6 months for 44 patients in group 1 (86.3 %) and 61 patients in group 2 (75.3 %). As shown in Table 1, no significant differences were detected at baseline

between the groups with regards to PSA, age, pathology, continence and urinary domain scores.

Urinary domain

The EPIC questionnaire's assessment of the urinary domain consists of a domain summary score, which includes both incontinence and irritative and obstructive symptoms. The urinary incontinence score exists as a subscale of this, assessing incontinence as a discrete component of the overall urinary HRQOL domain. Absolute continence is not formally scored in the EPIC questionnaire but can be assessed through responses to two questions, as described previously.

The baseline urinary summary scores were 92.7 % for group 1 and 89.8 % for group 2 (*p* = 0.13). There was a drop in scores to 68.3 versus 75.2 % at 1.5 months, 81.1

versus 87.7 % at 3 months, and 86.6 versus 91.3 % at 6 months, respectively (Fig. 3a). These changes were statistically significant over the 6 month follow-up period ($p = 0.005$). A similar trend was seen in the urinary incontinence scores between the two groups. Scores in group 1 and group 2 were 47.7 versus 59.5 % at

1.5 months, 67.5 versus 78.2 % at 3 months, and 79.3 versus 87.5 % at 6 months, respectively ($p = 0.012$) (Fig. 3b).

Absolute continence rates at baseline were 88.2 % for group 1 and 84 % for group 2. However, there was a statistically significant trend of improvement in the absolute continence scores in favour of group 2 post-operatively; these were 8.2 versus 20.5 % at 1.5 months, 26.7 versus 44.3 % at 3 months, and 47.7 versus 62.3 % at 6 months, in group 1 and group 2, respectively ($p = 0.025$) (Fig. 3c).

Discussion

The urinary summary and continence results obtained with the use of our technique supports the concept of bladder neck imbrication as a method to improve early urinary continence after RALP. Improvements in continence scores were seen at the initial post-operative assessment at 1.5 months and these benefits continued throughout the entire duration of the study.

Early return of continence forms an important aspect of HRQOL for patients after RP and numerous factors have been described that affect recovery, including age, body mass index, pre-operative symptoms and membranous urethral length [3, 16]. As the patient and anatomical factors cannot be altered to a large extent, interest has focused on the impact of surgical technique. Modification of the bladder neck anastomosis has been shown previously to significantly improve early continence after prostatectomy [4, 11, 17–21]. Numerous techniques have been described in the literature, however interpretation and comparison of results is made difficult due to the lack of a standardised definition of continence, as well as the use of different methods to assess outcomes [22–24]. While many articles use ‘absolute’ continence, defined as 0 pad use and no leakage, a number use ‘social’ continence, which is varyingly described as 0 pad use, security pad use or 0 to 1 pad daily, slight problem or pad weight <30 g. In our study we defined continence as 0 pad use and rare of no leakage of urine. These responses are clearly defined within the validated EPIC questionnaire.

The most commonly described modifications of bladder neck anastomosis include posterior reconstruction, intussusception and bladder neck preservation. The role of each of these was considered during the development of our technique. The entire cohort underwent posterior reconstruction with a Rocco stitch, which has been shown to improve short-term continence outcomes [11, 12, 25]. The improved outcomes across all urinary domains demonstrate that our technique presents a benefit in addition to that of the posterior reconstruction alone. Conversely, our study is unable to show the independent effect of the two techniques.

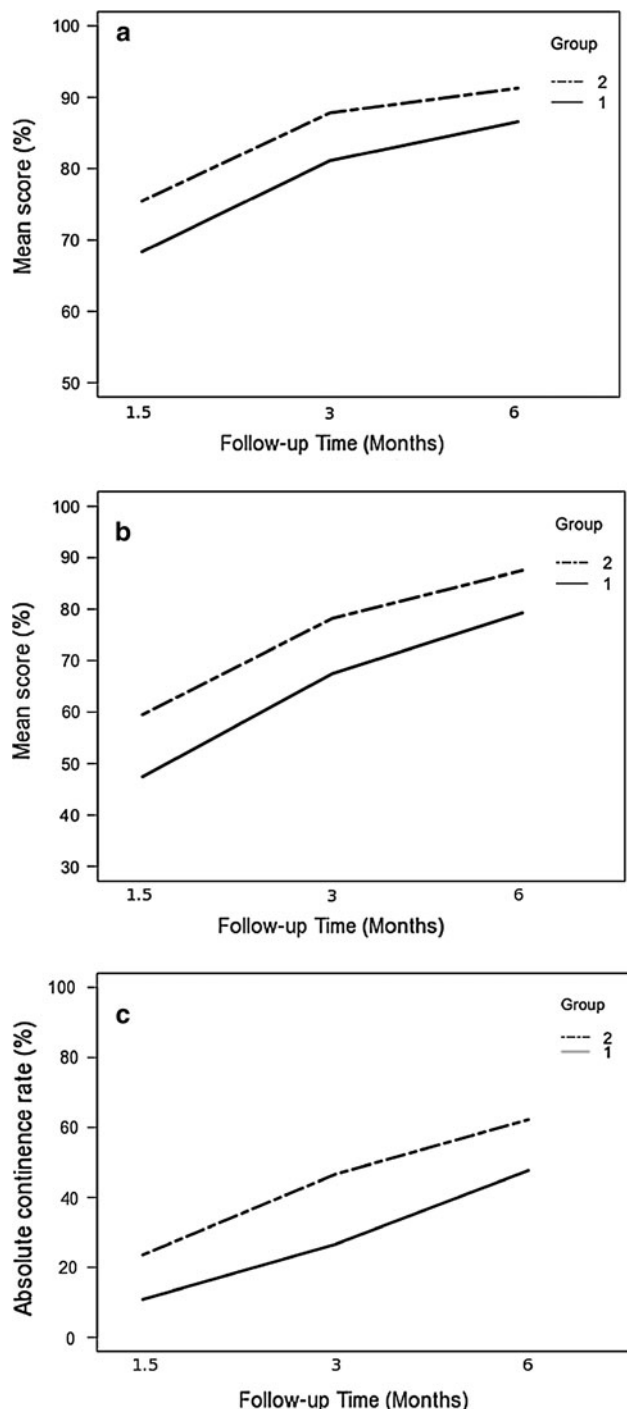


Fig. 3 a Changes in urinary summary score over time ($p = 0.005$). b Changes in urinary continence score over time ($p = 0.012$). c Changes in absolute continence rates over time ($p = 0.025$)

Studies looking at bladder neck intussusception have provided mixed results [4, 26, 27]. Given the difficulty in accessing the posterior bladder in RALP, use of the intussusception technique as described by Walsh et al. is not feasible. Our technique allows adaptation of this concept in order for it to be utilised in RALP, with the second layer of our imbrication acting in a similar manner to the buttressing sutures used to intussuscept the bladder neck. This can, theoretically, prevent the bladder neck from pulling apart as the bladder fills, and may provide some increase in functional urethral length by preventing the proximal end of the urethral stump from opening. It may also create a valve-like effect when the bladder is full.

Bladder neck preservation has been shown to possibly significantly improve early continence outcomes [17–19]. However in patients with more extreme basal tumours or T2 disease, a wider resection of the bladder neck is deemed necessary, as oncological outcomes are felt to be of greater priority than bladder neck preservation. While there is evidence to suggest that bladder neck preservation does not compromise oncologic control, it has been shown that in higher stage tumours it may be linked to positive margin status and biochemical failure [28]. Our technique allows for surgeons to confidently perform a wide bladder neck resection while also achieving satisfactory urinary outcomes.

It has been shown that men recall their pre-treatment HRQOL poorly [29]; however, the prospective nature of this study avoids recall bias. Our study is also strengthened by the use of a self administered, written survey with submission to a third party, which evidence shows is the most accurate method of recording symptoms [30]. Sixty-five percent of patients eligible for inclusion in this study consented to participate in the QOL survey, with follow-up of 79.5 % at 6 months. Given the prospective nature of enrolment and absence of significant differences between the two groups at baseline, there is no clear reason why our participation rate should give rise to a significant bias within the results. We chose to limit our assessment to a period of 6 months as long-term continence rates exceed 90 % at 12 months in most RALP studies [2] and our primary interest was in early continence recovery post-procedure.

We are aware of some limitations of this study. Firstly, the fact that the patients were not randomised into the respective treatment arms could introduce selection bias. However, the two-sample *t* test demonstrated no significant difference in patient demographics or clinical characteristics at baseline. Secondly, as a single surgeon series, development of technique could contribute to the improved continence outcomes. Our unit has previously demonstrated [3] that the learning curve for RALP plays a significant role in patient outcomes, with diminished effect after 110–200 cases. While we have attempted to minimise

the effect of the learning curve by excluding the surgeon's initial 100 cases, it would be impossible for us to completely remove this as a source of bias. That being said, we feel the significance of our results, in particular the rapid recovery of absolute continence, is unlikely to be explained through development of surgical skill alone.

Conclusions

Bladder neck imbrication following RALP demonstrates significant improvement in urinary QOL outcomes at all points of assessment up to 6 months. It provides a straightforward manner in which to improve QOL outcomes and these results indicate the use of this technique in combination with posterior reconstruction may be of benefit in patients undergoing RALP.

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Conflict of interest None.

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