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Surgery in Motion

Randomized Controlled Trial of Barbed Polyglyconate Versus Polyglactin Suture for Robot-Assisted Laparoscopic Prostatectomy Anastomosis: Technique and Outcomes

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Abstract

Background: Transperitoneal robot-assisted laparoscopic prostatectomy (RALP) urethrovesical anastomosis is a critical step. Although the prevalence of urine leaks ranges from 4.5% to 7.5% at high-volume RALP centers, urine leaks prolong catheterization and may lead to ileus, peritonitis, and require intervention. Barbed polyglyconate sutures maintain running suture line tension and may be advantageous in RALP anastomosis for reducing this complication.
Objective: To compare barbed polyglyconate and polyglactin 910 (Vicryl, Ethicon, Somerville, NJ, USA) running sutures for RALP anastomosis.
Design, setting, and participants: This was a prospective, randomized, controlled, single-surgeon study comparing RALP anastomosis using either barbed polyglyconate ($n = 45$) or polyglactin 910 ($n = 36$) sutures.
Surgical procedure: RALP anastomosis using either barbed polyglyconate or polyglactin 910 sutures was studied.
Measurements: Operative time, cost differential, perioperative complications, and cystogram contrast extravasation by anastomosis suture type were measured.
Results and limitations: Although baseline characteristics and overall operative times were similar, barbed polyglyconate sutures were associated with shorter mean anastomosis times of 9.7 min versus 9.8 min ($p = 0.014$). In addition, anastomosis with barbed polyglyconate rather than polyglactin 910 sutures was associated with more frequent cystogram extravasation 8 d postoperatively (20.0% vs 2.8%; $p = 0.019$), longer mean catheterization times (11.1 d vs 8.3 d; $p = 0.048$), and greater suture costs per case ($51.52 vs $8.44; $p < 0.001$). After 8 of 29 (27.6%) barbed polyglyconate anastomosis sites demonstrated postoperative day 8 cystogram extravasation, we modified our technique to avoid overtightening, reducing cystogram extravasation to 1 (6.3%) of 16 subsequent barbed polyglyconate anastomosis sites. Potential limitations include small sample size and the single-surgeon study design.
Conclusions: Compared to traditional sutures, barbed polyglyconate is more costly and requires technical modification to avoid overtightening, delayed healing, and longer catheterization time following RALP.
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1.   Introduction

Robot-assisted laparoscopic prostatectomy (RALP) has been rapidly adopted [1,2], and the robotic surgical platform facilitates the laparoscopic surgical approach [3,4]. However, anastomosis remains a challenging step in the RALP procedure. Although the prevalence of RALP urine leaks ranges from 4.5% to 7.5%, with Clavien classification reporting from high-volume referral centers [5,6], urine leaks prolong catheterization times and may require discharge with a drain lest they result in ileus, peritonitis, and hospital readmission. Moreover, urine leaks are associated with anastomotic strictures during open radical prostatectomy (RP) [7,8].

Barbed (Covidian; Mansfield, MA, USA) sutures have been applied in plastic and reconstructive surgery [9], gynecology [10], and porcine [11] and microfiber models [12] in urology. The unidirectional barbs maintain running suture line tension and purportedly obviate the need for knot tying. We hypothesized that barbed polyglyconate versus conventional suture material may reduce urine leaks and operative

time. The purpose of our prospective, randomized study was to compare RALP anastomosis outcomes using barbed polyglyconate sutures versus polyglactin 910 (Vicryl, Ethicon, Somerville, NJ, USA) sutures. The accompanying video demonstrates our anastomosis technique and modifications developed for barbed polyglyconate suture use. Finally, we assessed RALP procedures performed prior to our trial to determine whether urine leaks were associated with reduced urinary function or more anastomotic strictures.

2.   Methods

2.1.   Enrollment

Our prospective, randomized, controlled trial of barbed polyglyconate versus polyglactin 910 sutures in 82 men undergoing RALP was approved by the Brigham and Women's Hospital institutional review board and conducted between February and May 2010 (Fig. 1). Prior to initiation of the study, the surgeon (JCH) logged 397 RALP procedures during fellowship training and 765 RALP procedures as an attending surgeon
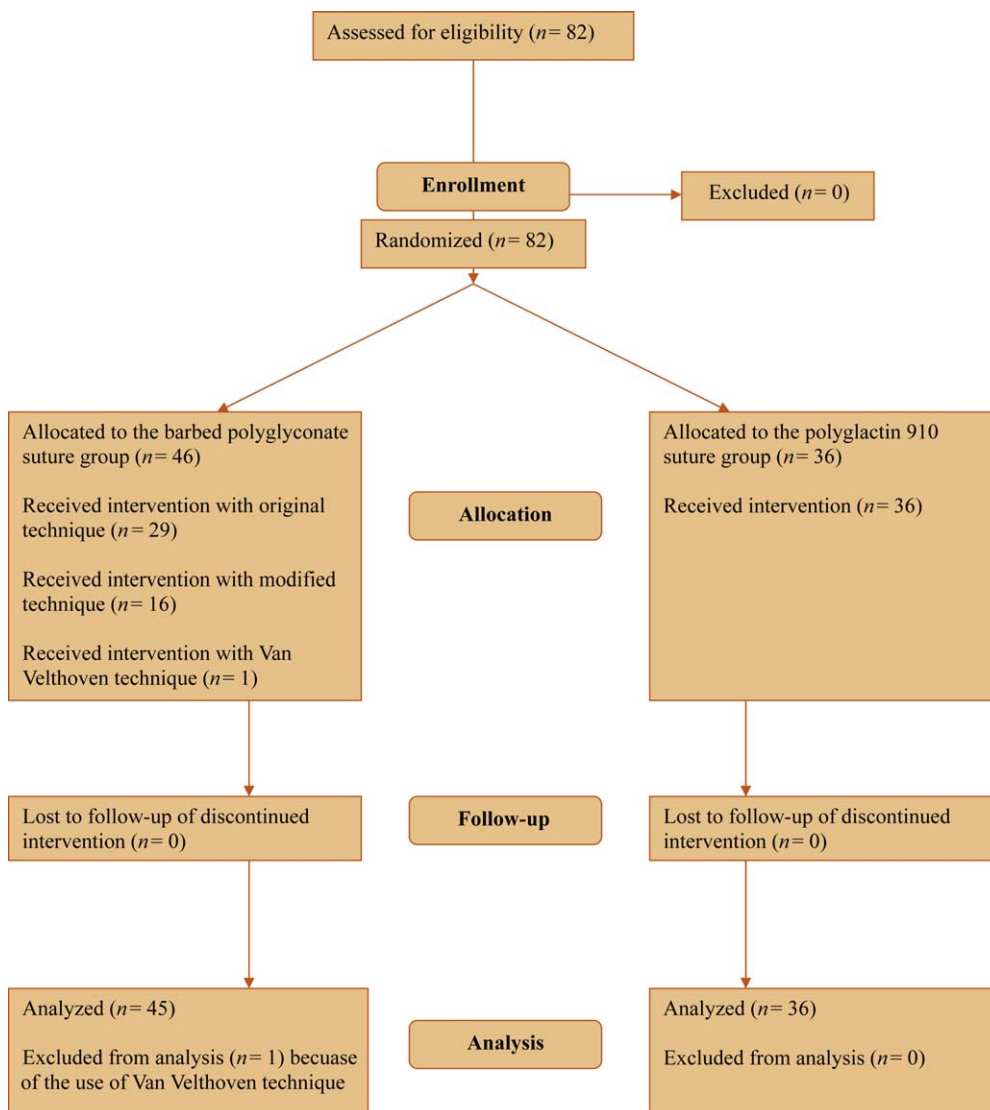

Fig. 1 – Consort diagram illustrating randomization study design.

using polyglactin 910 suture anastomosis from September 2005 through January 2010, but he did not have prior experience with barbed polyglyconate sutures. Primary outcomes of interest for the randomized trial included operative time, perioperative complications, length of catheterization time, and costs attributable to suture material. To assess potential long-term urine leak sequelae such as anastomotic strictures and incontinence, we assessed prospectively collected data from the 765 RALP procedures performed prior to the randomized trial.

2.2. Surgical technique

The sequential steps for our transperitoneal RALP approach [13] and urethrovesical anastomotic technique using a single posterior interrupted suture and two running sutures have been previously described [14]. Using a four-armed da Vinci S Surgical System (Intuitive Surgical, Sunnyvale, CA, USA), we perform a completely antegrade approach in the following order: (1) bladder neck and seminal vesicle dissection, (2) antegrade nerve sparing, (3) apical dissection, and (4) anastomosis. Bladder neck preservation was carried out in all men. Moreover, to limit needle exchanges, we divide the dorsal venous complex (DVC) and the anterior urethra, leaving the posterior urethra as the only remaining attachment of the prostate. To minimize bleeding from the DVC that may occur without prior suture ligation, the assistant bedside surgeon counterintuitively minimizes suctioning, because it lowers the pneumo-peritoneum and exacerbates venous bleeding [13]. The robotic Maryland bipolar and curved scissors are then exchanged for a large robotic suture cut and regular needle driver. This is the first and only robotic instrument change. A 3-0 polyglactin 910 suture cut to 23 cm is then used to ligate the DVC. The same suture is placed in an inside-out fashion through the urethra at the 6 o'clock position (Fig. 2) prior to division of the posterior urethra with standard laparoscopic scissors by the assistant bedside surgeon to avoid switching back to the robotic curved scissors (Fig. 3). After placement of the specimen into a laparoscopic bag and irrigation of the prostatic fossa, the 6 o'clock anastomotic suture is placed in an outside-in fashion through the bladder, and a surgeon's knot placed on the bladder mucosa parachutes and secures the bladder down to the urethra (Fig. 4). With our standard polyglactin 910 anastomosis, the remaining suture material is used as the 5 o'clock anastomotic suture (with the knot placed on the bladder mucosa) and run to 12 o'clock. Thus, the original suture was cut to a longer length for DVC ligation, the posterior interrupted 6 o'clock, and one of the running sutures that comprise half of the anastomosis. Using the same suture limits needle exchanges and promotes efficiency.
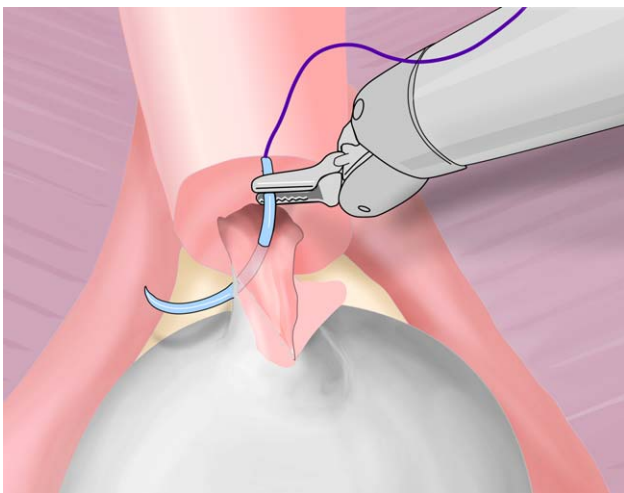
Fig. 2 – Six o'clock anastomotic suture placed inside-out of the urethral mucosa prior to transection of the posterior urethra to avoid retraction of the urethral stump.
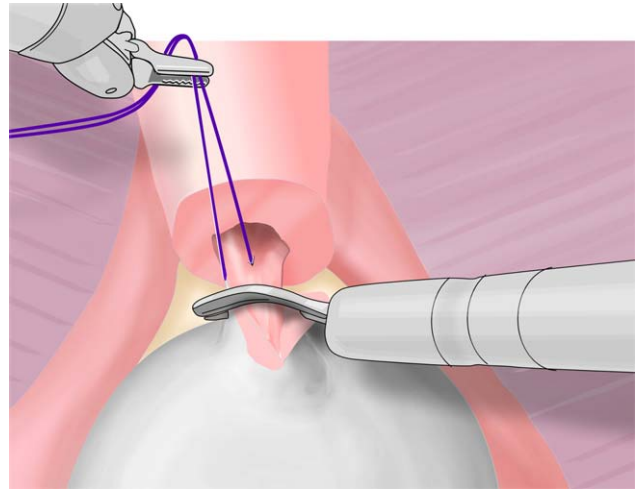

Fig. 3 – An assistant divides the posterior urethra with laparoscopic scissors to avoid additional robotic instrument change, and the specimen is placed into a laparoscopic bag.
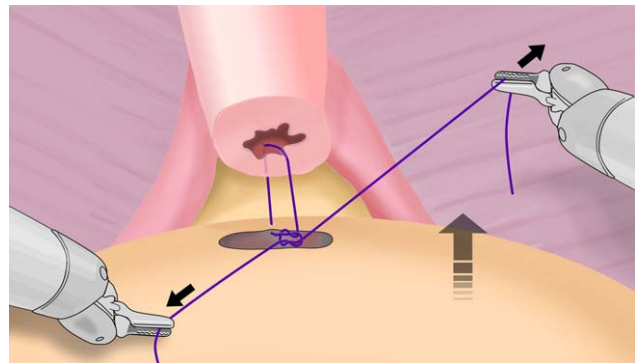
Fig. 4 – A surgeon's knot on the bladder mucosa is used to parachute down the bladder. Tying the knot on the inside versus the outside of the anastomosis allows the surgeon to directly visualize the suture and ensure that the knot is down.

In a mirror-image fashion, another 3-0 polyglactin 910 suture cut to 18 cm is knotted at 7 o'clock and run to 12 o'clock, forming the other half of the anastomosis. To promote efficiency of the running sutures, the needles are passed outside-in the bladder and inside-out the urethra in one throw. Moreover, the suture is pulled through perpendicular to the urethral stump rather than pulling it back toward the camera, which results in the suture taking a U-turn through the urethral wall and increases the risk of sawing through and causing a urethral tear. Simultaneously, the other needle driver forms a "V" where the suture exits the urethra and buttresses as slack is removed from the suture line (Fig. 5). At the anterior anastomosis, both sutures exit the urethra side because of the one-bite technique described above. One running suture is passed through the anastomosis inside-out of the bladder to allow knotting across the anterior anastomosis. The bladder is filled with 120 ml of irrigation, and the 16F working catheter is exchanged for the 20F final catheter.

A 15F Blake drain is placed at the fourth robotic arm trocar site located medial to the left anterior superior iliac spine. The drain was removed when output was <50 ml over 8 h, and all men received ketorolac around the clock and intravenous or oral narcotics for breakthrough pain. All men were discharged on the first postoperative day without a drain and underwent cystograms on postoperative day 8; urinary catheters were
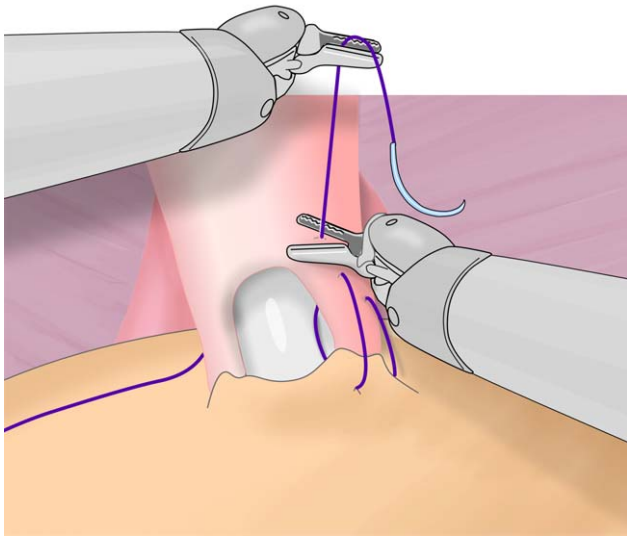
Fig. 5 – To remove slack from the suture line during the running component of the anastomosis, the suture is pulled through perpendicular to the urethral stump versus pulling it back toward the camera. Simultaneously, the other needle driver forms a "V" where the suture exits the urethra and buttresses as slack is removed from the suture line. However, this maneuver must be avoided with barbed polyglyconate sutures to avoid overtightening and potential tissue strangulation.

removed if contrast extravasation was absent. If extravasation was present, cystograms were repeated weekly until extravasation resolved or a limited extraperitoneal leak was demonstrated. At this point, urinary catheters were removed.

Men were randomized to either barbed polyglyconate or polyglactin 910 sutures when scheduled for surgery using Random.org's Random Integer Generator (https://www.random.org/integers) to generate an integer between 1 and 2 for each subject; subjects assigned a 1 were placed in the barbed polyglyconate suture group, and those assigned a 2 were placed in the polyglactin 910 suture group. For men randomized to the barbed polyglyconate suture group, 3-0 polyglactin 910 suture was used for dorsal vein ligation and the posterior 6 o'clock suture, as mentioned previously. However, two barbed polyglyconate sutures were passed inside-out the urethra and outside-in the bladder mucosa at 5 o'clock and 7 o'clock before each needle was passed through its corresponding manufactured loop end to initiate the suture line at the respective locations. The running barbed polyglyconate suture completed the anastomosis in the same fashion as described above for polyglactin 910. The surgical technique was the same for the barbed polyglyconate and polyglactin 910 suture groups; however, we avoided overtightening (Fig. 5) in 16 barbed polyglyconate subjects after disappointing results for the initial 29 barbed polyglyconate subjects. One subject for whom we passed the barbed polyglyconate suture through the manufactured loop of another barbed polyglyconate suture to form a double-armed suture for Van Velthoven anastomosis was excluded from the study [15].

2.3. Outcome measures

Data were collected prospectively by research personnel uninvolved with clinical care. Operative time comprised the interim between Veress needle insertion and completion of skin closure, while anastomosis time comprised the interim between 6 o'clock anastomotic suture placement/division of the posterior urethra and the knotting of the running sutures at 12 o'clock. Contrast extravasation on postoperative day 8 cystogram was characterized as delayed healing; postoperative day of

catheter removal was defined as length of catheterization time. Moreover, to determine whether the barbed polyglyconate suture were associated with a greater degree of gross hematuria, clinicians prospectively assessed whether there was a reddish tint to the catheter output versus clear or tea-colored urine at the time of postoperative cystograms. Men with gross hematuria were asked when they first observed gross hematuria. Deviations from the normal perioperative course were noted.

Finally, 765 RALP procedures performed prior to the randomized trial were assessed to determine whether urine leaks were associated with a greater risk for anastomotic strictures or decreased urinary control, as measured by the urinary function scale of the Expanded Prostate Cancer Index [16]. The urinary function scale is scored from 0 to 100, with higher scores representing better outcomes.

2.4. Power calculation and statistical analysis

The urine leak rate was 3.5% for the 765 RALP polyglactin 910 anastomosis procedures performed prior to randomization, and we hypothesized that use of barbed polyglyconate sutures would eliminate urine leaks. Power calculations revealed that a total of 94 subjects in the barbed polyglyconate and polyglactin 910 study arms, respectively, provides 80% power at a significance level of 0.05 to detect at least a 3.4% improvement in urine leak complications. However, barbed polyglyconate suture leaks were more frequent than anticipated and costs were significantly higher for barbed polyglyconate sutures versus polyglactin 910 sutures and postoperative cystograms. Consequently, the study was terminated and data analyzed prior to enrollment targets being met because barbed polyglyconate suture superiority was not demonstrable.

We used the 2-sided student t test to compare continuous variables; we used the Fisher exact test and the Pearson χ^2 test to compare categorical variables. A 2-sided result of $p < 0.05$ was considered statistically significant. All statistical analyses were performed using SAS v.9.2 (SAS Institute, Cary, NC, USA).

3. Results

Table 1 shows demographic and biopsy characteristics, which did not differ by suture anastomosis type. Table 2 shows perioperative outcomes. Although the mean anastomosis time was statistically shorter for barbed polyglyconate suture versus polyglactin 910 suture (9.7 min vs 9.8 min; $p = 0.014$), there was no difference in the overall operative times (103.8 min vs 110.4 min; $p = 0.163$; Table 2). Moreover, we experienced difficulty with the catheter exchange after completion of the anastomosis in four barbed polyglyconate suture cases versus zero polyglactin 910 suture RALP anastomosis cases. For three men, a 20F coude catheter traversed the anastomosis successfully; this maneuver failed for one man, who required flexible cystoscopy and council tip catheter placement over a guidewire. Interestingly, none of these men experienced contrast extravasation on postoperative day 8. However, overall, barbed polyglyconate suture versus polyglactin 910 suture was associated with more frequent contrast extravasation on postoperative day 8 cystograms (20.0% vs 2.8%; $p = 0.019$) and longer catheterization times (11.1 d vs 8.3 d; $p = 0.048$). The same subjects experiencing cystogram contrast extravasation also had gross hematuria at the time of cystograms, and these men reported that they were discharged with clear urine that became bloody between postoperative days 5 and 7. Furthermore, the degree of barbed polyglyconate suture

Table 1 – Comparison of preoperative characteristics by suture type

	Barbed polyglyconate (*n* = 45)	Polyglactin 910 (*n* = 36)	*p* value
Age, yr, mean (SD)	59.0 (7.0)	60.3 (5.1)	0.357
BMI, kg/m^2, mean (SD)	28.4 (4.1)	28.3 (5.3)	0.884
Baseline urinary function, mean (SD)	96.7 (8.2)	98.5 (4.4)	0.220
Baseline sexual function, mean (SD)	72.8 (27.0)	72.9 (27.0)	0.989
Caucasian race, No. (%)	41 (91.1)	32 (88.9)	0.739
PSA, ng/ml, mean (SD)	6.7 (3.0)	6.1 (4.5)	0.543
Clinical stage, No. (%)			
T1c	43 (95.6)	36 (100)	0.440
T2a	1 (2.2)	0 (0)	–
T2b	1 (2.2)	0 (0)	–
Past medical history, No. (%)			
Hypertension	9 (20)	8 (22.2)	0.807
Diabetes	0 (0)	2 (5.6)	0.109
Smoking	7 (15.6)	6 (16.7)	0.892

SD = standard deviation; BMI = body mass index; PSA = prostate-specific antigen.

Table 2 – Comparison of operative characteristics by suture type

	Barbed polyglyconate (*n* = 45)	Polyglactin 910 (*n* = 36)	*p* value
Operative time, min, mean (SD)	103.8 (21.2)	110.4 (19.4)	0.163
Anastomosis time, min, mean (SD)	9.7 (0.2)	9.8 (0.2)	0.014
Contrast extravasation on postoperative day 8, No. (%)	9 (20)	1 (2.8)	0.019
Length of catheterization, d, mean (SD)	11.1 (8.3)	8.3 (3.8)	0.048
Difficulty with intraoperative catheter change, No. (%)	4 (8.9)	0 (0)	0.125
EBL, ml, mean (SD)	181.5 (78.1)	173.3 (49.7)	0.580
Pathologic stage, No. (%)			
T2	39 (86.6)	29 (80.5)	0.553
T3a	3 (6.7)	5 (13.9)	–
T3b	3 (6.7)	2 (5.6)	–
PSM, No. (%)	5 (11.1)	4 (11.1)	1.000
Suture cost, US$	51.52	8.44	<0.001

SD = standard deviation; EBL = estimated blood loss; PSM = positive surgical margin.

cystogram extravasation worsened on postoperative day 15 cystograms.

The cost of two barbed polyglyconate suture cases and one polyglactin 910 suture case compared to two polyglactin 910 suture cases was $51.52 versus $8.44 (*p* < 0.001). After 8 cystogram leaks in the first 29 barbed polyglyconate suture subjects, we modified our technique to approximate the bladder and urethral stump without overtightening, avoiding the maneuver to cinch and remove running suture line slack

(Fig. 5), resulting in only one cystogram leak in the subsequent 16 barbed polyglyconate suture subjects (27.5% vs 6.3%; *p* = 0.127).

Comparisons of RALP with and without urine leak performed prior to our randomized, controlled trial are shown in Table 3. Although men with and without urine leaks required longer catheterization times (17.8 d vs 7.6 d; *p* < 0.001), recovery of urinary function was similar for those with and without urine leaks at 6, 12, and 24 mo. Moreover,

Table 3 – Comparison of stricture rate and urinary function for robot-assisted laparoscopic prostatectomy with and without postoperative urinary leaks performed prior to the prospective randomized trial

	Urine leak (*n* = 26)	No urine leak (*n* = 739)	*p* value
Age at surgery, yr, mean (SD)	59.4 (6.8)	58.5 (6.8)	0.921
BMI, ml, mean (SD)	30.3 (5.1)	28.8 (4.7)	0.112
Baseline urinary function, mean (SD)	98.3 (4.8)	95.7 (11.3)	<0.001
Urinary function, No., mean (SD)			
6 mo	70.6 (34.2)	68.9 (26.7)	0.845
12 mo	77.0 (24.5)	78.5 (21.2)	0.804
24 mo	81.6 (19.3)	83.7 (21.6)	0.813
Anastomotic stricture, No. (%)	0 (0)	6 (0.8)	0.651

SD = standard deviation; BMI = body mass index.

the anastomotic stricture rate did not differ for men with versus without urine leaks (0% vs 0.8%; $p = 0.651$).

4.   Discussion

Minimizing urine leak from the urethrovesical anastomosis—particularly with the transperitoneal approach—is critical during RALP, and the anastomosis is one of the most challenging steps of the procedure for novices [17]. Although our urine leak rate was relatively low in our RALP series that employed more bladder neck preservation over time [18], this complication prolongs catheterization time and may cause peritonitis and ileus requiring bowel rest and parenteral nutrition as well as require image-guided drain placement [5]. Therefore, we examined whether barbed polyglyconate sutures may offer advantages over polyglactin 910 sutures in terms of reducing urine leaks, operative time, and length of catheterization time. Barbed sutures were developed to allow tissue approximation with minimal tension and less foreign body reaction, which may lead to better wound healing [9,10,12,19].

Although performed in a microfiber model system, Moran et al sought to explore the use of a bidirectional barbed suture to create a hybrid of "suturing and gluing" when performing a knotless running anastomosis [12]. In addition, others have explored the use of barbed sutures in plastic and reconstructive procedures [9,20] and orthopedics [21] to repair tendons with less inflammatory reaction. The only other report on the use of a barbed suture urethrovesical anastomosis was in vitro [12], with limited data analysis; we sought to explore this concept in vivo.

Our paper has several important findings. First, technical adjustments must be made when transitioning from traditional suture materials such as polyglactin 910 or poliglecaprone 25 (Monocryl; Ethicon, Somerville, NJ, USA) to barbed polyglyconate for RALP anastomosis. Overtightening is problematic with barbed polyglyconate suture and may lead to delayed urine leak, the symptom being bloody urine after postoperative day 5. In addition, we observed greater contrast extravasation on the second versus first cystogram performed at day 15 versus day 8, suggesting that tissue necrosis may be the mechanism of injury. Moreover, the urine leak rate decreased after we did not tighten the suture line beyond the point of the bladder and the urethral tissue approximation. However, the barbed polyglyconate suture postmodification contrast extravasation rate was not superior to the polyglactin 910 suture group.

Second, the cost of barbed polyglyconate suture material compared to polyglactin 910 suture material and monofilaments such as poliglecaprone 25 is significantly higher. The retail price of barbed polyglyconate per suture is $23.65, while polyglactin 910 and poliglecaprone 25 retail for $4.22 and $10.09, respectively; the greater barbed polyglyconate suture material expense exacerbates the cost disadvantage of RALP versus open RP. Zorn described the use of absorbable suture clips placed on the running suture to maintain tension, but these clips cost $29.50 per clip [22]. In addition, although the difference in anastomosis time was statistically significant because of narrow variance from the mean barbed

polyglyconate and polyglactin 910 anastomosis times, 6 s is not clinically significant and does not significantly reduce operating room costs. Therefore, surgeons should weigh their individual risk of urine leak and use absorbable suture clips or barbed polyglyconate suture material selectively to reduce costs. For instance, barbed polyglyconate sutures can be used for men with benign prostatic hyperplasia and larger bladder necks. Alternatively, neophyte robotic surgeons may prefer barbed polyglyconate sutures to minimize urine leaks early in the learning curve for performing the anastomosis. In addition, barbed polyglyconate sutures may be preferred in training settings; the attending surgeon can visualize tissue approximation with barbed polyglyconate sutures rather than relying on trainees to cinch and remove slack from the running suture line, which may be difficult for the attending surgeon to judge in terms of appropriate suture line tension.

Third, data from RALP procedures performed prior to our randomized trial did not reveal more anastomotic strictures or worse urinary function for men who experienced urinary leak complications versus those who did not. This is consistent with other RALP series [23]. In contrast, open RP urine leaks are associated with an increased risk for anastomotic strictures [7,8]. This conflicting evidence may result from differences between a running anastomosis versus interrupted sutures and/or differences in visualization for RALP versus open RP. However, for men requiring prolonged catheterization as a result of urine leaks, our findings may reassure them that they are not at increased risk for anastomotic stricture or incontinence.

Our findings should be interpreted in the context of the study design. First, although we used a prospective, randomized study design, this was a single-surgeon study, and our findings are dependent on surgeon-specific technique. For instance, more urine leaks may be expected with larger bladder necks or earlier in the RALP learning curve. However, our findings likely extend to anastomotic techniques that employ running sutures, such as the Van Velthoven technique [15]. In addition, we do not perform posterior reconstruction, which has been shown to reduce urine leaks [24]. Second, our sample size is relatively small, because we do not routinely perform cystograms on all RALP patients because of additional resource consumption; to demonstrate superiority to the polyglactin 910 group, we would have to perform another 275 barbed polyglyconate suture anastomosis procedures without cystogram contrast extravasation. Moreover, our small sample size limits interpretation of our findings beyond our barbed polyglyconate suture learning curve and technique modification, although outcomes appear similar to polyglactin 910 cases. Third, our method of identifying bloody urine postoperatively is subject to recall bias. Patient diaries may attenuate this bias, but this method may also result in more missing data for non-responders. Development of gross hematuria after RALP hospital discharge with previously clear urine may be a sign of incomplete anastomotic healing and may serve as a proxy to cystograms. In other words, surgeons may delay voiding trials until gross hematuria resolves. Finally, we do not have urinary function comparisons by suture material; however,

comparison of prestudy patients did not reveal a difference in urinary function for RALP with and without urine leak.

5. Conclusions

Barbed polyglyconate sutures are more costly than traditional sutures and require technical modification to avoid overtightening, delayed healing, and longer catheterization times following RALP.

Appendix A. Supplementary data

The Surgery in Motion video accompanying this article can be found in the online version at doi:10.1016/j.eururo.2010.07.021 and via www.europeanurology.com. Subscribers to the printed journal will find the Surgery in Motion DVD enclosed.

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