Long-term urinary functional outcome of vesicourethral anastomosis with bidirectional poliglecaprone (Monocryl®) vs. barbed polyglyconate suture (V-Loc™ 180) in robot-assisted radical prostatectomy

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Abstract

Introduction: We aimed to evaluate urinary continence recovery following robot-assisted radical prostatectomy (RARP) using monofilament poliglecaprone (Monocryl®) suture vs. barbed suture (V-Loc™ 180) during vesicourethral anastomosis.
Methods: In this prospective, observational cohort, data were collected on 322 consecutive patients. All patients underwent continuous, bidirectional, single-layer running anastomosis with either 3.0-monofilament suture (n=141) or 3.0 barbed suture (n=181). The primary outcome was continence recovery defined as time to 0 pad at one, three, six, 12, and 24 months following surgery.
Results: Continence rates were significantly better with monofilament VUA at all followup time points up to one year. Median time to continence was one month vs. five months in the monofilament group vs. barbed group, respectively (p<0.001). Continence rates in monofilament suture vs. barbed group at one, three, six, 12, and 24 months were 56% vs. 26% (p<0.001), 73% vs. 36.4% (p<0.001), 84.4% vs. 60.2% (p<0.001), 90.8% vs. 71.9% (p<0.001), and 93.5% vs.87.1% (p=0.1), respectively. Anastomosis time was shorter in the barbed group, with a median of 23 vs. 30 utes (p<0.001). Patients anastomosed with Monocryl suture had smaller prostate weight (median 42.5 g vs. 50 g; p<0.001) and harbored less advanced disease (T2a–c 76.6 vs. 74%; p=0.01) relative to patients treated with V-Loc 180 suture. However, in a multivariate Cox logistic regression analyses, independent predictors of continence recovery were suture type (hazard ratio [HR] 53; 95% confidence interval [CI] 0.41–0.68; p=0.02] and prostate size (HR 0.99; 95% CI 0.98–0.99; p<0.001).

Conclusions: Barbed VUA contributed to delayed continence recovery compared to monofilament poliglecaprone suture during the first year post-RARP. However, no statistically significant difference was recorded at two years post-RARP. These results warrant special attention, especially with the widespread use of barbed suture in recent years.

Introduction

Robot-assisted radical prostatectomy (RARP) has been widely adopted since it was first promoted more than a decade ago.[1] Several predictive risk factors of continence recovery have been identified including patient age, prostate size, neurovascular bundle preservation, membranous urethral length, uroflow stop test, and technical aspects of vesicourethral anastomosis (VUA).[2-6]

Initially, VUA in laparoscopic radical prostatectomy used interrupted sutures.[7] Subsequently, Van Velthoven et al. introduced the use of bidirectional 3.0 polyglycolic acid running suture with one end dyed and the other end undyed.[8] They reported a shorter anastomosis time and no perioperative complications compared to their historic cohort with interrupted sutures.

During the era of laparoscopic radical prostatectomy different anastomotic sutures were traditionally used including the braded suture type polyglactin-910 (Vicryl®; Ethicon, J and J Medical, Somerville, NJ, USA) and monofilament suture type poliglecaprone-25 (Monocryl®, J and J Medical, Somerville, NJ, USA). Monocryl® has gained additional popularity with RARP due to its smooth texture and ease of use for running VUA. Lately, bidirectional barbed suture (V-LocTM Wound Closure Device, Covidien, Mansfield, MA, USA) has been widely used after its introduction in 2009 due to several advantageous properties that include holding tissue tension, avoiding knot tying, decreased the risk of a urine leak, and shorter anastomotic time.[9,10] However, there is a paucity of data examining continence recovery over long-term follow-up with the barbed suture. The aim of this study is to explore the impact of barbed suture compared to monofilament suture in VUA, on continence recovery post RARP.

Methods

Study population characteristics

Following institutional review board approval, the current retrospective study was conducted from a prospectively collected RARP database. Between January 2006 and May 2015, a total of 322 consecutive patients underwent RARP for clinically localized prostate cancer by a single surgeon (AEH) at Hôpital du Sacré Coeur de Montréal, Montreal, Quebec, Canada. All data were documented at the time of surgery and during follow-up visits in a standardized sheet. Approximately 80% of patients had a minimum of 2-years follow-up. No patient had previous endoscopic prostate surgery or pelvic radiation

Objectives and endpoints

The primary endpoint of the study was to test postoperative continence recovery among both groups, defined as 0-pad usage per day which was recorded at 1, 3, 6, 12, and 24 months following surgery using a self-administered questionnaire. Initially, patients are followed at 6th week after surgery with prostate specific antigen (PSA), uroflow test and post void residual urine volume to exclude obstruction. Then, they are followed every 3 months for 1 year, and every 6 months for the subsequent 4 years, then yearly thereafter with PSA, Sexual Health Inventory for Men (SHIM) score, and modified IPSS (including additional questions on how many pads per day is patient using: 0, 1-liner, 1 pad - 2 pads - 3 or more pads).

Covariates

Baseline characteristics were collected from the database. Age at surgery, PSA level, pathological prostate size, estimated blood loss, and anastomosis time was coded as continuous variables. Pathological stage was categorized into 4 groups: T2a-b, T2c, T3a, and T3b-T4, using TNM 7th edition classification. Pathological Gleason grade was stratified into 4 groups: ≤6, 3+4, 4+3, and 8-10. Bladder neck reconstruction and nerve preservation were also included.

Anastomosis surgical technique

Patients were grouped according to the type of sutures used for VUA during RARP: the bidirectional 3 0 Monocryl® versus the bidirectional V-LocTM 180 suture. The Monocryl® suture was used in the first 141 consecutive patients treated between 2006 and January 2009. Whereas, the V-LocTM 180 suture was used in the subsequent 181 patients treated between January 2009 and May 2015. Both arms underwent the same athermal robotic technique.[11,12]

The anastomoses techniques for both study arms followed a modified Van Velthoven technique (REF) and consisted of applying two stitches at 6 o'clock of the bladder outside-in, then inside-out on the urethral stump. An additional suture was placed on each side, at 5 and 7 O'clock respectively, before the bladder was synched down. Thereafter, both mucosal edges of the bladder and urethra were approximated before further running the continuous sutures. The latter was performed in anti-clockwise in the right and clockwise in the left side. Both arms had single running anastomosis without a separate Rocco posterior reconstructive layer. However, all V-LocTM 180 group had the posterior bladder retrotrigonal layer incorporated with the anastomosis, and deeper throws on the first couple urethral stitches to incorporate the so-called urethrorectalis muscle. All cases were tested at the end of the anastomosis with 120-180 ml normal saline bladder filling to rule out a leak. All patients had catheter removal on a postoperative day 7 without cystogram. Neurovascular bundle sparing and bladder neck preservation was attempted whenever feasible.

Statistical analyses

Descriptive statistics focused on frequencies and proportions for categorical variables. Means, medians and interquartile ranges were reported for continuous variables. The Mann-Whitney test and chi-square test were used to compare statistical significance differences in medians and proportions, respectively.

First, continence rates at 1, 3, 6, 12, and 24 months were compared between both suturing types. Subsequently, the log-rank test was used to compare continence rates between the two study arms. Finally, univariate and multivariate Cox-regression analyses were fitted to predict the effect of baseline clinical, operative and pathological characteristics, as well as the type of suture on postoperative urinary continence rate.

All statistical tests were performed using the R software environment for statistical computing and graphics (Vienna, Austria, version 3.0.1). All tests were 2-sided with a significance level set at $p<0.05$.

Results

Baseline clinical, pathological, and operative characteristics stratified according to anastomotic suture type are summarized in Table 1. 141 (44%) patients had anastomotic Monocryl® suture and 181 (56%) patients had V-LocTM 180 anastomotic suture. Median age, pathological Gleason grade distribution, median estimated blood loss as well as the proportion of patients who underwent bladder neck reconstruction and/or nerve preservation were comparable between both groups. However, patients anastomosed with Monocryl® suture had smaller prostate weight (median: 42.5 g v. 50 g; $p<0.001$) and harbored less advanced disease (T2a-c 76.6 vs. 74%; $p=0.01$) relative to patients treated with V-Loc 180 suture. Similarly, lower PSA level (5.2 vs. 6; $p=0.002$) and longer anastomosis time (30 vs. 23 min; $p<0.001$) were found in the Monocryl® group compared to their counterpart. No bladder neck contracture or anastomotic stricture were identified in either cohort.

Postoperative urinary continence recovery rates were highly statistically significant between the two study groups favoring Monocryl® suture, at 1month (Monocryl®: 56 vs. V-LocTM 180: 26%; $p<0.001$), 3 months (73 vs. 46; $p<0.001$), 6 months (84 vs. 60%; $p<0.001$), and 12 months (91 vs. 72%; $p<0.001$) after surgery [Table 2 & Figure 2**]**. However, the difference in postoperative continence rate wasn't statistically significant between the two groups at 24 months post-surgery (93.6 vs. 87.1%; $p=0.1$). Figure 1 depicted the continence rate during follow-up. The median time to continence in the Monocryl® arm was 1 month compared to 5 months for VLocTM 180 group ($p<0.001$). There was no anastomotic strictures or bladder neck contracture. No urine leak was identified on JP drain postoperative.

In Multivariable Cox-regression analyses [Table 3] after controlling for all potential confounders, suture type (HR 0.53; $p<0.001$) and prostate weight (HR 0.99; $p=0.02$) were both independent predictors for postoperative continence after RARP. However, date of surgery, age, body mass index, PSA level, pathological stage, and grade, estimated blood loss, bladder neck

reconstruction, and nerve-sparing were not a predictor of postoperative continence after RARP (all p>0.2).

Discussion

RARP gained worldwide acceptance during the past decade in the treatment of clinically localized prostate cancer. VUA represents a pivotal step during prostatectomy. In general, VUA should be manipulated gently and sutured with absorbable sutures in a watertight, tension free fashion to limit urinary leak, reduce morbidity and provide early continence recovery

Recently, barbed sutures were introduced as a technically advantageous suture in laparoscopic and robot-assisted radical prostatectomy. The barbed suture was shown to be comparable to traditional sutures in term of postoperative urinary leak and safety. However, a paucity of data exists on the long-term continence recovery in patients sutured with barbed sutures compared to the traditional monofilament sutures.[10,13-15] Based on this consideration, we conducted a single institution study to address this issue. Our results showed that barbed suture group was associated with a delayed continence recovery relative to the monofilament suture group (HR 0.52 CI 0.41-0.66; p<0.001) during all scheduled visits in the first year following surgery. In multivariable Cox regression analyses, Monocryl® suture was an independent predictor of continence recovery (HR 0.53 CI 0.41-0.68; p<0.001) and the cohort consistently confirmed with the previously reported short anastomosis time in favor of barbed suture (p<0.001).

The physical properties of barbed suture differ from Monocryl® suture. First, the extended dissolved time of the V-LocTM 180 biomaterial is longer than Monocryl® (half-life 7-14 days), 180-days vs 90-days; respectively.16-19 This could contribute to the prolonged continence recovery in the barbed group due to the risk of an inflammatory response to foreign body material, encrustation, and stretch of the urethral sphincter complex. Second, breaking strength retention of suture (Tensile strength of suture in vivo) is prolonged in the V-LocTM 180 material with 65% of the initial strength at 9 months compared to 20-30% of initial strength at the second week of the undyed (30-40% dyed) Monocryl® materials, at 1 week, strength is at 50–60% undyed (60–70% dyed). Persistence of suture tensile strength for a prolonged time at close proximity to external urethral sphincter perhaps compromises the external sphincter function and blabber neck after surgery.[16-19] Lastly, the presence of valves on V-LocTM 180 suture, might contribute to micro-infarctions and strangulation of the muscular component of the sphincter after application.

In a retrospective study, Polland and his group compared the V-LocTM 180 suture with the standard 3.0 monofilament and showed no difference in continence recovery between the study and control groups at 6 weeks (52% and 48%, respectively) and at 6 months (88% and 84%, respectively). They included 84 patients in a mixed consecutive method rather than formal randomization with a high chance of selection bias in the study. The primary endpoints were to evaluate the efficacy during the surgery and perioperative complications.[20] Hemal et al.

conducted a prospective pilot study of 50 patients comparing the same type of sutures and reported the safety and efficacy of barbed suture intraoperatively. In the immediate postoperative period, none of the patients had symptomatic urine leak, retention, or anastomotic stricture. However, they did not look at continence recovery outcome longitudinally.[21]

William et al. reported the traumatic effect of barbed suture over Monocryl®**.** They documented contrast leak in barbed suture arm after randomization with a control group (Monocryl®**)** based on cystogram. The rate of extravasation in day 8 following surgery was higher in barbed group (20.0% vs. 2.8%; p=0.01), longer catheterization time (11.1-days vs. 8.3-days; p = 0.04), and greater suture cost per case (p<0.001). During the study, they modified their technique to avoid overtightening and consequently, the incidence of subsequent cystogram extravasation was reduced to 6.3% in barbed group.[22]

Another randomized controlled trial was conducted by Sammon colleagues to assess barbed suture with the standard monofilament. Continence was assessed at sixth weeks by a modified questionnaire mailed to patients to assess continence for the past week only. Although the functional outcomes were equivalent at a one-time point in both group, the study was limited by the small number of the patient.10 Furthermore, Massoud and his group prospectively evaluated the use of V-Loc running suture with a single needle driver versus interrupted polyglactin sutures.23 Their results favor the V-Loc arm in terms of shorter anastomosis time and the feasibility of the reported single needle driver technique. However, the difference in continence rates (0-pad) at 12-months was not statistically significant among both groups (97.5% V-Loc vs 95% polyglactin, P-value = 0.37). While V-Loc arm has a non-significant prolonged healing time than control, their results lack the detailed continence recovery during the first year after surgery.19 Despite the novel evolution in the described surgical techniques of VUA in the literature and the shorter VUA time within the last two decades, the concurrent reported continence recovery is still underreported and not fully explained.[23,24]

As already known with any new emerging appliance, safety and efficacy should be evaluated first prior to adopting it widely. We thought that the reason behind the scarcity of data and heterogeneity in studying continence recovery in the previous studies due to its recent application. And it still mandates further researches specifically looking for continence recovery for a different time point in a well-designed study with sufficient data to be proven. Further workup on the nature of the biochemical and physical properties of the barbed suture might improve the results of continence recovery in addition to its advantageous technical property. By doing so, devastating quality of life sequels following RARP will improve further and hence satisfaction with the da Vinci surgical system especially in the current era of active surveillance.

Several advantages in the current report deserve to mention. First, our report is the only study exhibiting long-term follow-up for continence recovery following RARP as compared to previous clinical studies. Second, while the majority of previous studies have concentrated on perioperative surgical outcomes (i.e. VUA time, contracture, and urinary leakage at the

anastomotic site), we longitudinally evaluated postoperative functional outcome using a self-administered questionnaire. However, this study is not devoid of Limitations. Both arms were not comparable in some baseline characteristics including body mass index, prostate size, and tumor stage. These resulted from the selection of best patient characteristics in the initial experience of the operating surgeon. However, the multivariate analysis confirmed the independence of suture type for predicting continence recovery. Additionally, we expected a delayed continence recovery with the initial experience that was at the time of monofilament usage but surprisingly we found the opposite result in favor of monofilament suture. Furthermore, due to sequential inclusion of patients in the study, all patients in the monofilament arm completed the follow-up period for 24 months and there was a dropout in the follow up of the barbed arm who did not complete the follow-up period. About 84% and 64% of barbed arm completed the follow up at the end of 12 months and 24 months, respectively. Although there was no dropout at the initial two visits, the continence rate is still favorable in the monofilament arm. However, a further confirmatory study might be needed in the future to clarify the association.

Conclusions

Urinary incontinence is a common adverse effect after radical prostatectomy, the effect of which can be upsetting for patients and their quality of life. Although robotic surgery hastens early continence recovery, selecting the optimal suture type is still of clinical relevance for early acquisition of continence. Current study proves the superiority of monofilament over barbed suture in the recovery of urinary continence. Nevertheless, more research is needed in the form of randomized studies to confirm the current results.

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Figures and Tables

Fig. 1. Clustered columns chart shows the comparison between Monocryl® and V-Loc™ 180 continence rates at 1, 3, 6, 12, and 24 months.

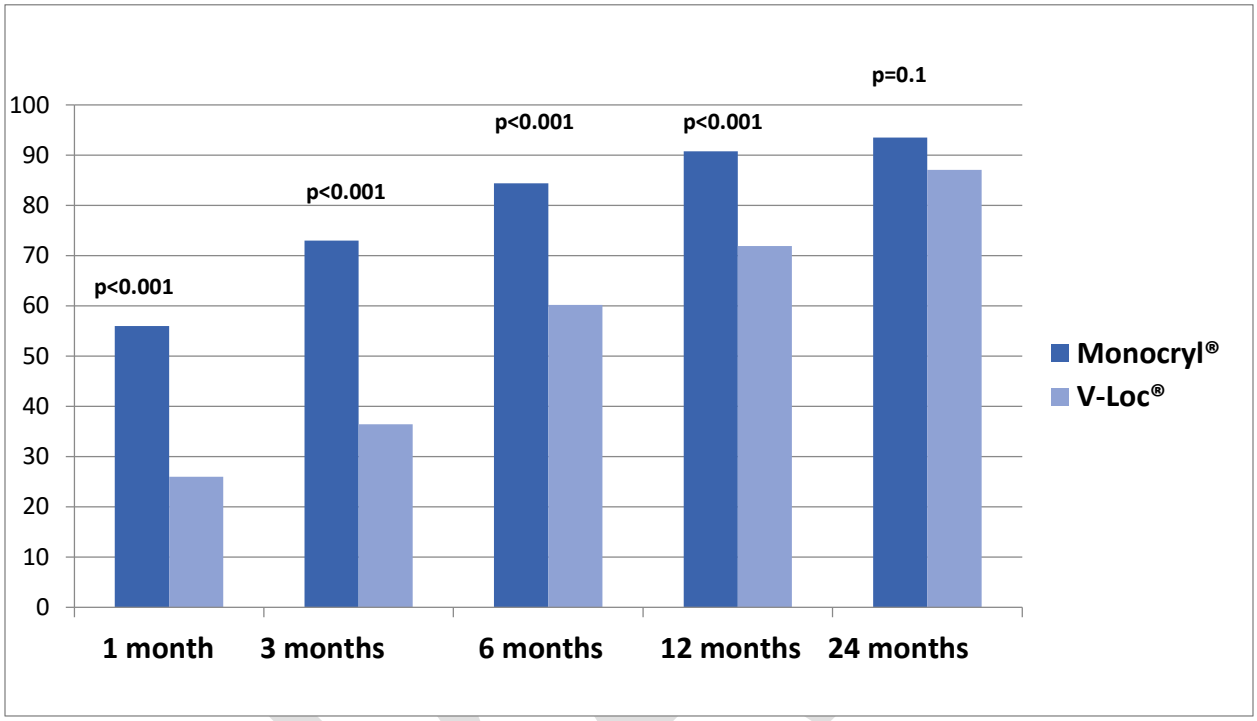

Table 1. Perioperative baseline characteristics of patients treated with Robotic-assisted radical prostatectomy (RARP)			
Patient characteristic	**Polyglecaprone suture, mean (median) n=141**	**Barbed Suture, mean (median) n=181**	**p**
Age (years)	60.6 (61)	61 (61)	0.7
BMI			
Normal	26 (18.4)	36 (19.9)	
Overweight	70 (49.6)	64 (35.4)	**0.04**
Obese	28 (19.9)	42 (23.2)	
Unknown	17 (12.1)	39 (21.5)	
PSA (ng/ml)	6.5 (5.2)	7.1 (6)	**0.002**
Prostate volume (gm)	46 (42.5)	52.3 (50)	**<0.001**
Pathological stage			
T2a–b	21 (14.9)	52 (28.7)	
T2c	87 (61.7)	82 (45.3)	**0.01**
T3a	25 (17.7)	36 (19.9)	
T3b–T4	8 (5.7)	11 (6.1)	
Gleason score			
≤6	26 (18.4)	24 (13.3)	
3+4	90 (63.8)	111 (61.3)	0.1
4+3	13 (9.2)	15 (8.3)	
8–10	12 (8.5)	31 (17.1)	
Anastomosis time (min)	31.6 (30)	24.5 (23)	**<0.001**
Blood loss (ml)	336 (300)	325 (300)	0.5
BN reconstruction			
No	131 (92.9)	173 (95.6)	0.3
Yes	10 (7.1)	8 (4.4)	
Nerve preservation			
Complete	94 (66.7)	105 (58)	0.4
Partial	36 (25.5)	57 (31.5)	
No	11 (7.8)	19(10.5)	
Pads usage*			
Yes	6/141(4.2%)	12/152(8%)	0.2
No	138/141(97.4%)	140/152(92%)	

*The number of pads usage at the end of the first year. BMI: body mass index; PSA: prostate-specific antigen.

Table 2. Continence rates, 0-pad, at 1, 3, 6,12, and 24 months after robotic-assisted radical prostatectomy according to anastomotic suture type					
Suture type	**1 month n=322**	**3 months n=322**	**6 months n=312**	**12 months n=294**	**24 months n=257**
Polyglecaprone (Monocryl®) Continent, n (%) Incontinent, n (%)	79 (56%) 62 (42%)	103 (73%) 38 (27%)	119 (84.4%) 22 (15.6%)	128 (90.8%) 13 (9.2%)	132 (93.5%) 9 (6.4%)
Barbed (V-Loc 180®) Continent, n (%) Incontinent, n (%)	47 (26%) 134 (74%)	84 (36.4%) 97 (53.6%)	103 (60.2%) 68 (39.8%)	110 (71.9%) 42 (28.1%)	101 (87.1%) 15 (12.9 %)
p	**<0.001**	**<0.001**	**<0.001**	**<0.001**	0.1

Table 3. Univariable and multivariable Cox logistic regression analysis predicting independent variable for time to 0-pad after RARP				
Covariants	**Univariable**		**Multivariable**	
	HR (95% CI)	**p**	**HR (95% CI)**	**p**
Age	0.98 (0.96–1)	0.06	0.99 (0.97–1.01)	0.5
BMI				
Normal	Ref.	Ref.	Ref.	Ref.
Overweight	0.95 (0.68–1.32)	0.8	0.9 (0.65–1.26)	0.5
Obese	0.88 (0.61–1.27)	0.5	0.88 (0.6–1.29)	0.5
Unknown	0.76 (0.51–1.13)	0.2	0.82 (0.55–1.24)	0.4
PSA	0.99 (0.96–1.02)	0.6	1 (0.97–1.03)	0.9
Prostate size	0.99 (0.98–0.99)	0.002	0.99 (0.98–0.99)	0.02
Pathological stage				
T2a–b	Ref.	Ref.	Ref.	Ref.
T2c	1.05 (0.78–1.41)	0.7	0.97 (0.72–1.31)	0.8
T3a	0.84 (0.58–1.24)	0.4	0.81 (0.54–1.23)	0.3
T3b–T4	1.3 (0.76–2.23)	0.3	0.97 (0.5–1.88)	0.9
Gleason score				
6	Ref.	Ref.	Ref.	Ref.
3+4	0.81 (0.58–1.13)	0.2	0.79 (0.55–1.12)	0.2
4+3	0.9 (0.55–1.49)	0.7	0.93 (0.53–1.62)	0.8
≥8	0.93 (0.6–1.44)	0.7	1.18 (0.60–2.02)	0.6
EBL	1 (1–1)	0.6	1 (1–1)	0.5
Bladder neck reconstruction				
No	Ref.	Ref.	Ref.	Ref.
Yes	0.91 (0.54–1.52)	0.7	1.05 (0.61–1.84)	0.9
Nerve preservation				
Complete	Ref.	Ref.	Ref.	Ref.
Partial	0.98 (0.75–1.29)	0.9	1.13 (0.84–1.5)	0.4
No	0.71 (0.46–1.09)	0.1	0.79 (0.49–1.28)	0.3
Type of anastomosis				
Monocryl	Ref.	Ref.	Ref.	Ref.
V-Loc	0.52 (0.41–0.66)	<0.001	0.53 (0.41–0.68)	<0.001

BMI: body mass index; CI: confidence interval; EBL: estimated blood loss; HR: zazard ratio; PSA: prostate-specific antigen.