Retrograde leak point pressure measurement improves outcomes of the Virtue male sling for postprostatectomy incontinence

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Cite as: *Can Urol Assoc J* 2017;11(7):E271-6. http://dx.doi.org/10.5489/cuaj.4381
Published online July 11, 2017

Abstract

Introduction: We aimed to compare the efficacy of two different sling tensioning approaches, and to report our experience, including safety and impact on quality of life (QoL) of the Virtue® male sling for the treatment of postprostatectomy incontinence (PPI).
Methods: From our prospectively maintained database, we retrospectively identified all men treated with the Virtue male sling for PPI between March 2009 and February 2014 by two urologists in two institutions. Baseline demographic data and the sling tensioning method were abstracted from the database. Likewise, the Patient Global Impression of Improvement (PGI-I) scale, severity of incontinence, and clinical outcomes were also abstracted.
Results: 48 patients were treated with the Virtue quadratic male sling. Sling tensioning was done using cystoscopy in the first 18 patients (Group 1), while per-operative retrograde leak point pressure (RLPP) measurement was done in the last 30 patients (Group 2). The median (interquartile range [IQR]) followup from the day of surgery was 22 (15–41) months. At the last followup visit, 7 (39%) patients in Group 1 were cured or improved of their PPI, compared to 21 (70%) patients in Group 2 (p=0.03). The final median (IQR) RLPP in these patients was 41 (37–48) cm H_2O. Transient pain was the most common adverse event, occurring in 23 (48%) of patients. Twenty-one (70%) patients in Group 2 were "much better" or "very much better" with their device, compared to 7 (39%) in Group 1 (p=0.0008).
Conclusions: The Virtue male sling is a valuable treatment option for PPI. Per-operative RLPP measurement significantly improves cure and satisfaction rates.

Introduction

Postprostatectomy incontinence (PPI) accounts for the majority of cases of iatrogenic urinary incontinence. The reported incidence varies from 1–30%, depending on who reports the incontinence (patient or physician), timing from diagnosis, and degree of bother.[1-3] The artificial urinary sphincter (AUS) has long been considered the gold standard to treat PPI.[4-6] Male slings were introduced in the late 1990s as a treatment alternative. Reports have shown them to be safe and effective while being considered less invasive than the AUS. Moreover, Kumar et al[7] demonstrated that many patients would prefer a non-mechanical device, such as a male sling, as opposed to a mechanical one, such as the AUS, due to ease of use. Male slings include bone-anchored slings (which have been withdrawn from the market), adjustable retropubic or transobturator slings, retrourethral transobturator slings, and quadratic slings, such as the Virtue® male sling (Coloplast, Humlebaek, Denmark). The success rate of these slings ranges from 40–91%.[8]

The Virtue quadratic sling is a device for treating PPI consisting of a large pore-knitted monofilament polypropylene mesh with two pre-attached inferior (transobturator) extensions and two superior (prepubic) extensions. One of the challenges with male slings is evaluating adequate tensioning of the sling and the degree to which the sling should be tightened intraoperatively. Surgeons may maximally tighten the sling or may visualize urethral compression using cystoscopy; however, these may not accurately or objectively reflect the true urethral resistance to flow. Retrograde leak point pressure (RLPP) measurement offers an objective measure of urethral resistance to flow and has been validated as a useful measurement of urethral resistance in male anti-incontinence surgeries.[9] Comiter et al demonstrated that each set of arms of the Virtue quadratic sling contributed to increasing the urethral resistance measured intraoperatively by the RLPP.[10]

As the surgical use of the Virtue quadratic sling and other slings has become increasingly popular, it is important to evaluate the safety and efficacy of these devices. The objectives of this study were to report our experience with the Virtue quadratic sling and to report its efficacy, safety, and impact on quality of life (QoL). Additionally, we compared the impact of the two different sling tensioning approaches (cystoscopy vs. RLPP) on the PPI cure/improvement rates.

Methods

Patient selection and evaluation

This was an institutional review board-approved retrospective study. All men who underwent surgery with implantation of the Virtue quadratic male sling between March 2009 and February 2014 were identified from our prospectively maintained database. Individuals were followed until they experienced device failure, death, loss to followup, or data cutoff (November 30, 2015).

All slings were implanted by two urologists (LMT, JM) with significant experience in the treatment of PPI. Eligible subjects had stress urinary incontinence (SUI) (defined as bothersome stress incontinence that failed conservative management and for which patient desired to undergo a surgical intervention intended to relieve symptoms) as a result of open or laparoscopic radical prostatectomy. Exclusion criteria included: 1) previous implant to treat SUI; 2) external beam radiotherapy (EBRT), cryosurgery, or brachytherapy within six months of implantation; 3) postvoid residua (PVR) >150 mL; and 4) unsettled bladder neck or urethral conditions (e.g., vesicourethral anastomotic stricture) likely to require further transurethral procedures.

Preoperative evaluation included detailed medical and surgical history and physical exam, pads per day (ppd), average of 24-hour x three-day pad weight, urethrocystoscopy, urodynamic study including uroflowmetry, cystometry, PVR, and Valsalva leak point pressure (VLPP) measurement, and informed consent with other therapeutic options explained to the patient. Followup visits were at two, six, and 12 months, then yearly, and included an average of 24-hour x three-day pad weight, ppd, evaluation of postoperative pain. A uroflowmetry and PVR was also performed at 12 months. At each postoperative visit, the Patient Global Impression on Improvement (PGI-I) score (Appendix 1) was used to measure subjective QoL.

Data

The subjects demographic characteristics (age, prior radical prostatectomy approach, prior history of radiation treatments, prior bladder neck pathologies [e.g., vesicourethral anastomotic strictures, etc.], and status of urethral mobility/coaptation), urinary incontinence severity (ppd, average of 24-hour x three-day pad weight), urodynamic studies results, sling tensioning method (cystoscopy vs. RLPP), postoperative complications, and PGI-I scores were abstracted from the database.

Severity of incontinence was categorized as mild (0–2 ppd or 24-hour pad weight <100 g), moderate (3–5 ppd or 24-hour pad weight 100–400 g), or severe (>5 ppd or 24-hour pad weight >400 g). Postsling urinary incontinence status was defined as cured if the patients wore no pads, improved if he wore between 0–1 ppd or ≥50% daily pad reduction, and not improved if he had <50% daily pad reduction.

Sling placement

The Virtue quadratic male sling was placed according to the technique described by Comiter et al.[10] The ventral bulbous urethra and pubic rami were exposed through a 5 cm vertical perineal incision, leaving the bulbospongiosus muscle intact. The urethra was slightly detached from the perineal body to allow proximal urethral repositioning upon sling tensioning. The transobturator arms were then attached to the introducer and passed from medial to lateral behind the ischio-pubic rami through the obturator foramen. The transobturator arms were then pulled through a small stab incision in the groin. A stab incision was made 2 cm above the pubic symphysis and 2–3 cm lateral to the midline on either side, aiming to have the mesh and extensions laying adequately on the bulbospongious urethra. The introducer was passed from the pubic incision, anterior to the pubic bone, and out through the perineal incision lateral to the urethra on each side, using the index finger as a guide to safely bring the introducer out. The prepubic arms were attached to the introducer and pulled out through the incision on each side.

Sling tensioning – Cystoscopic technique

The quadratic sling tension was adjusted by pulling both the transobturator and prepubic arms to assure proper urethral compression by performing intraoperative cystoscopy. Upon confirming good urethral coaptation, the arms were then secured in place with hemostats.

Sling tensioning – RLPP measurement

The quadratic sling tension was adjusted using RLPP measurement.[10] RLPP was measured as the height of the water column (cm H_2O) at which sling resistance was overcome and fluid flow commenced. To calculate it, a 1 L bag of saline was connected to the catheter via cystoscopy tubing with the drip chamber half full. The bladder was first emptied and to ensure that the system was properly functioning, bladder pressure was measured and recorded. The catheter was then drawn back to the fossa navicularis and the column of water was placed at 60 cm H_2O. The transobturator arms were maximally tensioned and secured in place with hemostats. The prepubic arms were then tensioned until water stopped dripping in the drip chamber, at which point they were also secured in place with hemostats.

Sling fixation

Prior to sling placement, a 1-0 polypropylene suture was placed through the inferior aspect of the periosteum of the symphysis pubis. We used those sutures to fixate each prepubic arm, securing them to the periosteum and soft tissue overlying the bone (1–1.5 cm) lateral to the urethra on each side. The transobturator arms were fixed in place with 1-0 polypropylene suture placed through the soft tissue adjacent to the proximal bulbar urethra. The hemostats and plastic sleeves were removed, and the final RLPP after sling fixation was measured at this point and recorded.

A long clamp was then passed from the perineal incision to the ipsilateral groin stab wound and the sling arm was grasped and pulled back through to the perineal incision. The excess was cut. All wounds were profusely irrigated with bacitracin antibiotic solution. The perineal and four-arm incisions were closed. The Foley catheter was replaced in the bladder and removed the following morning. Oral antibiotics were given for five days.

Objectives

The primary objective of the study was to compare the impact of two different tensioning methods (cystoscopy vs. RLPP) on the objective and subjective improvement of continence using the Virtue quadratic male sling. Subjective improvement was measured using the the PGI-I score.[11-14]

Secondary objectives were to report the midterm efficacy, safety, and impact on QoL of the Virtue quadratic male sling.

Statistics

Continuous variables were reported as medians (interquartile range [IQR]), while categorical variables were described with proportions. The baseline characteristics and surgical outcomes of the subjects who had tensioning performed using cystoscopic guidance and those who had it done using the RLPP method were compared using the Wilcoxon rank-sum test for continuous variables and the chi-squared or Fisher's exact test for proportions, where appropriate. A multivariate logistic regression model was generated to test for an association between the type of sling adjustment method (cystoscopy vs. RLPP) and the odds of obtaining an improvement of the SUI (either improved or cured), while adjusting for preoperative PPI (moderate/severe vs. mild). The odds ratios (OR) are presented with their 95% confidence intervals (CI). Lastly, proportions were used to report the safety and patient satisfaction. All data were recorded and statistical analyses were conducted using SAS v.9.4 (SAS Institute Inc., Cary, NC, U.S.). All tests were two-sided and p values <0.05 were considered statistically significant.

Table 1. Baseline patient characteristics

	Overall n=48	Group 1 (Cystoscopy) n=18	Group 2 (RLPP) n=30	p
Age (years), median (IQR)	68 (62–72)	65 (62–70)	69 (62–73)	0.19
Radical prostatectomy, n (%)				
Retropubic	37 (77)	13 (72.2)	24 (81.8)	0.5
Laparoscopic	11 (23)	5 (27.8)	6 (18.2)	
EBRT, n (%)	14 (29)	3 (11.1)	11 (30.3)	0.14
Previous bladder neck pathologies, n (%)	10 (21)	5 (27.8)	5 (18.2)	0.5
Severity of Incontinence, n (%)				0.4
Mild	15 (31)	4 (22.2)	11 (33.3)	
Moderate	24 (50)	9 (50)	15 (48.5)	
Severe	9 (19)	5 (27.8)	4 (18.2)	
Pads per day, median (IQR)	3 (2–4)	3.5 (3–4)	2 (2–4)	0.06
Daily pad test (g), median (IQR)	129 (78–400)	400 (82–800)	108 (76–300)	0.06
Preoperative cystoscopy showing good urethral mobility and coaptation, n (%)	45 (94)	15 (83.3)	30 (100)	0.05
Urodynamic findings				
UDC, n (%)	4 (10)	2 (5)	2 (5)	0.6
Qmax (mL/sec), median (IQR)	19 (14–26)	22 (16–41)	17 (12–25)	0.07
PVR (mL), median (IQR)	0 (0-20)	0 (0-0)	10 (0-20)	0.01
Cystometric capacity (mL), median (IQR)	408 (340–495)	433 (363–525)	408 (300–488)	0.36
VLPP (cm H_2O), median (IQR)	96 (69–118)	87 (62–99)	108 (70–120)	0.03
Followup (months), median (IQR)	22 (15–41)	21 (14–61)	25 (15–35)	0.4

EBRT: external beam radiation therapy; IQR: interquartile range; PVR: post-void residual; Qmax: maximum flow rate; RLPP: retrograde leak point pressure; UDC: uninhibited detrusor contractions; VLPP: Valsalva leak point pressure.

Table 2. Complications and patient satisfaction of the Virtue male sling

	Overall n=48	Group 1 (Cystoscopy) n=18	Group 2 (RLPP measured) n=30	p
Complications, n (%)				
Dysesthesia/pain				
Overall	30 (63)	11 (61)	19 (63)	0.9
Transient	23 (48)	7 (39)	16 (53)	
Persistent	7 (15)	4 (22)	3 (10)	
Transient urinary retention	2 (4)	0 (0)	2 (6)	0.3
Wound dehiscence	2 (4)	0 (0)	2 (6)	0.3
Subsequent surgery for unimproved PPI	14 (29)	11 (61)	3 (10)	<0.001
Patient satisfaction (PGI-I score), n (%)				
"Much better" or "Very much better"	28 (58)	7 (39)	21 (70)	0.0008

PGI-I: Patient Global Impression of Improvement; PPI: postprostatectomy incontinence; RLPP: retrograde leak point pressure.

Results

During the study period, 48 men were treated with the Virtue quadratic male sling. Cystoscopy was used to measure sling tensioning in the first 18 patients (Group 1), while RLPP measurement was performed in the last 30 patients (Group 2). Overall median (IQR) followup was 22 (15–41) months: 21 (14–61) months for Group 1, compared to 25 (15–35) months for Group 2. Baseline characteristics are shown in Table 1.

Overall, at the time of their last visit, 28 (58%) patients were either improved or cured of their PPI following surgery at the last followup visit. Seven (39%) patients in Group 1 were cured or improved of their PPI, compared to 21 (70%) patients in Group 2 (p=0.03). Even after adjusting for baseline PPI, men in Group 2 were more likely to have demonstrated an improvement or a cure of their PPI than men in Group 1 (OR 3.5; 95% CI 1.02–12.1). Postoperative median (IQR) ppd for Group 1 vs. Group 2 was 1.5 (0–3) vs. 0 (0–1) (p=0.002); and three (1–5) vs. one (0-1) (p=0.004) at the two-month and last followup visit, respectively.

The most common complication was pain or dysesthesia (Table 2). This occurred transiently (diminishing/disappearing at the two-month followup visit) in the majority of patients (48%). Two (4%) patients had a wound dehiscence (one in the groin incision, the other in the perineal incision), both of which were debrided and primarily closed. There were no mesh erosions or infections in our series. Eleven (61%) patients in Group 1 compared to three (10%) patients in Group 2 had subsequent surgical treatments for their unimproved PPI (p<0.001).

The PGI-I score was used to measure patient satisfaction. Of the patients in Group 1, seven (39%) reported being either "much better" or "very much better" at the time of their last followup visit compared to 21 (70%) patients in Group 2 (p=0.0008).

Discussion

PPI accounts for the majority of male iatrogenic SUI, with resultant impairment of QoL. Various male slings have emerged over the last decade as alternatives to the AUS for the treatment of PPI. The design of the Virtue quadratic male sling overcomes drawbacks of other male slings through the absence of bone screws, which may lower perineal pain, and a combination of horizontal urethral compression by the transobturator arms, in addition to the vertical support of prepubic arms allowing a longer zone of urethral coaptation. Comiter et al[10] demonstrated that both the transobturator and prepubic components of the quadratic sling each contributed to increasing urethral resistance as measured by intraoperative RLPP. Additionally, the surgical procedure does not require opening of the bulbospongiosus muscle, facilitating implantation and decreasing the risk of urethral erosion.

Comiter et al[12] published the first clinical outcomes trial on the Virtue male sling. The objective success rate with sling fixation was 79.2% at 12 months, with success being defined as ">50% decrease in 24-hour pad weight." The cure rate, defined as a pad weight <1.3 g, was 46% at 12 months. McCall et al[15] recently published their series on 32 patients with a median followup of 55 months. There were 21 (68%) patients who were considered procedure failures (defined as the inability to reduce patient's preoperative pad use, sling explant for complications, and need for AUS due to continued incontinence), and they have consequently abandoned implantation of the sling. There were 14 (44%) cases of postoperative urinary retention. Their technique to assess for adequate sling tensioning, however, was not fully elucidated. Furthermore, no RLPP values were reported in their series. More recently, Ferro et al[11] reported on their outcomes in 29 patients. They tension the arms maximally and fix them to the periosteum with a prolene suture (without measuring RLPP). In their series, 82.7% of patients used no pads per day and

17.3% used one pad per day at 12 months after placement of the sling, an excellent short-term outcome.

In our series, although we initially set the RLPP at 60 cm H_2O for sling tensioning, re-measurement of RLPP after sling fixation with polypropylene sutures and hemostats removed yielded a median RLPP of 41 cm H_2O. Series on other male slings, such as the Argus® male sling, have reported that RLPP values of 45 cm H_2O or higher were associated with higher erosion rates, and suggested aiming for a value of 37 cm H_2O.[16] The "ideal" RLPP value for the Virtue male sling is still unknown. We believe that although the sling is initially tensioned at 60 cm H_2O, this does not reflect the true measure of urethral compression, but rather it is the final RLPP remeasured after sling fixation with sutures. With a median RLPP value of 41 cm H_2O, 13 (43%) patients were completely cured (0 ppd) of their incontinence, with an additional eight (27%) showing improvement of their incontinence, comparable to the patient-reported cure and improvement rates of other male slings in the literature.[8,12] Furthermore, there were only two cases (6%) of transient urinary retention.

One of the challenges is to firmly fixate the sling at the desired RLPP value. In our experience, we have found that fixating the prepubic arms to the symphysis pubis periosteum with a prolene suture on either side increases the final RLPP measurement (i.e., closer to the initially set value of 60 cm H_2O) and that this helps firmly anchor the sling in place as opposed to merely fixating it to the periurethral soft tissue.

Transient pain or dysesthesia occurred slightly more frequently in the group with RLPP measurement. There are two hypotheses to explain this phenomenon. One is that there is inflicted trauma to the superficial perineal nerve, a branch of the pudendal nerve, as demonstrated by Senechal et al.[17] This trauma is reduced per-operatively by maximally reducing electrocautery usage and by using careful blunt dissection, especially lateral to the bulbourethral muscle. The second hypothesis is that the dysesthesia/pain is caused by the compression of the Virtue male sling on the perineal neurovascular bundles. It has been our experience that most of these patients will complain of very mild, improving dysesthesia at the two-month followup visit, typically not bothersome, nor requiring any analgesics.

Limitations of this study include its small sample size and its retrospective nature. Additionally, the more favourable results with the RLPP group may be due in part to an improved ability of the surgeon to perform this procedure over time. Both surgeons, however, are very experienced with slings and we believe the learning curve had minimal impact on the results. This is, to our knowledge, the largest single-centre series to date, and the only one reporting on outcomes based on two different approaches to adequately tension the sling. Future studies should aim to find the "ideal" RLPP for the Virtue male sling, and find ways to improve sling fixation at the desired RLPP value.

Conclusion

The Virtue male sling is a safe and effective treatment option for men with PPI. Intraoperative RLPP measurement allows an objective estimation of our surgical tensioning and significantly improves cure/improvement rates. The ideal RLPP, however, remains to be defined for the Virtue male sling. Complications, including pain or dysesthesia, are usually transient, and the majority of patients are satisfied with the sling.

Competing interests: The authors report no competing personal or financial interests.

This paper has been peer-reviewed.

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Appendix 1. Patient Global Impression in Improvement score

Check the number that best describes how your postoperative condition is now, compared with how it was before you had surgery	
Very much better	1
Much better	2
A little better	3
No change	4
A little worse	5
Much worse	6
Very much worse	7