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ORIGINAL ARTICLE

Comparing postoperative voiding dysfunction after mid-urethral sling using either a Babcock or Kelly clamp tensioning technique

Olivia H. Chang[1,2] · Michele R. Hacker[1,2] · Peter L. Rosenblatt[2,3] · Dayna Neo[1] · Emily Von Bargen[2,3] · Iman Berrahou[2] · Amy Le[2] · Roger Lefevre[1,2] · Lekha S. Hota[2,3]

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Abstract

Introduction and hypothesis The objective was to compare postoperative urinary retention using the Babcock and Kelly clamps for retropubic midurethral sling (RPS) tensioning.

Methods This was a retrospective cohort of isolated RPS procedures from December 2010 through April 2016 by five fellowship-trained surgeons at two institutions. Slings were tensioned with a Babcock clamp by grasping a 3-mm midline fold of mesh (RPS-B) or a Kelly clamp as a spacer between the sling and suburethral tissue (RPS-K). Assessment of urinary retention included the primary outcome of postoperative catheterization and several secondary outcomes, including discharge home with a catheter, within 1 year of surgery. Analysis of covariance was used to compute the mean difference in duration of catheterization and log-binomial regression was used to calculate risk ratios (RR) and 95% confidence intervals (CI).

Results We included 240 patients. The RPS-B group had a lower body mass index and was more likely to be menopausal, have had pelvic organ prolapse surgery, and have a lower maximum urethral closure pressure than the RPS-K group. The mean duration of catheterization was similar, as demonstrated by the crude (0.21 days [−0.30–0.71]) and BMI-adjusted (0.07 days [−0.41–0.55]) mean difference in duration of catheterization. The incidence of postoperative OAB symptoms was comparable between the groups (BMI-adjusted RR: 0.95 (0.80–1.1)), and the incidence of revision did not differ ($p = 0.7$).

Conclusions The Babcock and Kelly clamp tensioning techniques appear comparable, with a low incidence of prolonged postoperative catheterization. Most catheters were removed on the day of the surgery. It is reasonable to tension retropubic midurethral slings with either method.

Keywords Retropubic midurethral sling · Sling tensioning · Urinary retention · Sling revision

Introduction

An estimated 44–57% of middle-aged and post-menopausal women experience urinary incontinence [1]. Of these women, at least half suffer from stress urinary incontinence, which is defined as loss of urine with exertion, such as a cough, laugh or sneeze [2].

Some women choose conservative treatments for stress urinary incontinence, such as lifestyle modifications or pelvic floor muscle therapy, but others proceed directly to surgical treatment. Surgery is a reasonable first-line option, as a midurethral sling has high rates of subjective and objective cure at 1 year after surgery [3].

The midurethral sling was first introduced by Ulmsten et al. in 1995 to treat female stress urinary incontinence [4]. In a Cochrane review, the midurethral sling was shown to be an effective treatment for stress urinary incontinence compared with open retropubic colposuspension [5]. The midurethral sling is a well-studied treatment for stress urinary incontinence with over 80 randomized or quasi-randomized controlled trials as of 2015 [6]. Intraoperative and postoperative complication rates are low, with the most common intraoperative complication being bladder perforation (3.5%) [7] and the most common postoperative complication being bladder outlet obstruction (1.6–19.0%) [6, 8–12].

✉ Lekha S. Hota
lhota@mah.harvard.edu

[1] Department of Obstetrics and Gynecology, Beth Israel Deaconess Medical Center, Boston, MA, USA

[2] Department of Obstetrics, Gynecology, and Reproductive Biology, Harvard Medical School, Boston, MA, USA

[3] Department of Obstetrics and Gynecology, Mount Auburn Hospital, 725 Concord Avenue, Suite 1200, Cambridge, MA 02138, USA

Bladder outlet obstruction often presents as urinary retention, urinary hesitancy, straining to void, and urinary frequency. The mostly likely cause of this complication is excessive tension against the suburethral tissue, which results in difficulty with voiding. Ulmsten's original description of the TVT procedure emphasizes the tension-free nature of the procedure, but the techniques employed for ensuring a tension-free placement are varied and subjective as there are no guidelines on how to tension a sling. Surgeons use a variety of instruments for tensioning, including cervical dilators [9], number 8 Hagar dilators, right-angled clamps [10], Kelly clamps or any easily accessible surgical instrument in the standard vaginal surgery kit. In 2003, de Leval introduced a method to tension the sling that allows for a standardization of tensioning by grasping the folded mesh with a Babcock clamp [12]. Given the importance of placing a sling with minimal tension, we compared a standardized method utilizing a Babcock clamp to uniformly reserve a small portion of mesh tape with a method using a Kelly clamp.

The objective of this study was to determine the differences in postoperative urinary retention and sling complications at 1 year among patients who underwent an isolated retropubic midurethral sling (RPS) placement, tensioned with a Babcock (RPS-B) compared with a Kelly clamp (RPS-K). Postoperative urinary retention was assessed by length of postoperative catheterization and several secondary outcomes, including discharge with a catheter. We hypothesized that procedures using the RPS-B tensioning method might have a shorter duration of postoperative catheterization than those that used the RPS-K method.

Materials and methods

This retrospective cohort study included patients who had an isolated RPS (TVT; Gynecare, Somerville, NJ, USA/ Advantage Fit; Boston Scientific, Boston, MA, USA) placed from December 2010 through April 2016 at two institutions. Both institutions used a combination of Gynecare TVT and TVT Exact slings and Boston Scientific TVT Advantage Fit. We included all procedures for which the following eligibility criteria were met: RPS placed with either the RPS-B or RPS-K methods, isolated placement of RPS without concomitant surgery and available postoperative voiding trial results. Procedures were performed by five fellowship-trained female pelvic medicine and reconstructive surgeons.

We reviewed medical records to extract demographic characteristics. medical and surgical history. preoperative testing with urodynamics. and intraoperative and postoperative data. The primary outcome was duration of postoperative catheterization, reported as days from the time of surgery to the time of Foley catheter removal. Urinary retention was also assessed with several secondary outcomes, including discharge with a catheter, indwelling catheter at 1 week after surgery, elevated (≥150 mL) post-void residual (PVR) volume at 6 weeks after surgery, new or persistent overactive bladder (OAB) symptoms such as urinary urgency and frequency, and postoperative complications within 1 year, including sling exposure and revision.

The RPS-B tensioning method was standardized using a Babcock clamp to grab 6 mm of mesh by grasping a 3-mm midline fold of mesh after slightly retracting the plastic sheaths, and slack was removed from the sling and sheath until the Babcock was in contact with the suburethral tissue. The plastic sheaths were then removed from the mesh, and the Babcock clamp was released. The mesh was inspected for placement and the incision was closed using synthetic polyglactin suture.

For the RPS-K tensioning method, a Kelly clamp was placed between the sling and suburethral tissue, and slack was removed from the sling and sheath until desired tension was achieved. The Kelly clamp was then held in place while the plastic sheaths were removed from around the mesh. Following sheath removal, the Kelly clamp was withdrawn, and the mesh was inspected for appropriate placement. The incision was closed using synthetic polyglactin suture.

For the postoperative voiding trial, Institution A used a one-step voiding trial. The bladder was backfilled with 300 mL of sterile saline, and the patient was required to void within 30 min. The voided volume was recorded. If the voided volume was greater than or equal to 200 mL, then it was considered a successful voiding trial. If the patient passed the voiding trial, she was discharged without a catheter. If the patient failed the voiding trial, she was discharged with a Foley catheter and scheduled for removal within 5 days of discharge pending patient and clinic availability. At Institution B, some patients had the one-step voiding trial described above. Other patients had two voiding trials, where the one-step voiding trial as described was performed, but the residual was confirmed with a straight catheter. If the PVR was elevated, then a second voiding trial was performed within 30–60 min using the same technique described. If the patient failed the second voiding trial, a Foley catheter was placed at the time of discharge. Whether the patient had a one-step or two-step voiding trial was not consistently documented; only whether the voiding trial was successful or not.

Data are presented as mean with standard deviation (SD) or proportion. Chi-squared and Fisher's exact tests were used to compare categorical variables and a *t* test was used to compare continuous variables. We used analysis of covariance to compute the mean difference in length of catheterization and log-binomial regression to calculate risk ratios (RRs) and 95% confidence intervals (CIs). We considered age, body mass index, parity, history of pelvic organ prolapse surgery, and preoperative lower maximum urethral closure pressure to be potential confounders. Variables were retained in the model if

they appreciably altered the crude effect estimate. A p value ≤0.05 was considered statistically significant, and all tests were two sided. All statistics were calculated using SAS 9.4 (SAS Institute, Cary, NC, USA). The Beth Israel Deaconess Medical Center and Mount Auburn Hospital institutional review boards approved this study.

Results

We identified 270 eligible patients. After reviewing the medical records, we excluded 30 patients who did not meet the eligibility criteria: 5 slings tensioned with Hagar dilators, 1 tensioned with Metzenbaum scissors, and 24 procedures that did not have documentation of the tensioning method. Thus, we included 240 procedures, of which 70 used the RPS-B method and were performed at Institution A and 170 used the RPS-K method and were performed at Institution B.

The groups were similar with regard to age and parity, and approximately half of each group had preoperative OAB symptoms (Table 1). Patients in the RPS-B group had a lower body mass index, were more likely to be menopausal, were more likely to have a history of surgery for pelvic organ prolapse, and had a lower maximum urethral closure pressure compared with the RPS-K group.

The incidence of voiding trial failure on the day of surgery was 27.6% among patients in the RPS-K group and 34.3% among those in the RPS-B group. Although patients in the RPS-K group were less likely to fail their voiding trial on the day of surgery and thus less likely to be discharged with a catheter than patients in the RPS-B group, this difference was not statistically significant (RR: 0.81; 95% CI: 0.54–1.2; Table 2). Adjusting for BMI attenuated the RR slightly; none of the potential confounders influenced the RR. The mean length of catheterization was 0.94 ± 2.0 days in the RPS-K group and 0.73 ± 1.2 days in the RPS-B group, which was not significantly different, as demonstrated by the crude (0.21 days [−0.30–0.71]) and BMI-adjusted (0.07 days [−0.41–0.55]) mean difference in length of catheterization. Similarly, there was no significant difference in the risk of having a catheter 1 week after surgery (Table 2).

In the RPS-K group, 15.3% of patients did not attend their 6-week postoperative visit compared with 1.4% of the RPS-B group ($p = 0.002$). The 144 patients in the RPS-K group and the 69 in the RPS-B group who returned for the 6-week visit had a similar incidence of PVR ≥150 mL (RR: 1.3; 95% CI: 0.26–6.5). The incidence of postoperative urinary urgency or frequency at 6 weeks was also comparable in the RPS-K and RPS-B groups (BMI-adjusted RR: 0.94; 95% CI: 0.80–1.1). By 1 year after surgery, there were 5 cases of documented sling exposure in the RPS-K group (2.9%) and no cases documented in the RPS-B group (0.0%; $p = 0.02$). All 5 patients who had sling exposure subsequently had a sling revision. In the RPS-B group, 1 case of revision was for voiding dysfunction (1.4%). There was no difference in the incidence of revision between the groups (RPS-K group = 2.9%, RPS-B group = 1.4%, $p = 0.7$).

Table 1 Baseline patient characteristics

	RPS-B $N = 70$	RPS-K $N = 170$
Age (years)	50.7 ± 10.6	50.1 ± 10.2
Body mass index (kg/m^2)	27.3 ± 5.9	29.7 ± 6.3
Parity	2.4 ± 0.9	2.4 ± 1.1
Menopausal status		
Menopausal	28 (40.0)	51 (30.0)
Pre-menopausal	40 (57.1)	102 (60.0)
Unknown	2 (2.9)	17 (10.0)
Previous pelvic organ prolapse surgery		
Yes	25 (35.7)	7 (4.1)
No	45 (64.3)	162 (95.3)
Unknown	0 (0.0)	1 (0.6)
Preoperative overactive bladder		
Yes	38 (54.3)	100 (58.8)
No	31 (44.3)	66 (38.8)
Unknown	1 (1.4)	4 (2.4)
Preoperative MUCP (cm H_20)	55.2 ± 20.7	76.4 ± 27.9

Data are presented as mean ± standard deviation or n (%)

MUCP maximum urethral closure pressure, *RPS-B* retropubic midurethral sling tensioned with a Babcock clamp, *RPS-K* retropubic midurethral sling tensioned with a Kelly clamp

Discussion

This retrospective cohort study demonstrates that the Babcock and Kelly clamp tensioning techniques appear to be comparable, with a low incidence of prolonged postoperative catheterization. In both groups, most catheters were removed on the day of surgery, and the duration of catheterization was similar. In addition, there was no significant difference in urinary retention, defined as PVR ≥150 mL, at the 6-week visit. Our finding of persistent postoperative urinary retention is similar to another study that reported that 2–4% of patients had postoperative retention lasting longer than 4 weeks [8, 13]. Thus, it appears that the risk of urinary retention does not differ whether the sling is tensioned with a Babcock clamp or with a Kelly clamp. This suggests that it might be more important to ensure an adequate amount of space between the sling and the suburethral tissue at the time of placement. In addition, the incidence of revision was similar in the RPS-B (1.4%) and RPS-K (2.9%) groups and consistent with existing literature [14].

Table 2 Risk of postoperative outcomes stratified by tensioning method

	Type of tensioning	*n* (%)	Crude RR (CI)	BMI-adjusted RR (CI)
Discharged with catheter on the day of surgery	RPS-K	47 (27.6)	0.81 (0.54–1.2)	0.73 (0.47–1.1)
	RPS-B	24 (34.3)	Reference	Reference
Catheter indwelling at 1 week	RPS-K	5 (2.9)	2.1 (0.24–17)	NC
	RPS-B	1 (1.4)	Reference	Reference
Post-void residual ≥150 mL at 6 weeks	RPS-K	5 (3.5)	1.3 (0.26–6.5)	NC
	RPS-B	2 (2.9)	Reference	Reference
Overactive bladder symptoms at 6 weeks	RPS-K	32 (19)	0.97 (0.84–1.1)	0.94 (0.80–1.1)
	RPS-B	14 (20)	Reference	Reference

NC not calculated (adjusted risk ratios could not be calculated because there were too few events)

Similar to what we found in the RPS-K group, in a large systematic review of 31 trials with 4,743 participants, the incidence of sling exposure was 2.1% [6]. Although low in both groups, the incidence of sling exposure in our study appears to be higher with the RPS-K method (2.9%) compared with the RPS-B method (0.0%). However, the sample size, particularly in the RPS-B group, makes the estimate imprecise and limited our ability to detect a difference between the groups. In addition, there was variation in which type of sling was used. The slings are made of macroporous, knitted and monofilament polypropylene, but there are slight differences to the mesh. Advantage Fit [15] mesh has a de-tanged suburethral portion that reduces irritation to the anterior urethral wall and the thickness is 0.66 mm, compared with 0.70 mm for TVT and TVT Exact [16, 17]. These small differences could have an impact on sling exposure.

Additionally, postoperative complications of new onset or worsening OAB symptoms of urgency, frequency and urgency incontinence have often been reported after retropubic sling placement [6]. In our study, preoperative OAB symptoms were present in approximately half of patients in each group; however, the incidence of postoperative OAB symptoms decreased and was similar in the groups. Other studies [18, 19] have suggested a similar postoperative improvement in OAB symptoms. The method of tensioning does not seem to affect postoperative OAB symptoms.

Our study has several limitations. First, the retrospective design of the study meant that we were limited to data that were documented in the chart. Thus, we had to exclude 24 patients for whom the tensioning technique was not documented and may have missed cases of sling exposure or revision for patients lost to follow-up. However, we do not expect that either of these issues would have been differential with regard to tensioning method. Second, we had a modest sample size. Coupled with the low incidence of adverse outcomes, we had limited power to detect differences between the groups. For example, our post hoc power calculation demonstrated that we had only 17% power to demonstrate statistical significance in the observed difference in the primary outcome—length of postoperative catheterization. Third, there were differences in how the voiding trials were performed and these data was not consistently documented on the chart. However, the voiding trials were based on a study by Kleeman et al. that demonstrated that voiding efficiency was seen in patients who voided >68% of total bladder volume [20]. As a result, we do not believe that the different types of voiding trials affected the outcomes in this study. Fourth, there is the logistical limitation that patients who were discharged home with a catheter returned for their repeat voiding trial at various times depending on patient and clinic availability. It is possible that some patients may have been able to void spontaneously before their clinic appointment. We believe that this limitation would affect the RPS-B and RPS-K groups similarly and thus would not create bias.

The strengths of our study are that it included two institutions with procedures performed by multiple surgeons, that we used an objective measurement of urinary retention rather than subjective findings of voiding dysfunction, and that the incidences of postoperative complications reported here are similar to those seen in published data. Therefore, we believe that our findings are generalizable beyond our institutions. However, larger prospective studies are needed to draw more definitive and robust conclusions.

This retrospective cohort study suggests that the Babcock and Kelly clamp tensioning techniques appear to be comparable, with a low incidence of prolonged postoperative catheterization. In both groups, most catheters were removed on the day of surgery and the incidence of postoperative complications was low. It is reasonable to tension retropubic midurethral slings using either the Kelly or the Babcock method. However, our study had limited power to detect potentially meaningful differences. To draw definitive conclusions about specific tensioning techniques, large, prospective studies are required.

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Compliance with ethical standards

Conflicts of interest PR is a consultant and has received research support from Boston Scientific and Coloplast. For the remaining authors no conflicts of interest were declared.

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