# *Foley catheter guide use during midurethral slings: does it make a difference?*

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***Introduction:*** *Our objective was to evaluate whether foley catheter guide use decreased the risk of cystotomy and urethrotomy during retropubic midurethral sling placement.*

***Materials and methods:*** *This retrospective cohort study included all women undergoing retropubic synthetic midurethral sling placement at a single academic institution between January 2011 and September 2012. Patients were divided into groups based on whether or not the foley catheter guide was used during surgery. The primary outcome was the incidence of cystotomy.*

***Results:*** *A total of 310 patients underwent retropubic midurethral sling placement. The foley catheter guide was used in 76/310 cases (24.5%). The mean age was 57 ± 11 and mean body mass index was 28 ± 7. More patients in the no-guide group had preoperative urgency (70% versus 58%, p = 0.049), anterior prolapse (95% versus 78%, p < 0.0001), and concomitant prolapse surgery (65% versus 51%, p = 0.03). There was no difference in preoperative urgency urinary incontinence, medical comorbidities, previous surgical history, intraoperative time, blood loss, or postoperative voiding dysfunction rates between groups. Fourteen of the 310 patients (4.5%) had cystotomies: 1/76 (1.3%) in the foley catheter guide group and 13/234 (5.6%) in the no-guide group (p = 0.12). No patients had urethrotomies. On multiple logistic regression, there was no difference in the odds of cystotomy between groups after adjusting for previous prolapse and anti-incontinence surgery, concomitant prolapse repair, level of first assistant, and retropubic local anesthesia use (AOR = 0.2 [95% CI 0.02-1.7]).*

***Conclusions:*** *Foley catheter guide use did not decrease the risk of intraoperative lower urinary tract injury during retropubic midurethral sling placement. Larger prospective studies are needed to confirm this finding.*

**Key Words:** foley catheter guide, lower urinary tract injury, midurethral sling

## Introduction

Synthetic midurethral sling procedures have revolutionized the treatment of stress urinary incontinence (SUI). They offer an effective, minimally invasive surgical option that can be performed on an outpatient basis. Over the past 18 years, midurethral slings have become one of the most well-studied urogynecologic procedures. Currently considered the gold standard surgery for SUI, they account for the majority of SUI procedures performed annually in the United States.[1] Although the original tension free vaginal tape (TVT, Gynecare, Somerville, NJ, USA) involved trocar passage through the retropubic space, midurethral slings can now be placed using either a retropubic or transobturator approach.[2]

Compared to other anti-incontinence procedures, synthetic midurethral slings have a relatively low complication profile. Nevertheless, complications

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related to midurethral slings have traditionally been underreported in the literature.[3] Serious complications such as major vascular and bowel injury are rare, but prompted the development of the transobturator approach to avoid blind passage of sling trocars through the retropubic space. Intraoperative complications that occur more commonly during retropubic sling placement include hematoma formation and lower urinary tract injury, affecting up to 8% and 9.5% of patients, respectively.[4]

Different techniques have been introduced to decrease the risk of lower urinary tract injury during retropubic midurethral sling placement. One such technique involves use of a rigid foley catheter guide. First described by Ulmsten and Petros in 1995, the rigid catheter guide is typically introduced through an 18-Fr foley to deflect the bladder neck and urethra away from the path of the sling trocars to help prevent lower urinary tract injury.[2] Although the manufacturer of the original TVT continues to recommend foley catheter guide use in its instructions, it is unclear whether this device decreases the risk of intraoperative lower urinary tract injury.[5] The objective of this study was to determine whether foley catheter guide use reduced the risk of cystotomy and urethrotomy during retropubic midurethral sling placement.

## Materials and methods

This was an IRB-approved retrospective cohort study of women who underwent retropubic midurethral sling placement with the Section of Female Pelvic Medicine and Reconstructive Surgery at a single academic institution between January 2011 and September 2012. This interval was chosen because a new electronic billing system was implemented during this time. This system facilitates analysis of the types of surgical cases that are performed.

We included all women who had synthetic retropubic slings placed during this time period regardless of whether or not they had concomitant surgical procedures. All surgeries were performed by one of four fellowship-trained urogynecologists, usually with a resident or fellow as first assistant. Women who underwent autologous bladder neck, transobturator, retropubic "top-down," or mini/single incision slings were excluded.

Each surgeon used the same surgical technique regardless of the type of retropubic midurethral sling placed. The sling suprapubic exit sites were marked 2.5 cm lateral to the midline just above the pubic symphysis. In cases where retropubic anesthesia was administered, 10 mL of local anesthetic was injected at these sites down into the space of retzius. Although the choice of local anesthetic agent was left to the discretion of the surgeon, an epinephrine-containing agent was used. The most commonly used agents included 0.5% lidocaine with epinephrine, 0.5% bupivacaine with epinephrine, and 1% lidocaine with epinephrine diluted in equal parts injectable saline. The needle attached to the syringe containing the local anesthetic was inserted at an angle with the goal of contacting the pubic bone, after which it was "walked" behind the bone to ensure insertion in the correct location prior to injection. At several points during injection, the syringe was aspirated to confirm no blood, urine, or bowel contents were obtained. The goal of retropubic anesthesia was to provide hydrodissection and vasoconstriction in addition to providing local anesthesia.

The vaginal dissection was performed in the following fashion. The vaginal epithelium overlying the midurethra was grasped with two allis clamps. The first was placed 1 cm proximal to the external urethral meatus while the second was placed at the bladder neck. The area between the allis clamps was injected with local anesthetic. Local anesthetic agent was also injected laterally where the periurethral tunnels were to be created. A 0.5-1 cm vertical midline incision was made in the vaginal epithelium overlying the midurethra with the scalpel. Two periurethral tunnels were created sharply using Metzenbaum scissors. Three of the four surgeons performed minimal vaginal dissection, just enough to pass the trocar. The width of this dissection was limited to 5 mm. One of the four surgeons performed a more extensive dissection, wide enough to admit a finger. The sling trocars were inserted through the vaginal dissection. With the patient in steep Trendelenberg position, the sling trocars were passed around the inferior pubic ramus directed toward the ipsilateral shoulder. Upon piercing the urogenital diaphragm, they were redirected toward the midclavicular line exiting the previously marked sites.

Operative records were reviewed, and patients were divided into groups for analysis based on whether or not the foley catheter guide was used during sling placement. Catheter guide use was left to the discretion of the surgeon. Our primary outcome was the incidence of cystotomy. Other outcomes included cystotomy location and the incidence of urethrotomy.

Demographic data, clinical characteristics, and perioperative details were abstracted from patients' medical records. Bivariate analyses were performed as appropriate. Multiple logistic regression was performed to estimate the effect of foley catheter guide

use on the risk of cystotomy adjusting for previous prolapse or anti-incontinence surgery, concomitant prolapse repair, level of first assistant, and use of retropubic anesthesia. P values less than 0.05 were considered statistically significant. All statistical analyses were performed with SAS version 9.3 (Cary, NC, USA).

## Results

Three hundred ten women underwent retropubic midurethral sling placement during the study time period. The majority (258/310, 83.2%) had Advantage Fit slings placed (Boston Scientific, Natick, MA, USA) while Desara (Caldera Medical Inc, Agoura Hills, CA, USA) and TVT Exact slings (Gynecare, Somerville, NJ, USA) were used in 13.5 % (42/310) and 3.2% (10/310), respectively. All the Desara slings included in this study were placed transvaginally.

The foley catheter guide was used in 76/310 cases (24.5%). There were no significant differences in mean age, mean body mass index (BMI), previous prolapse or anti-incontinence surgery, medical comorbidities, or smoking status between the foley catheter guide group and the no-guide group, Table 1. Although a larger proportion of patients in the no-guide group had preoperative urgency (70.1% versus 57.9%, p = 0.049), there was no difference in preoperative

TABLE 1. **Baseline demographics and clinical characteristics**

| **Variable** | **Catheter guide n = 76** | **No catheter guide n = 234** | **p value** |
|---|---|---|---|
| Age (mean, std) | 56.9 ± 10.8 | 59.5 ± 12.4 | 0.13[a] |
| BMI (kg/m$^2$; mean, std) | 27.9 ± 6.7 | 29.4 ± 8.8 | 0.09[a] |
| Previous anti-incontinence surgery (n, %) | 13 (17.1) | 23 (9.8) | 0.09[b] |
| Previous prolapse surgery (n, %) | 15 (19.7) | 32 (13.4) | 0.20[b] |
| Other previous pelvic surgery (n, %) | 51 (67.1) | 162 (69.2) | 0.73[b] |
| History of pelvic fracture (n, %) | 0 (0) | 1 (0.43) | 0.57[c] |
| Preoperative urgency (n, %) | 44 (57.9) | 164 (70.1) | 0.049[b] |
| Preoperative urgency incontinence (n, %) | 39 (51.3) | 116 (49.6) | 0.79[b] |
| Comorbidities (n, %) | | | |
| Diabetes | 7 (9.2) | 24 (10.3) | 0.79[b] |
| HTN | 28 (36.8) | 94 (40.2) | 0.61[b] |
| Heart disease | 9 (11.8) | 24 (10.3) | 0.70[b] |
| Stroke | 1 (1.32) | 3 (1.28) | 0.98[c] |
| Arthritis | 22 (29.0) | 71 (30.4) | 0.82[b] |
| Endometriosis | 2 (2.6) | 5 (2.1) | 0.80[c] |
| Smoking status (n, %) | | | 0.26[b] |
| Nonsmoker | 54 (71.1) | 147 (62.8) | 0.19[b] |
| Former smoker | 18 (23.7) | 64 (27.4) | 0.53[b] |
| Current smoker | 3 (4) | 21 (9) | 0.15[c] |
| Concomitant prolapse (n, %) | 66 (86.8) | 227 (97.0) | 0.0007[b] |
| Apical | 37 (48.7) | 179 (76.5) | < 0.0001[b] |
| Anterior | 59 (77.6) | 222 (94.9) | < 0.0001[b] |
| Posterior | 55 (72.4) | 213 (91.0) | < 0.0001[b] |
| POP-Q stage (n, %) | | | |
| 1 | 25 (32.9) | 47 (20.1) | 0.02[b] |
| 2 | 26 (34.2) | 91 (38.9) | 0.40[b] |
| 3 | 15 (19.7) | 79 (33.8) | 0.02[b] |
| 4 | 0 (0) | 10 (4.3) | 0.07[c] |

BMI = body mass index; HTN = hypertension; [a] = p value obtained using Wilcoxon rank sum test; [b] = p value obtained using Chi-square test; [c] = p value obtained using Fisher exact test

urgency urinary incontinence between groups. More patients in the no-guide group had pelvic organ prolapse (97.0% versus 86.8%, p < 0.001), and prolapse in this group was more severe, Table 1. One patient in the no-guide group had a history of a pelvic fracture.

Concomitant prolapse repairs were performed at the time of sling placement for a greater proportion of patients in the no-guide group (65.0% versus 51.3%, p = 0.03, Table 2). More patients in the no-guide group also had surgery under general anesthesia (64.5% versus 51.3%, p = 0.04). Conversely, retropubic local anesthesia was used in a larger proportion of cases in the foley catheter guide group (96.1% versus 71.4%, p < 0.0001). One hundred and ninety-six of the 258 (76%) women who had Advantage Fit slings placed, 36/42 (85.7%) women who had Desara slings placed, and 8/10 (80%) women who had TVT Exact slings placed received retropubic anesthesia.

More patients in the foley catheter guide group had a trainee as the first assistant (98.7% versus 91.0%,

TABLE 2. **Perioperative details**

| Variable | Catheter guide n = 76 | No catheter guide n = 234 | p value |
|---|---|---|---|
| Concomitant prolapse repair (n, %) | 39 (51.3) | 152 (65.0) | 0.03[b] |
| Anterior repair | 24 (31.6) | 132 (56.4) | 0.0002[b] |
| Posterior repair | 29 (38.2) | 129 (55.1) | 0.01[b] |
| Enterocele repair | 1 (1.3) | 35 (15.0) | 0.001[c] |
| Apical repair | 25 (32.8) | 112 (47.8) | 0.002[b] |
| USLS | 6 (7.9) | 22 (9.4) | 0.69[b] |
| SSLS | 3 (3.95) | 16 (6.8) | 0.36[c] |
| Lap sacrocolpopexy | 13 (17.1) | 64 (27.4) | 0.07[b] |
| Abd sacrocolpopexy | 1 (1.3) | 3 (1.28) | 0.98[c] |
| Iliococcygeus suspension | 0 (0) | 1 (0.4) | 0.57[c] |
| Hysteropexy | 2 (2.6) | 6 (2.56) | 0.97[c] |
| Colpocleisis | 1 (1.3) | 13 (5.6) | 0.12[c] |
| Concomitant hysterectomy (n, %) | 14 (18.4) | 59 (25.2) | 0.23[b] |
| Vaginal | 13 (17.1) | 49 (20.9) | 0.47[b] |
| Abdominal | 1 (1.3) | 0 (0) | 0.08[c] |
| Laparoscopic | 0 (0) | 10 (4.3) | 0.07[c] |
| Level of first assistant (n, %) | | | |
| Resident | | | |
| Ob/Gyn | 17 (22.4) | 32 (13.7) | 0.07[b] |
| Urology | 4 (5.3) | 8 (3.4) | 0.47[c] |
| Fellow | | | |
| 1st year | 18 (23.7) | 68 (29.1) | 0.36[b] |
| 2nd year | 23 (30.3) | 66 (28.2) | 0.73[b] |
| 3rd year | 13 (17.1) | 39 (16.7) | 0.93[b] |
| Physician assistant | 1 (1.3) | 21 (9.0) | 0.02[c] |
| EBL (cc; mean, std) | 81.1 ± 97.8 | 89.9 ± 105.3 | 0.41[a] |
| Type of anesthesia (n, %) | | | |
| Monitored anesthesia care | 27 (35.5) | 62 (26.5) | 0.13[b] |
| Laryngeal mask airway | 10 (13.2) | 17 (7.3) | 0.11[b] |
| General | 39 (51.3) | 151 (64.5) | 0.04[b] |
| Local retropubic | 73 (96.1) | 167 (71.4) | < 0.0001[b] |
| Initial voiding trial passed (n, %) | 4 1(54.0) | 149 (64.0) | 0.12[b] |
| Repeat voiding trial passed (n, %) | 35 (46.1) | 84 (35.9) | 0.52[b] |

USLS = uterosacral ligament suspension; SSLS = sacrospinous ligament suspension; [a] = p value obtained using Wilcoxon rank sum test; [b] = p value obtained using Chi-square test; [c] = p value obtained using Fisher exact test

TABLE 3. **Incidence and location of cystotomy**

| Variable | Catheter guide n = 76 | No catheter guide n = 234 | p value |
|---|---|---|---|
| Cystotomy (n, %) | 1 (1.3) | 13(5.6) | 0.12[a] |
| Cystotomy location[b] (n, %) | | | 0.58[a] |
| Dome | 1 (1.3) | 4 (1.8) | |
| Lateral wall | 0 (0) | 3 (1.3) | |

[a] = p value based on Fisher exact test; [b] = cystotomy location only recorded in 8 of 14 cases

p = 0.02), but there was no difference in level of trainees between groups, Table 2. There were no differences in mean intraoperative time, mean blood loss, or rates of postoperative voiding dysfunction (p > 0.05 for all). The mean hospital stay was less than 1 day for all patients.

Fourteen of the 310 women included in the study (4.5%) had cystotomies. Of these cystotomies, 1 occurred in the foley catheter guide group while the remainder occurred in the no-guide group (1.3% versus 5.6%, p = 0.12, Table 3). There were no differences in cystotomy location between groups and there was no difference in cystotomy rate by sling type or surgeon. No patients had urethrotomies. On multiple logistic regression, there was no significant difference in the odds of cystotomy with foley catheter guide use after adjusting for previous prolapse and anti-incontinence surgery, concomitant prolapse repair, level of first assistant, and use of retropubic anesthesia (AOR = 0.2 [95% CI 0.023-1.74]).

## Discussion

In this retrospective cohort study, we found no difference in cystotomy rates between the foley catheter guide group and the no-guide group. Foley catheter guide use did not reduce the risk of cystotomy even after adjusting for confounding variables and other baseline differences between groups. Our results are consistent with a previous study by Neuman who reported no difference in the rate of cystotomy during TVT placement between cases in which the foley catheter guide was and was not used.[6] In Neuman's study, cystotomy occurred in 4/50 cases (8%) in which the catheter guide was used, and 3/50 cases in which it was not used (6%). However, because specific clinical characteristics and perioperative details were not described, it is unclear whether these groups were similar at baseline and whether other confounding factors for cystotomy influenced these results. In contrast, our study is larger and involves multiple surgeons as well as trainees. Additionally, we provide baseline demographic data and clinical characteristics as well as specific perioperative details about the patients included in our analyses.

Our study is limited by its retrospective design. Our sample is one of convenience and the foley catheter guide was only used in approximately 25% of all cases. Furthermore, the majority of slings that were placed were Advantage Fit slings, and it is unclear whether our results may have been different if an equal proportion of other retropubic sling types were included. Our overall cystotomy rate, however, was similar to that reported in previous studies involving TVTs.[7-10]

Three of the four surgeons in our study performed minimal vaginal dissection, just enough to pass the sling trocar. The width of this dissection was limited to 5 mm. One of the four surgeons performed a more extensive dissection, wide enough to admit a finger. A more extensive periurethral dissection prior to sling trocar passage may provide for greater lateral movement of the trocar, which could result in a higher lower urinary tract injury rate. Conversely, one may argue that a dissection wide enough to admit the surgeon's finger may help him or her confirm that the trocar is truly hugging the inferior pubic ramus prior to passing it around the pubic bone. Nevertheless, there were no differences in cystotomy or urethrotomy rates by surgeon in this study.

Optimal postoperative management of cystotomy at the time of midurethral sling remains controversial. At our institution, voiding trials are performed prior to discharge on all patients who have had midurethral slings placed. The bladder is backfilled with 300 mL of normal saline or sterile water and the patient is required to void at least 200 mL to prevent catheter replacement. When a cystotomy occurs at the time of midurethral sling, we tend to leave a foley catheter in place for 24 to 48 hours prior to performing a voiding trial regardless of the sling type used. Patients who are discharged the day of surgery usually return to the office for this procedure. Prophylactic antibiotics are prescribed for use while the catheter is in place.

Consequently, cystotomy at the time of midurethral sling impacts patient care in our clinical practice.

No urethrotomies occurred during the study time period. Even so, our study was likely underpowered to detect a difference in urethral injury with foley catheter guide use given it is a rare complication of midurethral sling placement. It is also possible that our study was underpowered to detect a difference in cystotomy rates between the foley catheter group and the no-guide group, potentially resulting in a type 2 error. A post hoc analysis we conducted revealed that 327 patients would be needed in each group to detect a 4.3% difference in cystotomy rates with a power of 80% and an alpha of 0.05.

## Conclusion

In conclusion, our results suggest foley catheter guide use does not decrease the risk of cystotomy and may be unnecessary during retropubic midurethral sling placement. However, larger prospective studies are needed to confirm this finding. □

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