ISSN: 2469-5742

Tavakoli et al. Int Arch Urol Complic 2019, 5:057
DOI: 10.23937/2469-5742/1510057
Volume 5 | Issue 1
Open Access

International Archives of
Urology and Complications

RESEARCH ARTICLE

The Impact of the Rigid Catheter Guide on Trocar Injury during Mid-Urethral Sling Placement

Amin Tavakoli, BS[1,2], Azadeh Nasiri, MD[1,3] and Felicia Lane, MD[1*]

[1]*Irvine School of Medicine, University of California, USA*

[2]*David Geffen School of Medicine, University of California, Los Angeles, USA*

[3]*South Nassau Communities Hospital, USA*

***Corresponding author:** *Felicia Lane, MS, MD, Irvine School of Medicine, University of California, 333 City Blvd W STE 1400, Orange Ca 92868, Los Angeles, USA, Tel: 1-714-456-8564*

Abstract

Background: Our goal was to identify general risk factors associated with trocar bladder injury during a retropubic mid-urethral sling (MUS) placement and evaluate the effect of using the rigid catheter guide on cystotomy rates.

Methods: This is a retrospective cohort with nested case control study of 291 patients who underwent a MUS procedure between January 2002 and December 2012 at a single academic medical center. Logistic regression was used to conduct multivariate analysis to predict bladder injury.

Results: There was no evidence that any of the hypothesized risk factors, including the use of the rigid catheter guide, were associated with a significant difference in rate of bladder injury during a retropubic MUS placement.

Conclusions: Eliminating the catheter guide from the operative procedure has the potential to reduce operative steps without necessarily increasing morbidity. This study is unable to detect small differences due to the low frequency of trocar injury and adjusting for covariates does not change these results. Therefore, further studies are needed confirm our conclusion.

Keywords

Mid-urethral sling, Trocar injury, Bladder perforation, Rigid catheter guide

Introduction

Stress urinary incontinence (SUI) is the most common type of female urinary incontinence, affecting up to one out of three women [1]. SUI can be managed conservatively or surgically. The Mid-urethral sling (MUS) has become the most common surgical method to treat stress urinary incontinence [2]. The first mid-urethral sling, the tension-free vaginal tape (TVT), was described by Ulmsten in 1996 [3]. Since then, many variations of retropubic and mid-urethral transobturator slings have been introduced.

Although MUS has high cure rates and low incidence of side effects, bladder perforation is a common intraoperative problem encountered with the sling. Bladder injury is a common intraoperative complication of MUS placement as bladder perforation occurs in approximately 5% of retropubic sling placements [4]. Women with prior pelvic surgery for prolapse repair may be even more susceptible to bladder perforation during MUS sling placement [5]. When unrecognized or improperly treated, bladder perforation can result in the development of considerable consequences such as vesicovaginal fistulae. Patients may also exhibit symptoms such as long-lasting dysuria, de novo urgency, persistent urinary leakage, hematuria, recurrent infections, chronic pain, and voiding difficulties [6].

A rigid catheter guide can be used during MUS placement to theoretically protect the bladder and urethra during trocar passage. A Foley catheter is used to place the catheter guide, which then deflects the urethra and bladder away from the trocar passage to reduce injury. 2D transperineal ultrasound demonstrates that the catheter guide displaces the bladder neck laterally by an average of 1.4 cm to either side. Since the lateral bony edges of the pubic rami are 3.6 cm apart, the blad-

Citation: Tavakoli A, Nasiri A, Lane F (2019) The Impact of the Rigid Catheter Guide on Trocar Injury during Mid-Urethral Sling Placement. Int Arch Urol Complic 5:057. doi.org/10.23937/2469-5742/1510057

Accepted: April 27, 2019: **Published:** April 29, 2019

der neck cannot be displaced further laterally [7].

Manufacturer's directions recommend surgeons use a rigid catheter guide inserted into a Foley catheter for the bottom-up approach [3]. However, the standard of care in many centers is to use the catheter guide for both the top-down and bottom-up approach. As trocars became smaller and bladder injuries became less severe, many centers started to abandon the catheter guide step during all retropubic MUS placement.

The intention of the catheter guide was to reduce bladder injury; however, we were not able to identify any published literature to validate this claim. On the other hand, two separate studies have suggested a rigid catheter does not necessarily reduce risk of trocar injury [8,9]. Bladder perforations can be debilitating to patients, especially if unrecognized. Therefore, given the number of women who choose MUS placement to treat their SUI, it is important to evaluate general risk factors and also the role of the rigid catheter guide in this popular procedure.

Methods and Materials

This was an institutional review board (IRB) approved retrospective cohort with nested case control study of 291 patients who elected to undergo a retropubic MUS procedure for urodynamic stress or mixed incontinence at an academic medical center between January 2002 - December 2012. These dates were chosen because half of the surgeons at our institute were using the rigid catheter for both the top-down and bottom-up retropubic MUS placements while others had stopped using the rigid catheter for all retropubic MUS placements. Of note, most of the slings in this study were placed via the retropubic top-down approach (98%).

The mid-urethral sling was routinely performed at the University beginning in 2001, however the first year of cases was excluded to limit surgeon experience bias. The study population comprised of women who had a physical exam notable for stress incontinence and urethral hypermobility and who had completed childbearing. Women with known or suspected disease affecting bladder function (i.e. multiple sclerosis, Parkinson's disease, spinal cord injury, etc.), women who were pregnant or desired to maintain fertility, women with histories of urethral diverticulum, women deemed medically poor candidates for abdominal surgery, and women actively undergoing chemotherapy or radiation treatment for malignancy were excluded from the study.

Each surgeon used the recommended technique for Boston Scientific's Lynx sling. First a 1 cm incision was made in the epithelium at the mid-urethra as described by Ulmsten. Then the surgeon tunneled to the descending pubic ramus bilaterally. Next, stab incisions were made along the anterior abdominal wall 2 cm from the midline on either side. The trocar was then passed through the stab incision directly over the surgeon's finger and brought through the previously made vaginal incision. A link to the instructions provided for Boston Scientific's Lynx sling can be found below.

(https://bsci-prod2-origin.adobecqms.net/content/dam/bostonscientific/uro-wh/sites/pfi/physicianResources/vac/lynx_vac_pack.pdf).

Of note, patients with bladder injury underwent 48 hours of bladder decompression with transurethral catheter followed by an office voiding trail. Passing a voiding trail was defined as voiding > 50% of the initial instilled volume (i.e. > 150 cc when 300 cc instilled).

All patients with trocar injury to the bladder were identified and compared to patients with no trocar injury. Bladder perforations were recorded when the surgeon's notes reported the passing of one or more trocars through the bladder. Surgeries were primarily performed by urogynecology fellows under the supervision of four fellowship trained female pelvic medicine and reconstructive surgery attending physicians. There was no notable difference in perforation rate between the different providers. Between the two groups, the number of patients with exposure to the trocar guide, prior sling surgery, and current systemic hormone replacement therapy were compared for possible confounders. Finally, the administration of retropubic Marcaine (30 cc per side) was compared between the cases and the controls to look for possible confounders with regard to trocar injury and post-operative voiding dysfunction.

Demographics including age, body mass index, parity, smoking, preoperative prolapse stage, and histories of prior pelvic surgery were also recorded. Voiding trial in the hospital, duration of catheterization and hospitalization, persistent stress incontinence post-sling procedure, operative details, and adverse effects after the surgery were compared between the two groups.

Patients with trocar injury to the bladder were compared to those without bladder injury using a two-group t-test or nonparametric Kruskall-Wallis test for continuous variables and Chi-square or Fisher Exact tests for categorical variables. Chi-square was also used to compare rate of cystotomy between the group that used a rigid catheter and the group that did not. Multivariate analysis to predict bladder injury was conducted using logistic regression, variables with $p < 0.10$ were included in multivariate analysis.

Results

Of the 291 patients who underwent a MUS procedure, 155 cases utilized a rigid catheter guide while 136 cases had not used a rigid catheter guide. Overall 8% (23/291) of retropubic MUS procedures were complicated by a bladder perforation. Of these 23 bladder perforations, 70% (16/23) had been in the rigid catheter group and 30% (7/23) had been in the no rigid catheter group. The overall rate of cystotomy was 10% (16/155) in the rigid catheter guide group and 5% (7/136) in the

Table 1: Demographic characteristics of patients with trocar injury vs. no trocar injury.

Characteristics	Trocar injury (n = 23) Mean (SD)	No Trocar injury (n = 268) Mean (SD)	p-value
Age (Year)	64.6 (13.6)	59.0 (13.0)	0.051
Body mass index (BMI)	25.8 (5.6)	27.5 (5.7)	0.175
Parity	2.5 (1.2)	2.8 (2.0)	0.630
	N (%)	**N (%)**	**p-value**
Smoking	2 (9%)	20 (8%)	0.700
Exposure to the rigid catheter guide	16 (70%)	139 (52%)	0.106
Hormone replacement therapy	8 (30%)	51 (19%)	0.104
Prior hysterectomy	13 (57%)	101 (38%)	0.076
Previous sling surgery	5 (22%)	25 (9%)	0.073

Table 2: Univariate analysis in patients with trocar vs. no trocar injury group.

Operative Variables	Trocar injury N (%)	No Trocar injury N (%)	p-value[a]
Concomintant surgery			
Anterior prolapse surgery	7 (30%)	79 (29%)	0.923
Posterior prolapse surgery	4 (17%)	52 (19%)	1.000
Apical prolapse surgery	1 (4%)	13 (5%)	1.000
Hysterectomy	0 (0%)	7 (3%)	1.000
Retropubic Marcaine	20 (87%)	119 (75%)	0.184
Total operative Time-mean (SD)	114.5 (45.7)	111.2 (77.1)	0.204
Blood Loss-mean (SD)	112.0 (75.7)	117.3 (99.6)	0.793
Postoperative Variables			
Postoperative sling erosion	0 (0%)	13 (5%)	0.609
Postoperative urinary retention	2 (9%)	17 (6%)	0.653
Need for sling tape release	0 (0%)	8 (3%)	1.000
New overactive bladder symptom	5 (22%)	73 (30%)	0.480
One or more UTIs	7 (30%)	47 (19%)	0.274
Postoperative reoperation	0 (0%)	11 (5%)	0.606
Passing voiding trial in hospital	3 (13%)	157 (71%)	< 0.001
Persistent stress incontinence	4 (17%)	12 (5%)	0.040
Duration of hospitalization-mean (SD)	1.7 (0.6)	1.3 (0.5)	0.001
Duration of catheterization-mean (SD)	3.6 (2.5)	1.7 (1.7)	< 0.001

[a]Fisher's exact test for categorical variables, Mann-Whitney test for continuous variables.

no rigid catheter guide group (p = 0.12). There was no statistically significant difference between the trocar injury group and the no injury group with regard to the demographic factors or with the use of the rigid catheter guide (Table 1).

Similarly, there was no statistically significant difference between the trocar injury group and no injury group in the operative variables such as concomitant surgery, retropubic Marcaine, total operative time, or blood loss (Table 2). With respect to postoperative variables, the no trocar injury group was more likely to undergo and pass the voiding trial in the hospital (Table 2). The no trocar injury group was also more likely to have a shorter duration of catheterization and hospitalization while the trocar injury group was more likely to have persistent stress incontinence (Table 2).

Post hoc power analysis revealed that with the available sample size of 291 patients, there was only 38% power to detect this difference. Given the low probability of bladder injury (8%), a cohort of 864 patients would be needed to have 80% power to detect a significant increased risk of bladder injury with use of the catheter guide. Power was also limited to detect the observed increase in bladder injury with older age and prior surgery.

In multivariate analysis, exposure to the rigid catheter guide was not associated with a significantly different risk of bladder injury after adjusting for age, prior sling, or repair surgery (Table 3).

Discussion

Bladder injury is one of the more common intraoperative problems encountered with MUS placement. The rate of bladder injury has previously been reported

Table 3: Multivariate Analysis of independent risk factors for bladder injury.

Variable	Coefficient	SE	p-value	Odds Ratio	Lower 95% CI	Upper 95% CI
Catheter guide	0.65	0.48	0.174	1.91	0.75	4.84
Age (continuous)	0.03	0.02	0.09	1.03	1.00	1.07
Prior sling or repair surgery	0.70	0.49	0.151	2.02	0.77	5.26

to range from 0.7%-24% of cases and more recently reported to occur in about 5% of retropubic sling placements [4,10]. In our study, 8% of patients had bladder injury during MUS placement, which is similar to previous reports. The manufacturer recommends using the rigid catheter guide during trocar placement to reduce the rate of bladder perforation. Neuman et al. reported that using a rigid catheter guide may be an unnecessary step during MUS placement but because of the timeline of their data they were not able to rule out surgeon's experience as a confounding variable [8]. To avoid this, our study was conducted over a much longer time period and the first year of data was eliminated to diminish experience bias. More recently, Miranne et al. also concluded that using a catheter guide does not decrease the risk of cystotomy and may be an unnecessary step [9].

Results shown in Table 3 demonstrate that use of the catheter guide during MUS placement was non-significantly higher among those with bladder perforation than among those with no injury in univariate (70% vs. 52%, p = 0.106) and multivariate analysis (OR = 1.9, p = 0.17). Also, the rate of cystotomy in the rigid catheter group was double (10% vs. 5%) the rate of cystotomy in the no rigid catheter group. Although these numbers are not statistically significant, most likely due to the limited sample size, a possible explanation for the higher number of bladder perforations in the rigid catheter group is that the urethra and bladder neck are fixed between the catheter guide and bony edge of pubic ramus and arch, and therefore, less likely to be deflected from the trocar. The rigid catheter guide requires a 16 french catheter for accommodation, which can cause local trauma. Therefore, routine utilization should continue only if risk reduction is confirmed.

Stav et al. reported previous colposuspension and previous cesarean section were all significant risk factors for bladder perforation. The authors implied that perforation might be the result of the adhesive disease to the back of the pubic bone [11]. Patients with prior hysterectomy or sling surgery were not significantly associated with bladder injury in our multivariate analysis. Also, there were no significant differences in preoperative prolapse stage, prior surgery in the anterior, posterior and apical compartments between the two groups.

Stav et al. also noted age had no impact on the risk of bladder perforation [11]. In contrast, McLennan et al. noted that the cystotomy group was on average younger and lighter than patients without bladder perforation [12]. In this study, older age trended toward an increased risk for trocar bladder injury, however, this difference was not statistically significant in multivariate analysis (OR = 1.03, 95% CI = 1.0-1.07). A possible explanation for the trend we saw is that older patients are likely to have soft tissue atrophy putting them at a higher risk of bladder perforation.

Obesity is a risk factor that remains controversial with regards to intraoperative injuries. Some studies have reported more bladder perforation in non-obese patients [13]. However, Rafii et al. noted there is no relation between obesity and the occurrence of bladder injury [14]. There was no evidence of BMI having an effect on bladder perforation in our study.

The duration of catheterization (1.73 vs. 3.61 days) and hospitalization (1.29 vs. 1.65) was longer in patients with trocar injury. This correlates with routine post-operative management of bladder perforation at our institution with catheter drainage for 24-72 hours postoperatively.

Chawla et al. reported that independent risk factors for persistent leak after sling procedures include the presence of co-morbid diseases, preoperative urgency or urinary incontinence, associated severe grade anterior prolapse, and the type of corrective procedure carried out (TVT or TOT) [15]. The trocar injury group in our study was more likely to have persistent stress incontinence (17% vs. 5%). This may be as a direct effect of trocar injury and bladder perforation or be related to the fact that in our study more patients had previous sling surgery in the trocar injury group. Patients who have had a failed sling in the past are at increased risk of persistent stress incontinence.

While this study has several strengths such as the inclusion of multiple surgeons to improve generalizability of the results, it also has limitations. Limitations include both being underpowered and information bias, as it relies on accurate record keeping. While we hypothesized several risk factors associated with increased bladder injury, one cannot conclude that risk is increased with any of these risk factors due to limited sample size.

This retrospective cohort with nested case control study failed to show a statistically significant difference in bladder injury during a MUS placement when considering various risk factors such as rigid catheter guide use, patient age, and history of prior sling surgery. These findings are most likely due to insufficient sample size and further investigation of larger groups will be re-

quired to determine whether bladder injury rates vary with the use of the rigid catheter guide.

References

1. Luber KM (2004) The definition, prevalence, and risk factors for stress urinary incontinence. Rev Urol 6: S3-S9.
2. Suskind AM, Kaufman SR, Dunn RL, Stoffel JT, Clemens JQ, et al. (2013) Population-based trends in ambulatory surgery for urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 24: 207-211.
3. Ulmsten U, Henriksson L, Johnson P, Varhos G (1996) An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 7: 81-85.
4. Ford AA, Rogerson L, Cody JD, Aluko P, Ogah JA (2017) Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev.
5. Richter HE, Albo ME, Zyczynski HM, Kenton K, Norton PA, et al. (2010) Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med 362: 2066-2076.
6. Glavind K, Larsen EH (2001) Results and complications of tension-free vaginal tape (TVT) for surgical treatment of female stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 12: 370-372.
7. Abbasy SA, Kenton K, Brubaker L, Mueller ER (2011) Measurement of transurethral bladder neck displacement during tension-free vaginal tape procedure. Int Urogynecol J 22: 721-724.
8. Neuman M (2006) The catheter straight guide does not reduce the incidence of bladder penetration during TVT placement by the experienced surgeon. Gynecol Surg 3: 23-24.
9. Miranne JM, Dominguez A, Sokol AI, Gutman RE, Iglesia CB (2015) Foley catheter guide use during midurethral slings: Does it make a difference? Can J Urol 22: 7811-7816.
10. Daneshgari F, Kong W, Swartz M (2008) Complications of mid urethral slings: Important outcomes for future clinical trials. J Urol 180: 1890-1897.
11. Stav K, Dwyer PL, Rosamilia A, Schierlitz L, Lim YN, et al. (2009) Risk Factors for Trocar Injury to the Bladder During Mid Urethral Sling Procedures. J Urol 182: 174-179.
12. McLennan MT, Melick CF (2005) Bladder perforation during tension-free vaginal tape procedures: Analysis of learning curve and risk factors. Obstet Gynecol 106: 1000-1004.
13. Lovatsis D, Gupta C, Dean E, Lee F, Lobel RW (2003) Tension-free vaginal tape procedure is an ideal treatment for obese patients. Am J Obstet Gynecol 189: 1601-1604.
14. Rafii A, Daraï E, Haab F, Samain E, Levardon M, et al. (2003) Body mass index and outcome of tension-free vaginal tape. Eur Urol 43: 288-292.
15. Chawla A, Reddy S, Thomas J (2008) Risk factors for persistent stress urinary incontinence after mid-urethral procedures. Indian J Urol 24: 130-131.