Received: 3 January 2019 | Revised: 24 February 2019 | Accepted: 3 March 2019

DOI: 10.1111/luts.12263

WILEY

ORIGINAL ARTICLE

Exploring stress urinary incontinence outcomes after sling excision for perforation or exposure

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Objective: This study assessed stress urinary incontinence (SUI) outcomes after sling excision for urinary tract perforation or vaginal exposure, and compared the outcomes of concomitant versus staged autologous fascia pubovaginal sling (AFPVS).

Methods: A retrospective chart review of all patients who underwent midurethral sling (MUS) excision for urinary tract perforation or vaginal exposure at a tertiary referral center between 2010 and 2015 was performed. Therapeutic strategies were categorized as concomitant AFPVS, staged AFPVS, and no anti-incontinence procedure.

Results: In all, 32 patients were included for analysis: 13 with vaginal tape exposure (40.6%) and 19 with urinary tract tape exposure (59.4%). In patients who had SUI prior to sling excision (43.8%), the rate of resolved or improved SUI postoperatively was higher in the concomitant AFPVS group than in those who underwent sling excision alone (83.3% vs 12.5%, respectively; $P = 0.03$). Of 18 patients with no SUI prior to sling excision, 12 experienced recurrent SUI after sling removal (66.7%). The rate of recurrent SUI was lower in patients with vaginal MUS exposure than urinary tract MUS perforation, but this did not reach statistical significance (57.1% vs 72.7%, respectively; $P = 0.63$). The rates of resolved SUI after AFPVS were comparable in patients with concomitant and staged AFPVS (66.7% vs 71.4%, respectively; $P = 0.99$).

Conclusions: Many patients with MUS perforations or exposures will have SUI at initial presentation or develop SUI after removal of the synthetic sling. The decision to perform a concomitant AFPVS or to stage the surgical management of SUI can be individualized.

KEYWORDS

complication, exposure, midurethral sling, perforation, stress urinary incontinence

1 | INTRODUCTION

Stress urinary incontinence (SUI) is common in women and increases with age with a reported prevalence of up to 30% to 60%.[1] Over the past two decades, the use of synthetic midurethral slings (MUS) has become the gold standard surgical treatment of SUI in female patients.[1,2] However, the use of MUS is associated with complications such as sling perforation into the urinary tract (bladder or urethra) or vaginal exposure, with reported rates ranging between 0.3% and 3.3% for sling perforation into the urinary tract and between 0% and 8.1% for vaginal exposure.[3–5] In most cases of tape perforation into the urinary tract and in some case of vaginal exposure (ie, when symptomatic and not responding to topical estrogen therapy), surgical excision of the sling is required.[6] This excision or removal of the sling may compromise the underlying urethral support and result in recurrent SUI.[7] Because the use of synthetic material after tape-related complications is usually considered risky, most clinicians favor autologous slings to manage recurrent SUI in these patients.[2,6] Two strategies have been described: (a) to place autologous fascia pubovaginal sling (AFPVS) at the time of sling excision; or (b) to stage the approach.[2,3,6,7] There is scant evidence regarding the risk of recurrent SUI after MUS excision for urinary tract perforation or vaginal exposure, and data regarding the outcomes of concomitant versus staged anti-incontinence surgical procedures in this population are lacking. The aims of the present study were to assess SUI outcomes after sling excision for urinary tract perforation or vaginal exposure, and to compare the outcomes of concomitant versus staged AFPVS.

2 | METHODS

2.1 | Study design

After the study had received approval from the Institutional Review Board of the New York University medical center, the charts of all patients who underwent sling revision surgery (ie, sling excision or urethrolysis) at a tertiary referral center between 2010 and 2015 were screened retrospectively. Patients were identified using the following current procedural terminology codes: 57287 (removal or revision of sling for stress incontinence), 53500 (urethrolysis), and 57295 (revision or removal of vaginal mesh). Indications for sling excision were categorized as follows: (a) tape perforation involving the urethra or the bladder (defined as urinary tract tape perforation group, 4B according to the International Urogynecological Association [IUGA] classification[8]); and (b) vaginal exposures (defined as vaginal tape exposure group, 3B according to the IUGA classification[8]). The inclusion criteria were MUS excision for urinary tract perforation or vaginal exposure. Patients who did not undergo AFPVS (either concomitant or staged) were included in the study to address our secondary aim and assess the natural history of SUI after sling excision (ie, chance of resolution in those with persistent SUI preoperatively and risk of recurrent SUI in those without persistent urinary incontinence preoperatively). The only exclusion criterion was simultaneous MUS excision and new synthetic MUS placement.

2.2 | Therapeutic strategies

Patients who had symptomatic SUI at the time of revision surgery were offered a concomitant anti-incontinence procedure, with AFPVS or a synthetic MUS. The MUS was offered only to patients with vaginal exposure, whereas those with urinary tract perforation were only offered AFPVS. Patients who developed SUI following sling excision were offered bulking agent therapy and/or an anti-incontinence pessary initially, with AFPVS performed a minimum of 3 months after sling revision if indicated. Therapeutic strategies were categorized as concomitant AFPVS and staged AFPVS.

Partial MUS excisions were performed in most cases through a transvaginal approach. Although partial by definition because the transobturator/retropubic arms were not removed, these excisions were still relatively extensive, involving all the portion of the sling accessible through a transvaginal approach. A combined (ie, transabdominal and transvaginal) approach with cystotomy was used at the surgeon's discretion in case of bladder perforation not amenable to excision through an exclusive transvaginal approach. Complete excision of the sling was performed only in case of concomitant pain. A urethroplasty was performed concomitantly in case of urethral perforation, and an indwelling urethral catheter was left for 10 to 14 days postoperatively in those cases. All sling excisions and concomitant or subsequent anti-incontinence procedures were performed by one of four board-certified Female Pelvic Medicine Reconstructive Surgery surgeons (including NR, VN and BB).

2.3 | Covariates

Information on preoperative demographics (including age and body mass index), characteristics of the original sling placement (sling route, concomitant procedures), preoperative history (pelvic radiation, menopausal state, prior vaginal surgery), presence or absence of SUI (on examination and/or on videourodynamic studies), number of pads per day preoperatively, preoperative post-void residual (PVR) volume, and the presence or absence of storage symptoms (defined as experiencing urgency, with or without urgency incontinence and frequency) was collected, as was the type of sling revision.

2.4 | Outcomes

The primary endpoint was continence status 1 month after AFPVS (either concomitant or staged) self-assessed subjectively by the patient during clinical interview and categorized as resolved, improved, stable or worsened urinary incontinence. The secondary endpoint was continence status 1 month after sling excision, defined as mentioned before.

The other outcomes of interest were postoperative PVR, number of pads used per day, new onset of storage symptoms after sling excision, the need for postoperative medical and/or surgical interventions after the index sling excision, and postoperative complications graded according to the Clavien–Dindo classification.[9] Major complications were defined as any Clavien grade ≥3 complication.

2.5 | Statistical analysis

Data are reported as the mean ± SD for continuous variables, and as proportions for nominal variables. Comparisons between groups (concomitant AFPVS vs no anti-incontinence procedure in those with SUI before sling revision, and concomitant AFPVS vs staged AFPVS) were performed using the χ^2 test or Fisher's exact test for discrete variables, and the Mann–Whitney test for continuous variables. Changes in continuous variables over time were assessed using the McNemar test. Univariate logistic regression analysis was performed to assess predictors of recurrent SUI after tape excision. For continuous variables, odd ratios (ORs) were expressed as a range (per change in regressor over entire range). Statistical analyses were performed using JMP v.12.0 (SAS Institute, Cary, North Carolina). All tests were two-sided, with $P < 0.05$ considered significant. A post hoc power calculation was included for each outcomes comparison.

3 | RESULTS

3.1 | Patient characteristics

Between 2010 and 2015, 34 patients who underwent sling excision for perforation or exposure were identified. After exclusion of two patients who underwent synthetic MUS placement at the time of MUS excision, 32 patients were included for analysis in this study: 13 with vaginal MUS exposure (40.6%) and 19 with urinary tract MUS perforation (59.4%; 13 involving the urethra and 6 involving the bladder). Patient characteristics are summarized in Table 1. The

TABLE 1 Preoperative patient characteristics

	Vaginal exposure (n = 13)	Urinary tract perforation (n = 19)	*P*-value
Age at time of revision (y)	57.2 ± 12.1	56.4 ± 13.8	0.88
BMI (kg/m^2)	30.9 ± 4.5	28 ± 4	0.14
Menopausal at time of revision	11 (84.6)	14 (77.8)	0.63
History of prior vaginal surgery	2 (15.4)	2 (10.5)	0.68
History of pelvic radiation therapy	0 (0)	0 (0)	NA
Original sling route			
Unknown	4 (30.8)	7 (36.8)	
Obturator sling	8 (61.5)	8 (42.1)	0.46
Retropubic sling	1 (7.7)	4 (21.1)	
History of prior revisions	3 (23.1)	7 (36.8)	0.41
Time from initial sling placement to excision (y)	4.9 ± 4.8	6 ± 4	0.32
Preoperative PVR (mL)	12.6 ± 13.6	100.8 ± 107.8	0.004
SUI prior to revision surgery	6 (46.2)	8 (42.1)	0.82

Abbreviations: BMI, body mass index; NA, not applicable; PVR, post-void residual; SUI, stress urinary incontinence.
Unless indicated otherwise, data are given as the mean ± SD or as n (%)..

preoperative PVR was significantly higher in the urinary tract perforation than vaginal exposure group (100.8 vs 12.6 mL, respectively; $P = 0.004$). Other preoperative characteristics were similar in both groups, including pre-sling excision SUI rates (42.1% vs 46.2%; $P = 0.82$). Most patients (29/32) underwent partial sling excision through an exclusive transvaginal approach. Two patients underwent complete sling excision with additional incision (suprapubic in one, at the obturator foramen in the other) due to pain. Another patient underwent a combined vaginal–abdominal approach with cystotomy due to severe bladder perforation.

3.2 | Concomitant pubovaginal sling versus no concomitant anti-incontinence procedure in patients with SUI prior to revision surgery

Fourteen patients had SUI prior to sling excision (43.8%): six underwent AFPVS at the time of sling excision, while the other eight decided to undergo isolated sling excision as a first step (Table 2). The rate of resolved or improved SUI postoperatively was higher in the concomitant AFPVS group (83.3% vs 12.5%; $P = 0.03$; statistical power = 81.8%). There was a significant decrease from baseline in the number of pads used per day in the concomitant AFPVS group, compared with an increase in the "no concomitant AFPVS" group (−2.7 vs +0.5 pads/d; $P < 0.0001$; statistical power = 71%). The postoperative PVR change from baseline was similar in both groups (+5 vs +4 mL; $P = 0.78$; statistical power = 5%), as was the postoperative complications rate (33.3% vs 37.5%; $P = 0.99$; statistical power = 3.8%). Complications in the "no concomitant AFPVS" group were urinary tract infections (n = 2; Clavien grade 2) and gross hematuria (n = 1), whereas all complications in the concomitant AFPVS group were urinary retention (n = 2, requiring clean intermittent catheterization for 2 weeks and 1 month respectively, Clavien grade 1). No major postoperative complication was observed in any of the two groups.

TABLE 2 Comparison of concomitant pubovaginal sling versus no concomitant anti-incontinence procedure in patients with preoperative stress incontinence

	Concomitant pubovaginal sling (n = 6)	No concomitant anti-incontinence procedure (n = 8)	*P*-value
Mean no. pads (/d)			
Baseline	5 ± 1	1.8 ± 1.1	0.12
1 month postoperatively	2.3	2.3	0.96
Change	−2.7*	0.5	<0.001
Mean PVR (mL)			
Baseline	25 ± 25	64.9 ± 78.3	0.14
1 month postoperatively	30.3 ± 30.8	68.9 ± 45.5	0.21
Change	+5 ± 47	+4 ± 82	0.78
Postoperative complications	2 (33.3)	3 (37.5)	0.99
De novo postoperative OAB symptoms	3 (50)	2 (25)	0.58
Subsequent intake of OAB medications	2 (33.3)	3 (37.5)	0.99
Postoperative continence status			0.03
SUI resolved	4 (66.7)	0 (0)	
SUI improved	1 (16.7)	1 (12.5)	
SUI unchanged	1 (16.7)	3 (37.5)	
SUI worsened	0 (0)	4 (50)	
Subsequent synthetic or pubovaginal sling	0 (0)	4 (50)	0.08

Abbreviations: OAB, overactive bladder; PVR, post-void residual; SUI, stress urinary incontinence.
Unless indicated otherwise, data are given as the mean ± SD or as n (%).
*Significant change from baseline ($P < 0.05$).

3.3 | Recurrence of SUI in patients with no SUI prior to revision surgery

Of 18 patients with no SUI prior to MUS excision, 12 experienced recurrent SUI after sling removal (66.7%). The rates of recurrent SUI were lower in patients with vaginal MUS exposure versus urinary tract MUS perforation, but this difference did not reach statistical significance (57.1% vs 72.7%; $P = 0.63$; statistical power = 10.3%). No predictive factors of recurrent SUI were found in univariate logistic regression analysis (Table 3). After a median follow-up of 11.8 months after sling excision, eight of 18 patients with no SUI prior to sling excision (44.4%) had undergone a subsequent anti-incontinence procedure: two with bulking agents, two with a synthetic MUS and four AFPVS.

3.4 | Concomitant versus staged pubovaginal sling

Six patients underwent concomitant AFPVS at the time of sling excision and seven patients underwent AFPVS subsequent to sling excision (three with SUI prior to sling excision and four with recurrence of SUI after sling excision). The rates of resolved SUI after AFPVS were comparable in both groups (66.7% vs 71.4%; $P = 0.99$; statistical

TABLE 3 Predictors of recurrent stress urinary incontinence after sling excision (univariate analysis)

	OR (95% CI)	*P*-value
Interval between sling placement and mesh excision	2.71 (0.11–8.31)	0.53
Body mass index	5.76 (0.11–13.42)	0.47
Age	4.08 (0.29–9.00)	0.45
Indication for mesh excision		
Vaginal exposure	1 (reference)	–
Urinary tract perforation	2 (0.26–16.04)	0.49
Prior vaginal surgery	0.45 (0.16–13.07)	0.60
Concomitant urethroplasty	2 (0.27–18.76)	0.50

Abbreviations: CI, confidence interval; OR, odds ratio.

power = 3.8%) with a similar change in the number of pads postoperatively compared with baseline (−2.7 vs −2.3 /d; $P = 0.73$; statistical power = 6%; Table 4). The rates of postoperative complications did not differ significantly between the two groups (33.3% vs 42.9%; $P = 0.99$; statistical power = 5.2%). Most of these complications were urinary retention (Clavien grade 1), with similar rates in both groups (33.3% vs 28.6%; $P = 0.99$; statistical power = 3.8%). No major postoperative complication was observed in any of the two groups.

4 | DISCUSSION

There are no formal guidelines regarding the management of urinary tract perforations or vaginal exposures of MUS, but sling excision is usually performed in most of these patients.[10] The main caveat of sling excision is recurrent or worsened SUI, with a prevalence of postoperative SUI in this population up to 92% depending upon the extent of tape excision.[11] Concomitant anti-incontinence procedures may then be seen as attractive options to address, within a single procedure, both the tape complication and the risk of recurrent SUI.[12] However, evidence from the literature to support such a simultaneous approach is scarce. In the present series, we found that concomitant AFPVS at the time of tape excision did not increase perioperative morbidity while alleviating SUI in most patients. Furthermore, both concomitant and staged AFPVS provided similar functional outcomes with comparable postoperative complications rates. However, to properly analyze our findings, one should keep in mind our relatively small sample size with inherently underpowered statistical analyses. This prevented accurate estimation of the possible downsides of concomitant AFPVS, such as de novo urgency or voiding dysfunction. Although very difficult to demonstrate scientifically, one could also argue that concomitant AFPVS may jeopardize the assessment of possible benefits from the sling excision itself, for example in terms of obstruction or urgency, by acting as a confounder.

To our knowledge, concomitant pubovaginal sling at the time of sling excision has been reported in only three series to date.[12–14] Starkman et al[14] reviewed 19 patients who had undergone removal of MUS for treatment of sling perforation and exposure and reported recurrent SUI in 42% of patients. A concomitant AFPVS was placed in five patients for preoperative SUI. With 100% of these five patients cured of their SUI, Starkman et al[14] concluded that a concomitant

TABLE 4 Comparison of patient characteristics and outcomes for concomitant versus subsequent pubovaginal sling

	Concomitant pubovaginal sling (n = 6)	Subsequent pubovaginal sling (n = 7)	*P*-value
Mean no. pads (/d)			
Baseline	5 ± 1	2.9 ± 1.1	0.27
1 month postoperatively	2.3 ± 4.8	0.5 ± 0.8	0.73
Change	−2.7 ± 1.1*	−2.4 ± 1.1*	0.94
Postoperative complications	2 (33.3)	3 (42.9)	0.99
De novo postoperative storage symptoms	3 (50)	3 (28.6)	0.59
Postoperative continence status			0.99
SUI resolved	4 (66.7)	5 (71.4)	
SUI improved	1 (16.7)	2 (28.6)	
SUI unchanged	1 (16.7)	0 (0)	
SUI worsened	0 (0)	0 (0)	

Abbreviation: SUI, stress urinary incontinence.
Unless indicated otherwise, data are given as the mean ± SD or as n (%)..
*Significant change from baseline ($P < 0.05$).

AFPVS may help reduce recurrent SUI, although a significant proportion of patients who did not have concomitant sling placement did not require a staged procedure. Shah et al[12] reported a retrospective series of 21 patients with urethral or bladder perforation with concomitant pubovaginal sling in 19 of these patients. Continence rates of 71% were reported, although Shah et al[12] did not distinguish between those with concomitant repair or not. More recently, in the largest series to date, McCoy et al[13] reported similar success rates in 30 patients with concomitant pubovaginal sling and 16 patients with staged AFPVS after sling revision (80% vs 69%), but indications for revision surgery were heterogeneous (only 33% of perforation). Hence, our findings confirm those of previous series and suggest, for the first time, that the concomitant versus staged AFPVS placement may provide similar outcomes in the specific setting of tape excision for sling perforation.

Due to concerns regarding a possibly higher risk of MUS perforation in patients with a history of sling perforation or exposure, autologous slings are usually favored over synthetic MUS. To our knowledge, concomitant synthetic sling placement at the time of sling excision has not been reported. However, as a staged management, minimally invasive options such as bulking agents could bring satisfactory outcomes according to a recent series.[15] Postponing surgical treatment could make SUI amenable to less invasive anti-incontinence procedures, and the benefits and harms of this recently described approach should be weighed against those of concomitant or staged AFPVS to design future treatment algorithms. Hopefully future large randomized study will help better determine the role of SUI surgery at the time of sling revision, but this choice may ultimately still need to be individualized. Sling removal and/or sling revisions are the results of unexpected outcomes, and this may influence the outlook of the parties involved and the perceived risk of future anti-incontinence treatment.

The recurrent SUI rates reported in our series, ranging from 57.1% (vaginal mesh exposure) to 72.7% (urinary tract perforation), appear relatively high compared with other series of sling revision.[4,7] This may be due to the extensive dissection or tape excision performed in our cohort, with removal of all the portion of tape

accessible through a transvaginal approach, compared with sling incision or limited excision usually performed for example in case of bladder outlet obstruction. The extent of the tape removed at the time of sling revision is probably a key determinant of SUI recurrence. Although difficult to assess and report in a standardized way, a thorough evaluation of the optimal amount of tape to be excision for each type of sling-related complication may be of great help in treatment algorithms. In view of these very high rates of recurrent SUI, concomitant AFPVS may appear as an appropriate option for patients undergoing sling excision, especially for those with SUI before revision.

The present study has several limitations that should be acknowledged. The relatively small sample size is the main drawback of the study, which we tried to balance by adding post hoc power calculation. It is likely that some of the differences observed (e.g. the rates of recurrent SUI in the vaginal exposure vs urinary tract perforation group) would have been statistically significant with a larger cohort. Several interesting outcomes of interest, such as pad test, were not available in this retrospective chart review or validated questionnaires were not available owing to the retrospective nature of the study. Another drawback of the present study is the relatively short follow-up, which did not allow assessment of the long-term safety of concomitant AFPVS versus other management options. We decided to focus the analysis on the 1-month outcomes because they were available for all patients and because the primary endpoint (ie, postoperative SUI) is an immediate postoperative occurrence unlikely to either appear or resolve over time during follow-up. However, this could be regarded as a possible limitation of the present study. Purely prophylactic AFPVS in patients without SUI preoperatively was not assessed in the study, but our findings confirming the very high rate of recurrent SUI and the satisfactory outcomes of simultaneous AFPVS may warrant further investigation. Some factors that may have an effect on the decision to perform or not concomitant anti-incontinence surgery were not assessed in our series. For example, the lack of local inflammation may justify performing concomitant AFPVS, whereas the presence of infected tape would suggest staging the surgical treatment of SUI. Unfortunately, our analysis was not adjusted for this confounder because these data were not available. Finally, surgeons involved in this series were high-volume, fellowship-trained providers, and thus our findings may not be applicable to lower-volume surgeons and institutions.

In conclusion, many patients with MUS perforations or exposures will have SUI at initial presentation or develop SUI after removal of the synthetic sling. Concomitant AFPVS at the time of tape excision did not increase perioperative morbidity (vs tape excision alone) and provided satisfactory functional outcomes. Concomitant versus staged AFPVS were similar in terms of functional outcomes and perioperative morbidity. The present series suggests that performing a concomitant AFPVS may be reasonable in patients with SUI prior to sling excision and that the surgical management of SUI should be staged in those without SUI prior to sling excision. Larger studies with longer follow-up are now needed to confirm the appropriate care pathways for these patients.

DISCLOSURE

The authors declare no conflicts of interest.

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How to cite this article: Syan R, Peyronnet B, Drain A, et al. Exploring stress urinary incontinence outcomes after sling excision for perforation or exposure. *Lower Urinary Tract Symptoms*. 2019;1–5. https://doi.org/10.1111/luts.12263