Published in final edited form as:

Int J Urol. 2014 November ; 21(11): 1167–1170. doi:10.1111/iju.12544.

Analysis of patient and technical factors associated with midurethral sling mesh exposure and perforation

David J Osborn, Roger R Dmochowski, Catherine J Harris, Jill J Danford, Melissa R Kaufman, Stephen Mock, Laura Chang Kit, Benjamin McCormick, and W Stuart Reynolds

Department of Urology, Vanderbilt University Medical Center, Nashville, Tennessee, USA

Abstract

Objectives—To evaluate the technical and patient characteristics associated with the development of mesh perforation and exposure in patients after midurethral sling surgeries.

Methods—After a retrospective review of referred patients, the risk of mesh perforation of the urinary tract over exposure in the vagina was analyzed with multivariate logistic regression, adjusting for the possible predictors of age, body mass index, smoking status at the time of mesh placement, presence of diabetes, type of sling placed, type of surgeon and trocar injury at the time of mesh placement.

Results—A total of 77 women were identified, 27 with mesh perforation and 50 with mesh exposure. The patients' average body mass index was 29.2, and 13% were diabetic. Nine (33%) patients in the perforation group and two (4%) patients in the exposure group had evidence of trocar injury to the bladder or urethra at the time of mesh placement ($P < 0.001$). After multivariate logistic regression analysis, trocar injury (odds ratio 25.90, 95% confidence interval 2.84–236.58, $P = 0.004$) and diabetes (odds ratio 9.90, 95% confidence interval 1.125–78.64, $P = 0.03$) were associated with an increased risk of mesh perforation. Increased body mass index (odds ratio 0.88, 95% confidence interval 0.77–0.99, $P = 0.05$) was associated with a decreased risk of mesh perforation. Finally, postoperative hematomas and blood transfusions occurred more commonly in the mesh perforation group (15% vs 0%, $P = 0.01$).

Conclusions—Trocar injury, diabetes and bleeding complications at the time of surgery are associated with higher risk of mesh perforation in patients undergoing midurethral sling placement.

Keywords

complication; erosion; extrusion; incontinence; trocar

Correspondence: David James Osborn M.D., Department of Urology, Vanderbilt University Medical Center, A1302 Medical Center North, Nashville, TN 37232-2765, USA. david.osborn@vanderbilt.edu.

Conflict of interest
None declared.

Introduction

Before 1998, the most common surgeries for stress urinary incontinence were retropubic urethropexies, needle suspensions, autologous pubovaginal slings and collagen injections.¹ In 1998, the Food and Drug Administration approved the first midurethral sling for stress urinary incontinence. Over the next 10 years, the utilization of the midurethral sling increased dramatically, and multiple studies have shown its benefit over traditional surgeries for stress urinary incontinence not utilizing mesh.^{2,3} However, as the utilization of synthetic mesh increased, complications related to its implantation started to become apparent.⁴

The most common complications of mesh surgery are mesh exposure and dyspareunia, and the most serious complications are perforation of organs, such as the bladder, urethra and bowel. In 2010, the International Continence Society and International Urogynecological Association released a report intended to clarify and standardize the terminology related to complications from insertion of synthetic and biological materials during female pelvic floor surgery.⁵ According to that report, synthetic mesh is termed a prosthesis and a biological implant is termed a graft. Mesh located in the bladder or urethra is termed a perforation and extrusion of mesh through the vagina or skin is termed exposure.

Ranging from 0 to 8.1% in the literature, mesh exposure rates are variable with midurethral slings.^{6,7} In addition, the rate of bladder or urethral injury with a trocar at the time of surgery is also variable and ranges from 2.7 to 23.8%.^{8,9} Though few studies comment on mesh perforation into the bladder or urethra, the incidence in the literature falls between 0 and 0.6%.^{3,10,11} The purpose of the present study was to evaluate technical and patient characteristics associated with mesh perforation and mesh exposure after midurethral sling surgeries that utilize a trocar and synthetic mesh.

Methods

The Vanderbilt Institutional Review Board (IRB# 121734) approved the present retrospective study. The electronic medical records of all female patients referred to the urology and urogynecology services at Vanderbilt University Medical Center for mesh exposure and mesh perforation from January 2003 to January 2012 were reviewed. Patients were identified using Common Procedural Terminology (CPT) codes for endoscopic foreign body removal, urethrolisis, sling revision or removal, female urethroplasty, cystorraphy and simple or partial cystectomy. Any patient whose source procedure operative report was not available was excluded. The operative reports were examined for the following study variables: age, implanting surgeon (urologist or gynecologist), source procedure and perioperative complications. Symptoms and time to recognition and repair were also studied.

Statistical analysis

Discrete variables are reported as frequency and proportions as percentages. Continuous variables are reported as median and mean values. Initial statistical analysis of continuous variables, such as age, was carried out using the *t*-test mean comparison test, and analysis of categorical variables was carried out using Pearson's χ^2 -test or Fisher's exact test. The eligible cohort of patients was separated into two groups: patients who had mesh exposure in

the vagina and patients who had mesh perforation into the bladder or urethra. The associations between mesh perforation and age, BMI, smoking status, diabetes, type of surgeon, location of trocar passage, and perioperative complications including trocar injury were assessed with multivariate logistic regression.

Results

Overall, 123 patients were referred for mesh exposure ($n = 80$) and perforation ($n = 43$) related to midurethral sling surgery over the 10-year study period. Source operative reports were available for 77 patients (67%), who were included in this analysis. Of the 77 women, 27 had mesh perforation and 50 had vaginal mesh exposure. In the mesh perforation group, 15 women had mesh perforation of the urethra and 12 women had mesh perforation of the bladder. The average age was 49.4 years (range 26–81 years). The median time between mesh placement and presentation was 9.5 months (IQR 32). Table 1 shows the results of a comparison of demographic and clinical variables between the two study groups.

Trocar injury was defined as a trocar that had to be removed and replaced at the time of mesh placement because it was found to be in or too close to the bladder or urethral lumen during cystoscopy. In total, there were 11 documented trocar injuries. Only one of these 11 patients underwent transobturator midurethral sling placement.

Overall, four patients (all in the perforation group) developed a bleeding complication in the immediate postoperative period. There were two pelvic hematomas, one vaginal hematoma and one blood transfusion. Only one patient with a documented trocar injury at the time of surgery developed a bleeding complication.

Overall, 83% (64) of patients had a documented cystoscopy after passage of the midurethral sling trocar and 17% (13) of the study population did not. A total of 12 patients with no documented cystoscopy underwent a transobturator sling and one underwent a retropubic sling. Patients were defined as having a prior hysterectomy if they had a history of hysterectomy on a previous day. Patients were defined as having concomitant pelvic surgery if they underwent prolapse repair or a hysterectomy at the same time as their sling surgery.

The presenting symptom was the primary complaint of the patient at the time when their mesh perforation or exposure was first diagnosed. Table 2 shows the results of the different presenting symptoms in the two groups of patients. In the perforation group, five of the seven patients with incontinence had a concomitant vesicovaginal fistula. In 16 (59%) patients, mesh perforation was discovered on the first postoperative cystoscopy, and in eight (30%) patients perforation was discovered on the second cystoscopy.

After adjusting for covariates, an increased risk of mesh perforation was associated with trocar injury (OR 25.90, 95% CI 2.84–236.58) and diabetes (OR 9.90, 95% CI 1.1.25–78.64). Increased BMI appeared protective, with a decreased risk of mesh perforation (OR 0.88, 95% CI 0.77–0.99). Age, smoking status, the type of performing surgeon, previous incontinence surgery, concomitant pelvic surgery and transobturator versus retropubic trocar placement were not found to be significant risk factors for mesh perforation. Table 3 shows the results of a multivariate analysis of independent variables for mesh perforation.

Discussion

The present study sought to examine mesh complications after midurethral sling surgery by comparing two groups of patients that are commonly referred for tertiary surgical consultation. Because mesh perforation of the lower urinary tract is such a rare complication, it is difficult to examine this issue in a prospective manner. With an incidence rate of 0.6%, there is only one randomized prospective study in the literature that comments on mesh perforation into the bladder or urethra as an adverse event after midurethral sling surgery.³ Interestingly, this 0.6% incidence is consistent with the rate of mesh urinary tract perforation in two retrospective studies of over 1000 patients who underwent midurethral sling surgery.^{11,12}

In 2007, Chen *et al.* carried out a retrospective study of 247 patients who underwent consecutive midurethral sling surgeries, and found that diabetes mellitus was a significant risk factor for vaginal exposure.¹³ In the study herein described, diabetes mellitus was associated with an increased risk of mesh perforation into the bladder. Poor wound healing is a known problem related to diabetes mellitus after pelvic surgery.¹⁴ It is possible that diabetes affects the normal incorporation of mesh into the tissue of the pelvis.

In 2010, Stav *et al.* presented their results of a retrospective study of 1136 patients who underwent midurethral sling surgery examining risk factors related to trocar injury at the time of sling placement. That study found that among other factors, a low BMI ($<30 \text{ kg/mg}^2$) was associated with an increased risk of trocar injury. Similarly, the present study found a significant relationship between lower BMI and an increased risk of mesh perforation into the bladder or urethra. This might also have to do with the possibility that increased adipose tissue displaces the bladder away from the pubic bone. Surgeons should therefore make extra effort to stay in contact with the posterior bony surface during trocar passage in thin patients.

Previous studies have shown an association between concomitant pelvic surgery at the time of midurethral sling placement and complications.¹⁵ In the present study, we found no association between concomitant pelvic surgery and mesh perforation compared with exposure. In addition, previous studies have shown an increased incidence of bladder trocar injury in patients with previous incontinence surgery.^{16,17} Although the rate of previous incontinence surgery in the study herein described was higher in the mesh perforation group, this did not reach statistical significance.

In an attempt to examine if surgical training or experience was associated with a lower rate of mesh perforation, surgeon type was analyzed. Although univariate analysis showed that the rate of mesh perforation was higher with urologists, this significance was not maintained with multivariate analysis.

The established methods to prevent trocar bladder injury during midurethral sling surgery are to ensure that the bladder is drained before trocar passage and to keep the trocar in contact with the inferior surface of the pubic symphysis or ischiopubic rami during trocar passage. In addition, cystoscopy should always be carried out with a 70-degree lens in a completely filled bladder so that a fold of mucosa does not obscure a trocar injury.

Trocar injury to the bladder at the time of midurethral sling surgery is traditionally thought of as a benign complication; however, in the present study we found that it could be a risk factor for eventual mesh perforation. The limitations of the present small retrospective study make it impossible to conclusively state that there is a direct causal link between trocar injuries and mesh perforation. Clearly there are many potential confounding variables, such as a surgeon experience, and other unknown patient factors that might have contributed to this result. Further research in this area is required, but will most likely be limited by the uncommon nature of this complication.

In the present study, the time from mesh placement to diagnosis was delayed significantly more in the mesh perforation group when compared with the exposure group (22 vs 6 months). This highlights the need for physicians to maintain a high level of suspicion for mesh perforation in patients with hematuria or other lower urinary tract symptoms after midurethral sling surgery. Interestingly, even if a provider does suspect mesh perforation, the first cystoscopy after surgery only revealed mesh 59% of the time.

In our 10-year study from 2003 to 2012, 83% of surgeons documented an intraoperative cystoscopy. In the early 2000s, there was still considerable debate among pelvic surgeons as to whether intraoperative cystoscopy was necessary after midurethral sling surgery or anterior prolapse repairs.¹⁸ In fact, initial marketing of the transobturator and single-incision midurethral slings advertised the lack of need for intraoperative cystoscopy as an advantage over retropubic midurethral slings.¹⁹ Intraoperative cystoscopy is recommended by the authors of the present article during sling and prolapse surgeries to increase identification of intraoperative urinary tract injuries, which would otherwise be missed.^{20,21}

Patients with mesh perforation were also more likely to have a perioperative hematoma or require a blood transfusion after midurethral sling surgery. It is possible that bleeding complications are independent risk factors that contribute to mesh perforation. However, it is more likely that bleeding and mesh perforation of the urinary tract complications are the result of a mixture of patient and surgical factors.

In conclusion, mesh perforation into the urinary tract is an increasingly referred complication to tertiary care referral centers. Patients often have a delay in diagnosis and subsequent management when compared with mesh exposure patients. Our analysis suggests the risk for mesh perforation after midurethral slings is increased in patients with diabetes and trocar injury at the time of the procedure, and is inversely related to BMI. Although trocar injury at the time of midurethral sling surgery is traditionally thought of as a benign complication with no increased risk of an adverse outcome, the present study shows that this might not be the case. Because of the low incidence of mesh perforation, the results of the present study do not change the fact that if a trocar injury occurs during midurethral sling surgery, the surgeon should replace the trocar until it is outside the urinary tract and continue with the procedure.

Abbreviations & Acronyms

BMI body mass index

IQR interquartile range
UTI urinary tract infection

References

1. Jonsson Funk M, Levin PJ, Wu JM. Trends in the surgical management of stress urinary incontinence. *Obstet. Gynecol.* 2012; 119:845–851. [PubMed: 22433349]
2. Jonsson Funk M, Siddiqui NY, Kawasaki A, Wu JM. Long-term outcomes after stress urinary incontinence surgery. *Obstet. Gynecol.* 2012; 120:83–90. [PubMed: 22914395]
3. Ward KL, Hilton PUK. Ireland TVT Trial Group. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. *BJOG.* 2008; 115:226–233. [PubMed: 17970791]
4. Novara G, Galfano A, Boscolo-Berto R, et al. Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. *Eur. Urol.* 2008; 53:288–308. [PubMed: 18031923]
5. Haylen BT, Freeman RM, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related to native tissue female pelvic floor surgery. *Int. Urogynecol. J.* 2012; 23:515–526. [PubMed: 22527748]
6. Zullo MA, Plotti F, Calcagno M, et al. One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence: a prospective randomised trial. *Eur. Urol.* 2007; 51:1376–1382. discussion 1383–4. [PubMed: 17110021]
7. Tseng L-H, Wang AC, Lin Y-H, Li SJ, Ko YJ. Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women. *Int. Urogynecol. J. Pelvic Floor Dysfunct.* 2005; 16:230–235. [PubMed: 15875240]
8. Andonian S, Chen T, St-Denis B, Corcos J. Randomized clinical trial comparing suprapubic arch sling (SPARC) and tension-free vaginal tape (TVT): one-year results. *Eur. Urol.* 2005; 47:537–541. [PubMed: 15774255]
9. Porena M, Costantini E, Frea B, et al. Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial. *Eur. Urol.* 2007; 52:1481–1490. [PubMed: 17482343]
10. Richter HE, Albo ME, Zyczynski HM, et al. Retropubic versus transobturator midurethral slings for stress incontinence. *N. Engl. J. Med.* 2010; 362:2066–2076. [PubMed: 20479459]
11. Hammad FT, Kennedy-Smith A, Robinson RG. Erosions and urinary retention following polypropylene synthetic sling: Australasian survey. *Eur. Urol.* 2005; 47:641–646. discussion 646–7. [PubMed: 15826756]
12. Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstet. Gynecol. Scand.* 2002; 81:72–77. [PubMed: 11942891]
13. Chen H-Y, Yeh L-S, Chang W-C, Ho M. Analysis of risk factors associated with surgical failure of inside-out transobturator vaginal tape for treating urodynamic stress incontinence. *Int. Urogynecol. J. Pelvic Floor Dysfunct.* 2007; 18:443–447. [PubMed: 16909193]
14. Christian CK, Kwaan MR, Betensky RA, Breen EM, Zinner MJ, Bleday R. Risk factors for perineal wound complications following abdominoperineal resection. *Dis. Colon Rectum.* 2005; 48:43–48. [PubMed: 15690656]
15. Anger JT, Litwin MS, Wang Q, Pashos CL, Rodriguez LV. The effect of concomitant prolapse repair on sling outcomes. *J. Urol.* 2008; 180:1003–1006. [PubMed: 18639303]
16. Lo T-S, Horng S-G, Chang C-L, Huang H-J, Tseng L-H, Lian C-C. Tension-free vaginal tape procedure after previous failure in incontinence surgery. *Urology.* 2002; 60:57–61. [PubMed: 12100922]

17. Rezapour M, Ulmsten U. Tension-Free vaginal tape (TVT) in women with recurrent stress urinary incontinence-a long-term follow up. *Int. Urogynecol. J. Pelvic Floor Dysfunct.* 2001; 12(Suppl 2):S9–S11. [PubMed: 11450980]
18. Kwon CH, Goldberg RP, Koduri S, Sand PK. The use of intraoperative cystoscopy in major vaginal and urogynecologic surgeries. *Am. J. Obstet. Gynecol.* 2002; 187:1466–1471. discussion 1471–2. [PubMed: 12501048]
19. Farrell S, Chan M, Schulz J. Midurethral minimally invasive sling procedures for stress urinary incontinence. *J. Obstet. Gynaecol. Can.* 2008; 30:728–733. [PubMed: 18786297]
20. Appell RA, Dmochowski R, Blaivas JG. Guideline for the surgical management of female stress urinary incontinence: 2009 Update.
21. ACOG Committee Opinion. Number 372. July 2007. The role of cystourethroscopy in the generalist obstetrician-gynecologist practice. *Obstet. Gynecol.* 2007; 110:221–224. [PubMed: 17601926]

Table 1

Demographic and clinical characteristics of patients with mesh perforation and mesh exposure

Variables	Mesh perforation (<i>n</i> = 27)	Mesh exposure (<i>n</i> = 50)	<i>P</i> -value
Age	50.1 ± 12.1	49.0 ± 11.5	0.68
BMI	28.0 ± 5.2	29.9 ± 6.0	0.18
Smoker	7 (26)	16 (32)	0.31
Diabetes	5 (19)	3 (6)	0.09
Prior hysterectomy	23 (85)	43 (86)	0.92
Concomitant pelvic surgery	10 (37)	27 (54)	0.15
Previous Incontinence surgery	5 (18)	3 (6)	0.09
Cystoscopy performed	22 (81)	42 (84)	0.78
Trocar injury	9 (33)	2 (4)	<0.001
Postoperative hematoma or transfusion	4 (15)	0	0.01
Type of surgeon			
Gynecologist	13 (48)	27 (74)	0.03
Urologist	14 (52)	13 (26)	0.03
Direction of trocar passage			
Retropubic	20 (74)	27 (54)	0.09
Transobturator	7 (26)	23 (46)	0.09
Median (IQR) months presentation	22 (47)	6 (16.2)	0.01
Urinary presenting primary symptom	19 (70)	2 (4)	<0.001

Mean ± SD, *n* (%). Months presentation, months from mesh placement to discovery of complication.

Table 2

Comparison of primary presenting symptom between two groups

Presenting symptom, <i>n</i> (%)	Mesh perforation (<i>n</i> = 27)	Mesh exposure (<i>n</i> = 50)	<i>P</i> -value
Dyspareunia	2 (7)	18 (36)	0.01
Vaginal bleeding	0	10 (20)	0.01
Vaginal pain	4 (15)	10 (20)	0.57
Felt on exam	0	4 (8)	0.13
Partner sexual discomfort	0	3 (6)	0.19
Vaginal discharge	0	3 (6)	0.19
Incontinence	7 (26)	1 (2)	0.001
Recurrent UTI	2 (7)	0	0.05
Hematuria	1 (4)	0	0.17
Irritative voiding symptoms	11 (41)	1 (2)	<0.001

Table 3

Multivariate analysis of independent variables for mesh perforation

Variable	Odds ratio	95% confidence interval	P-value
Age	1.00	0.95–1.06	0.86
BMI	0.88	0.77–0.99	0.05
Concomitant pelvic surgery	0.43	0.11–1.62	0.21
Diabetes	9.90	1.25–78.64	0.03
Previous incontinence surgery	4.19	0.59–29.65	0.15
Retropubic trocar passage	0.92	0.24–3.50	0.90
Smoker	0.73	0.18–2.88	0.65
Trocar injury	25.90	2.84–236.58	0.004
Type of surgeon	1.40	0.40–4.94	0.60