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Postoperative pain outcomes after transvaginal mesh revision

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Abstract

Introduction and hypothesis—Although the current literature discusses mesh complications including pain, as well as suggesting different techniques for removing mesh, there is little literature regarding pain outcomes after surgical removal or revision. The purpose of this study is to determine if surgical removal or revision of vaginal mesh improves patient's subjective complaints of pelvic pain associated with original placement of mesh.

Methods—After obtaining approval from the Vanderbilt University Medical Center Institutional Review Board, a retrospective review of female patients with pain secondary to previous mesh placement who underwent excision or revision of vaginal mesh from January 2000 to August 2012 was performed. Patient age, relevant medical history including menopause status, previous hysterectomy, smoking status, and presence of diabetes, fibromyalgia, interstitial cystitis, and chronic pelvic pain, was obtained. Patients' postoperative pain complaints were assessed.

Results—Of the 481 patients who underwent surgery for mesh revision, removal or urethrolysis, 233 patients met our inclusion criteria. One hundred and sixty-nine patients (73 %) reported that their pain improved, 19 (8 %) reported that their pain worsened, and 45 (19 %) reported that their pain remained unchanged after surgery. Prior history of chronic pelvic pain was associated with increased risk of failure of the procedure to relieve pain (OR 0.28, 95 % CI 0.12–0.64, p=0.003).

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Conflicts of interest None.

Conclusions—Excision or revision of vaginal mesh appears to be effective in improving patients' pain symptoms most of the time. Patients with a history of chronic pelvic pain are at an increased risk of no improvement or of worsening pain.

Keywords

Mesh; Pelvic pain; Mesh exposure; Mesh revision; Mesh excision

Introduction

A US woman has an 11 % lifetime risk of undergoing surgery for urinary incontinence (UI) or pelvic organ prolapse (POP) by the age of 80 [1]. Since the introduction of vaginally placed synthetic mesh biomaterials (i.e., synthetic midurethral sling and transvaginal mesh prolapse systems or "mesh kits"), surgical treatment for UI and POP has changed dramatically over the past decade, marked by a rapid rise in the numbers of women treated [2]. In 2010, approximately 75,000 women underwent transvaginal mesh placement for POP and 210,000 for SUI [3]. Although these devices have improved outcomes [4], complications have also increased [5, 6], prompting the US Food and Drug Administration (FDA) to issue notifications regarding the safety and efficacy of polypropylene mesh used for pelvic organ prolapse [3]. Midurethral slings were omitted from this FDA warning and have been proven to be safe and efficacious for urinary incontinence. However, they are not without complications. An unfortunate, growing phenomenon facing all pelvic surgeons is the management of women with pelvic mesh complications, as this condition is multifaceted, complex, and challenging to treat.

Common complaints among patients with mesh complications are vaginal exposure, viscous perforations, infection, dyspareunia, partner pain, pelvic pain, and bladder pain [7]. The current published literature contains a myriad of studies describing the incidence and the management of most mesh complications [8–10]; however, there are few data regarding pain outcomes after surgical removal or revision. Pain in particular is an increasingly common reason why women are seeking mesh removal. However, the prevalence of chronic pelvic pain in the general population is 12–20 % [11]. It is estimated that 850 per 100,000 patients self-report interstitial cystitis, and fibromyalgia prevalence is 2 %.With this knowledge that pain is a complicated process, the objective of our study is to determine if patients who have undergone surgical procedures for mesh complications have experienced improvement of their pain. The secondary objective is to determine if there are any underlying characteristics that might be predictive of worse outcomes after surgery for pain from vaginally placed mesh.

Materials and methods

After Vanderbilt University Medical Center Institutional Review Board (IRB) approval, a retrospective analysis was performed. Using CPT codes 53500, 57287, 57295, 57296, a database of all women who underwent vaginal mesh excision, revision or urethrolysis between January 2000 and August 2012 in two departments, Urology and Gynecology, was

formed. Study data were collected and managed using RED-Cap electronic data capture tools hosted at Vanderbilt University [12].

Each patient encounter with the surgeon was evaluated. All visits that occurred prior to the mesh-revision surgery were reviewed for complaints of vaginal and/or pelvic pain. Patients were included in the study if the pain met two criteria: if the patient's pain began or worsened after placement of the mesh, and if the patient and/or provider attributed the pain to the mesh placement. The exclusion criterion was if the patient did not complain of pain prior to mesh excision or revision.

Once patients met the inclusion criteria, relevant demographic and medical data were extracted from the electronic medical record including: age; prior hysterectomy; menopause status; smoking history; diagnoses of diabetes, fibromyalgia, interstitial cystitis, and chronic pelvic pain; pre-revision physical examination findings and intraoperative revision findings of any vagina exposure or bladder or urethral perforation. When available, original operative reports for mesh placement were reviewed. Mesh placement surgeries were categorized as the following: apical; bladder neck suspension; anterior; posterior; anterior and posterior; sling; sling and apical; sling and anterior; sling and posterior; and sling, anterior, and posterior.

The primary outcome was defined as the patient's perception of pain improvement after revision/removal. This was determined from the most recent follow-up visit to the surgeon and if he or she categorized the patient's pain as better, worse or unchanged. The total duration of postoperative follow-up was calculated from the most recent visit with any provider in the Urology or Gynecology departments.

Chi-squared or Fisher's exact test was used for descriptive comparisons. Multivariate logistic regression modeling was used to determine the associations between pain improvement (vs no change or worse) when taking into account each potential risk factor for pain, including menopause, hysterectomy, smoking status, presence of diabetes, fibromyalgia, interstitial cystitis, chronic pelvic pain, vaginal mesh exposure, bladder perforation or extrusion, and urethral perforation or extrusion. Statistical significance was defined as $p < 0.05$. All analyses were performed using Stata 13.1 software.

Results

The original database collected 481 patients who underwent vaginal mesh revision, excision or urethrolysis. Of these 481 patients, 233 met our inclusion criteria of complaints of pain prior to mesh excision. Mean age of patient was 54 (range 23–89) and median follow-up was 12 months (range 1–120). The majority of these patients were postmenopausal (181, 78 %) and had undergone a prior hysterectomy (189, 81 %). Seventeen (7 %) patients reported a pre-existing history of fibromyalgia, 11 (5 %) of interstitial cystitis and 28 (12 %) of chronic pelvic pain before index mesh placement surgery (Table 1). Of the original mesh placement surgery, slings were placed in 187 patients (80 %), of whom 121 (65%) had a sling only and the other 66 (35 %) had a concomitant prolapse procedure (Table 2). The mesh revision surgeries were all performed in the operating room. There were eight different

providers during this time period performing these procedures. The majority of mesh excisions (209, 90 %) were performed transvaginally, and the remaining were completed abdominally (24, 10 %). Because several providers were involved, the methods of mesh revision or excision varied from minimal mesh revision to complete excision.

Overall, after mesh excision/revision surgery, 169 patients (73 %) reported improvement in pain, 45 (19 %) experienced no change in pain, and 19 (8 %) reported worsened pain (Table 1). There was no difference in improvement of pain if the mesh was removed vaginal or abdominally. Neither menopausal status nor hysterectomy predicted improvement in pain after mesh removal. Smoking and diabetes also showed an even distribution throughout the three outcome categories. However, in the pain syndromes, the chronic pelvic pain category had a smaller percentage in the improvement category than in the worsened and no change outcomes: 8 %, 26 %, and 22 % respectively.

One hundred and thirty-one (56 %) patients had mesh exposures: 103 (44 %) into the vagina, 14 (6 %) into the bladder, and 14 (6%) into the urethra (Table 3). Overall, mesh excision improved pain in 101 patients with exposure (77 %), whereas 7 (5 %) reported no improvement and 23 (18 %) reported worse symptoms. Pain outcomes did not vary appreciably by location of exposure. However, compared with patients without exposure, those with exposure were more likely to be improved (77%vs 67 %) and less likely to be worse after excision (5%vs 12%), although these differences were not statistically significant. Of the patients who had only sling placement, 77 % showed improvement, which is similar to those who had both SUI and POP mesh present.

Of all independent variables included in multivariate regression modeling, only chronic pelvic pain was predictive of pain outcomes in both univariate and multivariate regression models (Table 4). Patients with prior chronic pelvic pain were significantly less likely to experience improvement in pain symptoms (OR 0.28 CI: 0.12–0.66).

Discussion

In this large series, our findings demonstrate that the majority of patients who complain of pain after vaginal mesh placement will experience an improvement in their pain after surgical intervention. However, approximately 27 % of our patient population did not improve after surgical intervention, and of those, 8 % had worsening of their pain. From our patient population, all chronic pain disorders had odds ratios less than zero; however, chronic pelvic pain was the only subset that met statistical significance. This finding is consistent with other reports of patients with chronic pain syndromes, as patients who have chronic pain continue to have pain after other surgical interventions [13]. The ability to delineate the etiology of pain in this subset of patients is more difficult; therefore, pain that is attributed to synthetic mesh may not actually be related to the mesh. The pathophysiology of chronic pain may involve neuropathic changes that occurred before mesh was placed, which would prevent improvement after mesh removal [14].

Although there have been several publications on the complications of vaginal mesh and methods of removal, this is to our knowledge the first study that has specifically evaluated

pain outcomes after mesh revision surgery. Because one of the main complaints and complications of vaginally placed mesh is some type of pain—pelvic, vaginal, lower extremity or dyspareunia—patients are asking for mesh removal, often with pain as the only symptom.

Although mesh has been used for hernia repair in different anatomical compartments for the past 30 years, it is a foreign body. There are known complications; however, the mechanism of the pain component has not yet been fully identified. Several case reports have been published recently theorizing the etiology of postoperative pain following mesh placement. Klein et al. described a patient who underwent umbilical hernia repair with mesh, who subsequently had chronic pain syndrome. Computed tomography (CT) examination was performed showing shrinkage, and at the time of surgical removal, adhesions to and inflammation around shrunken mesh were discovered. Pain completely resolved after removal of the mesh [15]. Irritation or injury of nerves has also been implicated in pain from these procedures. Fisher and Lotze described two patients with postoperative pain following retropubic sling procedures, both of whom had temporary resolution after local nerve blocks. One of these patients required complete sling excision for permanent improvement of pain [16]. Van Ba et al. reported obturator neuralgia and motor deficits after placement of vaginal mesh through obturator foramen for anterior vaginal prolapse. CT did not show neuroma or compression of neurovascular bundles. Surgical removal of mesh was completed without evidence of infection or neuroma; however, granulomatous tissue and evidence of inflammation around mesh were present. Complete resolution of symptoms occurred [17]. Another proposed mechanism for pain is mesh migration. While this is less documented in vaginal surgery, there have been several case reports of postoperative pain present in areas other than the location of original mesh placement. Imaging in these instances shows mesh not in the original site of placement but present in the areas of pain. Rarely, mesh has traveled great distances. For example, there is one report of a patient complaining of rectal pain after a ventral repair. Surgical exploration found mesh present in the rectum [18]. Therefore, although etiology is an important component, knowing when to operate on a patient to remove the mesh is also valuable. Removal and revision of vaginal mesh is often an extensive and potentially morbid procedure, and one that should not be performed unless necessary.

Strengths of this study include the large number of patients involved as well as the multiple providers spanning two departments. To our knowledge, this study represents the largest series of patients with pain outcomes after mesh removal. This allows for a sampling of several different surgical procedures for mesh removal or revision. This is the first study that has looked specifically at the pain component of mesh complications and correlated it with postoperative outcomes. The fact that our median follow-up time was a year is also a strength. Many of our patients were followed for longer periods and some for up to 3–4 years.

Because this is a retrospective study, there are several limitations. First, the definition for our pain outcome was limited to “improved, not improved or worse.” We attempted to use a visual pain analog scale or some other measurement of pain symptoms. Because patients were seen by several different providers, a consistent evaluation of the pain was not

possible. Data are also lacking on the other aspects of the patient's pain including location, character, duration, and quality. When deciding if a patient is a good candidate for surgery, these may be good predictors for success. We did not collect data on the specific method of mesh revision or excision, which may also play a role in improvement. As there were several providers involved, the methods of excision and revision ranged from urethrolysis to partial excision and complete excision as well as different routes of surgery: vaginal versus urinary tract. The differing surgical approaches cause difficulty when attempting to draw conclusions regarding surgical intervention for mesh complications. To better understand if one method is superior to another, these would need a prospective evaluation.

While chronic pelvic pain was significant for worse outcomes, this patient population was small. In the same way, the other pain syndromes were small cohorts and could have reached statistical significance if the population were larger. In addition, the patients were placed into these groups because they had been given these diagnoses in their past medical history. Often diagnoses of these pain syndromes are made incorrectly, which would skew the data. Because the diagnosis was not standardized, there is a chance that some patients were misdiagnosed. There could also be patients who did have these diagnoses but were not placed in the category because the provider was not specifically looking for these syndromes.

Conclusion

Based on our study, the majority of the time when patients have pain that appears to be due to vaginal mesh placement, surgical intervention improves their pain. This may not be true in patients with chronic pelvic pain. This study is one of the first to delineate for which patients mesh revision surgery would be beneficial. Although our study showed less of an improvement in chronic pelvic pain, our methods may not be exact enough to see smaller increments of improvement. Using objective pain scales, descriptive pain terminology, and physical examination criteria would better categorize patient's pain and allow for a better understanding of the symptoms. Targeting appropriate candidates for surgery would theoretically decrease the number of patients for whom the surgery is not beneficial. This study is the initial step.

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Table 1

Cohort characteristics by pain outcome

	Total number	Pain improved, *n* (%)	Pain worsened, *n* (%)	Pain unchanged, *n* (%)	*p* value
All patients	233	169 (73)	19 (8)	45 (19)	
Mean age (54)		54.5	54.3	54.0	>0.05
Menopause	181	134 (79)	14 (74)	33 (73)	0.62
Prior hysterectomy	189	136 (80)	16 (84)	37 (82)	1.00
Current smoker	58	41 (24)	6 (32)	11 (24)	0.79
Diabetes	23	19 (11)	1 (5)	3 (7)	0.70
Fibromyalgia	17	9 (5)	3 (16)	5 (11)	0.10
Interstitial cystitis	11	6 (4)	1 (5)	4 (9)	0.26
Chronic pelvic pain	28	13 (8)	5 (26)	10 (22)	< 0.01

Table 2

Location of initial mesh placement

	Total number, *n* (%)
Apical	19 (8)
Bladder neck suspension	4 (2)
Anterior repair	7 (3)
Posterior repair	3 (1)
Anterior/posterior repair	6 (3)
Sling	124 (53)
Sling and apical	15 (6)
Sling and anterior	34 (15)
Sling and posterior	6 (3)
Sling, anterior, posterior	15 (6)

Table 3

Pain outcomes after mesh excision for patients with genitourinary mesh exposure/perforation

Site of mesh exposure/perforation	Total number (%)	Pain improved (%)	Pain worsened (%)	No change (%)	*p* value
Any exposure	131	101 (77)	7 (5)	23 (18)	0.19
No exposure	102	68 (67)	12 (12)	22 (21)	
Location					
Vagina	103 (80)	78 (76)	5 (5)	20 (19)	0.28
Bladder	14 (10)	11 (79)	1 (7)	2 (14)	1.00
Urethra	14 (10)	12 (86)	1 (7)	1 (7)	0.52

Table 4

Unadjusted and adjusted odds ratios for risk factors predicting pain improvement after excision vs no improvement or worsening symptoms

Risk factor	Unadjusted OR (95 % CI)	*p* value	Adjusted OR (95 % CI)	*p* value
Age	1.02 (1.00–1.04)	0.11	1.01 (0.98–1.05)	0.37
Menopause	1.4 (0.71–2.70)	0.33	1.22 (0.50–2.99)	0.67
Hysterectomy	0.85 (0.40–1.82)	0.68	0.84 (0.37–1.96)	0.71
Smoking	0.89 (0.46–1.71)	0.71	1.05 (0.51–2.15)	0.89
Diabetes	1.9 (0.62–5.82)	0.26	1.58 (0.49–5.02)	0.44
Fibromyalgia	0.39 (0.14–1.07)	0.07	0.44 (0.15–1.33)	0.15
Interstitial cystitis	0.43 (0.13–1.48)	0.18	0.52 (0.14–1.94)	0.33
Chronic pelvic pain	0.27 (0.12–0.61)	<0.01	0.28 (0.12–0.66)	<0.01
Vaginal exposure	1.32 (0.74–2.38)	0.35	1.49 (0.78–2.86)	0.23
Bladder perforation	1.41 (0.38–5.21)	0.61	1.41 (0.36–5.52)	0.62
Urethral perforation	0.85 (0.40–1.82)	0.68	2.84 (0.57–14.25)	0.20
Any mesh exposure/perforation	1.54 (0.87 2.75)	0.14	1.53 (0.29–6.52)	0.69