The Indication and Surgical Treatment of 286 Midurethral Synthetic Sling Complications: A Multicenter Study

Orawee Chinthakanan, MD, MPH
International Urogynecology Associates
Atlanta, Georgia and Beverly Hills, California
Clinical Instructor
Department of Obstetrics and Gynecology
Faculty of Medicine
Ramathibodi Hospital
Mahidol University
Bangkok, Thailand

John R. Miklos, MD
Director
International Urogynecology Associates
Atlanta, Georgia and Beverly Hills, California

Robert D. Moore, DO
Director
Advanced Pelvic Surgery
Atlanta, Georgia

Deborah R. Karr, MD
Assistant Professor
Division of Female Pelvic Medicine and Reconstructive Surgery
Department of Gynecology and Obstetrics
Emory University
Atlanta, Georgia

Gladys M. Nogueiras, MD
Department of Gynecology
Section of Urogynecology and Reconstructive Pelvic Surgery
Cleveland Clinic Florida
Weston, Florida

G. Willy Davila, MD
Chairman
Department of Gynecology
Section of Urogynecology and Reconstructive Pelvic Surgery
Cleveland Clinic Florida
Weston, Florida

ABSTRACT

Introduction and Hypothesis: 1) Evaluate the most common indication for sling removal in patients with synthetic mesh slings; 2) identify the location of pain for each of the three types of synthetic sling procedures including retropubic (RP) sling, transobturator (TOT) sling, and single incision slings (SIS), and 3) describe the surgical approach to each of the above and its associated complications.

Materials and Methods: A retrospective chart review of all patients who underwent surgical removal of a sling due to a mesh-related complications from 2011 to 2013 at three referral centers.

Results: There were 337 sling complications followed by the IUGA/ICS mesh complication classification. RP slings were more likely to have urinary tract complications (category 4) and intra-abdominal site complications (S5). Of those, 286 slings were removed, 106 (37.1%) were RP, 131 (45.8%) TOT, and 44 (15.4%) SIS. Vaginal pain was the most common reason for sling removal. Twenty-one percent of the TOT had groin
pain which was a five times higher risk than RP (OR 5.3, 95% CI 1.5–18.7), and the RP was three times more likely to have suprapubic pain than the TOT (OR 2.97, 95% CI 1.3–7.0). Fifteen percent of the TOT had either unilateral or bilateral groin mesh removal.

**Conclusion:** The most common indication for sling removal was vaginal pain. RP sling had a higher risk of suprapubic pain and TOT sling had a higher risk of groin pain. Patients with a history of SIS had a higher incidence of urethral erosion. TOT removal had the highest intraoperative complication rate.

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**INTRODUCTION**

First introduced by Ulmsten and Petros in 1996, the synthetic retropubic sling has become a gold standard of female stress urinary incontinence with high efficacy and safety. Subsequently, other retropubic (RP) slings and, more recently, transobturator (TOT) slings and single site incision slings (SIS) have been introduced, making midurethral sling procedures theoretically both less invasive and safer. Although a midurethral sling can be performed as an ambulatory surgery due to its minimally invasive technique, it can be associated with postoperative complications such as vaginal pain, dyspareunia, lower abdominal pain, vaginal mesh exposure, hematoma, bladder or bowel erosion, lower urinary tract symptoms, and even leg or thigh pain. Based on two systematic reviews and meta-analyses, there is evidence that the rate of bladder perforation and hematoma formation are higher in RP slings compared with other slings, while neurological adverse events (i.e., groin or leg pain) are more likely to occur after TOT slings. SIS are associated with higher reoperation rates for SUI due to inferior patient-reported and objective cure rates on short-term follow-up. The complications associated with midurethral slings are common and have been reported to range from 4.3%–75.1% for RP and 10.5%–31.3% for TOT. The FDA manufacturer and user facility database experience (MAUDE) database demonstrated that complications involving urethral and bladder perforations were likely under-diagnosed and under-reported.

This study was conducted at three tertiary referral centers that have a high volume of patients with complaint of midurethral sling complications. The objectives of this study were 1) to evaluate the most common indications for sling removal in patients with synthetic mesh slings, 2) identify and discuss the location of pain for each of the three types of synthetic sling procedures— including retropubic slings (RP), transobturator (TOT) and single incision slings (SIS), and 3) describe the surgical approach to each of the above as well as the associated complications.

**MATERIALS AND METHODS**

Between January 2011 and December 2013, an institutional review board-approved retrospective chart review of all patients who underwent surgical removal of mesh-related complications from 2011 to 2013 at three tertiary referral centers in the Southeast United States was conducted. We included all women who underwent sling removal. The databases were queried to identify potential subjects, the types of procedure performed, types of mid-urethral sling, and their demographic data. The type of synthetic mesh sling procedure was categorized to retropubic (RP), transobturator (TOT), and single incision sling (SIS). The surgical procedures for mesh revisions included cutting, partial removal, or total removal of the vaginal portion of the mesh, as well as removal of the majority of the mesh from the groin and retropubic areas. Patient preoperative complaints were confirmed via history and physical examination. Patients with mesh slings who complained of vaginal pain with or without intercourse underwent only the vaginal approach for surgical mesh removal. Patients with lower abdominal/suprapubic/groin and vaginal pain with an RP sling underwent both a vaginal and laparoscopic approach for mesh removal. Patients who complained of vaginal and groin pain who had a TOT sling underwent a vaginal and a transinguinal approach to sling removal.

Data was analyzed by using chi-square and a Fisher exact test for categorical data, and a Student's t-test and a Wilcoxon Rank Sum Test for continuous data. The measure of effect was determined by logistic regression analysis. A 5% level of significance was used for all statistical testing and all statistical tests were two-sided. The statistical analyses were performed using Stata® version 14.0 (StataCorp, LP, College Station, Texas).

**RESULTS**

There were 337 sling complications classified utilizing the IUGA/ICS mesh complication classification system. According to this classification, RP slings are statistically more likely to have urinary tract complications (category 4) and intra-abdominal site complications (S5) than other slings (Table I). Main indications for RP revision/removal were pain (53.9%), dyspareunia (14.6%), and urinary retention (6.9%), respectively. Main indications for TOT sling removal were pain (66.0%), dyspareunia (10.7%), and urinary retention (5.3%). Main indications for SIS removal were pain (57.5%), dyspareunia (14.6%), and erosion/extrusion (6.4%). Urinary retention was statistically more likely to be an indication for removal in the RP group (p=0.049). Of the 286 sling removed, 106 (37.1%) were RP, 131 (45.8%) TOT, and 44 (15.4%) SIS. Table II shows pain location among patients who underwent surgical treatment due to pain. Vaginal pain was the most common site across all sling types.
<table>
<thead>
<tr>
<th>Category</th>
<th>sling (n=330)</th>
<th></th>
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<th>P-value</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>RP (n=133)</td>
<td>TOT (150)</td>
<td>SIS (n=47)</td>
<td></td>
</tr>
<tr>
<td>1. Vaginal: no epithelial separation</td>
<td>85 (65.38)</td>
<td>101 (67.79)</td>
<td>33 (70.21)</td>
<td>0.814</td>
</tr>
<tr>
<td>2. Vaginal: smaller ≤ 1 cm exposure</td>
<td>12 (9.23)</td>
<td>15 (10.07)</td>
<td>10 (21.28)</td>
<td>0.067</td>
</tr>
<tr>
<td>3. Vaginal: larger &gt; 1 cm exposure, or any extrusion</td>
<td>8 (6.15)</td>
<td>14 (9.40)</td>
<td>1 (2.13)</td>
<td>0.207</td>
</tr>
<tr>
<td>4. Urinary tract: compromise or perforation including prosthesis (graft) perforation and fistula</td>
<td>13 (10.00)</td>
<td>4 (2.68)</td>
<td>2 (4.26)</td>
<td>0.030</td>
</tr>
<tr>
<td>5. Rectal or bowel: compromise or perforation including prosthesis (graft) perforation and fistula</td>
<td>2 (1.54)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0.219</td>
</tr>
<tr>
<td>6. Skin or musculoskeletal: complications including discharge pain lump or sinus tract formation</td>
<td>9 (6.92)</td>
<td>15 (10.07)</td>
<td>1 (2.13)</td>
<td>0.187</td>
</tr>
<tr>
<td>7. Patient: compromise including hematoma or systemic compromise</td>
<td>1 (0.77)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0.470</td>
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</table>

**Time (Clinically diagnosed)**

<table>
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<tr>
<td>T1: Intraoperative to 48 hours</td>
<td>1 (0.77)</td>
<td>0 (0)</td>
<td>0 (0)</td>
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<tr>
<td>T2: 48 hours to 2 months</td>
<td>4 (3.08)</td>
<td>4 (2.68)</td>
<td>0 (0)</td>
<td>0.490</td>
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<tr>
<td>T3: 2 months to 12 months</td>
<td>15 (11.54)</td>
<td>12 (8.05)</td>
<td>4 (8.51)</td>
<td>0.594</td>
</tr>
<tr>
<td>T4: Over 12 months</td>
<td>110 (84.62)</td>
<td>133 (99.26)</td>
<td>43 (91.49)</td>
<td>0.348</td>
</tr>
</tbody>
</table>

**Site**

<table>
<thead>
<tr>
<th>Site</th>
<th>sling (n=330)</th>
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<tbody>
<tr>
<td>S1: Vaginal: area of suture line</td>
<td>19 (14.62)</td>
<td>18 (12.08)</td>
<td>10 (21.28)</td>
<td>0.293</td>
</tr>
<tr>
<td>S2: Vaginal: away from suture line</td>
<td>59 (45.38)</td>
<td>86 (57.72)</td>
<td>28 (59.57)</td>
<td>0.075</td>
</tr>
<tr>
<td>S3: Trocar passage</td>
<td>7 (5.38)</td>
<td>11 (7.38)</td>
<td>2 (4.26)</td>
<td>0.664</td>
</tr>
<tr>
<td>S4: Other skin or musculoskeletal site</td>
<td>19 (14.62)</td>
<td>33 (22.15)</td>
<td>7 (14.89)</td>
<td>0.219</td>
</tr>
<tr>
<td>S5: Intra-abdominal</td>
<td>26 (20.00)</td>
<td>1 (0.67)</td>
<td>0 (0)</td>
<td>&lt;0.001</td>
</tr>
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</table>

Although midurethral slings have a low postoperative complication rate when compared with transvaginal mesh, these complications can have a significant impact on a patient's quality of life. Conventionally, most sling complications are reported as mesh exposure and perforation; however, our most common indication for surgical removal of midurethral slings is vaginal pain with or without intercourse. Perhaps the reason why our centers remove slings more commonly for pain is mesh exposure is an objective findings detected by laparoscopic combined with a vaginal approach, had more blood loss compared to a vaginal approach alone (mean 87.2 vs. 55.0 cc, p<0.001). For TOT removal, groin removal combined with vaginal approach had more blood loss compared with vaginal approach alone (mean 79.7 vs. 59.1 cc, p=0.008). Two patients who underwent laparoscopic RP removal received a blood transfusion, one of which required a reoperation for the evacuation of a retroperitoneal hematoma. Among TOT removals, three patients had intraoperative urethral injury and no TOT patient sustained a majora vascular or neurological injury nor required a blood transfusion.
physical examination\textsuperscript{12} and patients who present with exposure are readily recognized and treated by the implanting surgeon. Pain, however, is a subjective complaint and often goes undiagnosed by the examining physician. The key to making the appropriate diagnosis is reproducing the pain by palpation during the physical exam. Failure to reproduce vaginal pain by sling palpation rules out the sling as the etiology of the pain. Another reason for the under-diagnosis is perhaps the implanting surgeons are not aware of this potential complication.

Intraoperative bladder perforation and postoperative urinary retention is relatively common following RP procedures.\textsuperscript{11} Our study confirms this finding when comparing RP procedures to TOT and SIS. In addition, other unexpected postoperative midurethral sling complications may occur, for example, urethral stone\textsuperscript{14} and clitoral pain.\textsuperscript{15} We mention these complications so the reader has an understanding that various complications of midurethral sling can occur and often go under- or undiagnosed because the surgeon may not realize such complications can occur. Hence the suprapubic and lower abdominal pain in RP procedures, groin pain in TOT procedures, and vaginal pain without intercourse in all midurethral sling procedures.

A review of the MAUDE database reveals other serious complications including obturator nerve injuries, excessive blood loss, and ischiorectal fossa abscesses following TOT insertion.\textsuperscript{16} We found that 21\% of our TOT group underwent sling removal due to leg/groin pain. Obturator neuralgia is not uncommon for TOT especially for the inside-out procedures\textsuperscript{17} where the sling may have been placed too close to the obturator canal.\textsuperscript{18} Patients suffering from obturator neuralgia were treated surgically by removing the sling from the vagina as well as the affected groin unilaterally or bilaterally. Groin removal surgery was performed in 19 patients without a single complication.

The SIS was invented to be less invasive and to avoid complications such as bladder and bowel perforation associated with RP and leg and groin pain associated with TOT slings. Like other slings, the majority of SIS removals were for vaginal pain with or without intercourse. Interestingly the "least invasive" sling had the highest number of sling removal for urethral erosions.

To treat mesh complications, many experts recommend that mesh exposure should be treated with complete or maximum removal of the mesh.\textsuperscript{15,19,20} We ascribe to this recommendation based upon the location of the sling and the anatomical locations of the symptoms. If the symptoms (i.e., pain) fall along the surgical pathway of the sling, the sling is removed according to the associated symptoms. Patients suffering from only vaginal pain underwent surgery to remove only the suburethral and paraurethral portions of the sling. Patients suffering from groin pain were more often subjected to vaginal and groin dissection to remove the TOT, and patients suffering from suprapubic and lower abdominal pain were subjected to vaginal and laparoscopic dissection to remove the arms of the RP sling.

The strength of our study relies on the large number of patients that make up the cohort of midurethral sling-related complications cases and the fact that the data was gathered from three tertiary urogynecologic referral centers with diverse patient populations. The impact of this study is limited by its retrospective and descriptive nature. In addition, this cohort may not represent the general population, because they were complicated and often recurrent cases. Other limitations of this study include the lack of outcomes after sling revision/removal including the possible improvement of symptoms, quality of life, and sexual function. Future studies will be focused on the success rate of sling removal and improvement of the associated symptoms as well as treatment of SUI after or at the time of sling removal.

**CONCLUSION**

The most common indication for all sling removal was vaginal pain. RP sling has a higher risk of suprapubic pain and TOT sling has a higher risk of groin pain. TOT removal has a higher incidence of intraoperative urethral perforation. Total RP sling removal by utilizing both a vaginal and a laparoscopic approach has a higher average blood loss and an increased risk of blood transfusion. Overall, removing the maximum amount of symptom-producing mesh can be performed safely in experienced surgeon's hands.\textsuperscript{61}
AUTHORS' DISCLOSURES

Dr. Davila receives grant/research support from Coloplast Corp., Cook Medical Inc., and ACell. He is also on the Speaker’s Bureau for Cogentix Medical, Inc.

All other authors have no conflicts of interest to disclose.

REFERENCES