



Review article

Review on midurethral sling procedures for stress urinary incontinence

Nazura Bt Karim ^{a, b}, Tsia-Shu Lo ^{c, d, e, f, *}, Enie Akhtar bt Nawawi ^{b, g}, Pei-Ying Wu ^c^a Department of Obstetrics and Gynecology, Hospital Tuanku Jaafar, Seremban, Negeri Sembilan, Malaysia^b Fellow of the Division of Urogynecology, Department of Obstetrics and Gynaecology, Chang Gung Memorial Hospital, Linkou, Taoyuan, Taiwan, ROC^c Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Keelung Medical Center, Keelung, Taiwan, ROC^d Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Taipei Medical Center, Taipei, Taiwan, ROC^e Division of Urogynecology, Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Linkou Medical Center, Taoyuan, Taiwan, ROC^f Department of Obstetrics and Gynecology, Chang Gung University, School of Medicine, Taoyuan, Taiwan, ROC^g Department of Obstetrics and Gynecology, Hospital Raja Perempuan Zainab II, Kota Bharu, Kelantan, Malaysia

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ABSTRACT

Minimally invasive suburethral slings, namely the retropubic suburethral sling or the tension-free vaginal tape (TVT), has become the mainstay for surgical management of moderate to severe stress urinary incontinence (SUI) taking over the place of Burch's colposuspension after its introduction in the 1990s. Following the introduction of retropubic sling procedures are the transobturator (TVT-O) procedures and the mini-sling procedures. This review attempts to summarize the current trend of midurethral sling (MUS) procedures in the management of SUI.

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Introduction

Stress urinary incontinence (SUI) is defined by the International Continence Society as any involuntary leakage of urine on exertion or effort, or on sneezing or coughing. UI, although benign and non-life-threatening is a worldwide quality-of-life problem which significantly impairs the social, physical, and psychological well-being of affected women, with associated low self-esteem, embarrassment, and in severe forms, social isolation. Minimally invasive midurethral slings (MUS) are currently the mainstay for the surgical treatment of women with SUI following unsuccessful conservative management strategies such as lifestyle changes, physical therapies, scheduled voiding regimens, and behavioral therapies.

Burch colposuspension and pubovaginal sling was considered the first line of treatment in the past several decades. Cochrane

reviews have shown that Burch colposuspension had long term efficacy with overall cure rates of 68.9–88%.¹ However, since the introduction of MUS in the mid-1990s, the retropubic sling has become the gold standard for treatment of female SUI. This surgical procedure is associated with high subjective and objective SUI cure rates (80–90%) after > 11 years of follow-up.² The original tension-free vaginal tape (TVT) sling, as described by Ulmsten et al.,³ technique uses a retropubic route for the insertion of the tape. Intra- and postoperative complications resulting from the penetration of the surgical device into pelvic organs (bladder and bowel), nerves, and vessels, have been reported.^{4–6} In an attempt to minimize the blind passage of the retropubic space and the subsequent risk of major bleeding and bladder injury, in 2001, Delorme proposed an outside-in trans-obturator (TOT) passage through the obturator foramen for suburethral tape placement⁷ followed by an inside-out procedure (TVT-O) which was introduced in 2003 by De Leval.⁸ More recently single incision slings have been developed in order to eliminate and further minimize the complication of blind passage of trocar for the insertions of suburethral slings.^{9–11} This review will discuss the recent development on MUS, the efficacy, and complications.

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* Corresponding author. Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Keelung Medical Center, 222, Maijin Road, Keelung, 204, Taiwan, ROC.

E-mail address: 2378@cgmh.org.tw (T.-S. Lo).

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TVT

The TVT, also known as retropubic sling, is the most commonly used surgical approach for women who suffer from SUI. The entire procedure has been based on the integral theory. The elaboration of this theory demonstrated that the lack of support of the mid-urethra, due to weakness of the pubourethral ligaments and the anterior vaginal wall, is the main cause of SUI. The original TVT procedure described by Ulmsten et al³ in 1996 used the bottom-up approach. The TVT sling procedure is performed through a small suburethral incision in the vagina and two small lower abdominal incisions (2 cm each side of the midline) above the pubic bone. It may be done with either local or general anesthesia. Marcaine and adrenaline diluted with saline is injected in the retropubic space for hydrodissection followed by incisions as above. Vaginal wall tissue is dissected off the urethra to expose the mid urethra along with paraurethral dissection towards the endopelvic fascia. A catheter guard is then placed to deflect the bladder away. The TVT trocar attached to the tape is then advanced from the vaginal incision through the space of Retzius and to the anterior abdominal wall. The trocar must hug the posterior wall of the pubic symphysis during this maneuver to reduce the risk of bowel perforation. Cystoscopy examination, to rule out bladder perforation, is performed after which the plastic sheath covering the tape is removed and the tape is adjusted without excessive tension. The tape is then trimmed and the vaginal and skin incisions are closed with absorbable sutures. Another approach for doing this procedure is by the top-down approach, which was developed with a view to more control over the passage of the needles in the retropubic space. The SPARC Sling system (American Medical Systems, Minnetonka, MN, USA) consists of two disposable needles with dilator-connector tips to create the sling tract and also help to attach the ends of the plastic sheath enclosing the mesh.

Outcome evidence for TVT is the most extensively evaluated procedure. The longest reported follow-up to date by Nilsson et al⁴ showed a subjective and objective cure rate of 77% and 90%, respectively, at 11.5 years after TVT. In another study by Nilsson et al¹² looking at a 17-year follow-up, they report that 48/55 (87.2%) of the women regarded themselves cured or significantly better than before surgery. Objective cure, defined as a negative stress test, was seen in 42/46 women (91.3%). Only one woman had a further stress incontinence procedure. TVT is equally effective in treating SUI secondary to intrinsic sphincter deficiency (ISD) and urethral hypermobility.¹³ A multicenter randomized trial result at 5 years follow up comparing TVT with colposuspension showed equal efficacy of TVT to colposuspension for cure of SUI (81% for TVT and 90% for colposuspension, $p = 0.21$).^{14,15}

Although TVT is a minimally invasive technique, the reported complications that have been associated with the procedure have included urinary bladder perforations, bleeding complications, mesh erosions and, in some rare cases, bowel perforations. Bladder perforations reported were at the level of 2.7%, however, it seems that the bladder injury which resulted from the TVT inserter did not bring about any significant postoperative clinical morbidity. Vascular injury and bowel perforations are at 0.07% and 0.04%, respectively.^{16,17}

Transobturator tapes (TOT/TVT-O)

The transobturator slings procedure was first introduced in 2001 by Delorme,⁷ with the aim of decreasing the risk of complication associated with the retropubic passage of the trocar, especially bowel and bladder injury. The TOT procedure is performed with the female patient placed in the dorsal lithotomy position

with her thighs flexed at a 120° angle.¹⁸ A single vertical mid-urethral incision and two other smaller incisions in the groin inferiorly to the pubic ramus are then made. Two methods of inserting a transobturator tape are currently employed and both involve the passage of a curved needle through the obturator foramen. The difference is in the direction of penetration. The TOT procedure uses needles passed from the outside of the groin into the vagina, in the direction of the midurethral vertical incision, following the line of the pubic bone (outside-in). A small skin incision is made on either side 1.5 cm lateral to the ischiopubic ramus. Using specially designed needles, the obturator membrane is perforated and then the needle is turned medially. It is then guided with a finger in the vaginal incision to exit in the vagina. The tape is then loaded on to the needle and pulled through the skin incision. The TVT-O procedure uses plastic tubes containing the tape, helical passers, and an introducer. The vaginal incision and dissection are the same as in the outside-in approach. The obturator membrane is punctured with scissors and the introducer (wing guide) is passed at a 45° angle through the vaginal incisions. Groin incisions are made at a point 2 cm above the urethra and 2 cm lateral to the inner thigh folds. The tubing attached to the helical passer is placed within the introducer (wing guide) and rotated to exit through the groin incisions. The tubing is then pulled from the passer as the passer is brought back out through the vaginal incision and the tape is pulled through out to the groin (inside-out). In both orientations, the monofilament tape is adjusted to the appropriate tension.¹⁹

Outcome measures in a systematic review of the literature reported by Novara et al²⁰ verified that patients treated with TOT had slightly lower cure rates than the TVT group, but TOT had a significantly lower risk of bladder and vaginal perforations. Richter et al²¹ in a multicenter, randomized equivalence trial comparing outcomes with retropubic and transobturator MUS in 565 women with stress incontinence found objectively assessed treatment success rates were 80.8% in the retropubic-sling group and 77.7% at 12 months. Theoretically, the TOT avoids the retropubic space and therefore has less bladder, bowel, and blood vessel injuries compared with retropubic slings. However, the transobturator route is associated with an increased risk of groin and leg pain and a lower success rate in patients with ISD.²² In a randomized, controlled study of 164 women with ISD, Schierlitz et al²² found that the long-term cure rates for the retropubic sling were higher than TOT at 3 years follow-up; 15/75 (20%) women in the TOT group underwent repeat surgery to correct recurrent or persistent SUI compared with 1/72 (1.4%) in the TVT group. The median time to repeat surgery was 15.6 months and 43.7 months for TOT and TVT, respectively. Abdel-Fattah et al²³ in his study comparing both transobturator routes, inside-out versus outside-in slings, found that there were no differences in objective and subjective SUI cure rates. Meta-analysis by Madhuvrata et al²⁴ showed no evidence of statistically significant differences in subjective or objective cure/improvement [odds ratio (OR) 1.25, 95% confidence interval (CI) 0.78, 1.99; $p = 0.35$] and (OR 1.66, 95% CI 0.8, 3.34, $p = 0.17$) between the inside-out and outside-in groups. Sensitivity analysis confirmed similar results (OR 2.03, CI 0.82, 5.01, $p = 0.12$). Vaginal angle injuries were significantly higher with the outside-in route (OR 0.14, 95% CI 0.05, 0.41, $p = 0.0003$). Groin/thigh pain and *de novo* urgency were not significantly higher with the inside-out route (OR 1.42, 95% CI 0.94, 2.13, $p = 0.10$ and OR 1.46, 95% CI 0.63, 3.36, $p = 0.38$, respectively).

Single incision mini-sling

The first mini-sling introduced into the market in 2006 was the TVT-Secur (TVT-S; Gynecare, Bridgewater, NJ, USA) followed by

Mini-Arc (American Medical Systems, Minnetonka, MN, USA) in 2007. The aim of these techniques was to produce a shorter MUS tape with a safer mechanism of installation, to reduce post-operative pain, recovery time, and perioperative complications. Theoretically, it eliminates the risk of trocar-related injury, such as vessel injury or bladder perforation. This mini-sling, just like the others, is placed through a single incision underneath the urethra and fixed to the obturator internus muscle and its fascia. However, the current evidence regarding their short- and medium-term efficacy remains controversial. As an example, TVT-Secur (Gynecare) cure rates at mid-term appear to be lower than those after standard slings.^{25–27} More recently, a Single incision slings (SIS) procedure that allows a more precise tension adjustment (Ajust, C.R. Bard, Inc., Covington, GA, USA) was introduced, with promising short-term results.^{28–31} By contrast, Pickens et al³² and Kennelly et al³³ in a prospective observational study in women who underwent placement of the Mini Arc for the treatment of SUI, suggested that Mini Arc offers excellent objective and subjective outcomes that are durable at 1 year after treatment. Basu and Duckett³³ in 2013 in their 3-year results of a follow-up in a randomized trial of retro-pubic MUS versus the MiniArc single-incision sling concluded that there are much higher failure rates for MiniArc compared to retro-pubic midurethral procedures. A recent meta-analysis by Abdel-Fattah et al,³⁴ with a total of 758 women in nine randomized controlled trials, showed that single-incision slings had lower patient-reported and objective cure rates and higher reoperation rates for SUI on the short-term follow up compared with MUS. In summary, the results for single-incision slings to date are inferior to conventional MUS for the management of SUI, despite some favorable clinical advantages, such as short operation time and less pain.

Failure of SUI operation

Risk factors for failure have been analyzed and were reported to be similar in the retro-pubic and transobturator MUS. Stav et al³⁵ studied 1225 women following MUS; multivariate analysis revealed that body mass index > 25 (OR, 2.9), mixed incontinence (OR, 2.4), previous continence surgery (OR, 2.2), ISD (OR, 1.9), and diabetes mellitus (OR, 1.8) are significant independent predictors for MUS failure. Concomitant prolapse surgery decreased the likelihood of surgical failure after MUS (OR, 0.6). The patient's age and the type of MUS were not found to be risk factors for surgical failure. Richter et al³⁶ found risk factors for overall failure were previous SUI operation, Q-tip test <30°, severity of urge symptoms, and a high preoperative pad weight. Hsiao et al³⁷ concluded that risk factors for recurrence can be the preoperative detrusor overactivity after TVT, lower maximal urethral pressure and < 40 cm H₂O after TOT. Similar results by Houwert et al³⁸ in a retrospective cohort study determined the low maximal urethral closure pressure and mixed UI as risk factors for failure after TOT. Stav et al³⁹ in a retrospective study of 1225 women who underwent an MUS procedure with a mean follow-up of 5 years reported a subjective success rate of 86% for primary sling versus 62% in the repeat-sling group ($p < 0.001$). The repeat retro-pubic approach was significantly more successful than the repeat transobturator approach (71% vs. 48%, $p = 0.04$). The reported cure rates of MUS following previous anti-incontinence procedures is 47–100% based on objective measurements, such as cough stress test or pad test.^{40,41} Retro-pubic MUS, however, have been shown to be more effective than transobturator slings for recurrent SUI in patients who have failed a previous transobturator sling in recurrent SUI associated with ISD and following a Burch colposuspension.^{39,42}

Pelvic organ prolapse and SUI

SUI often coexists in up to 80% of women with pelvic organ prolapse, however, the presentation varies from mild to severe and some may be asymptomatic. Women with pelvic organ prolapse without SUI who undergo surgery are at risk of developing post-operative UI in 16–51%. The decision whether to perform concomitant anti-incontinence and prolapse surgery or prolapse surgery alone needs to be balanced against the risk of incomplete treatment and the risk of exposing a woman to possible morbidity of an unnecessary procedure. Recent studies have shown that performing concomitant anti-incontinence procedures could reduce the risk of developing postoperative SUI.

Conclusion

The International Urogynecological Association supports the use of MUS as one of the options for the surgical management of female SUI.

There is robust evidence to support the use of MUS from over 2000 publications, making this treatment the most extensively reviewed and evaluated procedure for female SUI now in use.¹¹ These scientific publications studied all types of patients, including those with comorbidities such as prolapse, obesity, and other types of bladder dysfunction. It is, however, acknowledged that any operation can cause complications. For MUS, these include bleeding, damage to the bladder and bowel, voiding difficulty, tape exposure, and pelvic pain; all of these may require repeat surgery, but this is uncommon. Nevertheless, the results of a recent large multicenter trial have confirmed excellent outcomes and a low rate of complications to be expected after treatment with MUS. Additionally, long term effectiveness of up to 80% has been demonstrated in studies, including one which has followed up a small group of patients for 17 years.^{19,20}

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