Focusing on long-term complications of mid-urethral slings among women with stress urinary incontinence as a patient safety improvement measure

A protocol for systematic review and meta-analysis

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Abstract

Background: There are 3 different types of mid-urethral sling, retropubic, transobturator and single incision performed for women with stress urinary incontinence. Prior studies comparing these three surgeries merely focused on the successful rate or efficacy. But nevertheless, what is more clinically important dwells upon investigating postoperative complications as a safety improvement measure.

Methods: A systematic review via PubMed, Ovid, and the Cochrane Database of Systematic Review and studies were applied based on the contents with clearly identified complications. Selected articles were reviewed in scrutiny by 2 individuals to ascertain whether they fulfilled the inclusion criteria: complications measures were clearly defined; data were extracted on study design, perioperative complications, postoperative lower urinary tract symptoms, postoperative pain, dyspareunia, and other specified late complications.

Results: A total of 55 studies were included in the systemic review. Perioperative complications encompassed bladder perforation, vaginal injury, hemorrhage, hematoma, urinary tract infection. There were postoperative lower urinary tract symptoms including urine retention and de novo urgency. Furthermore, postoperative pain, tape erosion/ extrusion, further stress urinary incontinence surgery, and rarely, deep vein thrombosis and injury of inferior epigastric vessels were also reported.

Conclusions: Complications of mid-urethral sling are higher than previously thought and it is important to follow up on their long-term outcomes; future research should not neglect to address this issue as a means to improve patient safety.

Abbreviations: LUTS = lower urinary tract symptoms, MUS = midurethral sling, OAB = overactive bladder, PISQ = Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, RCT = randomized controlled trial, RP = retropubic approach, SI = single incision, SUI = stress urinary incontinence, TO = transobturator approach, TOT = transobturator tape using the out–in technique, TVT = tension-free vaginal tape using the retropubic technique, TVT-O = transobturator tape using the in–out technique, UTI = urinary tract infection.

Keywords: complications, female, mesh, midurethral sling, slings, urinary incontinence
1. Introduction

Stress urinary incontinence (SUI) is urinary incontinence caused by increasing intra-abdominal pressure increases, such as on effort or exertion, such as cough or sneezing. SUI affects many women, especially the aged and although it is not life-threatening, SUI can compromise social, economic functions and psychology of affected individuals. Treatment for SUI can begin with conservative means including lifestyle modification, physiotherapy (pelvic floor muscle training or using incontinence pessary), or injection of periurethral materials, whereas surgical treatment may be considered should conservative management fail.

Among all kinds of surgeries for SUI, open abdominal retropubic suspension, laparoscopic retropubic suspension, anterior vaginal repair, needle suspensions, and traditional suburethral sling were once preferred surgical interventions yet become less in use because of lower effectiveness and higher risk of postoperative complications. With the evolution of surgical methods, mid-urethral sling (MUS) is the current mainstay surgical treatment of SUI. There are 3 different types of MUS, retropubic (RP), transobturator (TO), and single incision (SI).

2. Materials and methods

2.1. Literature search

In September 2020, we applied the optimized literature search algorithm Etblast (http://etest.vbi.vt.edu/etblast3) to retrieve relevant studies on the topic of MUS procedures for women with SUI from the MEDLINE. We utilized both “MeSH” and “free text” protocols as complex search strategy. Specifically, we used the MeSH terms “urinary incontinence,” “midurethral slings,” and “complications” in combination. Multiple “free text” searches were performed by using the following terms singly and in combination: midurethral sling, retropubic, TVT, tension free tape, transobturator, transobturator tape, trans-obturator tape using the out–in technique (TOT), TVT-O, Monarc, suprapubic arc, and single incision sling, Needleless and Adjust. Additionally, references from retrieved publications were checked to find extra articles on the topic. Published articles from 2009 to September 2020 were selected for analysis.

2.2. Selection criteria

The collected searches were subject to the following limits: full text available, meta-analysis, randomized controlled trial (RCT), systematic review, review; female participants >18 years diagnosed with SUI; the outcomes should include postoperative complications of MUS and patients’ subjective cure rate and objective cure rate; 10 years, species (humans), sex (female), language (English). The “Find Expert” and “Find Journal” functions of the eTBLAST suggested published relevant studies to the query. References and reports cited in identified research articles were also examined.

2.3. Data extraction and quality assessment

Two authors (LYH and LCK) assessed the abstracts and full texts to select the articles relevant to the review topic by the following criteria (Fig. 1): they were studies (eg, meta-analysis, RCT, systematic review, review) of MUS for SUI; complications measures were clearly defined. All follow-up periods were available. Subsequently, we evaluated those articles and abstracted the following information: study design, type of intervention, number of patients, follow-up in months, perioperative complications (defined as vascular or bladder/vaginal injury, hematoma, infection), postoperative lower urinary tract symptoms (including storage and voiding), postoperative pain, dyspareunia, sexual dysfunction, and late complications such as

Studies were searched in Medline, Embase, Pubmed

(n = 378)

Studies irrelevant were excluded

(n = 297)

Studies underwent full-text reading (n = 81)

Studies failed to meet inclusion criteria

(n = 26)

Studies were included in the systemic review

(n = 55)

Figure 1. Flowchart of study selection in the systematic review.
tape erosion and/or extrusion. The study did not take in the TVT-Secur (ETHICON) and the MiniArc (ASTORA) which were withdrawn or recalled from the market. Since this study was a systematic review, it was exempted from human research review committee approval.

3. Results

Our search identified 378 published articles, of which 323 were excluded on the basis of title or abstract due to procedures other than MUS in retropubic, transobturator or single incision route, or lack of discussions about complications. Among the remaining 55 articles, 35 were RCTs, 12 were systematic review and meta-analysis, and 8 were reviews. Since no reported RCT focused on complications of MUS, effect estimate statistics are not suitable for meta-analysis so a meta-analysis cannot proceed.

The 55 articles were summarized chronologically in Table 1 with detailed information on study design, intervention and comparator, measurements of reported complications and follow-up duration that were listed by the following order: RCT, systematic review/meta-analysis and review.[111–65]

Perioperative complications were summarized in Table 2 for comprehensive comparing in percentages between the groups. All collected studies were listed in the reference section.

4. Discussion

The present study used the data of 55 studies which composed of 4188 participants to evaluate the complications of MUS for women with SUI.

Presently, the most popular surgical methods for SUI are minimally invasive techniques using retropubic, transobturator, and single incision approaches, their names indicating their distinct variation. The advantages of these techniques include short operation time, less hospital stay, and thus rapid recuperation, allowing patients earlier returning to their daily work activities. However, complication of these procedures is one of the most important factors affecting patients’ safety, which is less addressed or under reported.[66,67]

In our review, the RP-MUS was associated with a high incidence of perioperative complications; among them, bladder perforation (0.8%–11.4%), hemorrhage (1.6%), hematoma (0.7%–5.5%), urine retention (0.8%–11.4%), and de novo urgency (0%–29%), whereas deep vein thrombosis (2.5%) and injury of inferior epigastric vessels (2.2%) were rarely reported.

Bladder perforation was a common complication observed during the MUS procedures where the blind retropubic passage of trocars between the vagina and the abdomen is responsible for a high bladder perforation rate and sometimes bowel and major vascular injuries. In contrast, the TO and SI-MUS avoided the retropubic passage, thereby reducing the risk of bladder and bowel injury. Once bladder perforation was recognized, the trocar should be removed and replaced immediately. According to the size of the injury, one might consider draining the bladder for 24 to 48 hours with an indwelling catheter. Hematoma was caused by extravascular pooling of blood within tissue due to vascular injury and with the same reason for bladder perforation, the blind retropubic passage caused a higher incidence of vessel injury. In our department, we routinely performed suprapubic ultrasonography after continence taping procedures (the RP-MUS) (Fig. 2) for detecting any concealed hematoma. It is a procedure noninvasive, without any radiation hazard, and easy to apply. It is of paramount importance to detect subcutaneous or retropubic hematoma left unrecognized by the surgeon.[68]

Nevertheless, in spite of circumscribing the space of Retzius and thus reducing the risk of bladder injury, the TO and SI-MUS might potentially cause obturator neurovascular bundle injury and high hematoma. Luckily, conservative management would be sufficient in most cases.

Voiding dysfunction, which results in urinary retention and increased postvoid residual volume, might compromise a patient life quality. The incidence of voiding dysfunction was higher in the RP-MUS as a sling inserted in this manner has a propensity to cause more obstruction owing to a roughly vertical sling axis in relation to the urethral axis.[69] In contrast, the TO and SI-MUS create a more horizontal sling axis. Consequently, TO and SI-MUS cause less circumferential compression of the urethra, which is consistent with a sling that is less obstructive[66] and is a distinct advantage. Overall, overactive bladder (OAB) and obstruction make up the most complications and this information should be explained to patients, so they can pay attention to the need for a long-term follow-up.

Among MUS, TO-MUS was associated with the highest incidence in peri/post-operative complications, including vaginal injury (0.8%–15%), urinary tract infection (UTI) (1%–33%), lower urinary tract symptoms (LUTS) (1%–33%), post-op pain (1.5%–26.7%), tape erosion/ extrusion (1.9%–10%), and further SUI surgery (1.4%–19.6%). Vaginal injury (including bleeding and laceration) and post-op pain were encountered more often in the TO-MUS because the tape is passed beneath the pubic bone through the groin. During passage of trocars through the TO route, it may cause mechanical injury to tissues (muscles, tendons, and nerves) and results in adductor muscle injury, osteitis pubis, obturator/groin abscess, inflammation and edema or nerve entrapment of the anterior branch of the obturator nerve, and structural adhesions.[70] Regarding the persistent groin or thigh pain, we had some experiences in handling this kind of complications; if conservative treatments failed, we would usually perform a urethrolysis procedure or add a Martius flap interposition for relief of the tension.

UTI, in this review, included culture proven, empiric infection, and recurrent infection. Recurrent UTI was defined as at least 2 documented urinary tract infections in the first 3 months postoperatively.[71] Treatment of acute UTI is highly effective and the occurrence of acute cystitis was considered a minor postoperative complication. But management of recurrent episodes of UTI is, however, difficult and may require long-term antibiotics coverage or even reoperation.[72] Late complications such as tape extrusion and erosion, in our review, were more frequent in the TO-MUS. Extrusion may be associated with symptoms affecting daily life: discharge, discomfort, pain, or dyspareunia. Management of extrusion can range from observation to more aggressive surgical intervention. As to tape erosion into the urethra and even the bladder, open excision may be a preferred choice.

Postoperative LUTS are the common most among all the complications of MUS. LUTS include de novo overactive bladder and de novo urgency with/ without incontinence. The development of OAB symptoms after anti-incontinence surgery[71] has a severe impact on the quality of life (QOL).[73] It is also known that urgency and urgency urinary incontinence worsen quality of life more than SUI.[69] Women who develop post-surgical OAB and feel worse than their pre surgical status should be carefully evaluated.
### Table 1
Summary of chronological reported studies.

| Study               | Design  | Intervention | Comparison | Follow-up duration | Complications                        |
|---------------------|---------|--------------|------------|--------------------|---------------------------------------|
| Palos et al.[11] 2018 | RCT    | TOT 47       | RP-MUS 45  | 12 mo              | Bladder perforation: RP 2.5%, TO 2.4% |
|                     |         |              |            |                    | Urinary infection: RP 29.3%, TO 30%    |
|                     |         |              |            |                    | Deep vein thrombosis: RP 2.5%, TO 0%  |
|                     |         |              |            |                    | Tape extrusion: RP 0%, TO 2.4%        |
|                     |         |              |            |                    | Urinary retention: RP 7.5%, TO 2.4%   |
|                     |         |              |            |                    | De novo urgency: RP 0%, TO 2.4%        |
|                     |         |              |            |                    | Dyspareunia: RP 2.5%, TO 0%           |
|                     |         |              |            |                    | Complications: Bladder perforation: RP 2.5%, TO 2.4% |
|                     |         |              |            |                    | Urinary infection: RP 29.3%, TO 30%    |
|                     |         |              |            |                    | Deep vein thrombosis: RP 2.5%, TO 0%  |
|                     |         |              |            |                    | Tape extrusion: RP 0%, TO 2.4%        |
|                     |         |              |            |                    | Urinary retention: RP 7.5%, TO 2.4%   |
|                     |         |              |            |                    | De novo urgency: RP 0%, TO 2.4%        |
|                     |         |              |            |                    | Dyspareunia: RP 2.5%, TO 0%           |
| Tammaa et al.[12] 2018 | RCT    | TVT-O 170    | TVT 161    | 60 mo              | Complications: TVT 3%, TVT-O 3%       |
|                     |         |              |            |                    | Urinary infection: TVT 21.2%, TVT-O 18.2% |
|                     |         |              |            |                    | LUTS: TVT 2.8%, TVT-O 7.9%            |
|                     |         |              |            |                    | Tape-related pain: TVT 1.4%, TVT-O 2.7% |
|                     |         |              |            |                    | Detrusor overactivity: TVT 6.4%, TVT-O 6.4% |
| Dogan et al.[13] 2018 | RCT    | Si-MUS 84    | TVT-O 41   | 18 mo              | Palpable mesh fiber on anterior vaginal wall in Si group (2.4%), else not mentioned |
| Pascom et al.[14] 2018 | RCT    | Si-MUS 69    | TOT 61     | 36 mo              | Complications: Further SUI surgery: Si 17%, TOT 4.9% |
|                     |         |              |            |                    | Tape exposure: Si 4.9%, TOT 4.9%      |
|                     |         |              |            |                    | De novo urgency: Si 12.2%, TOT 4.9%   |
| Schellart et al.[15] 2018 | RCT    | TOT 75       |            | 36 mo              | Reintervention: 5.2%                  |
|                     |         |              |            |                    | Unintentional perforation: 5.2%       |
|                     |         |              |            |                    | Post voiding residual: 1%              |
|                     |         |              |            |                    | Dyspareunia: 0%                       |
| Tieu et al.[16] 2017 | RCT    | TOT 42       |            | 12 mo              | De novo urgency: 0.7%                  |
|                     |         |              |            |                    | Repeat SUI surgery: 12%               |
|                     |         |              |            |                    | Vaginal mesh exposure: 6.1%           |
| Fernandez et al.[17] 2017 | RCT    | Si-MUS 87    | TOT 96     | 12 mo              | De novo urgency: Si 10.1%, TOT 12.5%  |
|                     |         |              |            |                    | Persistent urgency: Si 20.2%, TOT 11.5% |
|                     |         |              |            |                    | Difficulty urinating: Si 0%, TOT 2%   |
|                     |         |              |            |                    | Mesh extrusion: Si 4.5%, TOT 7.3%     |
|                     |         |              |            |                    | UTI: Si 2.2%, TOT 1%                  |
| Zhang et al.[18] 2016 | RCT    | TVT 58       | TVT-O 62   | 95 mo              | Complications: Postoperative urinary difficulty: TVT 10%, TVT-O 2.9% |
|                     |         |              |            |                    | De novo voiding symptoms: TVT 20.7%, TVT-O 11.3% |
|                     |         |              |            |                    | De novo storage symptoms: TVT 12.1%, TVT-O 9.7% |
|                     |         |              |            |                    | Recurrent UTI: TVT 8.6%, TVT-O 4.8%   |
|                     |         |              |            |                    | De novo dyspareunia: TVT 5.2%, TVT-O 8.1% |
|                     |         |              |            |                    | Tape exposure: TVT 3.5%, TVT-O 8.1%   |
|                     |         |              |            |                    | De novo storage symptoms: TVT 5%, TOT 14.9% |
|                     |         |              |            |                    | De novo voiding symptoms: TVT 12.5%, TOT 14.9% |
|                     |         |              |            |                    | Mesh complication: TVT 5%, TOT 14.9%  |
|                     |         |              |            |                    | Urine retention requiring intervention: TVT 2%, TOT 7% |
|                     |         |              |            |                    | Vaginal mesh exposure: TVT 6%, TOT 4%  |
|                     |         |              |            |                    | Vaginal tape erosion: TVT 6%, TOT 4%   |
|                     |         |              |            |                    | De novo urgency: TVT 20.7%, TVT-O 11.3% |
|                     |         |              |            |                    | De novo dyspareunia: TVT 8.6%, TVT-O 4.8% |
|                     |         |              |            |                    | Reoperation for SUI: TVT 5.2%, TVT-O 8.1% |
|                     |         |              |            |                    | Mesh complication: TVT 5%, TOT 14.9%  |
|                     |         |              |            |                    | Urine retention requiring intervention: TVT 2%, TOT 7% |
|                     |         |              |            |                    | Vaginal mesh exposure: TVT 6%, TOT 4%  |
| Schellart et al.[19] 2016 | RCT    | TOT 72       |            | 24 mo              | Substantial pain: TVT 21%, TOT 10%    |
|                     |         |              |            |                    | Haemorrhage right groin: 2%            |
|                     |         |              |            |                    | Exposure requiring re-operation: 4%   |
|                     |         |              |            |                    | Failure needing re-operation: 4%       |
|                     |         |              |            |                    | UTI: 33%                               |
|                     |         |              |            |                    | Overactive bladder symptoms: 13%      |
|                     |         |              |            |                    | Pain limiting normal mobility: 17%     |
|                     |         |              |            |                    | De novo urgency: TVT-O 8.5%, TOT 10.2% |
|                     |         |              |            |                    | De novo dyspareunia: TVT-O 0%, TOT 6.3% |
|                     |         |              |            |                    | Reoperation for SUI: TVT-O 1%, TOT 0%  |
|                     |         |              |            |                    | Tape erosion: TVT-O 0%, TOT 0%         |
|                     |         |              |            |                    | Major postoperative complications: TVT-O 0%, TOT 0% |
|                     |         |              |            |                    | Vaginal tape erosion: TVT-O 0%, TOT 0%  |
|                     |         |              |            |                    | De novo urge incontinence at 1 month: Si 7.1%–11.6%, TVT-O 5.7% |
|                     |         |              |            |                    | De novo voiding difficulty at 1 month: Si 4.3%–8.7%, TVT-O 2.9% |
|                     |         |              |            |                    | De novo urgency: Si 8.4%, TVT-O 12.9%  |

(continued)
| Study                          | Design | Intervention | Comparison | Follow-up duration | Complications |
|-------------------------------|--------|--------------|------------|-------------------|---------------|
| Lee et al. [26] 2015          | RCT    | TOT 103      | TVT-O 62   | 12 mo             | Difficulty urinating: SI 0.7%, TVT-O 0.9% |
|                               |        |              |            |                   | Mesh extrusion: SI 2.3%, TVT-O 1.9% |
|                               |        |              |            |                   | Recurrent UTI: SI 0.7%, TVT-O 0.9% |
|                               |        |              |            |                   | Repeat surgery: 1.8% |
|                               |        |              |            |                   | Groin pain: 6.2% |
|                               |        |              |            |                   | Urinary tract infection (UTI): 19.6% |
|                               |        |              |            |                   | De novo urgency: 4.3% |
|                               |        |              |            |                   | Postoperative anti-incontinence surgery: 19.6% |
| Tommaselli et al. [27] 2015   | RCT    | TVT-O 62     | TOT 103    | 60 mo             | De novo urgency incontinence: TVT 3.1%, TVT-O 2.4% |
|                               |        |              |            |                   | Urinary tract infection (UTI): TVT 20.6%, TVT-O 22.1% |
|                               |        |              |            |                   | No woman had any sign of tissue reaction, erosion, or tape protrusion. |
|                               |        |              |            |                   | No de novo urgency incontinence |
|                               |        |              |            |                   | Pelvic pain: 6.2% |
| Laurikainen et al. [28] 2014  | RCT    | TVT-O 123    | TOT 131    | 60 mo             | De novo urgency incontinence: TVT 3.1%, TVT-O 2.4% |
|                               |        |              |            |                   | Urinary tract infection (UTI): TVT 20.6%, TVT-O 22.1% |
|                               |        |              |            |                   | No woman had any sign of tissue reaction, erosion, or tape protrusion. |
|                               |        |              |            |                   | No de novo urgency incontinence |
|                               |        |              |            |                   | Pelvic pain: 6.2% |
| Nyssönen et al. [29] 2014     | RCT    | TVT 50       | TOT 50     | 46 mo             | De novo urgency incontinence: TVT 3.1%, TVT-O 2.4% |
|                               |        |              |            |                   | Urinary tract infection (UTI): TVT 20.6%, TVT-O 22.1% |
|                               |        |              |            |                   | No woman had any sign of tissue reaction, erosion, or tape protrusion. |
| Scheiner et al. [30] 2014     | RCT    | TVT 50       | TOT 28/TVT-O 34 | 12 mo             | Pelvic pain: 6.2% |
|                               |        |              |            |                   | Pelvic pain: 6.2% |
| Abel et al. [31] 2014         | RCT    | TVT-O 126    | TOT 112    | 36 mo             | Pelvic pain: 6.2% |
|                               |        |              |            |                   | Pelvic pain: 6.2% |
| Bianchi et al. [32] 2014      | RCT    | TVT-O 54     | TOT 54     | 24 mo             | Pelvic pain: 6.2% |
|                               |        |              |            |                   | Pelvic pain: 6.2% |
| Ross et al. [33] 2014         | RCT    | TVT 30       | TOT 56     | 12 mo             | Pelvic pain: 6.2% |
| Djehdian et al. [34] 2014     | RCT    | SI-MUS 64    | TVT 36     | 12 mo             | Pelvic pain: 6.2% |
| Schellart et al. [35] 2014    | RCT    | TOT 87      | SI-MUS 84  | 12 mo             | Pelvic pain: 6.2% |
| Wade et al. [36] 2013         | RCT    | TVT 36       | TOT 35     | 24 mo             | Pelvic pain: 6.2% |
| Basu et al. [37] 2013         | RCT    | TVT 33      | SI-MUS 69  | 36 mo             | Pelvic pain: 6.2% |
| Mostafa et al. [38] 2013      | RCT    | TVT-O 62     | SI-MUS 69  | 12 mo             | Pelvic pain: 6.2% |
| Grigoriadis et al. [39] 2013  | RCT    | TVT-O 86     | SI-MUS 85  | 22.3 mo           | Pelvic pain: 6.2% |
| Schierlitz et al. [40] 2012   | RCT    | TVT 72      | TOT 75     | 36 mo             | Pelvic pain: 6.2% |
| Barber et al. [41] 2012       | RCT    | TVT 127     | SI-MUS 69  | 36 mo             | Pelvic pain: 6.2% |

(continued)
| Study | Design | Intervention | Comparison | Follow-up duration | Complications |
|-------|--------|--------------|------------|--------------------|---------------|
| Masata et al. [42] 2012 | RCT | TVT-O 68 | | 24 mo | De novo urgency | 19.1% |
| | | | | | Tape cut | 2.9% |
| | | | | | Tape erosion | 1.5% |
| | | | | | UTI | 2.9% |
| Teo et al. [43] 2011 | RCT | TVT 66 | TVT-O 61 | 12 mo | Hemorrhage | TVT-O 1.5%, TVT 1.6% |
| | | | | | Intermittent self-catheterization | TVT-O 1.6%, TVT 4.5% |
| | | | | | Vaginal injury | TVT-O 4.9%, TVT 0% |
| | | | | | Leg pain | TVT-O 26.4%, TVT 1.7% |
| | | | | | De novo/worsening overactive bladder | TVT-O 11.3%, TVT 5.1% |
| | | | | | Vaginal tape erosion | TVT-O 2%, TVT 2.7% |
| | | | | | De novo urgency | TVT 5.7%, TVT-O 2.7% |
| | | | | | Urinary retention | TVT 0%, TVT-O 0% |
| | | | | | Chronic pelvic pain | TVT 0%, TVT-O 2.7% |
| | | | | | Pain during intercourse | TVT 2.9%, TVT-O 0.27% |
| | | | | | Incontinence during intercourse | TVT 5.7%, TVT-O 5.4% |
| Angiolli et al. [44] 2010 | RCT | TVT 35 | TVT-O 37 | 60 mo | Vaginal erosions | TVT-O 5.7%, TVT 2.7% |
| | | | | | Bladder injury | TVT 5%, TVT-O 2% |
| | | | | | Urinary retention | TVT 0%
| | | | | | Chronic pelvic pain | TVT 0%
| | | | | | Bladder injury | TVT 0%
| | | | | | Vaginal erosions | TVT-O 5.7%, TVT 2.7% |
| | | | | | De novo urgency | TVT 5.7%, TVT-O 2.7% |
| | | | | | Urinary retention | TVT 0%
| | | | | | Chronic pelvic pain | TVT 0%
| | | | | | Bladder injury | TVT 0%
| | | | | | Vaginal erosions | TVT-O 5.7%, TVT 2.7% |
| Deflieux et al. [45] 2010 | RCT | TVT 75 | TVT-O 74 | 24 mo | Bladder injury | TVT-O 10%, TVT-O 5% |
| | | | | | Urethral injury | TVT-O 2.1%–7.2% |
| | | | | | Vaginal erosion | TVT-O 1%–4.3% |
| | | | | | Vaginal tape erosion | TVT-O 1.5%–4.3% |
| | | | | | Repeated surgery | TVT-O 1%–4.3% |
| | | | | | De novo urgency and/or worsening of preexisting surgery | TVT-O 1%–4.3% |
| | | | | | Bladder injury | TVT-O 1%–4.3% |
| | | | | | Vaginal erosions | TVT-O 1%–4.3% |
| | | | | | Urinary retention | TVT-O 1%–4.3% |
| | | | | | Bladder perforation | TVT-O 1%–4.3% |
| | | | | | De novo urgency | TVT-O 1%–4.3% |
| | | | | | Urethral injury | TVT-O 1%–4.3% |
| | | | | | Vaginal mesh erosion | TVT-O 1%–4.3% |
| | | | | | Sexual function | TVT-O 1%–4.3% |
| Kim et al. [46] | Meta-analysis | Oct. 2017 | 29 included RCTs | | Standard midurethral slings (SMUS) vs SI-MUS | |
| | | | | | Sexual function: No significant difference | |
| | | | | | Postoperative pain scores: No significant difference | |
| | | | | | Bladder injury, UTI, urinary retention, de novo urgency, mesh extrusion, groin pain, vaginal erosion, tape release, urgency, and re-operation: No significant difference | |
| | | | | | Voiding dysfunction was less observed in SI-MUS | |
| Bai et al. [47] | Meta-analysis | Dec. 2016 | 8 studies | | Adjustable SI-MUS (Ajust) vs other slings (TOT, TVT-O) | |
| | | | | | Groin pain | SI 2%, TOT/TVT-O 5.8% |
| | | | | | Repeated continence surgery | SI 2.1%–7.2% |
| | | | | | Postoperative voiding difficulties | SI 2.2%–4.3% |
| | | | | | Vaginal tape erosion | SI 1.5%–4.3% |
| | | | | | De novo urgency and/or worsening of preexisting surgery | SI 7%–25% |
| Jiao et al. [48] | Meta-analysis | Nov. 2017 | 12 studies | | Single-incision mini-slings (MiniArc) vs transobturator mid-urethral slings | |
| | | | | | Postoperative groin pain | TO 3.6%–57.6% |
| | | | | | Urinary retention | TO 1.9%–51% |
| | | | | | Repeat stress incontinence surgery | TO 1%–6.7% |
| | | | | | Bladder perforation | TO 1.8%–5.2% |
| | | | | | De novo urgency | TO 4.4%–19.5% |
| | | | | | UTI | TO 4.4%–19.5% |
| | | | | | Vaginal mesh erosion | TO 1.4%–1.8% |
| | | | | | Sexual function | TO 0% |
| Fusco et al. [49] | Meta-analysis | Nov. 2016 | 28 studies | | The comparative data on colposuspensions, pubovaginal slings, and midurethral tapes | |
| | | | | | Bladder/vaginal perforation | RP-TVT 0.8%–11.4%, TVT-O 0.8%–10% |
| | | | | | Pelvic haematomata | RP-TVT 0.7%–5.5%, TVT-O 1.4%–2.4% |
| | | | | | Vaginal erosions | RP-TVT 1.2%–5.9%, TVT-O 0.8%–7% |
| | | | | | UTI | RP-TVT 3.5%–20.6%, TVT-O 0.7%–21.9% |
| | | | | | Storage lower urinary tract symptoms | RP-TVT 2.2%–35.3%, TVT-O 1.2%–28.6% |
| Study                        | Design          | Intervention   | Comparison     | Follow-up duration | Complications                                                                 |
|-----------------------------|-----------------|----------------|----------------|-------------------|--------------------------------------------------------------------------------|
| Ford et al[53]              | Meta-analysis   | Jun. 2014      | 81 studies     |                   | Voiding lower urinary tract symptoms RP-TVT 2.6%–21.4%, TVT-O 0.8%–15.7%     |
|                            |                 |                |                |                   | CIC RP-TVT 0.7%–13.9%, TVT-O 1.5%–17%                                       |
|                            |                 |                |                |                   | Reoperation rate RP-TVT 1.5%–17.6%, TVT-O 0.4%–17%                           |
|                            |                 |                |                |                   | Mid-urethral sling Bladder or urethral perforation RP 4.9%, TO 0.6%          |
|                            |                 |                |                |                   | Voiding dysfunction De novo urgency or urgency incontinence RP 7.2%, TO 3.8% |
|                            |                 |                |                |                   | Groin pain RP 1.4%, TO 6.6%                                                  |
|                            |                 |                |                |                   | Suprapubic pain RP 2.9%, TO 0.8%                                              |
|                            |                 |                |                |                   | Vaginal tape erosion RP 2%, TO 2.2%                                           |
|                            |                 |                |                |                   | Repeat incontinence surgery RP 1.1%, TO 10%                                  |
| Nambiar et al[54]           | Meta-analysis   | Feb. 2013      | 31 studies     |                   | Single incision sling Major vascular or visceral injury Si 1.6%               |
|                            |                 |                |                |                   | Vaginal wall perforation Si 1.6%, RP 1.6%                                    |
|                            |                 |                |                |                   | Bladder or urethral perforation Si 0.7%–2.9%, RP 2.9%–4.7%                    |
|                            |                 |                |                |                   | Urinary retention Si 1.5%–10%, RP 2.4%–9.3%                                  |
|                            |                 |                |                |                   | Infection Si 10%, RP 5%                                                      |
|                            |                 |                |                |                   | Vaginal mesh exposure Si 5.4%, RP 0.7%                                         |
|                            |                 |                |                |                   | Mesh extrusion into the bladder or urethra Si 3.3%, RP 6.9%                   |
|                            |                 |                |                |                   | Dyspareunia Si 10%, RP 3.4%                                                   |
|                            |                 |                |                |                   | De novo urgency Si 13.3%–35.3%, RP 6.5%–15.6%                                |
|                            |                 |                |                |                   | New-onset detrusor overactivity Si 5.4%, RP 6%                                |
|                            |                 |                |                |                   | Repeat stress incontinence surgery Si 1.5%–24.3%, RP 3.1%                    |
| Pergialiotis et al[52]      | Meta-analysis   | 2016           | 32 studies     |                   | De novo overactive bladder following midurethral sling procedures              |
|                            |                 |                |                |                   | De novo OAB Si 7.4%–10.2%, TO 2.4%–8.5%, RP 3%                               |
| Leone et al[53]             | Meta-analysis   | Oct. 2016      | 16 studies     |                   | Long-term outcomes of TOT and TVT procedures                                  |
|                            |                 |                |                |                   | De novo OAB TOT 3.9%–9.7%, TVT 1.4%–10.1%                                    |
|                            |                 |                |                |                   | Voiding dysfunction TOT 0.8%–11.3%, TVT 0.6%–20.6%                            |
|                            |                 |                |                |                   | Vaginal tape erosion TOT 0.8%–14.9%, TVT 1.6%–6.4%                            |
|                            |                 |                |                |                   | Bladder tape erosion TOT 2.6%, TVT 0.6%                                       |
|                            |                 |                |                |                   | Groin pain TOT 3.9%–33.9%, TVT 1.7%–6.7%                                     |
|                            |                 |                |                |                   | Recurrent UTI TOT 4.3%–4.8%, TVT 7.5%–8.6%                                    |
| Tommaselli et al[54]        | Meta-analysis   | Jun. 2014      | 11 studies     |                   | Midurethral slings                                                           |
|                            |                 |                |                |                   | Pain RP 1.8%, TO 5.7%                                                        |
|                            |                 |                |                |                   | Urinary retention RP 5.4%, TO 4%                                               |
|                            |                 |                |                |                   | Infection RP 2.7%, TO 3.8%                                                    |
|                            |                 |                |                |                   | Hematoma/bleeding RP 3.7%, TO 3.9%                                            |
|                            |                 |                |                |                   | Vaginal injury RP 0.4%, TO 3.3%                                               |
|                            |                 |                |                |                   | Bladder/urethral injury RP 2.5%, TO 0.4%                                      |
|                            |                 |                |                |                   | UTI RP 9.3%, TO 3%                                                            |
|                            |                 |                |                |                   | De novo urgency RP 10%, TO 10.2%                                              |
|                            |                 |                |                |                   | Tape erosion RP 2.1%, TO 2.7%                                                 |
| Sun et al[55]               | Meta-analysis   | 2011           | 18 studies     |                   | Comparison between the retropubic and transobturator approaches              |
|                            |                 |                |                |                   | Bladder perforation TO 0.2%–0.7%, RP 0.3%–0.5%                                |
|                            |                 |                |                |                   | Hematoma TO 1.4%, RP 1.9%–2.9%                                                 |
|                            |                 |                |                |                   | Thigh/groin pain TO 8%–8.4%, RP 2.9%–4.6%                                    |
|                            |                 |                |                |                   | Voiding dysfunction TO 0.5%–2.4%, RP 3.3%–4.4%                                |
|                            |                 |                |                |                   | De novo urgency TO 5.9%–6.5%, RP 5.6%–8.6%                                    |
|                            |                 |                |                |                   | Tape erosion TO 1.5%–1.9%, RP 0.7%–1.8%                                        |
| Seklehner et al[56]         | Meta-analysis   | Jan. 2014      | 21 studies     |                   | The performance of retropubic mid urethral slings vs transobturator mid urethral slings |
|                            |                 |                |                |                   | Mesh erosion/exposure TO 0.8%–5.4%, RP 0.9%–5.7%                               |
|                            |                 |                |                |                   | Urinary retention TO 0.6%–17%, RP 2.7%–15.8%                                  |
| Study | Design | Intervention | Comparison | Follow-up duration | Complications |
|-------|--------|--------------|------------|--------------------|---------------|
| Jha et al[57] | Meta-analysis | 2009 | 21 studies | | Impact of incontinence surgery on sexual function |
| | | | | | A significant reduction in coital incontinence |
| | | | | | Synthetic midurethral slings |
| | | | | | Bladder perforation 1%–34%; More common with RP passage |
| | | | | | Vascular injury RP 0.7%–8%, TO 0–2% |
| | | | | | Bowel injury RP 0.03%–0.07% |
| | | | | | Postoperative pain, groin pain TO > RP |
| | | | | | 1.3% persistent urinary urgency (which was present preoperatively) |
| | | | | | De novo urinary urgency, and/or bladder outlet obstruction RP 3% TO 0% |
| | | | | | Urinary retention 21.8% |
| | | | | | Vaginal mesh exposure 1.5% to 2% |
| Gomes et al[58] | Review | 2017 | | | Update on complications of synthetic suburethral slings |
| | | | | | Bleeding RP 0.7%–8%, TO 0–2% |
| | | | | | Bladder injury RP 0.7%–24%, TO 0–16% |
| | | | | | Urethral injury RP 0.1%–0.2%, TO 0.1%–2.5% |
| | | | | | Urethral erosion RP 0.03%–0.8%, TO 0.03%–0.8% |
| | | | | | Intestinal injury RP 0.03%–0.7%, TO 0% |
| | | | | | Vaginal erosion RP 0–1.5%, TO 0%–10.9% |
| | | | | | UTI RP 7.4%–13%, TO 7.4%–13% |
| | | | | | Pain RP 4%, TO 9.4% |
| | | | | | Urgency “de novo” RP 0.2%–25%, TO 0–15.6% |
| | | | | | Bladder outlet obstruction RP 6%–18.3%, TO 3.0%–11% |
| | | | | | Urinary retention RP 4.1%–19.5%, TO 2.7%–11% |
| Alwaal et al[60] | Review | 2016 | | | Female sexual function following mid-urethral slings |
| | | | | | PISQ-12 Improvements |
| | | | | | Sexual Function and Quality of Life: TOT vs SI-MUS |
| | | | | | Improved in all the six Female Sexual Function Index domains |
| | | | | | Safety considerations for synthetic sling surgery |
| | | | | | Urethral obstruction/voiding dysfunction 5.5% |
| | | | | | Urethral obstruction requiring surgery 3.2% |
| | | | | | Urinary infections 4.5% |
| | | | | | De novo OAB 10.2% |
| | | | | | Pelvic organ perforation 3.3% |
| | | | | | Mesh exposure/erosion/extrusion 2.7% |
| | | | | | Refractory pain 3.5% |
| | | | | | Neurologic symptoms 2.0% |
| | | | | | Fistulas 0.3% |
| Pastore et al[61] | Review | 2016 | | | Indications, contraindications, and complications of mesh in the surgical treatment of urinary incontinence |
| | | | | | Failure to correct incontinence 27%–18% |
| | | | | | Voiding dysfunction RP 2.7%, TO 2.7% |
| | | | | | Postoperative urge symptoms RP 6%–25%, TO 6% |
| | | | | | De novo urgency incontinence RP 0%, TO 0.3% |
| | | | | | Persistent postoperative urgency incontinence RP 12%, TO 10% |
| | | | | | UTI RP 12.8%, TO 17.7% |
| Blaivas et al[62] | Review | 2015 | | | Bladder and urethral perforation RP 3.5%, TO 6.6% |
| | | | | | Vaginal perforation RP 2%, TO 4% |
| Kirby et al[63] | Review | 2013 | | | Pelvic hematomas 1.4% |

(continued)
As mentioned before, only 6 of 35 (17.1%) RCTs in our review took into account sexual dysfunction. Palos et al[11] reported a total of 92 complications from patients of MUS and they found the RP-MUS had a proportionately higher number of dyspareunia (2.5% vs 0%) compared to the TO-MUS. Schellart et al[15] reported a total of 75 patients with complications of TOT and they found none of them complaining of dyspareunia. Zhang et al[18] discovered a total of 110 patients with complications of MUS and they found the TVT-O group had more cases of dyspareunia (8.1% vs 5.2%) compared to the TVT group. Masata et al[22] reported a total of 96 patients with complications of MUS where the SI-MUS had more de novo dyspareunia (6.3% vs 0%) in comparison with the TVT-O group. Scheiner et al[30] reported a total of 112 patients with complications and among them the TVT-O group had a higher number of patients with sexual dysfunction (17.2%, 1.9%, 0%) than the TVT/TOT group. In addition, Angioli et al[44] found a total of 72 patients with complications of MUS with the TVT group showing slightly more patients with pain during intercourse (2.9% vs 2.7%) than the TVT-O group. We thought the reasons might be related to the formation of paraurethral bands (anterior vaginal wall banding in the paraurethral folds immediately adjacent to the midurethral placement of the sling) or the localization of the MUS resulting in vaginal narrowing due to more vaginal tissue (perineal membrane) incorporated. Sexual dysfunction has a severe impact on patients’ postoperative life, both physically and mentally; it should be clearly documented as a patient safety issue.

We also included systematic review/meta-analysis and review in our studies in order to find out any other situations that might

| Study         | Design | Intervention | Comparison | Follow-up duration | Complications |
|---------------|--------|--------------|------------|-------------------|---------------|
| Cerruto et al[64] | Review | 2011         |            |                   | Vaginal mesh exposure RP 4.4%, TO 2.7% |
|               |        |              |            |                   | Transobturant versus retropubic synthetic slings |
|               |        |              |            |                   | Postoperative pain RP 1.7%, TO 12% |
|               |        |              |            |                   | Voiding dysfunction RP 7%, TO 4% |
|               |        |              |            |                   | Bladder perforations RP 5.5%, TO 0.3% |
|               |        |              |            |                   | Adverse events over 2 y after retropubic or transobturator midurethral sling surgery |
|               |        |              |            |                   | Bladder perforation RP 4.4%, TO 0% |
|               |        |              |            |                   | Urethral perforation RP 0.4%, TO 0% |
|               |        |              |            |                   | Mesh erosion RP 0.4%, TO 0.5% |
|               |        |              |            |                   | Mesh exposure RP 4%, TO 2.3% |
|               |        |              |            |                   | Recurrent UTI RP 21%, TO 13% |
|               |        |              |            |                   | Surgical site infection RP 0.9%, TO 0% |
|               |        |              |            |                   | Neurologic symptoms RP 5.8%, TO 8.1% |
|               |        |              |            |                   | Voiding dysfunction RP 1.8%, TO 2.7% |
|               |        |              |            |                   | De novo urge incontinence RP 0%, TO 0.5% |
|               |        |              |            |                   | Persistent urge incontinence RP 15%, TO 14.9% |

| Brubaker et al[65] | Review | 2011         |            |                   | Bladder perforation RP 4.4%, TO 0% |
|                   |        |              |            |                   | Urethral perforation RP 12%, TO 4% |
|                   |        |              |            |                   | Mesh erosion RP 0.3%, TO 0.3% |
|                   |        |              |            |                   | Mesh exposure RP 0.4%, TO 0% |
|                   |        |              |            |                   | Recurrent UTI RP 0.2%, TO 0% |
|                   |        |              |            |                   | Surgical site infection RP 1%, TO 0% |
|                   |        |              |            |                   | Neurologic symptoms RP 0.2%, TO 0% |
|                   |        |              |            |                   | Voiding dysfunction RP 0.1%, TO 0.1% |
|                   |        |              |            |                   | De novo urge incontinence RP 0.1%, TO 0% |
|                   |        |              |            |                   | Persistent urge incontinence RP 0.1%, TO 0% |

LUTS = lower urinary tract symptoms, MUS = midurethral sling, OAB = overactive bladder, PISQ = Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, RCT = randomized controlled trial, RP = retropubic approach, SI = single incision, SUI = stress urinary incontinence, TO = transobturator approach, TVT = tension-free vaginal tape using the retropubic technique, TVT-O = transobturator tape using the in-out technique, UTI = urinary tract infection.

As mentioned before, only 6 of 35 (17.1%) RCTs in our review took into account sexual dysfunction. Palos et al[11] reported a total of 92 complications from patients of MUS and they found the RP-MUS had a proportionately higher number of dyspareunia (2.5% vs 0%) compared to the TO-MUS. Schellart et al[15] reported a total of 75 patients with complications of TOT and they found none of them complaining of dyspareunia. Zhang et al[18] discovered a total of 110 patients with complications of MUS and they found the TVT-O group had more cases of dyspareunia (8.1% vs 5.2%) compared to the TVT group. Masata et al[22] reported a total of 96 patients with complications of MUS where the SI-MUS had more de novo dyspareunia (6.3% vs 0%) in comparison with the TVT-O group. Scheiner et al[30] reported a total of 112 patients with complications and among them the TVT-O group had a higher number of patients with sexual dysfunction (17.2%, 1.9%, 0%) than the TVT/TOT group. In addition, Angioli et al[44] found a total of 72 patients with complications of MUS with the TVT group showing slightly more patients with pain during intercourse (2.9% vs 2.7%) than the TVT-O group. We thought the reasons might be related to the formation of paraurethral bands (anterior vaginal wall banding in the paraurethral folds immediately adjacent to the midurethral placement of the sling) or the localization of the MUS resulting in vaginal narrowing due to more vaginal tissue (perineal membrane) incorporated. Sexual dysfunction has a severe impact on patients’ postoperative life, both physically and mentally; it should be clearly documented as a patient safety issue.

We also included systematic review/meta-analysis and review in our studies in order to find out any other situations that might

| Complications                  | RP-MUS | TO-MUS | SI-MUS |
|-------------------------------|--------|--------|--------|
| Bladder perforation           | 0.8%–11.4% | 0.8%–10% | 0.7%–2.9% |
| Vaginal injury                | 0.8%–11.4% | 0.8%–15% | 1.6% |
| Hemorrhage                    | 1.6%   | 1.5%   |        |
| Hematoma                      | 0.7%–5.5% | 1.4%–2.4% |        |
| UTI                           | 0.9%–29.3% | 4.8%–33% | 0.7%–28.1% |
| LUTS                          | 0%–15% | 2.4%–29% | 4.3%–10.2% |
| Urine retention               | 0.8%–11.4% | 0.6%–10% | 0.7%–2.9% |
| De novo urgency               | 0%–29% | 0.7%–29% | 4.3%–12.2% |
| Post-op pain                  | 1.4%–21.1% | 1.5%–26.7% | 0%–3.5% |
| Tape erosion/extrusion        | 0%–5.7% | 1.9%–10% | 1.4%–4.5% |
| Further SUI surgery           | 0%–2.7% | 1.4%–19.6% | 0%–17% |
| Deep vein thrombosis          | 2.5%   | 0%     |        |
| Injury of inferior epigastric vessels | 2.2% |         |        |
| Sexual dysfunction            | 0%–5.2% | TOT 1.9%; TVT-O 0%–17.2% | 6.3% |

LUTS = lower urinary tract symptoms, MUS = midurethral sling, OAB = overactive bladder, PISQ = Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, RCT = randomized controlled trial, RP = retropubic approach, SI = single incision, SUI = stress urinary incontinence, TO = transobturator approach, TVT = tension-free vaginal tape using the retropubic technique, TVT-O = transobturator tape using the in-out technique, UTI = urinary tract infection.
not appear in RCTs. In Kim et al’s study which included 29 RCTs, they found there were no significant differences in sexual function, postoperative pain scores and other domains (bladder injury, UTI, urinary retention, de novo urgency, mesh extrusion, groin pain, vaginal erosion, tape release, urgency, and re-operation rate) among women undergoing MUS or SI-MUS. They did find voiding dysfunction was less frequently observed in SI-MUS group. Nambiar et al reported a total of 31 studies regarding SI-MUS procedures indicating that a major vascular or visceral injury was 1.6%. Pergialiotis et al reported a total of 32 studies specifically focusing on de novo OAB following MUS procedures and they found the SI-MUS was associated with a more elevated rate of OAB than the TO and RP-MUS (7.4%–10.2%, 2.4%–8.8%, 3%). In Seklehner et al’s study collecting 21 researches, they discovered patients in TO-MUS group had a higher incidence of neurologic symptoms than the RP-MUS group (2.7%–23% vs 1.3%–8.2%). In Blaivas et al’s review on the safety considerations for synthetic sling surgery, he pointed out some crucial points: at least 15% of women with MUS experienced a serious adverse outcome and/or recurrent sphincteric incontinence; A subset of women sustain refractory, lifestyle-altering complications that are unique to women with a MUS; MUS-associated complications are under-reported.

From our review, we can see that most studies did not discuss complications or report clearly defined complication measures. Patient safety should be the first priority to keep in mind all the time by surgeon throughout the pre and post-operative period. Besides, the World Health Organization also calls patient safety an endemic concern. Patient safety is a discipline that emphasizes safety in health care through prevention, reduction, reporting, and analysis of medical error that often leads to adverse events.

Despite that many series have documented complications with synthetic MUS, there is compelling evidence showing that these complications remain under-reported in the literature. Deng et al reviewed the MAUDE (Manufacturer and User Facility Device Experience) database and identified 161 major complications included 39 vascular injuries, 38 bowel injuries, and 10 deaths due to surgical complications of synthetic sling placement. They think the under-reporting of major complications of sling procedures is likely due to surgeon awareness, referral patterns and failure to diagnose. In the same study, the ratio of major to total complications in the MAUDE database as compared to literature review suggested significant under-reporting of major complications resulting from synthetic sling placement. They also indicate that surgeons need to proceed with caution as serious complications do occur and be aware of the nature and symptoms of tape related complications for prompt diagnosis and appropriate postoperative management.

5. Conclusions
In summary, any common surgery might carry potential risk and result in long term complications. Physician should always keep in mind that patient safety is the first major concern instead of merely concentrating on the successful rate or efficacy of the surgery. It is indispensable for physician to counsel patient with regard to long-term complications of MUS before surgery, offer all relevant information possible, and have what is in the best interest of patients in mind.

Author contributions
Ling-Hong Tseng and Cheng-Kai Lee wrote the article; Shuenn-Dyh Chang developed analytical tools and analyzed data; Pei-Chun Chien and Yu-Ying Hsu validated the results; Ling-Hong Tseng supervised the project.
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