

# 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

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LYH and LCK contributed equally to this work.

The authors report no conflicts of interest.

The datasets generated during and/or analyzed during the current study are publicly available.

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## 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.<sup>[1]</sup> 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.<sup>[2]</sup> 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.<sup>[3]</sup> 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). The RP-MUS has incisions on the abdominal wall and the vagina, and the tape is passed through the retropubic space. The tape can be inserted from vagina to abdominal wall (bottom-to-top, eg, tension-free vaginal tape [TVT] [Ethicon Inc., Somerville, NJ])<sup>[4]</sup> or from abdominal wall to vagina (top-to-bottom, eg, suprapubic arc [American Medical Systems, Minnetonka, MN]).<sup>[5]</sup> For the TO-MUS, the tape is inserted through the 2 obturator foramen, either from the vagina to the skin of groin area (inside-out, eg, TVT-O [Gynecare TVT-Obturator System, Ethicon, Inc., Somerville, NJ])<sup>[6]</sup> or from the skin of groin area to vagina (outside-in, eg, TOT/MONARC [American Medical Systems, Minnetonka, MN]).<sup>[7]</sup> The SI-MUS (eg, Needleless [Mayumana Healthcare, Lisse, The Netherlands])<sup>[8]</sup>; Adjust [CR Bard Inc., Covington, GA])<sup>[9]</sup> is different from full-length RP and TO-MUS in 2 ways: they (the tapes per se) are shorter, approximately 8 cm rather than 40 cm, and they require only a vaginal incision, and not an abdominal incision.

Initiating patient safety awareness is an attribute of health care systems in hopes to minimize the incidence and impact of, and maximize recovery from, adverse events. Thus, it is clinically relevant is to investigate postoperative complications and consequently figure out how to manage those conditions to bring benefits to patients. The objective of this article was to update the available data pertaining to operative complications of MUS procedures. We have used the optimized literature search algorithm to identify appropriate literatures on the subject of MUS procedures for women with SUI from the MEDLINE.<sup>[10]</sup>

## 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-

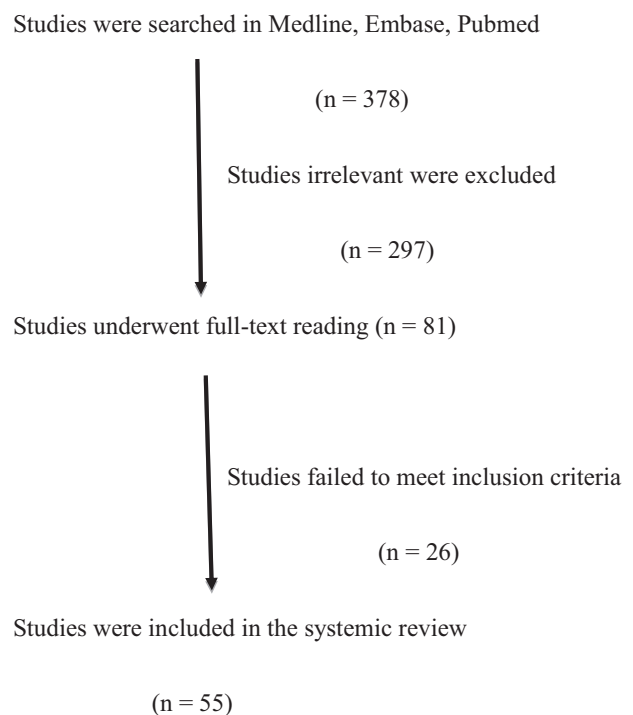
obturator tape using the out-in technique (TOT), TVT-O, Monarc, suprapubic arc, and single incision sling, Needleless and Adjust. Additionally, references from retrieved publications were checked to find extra articles on the topic. Published articles from 2009 to September 2020 were selected for analysis.

### 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



**Figure 1.** Flowchart of study selection in the systemic 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.<sup>[11–65]</sup>

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.<sup>[66,67]</sup>

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.<sup>[68]</sup> 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.<sup>[69]</sup> 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<sup>[66]</sup> 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.<sup>[70]</sup> 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.<sup>[71]</sup> 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.<sup>[72]</sup> 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<sup>[71]</sup> has a severe impact on the quality of life (QOL).<sup>[73]</sup> It is also known that urgency and urgency urinary incontinence worsen quality of life more than SUI.<sup>[69]</sup> 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, <sup>[11]</sup> 2018	RCT	TOT 47	RP-MUS 45	12 mo	Bladder perforation Urinary infection Deep vein thrombosis Tape extrusion Urinary retention De novo urgency Dyspareunia	RP 2.5%, TO 2.4% RP 29.3%, TO 30% RP 2.5%, TO 0% RP 0%, TO 2.4% RP 7.5%, TO 2.4% RP 0%, TO 2.4% RP 2.5%, TO 0%
Tammaa et al, <sup>[12]</sup> 2018	RCT	TVT-O 170	TVT 161	60 mo	Tape erosions UTI LUTS Tape-related pain Detrusor overactivity	TVT 3%, TVT-O 3% TVT 21.2%, TVT-O 18.2% TVT 2.8%, TVT-O 7.9% TVT 1.4%, TVT-O 2.7% TVT 6.4%, TVT-O 6.4%
Dogan et al, <sup>[13]</sup> 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, <sup>[14]</sup> 2018	RCT	SI-MUS 69	TOT 61	36 mo	Further SUI surgery Tape exposure De novo urgency	SI 17%, TOT 4.9% SI 4.9%, TOT 4.9% SI 12.2%, TOT 4.9%
Schellart et al, <sup>[15]</sup> 2018	RCT		TOT 75	36 mo	Reintervention Unintentional perforation Post voiding residual Dyspareunia	5.2% 5.2% 1% 0%
Tieu et al, <sup>[16]</sup> 2017	RCT		TOT 42	12 mo	De novo urgency Repeat SUI surgery Vaginal mesh exposure	0.7% 12% 6.1%
Fernandez et al, <sup>[17]</sup> 2017	RCT	SI-MUS 87	TOT 96	12 mo	De novo urgency Persistent urgency Difficulty urinating Mesh extrusion UTI	SI 10.1%, TOT 12.5% SI 20.2%, TOT 11.5% SI 0%, TOT 2% SI 4.5%, TOT 7.3% SI 2.2%, TOT 1%
Zhang et al, <sup>[18]</sup> 2016	RCT	TVT 58	TVT-O 62	95 mo	Postoperative urinary difficulty De novo voiding symptoms De novo storage symptoms Recurrent UTI De novo dyspareunia Tape exposure	TVT 10%, TVT-O 2.9% TVT 20.7%, TVT-O 11.3% TVT 12.1%, TVT-O 9.7% TVT 8.6%, TVT-O 4.8% TVT 5.2%, TVT-O 8.1% TVT 3.5%, TVT-O 8.1%
Costantini et al, <sup>[19]</sup> 2016	RCT	TVT 40	TOT 47	100 mo	De novo storage symptoms De novo voiding symptoms Mesh complication	TVT 5%, TOT 14.9% TVT 12.5%, TOT 14.9% TVT 5%, TOT 14.9%
Ross et al, <sup>[20]</sup> 2016	RCT	TVT 93	TOT 83	60 mo	Vaginal mesh exposure Urine retention requiring intervention	TVT 2%, TOT 7% TVT 6%, TOT 4%
Schellart et al, <sup>[21]</sup> 2016	RCT		TOT 72	24 mo	Substantial pain Haemorrhage right groin Exposure requiring re-operation Failure needing re-operation UTI Overactive bladder symptoms Pain limiting normal mobility	TVT 21%, TOT 10% 2% 4% 4% 33% 13% 17%
Masata et al, <sup>[22]</sup> 2016	RCT	SI-MUS 49	TVT-O 47	12 mo	De novo urgency De novo dyspareunia Reoperation for SUI Tape erosion	TVT-O 8.5%, SI 10.2% TVT-O 0%, SI 6.3% TVT-O 1%, SI 0% TVT-O 0%, SI 0%
Jurakova et al, <sup>[23]</sup> 2016	RCT	SI-MUS 44	TVT-O 46	12 mo	Major postoperative complications Vaginal tape erosion	TVT-O 0%, SI 0% TVT-O 0%, SI 0%
Gaber et al, <sup>[24]</sup> 2016	RCT	SI-MUS 69/70	TVT-O 70	12 mo	De novo urge incontinence at 1 mo De novo voiding difficulty at 1 month	SI 7.1%–11.6%, TVT-O 5.7% SI 4.3%–8.7%, TVT-O 2.9%
Martinez et al, <sup>[25]</sup> 2015	RCT	SI-MUS 131	TVT-O 108	54 mo	De novo urgency	SI 8.4%, TVT-O 12.9%

(continued)

**Table 1**  
(continued).

Study	Design	Intervention	Comparison	Follow-up duration	Complications
Lee et al, <sup>[26]</sup> 2015	RCT		TOT 103	12 mo	Difficulty urinating SI 0.7%, TVT-O 0.9%
Tommaselli et al, <sup>[27]</sup> 2015	RCT		TVT-O 62	60 mo	Mesh extrusion SI 2.3%, TVT-O 1.9%
Laurikainen et al, <sup>[28]</sup> 2014	RCT	TVT 131	TVT-O 123	60 mo	Recurrent UTI SI 0.7%, TVT-O 0.9%
Nyysönen et al, <sup>[29]</sup> 2014	RCT	TVT 50	TOT 50	46 mo	Repeat surgery 1.8%
Scheiner et al, <sup>[30]</sup> 2014	RCT	TVT 50	TOT 28/TVT-O 34	12 mo	Groin pain 6.2%
Abdel et al, <sup>[31]</sup> 2014	RCT	TOT 112	TVT-O 126	36 mo	UTI 19.6%
Bianchi et al, <sup>[32]</sup> 2014	RCT		TVT-O 54	24 mo	De novo urgency 4.3%
Ross et al, <sup>[33]</sup> 2014	RCT	TVT 30		12 mo	Repeated anti-incontinence surgery 19.6%
Djehdian et al, <sup>[34]</sup> 2014	RCT	SI-MUS 64	TOT 56	12 mo	De novo urgency incontinence TVT 3.1%, TVT-O 2.4%
Schellart et al, <sup>[35]</sup> 2014	RCT		TOT 87	12 mo	UTI TVT 20.6%, TVT-O 22.1%
Wadie et al, <sup>[36]</sup> 2013	RCT	TVT 36	TOT 35	24 mo	No woman had any sign of tissue reaction, erosion, or tape protrusion.
Basu et al, <sup>[37]</sup> 2013	RCT	TVT 33		36 mo	De novo urgency TVT 3%–25%, TOT 6%–25%
Mostafa et al, <sup>[38]</sup> 2013	RCT	SI-MUS 69	TVT-O 62	12 mo	Bladder perforation TOT/TVT-O 0%, TVT 3.7%
Grigoriadis et al, <sup>[39]</sup> 2013	RCT	SI-MUS 85	TVT-O 86	22.3 mo	Vaginal perforation TOT/TVT-O 1.3%–15%, TVT 10%
Schierlitz et al, <sup>[40]</sup> 2012	RCT	TVT 72	TOT 75	36 mo	Voiding obstructions TOT/TVT-O 2.5%, TVT 2.5%
Barber et al, <sup>[41]</sup> 2012	RCT	TVT 127		12 mo	Vaginal tape exposure TOT/TVT-O 1.5%–10%, TVT 0%
					Thigh or groin pain TOT/TVT-O 1.5%–8.3%, TVT 2.7%
					Sexual dysfunction TOT/TVT-O 1.9%–17.2%, TVT 0%
					None of the women reported thigh pain
					Late vaginal erosion TOT 1.8%
					Recurrent UTI 1.7%
					Repeat continence surgery 6%
					Urinary retention 3.5%
					UTI 7.1%
					Thigh pain 26.7%
					Tape exposure 5.3%
					De novo urgency 3.5%
					SUI surgical revision 3.5%
					Bladder perforation 2.9%
					Tape exposure SI 9.4%, TOT 8.9%
					De novo urgency SI 6.3%, TOT 7.1%
					UTI SI 28.1%, TOT 21.4%
					Thigh pain SI 0%, TOT 7.1%
					Ecchymosis SI 0%, TOT 5.4%
					UTI 4.2%
					Reoperation 3.1%
					Bladder retention 1%
					Bladder injury TVT 6.7%, TOT 2.4%
					Thigh pain TOT 9.5%
					De novo urge TOT 7.1%
					Vaginal extrusion TOT 2.4%
					Prolonged retention TVT 2.2%, TOT 2.4%
					Injury of inferior epigastric vessels TVT 2.2%
					Repeat continence procedure 0%
					SUI symptoms 9%
					Voiding dysfunction SI 1.4%, TVT-O 2.9%
					Vaginal erosion SI 1.4%, TVT-O 2.9%
					Postoperative groin pain TVT-O 5.8%
					Dull pain deep inside the vagina SI 3.5%
					No postoperative urinary retention
					SUI at 6 or 12 mo TOT 28%, TVT 16.3%
					Repeat sling procedure at 36 mo TOT 18.3%, TVT 1.2%
					Stress incontinence 14%
					Urge incontinence 29%
					Bladder perforation 4.8%
					Voiding dysfunction 2.4%

(continued)

**Table 1**  
**(continued).**

Study	Design	Intervention	Comparison	Follow-up duration	Complications
Masata et al, <sup>[42]</sup> 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, <sup>[43]</sup> 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%
Angioli et al, <sup>[44]</sup> 2010	RCT	TVT 35	TVT-O 37	60 mo	Vaginal tape erosion TVT-O 2%, TVT 5.3% 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 2.7% Incontinence during intercourse TVT 5.7%, TVT-O 5.4%
Deffieux et al, <sup>[45]</sup> 2010	RCT	TVT 75	TVT-O 74	24 mo	Vaginal erosions TVT 5.7%, TVT-O 2.7% Bladder injury TVT 5%, TVT-O 2% Urethral injury TVT 1% Vaginal extrusion TVT-O 1% Repeat surgery (reintervention) TVT 2.7%, TVT-O 1.4% Bladder outlet obstruction symptoms TVT 10%, TVT-O 5%
Kim et al <sup>[46]</sup>	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 <sup>[47]</sup>	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% TOT/TVT-O 1.9%–4.4% Postoperative voiding difficulties SI 2.2%–4.3% TOT/TVT-O 2%–11.7% Vaginal tape erosion SI 1.5%–4.3% TOT/TVT-O 1.6%–1.8% De novo urgency and/or worsening of preexisting surgery SI 7%–25% TOT/TVT-O 8.7%–21.1%
Jiao et al <sup>[48]</sup>	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 <sup>[49]</sup>	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 haematoma 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%

(continued)

**Table 1**  
**(continued).**

Study	Design	Intervention	Comparison	Follow-up duration	Complications	
Ford et al <sup>[50]</sup>	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	RP 7.2%, TO 3.8%
					De novo urgency or urgency incontinence	RP 8.2%, TO 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%
Nambiar et al <sup>[51]</sup>	Meta-analysis	Feb. 2013	31 studies		Repeat incontinence surgery	RP 1.1%, TO 10%
					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%
Pergialiotis et al <sup>[52]</sup>	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 <sup>[53]</sup>	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%
					Midurethral slings	
Tommaselli et al <sup>[54]</sup>	Meta-analysis	Jun. 2014	11 studies		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 <sup>[55]</sup>	Meta-analysis
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%–8.5%, RP 5.6%–8.6%					
Tape erosion	TO 1.5%–1.9%, RP 0.7%–1.6%					
The performance of retropubic mid urethral slings vs transobturator mid urethral slings						
Seklehner et al <sup>[56]</sup>	Meta-analysis	Jan. 2014	21 studies		Mesh erosion/exposure	TO 0.8%–5.4%, RP 0.9%–5.7%
					Urinary retention	TO 0.6%–17%, RP 2.7%–15.8%

(continued)

**Table 1**  
**(continued).**

Study	Design	Intervention	Comparison	Follow-up duration	Complications
Jha et al <sup>[57]</sup>	Meta-analysis	2009	21 studies		LUTS TO 0.6%–17%, RP 2.7%–15.8% Perforation bladder TO 1.4%–4.8%, RP 0.7%–8% Perforation vagina TO 4.2%–12.5%, RP 1.1%–2% Infection TO 0.7%–29.3%, RP 3.4%–26.1% Neurologic symptoms TO 2.7%–23%, RP 1.3%–8.2% Impact of incontinence surgery on sexual function A significant reduction in coital incontinence (OR 0.11; 95% CI 0.07–0.17)
Linder et al <sup>[58]</sup>	Review	2019			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 <sup>[59]</sup>	Review	2017			Update on complications of synthetic suburethral slings Bleeding RP 0.7%–8%, TO 0–2% Bladder injury RP 0.7%–24%, TO 0–15% 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 <sup>[60]</sup>	Review	2016			Female sexual function following mid-urethral slings PISQ-12 Improvements
Pastore et al <sup>[61]</sup>	Review	2016			Sexual Function and Quality of Life: TOT vs SI-MUS Improved in all the six Female Sexual Function Index domains
Blaivas et al <sup>[62]</sup>	Review	2015			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%
Kirby et al <sup>[63]</sup>	Review	2013			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% Bladder and urethral perforation RP 3.5%, TO 6.6% Vaginal perforation RP 2%, TO 4% Pelvic hematomas 1.4%

(continued)



**Table 1**  
(continued).

Study	Design	Intervention	Comparison	Follow-up duration	Complications
Cerruto et al <sup>[64]</sup>	Review	2011			Vaginal mesh exposure RP 4.4%, TO 2.7% Transobturator 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%
Brubaker et al <sup>[65]</sup>	Review	2011			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%

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.

As mentioned before, only 6 of 35 (17.1%) RCTs in our review took into account sexual dysfunction. Palos et al<sup>[11]</sup> 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<sup>[15]</sup> reported a total of 75 patients with complications of TOT and they found none of them complaining of dyspareunia. Zhang et al<sup>[18]</sup> 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<sup>[22]</sup> 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<sup>[30]</sup> 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<sup>[44]</sup> 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

**Table 2**  
Perioperative complications between the groups.

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%	0.8%–10%	0.7%–2.9%
De novo urgency	0%–29%	0.7%–25%	4.3%–12.2%
Post-op pain	1.4%–2.1%	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, RP = retropubic approach, SI = single incision, SUI = Stress urinary incontinence, TO = transobturator approach, TOT = transobturator tape using the out-in technique, TVT-O = transobturator tape using the in-out technique, UTI = urinary tract infection.



**Figure 2.** A retropubic hematoma following the TVT procedure detecting by suprapubic ultrasonography.

not appear in RCTs.<sup>[46–65]</sup> In Kim et al's study<sup>[46]</sup> 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<sup>[51]</sup> reported a total of 31 studies regarding SI-MUS procedures indicating that a major vascular or visceral injury was 1.6%. Pergialiotis et al<sup>[52]</sup> 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<sup>[56]</sup> 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<sup>[62]</sup> 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 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.<sup>[74]</sup> 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<sup>[75]</sup> reviewed the MAUDE (Manufacturer and User Facility Device Experience) database<sup>[76]</sup> 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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