



Arab Journal of Urology (Official Journal of the Arab Association of Urology)

www.sciencedirect.com



URODYNAMICS/FEMALE UROLOGY

REVIEW

The fate of synthetic mid-urethral slings in 2013: A turning point

Paholo G. Barboglio, E. Ann Gormley *

Dartmouth-Hitchcock Medical Center, Lebanon, NH, USA

Received 13 March 2013, Received in revised form 16 April 2013, Accepted 17 April 2013
Available online 14 June 2013

KEYWORDS

Mid-urethral;
Sling;
Synthetic;
Stress urinary inconti-
nence;
Retropubic;
Transobturator tape

ABBREVIATIONS

DUPS, distal urethral
polypropylene sling;
FDA, United States
food and drug admin-
istration;
ISD, intrinsic sphinc-
teric deficiency;
MUS, Mid-urethral

Abstract Introduction: Since the introduction of the first retropubic tension-free synthetic sling to treat stress urinary incontinence (SUI), newer approaches, different techniques and new devices have been created. Transobturator and single-incision sling (SIS) techniques were developed with the goal of diminishing the rate of complications and speeding the recovery phase.

Methods: For this review we searched Medline for relevant papers, with an emphasis on meta-analysis and randomised controlled trials (RCTs). Specially selected reports were identified to address both 'index patients' (defined as those with genuine SUI and no previous anti-incontinence procedure or other genitourinary sign or symptom that might affect her SUI) and, briefly, non-index patients. Two authors independently reviewed papers for eligibility.

Results: Level 1 evidence from a Cochrane review and two meta-analyses indicated that subjective outcomes with the mid-urethral sling (MUS) were similar to those from colposuspension. However, the MUS was better than colposuspension when assessing objective outcomes (Level 1). MUS are equally effective as autologous pubovaginal slings (Level 1). Two meta-analyses suggest that retropubic MUS (RMUS) might be better than transobturator MUS when assessing objective outcomes. Five more recent RCTs with longer term outcomes showed high success rates and only one reported a significant advantage for the RMUS in women with

* Corresponding author. Address: Dartmouth-Hitchcock Medical Center, One Medical Drive, Lebanon, NH 03766, USA.

E-mail address: Elizabeth.Ann.Gormley@hitchcock.org (E. Ann Gormley).

Peer review under responsibility of Arab Association of Urology.



Production and hosting by Elsevier

sling;
 OR, odds ratio;
 POP, pelvic organ prolapse;
 PVS, pubovaginal sling;
 RCT, randomised controlled trial;
 RMUS, retropubic mid-urethral sling;
 RR, relative risk;
 SIS, single-incision sling;
 SUI, stress urinary incontinence;
 TMUS, transobturator mid-urethral sling;
 TOT, transobturator tape;
 TVT, tension-free vaginal tape;
 TVT-O, TVT-obturator;
 TVT-S, TVT-Secur;
 TFS, tissue-fixation mini-sling;
 UITN, urinary incontinence treatment network;
 VLPP, Valsalva leak-point pressure

intrinsic sphincteric deficiency. One meta-analysis addressing the SIS showed inferior outcomes to the MUS (Level 1). New and improved SIS techniques have been used, but long-term outcomes are limited and results are still controversial when compared to the MUS.

Conclusion: MUS are still the standard to treat the index patient as previously stated by the American and European Associations of Urology. Currently data are lacking to define which sling and what approach works best. Complications are significantly different between sling types and are dependent on technique.

© 2013 Production and hosting by Elsevier B.V. on behalf of Arab Association of Urology.

Introduction

The purpose of this review was to assess the current role of mid-urethral slings (MUS) in the treatment of stress urinary incontinence (SUI). We reviewed data describing the historical development of MUS and its turning points. We also describe the current position of the AUA and the USA Food and Drug Administration (FDA) Notification on Vaginal Mesh. We present a concise literature review of the outcomes with the MUS in the 'index patient', defined as a woman with genuine SUI and no previous anti-incontinence procedure or other genitourinary sign or symptom that might affect her SUI, and then comment on the role of MUS in non-index patients.

History of mid-urethral slings

The first MUS procedure, the tension-free vaginal tape (TVT, Gynecare, Ethicon, Somerville, NJ, USA) was described by Ulmsten and Petros in 1995 [1]. The use of the TVT was based on reinforcing the pubococcygeal muscles at the level of the mid-urethra, as explained by the 'Integral Theory', developed by Petros and Ulmsten [2], which proposes that SUI results from a deficient

pubococcygeus muscle incapable of lifting the anterior vaginal wall to close the urethra against the pubourethral ligaments. The purpose of a MUS is to reinforce this deficient mechanism.

The TVT was developed as a minimally invasive procedure to treat SUI by supporting the mid-urethra mechanism with a synthetic polypropylene monofilament mesh placed by a retropubic, bottom-to-top approach. The initial results showed that it was very successful (91% success, as defined by the authors, at 1 year) with a low complication rate that included one bladder perforation and voiding dysfunction affecting four patients from a cohort of 130 women [3]. The first long-term data were from Nilsson et al. [4], who reported objective and subjective cure rates of 84.7% with a median follow-up of 56 months. Subsequently Nilsson et al. [5] reported the longest follow-up (11 years) in a prospective observational cohort of 90 women. They showed a 90% objective and 77% subjective cure rate with no long-term adverse events.

In 2001, Andonian et al. [6] described the use of the suprapubic arc system (SPARC, American Medical Systems, Inc., Minnetonka, MN, USA) using a top-to-bottom retropubic approach which proved to be equally

effective as the TVT, when assessing the objective cure data. However, when assessing adverse events, the SPARC had a higher mesh erosion rate than the TVT [6,7]. Given the high success rates and rapid recovery, the retropubic MUS (RMUS) became the new standard and replaced retropubic colposuspensions and the pub-ovaginal sling (PVS) for the surgical treatment of SUI [8].

As synthetic slings revolutionised the surgery for SUI, they also affected the commercial market. New sling kits using different synthetic materials, and different methods to introduce the sling material, were introduced (Table 1). As new sling kits were developed and marketed, surgeons introduced modifications of other surgical techniques, attempting to avoid the high cost of the kits. The most significant change to MUS technology was the introduction of the transobturator MUS (TMUS) in 2001 by Delorme [9]. He introduced the transobturator approach to avoid the blind passage of the needle into the retroperitoneal space, which can be associated with pelvic haematoma, bladder perforation and voiding dysfunction. As originally described by Delorme, the TMUS was inserted outside-in and was later modified to an inside-out approach by De Leval in 2003 [10]. The TMUS had comparable efficacy to the RMUS but with unique adverse events that included groin pain and potential neurovascular injury in the obturator region.

In 2003 Rodriguez and Raz [11] described the distal urethral polypropylene sling (DUPS). This MUS is placed retropubically distal to the pubourethral ligaments, under finger guidance, with the use of reusable Raz or Stamey needles. According to the limited reports, the DUPS has proven to be effective and safe, at a reduced cost.

A single-incision sling (SIS) was developed as a less invasive procedure with fewer adverse events. The first SIS (TVT-Secur®, Gynecare, Ethicon, Somerville, NJ, USA) was approved by the FDA in 2006. Subsequently other SISs were produced and by 2009 short-term data were published showing equally effective objective and subjective cure rates (Table 1) [12–14]. The TVT-Secur can be placed in one of two ways. The U-shaped technique consists of introducing the sling into the para-ure-

thral space, behind the pubic bone, with a bottom-to-top retropubic orientation. The H-shaped technique entails introducing the sling into the obturator internus muscle by an inside-out orientation approach, so that the sling supports the urethra like a hammock.

This new generation of slings appears to be associated with a lower risk of some complications and a quicker recovery phase, but adverse events like vaginal perforation, mesh erosion and urinary retention are not absent. There is still debate as to whether these SIS can achieve similar outcomes to the original MUS, given the lack of long-term outcomes and limited data from randomised controlled trials (RCTs) comparing them directly to MUS.

The AUA Guideline on the surgical management of female SUI

In 2009–2010 the AUA published a Guideline update on the surgical management of female SUI [8]. Although there was a meta-analysis of the various surgical treatments in this comprehensive review, significant portions of the Guideline were based on the consensus of the panel members. The TMUS data were not analysed in the Guideline as there were few long-term data in 2005 when the literature search was completed.

The Guidelines refer to the index patient; cure rates and improvement outcomes were calculated for all anti-incontinence procedures at 12 and 48 months with and without concomitant prolapse repair. RMUS placed via a transvaginal approach had a cure rate of 81–84% (at 12–48 months) with no concomitant prolapse repair, and 76–87% when placed during prolapse surgery [8].

The consensus of the Guideline was that although the five major types of procedures, including injectables, laparoscopic suspensions, MUS, PVS and retropubic suspensions, were not equivalent, all should be offered to the index patient. The AUA Guideline also reported on urgency, retention and complications. In the RMUS group with no prolapse surgery, the de novo urge incontinence rate was estimated to be 6%, and the rate for unspecified urgency was 22%. In patients treated with concomitant prolapse surgery the rates were 11% and 9%, respectively. Retention was defined as that for > 1 month or requiring intervention, and the rate was 3% for RMUS with or with no simultaneous prolapse repair. Complication rates for RMUS were ‘generally higher than recently reported data’ and included bladder injury in 6%, UTI in 11% and mesh extrusion in 8%, reported as vaginal in 7% and not defined in 1% [8].

The FDA notification on vaginal mesh

In October 2008 the FDA issued a public health statement announcing that although transvaginal surgical mesh complications are rare, these can have serious con-

Table 1 Synthetic slings.

| Name | Manufacturer | Technique/approach |
|-----------|-------------------|------------------------------------|
| TVT | Ethicon | RMUS bottom to top |
| SPARC | AMS | RMUS top to bottom |
| Advantage | Boston Scientific | RMUS bottom to top |
| Lynx | Boston Scientific | RMUS top to bottom |
| TVT-O | Ethicon | TMUS inside to out |
| Monarc | AMS | TMUS outside to in |
| ObTryx | Boston Scientific | TMUS outside to in |
| Aris | Coloplast | TMUS outside to in |
| TVT-Secur | Ethicon | Single incision |
| MiniArc | AMS | Single incision |
| Solyx | Boston Scientific | Single incision |
| Ajust | Bard | Single incision (adjustable sling) |

sequences when used to repair pelvic organ prolapse (POP) and/or SUI [15]. Later the FDA released an update (July 2011) stating that these complications are not rare and included mesh erosion (also called exposure, extrusion, or protrusion) and contraction. Moreover, the FDA noted that complications with the vaginal mesh might lead to severe pelvic pain, dyspareunia or inability to engage in sexual intercourse, and discomfort in the male sexual partner during sexual intercourse when there is exposed mesh [16].

The safety and efficacy were evaluated by reviewing reports from 1996 to 2011. This systematic review showed that transvaginal POP repair with mesh neither improved the symptomatic results nor the quality of life over a traditional mesh-less repair. The complications associated with the use of surgical mesh for POP repair have not been linked to one brand of mesh. The FDA in their notification discussed training for mesh insertion, and the consent procedure for the use of synthetic mesh. Although much of the FDA notification dealt with mesh used for transvaginal POP, mesh used for SUI was implicated by association. The FDA noted that they continue to evaluate reports for SUI surgery using surgical mesh, and that at a later date they would release additional information, but to date no additional information has been released [16].

The AUA Position Statement

The AUA released a Position Statement in November 2011 on the use of vaginal mesh for the surgical treatment of SUI [17]. The statement noted that the efficacy of synthetic polypropylene mesh slings is equivalent or superior to other surgical techniques, based on Level 1 evidence, with a follow-up to 10 years, and these are not associated with a significant increase in adverse events. The AUA agreed with the FDA recommendation of including a comprehensive informed consent before synthetic sling surgery, disclosing all possible risks and adverse events. Additional recommendations included not only rigorous urological training in pelvic anatomy and pelvic surgery, and intraoperative cystoscopy to exclude urinary tract injury, but specific surgical expertise on 'specific sling techniques' as well as the diagnosis and treatment of related complications. The statement concluded that 'synthetic slings are an appropriate treatment choice of women with stress incontinence, with similar efficacy but less morbidity than conventional nonmesh techniques' [17].

Patient evaluation

The purpose of the patient's evaluation is to diagnose and characterise the SUI, and to assess for other concomitant urinary issues, as well as other possible comorbidities. It is important to understand what the patient's

symptoms are and how the patient's quality of life is affected. The AUA SUI Guideline recommends a focused history that should include the characterisation of the incontinence, the frequency, bother and severity of the incontinence episodes, the effect of symptoms on life-style, and the patient's expectations of treatment [8]. Also, the patient's medical, surgical and gynaecological history, and her social history, might be important in counselling the patient about surgical therapy.

The remainder of the evaluation should be a focused physical examination, including an objective demonstration of SUI and additional tests such as a urine analysis and an assessment of the postvoid residual urine volume. In most patients this will constitute an adequate evaluation. The use of validated questionnaires and surveys is recommended to assess the patient's symptoms and bother. Voiding diaries, urodynamics, cystoscopy and other diagnostic imaging studies should be ordered if it is not possible to make a definitive diagnosis with the initial evaluation, or there is evidence of voiding dysfunction, POP, a history of previous incontinence surgery, excess postvoid residual volume, unexplained haematuria, pyuria, concomitant overactive bladder symptoms, or known or suspected neurogenic bladder [8].

The selection of the type of surgical management for SUI will rely not only on the diagnosis and characterisation of SUI, but also on the patient's treatment expectations. Women desiring a surgical correction of SUI should be advised about the outcomes and advantages and possible complications for all treatments for SUI, including the MUS.

Outcomes with the MUS

A review of reports identified using the word 'suburethral sling' in PubMed resulted in 1694 articles. When these were limited to humans (1637), the English language (1419), clinical trials (235) and meta-analyses (24), there was a total of 259 studies. RCTs already included in most recent meta-analyses were then excluded. In all, 16 articles were included in the present review of the outcomes of the MUS. The meta-analysis for the Update of the AUA Guideline on the surgical management of SUI [8] and two landmark meta-analyses by Novara et al. [18] and the Cochrane review by Ogah et al. [19] provide Level 1 evidence from the comparison of the outcomes of the MUS with those from colposuspension, PVS and when comparing the RMUS to the TMUS. Subsequently, five RCTs comparing the RMUS and TMUS, with longer term outcomes, were published [20–24]. A meta-analysis reviewing different TMUS approaches (inside-out vs. outside-in) was also included [25]. A data analysis of the SIS was obtained from one meta-analysis [26] and three recent RCTs [27–29]. Other selected articles were identified to briefly address non-

index cases, included women who had a concomitant prolapse repair [30], those undergoing second anti-incontinence surgery for recurrent SUI [31], those with intrinsic sphincteric deficiency (ISD) [24], and those with mixed UI [32]. Two authors independently reviewed and assessed these papers for eligibility.

MUS vs. colposuspension

MUS have equivalent patient-reported outcomes to colposuspension (Level 1 evidence) as supported by three meta-analyses [8,18,19]. The landmark study on colposuspension vs. TVT is the RCT reported by Ward and Hilton [33]. This trial showed similar objective cure rates, at 63% for TVT and 51% for colposuspension, with a follow-up of 2 years. Although other RCTs showed analogous results, Novara et al. [18] reported a meta-analysis which included 11 RCTs assessing the overall cure rate, and confirmed the superiority of MUS (odds ratio, OR, 0.61, 95% CI 0.46–0.82) over open colposuspension. Objective data also favoured the MUS when evaluating specifically a negative stress test (OR 0.38, 95% CI 0.25–0.57), which was available in three studies.

A Cochrane review by Ogah et al. [19] specifically examined the comparison of MUS with laparoscopic colposuspension, and also showed favourable results for MUS when assessing objective data (relative risk, RR, 1.15, 95% CI 1.0–1.24). However, there was no statistically significant difference when assessing specifically a negative pad test and subjective data [18,19]. Moreover, the Cochrane review showed that the MUS was associated with fewer perioperative complications, a shorter perioperative time and hospital stay, but a higher rate of bladder perforations (RR 4.24, 95% CI 1.71–10.52) when compared to open colposuspension [19]. Similarly, and not unexpectedly, the risk of bladder perforation reported by Novara et al. was five times higher for those women who had a MUS than in those with a Burch colposuspension [18].

MUS vs. PVS

There is also Level 1 evidence from meta-analyses that a MUS is as effective as an autologous PVS for treating the index patient with SUI [8,18,19]. This finding has significantly reduced the use of the PVS. Nonetheless, an autologous fascia PVS is sometimes advocated in patients in whom a MUS has already failed, and they remain an option for the patient who does not want a synthetic mesh sling. In some practices this has become important after the FDA warning about mesh. If a patient prefers not to have a synthetic sling, the best alternative might be a PVS instead of a colposuspension, as the latter has been shown to be inferior to a PVS [34]. In comparison to a PVS, the MUS is associated with a

quicker operation [19], less postoperative voiding dysfunction [18,19] and a lower reoperation rate [19]. This is explained by the PVS historically having been a tighter sling, with the potential need to cut the sling if the patient is unable to void after surgery or if the patient develops symptoms of voiding dysfunction.

RMUS ‘bottom-to-top’ vs. ‘top-to-bottom’

The largest available body of literature on the RMUS placed via the bottom-to-top approach is that for the classic TVT. Most of the data from RCTs on the top-to-bottom approach are with the SPARC. The Cochrane review from Ogah et al. [19] described five studies comparing the TVT and SPARC. Although both MUS approaches showed very high success rates, the bottom-to-top approach TVT had better subjective (RR 1.10; 95% CI 1.01–1.2) and objective (RR 1.06; 95% CI 1.01–1.11) outcomes at 12 months of follow-up, as well as fewer vaginal erosions (RR 0.27; 95% CI 0.08–0.95), fewer bladder perforations (RR 0.55; 95% CI 0.31–0.98) and a lower voiding dysfunction rate (RR 0.40; 95% CI 0.18–0.90) than the SPARC top-to-bottom approach [19].

RMUS vs. TMUS

Since the introduction of the TMUS by Delorme in 2001 there has been controversy about its efficacy compared to the retropubic approach. Studies have shown similar, superior and inferior outcomes when compared to the RMUS. There is no question that both techniques have very high cure rates in the index patient. In the Cochrane review the RMUS was judged to be better than TMUS (RR 0.96, 95% CI 0.93–0.99) [19]. However, given the narrow CI the difference between the groups might not represent a clinically significant difference, as indicated by the authors. Moreover, when assessing objective data, the analysis showed a moderate degree of heterogeneity ($I^2 = 47\%$), which weakens the result, due to inconsistency across the included studies. However, the meta-analysis of Novara et al. [18], published at almost the same time, confirmed this finding. The RMUS was better than the TMUS when assessing objective data (OR 0.80; 95% CI 0.65–0.99) with a follow-up of 12 months. Interestingly, in a subanalysis specifically comparing the (inside-out) TMUS to the TVT, the efficacy was no longer higher in the RMUS group (OR 0.9; 95% CI 0.66–1.22). Furthermore, there was no difference on the efficacy outcomes when reviewing subjective data.

When assessing surgical outcomes and adverse events, the TMUS was associated with a higher risk of groin pain (RR 5.95; 95% CI 3.22–11.02). The RMUS was associated with twice the risk of bladder perforation (OR 2.39; 95% CI 1.32–4.32), almost three times the risk

of pelvic haematoma (OR 2.62; 95% CI 1.35–5.08) and 1.35 times the risk of voiding dysfunction (95% CI 1.05–1.72) [18]. There is no difference in these complications when only the TMUS placed using the outside-in approach is compared to the RMUS. The risk of erosion was lower for the RMUS than the TMUS, and this difference remained significant when only the TMUS placed via an outside-in approach was subanalysed [18]. The operative duration appeared to be shorter, but the heterogeneity was very high in this analysis ($I^2 = 94\%$). Data suggest that the estimated blood loss was lower in the TMUS group and there was no statistically significant difference between the RMUS and TMUS when assessing UTI or reoperation rates [19].

Two large multi-institutional trials recently reported their 24-month treatment results of the RMUS compared to the TMUS. A French study included 149 patients with an 88% follow-up at 2 years. The classic TVT (bottom-up) was compared to TVT-O (inside-out) and there was no difference on objective and subjective outcome data when assessing success. Similarly, there was no difference ($P = 0.68$) when assessing bladder injury; the RMUS group had four of 75 and the TMUS group two of 74, and all were diagnosed intraoperatively. There was only one urethral injury and this occurred in the RMUS group, and one mesh extrusion that occurred at 2 months in the TMUS group. There was no difference in voiding dysfunction or repeat surgery, and although women had more pain after the TMUS, this was no longer statistically significant at 24 months [20].

The Urinary Incontinence Treatment Network (UITN) trial was a randomised equivalence trial that compared the TMUS and RMUS at 12 and 24 months. At 24 months they had a complete follow-up on 86.4% of 597 patients. Their study showed a trend of greater benefit with the RMUS approach, with the objective success rates not meeting the pre-specified criteria for equivalence. Clinical significance was based on a determination of equivalence, with the entire 95% CI for the difference between the two surgical groups required to be within the equivalence margin. Objective data showed equivalence at 1 year and this decreased at 24 months, from 81% to 77% in the RMUS group and 78% to 72% in the TMUS group. With this decrease in objective success rates at 2 years there was no longer equivalence between the groups (95% CI for the difference of 5.1% was -2.0 to 12.1), favouring the superiority to the RMUS approach. Subjective data were not equivalent at 12 or at 24 months, and also favoured the RMUS. Although equivalence was not met for the objective and subjective outcomes, the CIs suggested no statistical difference, as zero was included in the range. In this large multi-trial study the participants in both groups had a high level of satisfaction, despite a decrease in objective success rates, and there was no difference in urinary symptom severity or quality of life at 24 months.

However, neurological symptoms like groin pain, or thigh numbness, were more common in the TMUS group (10% vs. 5%; $P = 0.045$), whereas symptoms of voiding dysfunction requiring surgery (3% vs. 0%; $P = 0.002$), and UTI (17.1% vs. 10.7%; $P = 0.025$) were more common in the RMUS group [21].

Angioli et al. [22] reported on an RCT with a 5-year follow-up that included 72 patients, 35 in the RMUS group and 37 in the TMUS group, with a 72% complete follow-up. This study showed no significant difference in the objective cure rates between the RMUS (71%) and the TMUS (73%) group. There were also no differences in adverse events, but unlike many of the other studies, fewer patients (only 61%) were satisfied. The authors commented that dissatisfaction could be influenced by sexual dysfunction, which was found in six of 16 dissatisfied patients.

Two other trials reported on the 36-month follow-up outcomes. A Finnish multicentre RCT of 267 women by Palva et al. [23] reported no difference in efficacy between the RMUS vs. TMUS in objective and subjective outcomes, of 91% and 85%, respectively. Objective outcomes were measured by a negative stress test and pad weight, and subjective outcomes relied on patient satisfaction. These results confirmed previous reported outcomes at 12 months. An Australian RCT of 164 women by Schierlitz et al. [24] also confirmed their previous reported outcomes at 3 years. The authors reported a significant difference in objective outcomes favouring the RMUS over TMUS, but no difference in subjective outcomes. Objective failure was defined as the patient having repeat surgery for SUI and 20% of women (15 of 75) in the TMUS group required a second anti-incontinence operation, vs. only one in the RMUS group. Further analysis showed that repeat surgery could have been avoided in one of six women ($P < 0.001$) if the RMUS was used for all patients. It is important to recognise that women in this trial had ISD and the authors used one of the worst measures to assess the objective outcomes. Alternatively, women with poor outcomes who did not proceed to a second anti-incontinence procedure might have been lost to follow-up.

TVT-O vs. 'outside-in' approach

A recent meta-analysis published by Madhuvrata et al. [25] included five full articles and one abstract in their comparison analysis, as well as three cohort studies for a subsensitivity analysis. One type of sling (TVT-O) was used for the inside-out approach and different slings (Aris®; Monarc®; TOT® from Korea, Dow, Medics) were used in the trials for the outside-in approach. Both TMUS techniques were shown to be equally effective at the 12-month follow-up, as previously reported in the Cochrane review by Ogah et al. [19]. When assessing

surgical outcomes and adverse events, intraoperative vaginal-angle injuries were more common in the outside-in approach (RR 0.33; 95% CI 0.01–8.21). However, bladder or urethral perforations, voiding dysfunction, mesh erosion, groin or thigh pain and voiding dysfunction were not different [25].

The SIS

There are reports supporting the safety and efficacy of these products, with shorter operating times and an earlier return to work and other activities than with the standard MUS [35]. However, there is still controversy as to whether SIS achieve long-term outcomes similar to the other MUS [36,37].

There is Level 1 evidence from a recent meta-analysis that included nine RCTs showing inferior subjective (RR 0.83; 95% CI 0.70–0.99) and objective (RR 0.85; 95% CI 0.74–0.97) short-term outcomes, as well as higher reoperation rates for SUI (RR 6.72; 95% CI 2.39–18.89) than for MUS. Most of the trials included in the meta-analysis used the TVT-S, which has recently been removed from the market [26].

The largest and longest RCT comparing a SIS to a TMUS is that published by Sivaslioglu et al. [27], comparing the tissue-fixation mini-sling (TFS, Surgical, Adelaide, South Australia, Australia) with an outside-in TMUS. The authors reported more favourable outcomes with the TFS at 5 years, of 85% vs. 75% for the objective cure rate. Although they presented the 5-year follow-up with only a 10% loss in each group, their power was limited, with only 36 patients in each group.

It is also still not clear whether there is a significant difference between the two SIS insertion techniques. A recent RCT by Lee et al. [28] reported comparable cure rates but a lower quality of life/satisfaction rate for the H-type method. Unfortunately, in this study there were significant differences in the patient characteristics between the groups, with patients in the U-shaped sling group being older, having more urgency and twice the rate of detrusor overactivity. These differences might have influenced the quality-of-life results.

A more recent RCT by Barber et al. [29], that compared TVT-S placed in the U-position to the TVT showed similar subjective cure rates, but the efficacy of the SIS was inferior to the RMUS, as defined by a difference in the CI of 12%, based on a subjective outcome. The incontinence severity at 1 year was worse in those women who had the SIS. Another important finding was the high rate (8.8%) of device malfunction or technical difficulties encountered at the time of surgical implantation with the SIS. The TVT group had a worse bladder perforation rate, more pain in the first 3 days after surgery, and they were more like to need a urethral catheter at discharge.

Although this new generation of slings was developed to have lower complication rates, a systematic review of 10 observational studies on the TVT-S reported a vaginal perforation rate of 1.5%, mesh exposure of 2.4%, urinary retention of 2.3%, UTI of 4.4%, dyspareunia of 1% and a 10% incidence of de novo overactive bladder symptoms [38].

The right sling for the right patient

The index patient, as defined above, is likely to fare well regardless of what procedure she undergoes for SUI. These women should be offered an explanation of the risks and benefits of all the previously mentioned anti-incontinence procedures, and allowed to make an informed choice as to which procedure they want. Based on the available reports, both the RMUS and TMUS should be offered as first-line procedures. When assessing RMUS approaches, the data suggest that the bottom-to-top is better than top-to-bottom approach, based on a lower rate of genitourinary injuries [19]. However, further larger-sample trials are needed to assess this difference. Proponents of the DUPS procedure, which uses a re-useable needle passed from top to bottom, note that passage of the needle on the tip of the surgeon's finger might help to avoid bladder injuries [11]. The patient who does not want a synthetic sling should be offered a PVS.

The use of the SIS should only be offered in the setting of full disclosure. Although the data remain controversial, and even suggest inferior results for these types of slings, the level of uncertainty is even higher when assessing the long-term outcomes of these procedures [26]. We recommend that only those surgeons who are experienced with the SIS and who produce favourable long-term outcomes should offer a SIS.

Women with other signs and symptoms of lower urinary dysfunction should be properly evaluated, so they can be offered the most efficient therapy or surgical procedure available. Unfortunately there are few prospective RCTs that address these particular non-index patients.

Mixed UI

In the patient with mixed UI the goal of any incontinence surgery is to treat the SUI component and to not exacerbate the patient's urge component. As with other incontinence procedures, the urge component, particularly idiopathic detrusor overactivity, might improve after correcting the stress component with a MUS [39,40]. A recent meta-analysis by Jain et al. [32] found six RCTs and seven cohort studies. The authors reported an overall cure rate of 56.4% (95% CI 45.7–69.6) at 34.9 ± 22.9 months of follow-up, based on seven cohort prospective studies, and commented on the heterogeneity of their outcome measures. Further

subanalysis showed no difference in outcomes when they compared the RMUS and TMUS. The data remain scarce to define which MUS approach has better long-term outcomes for mixed UI.

Simultaneous prolapse repair

The most recent multicentre study by the Pelvic Floor Disorder Network showed that in 337 women undergoing prolapse repair, occult SUI was prevented with the use of a prophylactic MUS. Patients who had a TVT placed had significantly less SUI than patients who had a sham procedure, at the 1-year follow-up. This study also confirmed a higher rate of adverse events and complications for those who had the TVT. It was calculated by the authors that six women need to be treated with a TVT to prevent one case of SUI after prolapse repair [30].

ISD and urethral hypermobility

The definition of ISD remains controversial. Historically, ISD was defined in women with ‘pipe stem’ urethras that were fixed and rigid. These women were very incontinent. When ISD is defined using a strict urodynamic measure such as the Valsalva leak-point pressure (VLPP) or maximum urethral closure pressure, it can be diagnosed in women who have bladder neck mobility. Given that the mechanism of action of a MUS depends on bladder neck mobility, most clinicians favour either an injectable agent or a PVS for those women with no bladder neck mobility. There are data for MUS showing that in some women described as having ISD, a RMUS or TMUS is comparable to a PVS [41,42]. There is also Level 1 data suggesting that the RMUS approach has more favourable outcomes than TMUS, based on a 3-year follow-up RCT [24] and especially in women with urethral hypermobility [43].

Recurrent SUI

Recurrent SUI must be evaluated in an effort to understand why the patient leaks. If urethral mobility is lacking and the patient has a low VLPP, a PVS or an injectable bulking agent can be used. However, there are few long-term results on either of these procedures to treat patients with recurrent SUI. A recent Cochrane review reported no RCT to date and the authors were unable to draw any conclusions [31]. In the age of MUS there are minimal data on the treatment of a failed MUS with another MUS. Liapis et al. [44] reported favourable results with TVT, and Stav et al. [45] suggested that a RMUS might be better than a TMUS. Some surgeons have advocated using a different approach for the patient’s second surgery, although there are no data to support this.

When to avoid MUS

Following the FDA notification on synthetic mesh use and the subsequent legal actions against mesh manufacturers, some patients are not interested in having a mesh sling. Since the warning was not directed at the use of synthetic slings, this needs to be explained to patients as part of the informed-consent process. Patients need to be told that there are risks inherent to synthetic mesh, but that these risks are small. A woman who does not want a synthetic sling should be offered other treatments for her SUI. Furthermore, women who have been treated for a sling complication, particularly erosion into the urinary tract, and remain incontinent, are best re-treated without using more synthetic material. Patients who have had other previous extensive or significant genitourinary reconstruction, urethral fistula repair, urethral diverticulectomy, or a history of radiation, might be better treated with autologous tissue rather than a synthetic material. The MUS should also not be used when tension is required. MUS are designed to be placed without tension to avoid the risk of erosion. When more tension is desired to intentionally occlude the urethra and cause an emptying problem (urinary retention), as in some particular cases of neurogenic bladder, an autologous fascia PVS is preferred.

Summary

The most recent update on the AUA guidelines recommends the MUS for treating the index patient with SUI [46]. The European Association of Urology guideline similarly recommends the MUS [47]. The FDA warning needs to be considered when counselling patients, but it should not be used as a reason not to offer these procedures to patients. The FDA warning has also changed the way in which new slings will be released, and might lead to some products being withdrawn from the market.

In the present review we assess data which shows that for the index patient these are reasonable options. If clinicians choose not to use a synthetic sling they should at least discuss with their patient that a MUS is a reasonable option and offer a referral to a clinician who will do the procedure. The patient who chooses not to have a synthetic mesh implanted they should be offered other reasonable alternatives. We should not take a step backwards by doing surgical procedures that have been shown to have inferior outcomes. Patients need to be educated that there remain good surgical treatments for SUI.

For the non-index patient, including those in whom a previous MUS has failed, data as to how to best treat this patient are lacking. Large prospective clinical trials are needed to examine these issues. In these trials patients will need to be well characterised, and they will

need to be followed for sufficiently long periods. Until further data-driven recommendations are made as part of a Guideline process, clinicians should use the MUS as part of their clinical options in the treatment of patients with SUI.

At this point, the MUS remains the standard for the surgical treatment of female SUI in the index patient, and has a place in the treatment of the non-index patient.

Conflict of interest

None.

Funding

None.

References

- [1] Ulmsten U, Petros P. Intravaginal slingplasty (IVS). An ambulatory surgical procedure for treatment of female urinary incontinence. *Scand J Urol Nephrol* 1995;**29**:75–82.
- [2] Petros PE, Ulmsten UI. An integral theory of female urinary incontinence. experimental and clinical considerations. *Acta Obstet Gynecol Scand Suppl* 1990;**153**:7–31.
- [3] Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Nilsson CG, et al. A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1998;**9**:210–3.
- [4] Nilsson CG, Kuuva N, Falconer C, Rezapour M, Ulmsten U. Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;**12**(Suppl. 2), S5–8.
- [5] Nilsson CG, Palva K, Rezapour M, Falconer C. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2008;**19**:1043–7.
- [6] Andonian S, Chen T, St-Denis B, Corcos J. Randomized clinical trial comparing suprapubic arch sling (SPARC) and tension-free vaginal tape (TVT): one-year results. *Eur Urol* 2005;**47**:537–41.
- [7] Lord HE, Taylor JD, Finn JC, Tsokos N, Jeffery JT, Atherton MJ, et al. A randomized controlled equivalence trial of short-term complications and efficacy of tension-free vaginal tape and suprapubic urethral support sling for treating stress incontinence. *BJU Int* 2006;**98**:367–76.
- [8] Dmochowski RR, Blaivas JM, Gormley EA, Juma S, Karram DJ, Lightner DJ, et al. Update of AUA guideline on the surgical management of female stress urinary incontinence. *J Urol* 2010;**183**:1906–14.
- [9] Delorme E. Transobturator urethral suspension. Mini-invasive procedure in the treatment of stress urinary incontinence in women. *Prog Urol* 2001;**11**:1306–13.
- [10] de Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. *Eur Urol* 2003;**44**:724–30.
- [11] Rodriguez LV, Raz S. Prospective analysis of patients treated with a distal urethral polypropylene sling for symptoms of stress urinary incontinence: surgical outcome and satisfaction determined by patient driven questionnaires. *J Urol* 2003;**170**:63.
- [12] Dmochowski RR, Grier D, Franco N. One year results from a world-wide registry of TVT-secur in women with stress urinary incontinence; 95% CI [annual meeting abstract]. *J Urol* 2009;**181**:544.
- [13] Neuman M. Perioperative complications and early follow-up with 100 TVT-SECUR procedures. *J Minim Invasive Gynecol* 2008;**15**:480–4.
- [14] Kennelly MJ, Moore R, Nguyen JN, Lukban JC, Siegel S. Prospective evaluation of a single incision sling for stress urinary incontinence. *J Urol* 2010;**184**:604–9.
- [15] FDA Public Health Notification. Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence; 95% CI. Issued October 20, 2008. Available from: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/UCM061976>.
- [16] FDA Safety Communication. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse; 95% CI [Internet], July 13, 2011. Available from: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>.
- [17] AUA Position Statement on the Use of Vaginal Mesh for the Repair of Pelvic Organ Prolapse; 95% CI [Internet], November 2011. Available from: <http://www.auanet.org/content/aua-policies/position-statements/pelvic-organ-prolapse.cfm>.
- [18] Novara G, Artibani W, Barber MD, Chapple CR, Costantini E, Ficarra V, et al. Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. *Eur Urol* 2010;**58**:218–38.
- [19] Ogah J, Cody JD, Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev* 2009(4);CD006375, October 7.
- [20] Deffieux X, Daher N, Mansoor A, Debodinance P, Muhlstein J, Fernandez H. Transobturator TVT-O versus retropubic TVT Results of a multicenter randomized controlled trial at 24 months follow-up. *Int Urogynecol J* 2010;**21**:1337–45.
- [21] Albo ME, Litman HJ, Richter HE, Lemack GE, Sirls LT, Chai TC, et al. Treatment success of retropubic and transobturator mid urethral slings at 24 months. *J Urol* 2012;**188**:2281–7.
- [22] Angioli R, Plotti F, Muzii L, Montera R, Panici PB, Zullo MA. Tension-free vaginal tape versus transobturator suburethral tape. Five-year follow-up results of a prospective, randomised trial. *Eur Urol* 2010;**58**:671–7.
- [23] Palva K, Rinne K, Aukee P, Kivela A, Laurikainen E, Takala T, et al. A randomized trial comparing tension-free vaginal tape with tension-free vaginal tape-obturator: 36-month results. *Int Urogynecol J* 2010;**21**:1049–55.
- [24] Schierlitz L, Dwyer PL, Rosamilia A, Murray C, Thomas E, De Souza A, et al. Three-year follow-up of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency. *Obstet Gynecol* 2012;**119**:321–7.
- [25] Madhuvrata P, Riad M, Ammembal MK, Agur W, Abdel-Fattah M. Systematic review and meta-analysis of ‘inside-out’ versus ‘outside-in’ transobturator tapes in management of stress urinary incontinence in women. *Eur J Obstet Gynecol Reprod Biol* 2012;**162**:1–10.
- [26] Abdel-Fattah M, Ford JA, Lim CP, Madhuvrata P. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: a meta-analysis of effectiveness and complications. *Eur Urol* 2011;**60**:468–80.
- [27] Sivasioglu AA, Unlubilgin E, Aydogmus S, Keskin L, Dolen I. A prospective randomized controlled trial of the transobturator tape and tissue fixation mini-sling in patients with stress urinary incontinence: 5-year results. *J Urol* 2012;**188**:194–9.
- [28] Lee KS, Lee YS, Seo JT, Na YG, Choo MS, Kim JC, et al. A prospective multicenter randomized comparative study between

- the U- and H-type methods of the TVT SECUR procedure for the treatment of female stress urinary incontinence: 1-year follow-up. *Eur Urol* 2010;**57**:973–9.
- [29] Barber MD, Weidner AC, Sokol AI, Amundsen CL, Jelovsek JE, Karram MM, et al. Single-incision mini-sling compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. *Obstet Gynecol* 2012;**119**:328–37.
- [30] Wei JT, Nygaard I, Richter HE, Nager CW, Barber MD, Kenton K, et al. A midurethral sling to reduce incontinence after vaginal prolapse repair. *N Engl J Med* 2012;**366**:2358–67.
- [31] Bakali E, Buckley BS, Hilton P, Tincello DG. Treatment of recurrent stress urinary incontinence after failed minimally invasive synthetic suburethral tape surgery in women. *Cochrane Database Syst Rev* 2013;**2**:CD009407.
- [32] Jain P, Jirschele K, Botros SM, Latthe PM. Effectiveness of midurethral slings in mixed urinary incontinence: a systematic review and meta-analysis. *Int Urogynecol J* 2011;**22**:923–32.
- [33] Ward KL, Hilton P. UK & Ireland TVT Trial Group. A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. *Am J Obstet Gynecol* 2004;**190**:324–31.
- [34] Albo ME, Richter HE, Brubaker L, Norton P, Kraus SR, Zimmern PE, et al. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. *N Engl J Med* 2007;**356**:2143–55.
- [35] Tincello DG, Botha T, Grier D, Jones P, Subramanian D, Urquhart C, et al. A worldwide observational registry for long-term data. Safety and efficacy of suburethral sling insertion approaches for stress urinary incontinence in women. *J Urol* 2011;**186**:2310–5.
- [36] Hinoul P, Vervest HA, den Boon J, Venema PL, Lakeman MM, Milani AL, et al. A randomized, controlled trial comparing an innovative single incision sling with an established transobturator sling to treat female stress urinary incontinence. *J Urol* 2011;**185**:1356–62.
- [37] Hota LS, Hanaway K, Hacker MR, Disciullo A, Elkadry E, Dramitinos P, et al. A randomized trial of suburethral sling operative procedures. *Female Pelvic Med Reconstr Surg* 2012;**18**:41–5.
- [38] Walsh CA. TVT-secur mini-sling for stress urinary incontinence. A review of outcomes at 12 months. *BJU Int* 2011;**108**:652–7.
- [39] Duckett JR, Tamilselvi A. Effect of tension-free vaginal tape in women with a urodynamic diagnosis of idiopathic detrusor overactivity and stress incontinence. *BJOG* 2006;**113**:30–3.
- [40] Gamble TL, Botros SM, Beaumont JL, Goldberg RP, Miller JJ, Adeyanju O, et al. Predictors of persistent detrusor overactivity after transvaginal sling procedures. *Am J Obstet Gynecol* 2008;**199**(696):e1–7.
- [41] Rezapour M, Falconer C, Ulmsten U. Tension-free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD) – a long-term follow-up. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;**12**(Suppl. 2):S4–S12.
- [42] Jeon MJ, Jung HJ, Chung SM, Kim SK, Bai SW. Comparison of the treatment outcome of pubovaginal sling, tension-free vaginal tape, and transobturator tape for stress urinary incontinence with intrinsic sphincter deficiency. *Am J Obstet Gynecol* 2008;**199**:76.
- [43] Haliloglu B, Karateke A, Coksuer H, Peker H, Cam C. The role of urethral hypermobility and intrinsic sphincteric deficiency on the outcome of transobturator tape procedure: a prospective study with 2-year follow-up. *Int Urogynecol J* 2010;**21**:173–8.
- [44] Liapis A, Bakas P, Creatsas G. Tension-free vaginal tape in the management of recurrent urodynamic stress incontinence after previous failed midurethral tape. *Eur Urol* 2009;**55**:1450–5.
- [45] Stav K, Dwyer PL, Rosamilia A, Lee J. Long-term outcomes of patients who failed to attend following midurethral sling surgery – a comparative study and analysis of risk factors for non-attendance. *Aust NZ J Obstet Gynaecol* 2010;**50**:173–8.
- [46] Guideline for the surgical management of female stress urinary incontinence. Update, 2009: 95% CI [Internet], 2012 Available from: <http://www.uanet.org/content/media/stress2009-chapter1.pdf>.
- [47] Guidelines On Urinary Incontinence; 95% CI [Internet], 2012. Available from: <http://www.uroweb.org/guidelines/online-guidelines> > .