

TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months

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- Synthetic mid-urethral slings (MUSs) are considered the first choice surgical procedure for stress urinary incontinence. Recent publications have raised concerns about the efficacy of third generation single-incision mini-slings. The present paper is a systematic review of studies reporting 12-month outcomes after the TVT-Secur (TVT-S) procedure.

- Pubmed/Medline online databases, abstracts from recent International Continence Society and International Urogynecological Association annual scientific meetings and the *Clinicaltrials.gov* and *Controlled-trials.com* online trial registries were searched for English-language articles containing the terms 'TVT-Secur', 'TVT Secur' or 'mini-sling'. The primary outcomes were objective and subjective cure rates at 12 months. Secondary outcomes included peri-operative (vaginal perforation, urinary retention, urinary tract infection [UTI]) and postoperative (mesh exposure, *de novo* overactive bladder (OAB), dyspareunia and return to theatre) complication rates.

- Among 1178 women undergoing the TVT-S procedure, from 10 studies, both objective and subjective cure rate at 12 months was 76%, with objective cure significantly higher

What's known on the subject? and What does the study add?

Although synthetic mid-urethral slings are now generally accepted as the first-line surgical treatment of female stress incontinence, there is concern that newer slings are being used prematurely, before sufficient evidence exists. The 3rd generation "mini-slings" are inserted via a single incision which, theoretically, reduces iatrogenic morbidity. It is vital, however, that efficacy is not compromised. To date, a number of papers have examined short-term outcome data following the TVT-Secur, with wide variations in reported cure rates at up to one year.

This is the largest review of outcomes following TVT-Secur published to date ($n = 1178$ cases from 10 studies). Cure rate, both objectively and subjectively, was 76%, which is similar to more established mid-urethral slings. Intra-operative vaginal perforation rates and rates of mesh exposure in the first 12 months post-operatively were both 2%. The incidence of *de novo* OAB was 10%. No serious complications were recorded amongst this large cohort. Although the TVT-Secur appears to be a safe procedure, its long-term efficacy moving forward requires close scrutiny.

in women undergoing the 'U-type' approach. Vaginal perforation was a complication in 1.5% of cases, with a 2.4% incidence of mesh exposure in the first year. The incidence of *de novo* OAB symptoms was 10%. Rates of urinary retention (2.3%), UTI (4.4%), dyspareunia (1%) and return to theatre for complications (0.8%) were low. In the first year after a TVT-S procedure 5% of women required repeat continence surgery.

- Longer-term studies and randomized comparisons with more established MUSs are required before TVT-S should be routinely used in the surgical treatment of stress urinary incontinence.

KEYWORDS

TVT-Secur, mini-sling, single-incision, stress incontinence

INTRODUCTION

Female stress urinary incontinence (SUI) presents an enormous disease burden to women worldwide, affecting 1 in 3 adult women [1]. Minimally-invasive synthetic mid-urethral slings (MUSs) are now firmly established as the surgical intervention of first choice in women with SUI, refractory to pelvic floor muscle training. Since the original retropubic Tension-free Vaginal Tape (TVT; Gynecare, Sommerville, NJ, USA) report in 1996 [2], numerous variations of this

technique have emerged. A recent Cochrane meta-analysis found MUSs to be an acceptable alternative to more traditional surgical treatments for SUI, although it noted the lack of long-term studies supporting their use [1].

In 2006 the third generation of synthetic slings for SUI emerged, with the development of single-incision short tapes (or 'mini-slings'). The TVT-Secur (TVT-S; Gynecare) was described first and subsequently a number of other single-incision slings were reported. The TVT-S is an 8 cm × 1 cm laser-cut polypropylene

mesh which obviates the need to pass trocars blindly through the retropubic or obturator spaces. The TVT-S is inserted via a single suburethral incision and can either be fixed to the urogenital diaphragm ('U-type', similar to the original retropubic TVT) or in a hammock position in the obturator internus muscle ('H-type', more analogous to second generation transobturator approaches; Fig. 1) [3].

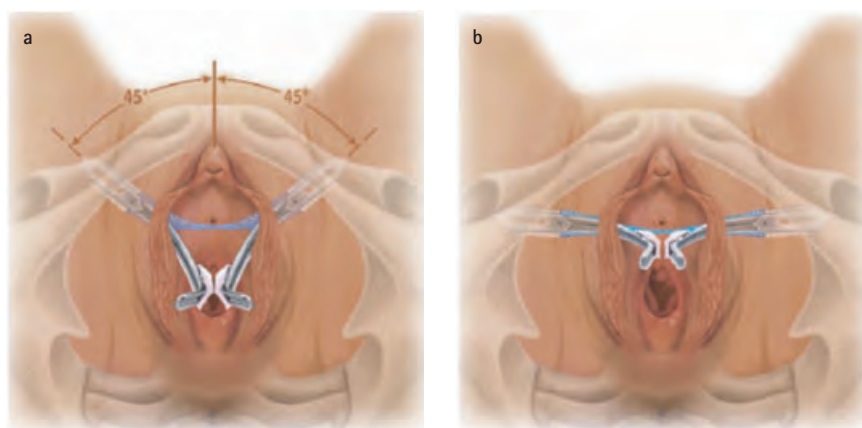
In principle, single-incision slings such as the TVT-S aim to eliminate trocar-related injury and can be performed under local

TABLE 1 Demographic data

| Authors | Study period | n | Mean age, years | Mean BMI | Menopausal, % | Preoperative urodynamic diagnosis | |
|-------------------------------|----------------|------|-----------------|----------|---------------|-----------------------------------|----------|
| | | | | | | Pure USI | USI +DO |
| Debodinance <i>et al.</i> [6] | Aug 06–Dec 07 | 150 | 56 | 28 | 64 | N/A | N/A |
| Kim <i>et al.</i> [7] | Mar 07–Jul 08 | 115 | 56 | 23.5 | 30 | 106 | 9 |
| Krofta <i>et al.</i> [8] | May 07–Oct 08 | 82 | 56 | 27.3 | N/A | 82 | Excluded |
| Liapis <i>et al.</i> [9] | Nov 06–Sept 09 | 82 | 58 | 26.6 | 78 | 82 | Excluded |
| Lee <i>et al.</i> [10] | N/A | 285 | 54 | 24 | 65 | 247 | 38 |
| Meschia <i>et al.</i> [11] | Nov 06–Sep 07 | 95 | 57 | 27.1 | 63 | 95 | Excluded |
| Molden <i>et al.</i> [12] | Apr 06–Jan 08 | 126 | 59 | 30 | N/A | N/A | N/A |
| Neuman [13] | Sep 06–Dec 06 | 100 | 54 | N/A | N/A | N/A | N/A |
| Oliveira <i>et al.</i> [14] | N/A | 106 | 55 | N/A | N/A | 106 | Excluded |
| Tommaselli <i>et al.</i> [15] | Mar 07–Mar 08 | 37 | 58 | 28.7 | 84 | N/A | N/A |
| Total | – | 1178 | 56 | 26.3 | 62 | – | – |

USI, urodynamic stress incontinence; DO, detrusor overactivity; N/A, not available.

FIG. 1. Surgical techniques for TVT-Secur: A, 'U-type' and B, 'H-type'. Reproduced with permission from Lee KS *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 Feb 19. Published by Elsevier [10].



anaesthesia. However, the durability of the TVT-S is under scrutiny and concern has been raised that the reduced trocar-related morbidity may be at the expense of therapeutic efficacy. A recent study of 3-year outcomes after TVT-S procedures reported a cure rate of only 40% among 45 women, significantly reduced from a short-term success rate of 94% [4]. In May 2008, the National Institute for Health and Clinical Excellence recommended that single-incision sling procedures should only be performed in the context of a research study, as data to support their safety and efficacy were insufficient [5]. Since then, numerous studies of TVT-S have been reported with widely varying success rates. This article

presents a systematic review of all studies reporting outcomes at 12 months after the TVT-S procedure.

METHODS

The Pubmed and Medline online databases were searched for the terms 'TVT-Secur', 'TVT Secur' and 'mini-sling'. The search was restricted to English-language articles published between 2006 and December 2010. As this is a rapidly evolving therapeutic method, abstracts from recent ICS and International Urogynecological Association annual scientific meetings and the *Clinicaltrials.gov* and *Controlled-trials.com*

online trial registries were searched. Citations reporting outcomes from <30 patients, those including an unspecified mini-sling and those without a clear definition of 'cure' were excluded. Additionally, multiple abstracts from the same authors/dataset and those giving rise to subsequent publications were identified to avoid duplication. In total, 25 citations and 59 conference abstracts were screened for eligibility. Ten studies were considered eligible and are included in this review (Table 1 [6–15]).

The primary outcomes were rates of objective and subjective cure at 12 months. For studies that divided success into 'cure' and 'improvement', only the proportion 'cured' was included to aid comparison across studies. Secondary outcomes included rates of intra-operative and postoperative complications. Intra-operative complications included vaginal perforation rates, estimated blood loss, UTI and urinary retention rates. Postoperative complications included mesh exposure, *de novo* overactive bladder (OAB) symptoms (urgency, frequency, nocturia and/or urge incontinence) and groin pain/dyspareunia. Where possible, cure rates and cases of vaginal perforation were subclassified according to the 'H-type' and 'U-type' surgical approach. Finally, the frequency of return to the operating theatre in the first postoperative 12 months were recorded and sub-divided into women returning because of an operative complication (mesh exposure or voiding dysfunction) and failed cases undergoing a repeat continence procedure.

TABLE 2 Therapeutic efficacy at 12 months

| Authors | Subjective cure | | | | Objective cure | | | |
|-------------------------------|------------------|--------------|--------------|---------------|----------------|--------------|--------------|--------------|
| | Definition | H-type % (n) | U-type % (n) | Total % (n) | Definition | H-type % (n) | U-type % (n) | Total % (n) |
| Debodinance <i>et al.</i> [6] | N/A | 69 (49/71) | 0 | 69 (49/71) | N/A | N/A | N/A | N/A |
| Kim <i>et al.</i> [7] | No SUI | 87 (54/62) | 89 (47/53) | 88 (101/115) | N/A | N/A | N/A | N/A |
| Krofta <i>et al.</i> [8] | ICIQ-SF | 60 (49/82) | 0 | 60 (49/82) | (-) CST | 52 (43/82) | 0 | 52 (43/82) |
| Liapis <i>et al.</i> [9] | Questionnaire | 61 (26/43) | 69 (27/39) | 65 (53/82) | (-) CST | 63 (27/43) | 72 (28/39) | 67 (55/82) |
| Lee <i>et al.</i> [10] | Questionnaire | 76 (106/140) | 77 (111/144) | 76 (217/284) | (-) CST | 80 (113/141) | 88 (126/144) | 84 (239/285) |
| Meschia <i>et al.</i> [11] | No SUI | N/A | N/A | 78 (71/91) | (-) CST | N/A | N/A | 81 (74/91) |
| Molden <i>et al.</i> [12] | Absolute dryness | N/A | N/A | 69 (103/149) | N/A | N/A | N/A | N/A |
| Neuman [13] | Questionnaire | 92 (83/90) | 0 | 92 (83/90) | N/A | N/A | N/A | N/A |
| Oliveira <i>et al.</i> [14] | N/A | N/A | N/A | N/A | (-) CST | 71% (75/106) | 0 | 71 (75/106) |
| Tommaselli <i>et al.</i> [15] | N/A | N/A | N/A | N/A | (-) CST | 84% (31/37) | 0 | 84 (31/37) |
| Total | | 75 (367/488) | 81 (240/296) | 76 (781/1024) | | 71 (289/409) | 84 (154/183) | 76 (517/683) |

CST, cough stress test; N/A, not available.

TABLE 3 Intra-operative data

| Author | Mean operation duration, min | Blood loss, mL | Vaginal perforation | | Urinary retention | | UTI % (n) |
|-------------------------------|------------------------------|----------------|---------------------|--------------|-------------------|--------------|--------------|
| | | | H-type % (n) | U-type % (n) | H-type % (n) | U-type % (n) | |
| Debodinance <i>et al.</i> [6] | 9 | N/A | 2.8 (2/71) | N/A | N/A | N/A | N/A |
| Kim <i>et al.</i> [7] | 14 | 62 | 4.8 (3/62) | 0 (0/53) | 1.6 (1/62) | 3.8 (2/53) | N/A |
| Krofta <i>et al.</i> [8] | 21 | 41.9 | 3.5 (3/86) | N/A | 3.5 (3/86) | N/A | 4.7 (4/86) |
| Liapis <i>et al.</i> [9] | N/A | N/A | 0 (0/43) | 0 (0/39) | 0 (0/43) | 0 (0/39) | 4.9 (4/82) |
| Lee <i>et al.</i> [10] | 17 | 44 | 2.1 (3/141) | 0 (0/144) | 2.1 (3/141) | 1.4 (2/144) | N/A |
| Meschia <i>et al.</i> [11] | N/A | N/A | N/A | | 8 (7/91) | | 10 (9/91) |
| Molden <i>et al.</i> [12] | 32 | 54 | 0 (0/126) | | 3.2 (4/126) | | N/A |
| Neuman [13] | N/A | N/A | 4.4 (4/90) | N/A | 2.2 (2/90) | N/A | 0 (0/90) |
| Oliveira <i>et al.</i> [14] | 12 | N/A | 0 (0/106) | N/A | 0.9 (1/106) | N/A | N/A |
| Tommaselli <i>et al.</i> [15] | 7 | N/A | 0 (0/37) | N/A | 0 (0/37) | N/A | 0 (0/37) |
| SUB-TOTAL % (n) | – | – | 2.4 (15/636) | 0 (0/236) | 1.6 (10/636) | 1.7 (4/236) | |
| Total % (n) | 16.7 | 36 | 1.5 (15/998) | | 2.3 (25/1089) | | 4.4 (17/386) |

Statistical analysis was performed using Statsdirect statistical package 2.7.2 (Statsdirect Ltd., UK). Categorical data were examined using Fisher's exact test, with odds ratios (OR) and 95% CIs generated where appropriate. Two-tailed *P* values were used throughout and a *P* value of 0.05 was considered to indicate statistical significance.

RESULTS

We identified 1178 published cases from 10 studies of 12-month outcomes after TVT-S procedures (Table 1). Study participants had a mean age of 56 years and a mean body mass

index (BMI) of 26 kg/m². Urodynamic stress incontinence was confirmed before surgery in all cases. The surgical approach was specified in six studies, with 62% (488/784) undergoing the 'H-type' and 38% (296/784) undergoing the 'U-type' approach (Table 2 [6–15]).

The overall subjective cure rate at 12 months, as assessed through either a questionnaire or by the woman reporting no stress leakage, was 76% (781/1024). A trend towards increased subjective cure amongst women undergoing the 'U-type' repair was found, which was not statistically significant (OR 1.41, 95% CI 0.98–2.09; *P* = 0.064; Table 2).

The 12-month objective cure rate after a TVT-S procedure, defined as negative cough stress test across all studies, was also 76% (517/683). Women were more likely to demonstrate objective cure after the 'U-type' approach compared with the 'H-type' approach (OR 2.2, 95% CI 1.38–3.59; *P* = 0.0005, Table 2).

The mean operating time for TVT-S in the included studies was 17 min, with a negligible average blood loss of 36 mL (Table 3 [6–15]). The overall rate of recognized intra-operative vaginal perforation was 1.5% (15/998). The 'H-type' approach conferred a significantly increased risk of vaginal perforation (2.4%)

TABLE 4 Post-operative complications

| Author | Mesh exposure % (n) | Return to operating theatre % (n) | | <i>de novo</i> OAB % (n) | Pain/dyspareunia % (n) |
|-------------------------------|---------------------|-----------------------------------|---------------|--------------------------|------------------------|
| | | Complication | Recurrent SUI | | |
| Debodinance <i>et al.</i> [6] | 1 (2/149) | N/A | N/A | 19 (8/44) | 2 (1/52) |
| Kim <i>et al.</i> [7] | 0 (0/115) | 0.9 (1/115) | 3.5 (4/115) | N/A | 0 (0/115) |
| Krofta <i>et al.</i> [8] | 7 (6/82) | N/A | 13 (11/82) | 24 (20/82) | 5 (4/82) |
| Liapis <i>et al.</i> [9] | 0 (0/87) | 0 (0/87) | N/A | 9 (8/87) | N/A |
| Lee <i>et al.</i> [10] | 0 (0/285) | 0 (0/285) | 4 (11/285) | 7 (21/285) | 0 (0/285) |
| Meschia <i>et al.</i> [11] | 2 (2/91) | N/A | 9 (8/91) | 10 (9/91) | 2 (2/91) |
| Molden <i>et al.</i> [12] | 0.8 (1/126) | 2.4 (3/126) | 7 (9/126) | N/A | 0.8 (1/126) |
| Neuman [13] | 10 (10/100) | 2 (2/100) | N/A | 10 (10/100) | 1 (1/100) |
| Oliveira <i>et al.</i> [14] | 6 (6/106) | 1 (1/106) | N/A | 6 (6/106) | N/A |
| Tommaselli <i>et al.</i> [15] | 3 (1/37) | N/A | N/A | 5 (2/37) | 0 (0/37) |
| Total % (n) | 2.4 (28/1178) | 0.85 (7/819) | 5 (43/799) | 10 (84/832) | 1 (9/888) |

compared with the 'U-type' approach (0%, $P=0.015$). There were no reported cases of bladder perforation in the 1178 cases included in the present review, although routine intra-operative cystoscopy was not performed consistently in all studies. In the first 12 months after surgery, the incidence of mesh exposure was 2.4% (28/1178).

The incidence of UTIs in the peri-operative period was 4% (Table 3). Approximately 2% (25/1089) of cases were complicated by urinary retention with no difference seen in this complication according to surgical approach (1.7% and 1.6% for the 'U-type' and 'H-type' respectively; OR 1.08, $P > 0.99$). The incidence of *de novo* OAB symptoms after TVT-S procedures was 10% (84/832). Only 1% of women reported dyspareunia or groin/leg pain at 12 months (Table 4 [6–15]). Although <1% of women returned to the operating theatre because of a complication, 5% (43/799) of patients underwent a repeat surgical procedure for SUI in the first year after a TVT-S procedure.

DISCUSSION

Synthetic MUSs are now considered to be the 'gold standard' surgical treatment for women with SUI and have become the benchmark against which newer therapeutic interventions must be assessed [1]. A recent meta-analysis of surgical options for SUI showed objective cure rates at 12–18 months of 74–100% after TVT and 52–100% after transobturator tape (TOT) procedures, with most studies reporting objective cure rates of > 80% for both approaches [16]. Recently, results from a large multicentre randomized

controlled trial of TVT vs TOT at 12 months reported objective cure in 81% and 78% of the TVT and TOT groups, respectively, with lower subjective cure rates of 62% and 56%. The authors from this trial attribute their lower subjective cure rates to the use of a composite outcome measure, with a stricter definition of success [17].

The present review finds both objective and subjective cure rates of 76% at 12 months after TVT-S procedures, using a single outcome measure in most cases (Table 2). Thus, based on a substantial body of literature, TVT-S appears to be associated with an objective cure rate lower than, but a subjective cure rate similar to, more established MUSs at 12 months. The present study suggests a likely advantage to the 'U-type' approach, with women twice as likely to be objectively cured compared with the 'H-type' approach (OR 2.2, $P < 0.001$), and with no apparent increase in peri-operative complications. However, 1-year outcomes would not generally be considered robust enough on which to base surgical decisions. To date, the longest reported outcomes are at 3 years after a TVT-S procedure [4]. That small study found a sharp fall in success rates over time, with only 40% of women cured at 36 months. It is vital therefore, that practitioners continue to report longer-term outcomes from the third generation mini-slings, to facilitate comparison with alternative operating approaches.

One of the most challenging issues in assessing outcome after continence surgery is the definition of success. Although continence (dryness) is the ideal, there are many patients who will not be dry after

surgery but may report significant improvement in their leakage. Indeed, such patients may be very satisfied with their surgery, so to record these patients as 'treatment failures' is controversial; however, neither are they truly objectively 'cured', hence the dilemma. Several of the studies included here reported outcomes in three categories: cure, improvement and failure. For the purposes of this review, only those cured were included in the success category but it is acknowledged that this is debatable.

In addition to therapeutic efficacy, the other major issue when assessing a newer intervention is surgical risk. The TVT-S may be inserted in two ways, the 'U-type' which is more analogous to the retropubic TVT, and a flatter 'H-type' trajectory, similar to the second generation TOT (Fig. 1). The present study found that intra-operative vaginal perforation was a complication in 1.5% of TVT-S insertions, with an unsurprising increased rate in the more lateral 'H-type' insertion. The rate of postoperative urinary retention was 2%, which was not influenced by surgical approach. These complication rates compare favourably with reported incidences from more established synthetic MUSs [16]. The absence of any bladder perforations in the 1170 cases reviewed here is very reassuring, although universal cystoscopy was not performed, raising the possibility of undiagnosed perforations.

One of the principal advantages offered by the TOT approach vs the retropubic approach, is a reduced incidence of *de novo* OAB symptoms [16]. It is important, therefore, that any new treatment method for SUI maintain

this benefit. In the present analysis, the incidence of *de novo* OAB symptoms at 12 months after TVT-S procedures was 10%. This is consistent with the 11% reported rate at 2–3 years after TVT-S procedures [4]. In contrast, recently published 5-year results from a randomized trial comparing TVT and TOT reported a long-term *de novo* urgency rate of 4% for first/s generation MUSs combined [18]. This was unchanged from the rate of *de novo* OAB at 1 year (4%) from the same trial, which was previously reported [19]. It is true that not all cases of *de novo* OAB are of similar severity as not every affected woman will be incontinent; in the largest trial included here, the incidence of *de novo* OAB was 7%, but none of these women had urge incontinence [10]. Nonetheless, based on the present study, rates of *de novo* OAB after a TVT-S procedure do not appear lower, and may indeed be higher, than established MUS techniques.

Mesh exposure is emerging as a significant complication after the use of synthetic mesh vaginally and rates of mesh exposure are an important variable to consider in assessing a novel therapeutic method. In the present review, the rate of mesh exposure was 2.4%, which is not higher than equivalent rates for TVT at 1 year [17]. Although <1% of women returned to theatre because of a complication, it is notable that several of the papers reporting mesh exposures did not comment on the level of re-intervention required for these patients (Table 4). Recently, the risk of para-urethral banding and dyspareunia post-MUS has come under focus, with higher rates reported after TOT than after TVT procedures [20]. Although, intuitively, banding would seem less likely with a short single-incision sling, this has not previously been reported. The present review suggests a low (1%) rate of dyspareunia after TVT-S procedures, but absence of data on the number of sexually active women in individual studies precludes an accurate analysis of this complication. The incidence of dyspareunia after a TVT-Secur mini-sling procedure demands further study.

The theoretical benefit of the single-incision sling techniques is a reduction in serious iatrogenic injury compared with, in particular, the retropubic approach. However, although in the cases of TVT-S included here major intra-operative complications are not reported, serious adverse outcomes after TVT-S procedures have been documented; there are a number of reports of significant

bleeding complications requiring laparotomy [21,22]. Recently, a case of internal pudendal artery injury after a TVT-S procedure was reported, which required radiological embolization to achieve haemostasis [23]. Furthermore, a case of a retained finger pad necessitating re-exploration in theatre has been documented after a TVT-S procedure, something which is not a risk after other MUS approaches [24]. Thus, we cannot assume that the use of a mini-sling eliminates the risk of serious adverse outcomes, although the rate of such events after TVT-S procedures remains unknown.

Many continence surgeons have moved away from the traditional TVT and now prefer transobturator slings as their procedure of first choice owing to the lower rates of bladder injury and voiding dysfunction and the equivalent surgical efficacy [17]. However, despite the emergence of the transobturator approach, there remain many practitioners who continue to routinely offer the retropubic TVT, based on longer-term outcome data and their own personal experience. To date, no prospective randomized study comparing TVT-S with either TVT or TOT has been reported. Randomized trials are currently recruiting in several international centres (<http://www.clinicaltrials.gov>: NCT00534365, NCT00676273, NCT00527696, NCT00685217, NCT00751088) and the results from these studies are eagerly awaited.

CONCLUSIONS

Numerous studies reporting 12-month outcomes after insertion of the TVT-S mini-sling for SUI have recently been reported. The present paper is the largest review of TVT-S published to date and finds that in middle-aged women of average BMI, TVT-S is associated with both objective and subjective cure rates of 76% at 12 months. Rates of vaginal perforation (1.5%), urinary retention (2.3%), mesh exposure (2.4%) and dyspareunia (1%) appear low. The 'U-type' approach is associated with better objective cure rates at 12 months without an apparent increased complication rate. The rate of *de novo* OAB symptoms is 10% which is not lower than other MUS techniques. Until data exist to correctly assess the medium- and long-term cure rates after TVT-S procedures, practitioners must be careful in choosing this surgical approach over more established surgical options.

CONFLICT OF INTEREST

None declared.

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- Abbreviations:** TVT-S, TVT-Secur; SUI, stress urinary incontinence; MUS, mid-urethral sling; TVT, Tension-free Vaginal Tape; OAB, overactive bladder; BMI, body mass index; TOT, transobturator tape.