Single-incision mid-urethral mini slings versus standard transobturator slings in management of women with stress urinary incontinence: a randomized controlled trial

Ahmed Radwan, Ahmed Higazy, Mohammed Metwally, Waleed Mousa, Mohamed Kandil, Mohamed A. Gamal

Departemnt of Urology, Ain Shams University Hospitals, Cairo, Egypt

Correspondence to Ahmed Maher Higazy, MSc of Urology, MRCS, Departemnt of Urology, Ain Shams University Hospitals, Cairo, Egypt. ORCID: https://orcid.org/0000-0002-9679-4241. Tel: +20/01002609801; e-mail: ahmeditich@live.com, Ahmedmaherhigazy@gmail.com

Received: 23 April 2020
Accepted: 3 June 2020
Published: 24 December 2020

The Egyptian Journal of Surgery 2020, 39:920–925

Purpose
To evaluate the single-incision suburethral mini-sling (SIMS) versus the transobturator tapes (TOT) procedure in the management of stress urinary incontinence (SUI) regarding safety, efficacy, postoperative pain, and the time to return to daily activity.

Patients and methods
A total of 40 female patients with SUI were included in our study and were divided into two equal groups: group A was managed by TOT, whereas group B was managed by SIMS. Patients were evaluated from day 1 till 6 months after surgery for postoperative pain, early return to daily activity, dyspareunia, and continence after surgery. Moreover, also any perioperative complications were recorded.

Results
Patients' demographics data were similar in both groups. We reported a success rate of 85% for patients of group A versus 80% success rate for patients in group B, with no statistically significant difference. A lower pain score in favor of group B was reported; these results were significant starting from day 1 till 1 month postoperatively, whereas at 3 and 6 months, the results were not statistically significant. Moreover, there was an earlier return to daily activity with group B compared with group A. We reported three cases of dyspareunia in group A compared with two cases in group B. No cases of vaginal erosions, as well as bladder, vascular, or vaginal injuries were encountered in our study.

Conclusion
The use of SIMS in the treatment of SUI is as effective and safe as TOT, with significantly lower postoperative pain and analgesic requirement and earlier return to daily activity.

Keywords:
mini tape, mini slings, single-incision mini slings, stress urinary incontinence, transobturator tape

Egyptian J Surgery 39:920–925

1110-1121

Introduction

Stress urinary incontinence (SUI) is an involuntary urinary leak secondary to an increased intra-abdominal pressure that may be associated with intrinsic sphincter deficiency, detrusor muscle overactivity, or pelvic organ prolapse. It is estimated to affect up to 35% of adult women worldwide, affecting their quality of life [1].

The actual prevalence of SUI is difficult to estimate as it is usually under-reported. Incontinence has often been considered as a natural consequence of the aging process or an embarrassing issue, which is unacceptable to discuss with others. Even some women are not aware of the available treatment options or have a fear of surgical treatment [2].

Retropubic and transobturator tension-free slings (standard mid-urethral slings) (SMUS) represent the most effective and popular procedures for the surgical treatment of SUI and are currently considered the gold standard [3].

The transobturator approach to the tension-free tape sling was developed to help minimize the morbidity associated with blind retropubic needle placement by passing through the groin and obturator space away from the viscera and neurovascular structures [4].

The transobturator approach appears to share efficacy comparable to that of the retropubic approach as demonstrated in various randomized and nonrandomized trials. This approach is also thought to place the sling in a more natural position that mimics

the pubourethral ligament, and its attachment to the levator muscle and pelvic sidewall [5].

Recently, single-incision mini-slings (SIMS) have been developed to limit the number of incisions and reduce the risks of blind needle passes through the groin or abdomen yet mimic the position of the transobturator tape (TOT) sling. The single-incision sling system provides such a minimally invasive approach for the treatment of female SUI. It uses self-fixating tips that provide immediate fixation into the obturator muscles, thereby eliminating the need for a full-length transobturator mesh [6].

SIMS requiring very limited intracorporeal dissection with a short route has been recently introduced proposing to further increase the safety of suburethral slings, without jeopardizing the success rates reported by conventional retropubic and transobturator access [7].

Several advantages of the SIMS over SMUS procedures are that it is associated with a shorter operative time, can be performed under local anesthesia, has less postoperative pain, and has reduced morbidity. All these features would support the use of SIMS as an office procedure. The SIMS procedure is considered as an effective alternative to the SMUS procedures [8].

We conducted our study to evaluate the safety and efficacy of SIMS versus TOT as an anti-incontinence procedure with special concern on the postoperative pain and early return to daily activity.

Patients and methods

Between August 2013 and March 2016 at the Faculty of Medicine, Ain Shams University Hospitals, 40 female patients with SUI were included in this study. Those patients were randomized into two equal groups with a 1 : 1 ratio using sealed envelopes prepared by the department's ethical committee. After obtaining written informed consent, patients were randomly divided into two groups. Group A (n=20) was managed by conventional TOT surgery whereas group B (n=20) was managed by SIMS surgery for SUI.

Patients were evaluated preoperatively by full history taking, complete physical examination including a cough stress test, pelvic abdominal ultrasound with the estimation of postvoided residual urine volume, and urodynamic evaluation. Patients with detrusor overactivity, any associated pelvic organ prolapse more than second degree, previous history of anti-incontinence surgery, previous pelvic irradiation, or previous history of pelvic tumors were excluded from our study.

Both techniques were done under spinal anesthesia with the patient in the lithotomy position and the legs flexed; the bladder was emptied with a Foley catheter. All surgeries were performed with two surgeons, both being experts in female urological surgeries.

SIMS procedure was done using Contasure-Needleless by Neomedic (Barcelona, Spain), through a 2-cm mid-urethral vaginal incision, and then lateral dissection till the posterior margin of the inferior pubic ramus was done. Using a curved introducer that was clipped into two plastic anchoring hooks on the ends of the sling; that was used to insert the sling and secure it to the obturator membrane. The sling was introduced through the formed paraurethral tunnel till reaching behind the inferior pubic ramus. The applicator was then pivoted slowly behind the ramus and through the obturator complex allowing the anchoring hook to maintain its position in the obturator membrane and muscles at points equivalent to 10 and 2 o'clock position in relation to the urethral orifice. These steps were repeated on the other side. Once the sling was introduced, adjustment of the tension around the urethra was done by introducing the tip of the forceps into the pocket positioning system and pushing the sling further up to adjust the sling support. When the sling was fully positioned the traction, the thread was cut and withdrawn.

The TOT procedure was done using TOT Obtryx II by Boston Scientific (Barcelona, Spain) by an outside-in technique, through a vertical midline vaginal incision over the middle third of the urethra. The vagina was released on either side of the urethra with Mayo scissors over a width of ~15 mm till the ischiopubic ramus. A puncture incision was made at the point of intersection of two lines; the vertical one was the thigh crease and the horizontal one passing by the clitoris. The needle was introduced through a skin incision till it punctured the obturator membrane. The needle was then turned to a horizontal position, with the handle pointing medially. The tip of the tunneller was directed medially toward the urethra, aiming above the urethral meatus and underneath the symphysis pubis. The safest method is to lead the tunneller around the ischiopubic ramus while remaining in contact with it. This procedure aimed to trace a perineal route with the instrument below the fascia of the levator ani. Then a finger was placed in the

incision to check that the tunneller is not piercing the vagina. This guiding finger helped to fold the urethra upward and protected it from the needle by contacting the tip of the tunneller laterally behind the pubic ramus into the vaginal incision. The procedure was repeated on the other side, and the tape was inserted tension free behind the urethra leaving a visible space between the tape and the urethra (a few millimeters) by putting mayo scissor between the tape and urethra, and the excess tape was trimmed.

Closure of the incision in both techniques was done by absorbable suture with a vaginal pack for 24 h. The Foley's catheter was removed in the following day. All patients received perioperative antibiotics and analgesics for 1 day and were evaluated for postoperative pain.

Patients were instructed to avoid intercourse for 1 month postoperatively. They were evaluated from day 1 till 6 months after surgery for postoperative pain, analgesic requirement, and early return to daily activity. Patients were asked about any lower urinary tract symptoms like dysuria urgency, deep pelvic pain, and gynecological problems such as vaginal discharge, erosion, or dyspareunia followed by a complete gynecologic examination. Surgery's success was defined by the improvement of the urinary continence based on the patient's symptoms, cough test showing no leakage of urine, and a 24-h pad test.

Ethical considerations

The study was approved by the Research Ethics Committee of Faculty of Medicine, Ain Shams University, with approval no. FWA 000017585.

Statistical analysis

Data were analyzed by SPSS, version 17.0 (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp, USA). Categorical variables were analyzed using the χ^2 or Fisher's extract test, and continuous variables were analyzed using the Student *t* test or Mann–Whitney *U* test. A *P* value less than 0.05 was considered statistically significant.

Results

A total number of 40 patients were equally distributed into two equal groups, as shown in Fig. 1. Demographic data of both groups were similar, and the mean age was 43.3±10 years (range, 28–60 years) for group A, whereas for group B, the mean age was 42.7±8 years (range, 28-61 years) (*P*=0.821). BMI was 29.40±6.311 kg/m^2 in group A compared with 30.30 ±5.805 in group B (*P*=0.641). Regarding the mean parity with vaginal deliveries, it was 2±1.4 for group A and 2±1.6 for group B (*P*=0.918).

The mean operative time was 30.8±5.3 min for group A, compared with 33.5±3.2 min for group B, with operative time being clinically shorter in group A. However, there was no statistically significant difference between both groups (*P*=0.06). The hospital stay was 1.3±0.5 and 0.9±0.3 for groups A and B, respectively, with shorter hospital stay with group B. The difference was statistically significant (*P*=0.013).

Postoperative pain in both groups was assessed by using a 0–10 Numeric Rating Scale at five different times at first day postoperative, first week, and 1, 3, and 6 months after surgery, as shown in Table 1.

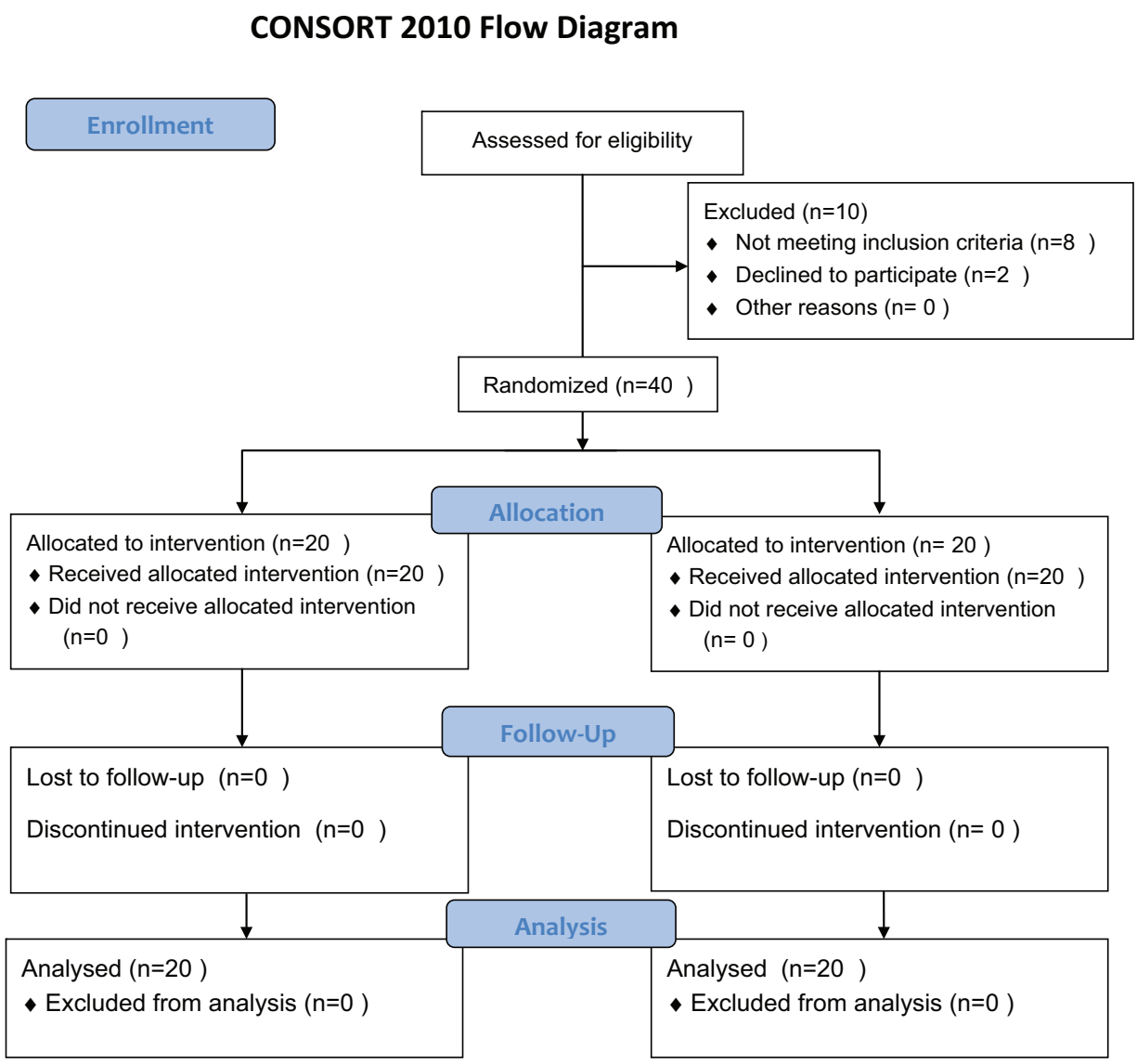
There was a discrepancy in pain score between both groups, where patients in group B encountered less pain than group A; the mean pain score in group A was 4.4 ±0.6 compared with 1.4±0.5 for group B, with *P* value less than 0.001, which is statistically highly significant. One week after surgery, the mean pain score for group A was 1.7±1.1 whereas it was 0.6±0.6 for group B, with *P* value less than 0.001, which is considered statistically highly significant. One month after surgery, the mean pain score for group A was 0.8±0.9, whereas it was 0.2 ±0.4 for group B, with *P* value 0.018, which is considered statistically significant. Three months after surgery, the mean pain score for group A was 0.2±0.5, whereas it was 0.1±0.2 for group B, with no statistically significant difference (*P*=0.1). Six months after surgery, the pain was negligible to be assessed by both groups.

As for the mean time to return to normal activity in group A, it was 6.5±1.2 days compared with 5.1±0.7 days for patients in group B, with *P* value less than 0.001, which is considered statistically highly significant.

Success of the surgical procedure was assessed by the patient's symptoms, cough test, and a 24-h pad test. The success rate was noted in 17 (85%) cases and 16 (80%) cases in groups A and B, respectively, no statistically significant results being noted in the success rate (*P*=0.3).

Regarding postoperative complication in our study, two patients in group A required catheter re-insertion as the patients developed urinary retention after removal of the catheter, whereas no patients in group B developed urine retention. The urinary

Figure 1



CONSORT 2010 flow diagram.

retention was attributed to tissue edema from excess dissection and postoperative pain. Both cases were improved after 1 week on medical treatment of analgesics and anti-inflammatory medication.

Dyspareunia was reported in three patients in group A, whereas only two patients in group B reported dyspareunia, which was persistent in those cases till the end of our study follow-up. No cases of vaginal erosions; surgical site infection; bladder, vascular, or vaginal injuries; or postoperative hematoma formation were encountered in our study.

Discussion

SUI is estimated to affect up to 35% of adult women worldwide, leading to deterioration in quality of life. The mid-urethral slings (MUS) are considered the gold standard treatment for SUI in women, with continuously new surgical techniques being described [9].

MUS have been evolved from retropubic transvaginal tapes in 1996 by Ulmsten *et al.* [10] to the second-generation using the transobturator route, and finally with third-generation, most commonly described as SIMS, being first introduced in 2006 [6,11].

The European guidelines described two concepts of MUS for the surgical treatment of SUI in women, which are tension-free MUS that include all MUS that depend on their postinsertion fixation mechanism on friction to nearby tissues within their relatively long trajectory of insertion, and the anchored MUS, which are characterized by the short trajectory of insertion and therefore need a robust anchoring mechanism to the

Table 1 Pain score, time to normal activity, and success rate

	Group A: TOT	Group B: SIMS	*P* value
Pain score			
1st day	4.4±0.6	1.4±0.5	<0.001
1st week	1.7±1.1	0.6±0.6	<0.001
1st month	0.8±0.9	0.2±0.4	0.01
After 3 months	0.2±0.5	0.1±0.2	0.1
After 6 months	0	0	0
Time to return to normal activity (days)	6.5±1.2	5.1±0.7	<0.001
Success rate evaluated at 1 month	17 (85%) cases	16 (80%) cases	0.3

SIMS, single-incision mini-sling; TOT, transobturator tape.

obturator complex with a strong postinsertion pullout force. All currently available SIMS share the same tape material (type 1 polypropylene) and the insertion technique through a single vaginal incision. However, they differ in the type of anchorage mechanism used (Kocjancic *et al.*, 2012). SIMS aims to provide a similar success rate with less morbidity [12,13].

Our study included a total number of 40 patients with SUI. Patients were divided into two equal groups. Group A was managed by conventional TOT surgery, whereas group B was managed by SIMS surgery. Both groups showed similar demographic data, with no statistically significant difference in mean age, BMI, or parity.

In our study, the mean operative time was 30.8 min for group A, whereas it was 33.5 min for group B, with no statistically significant difference in between. These results were comparable to the study done by Masata and colleagues, who reported a mean operative time of 33.8 min for SMUS group and 32.2 for the SIMS group, whereas the shortest operative time was reported by Tieu *et al.*, who reported 10.4 min for the SMUS patients versus 7.6 min for the SIMS group [14,15].

Success rate in our study was 85% in TOT group compared with 80% in SIMS group, with no statistically significant difference between both groups (P=0.3). These results were comparable to Djehdian *et al.*, Mostafa and colleagues, and Oliveira and colleagues, who reported a success rate of 87, 85, and 80%, respectively, in the TOT group, and less than Schellart and colleagues and Martinez Franco and Amat Tardiu, who reported a success rate of 91 and 94%, respectively. However, for the SIMS group, our results were lower than studies done by Djehdian *et al.*, Mostafa and colleagues, Oliveira and colleagues, Schellart and colleagues, and Martinez Franco and Amat Tardiu, who reported objective success rates of 87, 84, 86, 80, 89, 91, and 94%, respectively, but better than Tieu *et al.*, who reported only 48% success rate in the SIMS group [16–20].

One of the most important parameter that showed statistically significant difference between the two groups was the postoperative pain score. These results were significant starting from day 1 till 1 month postoperative, whereas at 3 and 6 months, results were not statistically significant. Mean pain score of SIMS group was 0.6 compared with 1.7 for the TOT group at the first week, which was comparable to the studies done by Mostafa *et al.* and Oliveira *et al.*, who reported a mean pain score of 0.9 and 1, respectively, for the SIMS group, whereas the mean pain score was 3.3 and 4.5, respectively, for the TOT group. The less pain encountered by SIMS group was reflected in the need for analgesics, which was less compared with the TOT, and on the earlier return to daily activities as well [18,20].

In our study, patients in SIMS group showed significantly earlier return to normal activity with mean of 5.1 days in comparison with conventional TOT group (6.5 days), which was less than the results shown in the study done by Mostafa *et al.*, who showed 7.3 days for the SIMS group but longer time with TOT group, with mean 10.6 days, and also earlier than time reported by Gopinath and colleagues, who reported 15.1 days in the TOT group versus 7 days in the SIMS group [18,21].

In our study, we reported three (15%) cases of postoperative dyspareunia in TOT group, whereas only two (10%) cases in SIMS group, with no statistically significant difference between both groups, which was comparable to the study done by Mostafa *et al.*, who also reported no statistically significant difference in both groups regarding postoperative dyspareunia [18].Regarding postoperative complication in our study, two patients in group A required catheter re-insertion, as the patients developed urinary retention after removal of

the catheter, whereas no patients in group B developed urine retention. The urinary retention was attributed to tissue edema from excess dissection and postoperative pain. Both cases were improved after 1 week on medical treatment of analgesics and anti-inflammatory medication. No cases of vaginal erosions, surgical site infection, as well as bladder, vascular, or vaginal injuries were encountered in our study. These results were comparable to the results shown by Oliveira *et al.* and Mostafa *et al.* [18,20].

Conclusion

We concluded from our study that using SIMS in treatment of women with SUI is as effective and safe as TOT with significantly lower postoperative pain, less need for analgesics, and earlier return to daily activities.

Acknowledgements

Ahmed Radwan: primary surgeon, as well as methodology section writing; Ahmed Higazy (ORCID ID: *https://orcid.org/0000-0002-9679-4241https://orcid.org/0000-0002-9679-4241*): introduction, discussion, and abstract writing; Mohammed Metwally: data collection and results section writing; Waleed Mousa: data collection and results section writing; Mohamed Kandil: methodology section outline and abstract writing; and Mohamed A. Gamal: primary surgeon, as well as final revision and abstract writing.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1 Luber KM. The definition, prevalence, and risk factors for stress urinary incontinence. Rev Urol [Internet] 2004; 6(Suppl 3):S3–S9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16985863

2 Hunskaar S, Lose G, Sykes D, Voss S. The prevalence of urinary incontinence in women in four European countries. BJU Int [Internet] 2004; 93:324–330. Available from: http://www.ncbi.nlm.nih.gov/pubmed/14764130

3 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; 58:218–238.

4 Delorme E. Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women TT. Prog Urol 2001; 11:1306–1313.

5 Ross S, Robert M, Swaby C, Dederer L, Lier D, Tang S, *et al.* Transobturator tape compared with tension-free vaginal tape for stress incontinence. Obstet Gynecol 2009; 114:1287–1294.

6 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 (2):604–609.

7 Oliveira R, Resende A, Silva C, Dinis P, Cruz F. Mini-arc for the treatment of female stress urinary incontinence: long-term prospective evaluation by patient reported outcomes. ISRN Urol 2014; 2014:1–4.

8 Meschia M, Barbacini P, Ambrogi V, Pifarotti P, Ricci L, Spreafico L. TVT-secur: a minimally invasive procedure for the treatment of primary stress urinary incontinence.One year data from a multi-centre prospective trial. Int Urogynecol J Pelvic Floor Dysfunct 2009; 20:313–317.

9 Cox A, Herschorn S, Lee L. Surgical management of female SUI: is there a gold standard? Nat Rev Urol 2013; 10:78–89.

10 Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 1996; 7:81–86. doi:10.1007/BF01902378.

11 Abdel-Fattah M, MacLennan G, Kilonzo M, Assassa RP, McCormick K, Davidson T, *et al.* The SIMS trial: adjustable anchored single-incision mini-slings versus standard tension-free midurethral slings in the surgical management of female stress urinary incontinence.A study protocol for a pragmatic, multicentre, non-inferiority randomised con. BMJ Open 2017; 7:e015111.

12 Lucas MG, Bosch RJL, Burkhard FC, Cruz F, Madden TB, Nambiar AK, *et al.* EAU guidelines on surgical treatment of urinary incontinence. Eur Urol 2012; 62:1118–1129.

13 Jiao B, Lai S, Xu X, Zhang M, Diao T, Zhang G. A systematic review and meta-analysis of single-incision mini-slings (MiniArc) versus transobturator mid-urethral slings in surgical management of female stress urinary incontinence. Medicine (Baltimore) 2018; 97:e0283.

14 Mostafa A, Lim CP, Hopper L, Madhuvrata P, Abdel-Fattah M. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: an updated systematic review and meta-analysis of effectiveness and complications. Eur Urol 2014; 65:402–427.

15 Masata J, Svabik K, Zvara K, Drahoradova P, El Haddad R, Hubka P, *et al.* Randomized trial of a comparison of the efficacy of TVT-O and single-incision tape TVT SECUR systems in the treatment of stress urinary incontinent women—2-year follow-up. Int Urogynecol J 2012; 23:1403–1412.

16 Schellart RP, Oude Rengerink K, Van der Aa F, Lucot J, Kimpe B, de Ridder DJMK, *et al.* A randomized comparison of a single-incision midurethral sling and a transobturator midurethral sling in women with stress urinary incontinence: results of 12-mo follow-up. Eur Urol 2014; 66:1179–1185.

17 Yildiz G, Ceylan Y, Ucer O, Arslan D, Çelik O, Gunlusoy B. Safety and efficacy of single-incision sling for female stress urinary incontinence: 3 years' results. Int Urogynecol J [Internet] 2016; 27:1667–1671. Available from: http://link.springer.com/10.1007/s00192-016-3001-0

18 Mostafa A, Agur W, Abdel-all M, Guerrero K, Lim C, Allam M. A multicentre prospective randomised study of single-incision mini-sling (Ajust 1) versus tension-free vaginal tape-obturator (TVT-O TM) in the management of female stress urinary in. Eur J Obstet Gynecol 2012; 165:115–121.

19 Martinez Franco E, Amat Tardiu L. Contasure-Needleless® single incision sling compared with transobturator TVT-O ® for the treatment of stress urinary incontinence: long-term results. Int Urogynecol J 2015; 26:213–218.

20 Oliveira R, Silva C, Dinis P, Cruz F. Suburethral single incision slings in the treatment of female stress urinary incontinence: what is the evidence for using them in 2010? Arch Esp Urol 2011; 64:339–346.

21 Gopinath D, Smith ARB, Holland C, Reid FM. Why don't women participate? A qualitative study on non-participation in a surgical randomised controlled trial. Int Urogynecol J 2013; 24:969–975.