



Platinum Priority – Female Urology – Incontinence

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Exploratory Study Assessing Efficacy and Complications of TVT-O, TVT-Secur, and Mini-Arc: Results at 12-Month Follow-Up

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Abstract

Background: Contemporary surgical treatment of female stress urinary incontinence (SUI) includes retropubic and transobturator (TO) midurethral slings (MUS). Case series of single-incision slings (SIS) have shown similar outcomes with lower morbidity.

Objective: Our aim was to assess the cure rates, complications, and quality-of-life impact of one standard TO MUS and two SIS.

Design, setting, and participants: Ninety consecutive patients with clinically and urodynamically proven SUI were enrolled in an exploratory randomised phase 2 trial. Patients with previous SUI surgery, major pelvic organ prolapse, mixed incontinence, or detrusor overactivity were excluded.

Interventions: Patients were treated randomly with TVT-O, TVT-Secur, or Mini-Arc.

Measurements: Postoperative visits were scheduled at 6 and 12 mo. The King's Health Questionnaire (KHQ) was repeated at 6 mo. Cure was defined as the absence of urine leakage, no pad use, and a negative cough test at 12 mo. Pain and other complications were also investigated.

Results and limitations: Cure rate was 83% after TVT-O, 67% after TVT-Secur, and 87% after Mini-Arc. Improvement was found in 10%, 13%, and 7% of the patients, respectively. Failures were 7% after TVT-O and Mini-Arc and 20% after TVT-Secur.

TVT-O and Mini-Arc improved at least 15 points in >80% of the patients in six KHQ domains, whereas TVT-Secur could only achieve improvement in three of the nine domains. The pain score was lower in the Mini-Arc group. Complications were more numerous after TVT-O. This study has the limitations inherent in a phase 2 trial with a follow-up limited to 12 mo.

Conclusions: Mini-Arc offers cure and improvement rates similar to TVT-O, whereas TVT-Secur may yield an inferior outcome. These findings recommend the urgent launch of large randomised phase 3 studies comparing conventional MUS with SIS, with Mini-Arc the advised option.

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1. Introduction

Midurethral slings (MUS), either retropubic (RP) or transobturator (TO), are the most common contemporary surgical treatment for female stress urinary incontinence (SUI). Two facts have largely contributed to this situation: (1) Without compromising incontinence cure rate, RP MUS cause less morbidity and shorter hospital stays than the Burch colposuspension [1], and (2) RP and TO MUS have been shown repeatedly to have equivalent success rates [2,3]. Nevertheless, neither is free of complications, mainly dictated by the blind course of the introducer devices. The RP course may perforate the bladder, whereas the TO passage is associated with vaginal perforation and neurologic impairment leading to protracted thigh pain and upper leg weakness [4]. Both routes occasionally are associated with life-threatening complications including bowel perforation, major vessel disruption, and perineal gangrene [5]. In addition, voiding dysfunction and vaginal mesh exposures may also complicate MUS [6].

The quest to minimise the morbidity of MUS has determined the appearance of yet another group of shorter MUS, requiring a single vaginal incision for placement. Available data, mainly from case series [7,8], validate that assumption. However, reported success rates are extremely variable, ranging between 40% [9] and 100% [10], suggesting that considerable differences exist among single-incision slings (SIS) in what concerns efficacy. In spite of this evidence, comparative studies of SIS have not been performed up to now.

Our exploratory study assessed two SIS, TVT-Secur (Gynecare; Ethicon Inc., Somerville, NJ, USA) and Mini-Arc (American Medical Systems, Minnetonka, MN, USA), and TVT-O (Gynecare; Ethicon Inc., Somerville, NJ, USA), a conventional TO MUS. Cure and complication rates and quality of life were investigated at 6- and 12-mo follow-up. Previous results were presented elsewhere [11].

2. Patients and methods

We enrolled consecutive patients from our surgical waiting list with clinically and urodynamically proven SUI associated with urethral hypermobility between January and September 2008. The three slings investigated in the study were available in the hospital and could be indicated for any of the patients included. No patients refused randomisation. All patients gave written informed consent before entering the trial, which was authorised by the Ethics Committee of Hospital São João, Porto, Portugal.

Preoperative evaluation included a medical history comprising urogynaecologic and neurologic assessments and a urodynamic evaluation following International Continence Society recommendations [12,13]. Body mass index was determined according to the World Health Organisation definitions [14]. Cystometry and valsalva leak point pressure (VLPP; using intravesical pressure, measured in the lithotomy position, with the bladder filled at the normal desire to void) were performed. Intrinsic sphincter deficiency (ISD) was considered if VLPP was <60 cm H₂O [15].

Women with previous surgeries for SUI, genital prolapse stage ≥ 2 (by the Pelvic Organ Prolapse Quantification System), complaints of urgency, frequency, nocturia, or demonstrating detrusor overactivity were excluded.

Impact of SUI on the quality of life was assessed by the King's Health Questionnaire (KHQ) score [16]. A 15-point reduction in each domain was considered indicative of improvement. The surgeries were performed by the authors with the patient in the lithotomy position, with hips flexed at 90°. All the surgeons had a minimum experience of 30 cases for each procedure. For prophylactic antibiotherapy, intravenous ceftriaxone 1 g was used. A 16F Foley catheter was introduced and urine evacuated.

TVT-O was inserted according to De Leval [17]. TVT-Secur was positioned in the hammock position [7,18]. The Mini-Arc procedure followed the original description [8,19]. The surgical incisions were closed with a 3-0 running suture, and a vaginal gauze was left in place.

Postoperative analgesia included paracetamol (1 g orally three times a day) and ibuprofen (400 mg orally three times a day). On postoperative day 1, the vaginal gauze and the Foley catheter were removed and residual volume measured after spontaneous voiding (postvoiding residual). If <100 ml, patients were discharged on paracetamol 1 g orally three times a day. At discharge (postoperative day 1), women were asked to rate the pain they felt in the first 24 h, in spite of the standard analgesic protocol, using a 0–10 visual analogue scale.

Postoperative evaluations included visits at 6 and 12 mo following the procedure and were performed between January and September 2009. Patients were asked about lower urinary tract symptoms including urine leakage, pain, and complications. KHQ was repeated at the 6-mo visit. A cough test, at the volume the patient referred to as a normal desire to void, was performed at 12 mo.

Patients were considered cured if they did not report any episodes of urine leakage, ceased to wear any incontinence protection, and had a negative cough test. If a patient reported maintenance of SUI or a positive cough test, but the number of incontinence protections necessary decreased by >50% and she answered affirmatively to the question "Are you satisfied with the result of the surgery?", the patient was considered improved. All other cases were deemed failures. When used, the term *success rate* indicates the sum of cure and improvement rates.

Previous case series have shown that success rates after conventional TO MUS vary from 35% to 98% [20]; success rates reported after Mini-Arc and TVT-Secur vary from 40% to 100% [7,9,10,19]. Sample size was computed considering a one-stage procedure by Fleming. A minimum of 26 patients in each group was needed assuming a higher proportion for acceptance of 0.85, a lower proportion for rejection of 0.6, an α of 0.05, and a β of 0.1.

3. Results

Table 1 lists the demographics and baseline characteristics of the groups. No patients were lost to follow-up. Five patients had a VLPP slightly below 60 cm H₂O. However, surgeons maintained the surgical option because they believed the most important component for SUI was urethral hypermobility. One patient was randomised for TVT-O (VLPP: 59 cm H₂O), two for TVT-Secur (VLPP: 58 cm H₂O each), and two for Mini-Arc (VLPP: 54 cm H₂O and 58 cm H₂O).

At the 12-mo evaluation, 25 of 30 patients (83%) were cured and 3 of 30 patients (10%) were improved after TVT-O. After TVT-Secur, these numbers were 20 of 30 patients (67%) and 4 of 30 patients (13%), respectively. After Mini-Arc, these numbers were 26 of 30 patients (87%) and 2 of 30 patients (7%), respectively. Failures were 2 of 30 patients (7%) after TVT-O and Mini-Arc and 6 of 30 patients (20%) after TVT-Secur (Fig. 1).

TVT-O and Mini-Arc improved >80% of patients by a minimum of 15 points in six of the nine KHQ domains

Table 1 – Baseline demographics and clinical characteristics of the enrolled patients

	TVT-O	TVT-Secur	Mini-Arc
No.	30	30	30
Age, yr			
Mean ± SD	52.0 ± 11.7	52.7 ± 10.9	52.6 ± 11.8
Median (range)	52 (38–74)	52 (33–72)	51.5 (29–66)
BMI			
Mean ± SD	27.2 ± 5.3	26.3 ± 6.6	29.8 ± 5.4
Median (range)	27.0 (20.5–38.9)	26.2 (20.2–41.1)	29.1 (22.2–43.3)
Pads per day			
Mean ± SD	3.1 ± 2.0	2.5 ± 1.3	2.5 ± 1.8
Median (range)	3 (1–12)	2 (1–9)	2 (1–15)
Parity			
Mean ± SD	1.5 ± 1.1	1.8 ± 2	2.1 ± 2.2
Median (range)	2 (1–4)	2 (0–5)	2 (1–4)
Years of onset			
Mean ± SD	10.8 ± 8.5	8.4 ± 5.9	8.0 ± 6.1
Median (range)	10 (3–20)	6 (2–20)	8 (1–18)
VLPP			
Mean ± SD	109 ± 18.5	82 ± 39	95 ± 41
Median (range)	105 (59–142)	83 (58–126)	93.5 (54–166)

BMI = body mass index; SD = standard deviation; VLPP = Valsalva leak point pressure.

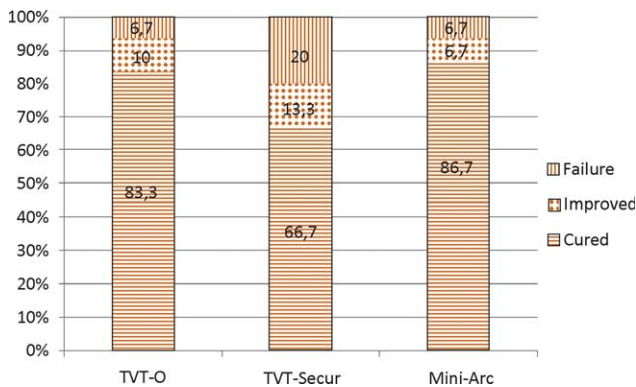


Fig. 1 – Cure, improvement, and failure rates after each midurethral sling at 12-mo follow-up.

(incontinence impact, role limitation, physical limitation, emotion, sleep, severity). TVT-Secur improved >80% of patients by a minimum of 15 points in three KHQ domains (physical limitation, emotion, severity) and very close to

80% in another three (role limitation, sleep, and social limitation) (Fig. 2).

No cases of intraoperative major bleeding, haematuria, urethral injury, or vaginal perforation were observed. No immediate associated surgical procedure was required.

Pain score in the first 24 h had its maximum expression in TVT-O and its minimum in Mini-Arc, and it was intermediate in TVT-Secur (Table 2). Nine patients submitted to TVT-O had some form of complication, and this MUS was, in fact, the sole one that had complications requiring surgical interventions. These surgeries, performed in two patients, consisted of sling transection due to recurrent urinary retention, carried out through a vaginal approach. Five patients developed moderate de novo urgency; two had referred prolonged thigh pain. Concerning TVT-Secur, complications occurred in five patients with one transient urinary retention, one urinary tract infection, and three cases of de novo moderate urgency. Mini-Arc was associated with six complications with one transitory urinary retention, one urinary tract infection, three cases of

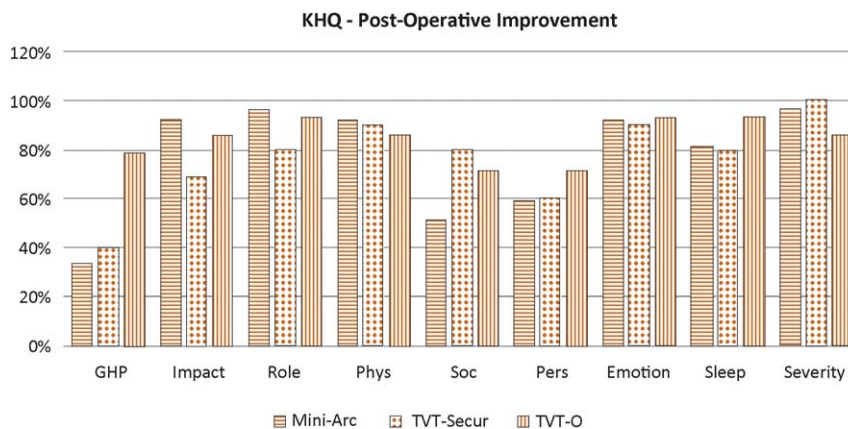


Fig. 2 – Percentage of patients with at least 15 points of improvement on the King's Health Questionnaire (KHQ) domains at 6 mo after placement of each tape. GHP = global health perception; Impact = incontinence impact; Role = role limitation; Phys = physical limitation; Soc = social limitation; Pers = personal limitation.

Table 2 – Postoperative pain score in first 24 h, assessed at discharge by a 0–10 visual analogue scale

	TVT-O	TVT-Secur	Mini-Arc
Postoperative pain			
Mean \pm SD	4.5 \pm 2.6	2.3 \pm 2.3	1.0 \pm 1.0
Median (range)	4 (1–10)	3 (0–6)	1 (0–3)
SD = standard deviation.			

de novo urgency, and one case of prolonged pain in the thigh.

4. Discussion

This phase 2 study evaluated two SIS, TVT-Secur and Mini-Arc, and TVT-O, a conventional TO MUS, as first surgical treatment for SUI. Data merit two considerations. First, all tested MUS had success rates above the minimum cut-off of 60%. Second, only TVT-O and Mini-Arc overtook the higher cut-off for acceptance.

The in-out TO sling TVT-O was chosen as the standard device due to its resemblance to TVT-Secur and Mini-Arc techniques. The option for TVT, the only MUS compared with Burch colposuspension [1], would introduce the possibility of complications only dictated by the retropubic passage of the needles [3]. In addition, the success rates achieved by RP and TO MUS in patients without ISD are identical [2,3]. As the standard technique, the 93% success rates observed here with TVT-O were similar to those of other studies at 12-mo follow-up. Zullo et al reported an 89% success rate [21], and Rinne et al reported a 93% cure rate [22]. The most common complications, de novo urgency, pain in the thigh, and urinary retention, were also similar to those reported elsewhere [2,3,6].

The 93% success rate attained here with Mini-Arc was identical to that of TVT-O. It should also be stressed that our success rate is in line with those previously reported also after 12-mo follow-up. In a prospective case series, Moore et al reported a cure rate of 91% based on a negative cough stress test ($n = 61$) [8]. DeBodinance and Delporte found a success rate of 90% ($n = 68$) [23]. In the two most recent and largest case series, Kennelly et al ($n = 157$) reported a negative cough test in 91% of the patients [13], and Oliveira et al ($n = 105$) accounted for a success rate of 91% [24]. Comparisons between conventional MUS and Mini-Arc are still sparse. De Ridder and Berkers compared Mini-Arc ($n = 75$) to Monarc (American Medical Systems, Minnetonka, MN, USA) ($n = 56$) in a retrospective study [25]. The objective cure rate of 85% at 12 mo was similar with both MUS. These data diverge, however, from those of Basu and Duckett, who randomly assigned 61 patients either to Mini-Arc or to a RP sling (Advantage TVT; Boston Scientific, Natick, MA, USA) [26]. At 6 mo, a failure rate of 41% was found in the Mini-Arc group as opposed to only 3% in the RP sling arm [26]. The limited previous experience of the authors with the TO route may explain such difference, already detected at the first follow-up visit at 6 wk [26]. Thus it may be concluded that the harpoon-like anchoring

extremities, once inserted in the internal obturator muscle, provide a grip equivalent to TVT-O. In the latter, fixation is obtained by the passage through the internal obturator muscle, obturator membrane, external obturator, and thigh muscles.

In contrast to Mini-Arc, TVT-Secur offered a success rate of 80%, lower than that observed with the other two MUS. Failures with TVT-Secur amounted to 20%, that is, almost three times higher than in the other groups. In agreement, TVT-Secur only improved (at least 15 points) in >80% of patients in three of the nine KHQ domains. In available case series, TVT-Secur cure rates are highly variable. Our own initial TVT-Secur experience with 105 patients showed success and failure rates at 15 mo similar to those found here [7]. Meschia et al reported similar success rates on 95 patients at 15 mo [27]. Cornu et al, with a mean follow-up of 30 mo ($n = 45$), reported a success rate of 58% [9]. In contrast, in the sole comparative study published up to date, TVT-Secur and TVT-O provided similar outcomes with a cure rate of 83% for TVT-Secur and 81% for TVT-O [28]. The fact that TVT-Secur has been associated with lower success rates deserves some consideration. TVT-Secur has a long learning curve [20]. Even among experienced surgeons, consistent positioning of the TVT-Secur tip may be difficult. Correct placement in some studies was <50% [29]. Moreover, mesh detachment from the introducer blades requires a twisting movement that may enlarge the internal obturator muscle area where the TVT-Secur tip was inserted, compromising mesh adhesion.

The study confirmed the low morbidity of SIS. Pain in the first 24 h was very low in the Mini-Arc group, whereas it was rated four times higher in the TVT-O arm. TVT-O was associated with two cases of urinary retention requiring sling transection. On the contrary, only one case of transient urinary retention occurred in the two SIS patient groups. Two patients in the TVT-O group reported prolonged referred thigh pain. This complication was not observed in the TVT-Secur arm. However, SIS may not be totally exempt from this complication because one patient in the Mini-Arc group complained of thigh pain for 6 mo. As in TVT-O, inadvertent violation of the obturator membrane, nerve lesioning, or haematoma formation could have been the cause of this problem [6]. However, it must represent a rare event because prolonged pain complaints had never been reported with Mini-Arc before [8,13,23–25].

This study has the inherent limitations of phase 2 trials, mainly a small number of patients and a relatively short follow-up time of 12 mo. Although this follow-up time is commonly used in studies investigating the outcome of conventional MUS [2,3], it might be desirable to evaluate SIS at considerably longer follow-up times. Nevertheless, this study clearly indicates the need to conduct well-powered multicentre randomised clinical trials comparing SIS with standard techniques. According to the present results, Mini-Arc should be chosen to be further compared against TO slings. Such comparative studies should probably be compulsory before the introduction of new devices for SUI treatment. A uniform report of outcomes, stating cure and improvement rates, would facilitate comparisons.

5. Conclusions

SIS may offer success rates for SUI equivalent to conventional TO MUS with less morbidity. These exploratory findings should be further investigated in randomised phase 3 studies.

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Study concept and design: Oliveira, C. Silva, Dinis, Cruz.

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Analysis and interpretation of data: Oliveira, Botelho, Dinis, Cruz.

Drafting of the manuscript: Oliveira, Dinis, Cruz.

Critical revision of the manuscript for important intellectual content: Oliveira, Dinis, Cruz.

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