

Mini-sling procedures in surgery of stress urinary incontinence: a literature review

AHMET AKIN SIVASLIOGLU, DILEK UYSAL

Department of Obstetrics and Gynecology, Katip Çelebi University, Atatürk Training and Research Hospital, Izmir - Turkey

Abstract: Sling surgery has been the gold standard treatment of stress urinary incontinence. Nevertheless, the 'zero tolerance' concept has led to searching for a new technique which would be minimally invasive as well as complication free. Hence, third generation slings, namely minislings have been developed. A general overview has been carried out to the minislings in the light of current literature.

Key words: Minislings, single incision minislings.

INTRODUCTION

Stress urinary incontinence (SUI) is a common condition that may affect up to 20% of women.¹ Over the past several decades, various surgical procedures and techniques have been available for the treatment of SUI. Sling therapy is the enhanced surgical support of the urethra, routinely performed by vaginal or abdominal (open or laparoscopic) routes, or, most recently, by access to the obturator foramen. Kelly's 1913 anterior vaginal repair is probably the oldest described procedure for incontinence. The Marshall-Marchetti-Krantz urethropexy (1949) sought to elevate the proximal urethra directly in the same way that the Burch colposuspension (1961) did indirectly by using the vagina as a hammock.

Since Ulmsten and Petros first described in 1996 the TVT procedure, use of tension-free suburethral tapes has become the gold standard for the treatment of SUI in women.² This treatment was based on the Integral Theory,³ which suggests that continence depends on urethral closure related to interplay between the pubourethral ligaments, a suburethral vaginal hammock and the pubococcygeous muscles. Its advantages include short operative time, quick postoperative recovery, low complication rate, and good effectiveness.⁴ Although cure rates were excellent with the retropubic approach, there were also complications associated with the blind-needle passage through the retropubic space including bladder perforation and nerve injury as well as major vascular and bowel injuries.^{5,6} In 2001, Delorme described the transobturator approach that offers similar efficacy with decreasing risk of complications.⁷ However, TOT has been associated with a small but defined risk of prolonged leg pain, owing to passage of the transvaginal mesh through the obturator foramen.^{8,9} Recently, a third generation of suburethral slings has been developed using a single vaginal incision and shorter polypropylene tape (8-14 cm: mini-sling).¹⁰ They were designed to support the mid-urethra in the same fashion as has been accomplished with the TVT and TOT but without the passage of a trocar or mesh through the retropubic space or obturator foramen. The goal of the single-incision midurethral sling (SIMS) is to provide comparable cured-dry rates, with fewer side effects and adverse events. They require local analgesia and a single vaginal incision.

Because of the relatively new market introductions of the mini-slings, there are limited published data available for either of these new products. The efficacy of single incision mini slings remains unknown as the current literature regarding minislings lacks long-term results. The present paper entails the current up-to-date literature on 'mini-sling' and aims to assess the technique, safety, and efficacy of mini-slings in the surgical treatment of the female SUI.

METHODS

The Pubmed and Medline online databases were searched for the term "mini-sling" and "single-incision sling". Only papers written in English were analyzed.

DISCUSSION

Recently, many different procedures have been introduced to the market. Some of these minislings (for example, the TVT Secur®) were withdrawn when low efficacy and high complication rates based on well-designed randomized controlled trials were published.¹¹ A number of single incision mini-slings (SIMS) are currently used in clinical practice; MiniArc® (American Medical Systems, Minnetonka, MN, USA), Ajust® (C.R. Bard, Murray Hill, NJ, USA), Ophira® (R. Promedon, Cordoba, Argentina), TFS® (Adelaide, Australia).

Kenelly et al present a multicenter prospective study evaluating MiniArc® placement in the treatment of female SUI.¹² The study population comprised 188 women, and 157 patients had been followed up for 1 year. The primary outcomes of the study was sling efficacy. Secondary outcomes were sling safety and procedure variables. The reported 12-month success rates ranged from 85-91%, depending on the outcome measure which were evaluated. A low rates of perioperative and postoperative adverse events were seen.

In 2011, Pickens reported on 108 patients undergoing the MiniArc® with a 94% cure rate at 12 months follow up.¹³ Both studies also showed statistically significant improvements in the UDI-6 and IIQ-7 scores. Prospective randomized studies with long-term follow up are needed to evaluate whether the MiniArc with benefits of single incision technique can still guarantee satisfying continence results after 5-10 years.

The Tissue Fixation System® (TFS) consists of an adjustable polypropylene mesh that uses two small plastic anchors to fix it into the inferior surface of the pelvic muscles and tissues below the retropubic space, in an hammock-like tension-free position. The initial dissection is similar to other midurethral tapes, and para-urethral dissection carried a few millimeters beyond the urogenital diaphragm, so the applicator is placed in this space and triggered to release the TFS® anchor. Then the tape is pulled with a short, sharp movement to set the anchor prongs into the tissues. Adequate fixation was tested by pulling the free end of the tape. After performing this on both sides, the tape was tensioned until it is placed firmly against but not indenting the urethra and the free end is cut. This single-incision sling was developed by Petros and their report at medium follow-up (3 years) provides data about 36 patients with stress incontinence. Cure rates on 31 eligible patients were 80%. Complication rates are not described.¹⁴

Author	Type of studies	Sling	n. pts	Evaluation Criteria	F/U months	Outcomes
Kennelly et al. ¹²	multicenter, prospective, single arm institutional review	Mini-Arc®	157	CST, PWT, IIQ-7, UDI-6 scores	12	Primary study outcomes included sling efficacy Secondary outcomes were sling safety and procedure variables.
Pickens et al. ¹³	Prospective, observational study	Mini-Arc®	108	UDI-6,IIQ-7 scores	12	Treatment success and adverse events
Petros et al. ¹⁴	Prospective	TFS®	36	The patients were contacted by telephone independently by a nurse	36	Symptomatic cure was reported
Sekiguchi et al. ¹⁵	Prospective	TFS®	45	urodynamic SUI	16	de novo urgency or urge urinary incontinence
De Ridder et al. ¹⁶	retrospective, dual-center, cohort study	Mini-Arc® Monarc®	75 56	CST, daily pad use, IIQ-7,UDI-6, and a 0-5 VAS for QoL.	12 12	Primary studi outcomes included sling efficacy
Hinoulet et al. ¹¹	Randomized multi-centre study	TVT-Secur® TVT-O®	96 98	UDI-6, and a 0-5 VAS for QoL	12 12	Objective cure at 12 mo, patient-reported cure, operation time, postoperative hospital stay, day 1 VAS pain score, QoL, and safety
Abdel Fattah et al. ¹⁷	Meta-Analysis	TVT-Secur®, 9 MiniArc® and studies Ophira® to standard mid-urethral sling		Meta-analysis of all randomised controlled trials (RCTs) comparing SIMS versus SMUS was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement	6-12	Primary outcomes were patient-reported and objective cure rates. Secondary outcomes included perioperative complications, quality of life (QoL) changes, and costs to health services.
Cornu et al. ¹⁸	Prospective	TVT-Secur®	45	PGI-I, PWT	30	objective cure, subjective cure and failure rates
Sivashoglu et al. ¹⁹	prospective randomized controlled trial	TFS® I-Stop®	80	urodynamically proven stress urinary incontinence	64	objective cure, subjective cure and failure rates
Alvarez-Bandres et al. ²⁰	retrospective, descriptive analysis	TVT-Secur® Mini-Arc®	50 105	clinical history, physical examination and two questionnaires of QoL	6	intraoperative, early (within the first month after surgery) and late complications (after a month)

Another report on TFS®, from Tokyo, describes a prospective study on 44 women with urodynamic SUI. This cohort had an high percentage of women with poor sphincteric function (34,1%). With a mean follow-up of 16,1 months, success was noted in 91% of patients, with 4 cases considered treatment failures (9%). Pain complaint at discharge was minimal. No significant blood loss was described. Five patients (11%) had transient voiding difficulties that resolved after 48 hours of indwelling catheterization. Nine patients (20%) had occasional urge incontinence in the post-operative follow-up, that resolved spontaneously or with pelvic floor exercises.¹⁵

Comparisons of single-incision mini-slings with standard mid-urethral slings

In a retrospective, dual-center, cohort study on the single incision MiniArc® sling and the transobturator Monarc® sling in the treatment of stress urinary incontinence one hundred thirty-one (MiniArc® n=75, Monarc® n=56) consecutive patients were evaluated. Evaluation was performed by cough stress test (CST), daily pad use, IIQ-7, UDI-6, and a 0–5 visual analog scale for quality of life. The results of the study were compiled after a 1-year follow-up. The authors of the article conclude that the MiniArc® and Monarc®

procedures are equally effective in the treatment of stress incontinence in female patients with in 1 year following treatment. A possible advantage of the MiniArc® sling which is confirmed in these study is the significant reduction of duration of the procedure (11 vs 19 min; $p < 0.0001$). Another possible advantage of a minimal invasive approach could be a reduced risk of postoperative groin pain due to transobturator passage.¹⁶

In a recent European study, the TVT Secur® was compared to the TVT-O® in a multicenter, prospective, randomized control trial.¹¹ One-year follow-up for 75 TVT Secur® and 85 TVT-O® patients showed objective post-op SUI of 16.4% with TVT Secur® versus 2.4% with TVT-O® ($P = 0.002$). Subjectively, 24% of TVT Secur® patients reported SUI versus 8.3% with a TVT-O® ($P = 0.008$). Up to the 2-week post-op period, significantly less pain was noted with the TVT Secur. Although this evolution has led to a less invasive procedure with decreased post-op pain and reduced recovery time, the efficacy could be the endpoint. Additional medium- to long-term data are needed to answer this question.

Recently, Abdel-Fattah et al.¹⁷ published a meta-analysis whose outcome was the clinical cure/ improvement of incontinence for single-incision minislings versus standard mid-urethral slings at 6- to 12-month follow-up. Moreover,

the authors evaluated the most important surgical outcomes, including perioperative and postoperative complications, impact on women's quality of life, sexual function and cost to health services. Nine studies were included comparing TVT-Secur®, MiniArc® and Ophira® to standard mid-urethral slings. On the whole, the data of the meta-analysis show that single-incision mini-slings were associated with lower patient-reported (OR: 0.83; CI: 0.70–0.99, $P = 0.04$) and objective (OR: 0.85; CI: 0.74–0.97, $P = 0.01$) cure rates on short-term follow-up when compared with standard mid-urethral slings and with significantly higher reoperation rates for SUI (RR: 6.72; 95% CI, 2.39–18.89; $P = 0.0003$). Abdel-fattah et al. demonstrated that repeat continence surgery and de novo urgency incontinence were significantly higher in the patients treated with mini-slings.

Data with longer follow-up are available from prospective case series. Cornu et al.¹⁸ demonstrated recurrence of SUI in about 40% of the patients treated with TVT-Secur® at a mean follow-up of 30 months. According to the National Institute for Health and Clinical Excellence in the UK, mini-slings should only be used in the context of research studies or through submission of data to a national register.

A prospective randomized controlled trial of the TOT and TFS in patients with stress urinary incontinence published in 2012.¹⁵ Contrary to reports in the literature of poor results with mini-slings, in this research the tissue fixation system mini-sling demonstrated a higher cure rate and lower complication rate than the transobturator tape. Total follow-up was 64 months. The objective cure, subjective cure and failure rates in the tissue fixation system group were 83% (30 cases), 6% (2 cases) and 11% (4 cases), respectively. The objective cure, subjective cure and failure rates in the transobturator tape group were 75% (27 cases), 3% (1 case) and 22% (8 cases), respectively. The difference in objective cure rates was statistically significant in favor of the tissue fixation system ($p = 0.029$). The difference in decreased cure rates between 5 and 3 years was 7% (90% to 83%) for the tissue fixation system vs 9% (84% to 75%) for the transobturator tape. The relative decrease in cure rates between the 2 groups was not statistically significant ($p = 0.16$).

Complications of female urinary incontinence surgery with mini-sling system

Alvarez-Bandres et al reported in a descriptive analysis of the complications of the surgery in a group of 155 women with urinary incontinence whom have had minisling surgery (50 TVTSecur® and 105 MiniArc®) from October 2006 to November 2008.²⁰ The complications were grouped into three categories: intraoperative, early (within the first month after surgery) and late complications (after a month). The complication rate was reported of 20% (22% TVT-Secur®, 17% MiniArc®). They reported one intraoperative complication corresponding to a bladder perforation (0.64%), managed conservatively with catheterization. All early complications were reported in the MiniArc® group: one obturator fossa hematoma (0.64%) spontaneously resolved, groin pain in 4 patients (2.5%) successfully treated with NSAIDs and one urethral obstruction (0.64%) that required mesh cutting. Late complications included: 8 vaginal erosions (5%), 4 required tape excision and vaginal wall closure; 2 were treated with vaginal estrogens, and the other 2 were asymptomatic so they did nothing. Six patients (3.8%) showed urethral obstruction: they performed mesh cutting in 5, whereas one patient improved with intermittent catheterization. Urge symptoms were reported in 10 patients (6.45%) and successfully managed with anticholinergic agents. Two patients suffered from recurrent infec-

tions (1.3%) confirmed by antibiogram, treating isolated episodes.

Urinary incontinence surgery using suburethral minislings is not free of complications (20%).²¹ However, such complications may be conservatively managed and are less severe than those caused by previous procedures, and this new generation of slings is therefore an effective and safe technique for correcting female stress urinary incontinence.

CONCLUSION

Single-incision slings appear to be a valid option to offer to patients with SUI. The theoretical advantage of the SIMS is the avoidance of the retropubic space and obturator fossa, and the lack of necessary thigh or suprapubic incisions. Most of the studies investigating minislings show that at best, they are not inferior when compared with the conventional TVT.

In addition, their lower complication rates as compared to our TVT and TOT series and the possibility of performing outpatient surgery under local anesthesia make this new generation of tapes a valid tool for SUI treatment. In conclusion, there is an extreme need for a high-quality randomized clinical trial.

The use of SIHS in the treatment of SUI with demonstrable urethral hypermobility and pure urodynamic SUI is established. Moreover, the indications for single incision minisling have been expanded to include other special situations such as mixed urinary incontinence, low leak-point pressures, minimal urethral hypermobility, recurrent SUI, concomitant prolapse surgery, obesity and advanced age.

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Correspondence to:

Ahmet Akın Sivaslioglu, MD
Associate Professor
akinsivasliglu@gmail.com