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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

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Abstract

Context: An updated systematic review and meta-analysis of randomised controlled trials (RCTs) comparing single-incision mini-slings (SIMS) versus standard midurethral slings (SMUS) in the surgical management of female stress urinary incontinence (SUI).
Objective: To evaluate the clinical efficacy, safety, and cost effectiveness of SIMS compared with SMUS in the treatment of female SUI.
Evidence acquisition: A literature search was performed for all RCTs and quasi-RCTs comparing SIMS with either transobturator tension-free vaginal tape (TO-TVT) or retropubic tension-free vaginal tape (RP-TVT). The literature search had no language restrictions and was last updated on May 2, 2013. The primary outcomes were patient-reported and objective cure rates at 12 to 36 mo follow-up. Secondary outcomes included operative data; peri- and postoperative complications, and repeat continence surgery. Data were analysed using RevMan software. Meta-analyses of TVT-Secur versus SMUS are presented separately as the former was recently withdrawn from clinical practice.
Evidence synthesis: A total of 26 RCTs (n = 3308 women) were included. After excluding RCTs evaluating TVT-Secur, there was no evidence of significant differences between SIMS and SMUS in patient-reported cure rates (risk ratio [RR]: 0.94; 95% confidence interval [CI], 0.88–1.00) and objective cure rates (RR: 0.98; 95% CI, 0.94–1.01) at a mean follow-up of 18.6 mo. These results pertained on comparing SIMS versus TO-TVT and RP-TVT separately. SIMS had significantly lower postoperative pain scores (weighted means difference [WMD]: −2.94; 95% CI, −4.16 to −1.73) and earlier return to normal activities and to work (WMD: −5.08; 95% CI, −9.59 to −0.56 and WMD: −7.20; 95% CI, −12.43 to −1.98, respectively). SIMS had a nonsignificant trend towards higher rates of repeat continence surgery (RR: 2.00; 95% CI, 0.93–4.31).
Conclusions: This meta-analysis shows that, excluding TVT-Secur, there was no evidence of significant differences in patient-reported and objective cure between currently used SIMS and SMUS at midterm follow-up while associated with more favourable recovery time. Results should be interpreted with caution due to the heterogeneity of the trials included.

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1. Introduction

Since our last systematic review and meta-analysis in 2011 [1], Professor Peter Petros updated us that he first introduced the first single-incision mini-sling (SIMS: Tissue Fixation System [TFS]) in September 2003 (pers. comm., P. Petros, Perth, Australia). Since then different types of devices have been designed and used in clinical practice. SIMS have a number of potential advantages that attracted the attention of many surgeons worldwide: (1) shorter length polypropylene tape and therefore less mesh to be inserted into the human body; (2) insertion through a single vaginal incision to create a similar suburethral hammock to standard midurethral slings (SMUS) while avoiding both retropubic and groin trajectories (in retropubic tension-free vaginal tape [RP-TVT] and transobturator tension-free vaginal tapes (TO-TVT), respectively); and (3) the ability to perform the procedure under pure local anaesthesia (LA) and therefore a shorter recovery and earlier return to work/normal activities [2]. These potential advantages, if proven, may be reflected in improving women's quality of life (QoL) and potential cost savings to health providers and society. However, the advantages just cited would be only relevant if SIMS are proven to have a similar or at least noninferior clinical efficacy compared with SMUS.

In an earlier systematic review and meta-analysis in 2011 [1], we showed that SIMS did not, at least at that stage, live up to their potential, and we recommended they only be used within the context of research. Over the last 2 yr, >20 randomised controlled trials (RCTs) comparing SIMS with SMUS were further reported, and additionally a number of RCTs published their longer-term follow-up. A significant event occurred when an extensively researched SIMS (TVT-Secur) was withdrawn from clinical practice by the manufacturer [3], having been shown to have poor clinical outcomes at the midterm follow-up [4–7]. This situation emphasises the importance of mid- to long-term follow-up of new technologies before they are adopted into clinical practice.

Following the Cochrane recommendation, we present this updated systematic review >2 yr since our last review. In this update we look at RCTs comparing SIMS with SMUS with a 12 to 36 mo follow-up. We aim to present clinically relevant results with the meta-analyses of TVT-Secur versus SMUS presented separately. In-addition, we present a subgroup analysis of the relatively new, adjustable and robustly anchored SIMS versus SMUS.

2. Evidence acquisition

An updated meta-analysis was performed per the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement guidance [8]. All RCTs and quasi-RCTS comparing one type of SIMS versus a SMUS in the surgical treatment of women with stress urinary incontinence (SUI), with a minimum follow-up of 12 mo, were eligible for inclusion. These included women with urodynamic or clinical diagnosis of SUI with or without symptoms of overactive bladder and with or without concomitant prolapse surgery. SMUS in this review included RP-TVT and TO-TVT (inside-out and outside-in); SIMS were defined as a midurethral sling performed through a single vaginal incision with no entry or exit skin incisions.

The literature search was last updated on May 2, 2013, using the Medline and Embase databases. Trials registered in the ClinicalTrials.gov, Australian or Netherlands clinical trials registry, World Health Organisation database, and Cochrane database of systematic reviews were searched. A manual search of the abstract databases of international conferences was performed including the International Continence Society, European Association of Urology, and the International Urogynaecology Association conferences. In addition, a hand search of bibliographies of the primary articles and relevant reviews was performed. No language restriction or publication types were applied, and search criteria were limited to humans, adult females, and entry date from 1996. The search was performed independently by two authors (A.M. and C.P.L.) and included Medical Subject Heading subheadings, word variations, and free text: *TVT Secur™, Mini tape, Ophira®, Contasure, Needleless, Solyx™, Mini arc™, Ajust®, Mini Sling, Zippere, Epilog, Altis®*, and *Tissue fixation system*. Figure 1 outlines the steps for the Ovid Medline and Embase database search. All identified studies were screened for eligibility, in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* [9] and independently assessed by two authors (A.M. and C.P.L.). Table 1 shows a list of the included RCTs.

Similarly, data extraction was independently performed by three authors (A.M., C.P.L., and L.H.) followed by cross-checking and clarification of any differences by the senior author (M.A.F.). Non-English articles were translated. All authors of included studies were contacted for missing data and data on longer follow-up durations if applicable. The quality of the retrieved RCTs was assessed using the Jadad score [10]. Risk of bias across studies was assessed according to the *Cochrane Handbook for Systematic Reviews* [9] and generated through RevMan software. Table 2 shows the list of excluded studies (n = 32) and the reasons for exclusion.

The primary outcomes assessed were the subjective (patient-reported) and objective cure/improvement rates. Secondary outcomes included operative data (duration of operation, length of inpatient stay, time to return to normal activity); perioperative complications (eg, organ injuries); postoperative complications (voiding dysfunction/intermittent self-catheterisation, postoperative pain scores, de novo detrusor overactivity, de novo urgency, tape erosion); repeat surgery for SUI; impact on women's QoL, sexual function, and costs to health services. Analysis was performed for comparing the primary outcomes in individual types of SIMS versus different types of SMUS, with a subgroup meta-analysis of the relatively new, robustly anchored and adjustable SIMS (Ajust and TFS) versus SMUS. Meta-analyses of TVT-Secur versus SMUS is presented separately being the least clinically relevant.

Data were analysed using RevMan v.5.2.20 (Cochrane Collaboration, Oxford, UK). Quantitative synthesis was done when more than one eligible study was identified. Where appropriate, a combined estimate of treatment effect across