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#### **CLINICAL ARTICLE**

## Outcomes of minimally invasive suburethral slings with and without concomitant pelvic organ prolapse surgery



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#### ABSTRACT

Objective: To assess subjective outcomes among patients who underwent minimally invasive suburethral sling (MIS) surgery for stress urinary incontinence with or without concurrent pelvic organ prolapse (POP) surgery. Methods: In a prospective study between 2002 and 2010, patients who underwent MIS surgery with or without concomitant POP surgery at Croydon University Hospital, UK, completed the ICIQ-FLUTS and ICIQ-LUTSqol questionnaires on lower urinary tract symptoms and quality of life before and 12 months after surgery. Results: Overall, 203 patients underwent MIS surgery alone and 91 underwent concomitant POP and MIS surgery. At 12 months, the response rate was 64.3%. Before surgery, there was no significant difference between the groups in any domain of ICIQ-FLUTS and ICIQ-LUTSqol, except for in the incontinence domain of ICIQ-FLUTS, for which scores were significantly worse in the MIS group (P = 0.018). All domains of ICIQ-FLUTS and ICIQ-LUTSqol had improved after 1 year in both groups, except for the voiding domain of the ICIQ-FLUTS in the MIS group (P = 0.054). After surgery, there was no difference between the groups in any domain (P > 0.05). Complication rates were low in both groups. Conclusion: MIS with concomitant POP surgery is as safe and effective as MIS surgery alone.

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#### 1. Introduction

Pelvic organ prolapse (POP) affects nearly 50% of parous women [1] and stress urinary incontinence (SUI) can coexist with POP in 15%–80% of patients [2]. Incontinence surgery is performed at the same time as POP surgery in 11%–41% of cases [3]. There is limited evidence on whether women with SUI and POP should be offered concomitant surgeries [4], although various observational studies have shown that concomitant surgery for POP and SUI is safe [5–8]. Performing incontinence surgery at the time of POP surgery has the benefit of preventing an additional surgical procedure for SUI at a later date, and patients are less likely to be diagnosed with a new prolapse [9]. However, concomitant incontinence surgery can lead to overtreatment [10], and may be associated with postoperative urinary outlet obstruction requiring further intervention (because patients are more likely to undergo postoperative urodynamic studies [9]) and increased in-hospital complications [3].

According to the Fifth International Consultation on Incontinence (ICI), there is only level 2/3 evidence supporting concomitant surgery for patients with overt SUI and POP [11], and cohort studies using the recommended standardized outcome assessment tools are lacking. The ICI recommends using grade A (i.e. valid, reliable, and responsive

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to change after standard psychometric testing) patient self-completed questionnaires or patient-reported outcomes. These assessment tools represent the most important clinical review of symptom impact and treatment benefit from a patient perspective. These tools also provide a standardized method of collecting data or an objective assessment of subjective phenomena from patients relating to incontinence, other lower urinary tract symptoms, and bowel problems.

Among women affected by urinary incontinence, the ICI Incontinence Modular Questionnaire—Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) is the recommended tool to assess the core symptoms and impact on health-related quality of life, including impact on sexual health. In addition, the ICI recommends the use of add-in modules such as the ICI Modular Questionnaire—Lower Urinary Tract Symptoms quality of life (ICIQ-LUTSqol) for an in-depth evaluation of lower urinary tract symptoms [12].

The aim of the present study was to compare subjective changes in urinary symptoms and quality of life 1 year after surgery among patients who underwent minimally invasive suburethral sling (MIS) surgery for SUI with or without concomitant anterior colporrhaphy for POP via the ICI-recommended questionnaires.

#### 2. Materials and methods

The present prospective study was conducted in the urogynecology department of Croydon University Hospital, Croydon, UK, among patients who underwent MIS surgery with or without concomitant

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**Table 1**Procedures performed for prolapse in addition to MIS surgery.

Type of surgery	Number of women	
MIS	203	
AR + MIS	62	
AR + PR + MIS	8	
AR + PR + VH + MIS	7	
AR + VH + MIS	14	
Total	294	

Abbreviations: MIS, minimally invasive suburethral sling; AR, anterior repair; PR, posterior repair; VH, vaginal hysterectomy.

anterior colporrhaphy (irrespective of any other prolapse procedures) between November 1, 2002, and June 30, 2010. Ethical approval was not required, because it is routine urogynecology practice to audit outcomes by asking patients to complete the validated questionnaires before and after surgery. Each patient completed a consent form stating that they were willing for their data to be used for research and audit purposes.

The study included all patients with urodynamically proven SUI and POP. Patients who underwent POP surgery without an anterior colporrhaphy and/or were unable to complete the validated questionnaires were excluded.

POP stage was reported according to the Baden-Walker system. This system was used owing to familiarity and its simplicity of use in clinical practice. The alternative POP quantification system is difficult to learn and time-consuming in clinical practice. The Baden-Walker system has good inter-examiner reliability, similar to that of the POP quantification system [13].

Urodynamic evaluation included provocative twin-channel subtracted cystometry at a filling rate of 70 mL/min and pressure-flow studies. In the presence of prolapse, the stress test was performed after reduction of the urogenital prolapse using a ring pessary. A positive stress test was defined as the involuntary loss of urine during increased intra-abdominal pressure without a change in the detrusor pressure. Patients with urodynamic SUI were scheduled for MIS surgery alone, whereas those with urodynamic SUI and POP were scheduled for MIS with concomitant anterior colporrhaphy and additional compartment surgery if required.

All patients with symptomatic SUI had completed at least 3 months of pelvic floor exercises prior to surgery. Preoperatively, they completed validated urinary incontinence questionnaires on lower urinary tract symptoms (ICIQ-FLUTS) and on quality of life (ICIQ-LUTSqol).

All procedures were recorded in the database of the British Society of Urogynaecology. Among patients who underwent MIS surgery alone, tape was inserted using the standard technique for retropubic tension-free vaginal tape (Gynecare TVT; Ethicon, West Somerville, NJ, USA) [14] or transobturator tape (Monarc; AMS, West Minnetonka, MN, USA) [15], and a diagnostic cystoscopy was performed to identify bladder or urethral perforation after the procedure. All patients were discharged on the same day. Before discharge, a voiding protocol was followed to ensure that no woman had a residual bladder volume of more than 200 mL. If this was not achieved, the patient was allowed

**Table 2**Demographics of the study groups.<sup>a</sup>

	MIS surgery ( $n = 203$ )	MIS + POP  surgery  (n = 91)	P value <sup>b</sup>
Age, y	51.7 ± 10.7	$52.8 \pm 11.7$ $2.7 \pm 1.4$ $27.1 \pm 3.9$	0.971
Parity	2.3 ± 1.2		0.979
BMI	28.2 ± 5.3		0.040

Abbreviations: MIS, minimally invasive suburethral sling; POP, pelvic organ prolapse; BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters).

**Table 3**Grade of prolapse among the study groups.<sup>a</sup>

Type of prolapse	Grade		P value <sup>b</sup>
	MIS surgery (n = 203)	$\begin{aligned} & \text{MIS} + \text{POP surgery} \\ & (n = 91) \end{aligned}$	
Cystocele Cervical descent Rectocele	1 (0-2) 0 (0-1) 0 (0-1)	2 (0-3) 0 (0-3) 1 (0-3)	<0.001 <0.001 <0.001

Abbreviations: MIS, minimally invasive suburethral sling surgery; POP, pelvic organ prolapse.

home with a urethral catheter and asked to return for a trial without the catheter after 2 days.

For patients in the concomitant surgery group, tape was inserted by a separate incision prior to POP surgery. Anterior colporrhaphy was performed by plication of the pubocervical fascia in the midline, and the vaginal skin was sutured with a delayed absorbable suture. A urethral catheter was inserted for continuous drainage in the concomitant group until the next morning, after which the voiding protocol was followed.

Surgical procedures were performed by one of two urogynecologists (R.T. and A.H.S) or by a trainee under their supervision. Patients were followed up for 6–8 weeks postoperatively, and the validated ICIQ-FLUTS and ICIQ-LUTSqol urinary incontinence questionnaires were sent to them by post 1 year after their surgery.

STROBE guidelines were followed to describe the outcomes of the study [16]. The primary outcome measure was rate of subjective cure for SUI 1 year after surgery. Cure was defined as a "no" response to the ICIQ-FLUTS question "Does urine leak when you are physically active, exert yourself, cough or sneeze?" The secondary outcomes were quality of life and complications such as perforation, voiding dysfunction, tape erosion, and retropubic hematoma.

The data were analyzed via SPSS version 17 (SPSS Inc, Chicago, IL, USA). An independent t test was used to compare baseline demographics between the two groups. Wilcoxon signed rank test was used to assess changes in the presurgery and postsurgery domain scores within each of the two groups. The Mann–Whitney U test was used to compare changes in the domain scores between the two groups before and after surgery. P < 0.05 was considered significant.

#### 3. Results

A total of 294 consecutive patients were enrolled in the study: 203 underwent MIS surgery alone, and 91 underwent MIS coupled with anterior colporrhaphy and/or other compartment POP surgery (Table 1). Overall, 189 (64.3%) patients responded to the postal questionnaire; 134 (66.0%) patients in the MIS group and 55 (60.4%) in the concomitant surgery group responded. The median duration of follow-up was 12 months (range, 12–36 months).

The patient characteristics of the two groups, including parity and body mass index (calculated as weight in kilograms divided by the square of height in meters) are shown in Table 2. The grade of prolapse was significantly higher among patients in the concomitant surgery group than in the MIS group (Table 3).

Prior to surgery, scores on the incontinence domain of the ICIQ-FLUTS questionnaire were significantly worse in the MIS group (summed scores: 151, MIS group; 127, concomitant group; P=0.018). There were no significant differences in the other domains of the ICIQ-FLUTS and ICIQ-LUTSqol questionnaires (Tables 4 and 5).

After surgery, there was no difference in any domain of the ICIQ-FLUTS and ICIQ-LUTSqol questionnaires between the two groups (Tables 4 and 5). Compared with presurgery scores, there was a significant improvement in all domains of the ICIQ-FLUTS in both groups

 $<sup>^{\</sup>mathrm{a}}$  Values are given as mean  $\pm$  SD, unless stated otherwise.

<sup>&</sup>lt;sup>b</sup> By independent *t* test.

<sup>&</sup>lt;sup>a</sup> Values are given as median (range) unless otherwise stated.

 $<sup>^{\</sup>text{b}}$  By  $\chi^2$  test.

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