

# Abstract 707: Single-incision mid-urethral sling under local anesthesia for SUI treatment: Prospective, single-center cohort study, 12 months follow-up.



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## Hypothesis / aims of study

Stress-related urine incontinence (SUI) in women is a serious health problem that impacts life quality. Surgery is a first-line recommended intervention for the treatment of moderate/severe SUI. This field of surgery is dominated by synthetic allografts, albeit in recent years, concerns about safety have surfaced. As early as 2006, single incision sub-urethral slings (SIS) were recommended as an alternative, minimally invasive therapy for SUI. The facts about the efficacy of the new generation SIS seem encouraging, notwithstanding the low success rates of the early SIS kits. (1) The study's objective is to describe the 12-month follow-up findings of a non-selected cohort of patients with moderate/severe urodynamic SUI or predominant SUI mixed urinary incontinence (MUI), who underwent SIS insertion under local anesthesia.

## Study design, materials and methods

All female patients who had received consecutive SIS treatment for moderate/severe SUI or predominant SUI MUI were included. The patients presented with SUI and they were initially examined in the outpatient department (history, POP-Q, cough stress test). Patients who had concomitant pelvic organ prolapse surgery or previous incontinence surgery were excluded.

Pe-operation evaluation includes:

- Urodynamic study
- Cough stress test (supine & standing position with 200-300ml bladder fill or at NDV)
- Introital ultrasonography for urethral mobility assess.
- Standard questionnaires (ICIQ-UI-SF, ICIQ FLUTS, ICIQ VS, FSFI)

All patients had SIS insertion under local anesthesia [40ml solution infusion mid- and para-urethrally: bupivacaine (10ml), lidocaine (12ml), Normal Saline (20ml)]. The duration of surgery, pain during surgery (visual analogue score 0-10), immediate post-operative problems, and overall satisfaction with surgery were all evaluated.

Post-operation evaluation includes (12-months):

- Cough stress test (supine & standing position with 200-300ml bladder fill)
- Erosion check
- POP-Q prolapse quantification
- Pelvic floor Ultrasound (urethral -sling mobility and position were included)
- Standard questionnaires: (PGI-I, PGI-S, ICIQ-UI-SF, ICIQ FLUTS, ICIQ VS, FSFI)

The success rate was defined as an objective cure: a negative cough stress test. Subjective cure was defined by PGI-I and ICIQ-UI-SF and ICIQ-FLUTS questionnaires.

Urethral and sling mobility was measured using a consistent and reproducible procedure reported by Schaer et al. (2) The statistical analysis was done utilizing EXCEL

Table 1

Baseline Characteristics, demographics & Urodynamics		
Baseline Characteristics	Statistics	
Total Number of patients, N	100	
Mean age, (SD) years	62,41 (11.39)	
BMI, (SD) kg/m <sup>2</sup>	29.19 (4.65)	
Parity, (SD) N	2.46 (0.86)	
Race/Ethnicity, n (%)	Caucasian, 100 %	
Menopause	76.00 %	
<b>Clinical Findings</b>	10.00 %	
Narrow introitus, (GH≤2)	10.00 %	
Mean ICIQ-VS score, (SD)	4.61(4.44)	
SUI severity, N - %	Total	100, 100%
	Moderate (1-2-3 CST test, leak at 2 <sup>nd</sup> -3 <sup>rd</sup> cough)	25, 25%
	Severe (1-2-3 CST test, leak at 1 <sup>st</sup> cough)	75, 75%
MUI, N - %	32, 32%	
Mean Stress test (SD), N <sup>o</sup> cough	1.23 (0.47)	
<b>Urodynamic results</b>		
Mean VLPP (SD)	68.6 (26.9)	
Mean MCC (SD), ml	414 (125)	
Mean F/F Qmax, (SD)	18.8 (10.0)	
Mean F/F Qave, (SD)	9.1 (5.3)	

SD=Standard Deviation; BMI=Body Mass Index; GH=Genital Hiatus; ICIQ=International Consultation Incontinence Questionnaire; SUI=Stress Urinary Incontinence; MUI=Mixed Urinary Incontinence; VLPP=Valsalva Leak Point Pressure; MCC=Maximum Cystometric Capacity; F/F=Free flow.

## Results and interpretation

A cohort of 100 adult Caucasian women with moderate/severe SUI underwent SIS for SUI and came back for a 12-month follow-up.

Pre-operatively, 75% of the patients had severe and 25% had moderate SUI (1 – 3 – 5 CST at NDV: 75 patients leaked at the 1st cough and 25 patients leaked at 2nd – 3rd cough) (3). Based on Urodynamics 32% presented mixed urinary incontinence and 15% showed detrusor overactivity. There were no patients who had abnormal post-void residual (PVR) volumes (Table 1). The average operative time was 30.85±8.15 min and there were no instances of complications. The average intraoperative pain score was 2.62±1.67 and 89.7% of women were discharged on the same day of surgical procedure. 99% of the participants would recommend the procedure to a friend. Upon discharge, all individuals exhibited a negative stress test result, indicating a PVR of less than 30ml.

At 12 months follow-up, the stress test was negative in 94% (94/100), 92% (92/100) had PGI-I score 1 and 2, and 85% (85/100) had PGI-S score 1. No instances of mesh erosion were identified (Table 2). Post-operative ICIQ-UI-SF score, ICIQ-FLUTS score, and urethral sonographic mobility were statistically significantly reduced (p<0.001). Eleven women had post-operative ICIQ-UI-SF score >6 (subjective moderate/severe incontinence). This group of patients consisted of older patients (64.6±12.3 vs 62.2±11.2 years, p<0.001) with increased BMI (32.7±7.2 vs 28.8±4.1, p<0.001), lower number of vaginal deliveries (0.1±0.3 vs 2.0±1.0, p<0.001), lower pre-operative VLPP (50.5±14.4 vs 70.4±27.2 mm H<sub>2</sub>O, p=0.053).

Table 2

Pre- vs Post-operative examination results				
Subjective cure		Pre-operative	12 months	p
PGI-S		N/A	1.16±0.45	-
PGI-I		N/A	1.24±0.64	-
ICIQ-SF	All	14.33±2.51	2.20±3.18	<0.001†
	Severe SUI	14.53±2.53	2.90±3.30	<0.001†
	Moderate SUI	13.72±2.57	2.50±3.50	<0.001†
ICIQ-FLUTS (Total)	All	19.04±6.40	6.70±5.67	<0.001†
	Severe SUI	19.40±6.18	6.76±5.73	<0.001†
	Moderate SUI	19.04±6.98	6.52±5.42	<0.001†
ICIQ-FLUTS (Filling)		7.89±6.08	3.42±3.18	<0.001†
ICIQ-FLUTS (Voiding)		1.88±1.86	1.45±1.79	0.0947
ICIQ-FLUTS (Incontinence)	All	11.69±3.19	2.41±3.44	<0.001†
	Severe SUI	11,89±3.29	2.53±3.60	<0.001†
	Moderate SUI	11.08±2.84	2,04±2.82	<0.001†
<b>Objective cure</b>				
Negative Stress test, N <sup>o</sup>	All	0/100, 0%	94/100 94%	-
	Severe SUI	0/75, 0%	69/75 92%	-
	Moderate SUI	0/25, 0%	25/25 100%	-
<b>Sonographic parameters</b>				
PFUS – Bladder neck mobility		1.50±0.68	1,00±0.47	0.017†
PFUS – Sling mobility		N/A	0.63±0.47	-
PFUS – Distance from urethra (cm)		N/A	0,39±0.09	-
PFUS – Distance from external orifice (cm)		N/A	1,60±0.21	-

†=statistically significant; PGI-S=Patient Global Impression-Symptoms, PGI-I=Patient Global Impression-Improvement; ICIQ=International Consultation Incontinence Questionnaire; SF=Short Form; FLUTS=Female Lower Urinary Tract Symptoms; PVR=Post-void residual; PFUS=Pelvic Floor Ultrasound

## Interpretation of results

SIS appears to be a valid alternative compared to trans-obturator and retropubic synthetic slings. In terms of objective outcome, the rates of negative CST is equal to other mid-urethral slings; in terms of subjective satisfaction, the responses to the questionnaires (PGI-I and ICIQ-UI-sf and ICIQ-FLUTS) indicate good results as well. This study includes women treated with SIS inserted under local anesthesia. The entire procedure appears to be well received by the patient, and their satisfaction rates are quite high. Using a local anesthetic is a great choice for mini-sling insertion. It enables patients to move around quickly and gives surgeons the flexibility to adjust the tape tension using a cough test in real-time. Theoretically, local anesthesia is considered to affect the tone of the urethral sphincter less compared to general or regional anesthesia, therefore the tensioning of the sling may be performed under minimal intervention and for this reason it may be more accurate.

## Conclusions

SIS insertion under local anesthesia can be a beneficial technique for treating SUI. It appears that the duration of operation and the hospital stay is brief and the success rates are satisfactory. The occurrence of complications during the operation is low, and there are minimal complications in the medium term.

## References

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