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Single incision mid-urethral slings: impact of obesity on outcomes

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ABSTRACT

Objectives: To assess the potential impact of obesity on the success rate of single incision slings (SIS).
Study design: This was a retrospective cohort study of women who underwent the SIS procedure for primary stress urinary incontinence. Women were divided into three different groups by body mass index (BMI) according to the WHO classification. The International Consultation on Incontinence-short form (ICIQ-SF), Women Irritative Prostate Symptoms Score (W-IPSS), Patient Global Impression of Severity (PGI-S) and Patient Global Impression of Improvement (PGI-I) questionnaires were used. Objective and subjective outcomes were the primary outcome measures of the study. SPSS software was used for data analysis.
Results: 206 patients who underwent the SIS procedure were reviewed. At 1 year follow-up there were 196 women available for the analysis: 69 were normal weight subjects, 91 overweight and 36 obese. Patients in all BMI groups reported a significant improvement in their condition. Nevertheless there was a trend towards lesser objective efficacy of SIS with increasing body weight, with a significant difference between obese women and normal subjects: 75% vs 91.3%, $p = 0.049$; OR 3.74 (95% CI 1.19–11.76). Analysis of the ICIQ-SF and PGI-I showed significant lower mean ± SD improvement in obese women when compared with their normal or overweight counterparts, together with a significantly lower number of obese patients reporting themselves as very much improved or much improved.
Conclusions: Single incision slings seem to be an effective treatment regardless of BMI, but obese women had nearly 4 times the odds of objective failure as compared to normal weight women.

1. Introduction

Obesity is an increasing health problem world-wide and several epidemiological studies have identified a positive association between obesity and an increased prevalence of stress urinary incontinence (SUI) [1,2]. Although weight loss may improve SUI in obese and overweight women, definitive treatment may be best obtained through surgical intervention [2]. There are conflicting reports regarding the impact of obesity on outcomes of anti-incontinence surgery, but most of the studies investigating the potential impact of obesity on mid-urethral slings (MUS) outcomes have not demonstrated a difference in outcome by BMI [3–7].

Single incision slings (SIS) have been recently introduced into clinical practice for the treatment of SUI in women. Different devices are available aiming to further reduce the invasiveness of the surgical procedures currently used for the treatment of SUI, avoiding the passage of the needle carriers through the retropubic or obturator regions, thus minimising the risk of intra-operative complications. Concerns regarding lower cure rates for currently available SIS have recently been raised, however, in a meta-analysis comparing SIS and standard mid-urethral slings [8]. The main reasons for failure were attributed to a lack of robustness of their anchoring mechanism to the obturator membrane/muscle, lack of post-insertion adjustability and in some studies, to their difficult insertion mechanism [9–11]. To date no data exist on the impact of other possible clinical and instrumental variables on outcomes of SIS.

The purpose of this study, therefore, was to assess the potential impact of obesity on the success rate of SIS and patient satisfaction one year following surgery.

2. Materials and methods

After obtaining institutional review board approval, we reviewed the records of women who had undergone two different SIS procedures – TVT-secur (Ethicon Inc., Sommerville, USA) and Ajust (C.R. Bard Inc., New Jersey, USA) – for primary urodynamic SUI between November 2006 and October 2009. Exclusion criteria

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for being treated with an SIS procedure were: previous anti-incontinence surgery, pelvic organ prolapse requiring treatment, any coexistent pelvic pathology, urethral hypomobility (Δ Q-tip ≤20°) and detrusor overactivity. Data were collected on patients from four different centres who had been previously involved in two prospective observational studies on SIS. Descriptions of the surgical devices and procedures have been previously reported [11,12].

All procedures were performed by trained surgeons and outcome data were collected by physicians not involved in the surgery. Preoperative evaluation included the following: a detailed urogynecologic history, a physical examination, a cotton swab test, a cough stress test in the supine and standing positions with a comfortably filled bladder (300 ml) and a multichannel urodynamic evaluation. The International Consultation on Incontinence-short form (ICIQ-SF), Women Irritative Prostate Symptoms Score (W-IPSS), Patient Global Impression of Severity (PGI-S) and Patient Global Impression of Improvement (PGI-I) questionnaires were used to evaluate the impact of incontinence and voiding dysfunction on quality of life (QoL) and to measure the patients' perception of incontinence severity and improvement. All the above questionnaires were validated in the Italian language [13–15].

The ICIQ-SF comprises three scored items: assessment of frequency (0–5), severity (0–6) and perceived impact of incontinence (0–10) and an unscored self-diagnostic item. The W-IPSS was developed to evaluate irritative (3 items) and obstructive (4 items) bladder symptoms: for each item the score ranges from 0 (never) to 5 (always). PGI-S and PGI-I are global indexes of severity and improvement that summarise the severity or improvement in single questions with four (0–3) and seven (1–7) response categories respectively.

The primary outcomes measures were assessed at one year and included: objective cure (negative cough stress test); patient-reported success (defined as "1 = very much improved or "2 = much improved" on the PGI-I); and patient perceived impact of incontinence (improvement in the ICIQ-SF score). Post-operative urodynamic tests were recommended only in those patients complaining of any voiding or storage symptoms.

Voiding difficulty and overactive bladder (OAB) symptoms were defined according to the recommendations of the International Continence Society report on voiding and post-micturition symptoms and bladder storage symptoms [16].

Women were divided into three different groups according to their BMI following the recommendations of the World Health Organisation [17]: normal weight (BMI <25 Kg/m^2), overweight (BMI 25–29.9 Kg/m^2) and obese (BMI ≥30 Kg/m^2)

The Statistical Package for Social Sciences (SPSS 14.0) was used for data analysis. Continuous data were reported as means ± standard deviation (SD) and analysed with Student's *t* test and one-way analysis of variance (ANOVA). Categoric relationships were analysed by the chi-squared test or Fisher's exact test as appropriate. Probability values of <0.05 were considered statistically significant.

Table 1
Population's demographics and characteristics.

Numbers	Whole sample 206	TVT-s 95	Ajust 111	*P*
Age, *y*, mean ± SD	56.5 ± 10	57 ± 10	56 ± 11	0.49
Parity, median (range)	2 (0–6)	2 (0–6)	2 (0–5)	1
BMI <25 kg/m^2, *n* (%)	73 (35%)	34 (36%)	40 (36%)	0.91
BMI ≥25–< 30 kg/m^2, *n* (%)	94 (46%)	42 (44%)	52 (47%)	0.81
BMI ≥30 kg/m^2, *n* (%)	39 (19%)	19 (20%)	19 (17%)	0.72
Patients with OAB Symptoms, *n* (%)	58 (28%)	28 (29%)	30 (27%)	0.81
ICI-Q SF, mean ± SD	15.1 ± 3.6	15.3 ± 3.8	14.9 ± 3.3	0.42
PGI-S, mean ± SD	2.2 ± 0.7	2.3 ± 0.6	2.1 ± 0.9	0.07
WIPSS, mean ± SD	9.5 ± 7.2	8.7 ± 6.6	10.3 ± 7.7	0.11

OAB, overactive bladder.

Table 2
Clinical characteristics by BMI.

	Normal *N* = 72	Overweight *N* = 95	Obese *N* = 39	*P*
Age, *y*, mean ± SD	55 ± 10	58 ± 11	57 ± 11	0.19
OAB symptoms, *n* (%)	20 (28%)	27 (28%)	16 (41%)	0.17
ICI-SF, mean ± SD	14.9 ± 3.6	15.2 ± 3.5	15.1 ± 3.9	0.87
PGI-S, mean ± SD	2.3 ± 0.7	2.2 ± 0.9	2.2 ± 0.7	0.69
WIPSS, mean ± SD	8.3 ± 6.8	9.2 ± 7.4	10 ± 8.1	0.48

OAB, overactive bladder.

A post hoc power analysis indicated that this study presents a power of >90% to detect an 15% difference in objective outcomes between obese and normal weight women.

3. Results

A total of 206 subjects had an SIS procedure during the study period, of whom 95 underwent the TVT-secur procedure and 111 the Ajust procedure. The demographic and clinical characteristics of the population are shown in Table 1. Data are presented for the whole group and separately by type of procedure. No differences were seen between groups either for demographics or for percentage of patients in each BMI category. The patients' clinical characteristics by BMI are shown in Table 2.

At one year follow-up there were 196 (91 and 105 respectively) women available for analysis: 69 were normal weight subjects, 91 overweight and 36 obese. Overall the objective cure rate for the whole sample was 88%, with no differences between procedures (85% vs 91%). Patients in all BMI groups reported a significant improvement in their condition, with a significant decrease in the ICIQ-SF and WIPSS questionnaires mean scores (Table 3).

Nevertheless there was a trend towards lesser objective efficacy of the SIS with increasing body weight, with a significant difference between obese women (BMI ≥30) and normal subjects (BMI <25): 75% vs 91.3%, $p = 0.049$; OR 3.74 (95% CI 1.19–11.76). Moreover there was a significantly lower improvement in the ICIQ-SF mean score and lower percentage of women with PGI-I scores 1–2 in the group of obese patients (Table 4). We did not find any difference in

Table 3
Pre and post-operative ICI-SF and WIPSS scores by BMI.

	Normal		Overweight		Obese	
	Pre *N* = 72	Post *N* = 69	Pre *N* = 95	Post *N* = 91	Pre *N* = 39	Post *N* = 36
ICI-SF, mean ± SD	14.9 ± 3.6	2.5 ± 3.9	15.2 ± 3.5	2.9 ± 4.1	15.1 ± 3.9	5.8 ± 6.2
P	<0.001		<0.001		<0.001	
WIPSS, mean ± SD	8.3 ± 6.8	4.9 ± 4.2	9.2 ± 7.4	5.2 ± 5.7	10 ± 8.1	6.4 ± 5.3
P	<0.001		<0.001		<0.05	