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ORIGINAL ARTICLE

Incontinence surgery in obese women: comparative analysis of short- and long-term outcomes with a transobturator sling

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Abstract
Introduction and hypothesis Midurethral slings (MUS) are still discussed in complex incontinence situations, such as obesity, lacking sustained efficacy validation in this particular sub-population. We hypothesized that the outcomes of a transobturator MUS, such as TVT-O, do not differ according to body mass index (BMI) over a 4-year period.
Methods We conducted a retrospective analysis of 281 women who underwent TVT-O at our institution, between 2004 and 2012. Patients were stratified into obese (BMI≥30 kg/m^2) or non-obese (BMI<30 kg/m^2). We compared preoperative and postoperative parameters, including objective cure (negative stress test), complications, and quality of life scores. Data were collected at 0, 6, 12, 24, and 48 months. We used Fisher's exact test for categorical variables and Student's *t* test or the Mann–Whitney *U* test for continuous variables.
Results Baseline characteristics of the obese (n=122) and non-obese groups (n=159) were similar. We found no significant differences between groups in terms of objective cure rates at all follow-up evaluations, with 95.8 % and 95 % at 48 months in the non-obese and obese groups respectively. There were no significant differences in the cumulative complication rates of both groups. Quality of life assessment also showed no significant differences between groups at all follow-up visits. At 48 months our follow-up rate was 59 % (n=96) and 60.4 % (n=72) in the non-obese and obese group respectively (p=0.9).
Conclusions The TVT-O procedure is effective and safe in the long term for stress incontinence treatment, regardless of BMI.

Keywords Stress urinary incontinence · Obesity · Midurethral sling · Incontinence surgery · Quality of life

Introduction

Urinary incontinence is a highly prevalent dysfunction in middle-aged and elderly women, figuring as a social stigma that has a negative impact on quality of life [1].

Many epidemiological studies have linked obesity to a higher risk of urinary incontinence, related to both stress and urgency [2–4]. Considering the increasing rates of obesity worldwide [5, 6], this specific subpopulation has to be taken into account whenever considering indications, risks, and outcomes of incontinence surgical procedures.

After the first description of tension-free vaginal tape (TVT) by Ulmsten and Petros in 1995 [7], midurethral slings (MUS) quickly became the most common surgical procedure performed for stress urinary incontinence, because of the reports of high success rates and low morbidity [8, 9].

Despite being the gold standard for treating genuine stress incontinence, the MUS of choice in complex incontinence situations, such as obesity, is still debatable. So far, conflicting data have been published regarding the outcomes of these procedures in obese women. As a number of studies have reported no differences in the outcome of midurethral slings according to BMI, others have suggested cure rates of 10 to 30 % lower than those seen in non-obese patients [10–24]. Importantly, significant

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limitations and potential confounders are reported in most of these studies, including small sample sizes, short-term follow-up analysis, and variable follow-up periods, the use of different body mass index (BMI) cut-offs to determine obesity, or the use of nonvalidated survey tools for primary outcome measurement.

As the present literature may be of little quality regarding the impact of BMI on the success of midurethral slings, these procedures are still lacking sustained validation in the obese sub-population.

The aim of our study was to evaluate the effectiveness and safety of a transobturator midurethral sling in incontinent obese women over a 4-year period. We hypothesized that the outcomes of a transobturator MUS, such as TVT-O, do not differ according to BMI.

Materials and methods

We conducted a retrospective comparative study of all women who underwent incontinence surgery using the inside-out mid-urethral transobturator sling TVT-O (Gynecare TVT™ Obturator System, Ethicon), between January 2004 and June 2012 at the Urogynecology Unit of a tertiary, University Hospital. Data were collected from an ongoing database designed for clinical research.

Written informed consent, approved by the Ethics Review Board (ERB) of our Institution, was obtained from all women at the preoperative consultation, concerning all medical interventions and the potential use of clinical data in future research studies. As this was a retrospective data analysis, with no interference in any medical decision or intervention, no additional ERB approval was needed.

All women had a chief complaint of involuntary urinary loss related to stress. Cases of mixed urinary incontinence were included whenever stress was the major symptom. A positive cough test on pelvic examination was mandatory for inclusion.

Cases of occult urinary incontinence or previous failed MUS were excluded. We also excluded any patient with an active urinary or vaginal infection, medication or any major medical condition possibly related to voiding dysfunction, such as poorly controlled diabetes, multiple sclerosis or spinal cord injury.

Cases of concomitant pelvic organ prolapse (POP) on pelvic examination or concomitant pelvic floor reconstructive surgery for POP at the time of the indexed surgery were not excluded from the analysis.

According to their body mass index (BMI), women were stratified in two groups—obese (BMI≥30 kg/m^2) and non-obese (BMI<30 kg/m^2)—using the cutoff points recommended by the World Health Organization for the western population [25].

Preoperative evaluation included a detailed medical history with symptom severity assessment, a pelvic examination with a cough test, urinalysis, and a complete urodynamic study, involving filling and voiding cystometries, uroflowmetry, and urethral pressure profile.

The impact on quality of life was assessed pre- and postoperatively using the King's Health Questionnaire (KHQ) validated for Portuguese [26], in which women are asked about urinary incontinence symptoms and quality of life related to urinary incontinence. With this instrument, a higher score indicates worse symptoms and poorer quality of life.

Postoperative follow-up was scheduled at 6, 12, 24, and 48 months. Symptom assessment, pelvic examination, and a cough test were performed at all visits. Only records with the preoperative and at least two postoperative visits were considered for the analysis.

Our primary outcome was the objective cure, defined as no urine leakage during the cough test performed with full

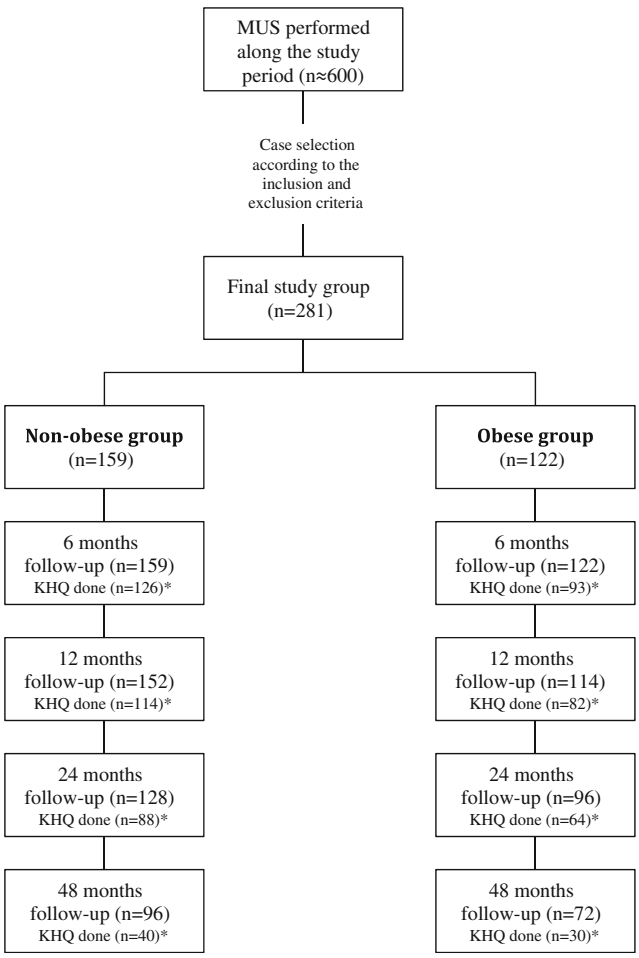

Fig. 1 Number of women considered for analysis at each study time point. All women who followed up provided a stress test on pelvic examination, but some did not provide a valid King's Health Questionnaire (KHQ)

Table 1 Baseline demographics and preoperative parameters

Characteristics	Non-obese (n=159)	Obese (n=122)	p value
Mean age in years (SD)	60.3 (10.1)	60.3 (9.6)	0.97
Mean BMI in kg/m^2 (SD)	26.9 (2.2)	33.2 (3.4)	<0.0001*
Median parity (range)	2 (0–6)	2 (0–8)	0.06
Type of UI			0.63
Pure stress	78 (49.1)	64 (52.5)	
Mixed	81 (50.9)	58 (47.5)	
Surgery performed			1.0
TVT-O	91 (57.2)	69 (56.6)	
TVT-O plus POP repair	68 (42.8)	53 (43.4)	

Data are expressed as n (%) except where otherwise indicated

BMI body mass index, *UI* urinary incontinence, *TVT-O* transobturator tape procedure, *POP* pelvic organ prolapse

*p<0.05, statistically significant

bladder at each follow-up visit [27]. The presence of any leakage with the same maneuver was considered to indicate surgical failure.

Our secondary outcomes were perioperative complications and impact on quality of life. As perioperative complications we considered the presence of excessive bleeding (ΔHb>2 g/dL), vaginal wall perforation, bladder perforation, urinary retention (postvoiding residue>100 ml), de novo overactive bladder (OAB) and vaginal mucosal erosion. As for the impact on quality of life, we relied on the variations in KHQ scores between baseline (preoperative) and each follow-up visit, stratified into three classes: "cured" if the KHQ score was<30; "improved" if the KHQ score was ≥30, but with an improvement from baseline>5 points; "not improved" if the KHQ score was≥30, with an improvement from baseline≤5 points or with any aggravation (KHQ score at follow-up above the baseline score).

Data were compared using the Chi-squared and Fisher's exact test for categorical variables and Student's t test or the Mann–Whitney test for continuous variables. GraphPad Prism 6 (GraphPad Software, San Diego, CA, USA) was used for the statistical purposes. A p value<0.05 was considered statistically significant.

Results

During the study period, approximately 600 women underwent an MUS procedure at our institution. Our final study group included 281 patients, 122 in the obese group and 159 in the non-obese group. The number of patients considered for analysis at each study timepoint is presented in Fig. 1. Patients' mean BMIs for the obese and non-obese groups were 33.2±3.4 kg/m^2 and 26.9±2.2 kg/m^2 respectively. Demographics and preoperative parameters of the groups were compared and no significant differences were found, except for BMI, as presented in Table 1.

For both groups the objective cure rate was higher than 90 % at each follow-up visit, with no significant differences (Table 2). At 48 months, our follow-up rate was 59 % (n=96) and 60.4 % (n=72) in the non-obese and obese groups respectively (p=0.9).

In terms of impact on quality of life, the improvement in the mean KHQ total scores after surgery was significant compared with the preoperative scores and there were no significant differences between groups (Fig. 2). Regarding the KHQ score variation by classes, we also found both groups to feel mainly "cured" or "improved" at all follow-up assessments, with no significant differences in the comparative analysis over the 4-year period (Table 3).

Concerning perioperative complications we registered in the non-obese group 1 case of excessive bleeding, 2 vaginal perforations, 1 case of de novo OAB, 2 vaginal mucosal erosions and no cases of urinary retention or bladder perforation. In the obese group there was 1 case of excessive bleeding, 3 vaginal perforations, 2 cases of de novo OAB, 1 case of urinary retention, 2 vaginal mucosal erosions, and no cases of bladder perforation. Comparing their cumulative rates, no significant differences were found in the incidence

Table 2 Objective cure rates according to the BMI group

Follow-up (months)	Cure rate % (n/total)		p value
	Non-obese (n=159)	Obese (n=122)	
6	98.1 (156/159)	95.1 (116/122)	0.18
12	96.7 (147/152)	92.9 (106/114)	0.22
24	96.9 (124/128)	92.7 (89/96)	0.41
48	95.8 (92/96)	95.0 (68/72)	1.0

BMI body mass index

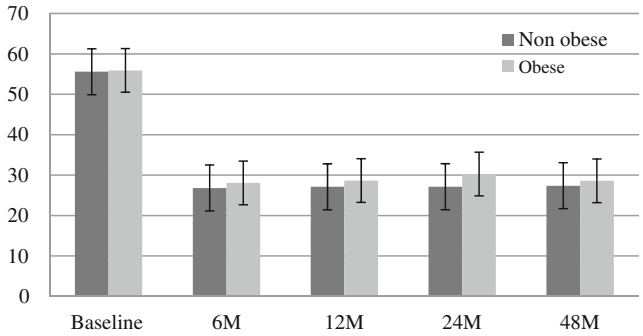

Fig. 2 Mean KHQ total scores before and after surgery (at 6, 12, 24, and 48 months), according to BMI group. The improvement at each follow-up visit was significant compared with baseline (p trend <0.0001) and there were no significant differences between groups. Baseline: non-obese n=159, obese n=122; 6 months: non-obese n=126, obese n=93; 12 months: non-obese n=114, obese n=82; 24 months: non-obese n=88, obese n=64; 48 months: non-obese n=40, obese n=30

of complications among groups (non-obese 3.8 % vs obese 7.4 %, p=0.19). We also registered a low re-operation rate, with 2.5 % of women (3 out of 122) in the obese group being subjected to a second related procedure (1 for mesh erosion, 1 for urinary retention, and 1 for surgical failure) and 1.3 % (2 out of 159) in the non-obese group (both for mesh erosion), p=0.66.

Discussion

In this study the objective cure rate showed no significant difference between obese and non-obese women. Also, considering the impact of surgery on quality of life, the variation in KHQ scores showed no significant differences between groups. We registered a low complication rate, with no significant differences related to BMI, and our global erosion rate was set at 1.4 % (4 out of 281).

Although no differences were found between groups, our objective cure rates were higher than the subjective cures based on the KHQ score analysis. This discrepancy can be related to the influence of overactive bladder symptoms—present in approximately half of the women before surgery—on the KHQ scores, conditioning higher improvements in this analysis. Additionally, a limitation related to objective cure-established criteria could also be pointed out. As the cough stress test was systematically performed in a lithotomy position and in a clinical environment, it is expected that some women with a negative stress test may actually experience some degree of urine leakage in their daily life activities, with a potential impact on their KHQ scores. Nevertheless, it is interesting to notice that, considering both women who were "cured" and "improved"

Table 3 Variation in KHQ scores according to BMI group

	Non-obese (n=159)	Obese (n=122)	p value
Mean KHQ score baseline (SD)	55.6 (12.1)	55.9 (13.8)	0.92
KHQ score at 6 months	126/159	93/122	
Cured	102 (81 %)	72 (77.4 %)	0.61
Improved	19 (15 %)	17 (18.3 %)	0.58
Not improved	5 (4 %)	4 (4.3 %)	1.0
KHQ score at 12 months	114/159	82/122	
Cured	92 (80.7 %)	60 (73.2 %)	0.23
Improved	15 (13.2 %)	17 (20.7 %)	0.17
Not improved	7 (6.1 %)	5 (6.1 %)	1.0
KHQ score at 24 months	88/159	64/122	
Cured	70 (79.6 %)	47 (73.5 %)	0.43
Improved	14 (15.9 %)	9 (14 %)	0.82
Not improved	4 (4.5 %)	8 (12.5 %)	0.12
KHQ score at 48 months	40/159	30/122	
Cured	29 (72.5 %)	22 (73.3 %)	1.0
Improved	11 (27.5 %)	6 (20 %)	0.58
Not improved	–	2 (6.7 %)	0.18

Data are expressed as n (%), except where otherwise indicated

"Cured" if KHQ score <30; "improved" if KHQ score≥30, but with an improvement from baseline>5 points; "not improved" if KHQ score≥30 with an improvement from baseline≤5 points or with any aggravation (KHQ score at follow-up above the baseline score)

BMI body mass índex, *KHQ* Kings Health Questionnaire

according to the KHQ class distribution, the rate of patient satisfaction comes closer to the objective cure, and this is true for both groups studied.

Obesity is a known independent risk factor for the development of stress urinary incontinence (SUI), although the exact underlying mechanism is not yet completely clear. Mommsen and Foldspang studied 2,589 women aged 30 to 59 years, and reported that, independently of other risk factors, BMI had a positive correlation with the incidence of urinary incontinence, most closely with stress urinary incontinence [3]. Obese patients experience higher levels of intra-abdominal pressure and damage to the pelvic floor functions may come from this chronic state [28].

Since the description of the TVT procedure by Ulmsten and Petros [7], minimally invasive MUS have been applied for the surgical treatment of SUI, with highly satisfactory results in index patients with genuine stress incontinence [8, 9, 29–31].

As slings also started to be used in obese women as a substitute for the previous invasive incontinence surgeries, concerns for lower cure rates and higher perioperative complications were raised, leading to several reports on the outcomes of these procedures in this at-risk population in the last 10 years [10–24]. Table 4 summarizes the features of the main studies previously published on this topic.

Liu et al. retrospectively compared TVT-O efficacy and safety in 29 normal, 58 overweight, and 32 obese women. At a median 24 months' follow-up, they found no differences in objective and subjective cure rates or postoperative complications among the three groups [15]. By contrast, Haverkorn et al. compared 117 obese women (BMI> 30 kg/m^2) with 161 normal controls (BMI<30 kg/m^2) at a minimum of 12 months after a MONARC procedure. Defining cure using both objective cough test and a validated questionnaire, they found a significantly lower cure rate in the obese population (81.2 % vs 91.9 %, p<0.001); however, they also reported that obese women were able to achieve an improvement in quality of life scores similar to those of the normal weight population, suggesting that the cure rate difference might not be clinically significant [10].

More recently, Brennand et al. published the results from a secondary analysis of a randomized control trial aimed at evaluating the impact of BMI on objective and subjective cure rates 12 months after MUS surgery. With 61 women enrolled in the obese arm of the study and 121 in the non-obese one, they found lower objective and subjective cure rates in the obese group (67.8 % vs 85.6 %, p=0.006 and 70.7 % vs 85.8 %, p=0.016 respectively), although no differences between groups were found in the quality of life improvement, assessed by validated questionnaires [22].

Given the contradictory data published on the outcomes of MUS in obese women, it is not clear to date if BMI should be considered as an independent risk factor for surgical failure. Discrepancies in the study results may be explained by differences in the designs, the types of surgeries performed, the number of patients enrolled, the BMI cutoffs considered, or, more importantly, the established definitions of success and outcome measuring tools.

The merit of this study lies in the long-term follow-up analysis, enabling assessment of this procedure's durability in obese women. Also, we highlight the use of large sample sizes and objective cure criteria, easily evaluated on pelvic examination. In terms of quality of life assessment, we consider that the established criteria helped to enrich the outcome analysis, as we compared not only mean KHQ total scores between groups, but also KHQ variations by pre-established improvement classes, enabling a broader awareness of the real impact of surgery in the daily life of these women.

Our patients were carefully selected, and despite the inclusion of cases of concomitant pelvic organ prolapse, all women had clinical symptoms of stress incontinence before surgery and urodynamic findings to confirm that.

Although this is not a prospective controlled trial, we point out that the variable in focus is also not liable to randomization, which limits the advantages of a truly prospective design. We did in fact rely on a prospective data collection for a clinical database, with standardized surgical protocols. In that way, we were able to ensure that all women had the same perioperative and follow-up assessment, which in our opinion strengthens our outcome analysis, despite the retrospective design.

Our main limitation lies in the lost to follow-up rate seen at 48 months, with 41 % drop-out in the obese group and 39.6 % drop-out in the non-obese group. Although this may weaken the strength of our long-term findings, there were no significant differences in this rate between groups (p=0.9).

Despite including women with mixed urinary incontinence and with concomitant POP repairs performed together with the index surgery, we found no differences in these distributions between groups, which in our opinion makes our samples reliable and at the same time more representative of the usual heterogeneous populations seen in clinical practice.

With this study we were able to demonstrate that in our clinical set, the outcomes of a transobturator sling in women with SUI can be similar, in spite of obesity. Both obese and non-obese women had sustained elevated cure rates at 4 years' follow-up, achieving great improvements in quality of life after surgery, and with a low rate of complications. We conclude then that TVT-O seems to be a effective and safe procedure for stress incontinence in the long term, regardless of BMI.

Table 4 Summarized features of previous studies evaluating the impact of obesity in the success of midurethral slings

Study	Design	Number of cases	BMI classes (kg/m^2)	Outcome measure	Follow-up (months)	Outcomes
Mukherjee and Constantine [17]	P	58 (NW) 98 (OW) 87 (O)	<25 25–29 ≥30	Self-reported cure	6	No differences between groups
Ku et al. [21]	R	81 (NW) 159 (OW) 45 (O)	18.5–23 23–27.5 ≥27.5	Negative CST	6	No differences in cure rate between groups (92.6 % vs 91.2 % vs 84.4 %, p=0.173)
Hellberg et al. [12]	R	239 (NW) 331 (OW) 115 (O) 48 (VO)	20–24 25–29 30–34 >35	Mailed survey, self-reported cure	60	Lower cure rate for very obese compared with normal weight women (52.1 % vs 81.2 %, p=0.001)
Killingsworth et al. [16]	R	68 (NW) 65 (OW) 62 (O)	20–24 25–29 ≥30	UDI-6 IIQ-7 PSQ	12	No differences between groups (stress UI p=0.91, irritative symptoms p=0.95, total UDI-6 p=0.22, total IIQ-7 p=0.17)
Tchey et al. [19]	R	55 (NO) 52 (O)	<25 ≥25	Phone or mail interview	12	No differences between groups (85.5 % vs 86.5 %, p=0.84)
Haverkorn et al. [10]	R	117 (O) 161 (NW)	<30 ≥30	SEAPI composite =0 and negative CST	12	Lower cure rate for obese group (81.2 % vs 91.9 %, p<0.001)
Liu et al. [15]	R	29 (NW) 58 (OW) 32 (O)	<23 23–27.5 >27.5	Urodynamic negative stress test	24	No differences between groups (87 % vs 79 % vs 72 %, p=0.16)
Esin et al. [18]	R	46 (NO) 50 (O)	<25 ≥30	Negative CST or no urodynamic SI	12	No differences between groups (91.3 % vs 92 %, p=0.77)
Hwang et al. [23]	R	103 (NW) 186 (OW) 34 (O)	18.5–22.9 23–27.5 ≥27.6	Absence of symptoms and patient satisfaction	12	No differences between groups (95.1 % vs 95.7 % vs 94.1 %, p=0.321)
Heinonen et al. [14]	R	100 (NW) 34 (O)	<30 ≥30	Mailed survey, patient satisfaction	78	No differences between groups (85 % vs 84 %, p=0.15)
Jeong et al. [24]	R	74 (NW) 124 (OW) 45 (O)	18.5–23 23.1–27.4 ≥30	Negative CST and absence of symptoms	58	Lower cure rate according to BMI (94.3 % vs 88.6 % vs 78.6 %, p=0.037)
Brennand et al. [22]	RCT, SA	121 (NO) 61 (O)	<30 ≥30	1-h pad test	12	Lower cure rate for obese women (67.8 % vs 85.6 %, p=0.006)

SEAPI, *UDI-6*, *IIQ-7*, *PSQ* validated questionnaires, *CST* cough stress test, *NW* normal weight, *OW* overweight, *O* obese, *VO* very obese, *P* prospective, *RCT* randomized controlled trial, *R* retrospective, *SA* secondary analysis, *SI* stress incontinence

As the published results still lack consistency, we consider it useful to clarify these findings in large prospective studies, particularly designed to address this matter.

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Conflicts of interest None.

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