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Efficacy and safety of the trans-obturator TVT-Abbrevo device in normal weight compared to overweight patients affected by stress urinary incontinence

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ABSTRACT

Objective: To investigate if TVT-Abbrevo has similar outcomes in normal weight and overweight patients.
Study design: Retrospective evaluation of 205 (105 normal weight women and 100 overweight women with BMI $\geq$ 25 kg/m^2) undergone TVT-Abbrevo positioning with 12 month follow-up. Primary outcomes were objective cure rate (defined as no leakage during CST) and subjective cure rate ("very much improved"/"much improved" at PGI-I), secondary outcomes were intra-operative and post-operative complications.
Results: Objective cure rates in the normal and overweight groups were 96.2% and 94%, respectively (p = .47). Subjective cure rates in the normal and overweight groups were 90.5% and 88%, respectively (p = .57). ICIQ-SF, I-QoL and PGI-S scores significantly improved in both groups with no differences between the two groups. No serious intra- or post-operative complications were observed. No differences were observed in pain VAS scores and number of analgesic vials administered.
Conclusions: TVT-Abbrevo seems to have similar efficacy and safety in normal weight and overweight women. More studies are needed to assess the efficacy of this device in frankly obese women and long-term outcomes.

Introduction

Trans-obturator tapes have become a valuable option for the treatment of female stress urinary incontinence (SUI), yielding similar cure rates and less complications in comparison with retropubic TVT [1–3].

To reduce groin and thigh pain [2,3] linked to the trans-obturator route, a modified inside-out device with a 12 cm tape has been developed to reduce the amount of prosthetic material left in the patients' bodies and, in association with modifications to the original technique, limit post-operative pain. This tape do cross the obturator membrane and the external obturator muscle, but not more superficial muscular layers [4]. It has been also shown that it has similar cure rates in comparison with the original inside-out trans-obturator tape (TVT-O) with significant less post-operative pain [5,6].

Obesity is epidemic among developed countries, with rates reaching as much as 30% of the Europe and US populations [7], and urinary incontinence is a common problem among obese subjects [8]. Overweight and obese subjects thus represent a significant proportion of patients undergoing mid-urethral tape positioning. Outcomes of mid-urethral slings in these patients are contradictory [9–22].

Considering that no data on the impact of high body mass index (BMI) on the efficacy and safety of the modified and shortened inside-out trans-obturator tape (TVT-Abbrevo) are available, aim of this retrospective study was to investigate if the new tape has similar outcomes in normal weight and overweight patients.

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Materials and methods

The clinical records of all patients undergone TVT-Abbrevo for the treatment of SUI at two urogynecology centers from September 2011 to March 2014 who had completed one year follow-up were reviewed.

Inclusion criteria were: SUI diagnosed by clinical evaluation and urodynamics, age > 40 years, complete 1-year follow-up. Exclusion criteria were: previous surgical and/or pharmacological treatment of SUI, predominant or isolated urge incontinence, detrusor overactivity (DO), genital prolapse more than or equal to stage 2 according to PoP-Q scoring system, and serious contra-indications to surgical procedures.

Two-hundred and five patients met the inclusion criteria and were included in the study. They were stratified into two groups based on body mass index (BMI) according to the WHO definition of overweight and obesity [23]: women with a BMI < 25 kg/m^2 (normal weight group, n = 105) and women with a BMI ≥ 25 kg/m^2 (overweight group, n = 100). Fourty-six patients in the overweight group had a BMI ≥ 30 kg/m^2 and were thus considered obese. No formal IRB approval was necessary according the Italian regulations on retrospective studies. This research has been performed in accordance with the ethical standards of the Declaration of Helsinki. Informed consent was obtained from all individual participants included in the study, which was accepted by our IRB.

Pre-operative evaluation included history, clinical examination with PoP-Q scoring, urodynamic tests, Q-tip test, challenge stress testing (CST) with 250-mL bladder filling, post-voidal residue (PVR) evaluation, and complete blood count. In addition, patients completed the Incontinence-Quality of Life (I-QOL), the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) [24], and the Patient Global Impression of Severity (PGI-S) questionnaires [25].

All procedures were performed by two investigators (G.A.T. and V.N.) who had already performed more than 10 TVT-Abbrevo procedures before the period considered for the study. All subjects received antibiotic prophylaxis (cefazolin 2 g i.v.) immediately before the procedure and underwent spinal anesthesia. A urinary catheter was placed and paraurethral hydrodissection with saline containing lidocaine hydrochloride and 1:250,000 epinephrine was performed at the beginning of the procedure.

The TVT-Abbrevo procedure was performed as previously described [5]. After performing a medial sagittal incision of the vaginal wall starting 1 cm proximal to the urethral meatus and continued caudally for 1 cm, a paraurethral dissection was carried only up to the pubic ramus, without perforating the obturator membrane with the scissors or guide. After the perforation of the obturator membrane with the trocar, the guide was removed, and the handle of the helical passer was dropped down to a vertical position, while concomitantly being rotated around the inferior pubic ramus. Bone contact was maintained at all times during insertion, ensuring a tight passage around the bony structure, with the tip of the passer exiting at the skin level 0.5–1 cm laterally of the crural plicae, more medial than the exit points described for the traditional TVT-O technique.

Neither cystoscopy nor the cough test was performed during the procedures. The urinary catheter was left in place for 24 h after the procedure. The duration of the procedure and intra-operative complications were recorded. Post-operative pain was assessed using a visual analog scale (VAS) from 0 (absence of pain) to 10 (maximum pain possible), 12 and 24 h after the procedure. Analgesia was administered only upon the request of patients and consisted in 1 g of oral paracetamol; if not effective, 100 mg of i.v. tramadol hydrochloride was administered and repeated each 8 h if necessary. The total amount of analgesia received by each patient was recorded. If no complications were observed, patients were discharged from hospital on the day after the procedure.

Postoperative follow-up was scheduled at 1 week after discharge, then at 1, 3, 6, and 12 months, and yearly thereafter. One year follow-up included CST with a 250 cc bladder filling to assess objective cure rate (defined as no leakage during the test), ICIQ-SF and I-QOL questionnaires and PGI-I questionnaire to assess subjective cure rate (defined as the patient stating to be "very much improved"/"much improved").

The primary outcomes were the objective and subjective cure rates 12 months after the procedure. Secondary outcomes were VAS pain scores, number of analgesic vials administered, and intra-operative and post-operative complications.

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 17.0 (SPSS, Chicago, IL, USA). Data distribution was evaluated with the Shapiro–Wilk's test. Differences in categorical variables were evaluated using the χ^2 test. Differences in continuous variables with normal distribution between and within groups were evaluated using the Student's t test for unpaired and paired samples, respectively. Differences in number of analgesic vials administered, and PGI-S and PGI-I values, which showed a non-normal distribution, were evaluated with the Mann–Whitney U test. Differences between baseline and post-operative PGI-S values were evaluated with the Wilcoxon test.

Results

Mean follow-up was 18.3 ± 4.3 months. Baseline characteristics were similar between the two groups, with the exception of BMI (Table 1).

101/105 (96.2%) and 94/100 (94%) women in the normal weight group and the overweight group were cured according to the objective cure definition, respectively (p = .47) (Table 2). Subjective cure rate for women in the normal weight group was 90.5% (95/105), while for women in the overweight group was 88% (88/100) (p = .57) (Table 2).

Considering the WHO definition, 46 patients in the overweight group (46%) were obese, with a mean BMI of 33.2 ± 3.1 kg/m^2 in comparison with 54 overweight women (54%; mean BMI 26.5 ± 2.7 kg/m^2). The objective cure rate of obese women was 91.3% (42/46), which was similar to overweight women (52/54, 96.3%; p = 29) (Table 3). Subjective cure rate (proportion of women answering "very much improved/improved" to the PGI-I questionnaire) was 87% (40/46) for obese women and 90.7% (49/54) for overweight women (p = .55) (Table 3). Both objective and subjective cure rates for obese and overweight women were not significantly different from normal weight women (Table 3), although objective

Table 1
Baseline characteristics of the patients and intra-operative details. Values are given as mean ± SD, median [range], or number (%), as appropriate.

	Normal weight (n = 105)	Overweight (n = 100)
Age (years)	55.9 ± 6.4	58.5 ± 7.6
Parity (n)	2 [0–4]	3 [0.4]
Body mass index (kg/m^2)	22.4 ± 2.1	28.6 ± 5.6*
Postmenopausal status (n)	81 (77.1)	80 (80)
Hormone therapy (n)	15 (14.3)	18 (18)
ICIQ-SF	6.3 ± 3.2	6.9 ± 3.1
I-QOL	42.3 ± 1.3	38.7 ± 3.2
PGI-S	4 [2–4]	4 [2–4]
VLPP (cm H_2O)	83.6 ± 11.5	89.2 ± 15.4
Procedure time (mins)	9.6 ± 2.3	11.3 ± 4.3
ΔHb levels (g/dL)	−1.1 ± 0.3	−1.0 ± 0.4
Intraoperative complications		
Vaginal injury	1	–

*p = <.0001.