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# TVT-O vs. TVT-Abbrevo per il trattamento dell'incontinenza urinaria da stress nelle donne: uno studio randomizzato

Abstract

**Introduzione:** Confrontare l'efficacia, la sicurezza e le complicazioni della TVT-O (in-out) e della sling di lunghezza minore (TVT-Abbrevo) per il trattamento della SUI femminile.

**Materiali e metodi:** Centocinquantotto pazienti reclutati sono stati randomizzati nel gruppo TVT-O o TVT-Abbrevo. La valutazione preoperatoria comprendeva anamnesi e valutazione generale, analisi delle urine e coltura delle urine, esame clinico uroginecologico, valutazione urodinamica e colloquio uroginecologico di ICIQ-SF-UI, PGI-I e PISQ12. In tutti i pazienti sono stati registrati prospetticamente tempo operatorio, complicanze peri-operatori, minzione spontanea, complicanze postoperatorie e degenza ospedaliera. A 3, 6, 12, 24 e 36 mesi dopo l'intervento chirurgico, i pazienti sono stati invitati a rispondere alle interviste uroginoecologiche da ICIQ-SF-UI, PGI-I e PISQ12. La valutazione urodinamica è stata eseguita a 12, 24 e 36 mesi. Il tasso di successo è stato valutato a 12, 24 e 36 mesi dopo l'intervento.

**Risultati:** Complessivamente, 138 su 158 pazienti (87%) sono stati curati per SUI a 36 mesi dopo l'operazione senza differenze significative tra i gruppi [69 (87%) e 69 (87%) pazienti nei gruppi TVT-O e TVT Abbrevo, rispettivamente]. I due gruppi non differivano significativamente per il tempo operatorio, perdita di sangue intraoperatoria e durata della degenza ospedaliera. Nove pazienti (11%) presentavano dolore all'inguine postoperatorio nel gruppo TVT-O e in un paziente nel gruppo TVT Abbrevo (p = 0,02). Al controllo triennale si è dimostrato un medesimo tasso di guarigione oggettivo in entrambi i gruppi. C'è stato un significativo miglioramento dei punteggi PISQ-12 e ICIQ-SF-UI totali in entrambi i gruppi a 36 mesi di FU.

**Conclusioni:** TVT-Abbrevo ha un'efficacia e una sicurezza simili alla TVT-O nelle donne affette da SUI; l'uso di una sling più corta riduce il dolore postoperatorio.

#### **ORIGINAL ARTICLE**



# TVT-O vs. TVT-Abbrevo for stress urinary incontinence treatment in women: a randomized trial

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#### Abstract

**Introduction** To compare the efficacy, safety and complications of the trans-obturator midurethral sling from inside to outside (TVT-O) and of the shorter trans-obturator midurethral sling (TVT-Abbrevo) for treatment of female SUI.

**Materials and methods** One hundred fifty-eight recruited patients were randomized into either the TVT-O or TVT-Abbrevo group. Preoperative assessment included history and general assessment, urinalysis and urine culture, urogynaecological clinical examination, urodynamic evaluation and urogynaecologic interview by ICIQ-SF-UI, PGI-I and PISQ12. Operative time, perioperative complications, spontaneous voiding, postoperative complications and hospital stay were prospectively recorded in all patients. At 3, 6, 12, 24 and 36 months after surgery, patients were asked to answer urogynaecological interviews by ICIQ-SF-UI, PGI-I and PISQ12. The urodynamic assessment was performed at 12, 24 and 36 months. Success rate was assessed at 12, 24 and 36 months postoperatively.

**Results** Overall, 138 of 158 patients (87%) were cured of SUI 36 months after the operation with no significant differences between groups [69 (87%) and 69 (87%) patients in the TVT-O and TVT Abbrevo groups, respectively]. The two groups did not significantly differ in operative time, intraoperative blood loss and length of hospital stay. Nine patients (11%) had postoperative groin pain in the TVT-O group and one patient in the TVT Abbrevo group (p = 0.02). Three-year control demonstrated an equal objective cure rate in both groups. There was a significant improvement in total PISQ-12 and ICIQ-SF-UI scores in both groups at 36 months FU.

**Conclusion** TVT-Abbrevo has similar efficacy and safety compared with TVT-O in women with SUI; the use of a shorter sling reduces postoperative pain.

Keywords Mid-urethral sling · Quality of life · Stress urinary incontinence · TVT-O · Mini-sling

# Introduction

Stress urinary incontinence (SUI) is defined as the complaint of involuntary loss of urine in effort or physical exertion, or on sneezing or coughing, by the International Urogynecological

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Association (IUGA) and the International Continence Society (ICS) [1]. It has been reported that the incidence ranges from 12.8% to 46.0% and is more common among Caucasian and Hispanic women. SUI can also have a significant negative impact on economic status and quality of life [2].

Since the report by Ulmsten and Petros in 1995 [3], the tension-free vaginal tape (TVT) technique has been the most commonly used surgical treatment for SUI thanks to its advantages such as minimal surgical trauma, shorter postoperative stay and long-term high cure rate, ranging from 81% to 95% [4].

Mid-urethral slings (MUS) now represent a gold standard in the treatment of female stress urinary incontinence (SUI) [5].

Second-generation inside-out transobturator slings (TVT-O) or the later outside-in transobturator (TOT) slings have proven to be as effective as retropubic TVT with fewer intraoperative complications [6]. The main reason for the change was the higher rate of bladder perforation and major vessel injuries (1-5% of patients) using the retropubic route, whereas TVT-O passage is related to vaginal damage and neurological impairment, leading to long-term thigh pain and upper-leg weakness (4% of patients) [7].

A third generation of the MUS inserted through a single vaginal incision (SIS) or constructed with less material (12 cm polypropylene), TVT Abbrevo, has become a means of overcoming significant postoperative thigh and groin pain [8].

This randomized trial compared use of the trans-obturator midurethral sling from inside to outside (TVT-O) and of the shorter trans-obturator midurethral sling (TVT-Abbrevo) for surgical treatment of SUI in terms of complications (primary end point) and medium-term success rate (secondary end point).

# Materials and methods

From January 2013 to July 2016, consecutive patients affected by SUI were included in the study. The institutional review board (IRB) approved the study protocol no. L002–1511/2013.

Inclusion criteria included SUI with no contraindications to vaginal surgery and signed informed consent. SUI was defined as the complaint of any involuntary loss of urine on effort or physical exertion (e.g., sporting activities) or on sneezing or coughing.

Exclusion criteria included: urogenital prolapse > stage 1, symptoms of overactive bladder (OAB), planned or present pregnancy, intrinsic urethral sphincter deficiency, previous antiincontinence surgery, residual urine volume > 100 ml, previous pelvic irradiation, recurrent urinary tract infections (> 4 during last year), neurological conditions such as multiple sclerosis, current treatment with corticoids, inability to understand the protocol and a history of genital or abdominal cancer or a pelvic mass.

Preoperative assessment included history and general assessment, urinalysis and urine culture, urogynaecological clinical examination and urodynamic evaluation.

During the urogynaecological interview the International Consultation on Incontinence Questionnaire (ICIQ-SF-UI) [9], and, if sexually active, the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ12) [10] were used to evaluate the influence of surgery on incontinence, quality of life and the woman's perception of improvement. Only sexually active women were asked to complete the PISQ-12.

During the urogynaecological examination, the degree of vaginal defects was evaluated using the pelvic organ prolapse quantification (POP-Q) system [11]. All patients underwent cough stress testing in the supine and standing positions at 300 ml bladder filling. Urodynamic evaluations were performed in accordance with criteria established by the International Continence Society (ICS) [12]. In the present study, patients were not masked but examinations were performed by physicians not involved in the study protocol. Maximum urethral closure pressure < 20 cmH<sub>2</sub>O and Valsalva

leak-point pressure  $< 60 \text{ cmH}_2\text{O}$  was considered an indicator of intrinsic sphincter deficiency.

After preoperative assessment, patients, who had signed informed consents, were randomly allocated to undergo a TVT-O (Gynecare, Ethicon) or TVT-Abbrevo (Gynecare, Ethicon) procedure using a computer-generated list in a 1:1 ratio. Surgical procedures were performed by the same experienced surgeon (M.A.Z.) according to the original techniques by De Leval [13, 14].

A short-term antibiotic prophylaxis was given 30 min prior to surgery (cefazolin 2 g). If the postoperative postvoid residual was > 100 ml, the patient carried out intermittent selfcatheterisation at home until a postvoid residual < 50 ml on two consecutive measurements was obtained.

Operative time, perioperative complications, spontaneous voiding, postoperative complications and hospital stay were prospectively recorded in all patients. At 3, 6, 12, 24 and 36 months after surgery, patients were asked to answer urogynaecological interviews using the ICIQ-SF-UI [9], Patient Global Impression of Improvement (PGI-I) [15] and PISQ12 [10]; in addition, physical examination was performed. Urodynamic assessment was performed at 12, 24 and 36 months. Classification of surgical complications was performed using the IUGA/ICS classification of complications of prosthesis and graft insertion [16]. Success rate was assessed at 12, 24 and 36 months postoperatively. Objective cure for SUI was defined as no leakage of urine while performing the cough stress test with 300 ml of saline solution in the bladder and at a mean pressure transmission ratio (PTR) >90% for the proximal three-fourths of the urethra. Subjective cure is related to the symptoms the patient reports and was defined as no stress urinary incontinence after surgery.

Urinary frequency was defined as a repeated voiding of a small volume of urine (> 8 times/day) in short intervals. Urgency was defined as a strong desire to void accompanied by fear of leakage or fear of pain; nocturia was defined as the need to awake more than twice a night to void. Bladder outlet obstruction was measured with a pressure-flow study according to the Blaivas and Groutz nomogram [17]. Severe pain was defined as presence of pain requiring analgesic therapy still 6 weeks after surgery.

The sample size calculation was performed assuming that the original TVT-O procedure would be associated with a 23% incidence of intra- and postoperative complications at 1-year follow-up and that a 16% decrease in intra- and postoperative complications would be clinically important. With an 80% statistical power (1- $\beta$ ) to show this 16% difference at  $\alpha$  = 0.05, it was determined that the sample size should be 150 patients, 75 patients in each group. To compensate for patients lost to follow-up postoperatively (estimated rate of 5%), 79 patients per group needed to be enrolled.

For analysis of continuous and nominal variables, Mann-Whitney and chi-squared tests, respectively, were used to calculate statistical differences between study groups. The patients lost at the 36-month follow-up (8 patients in both groups) were considered as a failure in the statistical analysis for the objective cure calculation. The Wilcoxon signed rank-sum test was used for comparison within groups. A p value < 0.05 was considered statistically significant.

#### Results

A total of 185 patients affected by SUI were assessed for eligibility. One hundred fifty-eight patients who met the inclusion and exclusion criteria and signed informed consent were enrolled. All 158 patients were treated on an intention-to-treat basis; 79 had the TVT-O procedure (TVT-O group) and 79



Fig. 1 CONSORT flow diagram for patients who were brought into the trial

#### Table 1 Patient characteristics

Variables	TVT-O group (79 patients)	TVT Abbrevo group	р
	(7) patients)	(19 patients)	
Age, years	55.8 + 11.2	56.8 + 8.9	ns
Body mass index, kg/m <sup>2</sup>	26.9 + 3.4	26.2 + 5.8	ns
Parity, n	2.3 + 0.8	2.1 + 1.4	ns
Menopausal status, n	21 (27%)	24 (30%)	ns
Hormone replacement therapy, n	8/21 (36%)	9/24 (37%)	ns
Previous hysterectomy, n	9 (11%)	7 (9%)	ns
POPQ system			
Stage 0	59 (75%)	54 (68%)	ns
Stage 1	20 (25%)	25 (32%)	ns

Values are given as mean + standard deviation (SD); ns = not significant

had the TVT-Abbrevo procedure (TVT Abbrevo group). Their progress through the trial is shown in Fig. 1. One hundred fifty-five were examined at 12-month follow-up, while 18 patients did not return for the 3-year follow-up, 8 patients were lost (4 in the TVT-O group and 4 in the TVT Abbrevo group), and 10 patients withdrew (5 in the TVT-O group and 5 in the TVT Abbrevo group). At 36-month follow-up two patients withdrew (one in the TVT-O group and one in the TVT Abbrevo group). Median follow-up was 39.7 months (range: 36–51).

Patient characteristics are shown in Table 1 and appear well balanced between the treatment groups after randomization.

The two groups did not differ significantly in operative time (minutes) (17.5 + 4.6 in the TVT-O group and 15.8 + 5.8 in the TVT Abbrevo, respectively), intraoperative blood loss (ml) (32.5 + 15.6 in the TVT-O group and 26.8 + 18.8 in the TVT Abbrevo, respectively), length of hospital stay (days) (1.9 + 0.6 in the TVT-O group and 1.8 + 0.9 in the TVT

Abbrevo, respectively) and time to return to normal activities (days) (2.9 + 2.6 in the TVT-O group and 2.4 + 2.8 in the TVT Abbrevo, respectively). None of the patients had intraoperative complications.

The postoperative complications are shown in Table 2. Nine patients (11%) had postoperative groin pain in the TVT-O group and one patient in the TVT Abbrevo group (p = 0.02). Groin pain resolved in all patients within 12 weeks with analgesic therapy.

Overall, 138 of 158 patients (87%) were objectively cured of SUI 36 months after the operation with no significant differences found between groups [69 (87%) and 69 (87%) patients for the TVT-O and TVT Abbrevo groups, respectively]. Urodynamic studies 3 years postoperatively demonstrated an equal objective cure rate in both groups (Table 3), although they were lower compared with the subjective cure rate (ICIQ-SF-UI). The ICIQ-SF-UI score was reduced equally in both groups compared with baseline values (preoperative value

Table 2Postoperativecomplications in 158 patients

Variables	TVT-O group	TVT Abbrevo group	р
	(79 patients)	(79 patients)	
Fever, <i>n</i>	1 (1%)	0	ns
Urinary tract infection, n	2 (2%)	3 (4%)	ns
Deep vein thrombosis, <i>n</i>	0	0	ns
Urinary retention for up to 7 days, n	1 (1%)	0	ns
Tape exposure, <i>n</i>	1 (1%)	2 (2%)	ns
Dyspareunia, n*	2 (3%)	1 (2%)	ns
De novo urgency	2 (2%)	2 (2%)	ns
De novo SUI	4 (5%)	4 (5%)	ns
Groin pain, <i>n</i>	9 (11%)	1 (1%)	0.02
Chronic pain**	1 (1%)	0	ns

SUI = stress urinary incontinence; ns: not significant

\*Dyspareunia "de novo" evaluated in sexually active patients after surgery

59 patients in the TVT-O group; 56 patients in the TVT Abbrevo group

The analyzed patients did not have dyspununia before surgery

\*\*Chronic pain: was defined as presence of pain requiring analgesic therapy still 6 weeks after surgery

## Table 3 Results at 36-month follow-up

Tuble 5 Results at 50 month follow up					
TVT-O group Objective cure, <i>n</i> *	n 69 (87%)	p ns	TVT Abbrevo group Objective cure, $n^*$	n 69 (87%)	p ns
Subjective cure (ICIQ-UI-SF), <i>n</i> **			Subjective cure (ICIQ-UI-SF), n**		
Question 3:" How often do you leak urine?"			Question 3:" How often do you leak urine?"		
Never, <i>n</i>	66 (94%)	ns	Never, <i>n</i>	66 (94%)	ns
About once a week or less often, n	2 (3%)	ns	About once a week or less often, $n$	2 (3%)	ns
Two or three times a week, $n$	2 (3%)	ns	Two or three times a week, n	1 (1%)	ns
Once daily, <i>n</i>	1 (1%)	ns	Once daily, n	2 (3%)	ns
Several times a day, n	0	ns	Several times a day, n	0	ns
All the time, <i>n</i>	0	ns	All the time, <i>n</i>	0	ns
TOT patients	71		TOT patients	71	
ICIQ score sum (questions 3–5), mean + SD	2.4 + 1.6	ns	ICIQ score sum (questions 3–5), mean + SD	27 + 1.8	ns

ns: not significant

\*Patients lost to 36-month follow-up (8 patients) were evaluated as failure

\*\*71 patients for both groups

7.8 + 4.8 vs. 3-year value 2.4 + 1.6 in the TVT-O group, p < 0.01; preoperative value 7.7 + 3.9 vs. 3-year value 2.7 + 1.8 in the TVT Abbrevo group, p < 0.01 (Table 3).

There was no significant difference in OAB symptoms between groups at the 36-month follow-up visit [5 (7%) and 3 (4%) patients for TVT-O and TVT Abbrevo groups, respectively] and for the urodynamic data between groups and within groups from baseline to the 36-month follow-up. No sling erosion was observed, and one patient in the TVT-O and two patients in the TVT Abbrevo group, respectively, expierenced a tape exposure.

The PGI-I declined similarly in both groups without any difference between the groups at the 3-year follow-up (Table 4).

One hundred fifteen patients (73%) were sexually active at the time of enrolment and 99 (total 142 patients, 70%) were sexually active at the 3-year postoperative visit. Five of the seven women who ceased sexual intercourse after the procedure did so because of partner-related issues. Three patients who were not sexually active before surgery became sexually active postoperatively. Table 5 summarizes the data in both groups. There was a significant improvement in total PISQ-12 scores in both groups. There were no differences between the two groups at baseline or 3 years after surgery, so we combined both groups for further comparisons. The analysis of the dichotomized responses to individual questions in the physical domain shows some interesting trends, which in some cases reached statistical significance (Table 5).

A sensitivity analysis was performed to explore the effect of different assumptions about withdrawals and lost patients: no differences were found.

# Discussion

This randomized trial seems to indicate that TVT-Abbrevo was as effective as TVT-O.

Variables	TVT-O group			TVT Abbrevo	group		р
	12 months (78 pts)	24 months (73 pts)	36 months (70 pts)	12 months (77 pts)	24 months (72 pts)	36 months (70 pts)	
Significantly improved, n	75 (96%)	71 (97%)	69 (99%)	73 (95%)	71 (90%)	69 (87%)	ns
Much improved, n	2 (3%)	1 (1.5%)	0	1 (1%)	1 (1%)	1 (1%)	ns
Some improvement, n	1(1%)	1 (1.5%)	1 (1%)	2 (3%)	0	0	ns
Unchanged, n	0	0	0	1 (1%)	0	0	ns
Slightly worse, n	0	0	0	0	0	0	ns
Worse, n	0	0	0	0	0	0	ns
Much worse, <i>n</i>	0	0	0	0	0	0	ns

Table 4 Comparisons of scores obtained from the PGI-I questionnaire at 12, 24 and 36-month follow-up

ns: not significant

TVT-O group	Baseline	36 months	d	TVT Abbrevo group	Baseline	36 months	d
PISO-12 total score, mean + SD Baseline-59 pts	31.5+6.3	38.4 + 4.2	< 0.01	PISQ-12 total score, mean + SD Baseline-56 pts	32.6+7.3	40.5.4 + 5.5	< 0.01
36 months FU-51 pts Pain during intercourse-PISQ12-question #5 Baseline-59 pts	13 (22%)	13 (25%)	us	36 months FU-48 pts Pain during intercourse-PISQ12-question #5 Baseline-56 pts	13 (23%)	12 (24%)	us
36 months FU-51 pts Urine incontinence during sex PISQ12-question #6 Baseline-50 we	51 (86%)	3 (6%)	< 0.01	36 months FU-48 pts Urine incontinence during sex PISQ12-question #6 Baseline-56 arts	47 (84%)	3 (7%)	< 0.01
36 months FU-51 pts Hear of incontinence restrict sexual activity PISQ12-question #7	41 (69%)	2 (4%)	<0.01	36 months FU-48 pts Fear of incontinence restrict sexual activity PISQ12-question #7	40 (71%)	1 (3%)	< 0.01
Baseline-59 pts 36 months FU-51 pts				Baseline-56 pts 36 months FU-48 pts			

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The most appropriate technique for the surgical treatment of SUI depends on both the degree and type of incontinence and the characteristics of the treated patients [18-22].

To improve the quality of life and sexual function of patients we must try to use the less least invasive techniques. However, it is also important to achieve the desired effectiveness and improve the symptomatology [23]. In fact, some minislings have been withdrawn from the market because of the lack of proven effectiveness compared with the classic sling [5]. Therefore, finding the right compromise between length and effectiveness is the way forward to improve the quality of life of patients. TVT-Abbrevo is an inside-out transobturator tape only 12 cm long, significantly shorter than the traditional TVT-O (19 cm of tape left in the patient's body) [24, 25].

This tape was created to eliminate the amount of foreign material and finally deal with the problem of groin pain. The groin pain may depend on possible neuro-muscular injuries, and the presence of the tape is believed to be one of the reasons for this pain. However, no contact with the obturator nerve or its branches was noted in any case reported in the literature. Furthermore, no injury to the urinary bladder or major vessels was noted in the series of patients that underwent TVT-Abbrevo [26].

Other authors compared the classic TVT-O with the new TVT-A reporting similar success rates and no intraoperative complications [26]. In our study, however, there was also a long-term analysis of sexual function and satisfaction of treated patients.

The present study confirms the high continence rates achieved by these procedures at a medium-term follow-up (objective cure: 87% TVT Abbrevo vs. 87% TVT-O). Furthermore, our data confirm that the mean operative time, intraoperative blood loss, length of hospital stay and time to return to normal activities were equivalent in both groups with no intraoperative complications. This randomized trial seems to indicate that TVT-Abbrevo was as effective as TVT-O, both objectively and subjectively, in patients with primary SUI due to urethral hypermobility and not for pure sphincter deficiency.

This study showed that TVT-Abbrevo is also a safe procedure, with no significant intra- and postoperative complications. In particular, no vaginal erosions were observed, but only one and two patients respectively experienced a tape exposure. De novo OAB symptom rate was limited in accordance with previous studies on TVT-O [27, 28]. Overweight does not seem to be a risk factor for intraoperative and shortterm complications. A longer follow-up is needed to assess whether a higher BMI might be a risk factor for longer term complications.Persistence of groin pain beyond the immediate postoperative period is a concern in TVT-O. In a retrospective study on TVT-O, groin pain was found to have persisted for up to 6 months in 3.6% of patients [20]. In contrast,

randomized clinical trials with TVT-Abbrevo have reported low rates of groin pain [14].

In our study, postoperative groin or thigh pain was 0% at 6 months at 2 and 3 years of follow-up, while 1.9% at 1 year. The positive impact that the anti-incontinence surgery has on the patients' sexual life is already known as it reduces the fear of coital incontinence [29, 30]. The last metanalysis showed no difference between the TOT and TVT for sexual function after surgery, because there was insufficient evidence to state the difference [5, 29]. Our data demonstrate a significant improvement in sexual function and quality of life measured by the ICIQ-UI-SF and PISQ-12 questionnaires in patients who underwent both techniques without differences between them. This could demonstrate that the impact of different surgical techniques does not affect the improvement that exists when urinary loss is resolved. Moreover, patient satisfaction at the median follow-up is excellent for both methods. In conclusion, the modified and shortened inside-out transobturator Abbrevo seems to have similar efficacy and safety compared with TVT-O in women with SUI.

Using a shorter sling could help to reduce the rate of groin pain associated with TVT-O. On the other hand, it is necessary to make a correct selection of the patient and to decide which is the best sling to use to increase effectiveness and improve quality of life by decreasing complications. More prospective studies are needed to assess the long-term efficacy and safety in normal-weight and obese women.

#### **Compliance with ethical standards**

Conflicts of interest None.

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