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ORIGINAL CLINICAL ARTICLE

TVT-O for treatment of pure urodynamic stress urinary incontinence: Efficacy and adverse effects at 13-years follow-up

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Abstract

Aim: To assess the efficacy and safety of tension-free vaginal tape-obturator (TVT-O) 13 years after implantation for the treatment of female pure stress urinary incontinence (SUI). This is the longest-term evaluation available of TVT-O outcomes.

Methods: A multicenter, prospective study was conducted in five tertiary referral centers in three countries. All consecutive women with urodynamically proven pure SUI treated by TVT-O were included. Data regarding subjective outcomes (International Consultation on Incontinence Questionnaire-Short Form, Patient Global Impression of Improvement, and patient satisfaction scores), objective cure (stress test) rates, and adverse events were collected during follow-up. Univariable and multivariate analyses was performed to investigate outcomes.

Results: One hundred sixty-eight women had TVT-O implantation. At 13 year after surgery, 150 of 157 patients (95%) declared themselves cured ($P = .8$). Similarly, at 10-year evaluation, 148 of 160 patients (92%) were objectively cured. No significant deterioration of objective cure rates was observed over time ($P = .1$). The multivariate analysis showed that previous anti-incontinence procedures and obesity independently predicted the subjective (odd ratio [OR]: 6.2 [95% confidence interval [CI], 1.8-13.6]; $P = .02$ and OR, 1.8 [95% CI, 1.3-3.0]; $P = .03$, respectively) and objective failure of TVT-O (OR, 5.8 [95% CI, 1.6-13.2]; $P = .02$ and OR, 1.6 [95% CI, 1.2-3.2]; $P = .03$, respectively). We found four cases of sling exposure; all of them occurred after the 10-year follow-up.

Conclusions: The 13-year results of this study showed that TVT-O is a highly effective and safe option for the treatment of SUI. We found that there is a significantly higher risk of having a sling exposure over 10 years after the procedure; however, the incidence is very low.

KEYWORDS
long-term follow-up, sling, stress urinary incontinence, tension-free vaginal tape-obturator, TVT-O, urinary incontinence

1 | INTRODUCTION

In the last years, there is public concern about the use of surgical mesh procedures for stress urinary incontinence (SUI). The recent NICE guidelines on management of female urinary incontinence and pelvic organ prolapse,[1] state that if a woman is thinking about a surgical procedure for SUI, colposuspension (open or laparoscopic), autologous rectus fascial slings, intramural bulking agents, and retropubic midurethral sling (R-MUS), must be offered. Surprisingly, transobturator midurethral slings (TO-MUS), are not included in these recommendations, as first-line option for SUI treatment, nevertheless it has been widely demonstrated that these surgical procedures are effective and safe for the management of SUI, compared with other techniques.[2,3] The reason of this exclusion, is the higher rate of tape exposure after TO-MUS than after R-MUS, reported in the ESTER systematic review study (two studies, 60-95 months post-surgery assessment: 12 out of 140 [8.6%] vs 4 out of 145 (2.8%); odd ration [OR] 3.25, 95% confidence interval [CI], 1.02-10.36),[4] while the rate of tape/mesh erosion or extrusion between the two surgical procedures, are similar (27 studies: 53 out of 2225 [2.4%] vs 48 out of 2298 [2.1%]; OR, 1.10, 95% CI, 0.70-1.70). However, the same authors highlighted that few data are available for the assessment of tape or mesh exposure, due to unclear distinction between the terms "extrusion" and "exposure" in the studies that assessed these outcomes. Furthermore, it has been demonstrated that in a long-term period, the rate of mesh sling removal, among women undergoing MUS insertion, is low, estimated as 3.3% at 9 years after the procedure; this removal rate seems to be lower in case of TO-MUS.[5] In addition, many studies supported the use of TO-MUS, showing that transobturator insertion gives equivalent patient-reported and clinician-reported cure rates at short- and medium-term follow-up, compared with retropubic insertion.[6-8] The long-lasting benefits of transobturator route needed to be addressed, although recent studies with over 10 years follow-up, reported excellent results in term of efficacy and safety.[9,10] The aim of the present prospective, multicenter study is to report, for the first time in the available literature, objective and subjective outcomes of women implanted with tension-free vaginal tape-obturator (TVT-O) for pure SUI, at 13-years follow-up, to assess the long-term efficacy, and the safety of this procedure. We carefully studied in particular the incidence over the time of sling exposure.

2 | MATERIALS AND METHODS

As previously described,[9] this was a multicenter, prospective evaluation in five tertiary reference centers in three countries. From January 2004, we have enrolled all consecutive women who complained of pure SUI symptoms with urodynamically proven urodynamic stress incontinence (USI). All patients recommended for surgery were scheduled for a TVT-O procedure (Gynecare TVT Obturator System; Ethicon Inc, Somerville, NJ). Exclusion criteria were as follows: women with previous history of radical pelvic surgery, psychiatric and neurologic disorders, concomitant vaginal prolapse greater than stage 1 according to the pelvic organ prolapse quantification (POP-Q) system,[11] Overactive bladder (OAB) symptoms, urodynamically proven detrusor overactivity, women ith age less than 40 years, women with voiding dysfunction, and postvoid residual more than 100 mL.[12] Preoperative evaluation included medical history, physical examination, a voiding diary, urinalysis, and complete urodynamic testing. Physical examination was performed with the patient in the lithotomy position and POP was described during a maximal Valsalva maneuver according to the POP-Q system.[11] All women were evaluated with urodynamic studies as previously described[13] (including uroflowmetry, filling cystometry, Valsalva leak-point pressure [VLPP] measurement, and pressure/flow study) by a trained urogynecologist, using a standardized protocol in accordance with the good urodynamic practice guidelines of the International Continence Society.[14] Urethral hypermobility was defined by a Q-tip test greater than 30°. Patients were included regardless of Q-tip test and VLPP values. All methods, definitions, and units were updated in agreement with the last version of the International Continence Society standardization of terminology.[15] All patients also completed the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) questionnaire.[16] All the TVT-O procedures were performed according to the technique originally described by de Leval.[17] General or spinal anesthesia was used in accordance with the anesthesiologic requirements and/or the patient's preference, as previously reported.[18] Postoperative evaluations were mandatory at 12-month, 60-month, 120-month, and 156-month in all centers and intermediate visits were scheduled at the physician's discretion. Every follow-up visit included medical history, physical examination, voiding diary, stress test, and evaluation of subjective satisfaction. A stress test was performed in the lithotomy and upright positions with a full bladder (ultrasonographic measurement 400 mL). Objective cure was defined as the absence of urine leakage during the stress test. To define the subjective outcomes at 1, 5, 10, and 13 years, all patients completed the ICIQ-SF, the Patient Global Impression of Improvement (PGI-I) Scale (a 7-point scale, with a range of responses from 1, "very much improved," to 7, "very much worse"),[19] and a Patient-satisfaction scale (a single, self-answered, Likert-type scale of 0-10 that grades the patient's degree of satisfaction regarding continence: 0 represents "not satisfied," and 10 "satisfied").[20] Subjective success was indicated both by "very much improved or

much improved" (PGI-I ≤ 2) and by a patient-satisfaction score greater or equal to 8, as previously described in 2011 by Abdel-Fattah et al.[21] The Declaration of Helsinki was followed, and preoperative written informed consent for TVT-O implantation was obtained from all patients in this observational prospective evaluation.

2.1 | Statistical analysis

Statistical analysis was performed with IBM-SPSS v17 for Windows (IBM Corp, Armonk, NY). Continuous variables were reported as median and interquartile range. We used the χ^2 test and χ^2 test for trend to analyze and compare the surgical outcomes during the follow-up. The χ^2 test for trend can better assess if the success of the surgical procedure tends to decrease over time, comparing the cure rates at the different follow-up visits (1, 5, 10, and 13 years). The null hypothesis is that there is not an association between the cure rate of TVT-O and the time. One-way analysis of variance was used to compare continuous series of variables in the comparison of the scores used to measure the subjective outcomes. The Cox proportional hazards model was used for univariate analysis to evaluate factors potentially affecting the risk of recurrence (subjective or objective) during the study period. Multiple logistic regression was performed to identify factors involved in the risk of recurrence of SUI. The multivariate model included those variables that achieve significance ($P < .05$) or association ($P \leq .10$) in the univariate analysis. Statistical significance was considered achieved when $P < .05$.

3 | RESULTS

As previously described, 168 women assessed for SUI at the five tertiary referral centers who fulfilled the inclusion criteria had TVT-O implantation. Figure 1 displays the study's flowchart. The baseline characteristics of the study group have been previously summarized. At 13-year follow-up, 157 patients (93%) were available for the evaluation and 11 patients (7%) were lost to follow-up or were no longer evaluable. Eight of these 11 women were subjectively cured at their last evaluation. Subjective and objective cure rates are summarized in Tables 1 and 2. These data do not show any significant change of the surgical outcomes over the follow-up period. In fact, 13 years after the surgery, 150 of 157 patients (95%) declared themselves cured ($P = .8$). Long-term data showed similar findings even assuming all missing data (withdrawals and lost to follow-up) as failures or as cured. Similar to the subjective outcomes, at the 13-year evaluation, 141 of 157 women (90%) were objectively cured. No significant deterioration of objective cure rates was observed over time ($P = .1$). Only three patients required a second surgical procedure (retropubic sling in two cases and a bulking agent in the other case). Table 3 reports univariate analysis of factors potentially involved in the risk of recurrent subjective and objective USI during the study period. Similarly to the 10-year follow-up, previous anti-incontinence procedures were significantly associated with subjective recurrent SUI in the univariate analyses ($P < .05$); moreover, at 13-year follow-up, also obesity was associated to a higher risk of recurrence. The multivariate analysis confirmed these findings; previous anti-incontinence procedures and obesity independently predicted the subjective (OR: 6.2 [95% CI, 1.8-13.6]; $P = .02$ and OR, 1.8 [95% CI, 1.3-3.0]; $P = .03$, respectively) and objective failure of TVT-O (OR, 5.8 [95% CI, 1.6-13.2]; $P = .02$ and OR, 1.6 [95% CI, 1.2-3.2]; $P = .03$, respectively). Table 4 summarizes the Clavien-Dindo classification of long-term or long-lasting complications of TVT-O. The onset of de novo OAB symptoms was reported by 25 of 157 patients (16%) at 13-year follow-up. Ten of these 25 patients (40%) were cases of wet OAB. During the last visit, only two patients reported persistent voiding difficulties, but both women did not need any treatment. We found four cases (2.5%) of tape exposure at 13-year follow-up visit. All these patients were symptomatic for dyspareunia and "hispareunia."[22,23] In these patients, we partially removed

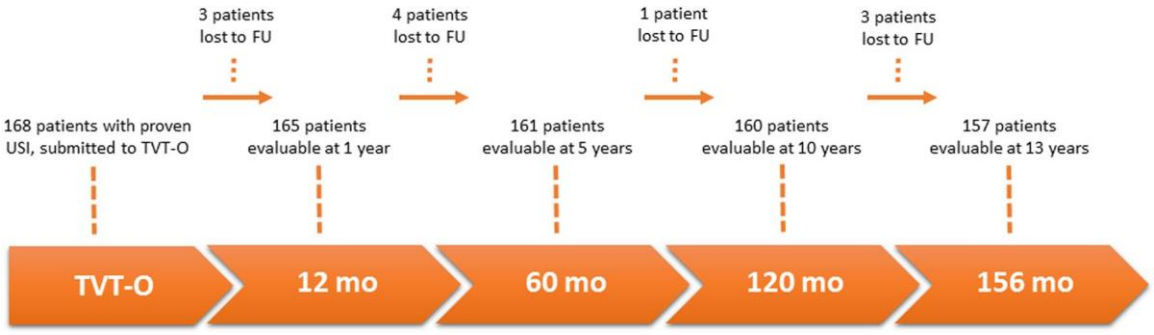

FIGURE 1 Progress of patients across the study period. FU, follow-up; TVT-O, tension-free vaginal tape-obturator; USI, urodynamic stress incontinence

TABLE 1 Cure rates at 1-year, 5-year, 10-year, and 13-year follow-up visit

	1y	5 y	10 y	13y	*P* value
Objective outcomes					
Women objectively cured with data available at 1, 5, 10, and 13, y	157/165 95%	149/161 91%	148/160 92%	141/157 90%	.34[a] .10[b]
Assuming all missing data (withdrawals and lost to follow-up) are failures	157/168 93%			141/168 84%	.31[a]
Assuming all missing data (withdrawals and lost to follow-up) are cured	160/168 95%			158/168 94%	.80[a]
Subjective outcomes					
Women subjectively cured with data available at 1, 5, 10, and 13, y	157/165 95%	155/161 95%	155/160 97%	150/157 95%	0.86[a] 0.78[b]
Assuming all missing data (withdrawals and lost to follow-up) are failures	157/168 93%			150/168 89%	0.24[a]
Assuming all missing data (withdrawals and lost to follow-up) are cured	160/168 95%			158/168 94%	0.80[a]

[a]χ^2 test.
[b]χ^2 test for trend.

the exposed sling and we resuture the vagina. In all cases women referred a complete resolution of the symptoms without any worsening of the urinary continence. No significant POP or bladder, or urethral erosion was registered in our study population. One patient noted persistent mild groin pain at 13-year follow-up with a visual analog scale score of 2 of 10, not requiring analgesic treatment. Four of 91 sexually active patients (4.4%) noted dyspareunia (without sling exposure) at 13 year, when asked whether they feel pain during intercourse. In these cases, we prescribed a local estrogenic treatment.

4 | DISCUSSION

This report is so far the longest follow-up study available in literature, on the evaluation of subjective and objective outcomes of the TVT-O procedure for treatment of female SUI. We found that TVT-O is a highly effective and safe procedure. The 13-year objective and subjective cure rates were found in 90% and 95% of patients, respectively, showing that TVT-O has long-lasting effectiveness. Moreover, for the first time in the available literature, we found that there is a low, but significantly higher, risk of having a sling exposure over 10 years after the procedure.

After the warning issued by the US Food and Drug Administration in April 2019, which orders at the manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse to stop selling all devices, also the use of mesh intended for treatment of SUI has been widely questioned, especially transobturator mesh midurethral slings. The recent NICE guidelines on management of female urinary incontinence and pelvic organ prolapse,[1] excluded transobturator route from available options for treatment of SUI, while colposuspension (open or laparoscopic), autologous rectus fascial slings, intramural bulking agents, and retropubic midurethral sling, could be offered. The reason of this statement, is that TO-MUS presented a higher rate of mesh exposure than R-MUS (OR, 3.25, 95% CI, 1.02-10.36), as reported in the ESTER

TABLE 2 Subjective outcomes scores over time after tension-free vaginal tape-obturator

	Baseline	5 y	10 y	13 y	*P* value
ICIQ-SF, median (IQR)	17 (16-17)	0 (0-2)	0 (0-2)	0(0-2)	<.0001*
"Very much better" or "much better" on PGI-I, number/total number (%)		155/168 (92%)	155/168 (92%)	150/168 (89%)	.53[a] .33[b]
Patient Satisfaction Scale, median (IQR)		10 (8-10)	10 (8-10)	10 (8-10)	

Abbreviations: ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; IQR, interquartile range; PGI-I, Patient Global Impression of Improvement.
*One-way analysis of variance.
[a]χ^2 test.
[b]χ^2 test for trend.

TABLE 3 Univariable analysis of variables potentially involved in the risk of failure of TVT-O at 13 year

	Subjective failure Univariable analysis[a]		Objective failure Univariable analysis[a]	
Variable	Hazard ratio (95% CI)	*P* value	Hazard ratio (95% CI)	*P* value
Elderly (age ≥ 65 y)	0.41 (0.23-1.14)	.13	2.12 (0.84-5.73)	.2
Obese (BMI ≥ 30 kg/m²)	**2.01 (1.13-5.12)**	**.03**	**1.93 (1.02-3.61)**	**.04**
Number vaginal deliveries (N ≥ 2)	0.42 (0.11-1.23)	.3	0.80 (0.31-2.34)	.8
Macrosome (≥4000 g)	0.71 (0.15-3.14)	.6	0.63 (0.12-2.83)	.5
Operative delivery	2.12 (0.63-7.62)	.2	0.53 (0.07-3.91)	.6
Cesarean section	0.04 (0.01-75.6)	.5	0.04 (0.01-41.4)	.3
Menopausal	0.33 (0.03-1.70)	.17	2.92 (0.34-4.33)	.4
HRT	1.55 (0.52-4.31)	.4	1.33 (0.43-3.82)	.7
Recurrent UTI	1.46 (0.45-4.20)	.5	1.59 (0.50-4.63)	.5
Smoking habits	0.57 (0.14-1.63)	.2	1.12 (0.83- 7.21)	.14
Previous anti-incontinence procedures	**5.34 (2.61-11.9)**	**.009**	**2.74 (1.64-10.7)**	**.01**
Surgeon's skill (resident vs expert)	0.29 (0.06-3.33)	.4	0.52 (0.06-3.50)	.5
Urethral hypermobility (Q-tip > 30°)	1.32 (0.24-10.23)	.8	1.41 (0.03-2.12)	.3
VLPP < 60 cmH_2O	1.31 (0.31-5.81)	.7	2.62 (0.81-3.42)	.09

Note: Bold numbers indicate the significant risk factors for recurrent SUI at univariate analysis.
BMI, body mass index; CI, confidence interval; HRT, hormone replacement therapy; TVT-O, tension-free vaginal tape-obturator; UTI, urinary tract infection; VLPP, Valsalva leak-point pressure
[a]Univariate Cox proportional hazard model.

systematic review.[4] However, is not so clear the distinction between the terms "extrusion" and "exposure" in the few studies that assessed these outcomes, whereas the rate of tape/mesh erosion or extrusion are similar for both procedures (OR, 1.10, 95% CI, 0.70-1.70). In fact this review concluded that, cure and improvement rates for R-MUS, TO-MUS, and traditional sling were generally better than other surgical procedures, although associated with some uncertainty and a lack of long-term data. Morling et al[24] in a large cohort study of 13 133 women undergoing a first, single incontinence procedure with mesh, showed that compared with nonmesh open surgery (colposuspension), mesh procedures had a lower risk of immediate complications (adjusted relative risk [aRR] 0·44 [95% CI, 0·36-0·55]) and subsequent prolapse surgery (adjusted incidence rate ratio 0.30 [0.24-0.39]), and a similar risk of

TABLE 4 Clavien-Dindo classification of long-term complications

Complication	N = 157	Action
CLAVIEN I		
Persistence of groin pain no (%)	1 (0.6%)	Observation
Persistence of voiding dysfunction	2 (1.3%)	Observation
CLAVIEN II		
De novo overactive bladder, no. (%)	25 (15.6%)	Antimuscarinics
De novo dyspareunia, no. (%)	4/91* (4.4%)	Local estrogenic therapy
CLAVIEN IIIa		
Tape exposure, no. (%)	4 (2.5%)	Partial removal and resuture

Note: Data are expressed as absolute number (%).
*Patients sexually active at 13 y.

further incontinence surgery (0.90 [0.73-1.11]) and later complications (1.12 [0.98-1.27]). Also Gurol-Urganci et al[5] in a retrospective cohort study of 95 057 women (60 194 women underwent retropubic insertion and 34 863 underwent transobturator insertion), examined long-term mesh removal and reoperation rates in women who had a first midurethral mesh sling insertion for SUI. The rate of midurethral mesh sling removal was 1.4% (95% CI, 1.3-1.4) at 1 year, 2.7% (95% CI, 2.6-2.8) at 5 years, and 3.3% (95% CI, 3.2-3.4) at 9 years. The 9-year removal risk after transobturator insertion (2.7% [95% CI, 2.4-2.9]) was lower than the risk after retropubic insertion (3.6% [95% CI, 3.5-3.8]; subdistribution hazard ratio, 0.72 [95% CI, 0.62-0.84]). The rate of reoperation for stress urinary incontinence was 1.3% (95% CI, 1.3-1.4) at 1 year, 3.5% (95% CI, 3.4-3.6) at 5 years, and 4.5% (95% CI, 4.3-4.7) at 9 years. In our study we found four cases of sling exposure (2.5%); this percentage was not too different than the rate of exposure reported by Gurol-Uranci et al.[5] All these exposures seemed to appear during the period between the 10-year control and the 13-year follow-up. It seems that there is a border-line significant increase ($P = .05$) of the incidence of sling exposure over 10 years after the sling; however, this rate is very low, even not negligible, the symptoms very slight and the resolution is easy to obtain, also without the complete removal of the sling. At the contrary it is evident that there is no worsening of objective and subjective outcomes after TVT-O procedures, even with a very long follow-up. These data confirm that is possible to consider TVT-O the gold standard for surgical treatment of SUI, with the highest efficacy and lowest complication rates. For this reason, we did not offer other surgical options at the patients included in the study.

However, 13 years is not long-enough for someone who is 30 years old when complications can arise at 15 or 20 years later. Further studies that support TVT-O long-term efficacy and safety, are needed. It may be interesting to highlight that, also 13 years after the surgical intervention, the history of previous failed anti-incontinence procedures remains an independent risk factor associated with a higher recurrence rate. Moreover, at the 13-year follow-up evaluation, obesity can also become independently related to the risk of late recurrence of SUI. We can hypothesize that in case of treatment of recurrent USI, we have to consider the use of the retropubic approach. Obesity, on the other hand, on the basis of our data, can be a risk factor for a higher recurrence rate in case of both a retropubic[12] and a transobturator approach.

Points of strength of this study are the following: (a) it was a multicenter study; (b) it used a highly homogeneous study population with the rigorous exclusion and inclusion criteria; (c) the subjective and objective outcomes were obtained using validated tools; and (d) the rate of loss to follow-up was very low. Conversely, we acknowledge that a limitation of this study could be that formal, validated quality-of-life questionnaires were not used because unfortunately, no validated quality-of-life questionnaire exists in Italian. Another limitation of the study, is that it focuses on objective and patient-reported outcomes, but no specific data about pain scores, inflammatory conditions, autoimmune disorders, and so forth were collected.

The last possible criticism could be that we did not offer other surgical options; such as retropubic tension-free vaginal tape, although we were experts in carrying out on this procedure.[25] However, despite we did not have long-term data on safety and efficacy of TVT-O, we proposed it, to reduce the complications due to retropubic route.

5 | CONCLUSIONS

The 13-year assessment demonstrated that TVT-O is a highly effective and safe option for the treatment of female SUI. The objective and subjective cure rates were very high and long-lasting. The risk of short-, medium-, and long-term complications, and of tape exposure, in particular, is low, but there is relevant increase of this complication over 10 years after the procedure.

AUTHOR CONTRIBUTIONS

MS assisted in protocol/project development, data collection, statistical analysis, and manuscript writing. AB helped in protocol/project development, data collection, and manuscript writing. GC, MT, SS, and SA done the data collection and critical revision. FG conducted the critical revision.

CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

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