Sonographic tape characteristics and outcome after tape anti-incontinence surgery: a cross-sectional study

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ABSTRACT

Background: Ultrasound (US) is an easy-to-perform imaging modality that allows in vivo evaluation of the tension free-vaginal tape obturator (TVT-O).

Aim: To investigate the position and shape of TVT-O using US, in order to correlate the findings to outcome.

Methods: Our cross-sectional study is based on the data obtained from 46 women with stress urinary incontinence (SUI) who underwent TVT-O insertion at a tertiary hospital between January 2015 and December 2016. These patients underwent a postoperative examination in 2020 (5 years after TVT-O). Patients who had undergone reoperation were excluded. The main outcome parameters were patient's symptoms, US measurements and dynamic changes in TVT-O shape at rest and during straining. A descriptive and comparative (bi- and multivariant) statistical analysis was performed by Stata v14.0.

Results: At five years, 76% (35/46) were continent, 17.4% (8/46) improved and 6.5% (3/46) were failures. The tape was stretched at rest and C-shaped during straining in 27 (58.7%) patients; 92.6% (25/27) of these women were continent after surgery. An unchanged tape shape was associated with a more failures. Patients with a stretched tape at rest and during straining failed in 57.7% and patients with a permanent curved shape in 42.3%.

SUI was most accurately predicted using a multiple linear regression model based on the independent variables: age, bladder wall thickness, distance of the tape from the bladder neck and study groups according to Kociszewski criteria.

Conclusions: Outcome was best in women in whom US demonstrated the elastic sling to lie parallel to the urethra at rest and assumed a transient C-shape during straining. However, other US measures could predict patient satisfaction or subjective cure/improvement.

KEYWORDS

Tension free-vaginal tape obturator, ultrasound, stress urinary incontinence.

Introduction

Stress urinary incontinence (SUI) affects up to 25% of women and can severely impact quality of life (QoL) [1,2]. Although pelvic floor muscle therapy is recommended for SUI as first line therapy, it has been shown to be inferior to mid-urethral tape surgery, which is the mainstay surgical treatment for SUI [3].

Mid-urethral tapes can be placed in a retropubic or transobturator position. While tension free-vaginal tape obturator (TVT-O) have a higher risk of repeat surgery, retropubic tapes are associated with a higher incidence of bladder injuries and postoperative voiding difficulties [4,5]. Despite this, studies that indicate satisfactory and stable long-term results and improved QoL with both the retropubic and the transobturator TVT [6].

Sonographic evaluation of the lower urinary tract has become an established component of the urogynecologic diagnostic workup of women presenting with urinary incontinence. Perineal or introital sonography can readily image sub-urethral tapes and may provide insights into the mechanisms of successful or unsuccessful outcomes [7-11].

Kociszewski et al. correlated the shape of the mesh with the existence of tension: a flat mesh indicates no tension, while a C shaped mesh does. Visualization of the C-shaped mesh at rest is correlated with an increase of symptoms of obstruction [8,9]. The aim of the present study was to summarize mid-term data on the relevance of the sonographically determined tape position and changes in TVT-O shape for the outcome of surgery.

Article history
Received 5 Aug 2022 - Accepted 12 Dec 2022

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Material and methods

Our cross-sectional study is based on the data obtained from 46 women with clinical SUI, proved by urodynamic testing, who underwent TVT-O insertion at the Department of Urogynecology of Hospital Parc Taulí (Spain) between January 2015 and December 2016 using the standard technique [12,13].

Two patients who had undergone reoperation were excluded. Two examinators, who had not operated on the patients, performed the follow-up examinations. The study protocol was approved by the local ethical committee of the participating institutions and all patients gave written consent.

The patients underwent a postoperative examination in 2020 (5 years after TVT-O). The follow-up examination included a relevant clinical history and evaluation of subjective and objective outcomes [14]. Subjective outcome was assessed with a standardized and validated questionnaire (International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form - ICIQ-UI SF) [15].

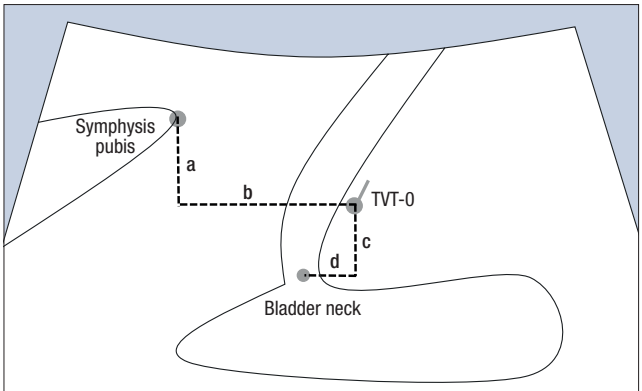
Standardized introital ultrasound was performed using a *General Electric Voluson E8*. Ultrasound examinations were performed by two examinators who had not operated the women themselves. In addition, parallel measurements were performed to exclude systematic errors. Patients were examined after emptying the bladder in a semi-supine position with the probe placed on the labia minora in a sagittal plane. Images were taken in the median sagittal plane and included the pubic symphysis, urethra, bladder, vagina, anal canal, rectum and the lowermost part of the levator ani muscle [16]. The following parameters were analyzed: the residual urine test (using Dietz's formula which uses the sagittal plane and a single conversion factor: $X \times Y \times 5.6$, where X and Y are the height and depth of the bladder content) [17], the tape's width and the bladder wall thickness.

The sub-urethral tape was identified as a hyperechoic structure and the position of the tape was measured in relation to the bladder neck and in relation to the pubic symphysis, both at rest and during Valsalva maneuver. Coordinates were obtained in a craniocaudal and dorsoventral direction. Figure 1 illustrates the eight measurements taken between the pubic symphysis, cranial tape margin and bladder neck (Dietz's distances): craniocaudal distance between tape and pubic symphysis pubis at rest, dorsoventral distance between tape and pubic symphysis at rest, craniocaudal distance between tape and bladder neck at rest, dorsoventral distance between tape and bladder neck at rest, craniocaudal distance between tape and pubic symphysis on Valsalva, dorsoventral distance between tape and pubic symphysis on Valsalva, craniocaudal distance between tape and bladder neck at Valsalva and dorsoventral distance between tape and bladder neck at Valsalva (Figure 1) [17-19].

Kociszewski *et al*. described changes in tape shape (tape functionality) during Valsalva maneuver. At rest, the hyperechoic TVT-O lies parallel to the hypoechoic urethra. This TVT-O shape is referred to as "stretched out". A typical change in TVT-O shape is observed during the Valsalva maneuver. The dorsocaudal movement of the bladder neck and urethra causes the latter to assume a C-shape and press against the TVT-O. The tape being elastic adjusts its shape to the bent urethra and briefly becomes what we refer to as "C-shaped" (Figure 2).

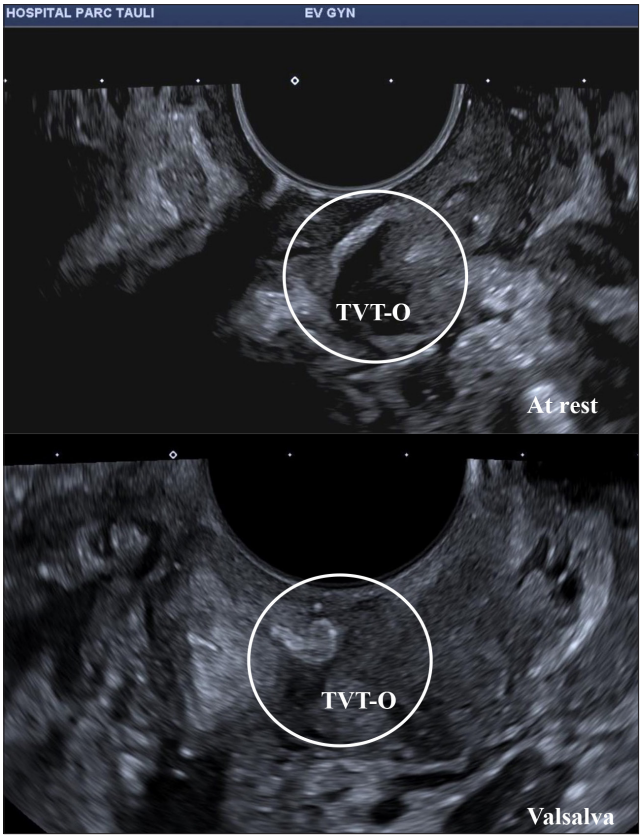
The maximum change observed in this setting served to divide the patients into three Kociszewski's groups: Group 1 (I-C): The tape is "stretched out" at rest and becomes "C-shaped" during straining; Group 2 (I-I): The tape lies parallel to the urethral lumen at rest and during straining; Group 3 (C-C): The tape is already "C-shaped" at rest and does not change upon straining [8].

Figure 1 Dietz's distances (sagittal plane of the tape positioning).



a. Craniocaudal distance between tape and symphysis pubis
b. Dorsoventral distance between tape and symphysis pubis
c. Craniocaudal distance between tape and bladder neck
d. Dorsoventral distance between tape and bladder neck

Figure 2 Ideal visualization of TVT-O: stretched out at rest, C-shaped upon Valsalva.



Furthermore, we analyzed some data in a transversal plane: urethral length, the distance between the posterior inferior symphysis margin and the echogenic center of the urethra, and the distance between the echogenic center of the urethra and the tape (Figure 3).

Statistical analysis began with a descriptive approach. Categorical variables are expressed as absolute values and percentages. Continuous variables with normal distribution were expressed as mean ± standard deviation (SD) and ranges (minimum maximum values). If these variables did not have a normal

distribution, median (interquartile ranges) was used. Secondly, comparison was based on the previous results of quantitative variables using t-Student test if they followed normal distribution (U Mann-Whitney for non-normal) and chi-square in the comparison of qualitative variables. Finally, we could follow the multivariate study with logistic regression models. In all hypothesis tests, the null hypothesis will be rejected with a type I or α error <0.05.

Results

The patients had a mean age of 58 years (range, 37–80) at the time of the first procedure, with 27 having SUI and 19 mixed incontinence. According to the Oxford scale [14], the patients had a median muscle grading of 1.5. Preoperative data of patients are presented in Table 1.

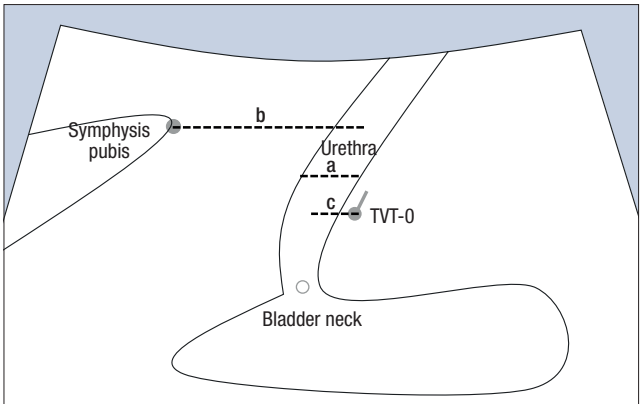
Table 1 Preoperative data of patients at time of TVT-O surgery (n=46).

Age (years, mean ± SD)	58 ± 21
BMI (kg/m^2 mean ± SD)	29 ± 5
Parity median (range)	2 (0–5)
Stress urinary incontinence (SUI)	27/46
Mixed incontinence	19/46
Muscle grading (Oxford scale[14]) (median)	1.5
Data are presented mean ± standard deviation (SD), median (range) or frequency	

At five years of follow-up, 35 of 46 women (76%) were cured, 8 (17.4%) had improved and 3 (6.5%) were failures.

Tapes were visualized in all 46 patients. The tape was stretched at rest and C-shaped during straining in 27 (58.7%) patients (Group 1), stretched tape at rest and during straining in 7 patients (Group 2), and curved at rest and during staining in 12 women (Group 3) (Figure 4).

Figure 3 Transversal distances.



a. Urethral lenght – **b.** Distance symphysis-urethra – **c.** Distance tape-urethra

The cure rate was 92.6% (25/27) in women with a stretched tape at rest and a C-shape during straining (Group 1). In contrast, the cure rate was 42.3% in patients with tape shapes according to Group 2 and 57.7% in patients with a permanent curved shape (Group 3) (p<0.05).

A multifactorial regression analysis taking into account all demographic and preoperative patient data (Table 1) revealed that the only factor influencing women outcome was age (p<0.05). Results of ultrasound examination at 5 years of follow-up are presented on Table 2. Ultrasound parameters of the relation of the tape to the urethra and the lower level of the pubic symphysis were not correlated between cured vs. non cured women (Table 2, Figure 2). However, the bladder wall thickness and the distance of the tape from the bladder neck at rest correlated with woman's outcome (p<0.05).

Dietz's distances at rest and at Valsalva are described in Table 3 (Figure 1). No significant differences were found between cured vs non cured women.

SUI was most accurately predicted using a multiple linear regression model based on the independent variables: age, bladder wall thickness, distance of the tape from the bladder neck and the Kociszewski's groups.

Figure 4 Kociszewski's groups: Group 1 (I-C) stretched at rest, C shaped during straining; Group 2: (I-I) stretched at rest, stretched during straining; Group 3: (C-C) C-shaped at rest, C-shaped during straining.

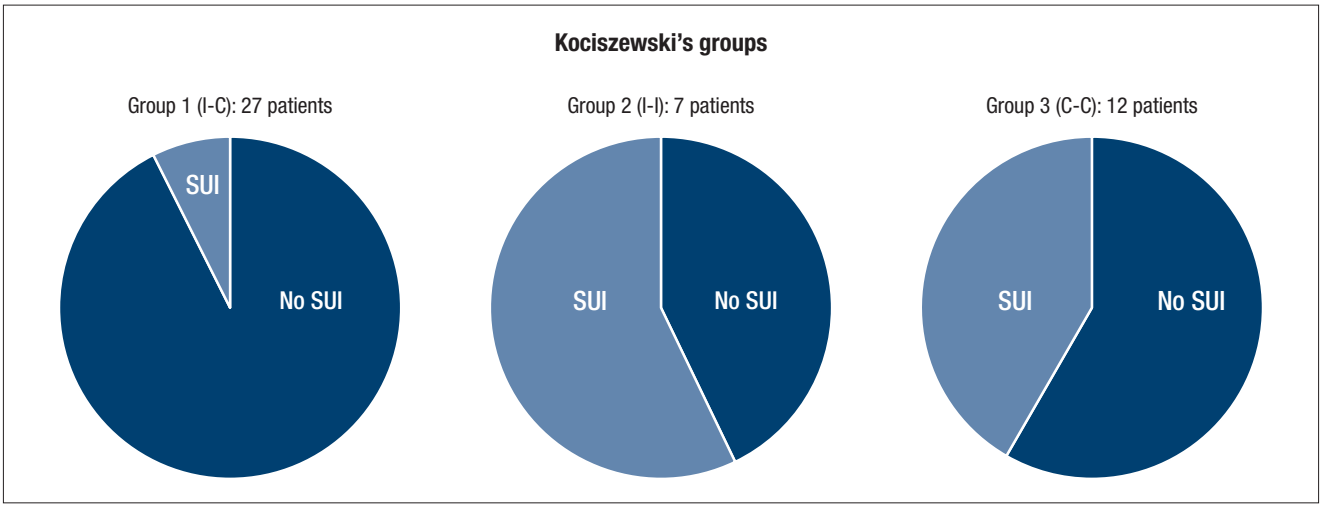


Table 2 Results of ultrasound examination at 5 years of follow-up.

Ultrasound parameters		Transversal distances	
Bladder wall thickness pre-micturition (mm)	4.96 ± 0.99	Tape-urethra distance (mm)	7.16 ± 2.00
Bladder wall thickness post-micturition (mm)	5.19 ± 1.01	Symphysis-urethra distance (mm)	16.34 ± 2.55
Residual urine test (mm)	8.43 ± 19.56	Urethral length (mm)	14.46 ± 3.12
Tape's width (mm)	6.77 ± 1.51		
Data are presented as mean ± standard deviation			

Table 3 Dietz's distances at 5 years of follow-up.

Dietz's distances (mean)	At rest	At Valsalva	Difference
Dorsoventral distance between tape and symphysis pubis (mm)	14.99 ± 4.79	13.94 ± 6.11	1.04 ± 5.60
Craniocaudal distance between tape and symphysis pubis (mm)	-2.66 ± 5.09	-1.93 ± 6.60	0.72 ± 4.30
Dorsoventral distance between tape and bladder neck (mm)	0.78 ± 7.15	-1.29 ± 9.92	2.06 ± 6.81
Dorsoventral distance between tape and bladder neck (mm)	-15.12 mm ± 8.45	-13.88 ± 6.72	1.24 ± 10.17
Data are presented as mean ± standard deviation			

Discussion

Ultrasound is a simple and non-invasive imaging modality that provides detailed information on the position of the TVT relative to the urethra and changes in shape during straining [8, 20, 21]. Our study has revealed specific US findings that are associated with a lower cure rate. Outcome was best in women in whom US demonstrated the elastic sling to lie parallel to the urethra at rest and assumed a transient C-shape during straining (Group 1 of the study according to Kociszewski et al.). Kociszewski *et al*. correlated the shape of the mesh with the existence of tension [8]. They assumed that this US finding suggests tension-free orthotropic positioning of the tape and that this position makes optimal use of the tape's elasticity reserve, thereby ensuring sufficient compression of the urethra during the Valsalva-manoeuvre [8]. Our data also indicate that if US shows this tape functionality at 5-years, the patient can expect mid-term cure and a low mid-term complication rate.

However, if the shape of the TVT remains unchanged during straining (Group 2 of the study according to Kociszewki et al.), women continue to experience involuntary loss of urine during stress. Kociszewski *et al*. [8,9] attributed failure in these cases to the fact that the urethra is not sufficiently pressed into the prolene tape or not at all, which is not related to absolute tape–urethra distance alone but also to urethral mobility. In these cases, the elasticity reserve of the tape is not fully exploited and tape position can be characterized as loose rather than tension-free.

Those cases where the sonographic findings show the tape to be C-shaped already at rest are associated with a higher rate of mid-term complications (Group 3 of the study according to Kociszewki *et al*.). A permanent C-shape may suggest that the tape has been placed with too much tension intraoperatively, resulting in permanent folding at the midline. In this setting, the tape has no elasticity reserve and cannot change its shaping during straining.

The effect of the age of the patient and outcome of a TVT-O has not been well characterized. There are some studies which have revealed that older women have more persistent symptoms of urgency UI and a worse impression of improvement in their urinary tract condition following primary mid-urethral sling as compared to younger women [22].

It is clear that there is no direct correlation between any US parameter and obstruction, but the coincidence between a high post-void residual and some of the US signs of obstruction lead us to consider a mechanical cause – excessive tension of the mesh – rather than a functional disorder. However, in our study we did not find differences in the residual urine. Several authors have shown that in these cases, early intervention attempting to reduce tension on the mesh either by relaxing it surgically or by sectioning, decreases obstruction and long-term irritative symptoms [23,24].

In our study the differences between women with or without surgical success in terms of the pubic symphysis-urethra distance were not significant. Nevertheless, the distance of the tape to the urethral lumen have also correlated with surgical success and complication rates in the study of Kociszewski *et al*. [8] A distance of the tape of more than 5 mm from the urethral lumen resulted in a lower cure rate. When the tape was positioned less than 3 mm from the urethral lumen *de novo* urge symptoms and voiding difficulties significantly increased.

Our results confirmed that the position of the tape in relation to the pubic symphysis has an impact on treatment outcomes in patients with SUI. According to Dietz, the sling moves within the arch around the pubic symphysis, which reduces the distance between the sling and the pubic symphysis on straining.

[17] Duckett et al. have pointed out that the effect of continence is achieved by urethral compression against the pubic symphysis and therefore, in their opinion, the distance between the tape and the pubic symphysis plays an important role in the successful treatment of SUI through sub-urethral sling placement [25].

Urogynecological introital US contributes to our understanding of the mechanism of action of the TVT-O. We can see in our results that the tape position and functionality affect outcome and complication rates. In our study outcome was best in patients with a dynamic change in tape shape during straining and with the correct position of the tape in relation to the pubic symphysis.

However, our study has some limitations. The findings obtained with the TVT-O used in our patients may not be transferable to other sub-urethral slings made of different materials. In addition, patients who had undergone reoperation, especially for voiding dysfunction, were excluded; information on these patients might provide more insights into the mechanisms of success and failure of mid-urethral tape surgery.

Conclusions

TVT-O is a reliable and successful therapeutic option that ensures mid-term cure of SUI. The mid-term results presented here show that the position of the tape in relation to the urethra and its shape at rest and at Valsalva as determined by introital US affects outcome. In our population, SUI was most accurately predicted using a multiple linear regression model based on the independent variables such as age, bladder wall thickness, distance of the tape from the bladder neck and the group according to Kociszewski et al. However, predictors of mid-term outcome after sub-urethral sling procedures are still a matter of scientific debate and we consider that further studies are required.

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