Neurourology and Urodynamics

Tape Functionality: Sonographic Tape Characteristics and Outcome After TVT Incontinence Surgery

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Aim: To investigate tension-free vaginal tape (TVT) position and shape using ultrasound (US) and correlate the findings to outcome. **Material and Methods:** The results of TVT surgery were investigated in 72 women with urodynamic stress urinary incontinence. The main outcome parameters were US tape position in relation to the urethra and dynamic changes in TVT shape at rest and during straining. **Results:** Sixty-two patients (86%) were continent, 6 (8%) significantly improved, and the operation failed in four cases (6%). The median tape position was at 66% of the urethral length measured by US. The median tape-urethra-lumen distance was 3.8 mm at rest. Tape placement in the upper or lower quarter of the urethra was associated with a higher failure rate. Tapes positioned less than 3 mm from the urethra significantly increased postoperative complications ($P < 0.0001$). The tape was flat at rest and curved during straining in 44 (61%) patients; 98% (43/44) of these women were continent after surgery. An unchanged tape shape was associated with a poorer outcome ($P = 0.00038$). Patients with a flat tape at rest and during straining failed in 25% and patients with a permanent curved shape in 10%. **Conclusions:** TVT position relative to the patient's urethra seems to play a role in treatment outcome. Outcome was best in patients with dynamic change in tape shape during straining and location of the tape at the junction between the lower and middle urethra and at least 3 mm from the urethral lumen. *Neurourol. Urodynam.*

Key words: introital ultrasound; outcome; stress urinary incontinence; tape functionality; tape position; tension-free vaginal tape (TVT)

INTRODUCTION

Tension-free vaginal tape (TVT) placement is an effective surgical procedure for the treatment of female urinary stress incontinence. Today it is used worldwide. Theoretically, the TVT ensures continence by supporting the pubourethral ligaments at their midurethral insertion without fixation or elevation of the urethra/bladder neck complex. However, the actual mechanism of TVT is still unclear.

Continence after TVT procedures may vary considerably[1] and we cannot fully explain why. Ultrasound (US) together with history, clinical examination and urodynamics, it has been shown to improve the accuracy of the diagnosis of the functional and morphological disorders of the lower urinary tract.[2–5] US studies have shown that the TVT procedure neither changes hypermobility nor elevates the bladder neck.[6] TVT insertion is supposed to be a midurethral procedure; however postoperative US shows that position and mobility of the TVT relative to bladder neck vary markedly, according to Dietz et al.[7] with relatively little effect on success and symptoms.

The aim of this prospective study was to investigate TVT position and shape at rest and during Valsalva (i.e., "tape functionality") using US and correlate the findings to outcome.

PATIENTS AND METHODS

Seventy-two consecutive women undergoing the TVT procedure between April 2000 and June 2002 were approached for inclusion in the study. Subjects were recruited for the study at their preoperative visit and formally enrolled after their first postoperative visit. Median age was 56.0 years (38–82), median body mass index (BMI) 26.1 kg/m^2 (16–39), and median parity 2.0 (0–5). Since all study patients underwent routine investigations and introital US was used for quality assurance purposes, the study was exempted from formal Ethics Committee approval by the Institutional Review Board of the University of Goettingen, Germany. Nevertheless all patients were informed about the study and consented to participate.

Preoperatively, all study patients underwent clinical and urodynamic workup (comprising cystometry, urethral pressure profilometry and uroflow studies). Since we used a similar study design as Ulmsten, patients completed a 3-day urinary diary and a 1-hr pad test. Patients' perception of their overall health, urinary symptoms, and treatment outcome were measured with a self-completed detailed urinary incontinence questionnaire.[8] Patients self-evaluated the severity of their incontinence

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symptoms using a visual analog scale (VAS) ranging from 0 to 10 (0 corresponding to no symptoms and 10 corresponding to maximum severity). Introital US was performed under standardized conditions using a vaginal 5–9 MHz probe of Ultramark HDI C9-5 ICT (ATL, Hamburg, Germany) with pressure-free probe application.[2,3,9] US was performed according to the guidelines for performing lower urinary tract US as part of urogynecologic functional assessment issued by the German Association of Urogynecology.[4]

With the patient in the semi-sitting position and a standardized bladder volume of about 300 ml, the US probe was positioned in the area of the vaginal introitus at the external urethral orifice without applying pressure and aligning the axis of the probe to the patient's long body axis (i.e., in coronal and sagittal planes) by one experienced sonographer.[3] Postoperative measurements were performed at a filling volume of 200–300 ml as determined by US. In addition, the US examination served to determine residual urine and to identify upper urinary tract dilatation. The urinary bladder, urethra and pubic symphysis were then evaluated in sagittal views. Tape position (mid-point of the TVT) was determined on the midsagittal view relative to the percent urethral length, L, as the shortest distance, A, in millimeters (mm) between the hypoechoic urethral lumen and the tape by drawing a perpendicular line from the urethra to the tape (Fig. 1). In addition shape and sonographic behavior of the tape from resting to Valsalva and back to rest were videotaped. Maximum excursion on Valsalva was used for categorizing into three groups by dynamic tape change observed (Table I):

- Group I: At rest the tape lies parallel to the urethral lumen (Fig. 2A). During Valsalva the tape becomes c-shaped (Fig. 2B).
- Group II: Both at rest and during Valsalva the tape runs parallel to the urethral lumen. The tape does not become c-shaped during Valsalva.
- Group III: Already at rest the tape is c-shaped and during Valsalva this curved shape is maintained.

Two-dimensional linear dorsocaudal movement (LDM) and hypermobility of the bladder neck (LDM > 15 mm) were defined and evaluated as described previously.[9,10] Two

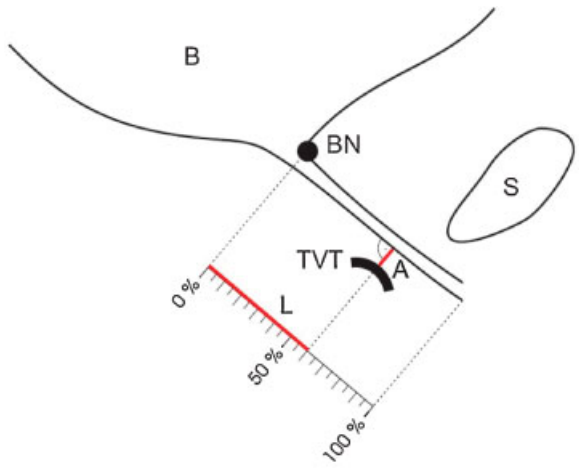

Fig. 1. Diagram of the tension-free vaginal tape (TVT) position relative to the percent urethral length and distance of the tape from the urethral lumen. B, bladder; BN, bladder neck; S, symphysis pubis; A, shortest distance of the tape from the urethral lumen; L, percent urethral length relative to the midpoint of the tape. For details, see Patients and Methods Section.

TABLE I. Sonographic Classification of Tape Behavior by Changes in Tape Shape

Tape functionality	Tape shape	
	At rest	During straining
Group I	Flat	c-shaped
Group II	Flat	Flat
Group III	c-shaped	c-shaped

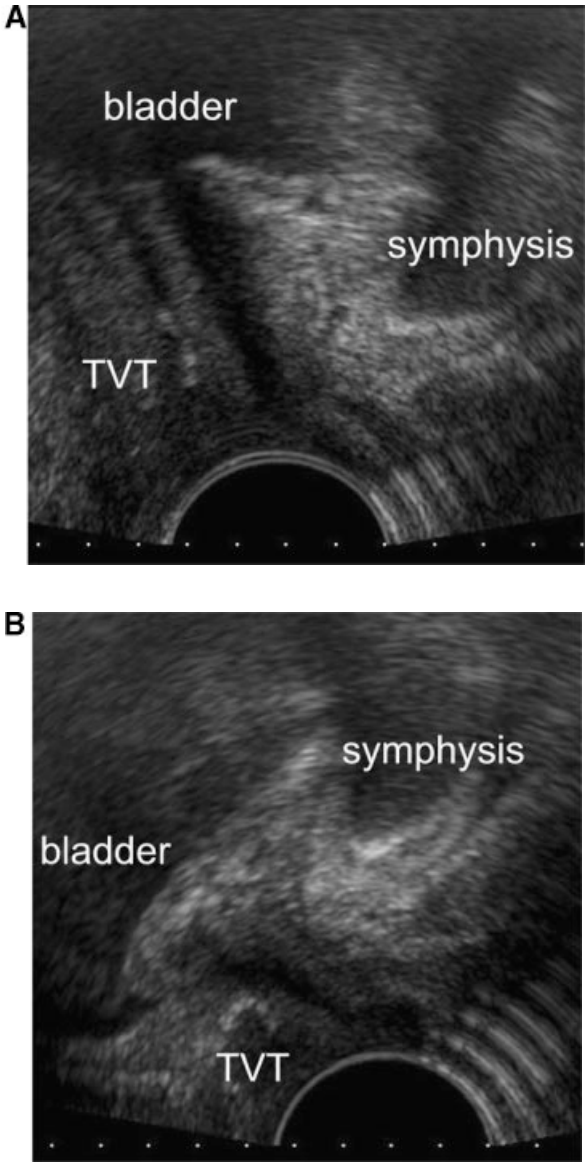

Fig. 2. Introital sonography of a continent woman after TVT placement. At rest the tape can be seen as a hyperechogenic, flat structure underneath the midurethra in (**A**). During Valsalva the tape is c-shaped (curved) as shown in (**B**).

experienced urogynecologists performed the surgical procedures using the tension-free technique of tape placement as described by Ulmsten et al.[11]

Outcome measurements were obtained preoperatively and two times postoperatively: between 2 and 5 days after the operation and after 6 months. Comprehensive follow-up was carried out at each of these visits, including subjective and objective parameters. Objective data included a standing stress test with a comfortably full bladder. Patients with postoperative incontinence or complications had full urodynamic assessment after 6 months.

The criteria for cure were adopted from Ulmsten et al.[8] or slightly modified. In detail, postoperatively the patients were regarded as objectively cured if they had a negative stress test, a negative 1-hr pad test (less than 2 g) and if the self-evaluated severity of their incontinence symptoms using a VAS improved at least 90% (score of 0–1). Patients were regarded as improved if they lost only a few drops during stress test, had 1-hr pad test with 2–10 g of urine loss (or reduction of >50% compared to preoperative test) and if the self-evaluated severity of their incontinence symptoms improved at least 75% (score of 2–3). Failure was defined as urine loss during stress test, 1-hr pad test with more than 10 g urine loss, or a score greater 3 for self-evaluated severity of incontinence symptoms.

Statistical evaluation was performed using the nonparametric Kruskal–Wallis for at least ordinal-scaled variables. Nominal variables were analyzed by the Pearson χ^2-test. Statistical significance was assumed at a P-value <0.05.

RESULTS

Using the predefined criteria, 62 patients (86%) were continent, 6 (8%) significantly improved, and the operation failed in four cases (6%). Six of 72 women complained of voiding difficulties (8%) and 4 of de novo urge incontinence (6%) including one patient suffering from both symptoms. Multifactorial logistic regression analysis taking into account demographic and preoperative factors such as age, parity, BMI, menopausal status, maximal urethral closure pressure (median MUCP 40 cm H_2O, range 10–70) and urethral mobility (median 14 mm, range 3–41) yielded no hint for an independent significant influence of any of these factors on outcome.

The median tape position measured from above by US was at 66% of the urethral length. The median tape-urethra-lumen distance was 3.8 mm at rest. In 44 (61%) patients the shape of the tape changed during straining: the tape was flat at rest and curved during straining (Fig. 1 and Table I); 98% (43/44) of these women were continent after surgery. There was improvement in one case (2%), and none of these patients was classified as failure. In 28 (39%) patients no change in tape shape was visible on US during straining, the tape was either permanently c-shaped (28%) or permanently flat (11%). Sixty-eight percentage (19/28) of these women were continent after surgery, 18% were improved and in 14% the procedure failed. The correlation of outcome and tape functionality (what we assume to be low- and high-tension groups) is summarized in Figure 3. The highest failure rate of 25% was seen in the patients of Group II with a tape position too far away from the urethra (flat tape at rest and during straining). An unchanged tape shape was associated with a poorer outcome ($P = 0.00038$). Patients in Group III had a 6.0-fold higher risk of postoperative complications, whereas the risk increased only 2.6-fold for patients in Group II compared to Group I, the sonographically tension-free group. Complication rates grouped by sonographic tape behavior on Valsalva are summarized in Table II.

Postoperative complications were found in 13% (9/72) of the patients among them 8% (6/72) with voiding dysfunctions and 6% (4/72) with de novo urodynamic overactive bladder (OABwet). The scattergram (Fig. 4) summarizes the association of the tape position at rest in relation to the urethra and different outcome measurements. Complications such as voiding dysfunction and frequency/urgency with or without incontinence were only seen in patients with a distance between the tape and urethral lumen of less than 3 mm ($P < 0.0001$). A tape-urethral-lumen distance greater than 5 mm was seen in 14 of 72 cases, the risk of surgical failure was 36% ($P = 0.0034$) in this subgroup and the relative risk for failure was increased 5.2-fold.

Analysis of sonographic tape location along the urethra showed marked differences in outcome. Tapes found between 50% and 80% of the urethral length were associated with a success rate of 91% (53/58), whereas the other tape positions (0–49% and 81–100% of urethral length) failed in 36% (5/14) ($P = 0.0085$).

DISCUSSION

Ultrasonography is a noninvasive method that provides exact information about the position and functional behavior of the TVT sling at rest and during straining.[2,4,9] The present study demonstrates that both a vaginal tape too far away and too close to urethra lead to specific sonographic tape appearances and result in reduced success rates and increased complication rates. As we observed that under Valsalva the tape very often acquires a c-shape on US we speculate that c-shape indicates that tension is exerted on the TVT. A TVT with a c-shape already at rest might thus be the result of

Fig. 3. Outcome in relation to dynamic changes in tape shape. Optimal results were seen with tapes flat at rest and curved during straining and was classified as optimal tension free (Group I). Suboptimal results were seen as consequence of too little (Group II) or too much tension ("overstabilized," Group III).

TABLE II. Number and Rate of Complications in Groups With Different Sonographic Tape Behavior

Changes in tape shape	Complications, N (%)	No complications, N (%)
Group I	2 (5%)	42 (95%)
Group II	1 (13%)	7 (88%)
Group III	6 (30%)	14 (70%)

too much tension on the tape. Several sonographic studies have been published so far but none to our knowledge has focused on the dynamic behavior and changes in TVT shape at rest and during Valsalva's maneuver. Furthermore, our study relates position and dynamic behavior of the tape to the urethra and not to the symphysis pubis as a reference point.[6,7,12,13] Dietz et al.[14] investigated tape position and mobility after TVT placement and correlated these data with symptoms of incontinence. They found marked variation in position and mobility of the TVT relative to bladder neck and symphysis pubis and concluded that the success of the TVT is largely independent of the exact position it is left in. The only association between tape position and outcome they found was an association between a "closer" tape and irritative voiding symptoms, such as frequency/urgency and urge urinary incontinence episodes. In our study both de novo urge symptoms and voiding difficulties were associated with a short distance (<3 mm) between the tape and the urethral lumen. Dietz et al. use the symphysis pubis as reference point to describe tape position. We believe that any movement of the tape primarily affects urethral function and behavior. This might explain some of the observed differences. Furthermore normal anatomical variation in urethral length is not considered by Dietz et al. We analyzed tape position in relation to the sonographically measured urethral length (median 33.8 mm; 18–44). Our results suggest that the relative and not the absolute tape position along the urethra affects outcome and the occurrence of complications. According to our results, the TVT tape ideally should be located at 50–80% of the urethral length for optimal results and minimal complications. The ideal distance of the tape to the external meatus therefore varies from one patient to another. As a consequence, for example, an incision for tape placement beginning at a distance 1.5 cm proximal to the external meatus can result in a tape close to the bladder neck in patients with a very short urethra measuring only 18 mm in length while it may result in too distal placement in patients with a very long urethra with a length of about 44 mm. Preoperative knowledge of urethral length contributes to optimal tape placement. We suggest using US to measure urethral length. Urethral length can also be measured during the TVT operation by pulling the transurethral Foley catheter while the balloon is filled. With this technique, however, urethral funneling can lead to underestimation of urethral length because the balloon is pulled down into the urethra. Interestingly the recommended site for suburethral incision has slightly changed over time. Where in his first publications Ulmsten suggests an incision "starting approximately 0.5 cm from the outer urethral meatus," in later publications the

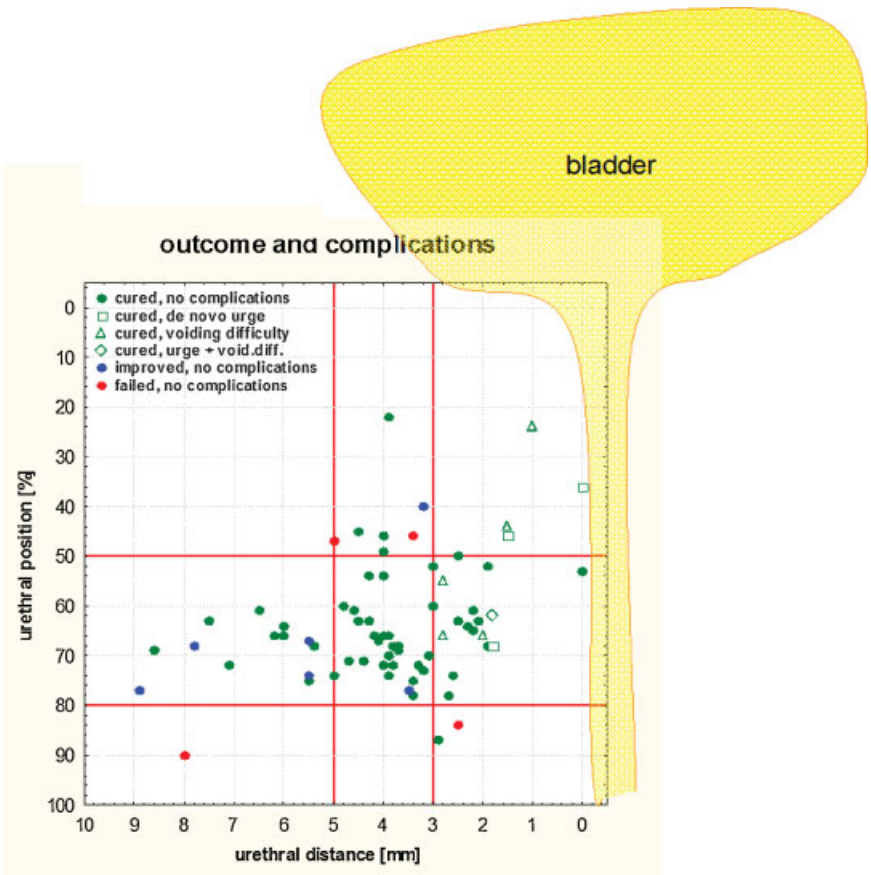

Fig. 4. The scattergram summarizes the association of the tape position at rest in relation to the urethra and different outcome measurements.

incision is described to be done slightly more proximal, "starting 1 cm from the outer urethral meatus."[8,15,16] This approach was also adopted by Gynecare and recommended as the standard cookbook procedure. In a review of incontinence surgery even "a small incision 1.5 cm from the outer urethral meatus" is suggested by experienced surgeons.[17] This illustrates that the optimal distance between external urethral meatus and suburethral start of incision is debatable. Our results suggest that some TVT positions could be associated with better success and fewer complications. Sonographically we were able to show that an optimally placed TVT shifts toward the middle third of the urethra during straining and reaches its target position in the area of the high-pressure zone as postulated by Westby et al.[18] Dietz et al.[7] suggest compression of the urethra against the symphysis pubis as a possible mechanism for tapes positioned closer to the bladder neck but consider this an unlikely mechanism for tapes lying closer to the external meatus. For distally positioned tapes they suggest urethral kinking as the mechanism, which is also confirmed by the uroflow measurements reported by Sander et al.[19]

The distance of the tape to the urethral lumen also correlates with success and complication rates in our patient population. 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. And again we observed patients with a tape quite close to the urethra without symptoms of obstruction. This may in part be explained by anatomic variation in urethral wall thickness. The thickness of the posterior (=vaginal) urethral wall probably varies in our sample but was not measured by preoperative US. Previous histological studies of posterior urethral wall thickness by one of the authors revealed remarkable variations in layer thicknesses in 25 urethral specimens.[20] In this study the average thickness of the posterior urethral wall was 3.7 mm. The urogenital striated muscle was found to decrease in thickness with age and was sometimes even absent in older women. This data would suggest that a tape 4–5 mm away from the urethral lumen should not lead to compression of the posterior urethral wall and not obstruct the urethral lumen.

Urethral mobility also affects outcome. If the tape lies in correct position relative to the individual patient's urethral length (i.e., at the junction from the middle to the lower third) but too far from the urethra, urethral mobility is of crucial importance. In this situation only a hypermobile urethra will reach the tape. In our series, nine patients were cured although the tape was more than 5 mm away from the urethral lumen (Fig. 4). In eight cases urethral hypermobility contributed to dynamic kinking (compression) of the urethra. In our sample 89% of patients showed hypermobility of the bladder neck with a LDM of the internal urethral meatus of more than 1.5 cm on Valsalva. Preoperatively measured mobility of the bladder neck was the same in all three groups ($P = 0.21$). This observation could explain why quite a number of patients with a tape "too far away" were cured. Of the four patients with the same constellation (tape placed at the optimal level but with a distance greater than 5 mm) who only showed improvement of stress incontinence, three had an immobile urethra and only one hypermobility (Fig. 4). Many components contribute to continence (urethral support, internal sphincter activity, and external sphincter function/compression). Any one alone may not be able to keep a patient dry. It is precisely because of the many interdependent parts that contribute to the continence mechanism that no single parameter can predict the success of an anti-incontinence procedure. There are several limitations to our study. First though this is a prospective study tape shapes on US were studied retrospectively. Our project is ongoing and in a new study we will perform the operation according to a modified and individualized cookbook that strictly takes into account the sonographically measured urethral length. These additional data are necessary before we can generalize our results. In addition the small numbers of patients in the subgroups might also have limited our ability to identify other known risk factors on multivariate analysis.

CONCLUSIONS AND OUTLOOK

We conclude that urogynecological introital US contributes to our understanding of the mechanism of action of the TVT. Our results show that the relative and not the absolute tape position along the urethra affects outcome and complication rates and that the mechanism of action of the TVT under strain depends not only on tape position but also on tape functionality. TVT proved to be a safe and effective procedure for the surgical treatment of stress urinary incontinence. In our study outcome was best in patients with a dynamic change in tape shape during straining and location of the tape at the junction between the lower and middle urethra and at least 3 mm from the urethral lumen.

AUTHOR DISCLOSURES

Daniele Perucchini—Speaker honorarium: Novartis, Astellas, UCB Pharma, and Pfizer. No conflict of interest reported by the other authors.

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