

Is Tension-free Vaginal Tape in the Correct Place? An Assessment by Postoperative Transperineal Ultrasonography at Three Months

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Objectives: To determine the position of tension-free vaginal tape (TVT) by transperineal ultrasound following placement by a standard blind insertion technique, and to investigate the relationship between position of TVT and associated clinical outcome.

Methods: Postoperative evaluation was conducted at 3 months with transperineal 2-dimensional ultrasound scan, standardised symptomatology questionnaire, visual analogue scale (VAS), and validated short form Incontinence Impact Questionnaire 7 in 32 women who had undergone TVT placement for genuine stress urinary incontinence.

Results: At 3-month examination, 90.6% of 32 women were subjectively cured. Tension-free vaginal tapes were placed within the target range of 50% to 70% of the urethral length in 65.6% of women. There was no difference in the urinary outcome between women with TVT placed within and outside the target range. Women with tape–longitudinal smooth muscle (tape-LSM) distance of <3 mm or >5 mm had a significant improvement in VAS score ($p=0.04$) compared with those with tape-LSM distance of 3 to 5 mm. Nonetheless those with tape-LSM distance of <3 mm had voiding dysfunction (15.4% vs. 0%; $p=0.08$). Tape width reduced from an initially manufactured 11 mm to a mean width of 6.4 mm.

Conclusions: About one-third of TVTs were found by postoperative transperineal ultrasound to have been placed outside the target range using a standard blind insertion technique.

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Introduction

Stress urinary incontinence in women is a common, distressing, and socially disabling condition. It is a major problem that affects more than 20% of the female population in the United States¹. Stress urinary incontinence is defined by the International Continence Society² as the complaint of involuntary loss of urine on effort or physical exertion or during sneezing or coughing. Urodynamic stress incontinence (USI) is confirmed during urodynamic testing in the presence of leakage of urine during filling cystometry associated with increased abdominal pressure, in the absence of a detrusor contraction.

Although non-surgical treatments such as pelvic floor exercises are effective in some women³, surgical intervention is superior in respect to subjective and objective cure and long-term cure⁴. During the last 10

years, the insertion of tension-free vaginal tape (TVT)⁵ has become the gold standard in treatment of stress urinary incontinence because of its minimally invasive nature, high success rate, and similar or even lower complication rate compared with traditional abdominal surgery, i.e. open or laparoscopic Burch colposuspension⁶⁻⁹.

According to Petros and Ulmsten's integral theory of female incontinence¹⁰, positioning of TVT should be at the middle third of the urethra, which is also known as the high pressure zone, in order to be maximally effective in ensuring continence postoperatively. Westby et al¹¹ estimated that this zone lies in an area between 53% and

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72% along the urethral length. According to the literature report from Kociszewski et al¹², there is a significantly higher cure rate (93.1% vs. 88.2%) when the TVT is placed within the target zone with 3-to-5-mm tape–longitudinal smooth muscle (LSM) distance ($p < 0.001$).

To date, TVT procedures have largely adopted a standard approach described by Ulmsten et al⁵ in which the vaginal incision is made 10 mm from the external urethral orifice. This technique does not take into account individual urethral length, and is highly dependent on the surgeon's experience. Because of the natural differences in urethral length, which can vary between 20 and 50 mm, a wide variation in tape position in relation to the mid-urethra has been observed¹³. These possible discrepancies in tape position have not been properly assessed in Hong Kong or many other developed countries.

With the development of high-resolution ultrasound machines, use of ultrasonography in urogynaecology has become a well-established, non-invasive real-time means of assessing the anatomy and function of the lower urinary tract^{14,15}.

This study aimed to assess the anatomical position of TVT, inserted by a blind technique, with the use of perineal ultrasound postoperatively, and to investigate its relationship with clinical outcome.

Methods

This prospective pilot cohort study recruited 32 women with USI who underwent a TVT procedure in the Department of Obstetrics and Gynaecology of a tertiary urogynaecology referral centre in Hong Kong between 1 December 2013 and 31 December 2014. Women who were aged above 18 years, mentally able to provide written consent, diagnosed with USI, and consented for TVT were recruited. Women who refused or were unable to give written consent, who had undergone previous continence surgery, and those who demanded tape excision for voiding dysfunction less than 3 months postoperatively were excluded.

Baseline demographic data including age, parity, number of vaginal deliveries, number of Caesarean sections, heaviest weight of baby delivered, and a history of genital tract trauma were collected for analysis. Preoperative evaluation included completion of a standardised symptomatology questionnaire, i.e. severity of stress incontinence ranging from 0 to 3, with 0 being no symptoms and 3 being severe symptoms; voiding

dysfunction assessment (screening for symptoms of poor stream, straining on voiding, sense of incomplete emptying and retention of urine); visual analogue scale (VAS) for subjective urinary incontinence symptoms ranging from 0 to 10, with 0 being 'no incontinence' and 10 being 'unbearable distress related to incontinence' on a 10-cm scale bar; and a validated short form Incontinence Impact Questionnaire 7 (IIQ7) in Chinese or English format for quality of life assessment. Data collection on demographics, symptoms and quality of life assessment was performed by our specialised continence nurse.

The TVT procedures were performed by a registered urogynaecologist or subspecialty trainees under direct supervision. Procedures were performed by one of four surgeons, each of whom had performed more than 30 TVT procedures prior to the beginning of this study. All TVT procedures were carried out using the GYNECARE TVT obturator device that comprises PROLENE polypropylene mesh 11 mm x 45 mm (Ethicon [J&J] Johnson & Johnson, US), according to the manufacturer's instructions, under general or regional anaesthesia and with preoperative antibiotic cover. A Foley catheter was inserted to empty the bladder before the procedure. The exit points were located by tracing a horizontal line 2 cm above the level of the urethral meatus; 2 cm lateral to the folds of the thigh. Two 0.5-cm transverse skin incisions were made bilaterally at the exit points. A 10-mm midline vaginal incision was made starting 10 mm proximal to the urethral meatus⁵. At the mid-urethral level, dissection was carried out from the vaginal skin incision behind the pubic bone towards the obturator foramen. With the safely winged guide, along the dissected track, the obturator membrane was perforated and the tip of the needle brought up to the skin incision. As soon as the needle tip reached the skin incision, the proximal end of the needle was disconnected and the tape was pulled upward through the skin. The procedure was then repeated on the other side. Check cystoscopy was performed to confirm integrity of the bladder. Caution was taken to avoid positioning the mesh with excessive tension by using Mayo curved scissors. Once the tape had been positioned properly, the plastic sheath was removed carefully. The ends of the tape were cut at skin level and vaginal and skin incisions were closed. All women received the same routine postoperative care that included Foley catheterisation for 1 day and analgesics on demand. Women were discharged on day 1 after surgery.

Postoperative evaluation of incontinence conducted at 3 months included transperineal ultrasound scan, standardised symptomatology questionnaire, VAS, and

IIQ7 questionnaire.

The postoperative transperineal ultrasound examinations were performed in a standard manner by qualified ultrasonographers using the ACCUVIX XG ultrasound system (Samsung Medison, South Korea). With the woman lying in the dorsal lithotomy position and standardised bladder-filling volume of 300 ml¹⁴, a clean probe (3.5 MHz) convex 2D transducer, covered with plastic wrap, was placed in the area of the vaginal introitus at the level of the external urethral orifice, exerting minimal pressure and aligning the axis of the probe with the women's body axis¹⁴. Sonographically, in the mid-sagittal plane, using the pubic symphysis as a landmark, and bladder, urethra and rectum as standard plane for measurement, the longitudinal position of the TVT in relation to the urethra was measured. The shortest perpendicular distance between the LSM complex and TVT, also called the tape-LSM distance, was measured to determine the approximation of the two structures. The tape width was measured and compared with the manufactured width to determine the effective postoperative tape width (Figure 1). Ultrasound images were captured and saved for offline analysis. Images were magnified for more precise measurement with three measurements made and the average calculated.

Women with no incontinence subjectively were considered cured at the time of postoperative evaluation. Women were classified as improved if they had decreased frequency of stress incontinence.

Statistical analysis was performed using the Statistical Package for the Social Sciences (IBM SPSS version 22.0). Descriptive statistics of women demographics, mean tape distance from the target zone, and the mean tape-LSM distance were analysed using t test. Results were considered clinically significant at $p \leq 0.05$ for all statistical analysis.

The ethics committee of the Kowloon Central Cluster/Kowloon East Cluster approved the study (Study No. KC/KE-13-0164/ER).

Results

Characteristics of the Study Population

From a total of 57 TVTs performed during the study period, 32 women were recruited. The remaining women were not recruited either due to refusal or manpower limitations. The mean (\pm standard deviation) age of the study subjects was 61.2 ± 9.7 years and mean number of previous vaginal deliveries was 2.4 ± 1.2 . Three of them

(9.4%) had a history of Caesarean section. The mean weight of the heaviest baby delivered was 3.4 ± 0.5 kg. No woman had any history of genital trauma or major perineal tear (Table 1). Within this cohort, seven women underwent concomitant vaginal hysterectomy for pelvic organ prolapse, one underwent laparoscopic sacrocolpopexy for vault prolapse, and one underwent total laparoscopic hysterectomy for adenomyosis and menorrhagia.

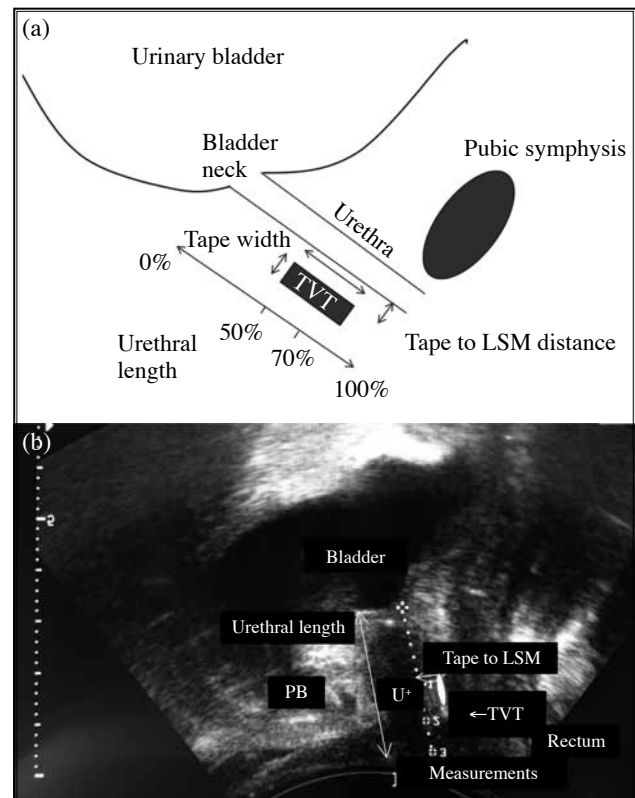


Figure 1. (a) Diagram and (b) transperineal ultrasound image showing standard transperineal ultrasound plane for measurement

Abbreviations: LSM = longitudinal smooth muscle; PB = pubic bone; TVT = tension-free vaginal tape; U+ = urethra

Table 1. Demographics of women who underwent tension-free vaginal tape insertion for stress urinary incontinence (n=32)

Demographics	Mean \pm standard deviation
Age (years)	61.2 \pm 9.7
Parity	2.6 \pm 1.0
No. of vaginal delivery	2.4 \pm 1.2
No. of Caesarean section	0.2 \pm 0.5
Heaviest baby delivered (kg)	3.4 \pm 0.5

All women had symptoms of USI, and 26 (81%) experienced stress urinary incontinence on a daily basis. The mean preoperative IIQ7 and VAS score was 39.2 ± 22.9 and 6.5 ± 2.1, respectively (Table 2).

Postoperative Outcomes

At 3-month follow-up, 29 (90.6%) women were subjectively cured, and the remaining three (9.4%) improved. Severity of stress incontinence was significantly lower in the postoperative group (p<0.001). The mean postoperative IIQ7 score at 3 months was 4.8 ± 13.4 and VAS score being 0.7 ± 1.2; both were significantly lower (p<0.001). Voiding dysfunction was present in two (6.3%) women; one had poor stream and one reported a sense of incomplete emptying. Neither had retention of urine with measured residual urine 0 ml (Table 2).

Ultrasound Findings

Ultrasonography showed that tape positioning between 50% and 70% urethral length was accomplished in 21 (65.6%) women (i.e. >50% of tape positioned 50%-70% along urethral length). The mean urethral length was 33.3 ± 4.8 mm. There was no significant difference in mean urethral length (32.4 mm vs. 35.1 mm) between the groups with tape placed within the target zone and outside the target zone (p=0.12).

The mean preoperative tape width reduced from 11 mm to 6.4 (± 1.2) mm postoperatively. There was no significant difference in the mean tape width between the groups with tape placed within the target zone and outside the target zone (6.2 mm vs. 6.5 mm; p=0.35). The mean tape-LSM distance was 3.6 ± 1.2 mm.

Subgroup Analysis of Clinical Outcomes in Relation to Tape Position

In subgroup analysis, women with tape positioned at the target zone had subjective cure rates comparable with those women with tape positioned proximal or distal to the zone (p=0.97). No significant difference in subjective severity, IIQ7 score or VAS score between these two groups were found (Table 3).

The mean tape width in the cure group was longer than that in the non-cured group, though not statistically significant (6.4 mm vs. 6.0 mm; p=0.62).

In tape-LSM distance subgroup analysis, women with tape-LSM distance of <3 mm or >5 mm showed a significant improvement in VAS (p=0.04) compared with women with tape-LSM distance of 3 to 5 mm. Nonetheless in this group there was an associated 15.4% incidence of voiding dysfunction that approached a level of statistical

Table 2. Overall outcome at 3 months' follow-up for women with tension-free vaginal tape for stress urinary incontinence*

	Mean ± standard deviation		p Value
	Preoperative	Postoperative	
Subjective severity of stress incontinence score	3.7 ± 0.7	1.0 ± 0.2	<0.001
Incontinence Impact Questionnaire 7 score	39.2 ± 22.9	4.8 ± 13.4	<0.001
Visual analogue scale score	6.5 ± 2.1	0.7 ± 1.2	<0.001

* Data are shown as mean ± standard deviation

Table 3. Comparison of outcomes based on tape positioning in relation to target zone

	At target zone (n=21)	Proximal / distal to target zone (n=11)	p Value
SI cure rate (%)	90.5	90.9	0.97
Mean improvement in subjective severity of SI	2.6	2.7	0.54
Mean improvement in IIQ7 score	33.3	36.6	0.70
Mean improvement in VAS	5.8	5.9	0.87
Voiding dysfunction (%)	9.5	0	0.29

Abbreviations: SI = stress incontinence; IIQ7 = Incontinence Impact Questionnaire 7; VAS = visual analogue scale

Table 4. Comparison of outcomes based on tape-LSM distance

	Tape to LSM 3-5 mm (n=19)	Tape to LSM <3 or >5 mm (n=13)	p Value
SI cure rate (%)	89.5	92.3	0.79
Mean improvement in subjective severity of SI	2.6	2.7	0.64
Mean improvement in IIQ7 score	29.8	41.3	0.15
Mean improvement in VAS score	5.2	6.7	0.04
Voiding dysfunction (%)	0	15.4	0.08

Abbreviations: SI = stress incontinence; IIQ7 = Incontinence Impact Questionnaire 7; VAS = visual analogue scale; LSM = longitudinal smooth muscle

significance (p=0.08). All women with voiding dysfunction had a tape-LSM distance of <3 mm. There was no significant difference in the improvement of subjective cure rate, subjective severity, or IIQ7 score between the two groups (Table 4).

Discussion

In our study, using a standard blind insertion technique to place TVT could only accomplish mid-urethral tape placement in 65.6% of women as revealed by ultrasonography at 3 months, with 6.2% (n=2) of TVTs placed closer to the bladder neck and 28.1% (n=9) closer to the urethral opening. This ultrasound success rate is comparable with the rate of 67.7% in an earlier study^{16,17}, according to the target zone suggested by Petros et al¹⁰ and Westby et al¹¹.

A sonographic observational study by Kociszewski et al¹³ found a wide variation in tape position relative to the percentage of urethral length in women who underwent TVT placement using the standard approach for starting the incision. Hence this group¹³ proposed the theoretical assumption that consideration of individual urethral length is required to achieve consistent placement of TVT at the target zone. Later study from the same group demonstrated a higher success rate of 88.2%, achieved by determining the incision position based on the preoperative sonographically measured urethral length¹². As illustrated in Figure 2, if there was no ultrasound to evaluate the urethral length preoperatively, tape tended to be placed closer to the bladder neck in women with a short urethra; on the contrary closer to the urethral opening in women with a long urethra. In our study, the mean urethral length of Hong Kong women was 33.3 (range, 26.8-42.8) mm. This result is comparable with a French study in which the mean urethral length was 33.1 mm¹⁸. We found no significant difference in mean urethral length (32.4 mm vs. 35.1 mm) between the groups with tape placed within and outside the target zone.

Another possible explanation that may contribute to the discrepancy in tape position is variable postoperative tape width. Our study observed that all tape width reduced postoperatively, from initially manufactured 11 mm to a mean of 6.4 (range, 3.3-8.9) mm. As demonstrated by Figure 3, a shortened tape width has a higher chance of placement outside of the target zone. Nonetheless this again was not well demonstrated in our study as there was no significant difference in the mean tape width between the two groups

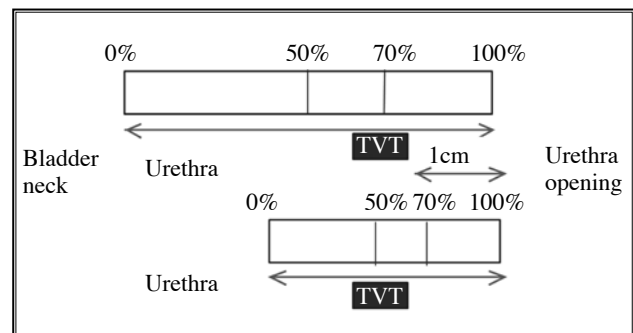


Figure 2. Diagram showing the estimated tape position in relation to urethral length by blind insertion technique
Abbreviation: TVT = tension-free vaginal tape

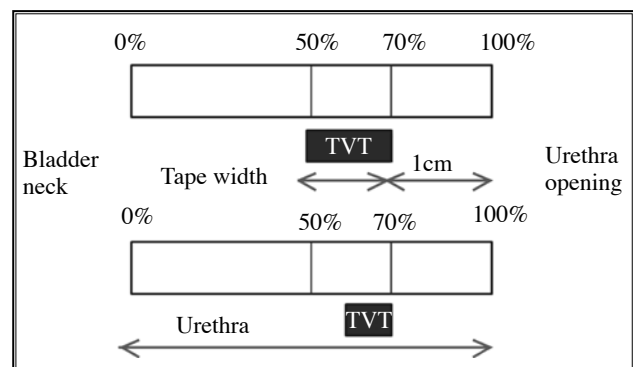


Figure 3. Diagram showing tape position in relation to tape width
Abbreviation: TVT = tension-free vaginal tape

(6.2 mm vs. 6.5 mm). We postulate that shortening of the tape could be due to folding inside the placement pathway that would happen if the dissected pathway was either too narrow, or if the tape became coiled inside the pathway during improper TVT placement. Another possible explanation was inappropriate tension adjustment during the TVT procedure. TVT is a polypropylene mesh with elastic properties due to its knitted composition. Under high tension, the tape may be stretched with consequent reduction in tape width.

In our study, women with ultrasound findings of tape within the target zone did not show significant difference in subjective cure rate, subjective severity, or quality of life assessment score when compared with the group with tape outside the target zone. Currently the relationship between tape position and clinical outcome remains contradictory. Earlier studies have demonstrated favourable clinical outcome when TVT is placed at the target zone^{13,19}. Nonetheless other published work has failed to show a significant difference in postoperative outcome in relation to tape position¹⁷. As the success of TVT is based on reinforcement of the defective pubourethral ligaments, theoretically, a reduced tape width may decrease treatment efficacy because the effective supportive zone is reduced. Mean tape width in the cure group was wider than that in the non-cured group although not to a level of significance. Future study with a larger sample size may provide a more representative conclusion about the relationship between target zone, tape width, and clinical outcome.

In our study, women with tape-LSM out of the optimal 3-to-5-mm zone showed a significantly higher improvement difference in VAS score compared with the other group. This may reflect better control of continence

and hence VAS with tape placed closer to the urethra. Nonetheless women with tape-LSM distance of <3 mm had more voiding dysfunction. This observation corresponds to findings in Kociszewski et al's study¹². Due to the limited sample size in our preliminary study, the difference was not statistically significant. TVT placed too far from the LSM may be associated with a higher risk of not being cured¹². On the contrary, TVT placed too close to the LSM will apply excessive tension and this close approximation may affect mobility or even obstruct the proximal urethra leading to voiding dysfunction. This demonstrates that tension adjustment is crucial in TVT placement, especially in women with pre-existing voiding dysfunction or a low peak flow rate. Ultrasound may play a role in the objective assessment of tension rather than the traditional technique of using a pair of Mayo scissors that is rather subjective and difficult to teach and learn.

The results of our study are limited by the fact that it was a single-centre pilot study with a small sample size. A prospective longitudinal multicentre study with a longer study period and more patients are needed for better statistical evaluation.

Conclusions

Our study determined by postoperative transperineal ultrasound that approximately one-third of TVTs were not placed at the target zone and most were placed too proximal, despite use of the standard described technique. Tape-LSM distance of <3 mm was associated with voiding dysfunction and hence appropriate tension adjustment is crucial in TVT placement to avoid this postoperative complication. Our current evidence for the relationship between target zone, tape width, and clinical outcome is inconclusive. Future study with a larger sample size is warranted.

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