

## Original Article

# Assessment of tape position in postoperative women with stress urinary incontinence by pelvic floor ultrasonography

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**Abstract:** Objective: This study aims to assess the tape position in women with stress urinary incontinence (SUI) after tension-free vaginal tape (TVT) by pelvic floor ultrasonography. Methods: Seventy-four moderate-severe SUI patients, who underwent TVT at the Department of Gynecology of Peking University People's Hospital from February 2014 to January 2017, were enrolled into this study. These patients underwent of transperineal ultrasonography during the postoperative follow-ups. Urethral length (U), the distance between the tape and urethral opening (B), the distance between the tape and inferior-posterior margin of the symphysis pubis during the resting state (Ar), and the distance between the tape and inferior-posterior margin of the symphysis pubis in the Valsalva state (Av) were measured; and the difference between Ar and Av (Ar-v) was calculated. Results: According to subjective symptom assessment, 44 patients were cured, 28 patients were improved, and two patients achieved an invalid result. The total satisfaction rate was 97.3%. Between the cured group and improved group, the differences in B value ( $1.98 \pm 0.38$  cm vs.  $1.89 \pm 0.39$  cm) and Ar value ( $1.85 \pm 0.33$  cm vs.  $1.76 \pm 0.28$  cm) were not statistically significant ( $P > 0.05$ ), while the differences in Av value ( $1.3 \pm 0.28$  cm vs.  $1.45 \pm 0.26$  cm) and Ar-v value ( $0.56 \pm 0.27$  cm vs.  $0.33 \pm 0.27$  cm) were statistically significant ( $P < 0.05$ ). Conclusion: Pelvic floor ultrasonography can display the position, state and trajectory of the tape, assist in assessing the efficacy of tape, and provide useful reference for clinical practice.

**Keywords:** Pelvic floor ultrasonography, stress urinary incontinence, tension-free vaginal tape

## Introduction

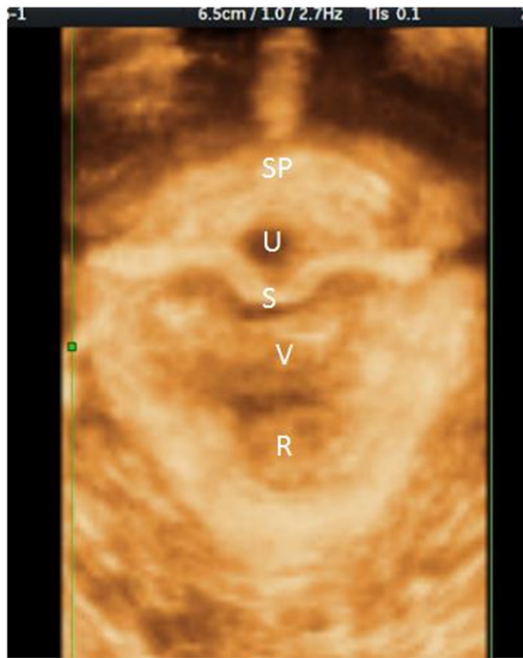
Female stress urinary incontinence (SUI) is a common disease in modern society. The reported incidence of this disease varies from place to place. Approximately 50% of middle-aged and elderly women suffer from varying degrees of SUI, and its incidence shows an upward trend [1-4]. Due to its harm and serious impact on the quality of life of diseased women, this disease has become a global social and economic problem [2]. Zyczkowski *et al.* [5] considered that the first choice of initial treatment for SUI is conservative treatment, such as lifestyle changes (physical exercise, eating habits and weight loss), medication and physical therapy. However, conservative treatment cannot achieve satisfactory effects. In the past few decades, surgical therapy procedures for SUI have considerably changed. Since the 1990s, the vaginal tape was accepted, and retropubic tension-free vaginal tape (TVT) and TVT-obturator

(TVT-O) have gradually become the new standard treatments [6-8]. Some studies reported that the long-term efficacy of TVT and TVT-O could reach 85-90% [9, 10]. Among many imaging technologies, transperineal pelvic floor ultrasonography has become the most reliable method for assessing the position and efficacy of the tape, and it is also the only method that the dynamic imaging of an implanted tape can be performed. In the present study, pelvic floor ultrasonography was used to observe and measure the shape and position of the tape in SUI patients, and postoperative recovery was analyzed on this basis, in order to understand the correlation between tape position and prognosis, and provide useful information for clinic.

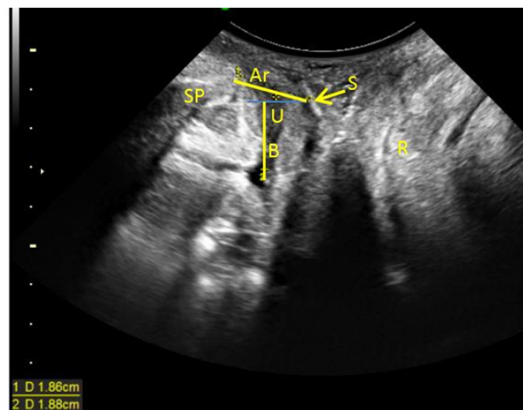
## Data and methods

### Study subjects

Seventy-four moderate-severe SUI patients who underwent TVT and TVT-O at the Depa-

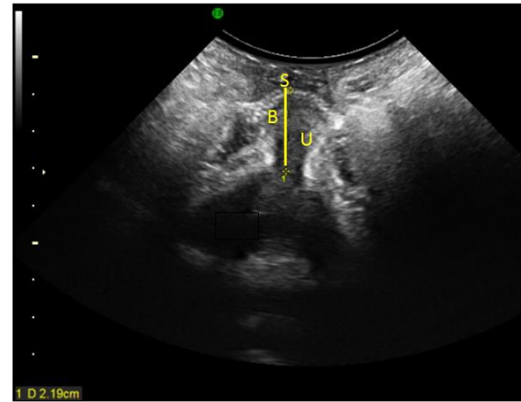


**Figure 1.** After TVT-O, the 3D images of the axis planes were reconstructed, showing the V-shaped tape in the posterior urethra, and extended this to the bilateral obturator foramina. SP: symphysis pubis, U: urethra, S: tape, V: vagina, and R: rectum.



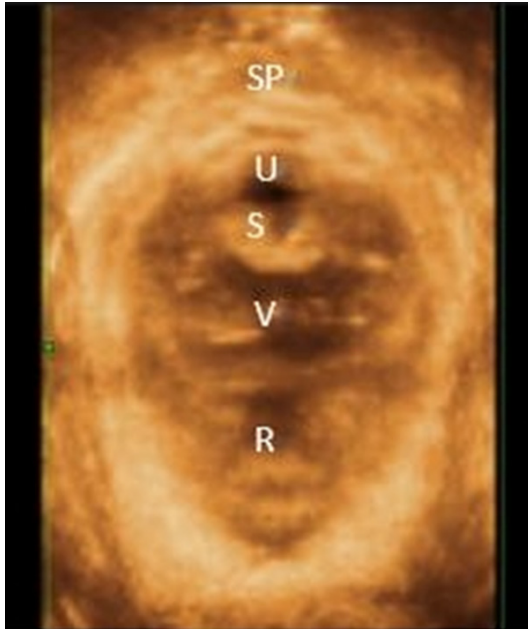
**Figure 2.** Cured group Two-dimensional pelvic floor ultrasonography: On the sagittal section, the strong echo (yellow arrow) at the posterior urethra represents the tape. SP: symphysis pubis, U: urethra, S: tape, R: rectum, and Ar: the distance from the midpoint of tape to the inferior-posterior margin of the symphysis pubis.

Department of Gynecology of Peking University People's Hospital from February 2014 to January 2017 were enrolled into this study. Inclusion criteria: patients who were diagnosed clinically with moderate-severe SUI underwent surgery.

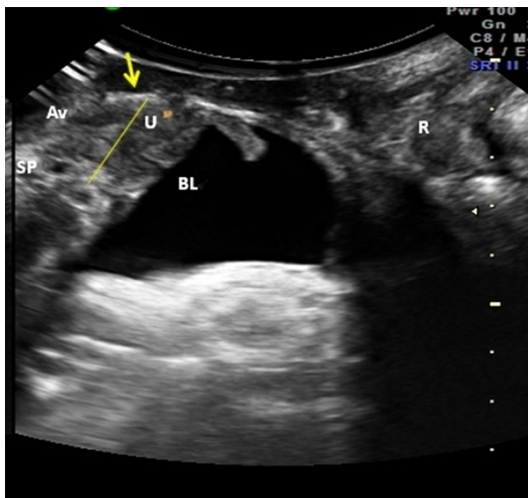


**Figure 3.** Two-dimensional pelvic floor ultrasonography: On the coronal section, the arched strong echo in the middle segment of the urethra represents the tape. U: urethra, S: tape (white arrow), and B: the distance from the midpoint of the tape to the internal urethral opening.

Exclusion criteria: patients with acute urinary incontinence, patients complicated with urethral diseases, cystocele and uterine prolapse. The age of these patients ranged within 28-75 years old, with an average age of  $57 \pm 9.7$  years old. The number of postmenopausal patients was 66 (89.2%). The mean body mass index was  $24.86 \pm 3.03$  Kg/m<sup>2</sup>. The parity ranged within 1-3 times, with an average of  $1.36 \pm 0.71$  times. Among these patients, 41 patients underwent TVT and 33 patients underwent TVT-O. These patients were followed-up for 6-24 months after the operation, with an average follow-up period of 11.3 months. The follow-up items included the following: the presence of recurrent urinary incontinence and urinary fistula; urinary stammering, thin urine, dysuria and urinary tract infection. Subjective symptom assessment criteria: the "cured" criterion was the absence of leakage of urine; the "improved" criteria were the infrequent and small amount of urine leakage when abdominal pressure increased, and the patient considered that the symptoms improved; the "invalid" criterion was that the incontinence was similar to that before the surgery, without improvement. According to the subjective symptoms evaluation, these patients were divided into three groups: cured group, improved group and invalid group. In the present study, the tape position in the cured group and improved group were compared and analyzed, while that in the invalid group was separately analyzed.



**Figure 4.** A case with failure of tape operation: the 3D images of the axis planes were reconstructed, showing the sling attaching to the urethra, suggesting that the sling is too tight. SP: symphysis pubis, U: urethra, S: tape, V: vagina, and R: rectum.



**Figure 5.** Improved group Two-dimensional pelvic floor ultrasonography: On the sagittal section, the strong echo (yellow arrow) at the posterior urethra represents the tape. SP: symphysis pubis, U: urethra, S: tape, R: rectum, and Ar: the distance from the mid-point of tape to the inferior-posterior margin of the symphysis pubis.

## Materials and methods

Instrument: A GE Voluson E8 color ultrasonic diagnostic apparatus (GE, Austria) equipped with RAB 4-8-D transabdominal probes was

used. The frequency ranged within 4-8 MHz [2]. Methods of examination and measurement of relevant data: All patients were followed up for 6-24 months after the surgery. During the follow-ups, pelvic floor ultrasonography was performed by the same experienced sonographer, and the data were recorded. Before the ultrasound examination, the patient emptied the rectum, and the residual urine volume in the bladder after urination was controlled to be <50 ml. Then, the patient was instructed to lie in the supine lithotomy position. The abdominal volume probe was coated with a coupling agent, covered with a disposable condom, and vertically placed in the sagittal plane of the perineum. The two-dimensional ultrasound images revealed the inferior margin of the symphysis pubis, bladder, urethra, vagina and the anus-rectum junction. In the middle segment behind the urethra, the strong echo segment represented the tape. The urethral length (U), distance between the tape and urethral opening (B) and distance between the tape and inferior-posterior margin of the symphysis pubis during the resting state (Ar) were measured. The probe was rotated by 90 degrees to form a coronal plane, causing the tape behind the urethra to become arc-shaped. The distance between the middle point of the tape behind the urethra and urethral opening (B) was measured again. The probe was returned to the median sagittal plane, the patient was instructed to perform the maximal Valsalva maneuver, the movement track of the tape was observed, and the distance between the tape and inferior-posterior margin of the symphysis pubis in the maximal Valsalva state (Av) was measured. The above parameters were measured three times, the means were calculated, and the difference between the Ar and Av values (Ar-v) was calculated. The shape, position and movement of the tape in the resting state and Valsalva maneuvers were observed using four-dimensional dynamic pelvic floor ultrasonography (Figures 1-5).

## Statistical methods

Data were analyzed using statistical software SPSS 14.0. Measurement data were expressed as mean  $\pm$  standard deviation ( $\bar{x} \pm SD$ ). The parameters of the tape position in SUI patients after surgery were compared using paired t-test.  $P < 0.05$  was considered statistically significant.

### Results

#### *Pelvic floor ultrasonography*

Two-dimensional and four-dimensional pelvic floor ultrasonography could both clearly display the materials of the implanted tape.

#### *Two-dimensional transperineal ultrasonography*

During the resting state, sagittal view images displayed the inferior-posterior margin of the symphysis pubis, urethra, vagina and anorectal angle. The urethra was hypoechoic, and the strong spot or segment echo at the back of the urethra was the tape. On the coronal plane images, the strip-shaped arc of the high echo at the back of the urethra was the tape. During the Valsalva state, the urethra and bladder neck rotated downward and backward around the symphysis pubis, the urethra presented with low echo or moderate echo signals, and the tape was moderately close to the urethra and migrated towards the symphysis pubis.

#### *Four-dimensional transperineal ultrasonography*

This technique dynamically displayed the axial planes after 3D reconstruction. During the resting state, at the back of the pubic symphysis, the urethra revealed a circular figure, in which the center presented with low echo and the peripheral areas presented with moderate to strong echoes. Between the urethra and vagina, a V-shaped strong echo band could be observed. TVT-O revealed the bilateral arms extending from the posterior urethra to the obturator cavity on both sides. During the Valsalva state, the dynamic images revealed that the tape migrated towards the urethra and held the urethra at the same time, showing a nearly bar shape. In the present study, one patient was found to have the tape showing a fold at the left side.

#### *Clinical efficacy assessment*

Seventy-four patients underwent TVT, one patient developed urinary tract infection, 14 patients developed mild urinary stammering, which gradually relieved, and two patients developed thin urine. After the operation, these patients were divided into four groups, according to subjective symptom evaluation: cured group (n=44), improved group (n=28), and invalid group (n=2). The total satisfaction rate was 97.3%.

#### *TVT efficacy assessment*

Forty one patients underwent TVT, 23 patients were cured, 17 patients were improved, and one patient achieved an invalid result. The patient who had an invalid result of TVT developed dysuria and thin urine after the operation, and the leakage of urine was not relieved when abdominal pressure increased.

#### *TVT-O efficacy assessment*

Thirty three patients underwent TVT-O, 21 patients were cured, 11 patients were improved, and one patient achieved an invalid result. For the patient with an invalid TVT-O result, after the operation, the symptom of urine leakage did not improve when abdominal pressure increased, compared with the preoperative state.

#### *Comparison of tape position*

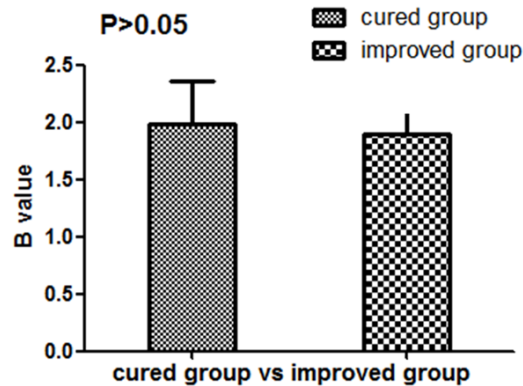
All 74 patients underwent transperineal ultrasonography during the postoperative follow-ups, and the related parameters were measured. According to a literature [11], the urethra can be divided into three segments: proximal segment (the segment  $<1/2$  from the inner opening), middle segment (the segment located within  $1/2$  to  $3/4$  from the inner opening), and distal segment (segment  $>3/4$  from the inner opening). According to the measured U and B, the tape position was divided into three sites: proximal, middle and distal segments. In the 74 patients, the U value was  $2.88 \pm 0.33$  cm (2.06-3.8 cm) and the B value was  $1.93 \pm 0.39$  cm (0.96-2.7 cm). The tape was located in the proximal segment of the urethra in five patients and in the middle segment in 69 patients (93.2%), while no patient had the tape in the distal segment of the urethra. Furthermore, the Ar value was  $1.84 \pm 0.31$  cm (1.12-2.88 cm), the Av value was  $1.36 \pm 0.31$  cm (0.73-2.53 cm), and the Ar-v value was  $0.47 \pm 0.30$  cm (-0.25-1.09 cm). In both the cured group and improved group, two patients had the tape located in the proximal segment of the urethra. The B, Ar, Av and Ar-v values between these two groups were compared and statisti-



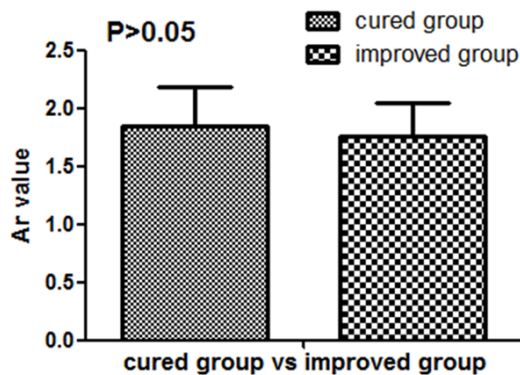
## Evaluation of tape position in SUI

**Table 1.** Comparison and analysis of the B, Ar, Av and Ar-v values between these two groups

	B	Ar	Av	Ar-v
The cured group	1.98±0.38 cm	1.85±0.33 cm	1.3±0.28 cm	0.56±0.27 cm
The improved group	1.89±0.39 cm	1.76±0.28 cm	1.45±0.26 cm	0.33±0.27 cm
P value	0.167	0.126	0.013	0.00037



**Figure 6.** The B value in cured group is  $1.98 \pm 0.38$  cm, the value in improved group is  $1.89 \pm 0.39$  cm. The differences in B values between the cured group and improved group were not statistically significant ( $P>0.05$ ).



**Figure 7.** The Ar value in cured group is  $1.85 \pm 0.33$  cm, the Ar value in improved group is  $1.76 \pm 0.28$  cm. The differences in Ar values between the cured group and improved group were not statistically significant ( $P>0.05$ ).

cally analyzed (Table 1). Two patients with invalid results: For one patient who had an invalid result after TVT, pelvic floor ultrasonography revealed that the tape was close to the back of the urethra, the B value was 1.55 cm, the location was in the middle urethra, Ar was 1.73 cm, Av was 0.73 cm, and Ar-v was 1 cm. During the Valsalva maneuver, the tape was attached to

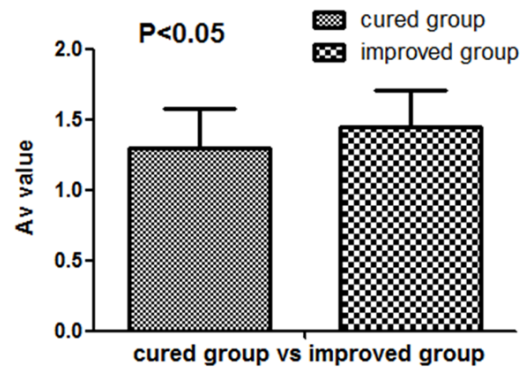
the symphysis pubis and compressed the urethra. For the other patient who had an invalid result after TVT-O, pelvic floor ultrasonography revealed that the

tape was close to the back of the urethra. During the resting state, the B value was 1.4 cm, the location was in the proximal urethra, Ar was 2.28 cm, Av was 2.53 cm, and Ar-v was -0.25 cm. During the Valsalva maneuver, the tape neither moved towards the symphysis pubis, nor lifted the urethra; and its position did not obviously change.

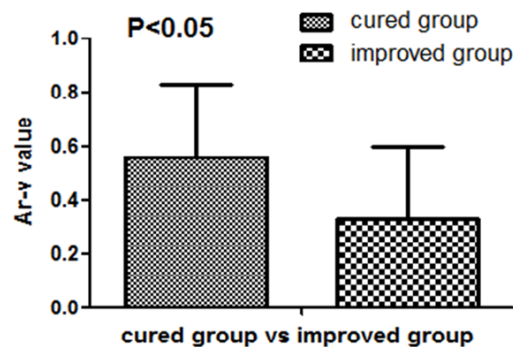
The differences in B and Ar values between the cured group and improved group were not statistically significant ( $P>0.05$ ) (Figures 6 and 7), while the differences in Av and Ar-v values were statistically significant ( $P<0.05$ ) (Figures 8 and 9). Since the difference in B and Ar were not significant, the ultrasound evaluation and clinically symptoms between two groups were inconsonant. B and Ar values were not suitable for evaluating the curative effect of the patients after TVT and TVT-O. However, the difference in Av and Ar-v were statistically significant, the ultrasound evaluation and clinically symptoms between two groups are anastomotic. Av and Ar-v values could be used to evaluate the curative effect better.

### Discussion

In 1994, DeLancey [12] proposed the “theory of hammock”, bringing a whole new understanding for the treatment of SUI. He referred to the tissue structures surrounding the posterior urethra and bladder neck as a “hammock” supporting the urethra. Among these tissues, the pubococcygeus, arcus tendineus fasciae pelvis and levator ani muscle can contract and pull forward the vagina when abdominal pressure increases, tighten the “hammock”, and flatten the urethra that distributes between the symphysis pubis and vagina, increasing its pressure to match the increased abdominal pressure and control urination. Both the “hammock theory” and “holistic theory” proposed by Petros consider that the middle segment of the urethra plays a major role in urinary control, and abnormalities in the “supporting plane”



**Figure 8.** The Av value in cured group is  $1.3 \pm 0.28$  cm, the Av value in improved group is  $1.45 \pm 0.26$  cm. The differences in Av values were statistically significant ( $P < 0.05$ ).



**Figure 9.** The value of Ar-v in cured group is  $0.56 \pm 0.27$  cm, the value of Ar-v in improved group is  $0.33 \pm 0.27$  cm. The differences in Ar-v values were statistically significant ( $P < 0.05$ ).

composed of various pelvic floor structures and tissues surrounding the middle segment of the urethra lead to the occurrence of SUI. Therefore, the theory of suspension of the middle urethra has become the gold standard for the treatment of female SUI [13]. For moderate-severe SUI patients, tension-free suspension of the middle urethra has become the first-line treatment [14]. Among these treatments, TVT and TVT-O have presently been well-recognized as safe and long-term effective minimally invasive treatments [15]. As reported by a literature, the total satisfaction rate at one year after the operation in 121 patients undergoing TVT and 98 patients undergoing TVT-O was 81.6-85.7% [16]. Another literature reported that [17] the total cure rate of taping in 142 patients was 95.07%. In the present study, patients were followed up for 6-24 months, and the total satisfaction rate was 97.3%, which was similar to that reported in literature.

Transperineal pelvic floor ultrasonography is a simple and non-invasive examination technique. Compared with X-ray and MRI, pelvic floor ultrasonography has no radiation, and allows dynamic observation in real-time. It is of great significance for the diagnosis and evaluation of the surgical curative effect of SUI [18, 19]. The position, migration and fixation points of the tape can be observed by pelvic floor ultrasonography after the operation for SUI, in order to understand the surgical treatment condition. Foreign studies have revealed that after TVT-O, the distance and angle between the pubis and urethra were greater in non-cured patients than in cured patients. Therefore, changes in these two indexes were detected and compared by pelvic floor ultrasonography to assess whether the operation was successful [20]. In the present study, the position and migration of the tape in SUI patients were assessed by measuring U, B, Ar, Av and Ar-v values using transperineal pelvic floor ultrasonography. According to a literature [6], it was reported that the U value in normal postmenopausal women was  $2.9 \pm 0.55$  cm, while the U value in premenopausal women was  $3.75 \pm 0.67$  cm. This shows that the urethra was shorter in postmenopausal women than in premenopausal women. In the present study, these SUI patients were mostly postmenopausal women, the U value was  $2.88 \pm 0.33$  cm. The tape position behind the urethra was evaluated according to the U value. The middle segment of the urethra plays a major role in urinary control, is the "supporting plane" of the urethra (that is, the septum-fusion junction between the urethra and vagina), mainly refers to the 1/2 to 3/4 length of the urethra from the inner urethral opening, and is at the site of approximately 2/3 of the urethra in average [11]. According to a literature, in the present study, the urethra was divided into three segments: proximal segment ( $<1/2$ ), middle segment (1/2 to 3/4) and distal segment ( $>3/4$ ). Yuan-Hong Jiang *et al.* [21] followed-up 153 SUI patients after retropubic TVT, and statistically analyzed the correlation between tape position and recurrence. Their results revealed that the recurrence rate was 50% in patients where the tape was located in the urethral opening, 18.5% in patients where the tape was located in the proximal segment of the urethra, 22.2% in patients where the tape was located in middle segment of the urethra, and 33.3% for patients where the tape was located in distal segment of the urethra. It is considered that the tape position is closely correlated to the postoperative recurrence of

SUI. In the present study, among the 74 patients, the tape was located in the middle segment of the urethra in 69 patients and in the proximal segment of the urethra in five patients. The tape position in all patients was associated with relatively lower recurrence rates, which was reasonable and effective. The difference in tape position between the cured group and improved group was not statistically significant. In order to obtain the index of tape migration in the present study, the Ar value of  $1.84 \pm 0.31$  cm (1.12-2.88 cm), the Av value of  $1.36 \pm 0.31$  cm (0.73-2.53 cm), and the Ar-v value of  $0.47 \pm 0.30$  cm (-0.25-1.09 cm) were used. Furthermore, the cured group and improved group were compared, and results revealed that the Ar value was  $1.85 \pm 0.33$  cm in the cured group and  $1.76 \pm 0.28$  cm in the improved group, and the difference between these two groups was not statistically significant ( $P>0.05$ ). In the cured group, the Av value was  $1.3 \pm 0.28$  cm and the Ar-v value was  $0.56 \pm 0.27$  cm, while in the improved group, the Av value was  $1.45 \pm 0.26$  cm and the Ar-v value was  $0.33 \pm 0.27$  cm; and the differences between these two groups were statistically significant ( $P<0.05$ ). These results revealed that the distance between the tape and symphysis pubis in the Valsalva state was shorter in the cured group than in the improved group, and the range of motion was slightly greater in the cured group than in the improved group. For the two patients that had an invalid result, the tape was close to posterior urethra and located in the middle segment of the urethra. In the Valsalva state, the Av value was 0.73 cm; which was smaller than that in patients in the above two groups. The Ar-v value was 1 cm, which was significantly greater than that in cured and improved patients. These results revealed that the tape was too tight in this patient, causing discomfort such as dysuria, difficulty in urination, and non-improvement of urinary incontinence. In the patient that had an invalid result after TVT-O, the tape was located in the proximal segment of the urethra. The Av value was 2.53 cm, which was greater than that in the above two groups, and the Ar-v value was -0.25 cm, which was significantly smaller than that in the above two groups and was negative. This suggests that in the Valsalva state, the tape did not migrate towards the symphysis pubis. On the contrary, it moved a little further away, and the tape was relaxed and did not hold up the urethra. Therefore, the urinary incontinence symptom was not improved in the patient after the operation. Through the above data, the present study

concluded that the tape should be placed in the middle segment of the urethra, holding up the urethra when abdominal pressure increases, and making it migrate toward the symphysis pubis. An extremely short distance would make the tape too tight, affect its efficacy and cause discomfort; while an extremely long distance would make the tape relaxed and ineffective, failing to play its role. Therefore, it is very critical to select the position and degree of tightness of the tape during the operation. In observing and measuring the position of the tape and the trajectory of the tape after the abdominal pressure increases, pelvic floor ultrasonography provides quantitative data for the assessment of placement position of the tape after the operation, assists clinicians in selecting the tape position during the operation, and evaluates the curative effect.

In the present study, the tape position was measured only by pelvic floor ultrasonography, each value was measured several times, and the average value was calculated. However, there were still measurement errors due to individual differences and laying position. The aim of the present study was to understand the position of the tape and the correlation between its migration and prognosis. The situation of the tape can be understood according to the data.

In summary, tension-free suspension of middle segment of the urethra is an effective therapeutic method for SUI, and the total satisfaction rate is 97.3%. The tape should be placed in the middle segment of the urethra and moderately close to the symphysis pubis in the Valsalva state, and should not be too tight or too loose. Pelvic floor ultrasonography can clearly display the urethra and neck of the bladder, other anatomical structures of the pelvic floor, and the position, state and trajectory of the tape. It can also assist in assessing the efficacy of tape placement, providing useful information in clinic.

## Disclosure of conflict of interest

None.

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