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Original Article

Long-term Outcomes of the Tension-Free Vaginal Tape Procedure for Female Stress Urinary Incontinence: 7-Year Follow-up in China

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ABSTRACT **Study Objective:** To estimate the long-term objective rates of cure, late complications, and satisfaction after tension-free vaginal tape (TVT) procedure.
Design: Retrospective study (Canadian Task Force classification II-3).
Setting: Single-center.
Patients: Fifty-five patients with moderate to severe stress urinary incontinence (SUI) underwent the TVT procedure from May 2002 to March 2005.
Intervention: TVT procedure.
Measurements and Main Results: Changes in 1-hour pad test results and incontinence quality-of-life (I-QOL) questionnaire scores before surgery and at 1- and 7-year follow-up were compared. Changes in objective rates of cure, late complications, and satisfaction at 1- and 7-year follow-up were also compared. The mean duration of follow-up was 6.80 years. Both the 1-hour pad test results and the I-QOL questionnaire scores improved significantly after surgery ($p < .001$). The TVT procedure satisfaction rate at 7-year follow-up decreased significantly compared with that at 1-year follow-up ($p = .001$); however, I-QOL score did not change significantly.
Conclusions: The TVT procedure is an effective treatment for SUI in female patients. Despite little persistent or recurrent SUI over 7-year follow-up, satisfaction with the procedure decreases. Therefore, other age-related bladder conditions must be considered when counseling patients about the TVT procedure. Assessment of the efficacy of the TVT procedure should include both objective and subjective standards. Journal of Minimally Invasive Gynecology (2012) 19, 201–205 © 2012 AAGL. All rights reserved.

Keywords: Late complications; Outcome; Stress urinary incontinence; Tension-free vaginal tape

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Stress urinary incontinence (SUI) is a condition that affects the quality of a woman's life. The tension-free vaginal tape (TVT) procedure was first described in 1996 [1], and has become the preferred treatment for female SUI because of its minimal invasiveness and high success rate. There are no long-term data concerning the TVT procedure in mainland China. Therefore, we estimated the long-term efficacy and complications of the TVT procedure as a treatment for female SUI, and satisfaction with the procedure.

Materials and Methods

This retrospective study, conducted from May 2002 to March 2005, included 55 consecutive patients who underwent the TVT procedure. Inclusion criteria were moderate to severe SUI with or without pelvic organ prolapse. Exclusion criteria were urinary tract infection, urge incontinence, post-void residual volume greater than 100 mL, or history of

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Table 1

Characteristics of 55 study patients[a]

Variable	Value
Age, yr	55.95 (12.57); 51.56–58.48
Body mass index	25.43 (3.06); 24.50–26.25
Parity, median (range)	2 (0–8)
Cystocele stage, No. (%)	
0	4 (7.27)
1	16 (29.09)
2	27 (49.09)
3	8 (14.55)
SUI degree, No. (%)	
Moderate	29 (52.73)
Severe	26 (47.27)
ALPP, cm H_2O	88.33 (10.08); 85.17–91.22
Flow rate, mL/sec	22.73 (8.33); 20.27–25.27
Post-voiding residual volume, median, mL (range)	0 (0–50)
Duration of incontinence, yr	10.35 (8.67); 8.01–12.70
Follow-up, mo	81.85 (10.78) 78.47–84.74
Q-tip, degree	32.84 (5.89); 31.19–34.50
Uterus/vault prolapse, No. (%)	8 (14.55)
Rectocele, No. (%)	15 (27.27)
Concomitant hysterectomy and pelvic reconstruction surgery, No. (%)	8 (14.55)
Intrinsic sphincter deficiency	0

ALPP = abdominal leakpoint pressure; CI = confidence interval; SUI = stress urinary incontinence.
[a] Unless otherwise indicated, values are given as mean (SD); 95% CI.

neurologic disease, urogenital malignancy, fistula, pelvic radiotherapy, or previous antiincontinence surgery [2]. All participants gave verbal and signed informed consent. The study was approved by the institutional ethics committee of Peking Union Medical College Hospital.

A detailed history of urinary incontinence was recorded, and gynecologic examination, urine culture, stress test, Bonney test, 1-hour pad test, and urodynamic study were performed. The pad test and urodynamic study were independently performed by the same well-trained nurse. The degree of SUI was determined using the 1-hour pad test, and was classified as mild, moderate, or severe if urine leakage weighed less than 2 g, 2 to 10 g, or more than 10 g, respectively [2]. The stage of vaginal defect was evaluated by pelvic organ prolapse quantification during the urogynecologic examination. Intrinsic sphincter deficiency (intrinsic sphincter deficiency) was defined as abdominal leakpoint pressure less than 60 cm H_2O.

The TVT procedure has been described previously [1,2]. Needles and tapes used were Gynecare products (Ethicon, Inc., Somerville, NJ). After the needles were in place but before the tape was pulled upward, cystoscopy was performed. Patients with pelvic floor disorders in addition to SUI underwent TVT along with hysterectomy and pelvic reconstruction surgery that included anterior colporrhaphy and rectovaginal fascia plication.

Follow-up included gynecologic examination, 1-hour pad test, and questionnaires. The urodynamic study was not performed at follow-up. The 1-hour pad test, questionnaires, and the visual analog scale were independently performed by properly trained nurses. In patients with voiding difficulty or urgency, the post-void residual urine volume was measured, and the result was deemed abnormal if the volume was more than 50 mL. Patients who reported urgency completed a 3-day voiding diary. The clinical outcome was considered an objective cure when the results of the 1-hour pad test was normal (<1 g) during follow-up visits. Compared with the results of the 1-hour pad test before surgery, a greater than 50% reduction in urine weight after surgery was considered improvement, and a less than 50% reduction was considered failure [3]. Patient satisfaction with the TVT procedure was evaluated using a visual analog scale, as follows: a score of 0 = extremely unsatisfied, 50 or less = unsatisfied, 51 to 79 = equivocal, and 80 to 100 = very satisfied. Complications were defined as follows. De novo urgency was defined as urgency symptoms that occurred only postoperatively. Vaginal mesh erosion was defined as vaginal exposure of mesh, with redness, dyspareunia, or discharge. Symptoms of minor voiding difficulties included slow urinary stream, extended urination, or urinary hesitancy. The patient answered the Incontinence Quality-of-Life questionnaire (I-QOL) (not validated) before surgery and at 1- and 7-year follow-up. The high score of the I-QOL was 100 points, with the higher scores indicating better QOL.

Statistical analysis was performed using the Wilcoxon signed-rank test and the McNemar χ^2 test for comparisons of objective rates of cure, late complications, and satisfaction at 1- and 7-year follow-up. The Spearman correlation coefficient was used to estimate the association between I-QOL scores and degree of SUI, because the Chinese translation of the I-QOL was not validated before use in this study. The 1-hour pad test results and I-QOL scores were compared by using analysis of variance for data with a normal distribution and homogeneity of variances. Otherwise, the rank-sum test was performed. The α value for multiple comparisons was 0.167. The standard normal distributional assumptions were evaluated using the Kolmogorov-Smirnov test, and the homogeneity of variances using the Levene test. A p value <.05 was considered statistically significant. All statistical tests were 2-sided. Normal quantitative data were expressed as mean (SD), and with the 95% confidence interval. The skewed data were expressed as median (range), and categorical data were expressed as percentage. Data were analyzed using commercially available software (SPSS version 18.0; SPSS, Inc., Chicago, IL).

Results

Fifty-five patients were followed up for almost 7 years (mean [SD], 6.80 years [81.85 ± 10.78 months]; range, 62–102 months). Patient characteristics are given in Table 1. Their mean (SD) age was 55.95 (12.57) years,