

## LONG-TERM DURABILITY AND FUNCTIONAL OUTCOMES OF THE TENSION-FREE VAGINAL TAPE PROCEDURE AND FACTORS FOR SURGICAL FAILURE: A SINGLE CENTER TWELVE-YEAR EXPERIENCE

### Hypothesis / aims of study

There are few long-term studies regarding the efficacy and safety of tension-free vaginal tape (TVT) procedure for women with stress urinary incontinence (SUI)<sup>1,2</sup>. Burch colposuspension or pubovaginal sling (PVS), the gold standards for SUI prior to the era of the TVT, proved long-term success at more than 10 years follow-up. Moreover, in the previous result, the cure rate of the TVT seemed to decrease significantly over time<sup>3</sup>.

We therefore investigated the long-term durability and functional outcomes of the TVT procedure for female SUI and identified the risk factors that may affect the long-term outcome at more than 10 years.

### Study design, materials and methods

We analyzed data of the patients with proven urodynamic SUI underwent the TVT procedure and were followed up for at least 12 years. Exclusions were neurological disease, concomitant surgery and repeat TVT. We contacted with the patients who completed postoperative 1-year, 5-year and 10-year follow-up visit to re-visit the clinic at postoperative 12 years. Preoperative evaluations included complete medical history, physical examination, 3-day voiding diary with urinary urgency scale, uroflowmetry, post-void residual urine measurement, and complete multichannel urodynamic study. When the patients re-visited the clinics, they were again evaluated by the Severity Index for Urinary Incontinence in Women, physical examination, uroflowmetry, post-void residual urine measurement and complications related to surgery. The patient global satisfaction, the assessment of goal achievement for treatment, whether patients would recommend TVT to other SUI patients with similar symptoms and whether patients would undergo TVT again if the same symptoms recurred were assessed at 12 years. We analyzed the long-term cure rates of TVT procedure for female SUI, patient satisfaction, late complications related to surgery and the risk factors related outcome. Cure was defined as the absence of any episodes of involuntary urine leakage on the Severity Index for Urinary Incontinence in Women at 12 years postoperatively.

### Results

The mean age at surgery was 54.2 (range: 38-78) years. The cure rate was 71.0% (66/93), improvement 24.7% (23/93), and failure 4.3% (4/93). The cure rates were 92.5% (86/93) at 1 year and 77.4% (72/93) at 5 years. Statistical analysis showed that the 5-year cure rates were lower than the 1-year cure rate ( $p=0.007$ ), and that the 5- and 12-year rates was similar ( $p=0.402$ ). The median goal achievement score was 4 and 75.3% (70/93) successfully achieved their preoperative goals for the treatment. The satisfaction rate was 88.2 % (82/93). The proportion of patients who would recommend TVT to other SUI patients was 94.6% (88/93), and 75.3% (70/93) of patients would undergo the same procedure if same symptoms recurred.

Among the patients with OAB symptoms preoperatively, 8 (34.8%) and 9 (29.0%) were free of OAB symptoms at the last follow-up and de novo urgency and urgency incontinence developed in 27.1% (13/48) and 15.5% (11/71) patients at 12 years. The mean maximal flow rate before the TVT procedure was  $23.3 \pm 9.0$  ml/s, but decreased significantly to  $18.8 \pm 6.7$  ml/s at 12 years after the operation ( $p=0.043$ ). The postvoid residual urine increased to  $42.3 \pm 107.3$  ml from  $7.6 \pm 10.9$  ml, which was not significantly different ( $p=0.168$ ).

On multivariate analysis, there were no independent risk factors related durability, satisfaction and de novo OAB symptoms. But, the patients' age with the disappearance of preoperative urgency symptoms were younger than that of sustainment of urgency ( $49.7 \pm 6.8$  years vs,  $56.2 \pm 7.8$  years, respectively) and the age was the only statistically significant parameter affecting the disappearance of preoperative urgency symptoms (Odds ratio (95% CI) = 0.88 (0.81-0.97),  $p=0.006$ )

One patient was required of CIC due to a large residual urine volume during follow-up. There was neither tape rejection nor removal.

### Interpretation of results

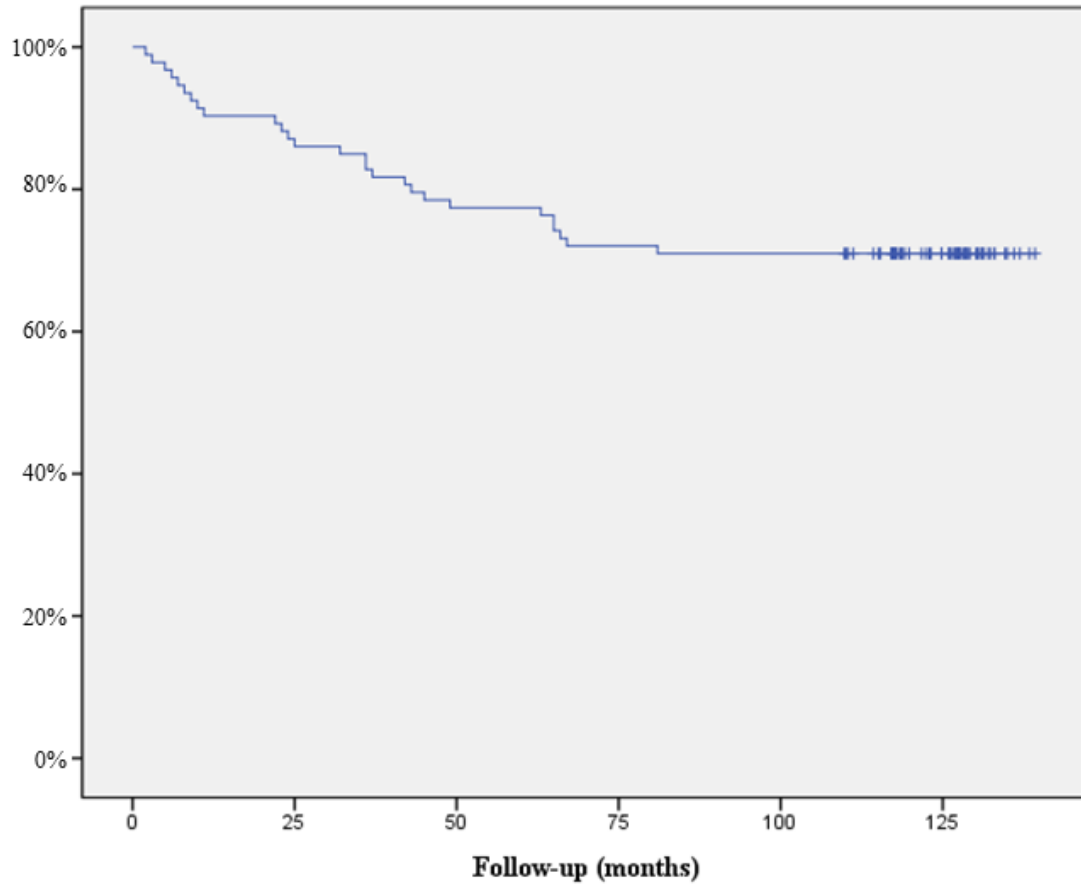
The TVT procedure was an effective long-term treatment for female SUI although its cure rate is decreasing with time. There were no independent risk factors related durability, satisfaction and novo OAB symptoms The age was the only predictor of the disappearance of preoperative urgency symptoms. There was neither tape rejection nor removal.

### Concluding message

The TVT procedure was found to be a safe and effective long-term treatment for female SUI although its cure rate is decreasing with time without any independent predictive factors affecting long-term durability and de novo OAB symptoms. The age was the only predictor of the disappearance of preoperative urgency symptoms.

Figure 1 - Kaplan-Meier survival curve without recurrence of stress urinary incontinence for the TVT procedure

% of cured patients



References

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Disclosures

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