Five-Year Outcomes of the Tension-Free Vaginal Tape Procedure for Treatment of Female Stress Urinary Incontinence

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Abstract

Objectives: We evaluated the long-term efficacy and safety of a tension-free vaginal tape (TVT) procedure for the treatment of female stress urinary incontinence (SUI) in a Korean population.

Methods: We included 134 patients (mean age, 52.3 ± 9.3 yr) who underwent the TVT procedure for SUI in three institutions and followed for 5 yr (mean, 67.0 mo; range, 60–76 mo) postoperatively. We analysed voiding diaries and complete multichannel urodynamic studies preoperatively as well as cough stress tests, uroflowmetry, and questionnaires postoperatively.

Results: The overall 5-yr success rates (cure/improved) were 94.9% (76.9% and 18.0%, respectively), with an 86.6% patient satisfaction rate. Although the success rates between 1 and 5 yr were similar (97.7% vs. 94.9%), the cure rate decreased from 90.1% to 76.9% (p < 0.001) at 5 yr. The 5-yr cure rate for mixed urinary incontinence (MUI) was 72.0%, which was not significantly different from pure SUI (78.0%, p > 0.05). Maximal flow rate dropped from 25.9 ± 10.3 ml/s to 20.4 ± 8.6 ml/s at 1 mo postoperatively and recovered to 24.8 ± 8.5 ml/s at 5 yr. Complications included bladder perforation in 5 patients (3.7%), tape cutting or release in 11 (8.2%), and persistent suprapubic pain in 3 (2.2%). Urgency and urge incontinence improved in 46.7% and 48.0% of patients, respectively.

Conclusions: TVT was an effective and safe procedure for SUI and MUI with high success rates in the long-term follow-up. It also improved concomitant overactive bladder symptoms and initially reduced postoperative urine flow, which recovered over time.
1. Introduction

The tension-free vaginal tape (TVT) procedure, first described in 1996, is a modified suburethral sling procedure for female stress urinary incontinence (SUI) based on the integral theory [1]. The TVT procedure has become the treatment of choice for SUI because it is a minimally invasive operation with high success rates after short- and intermediate-term follow-up [2,3]. Few long-term follow-up data on the TVT procedure are available, however, except from Scandinavian groups, who pioneered this method. Furthermore, no long-term data on the TVT procedure are available from Asian countries. We therefore evaluated the long-term efficacy and safety of the TVT procedure, with a follow-up of >5 yr, for the treatment of female SUI.

2. Methods

Between March 1999 and June 2000, 155 consecutive women with complaints of SUI underwent the TVT procedure in three institutions in Korea. Among these patients, 138 were followed up for at least 5 yr; the remaining 17 patients could not be followed up because they did not respond when contacted by mail and telephone. In 138 patients, 4 who underwent concomitant surgery (hysterectomy in 1, caruncule excision in 1, and cystocele repair in 2) were excluded from the evaluation because those procedures might have influenced the cure rates. The 134 patients studied had a mean age of 52.3 ± 9.3 yr (mean follow-up period, 67.0 mo; range, 60–76 mo).

Preoperative evaluations included medical history, physical examination, 3-d voiding diary, uroflowmetry, postvoid residual urine measurement, and complete multichannel urodynamic investigation. Urodynamic evaluation consisted of filling and voiding cystometry, Valsalva leak point pressure (VLPP), and maximal urethral closing pressure (MUCP) measurements. Nonintubated urine flow rates were obtained using an MMS flowstar calibrated by trained study assistants. Electronically measured peak urinary flow rates, average flow rates, and voided volume were determined. Measurements were repeated if voided volume was <150 ml. In cases of duplicate measurements, we used the highest rate in our analyses. Using the Aquarius 120, filling cystometry was performed at a rate of 100 ml/min using sterile saline with the subject seated in a chair. A 6F double-lumen cystometry catheter was placed into the urethra and bladder. When the patient felt a maximal desire to void, she was asked to void. During the voiding phase, the intravesical pressure, detrusor pressure, abdominal pressure, flow rate, and detrusor pressure at maximal flow rate were recorded. VLPP was obtained at a bladder volume of 200 ml by asking the patients to perform a Valsalva maneuver until leakage occurred. MUCP was measured by withdrawing the intravesical catheter at a rate of 1 m/min to create a urethral pressure profile and calculated by subtracting the baseline bladder pressure from the maximal urethral pressure. All definitions corresponded to those of the International Continence Society [4].

The TVT procedure was performed by experienced surgeons using the standard technique with some modifications [1]. The operations were usually performed using a combination of light sedation and local anaesthesia but general or spinal anaesthesia was used if requested by the patient or when concomitant pelvic or vaginal procedures were performed.

All patients visited the clinics 1 yr and 5 yr after surgery, at which time they were again evaluated by a medical history, physical examination, uroflowmetry, and postvoid residual urine measurement. A patient global satisfaction was assessed at 5 yr. We analysed the success rates of TVT for treatment of SUI and mixed urinary incontinence (MUI), patients’ perception of satisfaction, changes in overactive bladder symptoms after surgery, and complications related to surgery.

Cure was defined as the absence of any episodes of involuntary urine leakage during the stressful activities and stress cough test. Improvement was defined as a significant reduction of urine leakage, such that it did not require further treatment [5]. All other outcomes were regarded as failures. Patient perception of this operation was categorised as very satisfied, satisfied, so-so, and dissatisfied, with both very satisfied and satisfied scored as satisfied. Safety data were collected during the entire follow-up period.

Urgency was defined as a sudden compelling desire to pass urine, which was difficult to defer and urge incontinence was defined as involuntary leakage accompanied by or immediately preceded by urgency [4].

Normally distributed variables were compared with the Student t test. A 5% level of significance was used for all statistical testing and all statistical tests were 2-sided. Analyses were performed using statistical software (SPSS 11.0, SPSS, Chicago, IL).

3. Results

Table 1 shows the characteristics of the 134 patients. The mean parity of these patients was 3.2 ± 1.6, and their mean body mass index (BMI) was 24.2 ± 2.7 kg/m². Seventeen (12.7%) of these patients had previously undergone hysterectomy. Before surgery, 25 (18.7%) of the women complained of concomitant urge incontinence and 30 (22.4%) complained of urgency. Preoperative symptom grade was 1 (loss of urine only with coughing, sneezing, or lifting heavy objects) in 66 (47.8%) patients, 2 (loss of urine with minimal activity such as walking or standing from the sitting position) in 63 (47.0%), and 3 (totally incontinent while upright) in 5 (3.7%). Seven (5.2%) patients had previously undergone anti-incontinence surgery, including the Raz procedure, anterior vaginal wall sling, or bladder-neck suspension. Sixty-eight (50.7%) patients underwent TVT under local anaesthesia,
whereas 42 (31.3%) and 24 (17.9%) chose spinal and general anaesthesia, respectively. Mean operative time was 28.3 min (range, 17–100 min). Mean hospital stay was 2.1 d (range, 0–13 d) and mean urethral catheter indwelling time was 0.8 d (range, 0–6 d).

The success rates in these 134 women are presented in Table 2. The overall 1-yr cure and improvement rates were 90.1% (118 of 131) and 7.6% (10 of 131); treatment failed in three patients (2.3%). The overall 5-yr cure, improvement, and failure rates were 76.9% (103 of 134), 18.0% (24 of 134), and 5.2% (7 of 134), respectively. Although the 1- and 5-yr success rates were similar (97.7% vs. 94.9%), the cure rate of the TVT procedure decreased significantly over time (90.1% vs. 76.9%, \( p < 0.001 \)). A total of 116 (86.6%) women were satisfied with the operation.

The 1-yr cure rate of TVT for MUI was 83.3% (20 of 24), which was not significantly different from the 1-yr cure rate for pure SUI (98 of 107, 91.6%; \( p > 0.05 \)). The 5-yr cure rate (18 of 25, 72.0%) for MUI also did not differ significantly from the 5-yr cure rate for pure SUI (85 of 109, 78.0%; \( p > 0.05 \)). Twenty patients (80.0%) with MUI and 96 (88.1%) with pure SUI were satisfied with the operation (\( p > 0.05 \), Table 3).

The overall 5-yr cure rate of patients with VLPP < 60 cm H\(_2\)O was 50.0% (15 of 30), which was significantly lower than that of patients with VLPP \( \geq \) 60 cm H\(_2\)O (51 of 61, 83.6%, \( p = 0.001 \)). When we divided the patients into three groups according to symptom grade, we found that the cure rates were 87.9% (58 of 66) in women with grade 1, 68.3% (43 of 63) in women with grade 2, and 40% (2 of 5) in women with grade 3 (\( p = 0.004 \); Fig. 1).

The mean maximal flow rate before the TVT procedure was 25.9 ± 10.3 ml/s, but decreased significantly to 20.4 ± 8.6 ml/s at 1 mo after the operation (\( p < 0.001 \)). Over time, however, the urinary flow rate increased linearly, with the maximal flow rate

### Table 1 – Characteristics of 138 patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, yr (range)</td>
<td>52.3 (35–78)</td>
</tr>
<tr>
<td>Mean parity (range)</td>
<td>3.2 (0–10)</td>
</tr>
<tr>
<td>Mean body mass index, kg/m(^2) (range)</td>
<td>24.2 (17–31)</td>
</tr>
<tr>
<td>No. grade 2 cystocele (%)</td>
<td>6 (4.5%)</td>
</tr>
<tr>
<td>No. associated urge incontinence (%)</td>
<td>25 (18.7%)</td>
</tr>
<tr>
<td>No. urgency (%)</td>
<td>30 (22.4%)</td>
</tr>
<tr>
<td>No. concomitant posterior repair (%)</td>
<td>11 (8.2%)</td>
</tr>
<tr>
<td>No. SUI grade (%)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>66 (47.8%)</td>
</tr>
<tr>
<td>2</td>
<td>63 (47.0%)</td>
</tr>
<tr>
<td>3</td>
<td>5 (3.7%)</td>
</tr>
<tr>
<td>Mean 1-h pad test, g (range)</td>
<td>45.8 (5–500)</td>
</tr>
</tbody>
</table>

**Mean urodynamic parameters:**
- Peak urinary flow, ml/s (range) 25.8 (5–71)
- Voided volume, ml (range) 292.4 (55–578)
- Post-voided residual, ml (range) 13.6 (0–79)
- Maximum cystometric capacity, ml (range) 434.6 (220–652)
- Maximum detrusor pressure, cm H\(_2\)O (range) 28.5 (10–76)
- VLPP, cm H\(_2\)O (range) 79.5 (22–194)
- MUCP, cm H\(_2\)O (range) 53.3 (9–113)
- No. detrusor overactivity (%) 32 (23.9%)
- Mean functional bladder capacity, ml (range) 372.9 (200–600)
- No. anaesthesia (%)                    |
  - Local                                | 68 (50.7%)         |
  - Spinal                               | 42 (31.3%)         |
  - General                              | 24 (17.9%)         |

\( \text{SUI} = \text{stress urinary incontinence}; \text{VLPP} = \text{Valsalva leak point pressure}; \text{MUCP} = \text{maximal urethral closing pressure}. \)

### Table 2 – The 1- and 5-yr outcomes of tension-free vaginal tape for stress urinary incontinence

<table>
<thead>
<tr>
<th>Outcome</th>
<th>1 yr</th>
<th>5 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cured</td>
<td>90.1% (118/131)</td>
<td>76.9% (103/134)</td>
</tr>
<tr>
<td>Improved</td>
<td>7.6% (10/131)</td>
<td>18.0% (24/134)</td>
</tr>
<tr>
<td>Failed</td>
<td>2.3% (3/131)</td>
<td>5.2% (7/134)</td>
</tr>
<tr>
<td>Satisfaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfied</td>
<td>–</td>
<td>86.6% (116/134)</td>
</tr>
<tr>
<td>Equivocal</td>
<td>–</td>
<td>5.2% (7/134)</td>
</tr>
<tr>
<td>Unsatisfied</td>
<td>–</td>
<td>8.2% (11/134)</td>
</tr>
</tbody>
</table>

\( * p < 0.05. \)

### Table 3 – The 1- and 5-yr outcomes of tension-free vaginal tape for mixed urinary incontinence

<table>
<thead>
<tr>
<th></th>
<th>1 yr</th>
<th>5 yr</th>
<th>Satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MUI +</td>
<td>83.3 (20/24)</td>
<td>72.0 (18/25)</td>
<td>80.0 (20/25)</td>
</tr>
<tr>
<td>MUI –</td>
<td>91.6 (98/107)</td>
<td>78.0 (85/109)</td>
<td>88.1 (96/109)</td>
</tr>
<tr>
<td>( p )</td>
<td>0.256</td>
<td>0.600</td>
<td>0.329</td>
</tr>
</tbody>
</table>

\( * p < 0.05. \)

### Fig. 1 – Success rates relative to Valsalva leak point pressure (VLPP) and stress urinary incontinence (SUI) grade.
5 yr after surgery increasing to 24.8 ± 8.5 ml/s, which was similar to the preoperative flow rate. In contrast, the postvoid residual urine increased significantly, to 30.0 ± 47.1 ml (Fig. 2).

Compared with preoperative levels, a significant decrease was reported in micturition frequency per day (7.1 ± 1.8 to 6.5 ± 1.7, p = 0.004), but no significant change in patients with MUI (8.6 ± 1.7 to 7.6 ± 2.7, p = 0.248) over 5 yr. Functional bladder capacity did not change (358.9 ± 86.6 ml to 343.7 ± 91.3 ml, p = 0.460). Urgency and urge incontinence improved in 46.7% (14 of 30) and 48.0% (12 of 25) of patients, respectively. However, 11.5% (12 of 104) developed de novo urgency and urge incontinence, and another 3.8% (4 of 104) developed de novo urgency. Patients with persistent (n = 16) or de novo (n = 16) overactive bladder symptoms were managed with anticholinergics.

Five (3.7%) patients had a bladder perforation, which was managed with an indwelling urinary catheter for 1–3 d. Eight (6.0%) women had urinary retention after surgery. Short-term retention was treated with an indwelling catheter for 2–6 d. Two patients experienced recurrent urinary tract infection, and one patient required clean intermittent catheterisation due to voiding dysfunction. Eleven (8.2%) patients underwent a simple vaginal TVT release or incision procedure because of reduced stream and large amounts of residual urine. Three (2.2%) patients complained of persistent pain on the suprapubic area. There were no bowel, nerve, or major vessel injuries, and no vaginal or urethral erosion was identified (Table 4).

### Table 4 – Complications after tension-free vaginal tape procedure

<table>
<thead>
<tr>
<th>Complication</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder perforation</td>
<td>5 (3.7%)</td>
</tr>
<tr>
<td>Recurrent urinary tract infection</td>
<td>2 (1.5%)</td>
</tr>
<tr>
<td>Short-term voiding difficulty (indwelling catheter for 2–6 d)</td>
<td>8 (6.0%)</td>
</tr>
<tr>
<td>De novo urgency</td>
<td>16 (15.4%)</td>
</tr>
<tr>
<td>Tension-free vaginal tape release or cutting</td>
<td>11 (8.2%)</td>
</tr>
<tr>
<td>Persistent pain on suprapubic area</td>
<td>3 (2.2%)</td>
</tr>
<tr>
<td>Clean intermittent catheterisation</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Weakness in both legs</td>
<td>1 (0.7%)</td>
</tr>
</tbody>
</table>

4. Discussion

A Scandinavian group published 7-yr (mean, 91.9 mo) follow-up data of the TVT procedure in 80 patients. Results showed that both objective (negative stress test and <8 g in 24-h pad-weighing test) and subjective (completely dry) cure rates were 81.3% [6]. To our knowledge, there is only one long-term report on TVT other than this Scandinavian one [7]. Of the 52 patients who were followed for a mean of 55 mo, 41 (78.9%) were dry, indicating that the TVT procedure was safe and effective, making this technique the optimal surgical treatment for female SUI. In patients followed for a minimum of 5 yr, we found that the success (cured and improved) rate was maintained from 97.7% at 1 yr to 94.9% at 5 yr. Interestingly, although the success rate remained constant, the cure rate decreased significantly over time. A poor correlation was found between quality of life impairment and the cure [8], which could explain that our satisfaction rate was higher than the cure at the same time.

The success rates of the TVT procedure in women with MUI, however, are not consistent. In one study, the overall subjective cure rate at 6 mo was 91%, whereas a subgroup with MUI had a cure rate of 89% [9]. In contrast, a second study found that patients with SUI had a persistent cure rate of 85% from 2 to 8 yr after surgery, whereas the cure rate of patients with MUI steadily declined to 30% from 4 to 8 yr after surgery [10]. In our study, the 5-yr postoperative cure rate of patients with MUI was 72.0%, not significantly different from that of patients with pure SUI (78.0%). The small difference observed may have been due to the small numbers of patients with MUI, indicating a need for a study in a larger number of patients with MUI.

At present, the measurement of intrinsic sphincter deficiency has not been standardised. However, MUCP <20 cm H2O or VLPP <60 cm H2O have been the urodynamic criteria for the diagnosis of intrinsic sphincter deficiency [11].
overall cure rate of TVT 10 mo after surgery was
significantly lower in patients with low VLPP (<60 cm
H2O) than in those with higher VLPP (≥60 cm H2O; 82.0% vs. 93.1%) [12]. Our study confirmed this result.
However, data on the success of the SUI symptom
grade are sparse. In one report on factors for the cure of
TVT, preoperative symptom grade was not
associated with the cure rate of the operation [13].
In contrast, we found that high incontinence grade
may impair the efficacy of the TVT procedure.

Voiding dysfunction following anti-incontinence
surgery is not uncommon. Although the TVT proce-
dure makes a dynamic urethral kinking without
compressing the urethra at rest [14], 2.8–14% of
patients later develop obstructive voiding symptoms
[15]. Using univariate and multivariate analysis, we
previously found that only maximal flow rate could
predict women at risk for postoperative urinary
retention [16]. Both urethra and TVT tape are thought
likely to exhibit the same downward displacement,
resulting in a mechanical obstruction similar to that
observed on the Valsalva maneuver. In evaluating
uroflowmetry indices and voiding symptoms after
TVT placement, there was a significant increase in
maximal flow rate percentile, whereas postvoid
residual urine volume decreased significantly in
patients measured at least twice after surgery [17].
This may have been due to a slow downward
displacement of the tape and surrounding tissues,
which resulted in less marked urethral compression,
or to chronic obstruction resulting in progressive
detrusor hypertrophy and allowing better emptying
function. In another study with follow-up of multi-
channel urodynamic study, the mean preoperative
values of average flow rate, maximal flow rate,
postvoided residual urine volume, and the detrusor
pressure at peak flow during voiding cystometry
showed no significant differences compared with
values at 3, 6, and 12 mo after TVT operation [18]. We
found that the maximal flow rate decreased signifi-
cantly after surgery, but, during the 5-yr follow-up
period, it increased linearly, up to preoperative levels.
Although postvoid residual urine volume increased
permanently during the same follow-up period, it was
<30 ml, which was not significant clinically. We also
found, 5 yr after surgery, the mean maximal flow rate
and postvoid residual urine volume of completely dry
women were similar to those of women showing
improvement or failure and that it showed a pattern
similar to those shown by overall maximal flow rate
and postvoid residual. These findings suggest that the
voiding function after the TVT procedure is not
related to the cure rate of this surgery.

Bladder perforation is one of the most frequently
observed complications after the TVT procedure,
estimated to occur in 5.8% of women [19]. We
observed a similar rate (3.7%; 5 of 134 patients),
although most of these patients needed an indwel-
lung catheter for a short period of time. In addition,
11 patients (8.2%) underwent TVT release or incision
due to long-term voiding dysfunction after surgery,
a rate somewhat higher than that recently reported
(2%) [20]. In our experience, the anxiety over urinary
continence and the cough stress test during the
procedure soon after the introduction of the TVT
procedure to our country results in the application of
unnecessary tension to the sling. Rardin et al.
reported that of 23 patients who underwent the
TVT release procedure, 14 (61%) remained continent
and 3 (13%) had recurrence of stress incontinence
[20]. Of the 11 patients in this study with TVT release
or incision, 9 (81.8%) were completely dry at 5 yr
postoperatively, whereas only 1 (9.1%) returned to
the preoperative stress incontinence state.

In an analysis of the changes in urge incontinence
and overactive bladder symptoms after the TVT
procedure at a mean follow-up of 7.1 ± 8.1 mo, 4.3%
and 9.1% of patients with pure SUI had developed de
novo urgency and de novo incontinence, respectively
[21]. Of the patients with MUI, the urge component
resolved in 63.1%, whereas preoperative overactive
bladder symptoms resolved in 57.3% of patients after
the TVT procedure. In our study, at 5 yr after surgery,
11.5% of patients complained of de novo urgency
and urge incontinence, and another 3.8% complained of
de novo urgency. In contrast, preoperative urgency
and urge incontinence improved in 46.7% and 48.0%
of patients, respectively. Thus, the proportion of
patients who developed de novo urgency or urge
incontinence postoperatively was relatively low
compared to improvement rates of overactive symp-
toms that resolved after surgery.

5. Conclusions

The high long-term success rate of the TVT
procedure shows that this surgery is effective and
safe for the treatment of SUI and MUI. The TVT
procedure may have an obstructive effect on voiding
and may reduce maximal flow rate, which improves
over time. Concomitant overactive bladder symp-
toms also improved in many patients.

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