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ORIGINAL ARTICLE

# Treatment outcome of tension-free vaginal tape in stress urinary incontinence: comparison of intrinsic sphincter deficiency and nonintrinsic sphincter deficiency patients

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**Abstract** The object of this study was to compare the treatment outcomes of tension-free vaginal tape (TVT) for intrinsic sphincter deficiency (ISD) and nonintrinsic sphincter deficiency (NISD) patients in stress urinary incontinence (SUI) and to evaluate whether TVT can be effectively used in both groups of patients. 111 women with SUI treated by TVT procedure from June 2003 to June 2005 with follow-ups for at least 1 year postoperatively were included in this study. The patients were divided into two groups: 31 patients with ISD and 80 patients with NISD. ISD was defined as the cases with low Valsalva leak-point pressure (VLPP) or Maximal urethral closure pressure (MUCP). Patients were followed up at 1, 3, 6, and 12 months postoperatively. There were no significant differences found in demographics between ISD and NISD groups: mean age, parity, body mass index, menopausal status, and hormone replacement therapy ($p>0.05$). All urodynamic parameters except for VLPP and MUCP showed no significant differences. The cure rates of the two groups at 1 month follow-up (87.0 vs 100%; $p=0.0053$) showed a significant difference, but no significant differences were found at 3, 6, and 12 months. There were no differences in postoperative complication rates (voiding difficulty, de novo urgency, urinary tract infection, retropubic hematoma, and vaginal mesh erosion) between the two groups irrelevant of follow-up months. TVT is effective for SUI in both ISD and NISD patients.

**Keywords** Tension-free vaginal tape · Stress urinary incontinence · Intrinsic sphincter deficiency

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## Introduction

Stress urinary incontinence (SUI) is a relatively common condition developed in approximately 20% women over 45 years old [1, 2], and psychological, hygienic, and financial burden on patients caused by this condition is not small. It may be caused by urethral intrinsic sphincter deficiency (ISD) because of nerve injury, hypoestrogenism, mucosal atrophy, exposure to radiation, etc. as well as urethral hypermobility because of the relaxation of pelvic-supporting muscles and the fascia, which exist concomitantly in many cases. Treatments for SUI include surgical and nonsurgical options, but surgery is a main treatment mode. After the sling procedure using pyramidalis muscles by Goebell in 1910 [3], its surgical technique has been greatly improved; nevertheless, it has been associated with a greater incidence of intraoperative and postoperative complications [4].

Tension-free vaginal tape (TVT) was introduced by Ulmsten et al. [5] in 1996 as a treatment for SUI with urethral hypermobility, which is based on the integral theory that the closure of the urethra is controlled by the mid-urethra, not by the bladder neck [6]. According to this theory, SUI is induced by the loss of the urethral support in the area of the pubourethral ligament, the loss of the support of the vaginal anterior wall, dysfunction of pubococcygeus muscles, etc. Numerous studies have shown satisfactory results of TVT with lower risk of complications that is comparable to the pubovaginal sling procedure and retropubic urethropexy, which have been the standard anti-incontinence surgical procedures. Furthermore, high failure rates after performing retropubic urethropexy in patients with ISD has been noted in some studies [7, 8], and a few reports have suggested that TVT might be effectively used in such cases [9–11]. Nevertheless, there has been no well-controlled study to confirm these reports.

The object of this study was to compare the outcomes of TVT for ISD and nonintrinsic sphincter deficiency (NISD) patients in SUI and to evaluate whether TVT can be effectively used in both groups of patients.

## Materials and methods

This study was retrospectively conducted on 111 patients diagnosed as SUI, treated by TVT, followed up for at least 1 year postoperatively at the Department of Obstetrics and Gynecology, Division of Female Pelvic Medicine and Reconstructive Surgery, Yonsei Medical Center, from June 2003 to June 2005. The patients were divided into two groups, one with ISD consisting of 31 patients and another with NISD consisting of 80 patients.

All patients complained of involuntary urine leakage during physical exertion such as coughing, running, and walking. SUI was diagnosed by urodynamic testing (Dantec-5000, Copenhagen, Denmark), i.e., measuring the involuntary loss of urine in the absence of detrusor contraction, when the intravesical pressure exceeds intraurethral pressure. All procedures and definitions were conformed to those of the International Continence Society [12]. Multichannel cystometry was measured by a 7-Fr microtip transducer catheter, and Valsalva leak point pressure (VLPP) is the pressure that increases with the onset of leakage at 200 ml of bladder volume by Valsalva's maneuver. Abdominal pressure was measured by vaginal method. ISD was defined as the case that the maximum urethral closure pressure (MUCP)<20 cm $H_2O$ or VLPP< 60 cm $H_2O$, and NISD was defined as the case with MUCP> 20 cm $H_2O$ and VLPP>60 cm$H_2O$. Patients showing pelvic organ prolapse higher than stage II by the Pelvic Organ Prolapse Quantification system or patients with detrusor overactivity were excluded from this study. All TVT (polypropylene, Gynecare) procedures were performed by the same operator as originally described by Ulmsten.

Patients were followed up at 1, 3, 6, and 12 months after surgery, and at each visit, urologic symptoms or other problems were assessed. Cure was defined as when there is no urine leakage on cough stress test with full bladder and if no subjective urinary incontinence symptoms (cure/dry) are present. Intraoperative or postoperative complications such as bladder injury, voiding difficulty, de novo urgency, urinary tract infection (UTI), vaginal mesh erosion, and retropubic hematoma were evaluated. De novo urgency was defined as a sudden compelling desire to pass urine, which is newly developed postoperatively. UTI was defined as the infection, which had been confirmed by urine culture since the last visit. Voiding difficulty was defined as urinary retention or weak urine stream, which required medical or surgical intervention. We did not routinely perform an imaging study to assess retropubic hematoma, but in suspicious cases with a rapid drop of the level of hemoglobin, suprapubic tenderness, and erythematous swelling, etc., an imaging study was performed.

For statistical analysis, Fisher's exact test, $\chi^2$ test, and $t$ test were performed using SPSS 12.0 statistical software. $p<0.05$ was determined to be statistically significant.

## Results

The mean age of the patient group with ISD and NISD was 60.74 and 57.20 years, respectively, with no significant difference ($p>0.05$). Parity, body mass index, the proportion of postmenopausal patients, and the proportion of patients with the history of hormone treatment or currently under hormone treatment between the two groups were not significantly different ($p>0.05$; Table 1). On urodynamic testing, the value of VLPP of the patient group with ISD was 53.48±10.12 cm $H_2O$, the patient group with NISD was 107.23±42.95 cm $H_2O$, and a significant difference between the two groups was detected ($p<0.0001$). The value of MUCP of the patient group with ISD was 46.81± 24.29 cm $H_2O$, the patient group with NISD was 75.70± 32.61 cm $H_2O$, and a significant difference was also detected ($p<0.0001$). Other urodynamic parameters were not significantly different ($p>0.05$).

The cure rates of two groups at 1, 3, 6, and 12 months after surgery were compared, and it was found that at 1 month after surgery, the group with ISD was 87%, the patient group with NISD was 100%, and a statistically significant difference between the two groups was detected ($p=0.0053$). At 3 months after surgery, it was 84 vs 89%, at 6 months after surgery, 81 vs 86%, at 12 months after surgery, 74 vs 84%, and no significant differences between the two groups were detected ($p>0.05$; Table 2, Fig. 1).

The bladder injury during surgery occurred in none of the cases, and regarding voiding difficulty, de novo urgency, and UTI, the complication rates were not significantly different at each follow-up period ($p>0.05$). No vaginal mesh erosion and retropubic hematoma occurred.

**Table 1** Patient characteristics

| | ISD ($n$=31) | NISD ($n$=80) | $p$ Value |
|---|---|---|---|
| Age (mean±SD, years) | 60.74±10.00 | 57.20±10.94 | 0.1203 |
| Parity (mean±SD) | 3.55±2.11 | 3.03±1.46 | 0.1399 |
| BMI (mean±SD, kg/m$^2$) | 24.22±2.51 | 24.18±2.94 | 0.9471 |
| Menopause (%) | 87.10 | 70.00 | 0.0628 |
| HRT (%) | 20.69 | 21.25 | 0.8324 |

*BMI* Body mass index, *HRT* hormone replacement therapy, *ISD* intrinsic sphincter deficiency, *NISD* nonintrinsic sphincter deficiency

**Table 2** Cure rates of TVT in the ISD and NISD groups

| Follow-up (month) | ISD ($n$=31) | NISD ($n$=80) | $p$ Value |
|---|---|---|---|
| 1 | 27 (87%) | 80 (100%) | 0.0053 |
| 3 | 26 (84%) | 71 (89%) | 0.5395 |
| 6 | 25 (81%) | 70 (86%) | 0.3757 |
| 12 | 23 (74%) | 67 (84%) | 0.2842 |

## Discussion

SUI may result from urethral hypermobility or ISD. Traditionally, for the cases caused by urethral hypermobility, retropubic urethropexy has been preferably performed, and for the cases with ISD, the pubovaginal sling procedure has been performed. However, retropubic urethropexy requires the incision of the abdominal wall and a long hospital stay and has significant morbidities such as bleeding, infection, and wound hematoma and subsequent complications including voiding difficulty, de novo urgency, recurrent UTI, and uterovaginal prolapse [13, 14]. The pubovaginal sling procedure also has a risk of urethral erosion, infection, and more significant potential than retropubic urethropexy for severe, long-standing voiding dysfunction [4].

As a method that minimizes such shortcomings and has a comparable cure rate, Ulmsten et al. [5] introduced TVT procedure in 1996, which is a modified sling procedure that improves the urinary continence ability itself by installing a polypropylene tape in the mid-urethra. This procedure is based on the integral theory that demonstrates that SUI may occur because of a lack of support of the mid-urethra caused by weakness of the pubourethral ligaments and the anterior vaginal wall [6]. Since the first report by Ulmsten et al., numerous reports on the TVT procedure for the treatment of SUI have shown successful outcomes (80–90%). Furthermore, a few reports have presented satisfactory outcomes (73–91.4%) in patients with ISD [9–11].

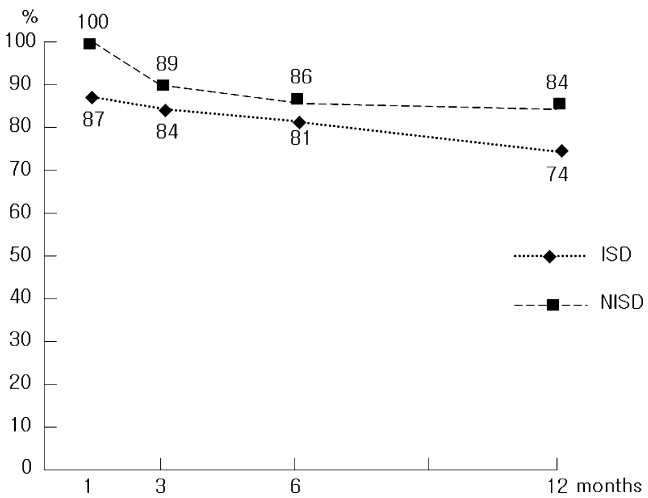


**Fig. 1** The cure rates of TVT in the ISD and NISD groups

The result of this study showed that 1 year after surgery, the cure rate was 74% in the patient group with ISD and 84% in the patient group with NISD, comparable to the results reported by other studies. When the cure rates of two groups at each follow-up period after surgery were compared, there were no significant differences between the two groups except for at 1 month after surgery (87 vs 100%). This result suggests that TVT can be effectively used for the treatment of SUI in both groups.

Some authors tried to declare predictive factors that could affect the cure rates of TVT. Mutone et al. [15] suggested that the high success rate of TVT in the treatment of genuine stress incontinence was associated with an increase in pressure transmission to the urethra but without a change in urethral closure pressure or a decline in urethral hypermobility. Cetinel et al. [16] demonstrated that low VLPP (<60 $cmH_2O$) did not predict the failure after the TVT procedure. Lipias et al. [10] indicated that female patients with SUI, adequate urethral mobility, and low MUCP could expect a very significant success rate after the TVT procedure, while patients with SUI, low MUCP, and fixed urethra should be treated with an alternative, more effective method. Further studies are required to declare high-risk factors to lead to failure after the TVT procedure, and at present, the patients with ISD, conventionally defined as low VLPP or low MUCP, appear to be effectively treated by the TVT procedure.

Complications of the TVT procedure are voiding difficulty, UTI, rejection reaction, bladder perforation, etc. Voiding difficulty is the most common postoperative complication reported as high as 49% [17], of which incidence is not smaller than the pubovaginal sling procedure and retropubic urethropexy. However, in most cases, the symptom was transient. In this study, at 1 month after surgery, in seven cases (23%) of the patient group with ISD and in five cases (19%) of the patient group with NISD, voiding difficulty developed. At 12 months after surgery, it was two (6%) and four cases (5%), respectively. The incidence was higher than in the results of other studies. The reason was that in this study, the cases with weak urine stream as well as urinary retention were considered to have voiding difficulty. Some reports presented the correlation of early voiding difficulty with preoperative urodynamic parameters such as uroflow pattern and configuration, low peak flow rate, and postvoid residual volume, but there is no concensus [16, 18, 19]. De novo urgency, a poorly understandable late complication, was reported to up to 25.9% [20]. In this study, it was found that at 1 month after surgery, it was two cases (6%) in the ISD patient group and three cases (4%) in the NISD patient group, and at 12 months after surgery, it was four (13%) and eight cases (10%), respectively, and a result comparable to the literature was shown. UTI is another relatively

common late complication after the TVT procedure and is reported 7.8% of incidence during the 5-year follow-up [21]. In this study, it was found that at 12 month after surgery, it was three cases (4.9%) in the ISD patient group and two cases (3.3%) in the NISD group. Bladder perforation was reported up to 11.6% in one study, 38.5% of which occurred in women with previous anti-incontinence surgery [20]. In this study, there was no case with previous anti-incontinence surgery, and no bladder injury occurred. Retropubic hematoma and vaginal mesh erosion, which are reported to be relatively less common, also could not be found in this study.

In conclusion, TVT is an effective treatment method for the ISD patient group as well as the NISD patient group.

This study has a limitation that the cases with ISD were relatively small. A large population should be recruited to have the analysis of data with valid power in treatment outcomes through power analysis—which is very difficult practically. To have a realistic chance of detecting a power level of 0.8, about 934 patients would be needed in the ISD group. Therefore, a multicenter study should be carried out. Another drawback of this study is that the follow-up period was relatively short, and thus it is thought that studies with the follow-up observation longer than 1 year including greater numbers of patients with ISD are required in the future.

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