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ORIGINAL ARTICLE

Transobturator adjustable tape for severe stress urinary incontinence and stress urinary incontinence with voiding dysfunction

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Abstract
Introduction and hypothesis This prospective multicenter study was conducted to evaluate the efficacy and safety of an adjustable mid-urethral sling (MUS) using transobturator adjustable tape (TOA) in women with severe stress urinary incontinence or combined stress urinary incontinence (SUI) and voiding dysfunction (VD).
Methods One day after placement of TOA, the tension was adjusted. Six months after surgery, changes in several questionnaires and uroflowmetry (UFM) parameters were evaluated.
Results Among the 65 women enrolled in the study, 27 (41.5%) required postoperative tension readjustments. At 6 months, the complete cure rate of SUI was 84.4%, and patient satisfaction with the operation was 86.2%. There was improvement in the total scores on several questionnaires. There were no significant changes in postoperative UFM parameters.
Conclusion Our results support the use of TOA as an effective modality for the treatment of SUI in women at risk for persistent postoperative SUI or obstructive symptoms.

Keywords Adjustable vaginal tape · Urinary incontinence

Abbreviations

MUS	Mid-urethral sling
TOA	Transobturator adjustable tape
SUI	Stress urinary incontinence
VD	Voiding dysfunction
UFM	Uroflowmetry

Introduction

Urinary incontinence is a major health issue for women. Stress urinary incontinence (SUI) is the most common form of this disease and is most commonly treated surgically, with the goal of rendering patients completely continent without generating significant morbidity.

Petros and Ulmsten proposed and developed intravaginal slingplasty (IVS) [1], the technique of surgically inserting synthetic mesh beneath the mid-urethra in a tension-free manner for the treatment of SUI, which Ulmsten later revised (GYNECARE TVT®, Ethicon Women's Health & Urology, Somerville, NJ). In 2001, Delorme [2] described

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the transobturator approach for tension-free suburethral vaginal tape (TOT), which is based on the same principle of the suburethral hammock as is the retropubic TVT, but with less risk of visceral damage. Recent reports have noted excellent long-term effectiveness of the transobturator tape procedure [3].

The amount of tension on the urethra following sling procedures may cause problems. Too little tension can result in continued incontinence [4]; too much tension can cause urinary obstruction. Based on Integral Theory [5], which states that SUI results from defective urethral support, the tape consists of a piece of prolene mesh loosely placed under the urethra to effectively recreate the pubourethral ligament. However, despite its tension-free nature, studies have shown that the tape causes postoperative voiding dysfunction in 2.8–14% of patients [6]. The published surgical results of the transobturator tape procedure indicate a high success rate of 80–95% [2, 7–9]. The usual reason for mid-urethral sling (MUS) failure is misplacement of the suburethral tape or inadequate tension on the tape.

Transobturator adjustable tape (Agency for Medical Innovations, AMI, Feldkirch, Austria) is a recent modification of the MUS system that enables the degree of tension applied during surgery to be readjusted postoperatively. Using patient-reported outcomes, we evaluated the effectiveness of transobturator adjustable tape (TOA) for the treatment of SUI in a population of Korean women with severe SUI or SUI with voiding dysfunction (VD).

Materials and methods

Subjects

In this prospective multicenter observational study, we included patients with SUI who received the TOA procedure between March 2008 and January 2009. We included women with severe SUI, defined as an abdominal leak point pressure ≤60 cm H_2O, Stamey symptom grade III [10], or combined SUI and VD, defined as a maximal flow rate ≤12 ml/s with a void volume ≥100 ml. Exclusion criteria included anti-coagulation therapy, active perineal or urethral lesions, pelvic organ prolapse, urinary tract infection, and combined pelvic organ prolapse surgery.

All patients were evaluated at baseline according to clinical medical history, physical examination, uroflowmetry (UFM), post-void residual (PVR), urinalysis and urine culture, standing stress test, pressure-flow study, and validated incontinence questionnaires. We used the validated Korean versions of the following questionnaires: the Bristol Female Lower Urinary Tract Symptoms-scored Form (BFLUTS-SF) [11], which measures the symptoms and impact of incontinence; the Sandvik Severity Index (SSI) [12], which measures the severities of incontinence symptoms; and the Incontinence Impact Questionaire-7 (IIQ-7) [13], which assesses the incontinence-specific quality of life.

Surgical procedure

Experienced surgeons at five medical centers in South Korea performed the procedure. The TOA procedure uses a special non-elastic tape made of a non-absorbable, macroporous polypropylene monofilament. It contains two groups of polypropylene threads; one group comprises two threads located laterally at 1.5 cm from the mesh midline that are exteriorized through the anterior vaginal surface and used to reduce tension. The other group consists of three threads in each branch of the mesh, located a distance from the midline, that are exteriorized with the mesh and allow for increased tension [14]. The procedure was performed with the patient in the lithotomy position. A 20-F Foley catheter was inserted to empty the bladder. On the competent area of the mid-urethra, a 1.5-cm vertical anterior vaginal wall incision was made. The vaginal wall was dissected in the direction of the bilateral obturator foramen. Bilateral skin punctures were made in the genitofemoral fold at the level of the clitoris. A reusable helicoidal stainless steel tunneler was introduced on one side, passed through the obturator foramen, and then out through the vaginal dissection site. The mesh was connected to the tunneler and exited through the initial incision site. The contralateral side was treated in the same manner. After positioning the midline of the mesh under the mid-urethra, the Foley catheter and plastic cover of the mesh were removed. During removal, care was taken to support the mesh to avoid tightening due to friction between the mesh and the cover. The exteriorized mesh was cut and the threads were left outside of the skin. The vaginal parts of the threads were crossed and exteriorized through the anterior vaginal surface. The vaginal incision site was closed in the normal fashion. The threads were secured to the skin.

Readjustment

One day after the operation, depending on the patient's condition, a standing stress test was performed. In cases with leakage on the standing stress test after filling with the minimal volume (250 ml), the mesh was tightened by pulling one of the inguinal threads approximately 0.5 cm, and the stress test was repeated in the clinic. This procedure was repeated until leakage was no longer observed. UFM and PVR were also checked. In the event of PVR >100 ml or a maximum flow rate (MFR) <10 ml/s, the mesh was loosened by pulling one of the vaginal threads 0.5 cm,

Table 1 Clinical characteristics of the patients

	Total (n=65)	SUI and VD (n=30)	Severe SUI (n=46)
Age (years)	57.3±9.4	59.1±8.5	56.9±9.8
BMI (kg/m^2)	24.8±3.2	25.5±3.4	24.5±2.8
Number of vaginal deliveries (N)	2.7±0.9	2.9±1.1	2.7±0.9
Frequency/24 h	9.6±5.0	8.8±2.5	9.6±5.6
UUI/24 h	2.3±5.8	1.4±2.3	2.7±6.5
Urgency episodes/24 h	5.3±6.4	6.2±4.0	4.7±6.8
MFR (ml/s)	20.2±9.7	14.5±8.3	22.8±9.7
PVR (ml)	18.6±30.4	28.6±41.4	19.7±31.3
ALPP (cm H_2O)	63.3±28.7	78.9±33.3	50.0±15.2
MUCP (cm H_2O)	44.4±20.6	42.7±15.1	45.0±23.9

Eleven (16.9%) women had symptoms of both SUI with VD and severe SUI

N number, *UUI* urge urinary incontinence, *MFR* maximal flow rate, *PVR* post-void residual, *ALPP* abdominal leak point pressure, *MUCP* maximal urethral closure pressure

followed by a stress test and measurement of UFM and PVR. When the patient was continent in all situations, had a maximum flow ≥10 ml/s, and there was insignificant PVR, the threads were cut and removed. The adjustment procedure was performed under local anesthesia.

Follow-up evaluation

Six months after the operation, the patients were re-evaluated using UFM and PVR, BFLUTS-SF, IIQ-7, SSI, and a complication and satisfaction questionnaire. The primary end point of the study was cure rate at 6 months after the operation. Cure was defined as "no urine leakage" on the Sandvik questionnaire.

Statistical analysis

Descriptive statistics were used to evaluate the patient characteristics. Paired *T* test with Bonferroni's correction or Wilcoxon signed rank test with Bonferroni's correction were used to compare the pre- and postoperative scores of the questionnaires and voiding parameters. Statistical significance was defined as $p<0.05$. SAS version 9.1 (SAS institute, Cary, NC, USA) was used to perform the statistical analyses.

Results

Patient characteristics

A total of 66 patients underwent the TOA procedure. One patient was lost to follow-up. The remaining 65 patients were followed in this study. There were 46 patients with severe SUI and 30 patients with combined SUI and VD. Of the 65 patients, 11 (16.9%) had both severe SUI and VD. The mean age of the enrolled patients was 57.3±9.4 years, the mean MFR was 20.2±9.7 ml/s, and the mean ALPP was 63.3±28.7 cm H_2O. Patients with urge incontinence in addition to SUI had a mean age of 45 years, and the mean number of urge incontinence episodes per 24 h was 2.3±5.8 (Table 1).

Immediate postoperative outcome

Twenty-seven of the 65 patients (41%) required tape readjustment. Fourteen patients (21%) underwent tension release, and 13 patients (20%) had the tape tightened. Among the patients with both severe SUI and combined SUI and VD (n=11), one patient required tension tightening, and another patient had the tension released (Table 2).

Table 2 Tension adjustments on the first postoperative day

	Total (n=65)	SUI and VD (n=30)	Severe SUI (=46)
Total	27[a] (41%)	12 (40%)	17 (37%)
Release	14[b] (21%)	9 (30%)	6 (13%)
Tightening	13[c] (20%)	3 (10%)	11 (24%)

SUI stress urinary incontinence, *VD* voiding dysfunction

[a] Two women had both symptoms

[b] One woman had both symptoms

[c] One woman had both symptoms

Table 3 Outcome measures at baseline and 6 months postoperative

	Baseline	Six months	*p* value
ICIQ-FLUTS			
Combined symptom score	19.3±8.4	8.1±7.6	<0.0001[a]
Filling score	6.5±3.0	3.2±2.6	<0.0001[a]
Voiding score	3.1±3.4	2.5±3.1	0.2680[a]
Incontinence score	9.7±4.6	2.4±3.7	<0.0001[a]
Sexual function score	2.0±1.9	0.5±1.1	<0.0001
QoL score	9.8±4.6	3.0±4.5	<0.0001
IIQ-7	57.9±26.3	14.2±25.5	<0.0001
Sandvik severity index			<0.0001
None	0	54	
Mild	1	1	
Moderate	11	7	
Severe	26	1	
Very severe	26	1	
Uroflowmetry (n=30)[b]			
MFR (ml/s)	14.5±8.2	17.8±10.7	0.4274[a]
MFR <12 ml/s	13 (52.0%)	11 (44%)	1.0000[a]
PVR (ml)	28.6±41.4	47.8±83.2	1.0000[a]
PVR >150 ml	0	3 (12%)	

QoL quality of life, *MFR* maximum flow rate, *PVR* post-void residual

[a] Bonferroni correction

[b] Completed for women with voiding dysfunction

Follow-up evaluation

Six months after surgery, 55 of the 65 patients replied "no leakage" on the Sandvik questionnaire, resulting in an overall cure rate of 84.6%. The cure rate for patients with combined SUI and VD was 76.7%, and the cure rate for patients with severe SUI was 89.1%. The cure rate among the patients with both severe SUI and combined SUI and VD was 81.8%. The BFLUTS-SF showed significant improvements in filling, incontinence, sexual function, and quality of life (QoL) scores, but the voiding score was not significantly different after the operation. The mean IIQ-7 score was significantly decreased from 57.9±26.3 to 14.2±25.5. In patients with combined SUI and VD, the mean MFR and PVR did not show significant changes. The number of patients with MFR ≤12 ml/s was decreased from 13 to 11. The number of patients with PVR >150 ml was increased from zero to three (Table 3). The overall postoperative satisfaction rate was 86.2%, with a 93.5% rating among patients with severe SUI and that of 80% among patients with combined SUI and VD (Fig. 1).

There were no intraoperative complications. One patient required cutting of the mesh due to persistent postoperative VD, and another patient's mesh was removed due to infection of the operative site.

Discussion

In this study, 41.5% of women who underwent TOA for either severe SUI or combined SUI and VD required tension adjustment after the operation. Six months after the adjustment procedure, the scores on most of the questionnaires were improved. Only one case experienced persistent VD that required cutting of the mesh. Mesh removal was necessary in another case due to wound infection. There were no intraoperative complications.

Currently, transobturator tension-free vaginal tape is widely used as a treatment for female SUI due to its high long-term efficacy and low complication rate. Despite its popularity, unsuccessful operations can result in postoperative VD or persistent stress incontinence. Because of these possibilities, some authors are against techniques that apply only minimal tension. Miller et al. [15] reported that, when TOT is planned, greater tension is needed to prevent persistent SUI in patients with low maximal urethral pressure, which is associated with intrinsic sphincter deficiency. On the other hand, postoperative urinary retention rates have been reported up to 13.3% [16], with

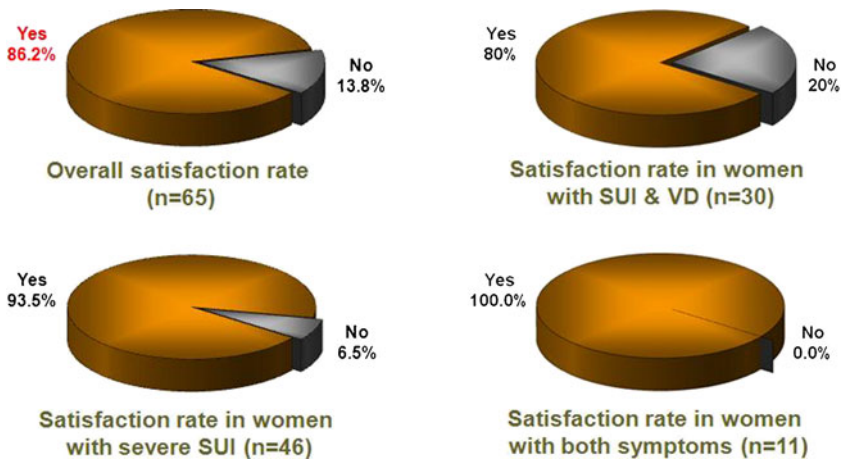

Fig. 1 Overall postoperative satisfaction rates

tape cutting or adjustment required in up to 5% of cases [15]. However, the success rate depends on the experience of the surgeon. Even when the surgeon is very experienced, it is difficult to determine the required degree of tension during surgery. Too much tension causes postoperative urinary retention; too little tension results in persistent SUI. For these reasons, close observation of postoperative voiding parameters and tape adjustment when needed are essential to maintain voiding function and to avoid upper urinary tract damage, especially in patients with preoperative VD or severe SUI.

In our study, which was targeted at patients with voiding risk factors, 41% of the patients required tape readjustment. In contrast to the high success rate of conventional TOT in the general population with SUI, this result shows a higher failure rate in the at-risk group. As expected, tape release cases outnumbered tightening cases in the combined SUI and VD group, and there were more tightening cases than releases in the severe SUI group. However, there were cases that required tightening of the tape in the combined SUI and VD group and releasing of the tape in the severe SUI group. The ideal amount of tension in these high-risk groups is so variable that postoperative readjustment is necessary in many cases.

In this regard, cough stress test or crede test in the operating room might be advocated. However, several studies have already revealed that intraoperative cough stress test did not help it. Lavy et al. [17] demonstrated no difference in outcome between the positive cough test group and negative cough test group. Low et al. [18] compared the outcome of two groups. One group underwent TVT under general anaesthesia and was unable to perform intraoperative cough stress test. The other group underwent TVT under spinal anaesthesia, and they were able to perform intraoperative cough test. There was no significant difference in outcome or complication rate between the two groups.

Six months after the operation, the overall cure rate according to the Sandvik questionnaire was 84.6%. This percentage is similar to the cure rate of conventional TOT in an ordinary SUI population. With the exception of the voiding score, every parameter on BFLUTS-SF (filling, incontinence, sexual function, quality of life) was improved. The voiding score showed a small amount of improvement, but it was not significant. In the group with combined SUI and VD, there were no significant changes in MFR or PVR. With a midurethral sling using TOT, Lee et al. [19] reported that the maximal flow rate was decreased significantly, but the PVR was not changed significantly in both the inside-out and outside-in TOT methods. Given this study's finding that the MUS using TOA did not exacerbate voiding symptoms or voiding parameters even in the patients with combined SUI and VD, we expect to use TOA without great concern for postoperative voiding problems.

There are a few articles published related to TOA. Romero Maroto et al. [20] introduced the benefits of transvaginal adjustable tape (TVA) and reported similar results in Spanish patients with mixed or stress SUI [21] In their data, 44% of the patients had mesh readjustment postoperatively. Ten percent of their patients had a MFR less than 10 ml/s, a PVR greater than 50 mL, or both. Prior to readjustment, 34% of the patients had persistent incontinence despite the operation. Both their study and ours demonstrate that it is preferable to use TOA in patients for whom it may be difficult to control the tension of the mesh.

Because the operative technique is almost the same as that in conventional TOT, except for leaving the threads, complications that occur with TOT, such as vaginal or urethral erosion, are expected [22]. However, such complications did not occur in this study. There was one case of persistent VD after readjustment that required cutting of the mesh, and a case with a wound infection that healed after removal of the mesh. Aside from these two minor complications, there were no other complications.

This study has several limitations that should be considered. It is a prospective observational study of TOA only. To characterize the efficacy and complications of TOA compared to those of conventional TOT, a randomized comparative study of TOA and TOT is necessary. With the data collected, it is difficult to conclude that TOA is better than TOT for severe SUI or for combined SUI and VD patients. Another limitation is that, in most cases, readjustment was performed 1 day after the operation. In a prospective study that compared the outside-in and the inside-out techniques of TOT in 100 patients, 20 patients required urethral catheterization on the first postoperative day; however, following catheter removal the next day, all showed good voiding function [19]. Therefore, readjustment just 1 day after the operation might be too early to evaluate patient postoperative voiding function. If readjustments were performed after the first postoperative day, such as after 1 week, the readjustment rate might be lower than what was observed. However, when we design the study, we thought that readjustment a day after operation would be better for the patients because keeping threads would bother them.

In conclusion, although this study is not a comparative study and further study is required, the use of a MUS in TOA is an effective method for SUI patients who have risk factors for postoperative VD or who have an increased likelihood of persistent SUI due to severe SUI.

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Conflicts of interest None.

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