



Recurrence rate of stress urinary incontinence in females with initial cure after transobturator tape procedure at 3-year follow-up

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Purpose: To assess recurrence rates of urinary incontinence in women with initial cure after transobturator tape (TOT) procedure at 3-year follow-up.

Materials and Methods: Between June 2006 and May 2013, a total of 402 consecutive patients underwent the TOT procedure for female stress urinary incontinence (SUI) at Dongguk University Ilsan Hospital. Of the 402 patients, 223 had sufficient medical records for analysis. Therefore, they were followed-up for 3 years postoperatively. Patient characteristics, urinary symptoms, physical examination, and urodynamic parameters were evaluated. The primary end point of "cure" was defined as the absence of any complaint of urinary leakage without needing pads for usual activities.

Results: Of the 223 patients, 196 patients (87.9%) were initially cured within 6 months postoperatively. Of the 196 patients, 70 (35.7%) had recurrent urinary incontinence at 3 years postoperatively, 51 (26.0%) had SUI, 16 (8.2%) had urgency urinary incontinence, and 3 (1.5%) had mixed urinary incontinence. In univariate analysis, preoperative urinary obstructive symptom was found to significant contributor to the recurrence of urinary incontinence at 3-year postoperatively ($p=0.004$).

Conclusions: In our study, 35.7% of the women with initial cure after TOT experienced the recurrence of urinary leakage during the 3-year follow-up. The cure rate of TOT was decreased as time went by, although the initial cure rate was high.

Keywords: Recurrence; Suburethral slings; Urinary incontinence

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INTRODUCTION

Stress urinary incontinence (SUI) is defined as a complaint of involuntary urine leakage under increased abdominal pressure such as sneezing, coughing, and physical exertion. SUI may affect up to 35% of the general female population [1]. Although SUI is a benign disease, it can be a problematic condition for women. It causes severely

debilitating physical, social, and psychological quality of life, induces low self-esteem, and causes social isolation of affected women.

SUI can be managed with both nonsurgical (i.e., pelvic floor muscle exercise) and surgical treatments. However, surgery is the only improved long-term curative therapeutic modality for SUI. Currently, midurethral sling (MUS) procedure has become the first-line surgical option for

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treatment of female SUI [2,3]. Retropubic tension-free vaginal tape (TVT) procedure was first introduced in 1996 [4]. Since then, various MUS procedures involving modifications of the TVT technique have been widely used in clinical practice, including trans-obturator tape (TOT), TVT obturator (TVT-O), and one-incision MUS procedures [2,3]. In short-term follow-ups (up to 12 months), the success rates of MUS procedures have been reported to range from 77% to 90% [3]. In particular, TOT procedure has shown short-term success rate comparable to that with retropubic approach [5].

In spite of these high short-term success rates, some complications related to MUS procedure have been reported, including transient urinary retention, pain, infection, tissue erosion, vascular or bladder injury, and so on [6]. In addition, recurrent or persistent SUI after MUS procedures may be a major concern not only for the patient, but also for clinician. In general, 5%–20% of patients treated with MUS are considered as surgical failures [7,8]. However, only a few studies are available on the mid and long-term outcomes of TOT alone or in comparison with other MUS procedures [9-11]. In the present study, we aimed to assess the midterm effects of the TOT procedure and identify risk factors for recurrent urinary incontinence in patients who were initially cured after the surgery.

MATERIALS AND METHODS

1. Ethics statement

This study design and the use of patients' information stored in the hospital database were approved by the Institutional Review Board at the Dongguk University Ilsan Hospital (approval number: H-2016-112). We were given exemption from getting informed consents by the IRB because the present study is a retrospective study and personal identifiers were completely removed and the data were analyzed anonymously. Our study was conducted according to the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

2. Study population

Between June 2006 and May 2013, a total of 402 consecutive patients underwent the TOT procedure for SUI at our institution. Of 402 patients, 223 had sufficient medical records for the analysis. Therefore, they were followed-up for at least 3 years postoperatively. Patients were excluded if they were not follow-up, or if they declined to participate.

3. Data acquisition

Preoperative evaluation comprised of medical history,

physical examination, urinalysis, 3-day voiding diary, 1-hour pad test, and Q-tip test. All patients were evaluated with a complete urodynamic testing as previously described by Serati et al. [12], including uroflowmetry, maximal urethral closing pressure, filling and voiding cystometry, and Valsalva leak point pressure measurement. All definitions followed those set by the International Continence Society [13]. Using Monarc Subfascial Hammock System (American Medical Systems, Minnetonka, MN, USA), all TOT procedures were performed according to the method described by Mellier et al. [14]. Patients were placed in dorsal lithotomy position under spinal anesthesia. For some cases, patients were under general anesthesia. Considering sphincter and detrusor status, the tension of the inserted tape was adjusted to a tension-free state with a right angle clamp or Mayo scissors. A 16-Fr urethral Foley catheter and vaginal packing with petrolatum gauze were placed at the end of the operation. Incontinence state and patient satisfaction were evaluated by history taking and patient reports at postoperative 6 months and 3 years, respectively. The primary end point in this study was "cure" defined as having the absence of any complaint of urinary leakage without needing pads for usual activities. All patients were surveyed for their satisfaction with five categories (full satisfaction, satisfaction, so-so, dissatisfaction, and extreme dissatisfaction).

4. Statistical analysis

Data analysis was performed with statistical software IBM SPSS ver. 18.0 (IBM Co., Armonk, NY, USA). All parameters were presented as frequency (percentage) or mean±standard deviation. Independent t-test and chi-square test (Fisher exact test) were used to compare continuous and categorical variables, respectively. All p-values were estimated. p<0.05 was considered as statistically significant.

RESULTS

Of the 402 patients, 223 had sufficient medical records for the analysis. They were followed-up for 3 years postoperatively. Of the 223 patients, 196 (87.9%) were initial cured within 6 months postoperatively. Of the 196 patients, 70 (35.7%) had recurrent urinary incontinence at 3 years postoperatively, 51 (26.0%) had SUI, 16 (8.2%) had urgency urinary incontinence, and 3 (1.5%) had mixed urinary incontinence (Fig. 1). Among the patient who showed urgency urinary incontinence, 4 patients took alpha-blocker preoperatively, 6 patients took anticholinergics postoperatively, 4 patients took alpha-blocker postoperatively and 1 patient undergoing hormone therapy. Of the 402

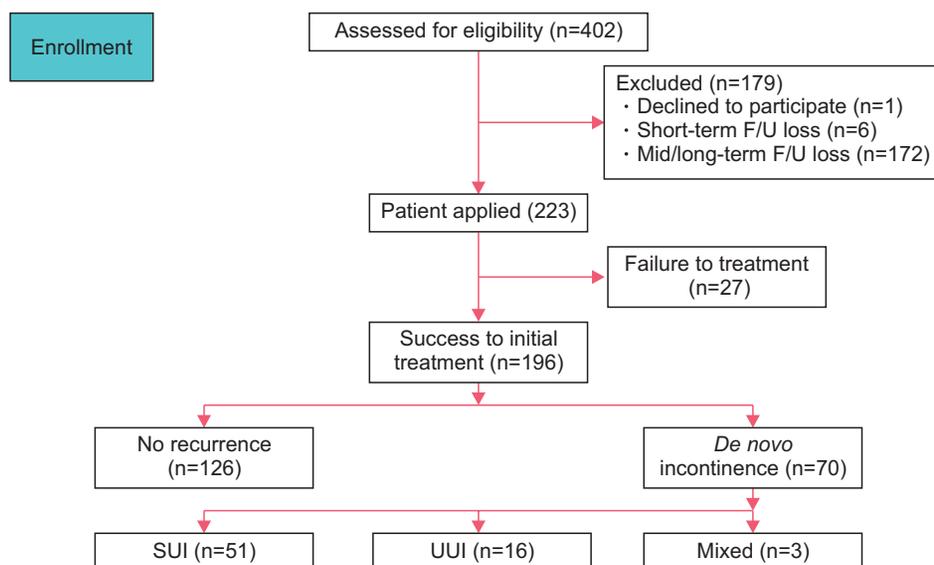


Fig. 1. Flow diagram of the study. SUI, stress urinary incontinence; UUI, urge urinary incontinence; F/U, follow-up.

patients there were few complications such as reoperation for releasing tape (0.4%) or retention requiring catheterization (2.4%), subjective postoperative voiding difficulty (10.5%), and erosion (0.8%).

The baseline demographics and urodynamic parameters of the 196 patients with initial cure are summarized in Table 1. The mean patient age at TOT was 51.9±9.1 years (range, 30–71 years). Of the 223 patients who were followed-up, 27 (12.1%) experienced previous hysterectomy, 4 (1.8%) had history of urinary retention, 25 (11.2%) had preoperative obstructive voiding symptoms (including hesitancy, slow stream, intermittency, and feeling of incomplete emptying). Preoperative storage symptoms included urgency in 107 (47.9%), frequency in 26 (11.6%), and nocturia in 17 (7.6%), 28 (12.6%) had preoperative Qmax<15 mL/s, 14 (6.3%) had significant postvoided residual (defined as >100 mL or >50% of voided volume). On preoperative urodynamic study, 31 patients (13.9%) had detrusor underactivity, 52 (23.3%) had female bladder outlet obstruction.

When we classified these subjects into groups according to the recurrence of urinary incontinence at postoperative 3 years, the group with recurrence had significantly more preoperative obstructive voiding symptoms (p=0.004) (Table 2) compared to the group without recurrence. Differences in baseline demographics such as age (p=0.664) and body mass index (p=0.548) were statistically insignificant between the recurrence group and the no recurrence group. No statistically significant differences were noted with respect to preoperative history of hysterectomy (p=0.643), severity of incontinence (p=0.064), previous urinary retention history (p=1.000) or storage symptoms (p>0.05). Urodynamic parameters were not significantly associated with the

Table 1. Preoperative patients' demographics and urodynamic parameters

Variable	Value
Demographics	
Age (y)	51.91±9.12
Body mass index (kg/m ²)	24.81±3.24
Menopause	78 (35.0)
Hysterectomy	27 (12.1)
Incontinence grade (Stamey) 2	59 (26.5)
Preoperative obstructive symptoms	25 (11.2)
Previous retention history	4 (1.8)
Nonspinal anesthesia	81 (36.3)
Concomitant pelvic surgery	38 (17.0)
Urgency	107 (47.9)
Frequency	26 (11.6)
Nocturia	17 (7.6)
Urodynamic parameters	
Preoperative Qmax under 15 mL/s	28 (12.6)
Significant PVR ^a	14 (6.3)
Underactive detrusor ^b	31 (13.9)
Female BOO ^c	52 (23.3)
Schafer contraction grade under 4	79 (35.4)
Detrusor overactivity	5 (2.5)
Q-tip angle over 30°	46 (20.6)
MUCP under 20 cmH ₂ O	92 (41.2)
VLPP under 60 cmH ₂ O	9 (4.0)

Values are presented as mean±standard deviation or number (%). Qmax, maximal flow rate; PVR, postvoid residual; BOO, bladder outlet obstruction.

^a:Significant PVR was defined as greater than 100 mL or PVR of more than 50% of voided volume. ^b:Underactive detrusor was defined as less than 20 cmH₂O in detrusor pressure at Qmax and lower than 15 mL/s in Qmax. ^c:Female BOO was defined as more than 20 cmH₂O in detrusor pressure at Qmax and lower than 15 mL/s in Qmax.

Table 2. Univariate analysis for preoperative risk factors of midterm recurrence

Variable	Midterm SUI		p-value
	Positive	Negative	
Age (y)	50.74±9.42	51.78±9.02	0.664
Body mass index (kg/m ²)	24.80±3.44	24.80±3.27	0.548
Menopause	35/20 (36.4)	49/42 (46.2)	0.246
Hysterectomy	57/8 (12.3)	107/12 (10.1)	0.643
Incontinence grade (Stamey) 2	53/13 (19.7)	79/38 (32.5)	0.064
Preoperative obstructive symptoms	43/12 (21.8)	100/7 (6.5)	0.004
Previous retention history	68/1 (1.4)	123/2 (1.6)	1.000
Nonspinal anesthesia	40/29 (42.0)	87/38 (30.4)	0.103
Concomitant pelvic surgery	58/11 (15.9)	104/21 (16.8)	0.877
Urgency	29/34 (46.0)	63/57 (52.5)	0.406
Frequency	10/9 (52.6)	16/18 (47.1)	0.697
Nocturia	7/11 (38.9)	9/26 (25.7)	0.322
Preoperative Qmax under 15 mL/s	56/11 (16.4)	110/13 (10.6)	0.246
Significant PVR ^a	62/5 (7.5)	113/6 (5.0)	0.529
Underactive detrusor ^b	54/7 (11.5)	75/19 (20.2)	0.155
Female BOO ^c	40/21 (34.4)	72/22 (23.4)	0.134
Schafer contraction grade under 4	25/30 (54.5)	44/45 (50.6)	0.642
Detrusor overactivity	2/60 (3.2)	3/116 (2.5)	1.000
Q-tip angle over 30°	17/20 (45.9)	25/42 (37.3)	0.390
MUCP under 20 cmH ₂ O	32/15 (68.1)	50/22 (69.4)	0.876
VLPP under 60 cmH ₂ O	4/51 (7.3)	9/92 (8.9)	1.000

Values are presented as mean±standard deviation or number (%).

Qmax, maximal flow rate; PVR, postvoid residual; BOO, bladder outlet obstruction; MUCP, maximum urethral closure pressure; VLPP, valsalva leak point pressure.

^a:Significant PVR was defined as greater than 100 mL or PVR of more than 50% of voided volume. ^b:Underactive detrusor was defined as less than 20 cmH₂O in detrusor pressure at maximal flow rate and lower than 15 mL/s in Qmax. ^c:Female BOO was defined as more than 20 cmH₂O in detrusor pressure at Qmax and lower than 15 mL/s in Qmax.

recurrence of urinary incontinence at 3 years postoperatively (p>0.05).

DISCUSSION

MUS procedure has become the standard treatment of choice in surgical management of SUI [15]. Even though TVT has been extensively used due to its simplicity, effectiveness, and minimally invasiveness, it is associated with several complications such as urinary retention and voiding problems including dysuria or *de novo* overactive symptoms, as well as bladder, bowel, and vascular injuries [6,16,17]. Since the introduction of transobturator route as an excellent alternative to the retropubic approach with a lower complication rates compared to TVT [18], many investigators have assessed the efficacy and morbidity of TOT procedure [5,14,19,20]. The objective and subjective cure rates after TOT are generally high in short-term follow-ups. Giberti et al. [19] have reported that the objective and subjective cure rates are 80% and 92%, respectively, in a mean follow-

up of 2 years after TOT. They also described a subjective satisfaction rate of 88% at postoperative 1 year [19]. Likewise, Taweel and Rabah [20] have reported 92% and 85% cure or improvement rates after 12 months and 24 months following TOT, respectively. These high cure rates in short-term follow-ups corresponded to our study results. Our initial cure rate within 6 months after TOT was 87.9%.

Despite these initial high cure rates of TOT, limited data are available concerning the long-term durability of TOT. In fact, studies in the literature about long-term outcomes of MUS procedures have mainly focused on TVT. Several studies have reported the long-term efficacy of TVT procedure [21-23]. However, conflicting results have been reported about the long-term outcomes of TOT. Heinonen et al. [24] have reported that the long-term objective and subjective cure rates are 89% and 83%, respectively, for 139 patients (66% SUI and 34% mixed incontinence) underwent TOT at a mean follow-up of 6.5 years. Similarly, Lo et al. [9] have reported that the objective and subjective cure rates of 56 SUI patients treated with TOT at 5 years of follow-

up are 89.3% and 87.5%, respectively [9]. All these findings indicate a favorable long-term durability of TOT. On the contrary, Yonguc et al. [25] have reported that in 139 women with pure SUI and mixed incontinence, although the objective and subjective cure rates at 1 year after TOT are 89.6% and 86.5%, respectively, after 5-year follow-up, the subjective cure rate is decreased to 65.9%, while the objective cure rate is stable at 87.3%. Likewise, Betari et al. [11] have described that, among 133 SUI women treated with TOT, 125 patients (93.9%) are initially cured in the short-term (1 year), but only 61% of those women who were initially cured have maintained continent state at 4 years of follow-up, suggesting a deteriorating long-term durability of TOT. These results are similar to the findings of our study. We found a high cure rate (87.9%) in short-term. However, only 64.3% of patients maintained the continent state at 3-year follow-up.

These contradictory results regarding the long-term outcomes of TOT may be attributable to several factors. First, the definition of cure rate varied in different studies. In general, the measurements of objective outcome include cough stress tests, pad test, and urodynamic evaluation. On the other hand, subjective outcome might be measured on the basis of patient self-assessment, validated questionnaires, patient satisfaction, and quality of life measurement [7]. In the present study, the assessment of outcomes after TOT was based on survey results reporting patients' satisfaction in a subjective manner. However, previous studies evaluated the long-term outcomes following TOT by using various measurement tools in objective and subjective manners [9,11,24,25]. Therefore, ununified definition of "cure" may lead to conflicting results among studies. Second, the type of urinary incontinence included in the study may affect the outcomes of different studies. In some studies on patients with preoperative urge urinary incontinence component (mixed incontinence), long-term subjective cure and patient satisfaction rates were lower than those of the patients with pure SUI [24,25]. The presence of preoperative overactive bladder symptoms (urgency, urge urinary incontinence) is known to be associated with lower cure rates in women undergoing MUS procedure [26]. However, in our study preoperative overactive bladder symptoms have not adversely affected the cure rate (64.3%) at 3-year follow-up. Although it was not clearly investigated in our study, there were no certain reasons for recurrence SUI, but concomitant vaginal hysterectomy may influence optimal sling position and tensioning so it might increase the recurrence rate of SUI [27,28]. By the same token, we assume that the positioning and tensioning of the tape can be changed as

time goes by, and therefore, it may cause the recurrence of SUI.

In addition to the presence of preoperative mixed incontinence, a variety of factors have been suggested to be associated with persistent or recurrent SUI after MUS procedures, including demographic factors such as advanced age, obesity, comorbid diseases, and the presence of severe cystocele [27-29]. Preoperative urodynamic parameters such as low maximum urethral closure pressure (MUCP) and the presence of uninhibited detrusor contraction may also contribute to persistent or recurrent incontinence after MUS [30]. Surgery related factors including inadequate tape material and inadequate surgical technique wherein the sling is not located at the midurethra or is applied too loosely have been noted as possible risk factors of persistent or recurrent SUI [7,26]. However, in the current study, we could not identify any risk factors related to persistent or recurrent SUI after TOT.

This study has several limitations. First, this was a retrospective study in nature that some inherent bias might have occurred. In addition, we did not take some perioperative variables into account, including comorbidities of patients, and additional treatments for recurrent SUI. This might have resulted in possible selection bias. Moreover, our surgical cases were performed by multiple surgeons. Variations in surgical expertise among surgeons could not be clearly identified in this study. These factors might have affected the cure rates following TOT. In consideration of the unreliability of a single institution-based retrospective data, our findings should be further verified in well-designed prospective studies using multi-institutional data.

CONCLUSIONS

Among 223 women who underwent TOT procedure for SUI, 196 (87.9%) were cured within 6 months postoperatively. However, 35.7% of these women with initial cure after TOT experienced recurrence of urinary leakage during 3-year follow-up. The cure rate of TOT appeared to be decreased over time, although the initial cure rate was high.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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