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Surgical outcomes of tension-free vaginal tape (TVT)-abbrevo® and TVT-obturator® for the treatment of stress urinary incontinence: a retrospective study

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Objective
We compared the efficacy and postoperative complications of tension-free vaginal tape (TVT)-abbrevo® (TVT-A) and TVT-obturator® (TVT-O) surgeries for the treatment of stress urinary incontinence (SUI).

Methods
We retrospectively analyzed the medical records of 143 female patients with SUI who underwent TVT-A or TVT-O surgery between January 2010 and December 2019 at the Asan Medical Center in Seoul. We evaluated intra- and postoperative complications such as bladder injury, groin pain, urinary retention, and mesh exposure. We also checked the success rate at 6 months after surgery.

Results
There were no complications, including fever, hematuria, hematoma of the vulva, or bladder injury, immediately after surgery in either group. Postoperative complications 2 weeks post-surgery were groin pain (11.3%), urinary retention (4.9%), and mesh exposure (0.7%). Groin pain was not significantly different between the two groups at 2 weeks, 3 months, and 6 months after surgery (TVT-O vs. TVT-A after 2 weeks: 12.5% vs. 10.3%, *P*=0.791; 3 months: 0.0% vs. 1.4%, *P*=0.999; and 6 months: 0.0% vs. 0.0%, *P*=0.999). Over 90% of the patients reported cure or improved symptoms in both groups. In the univariate logistic analysis, the type of TVT (TVT-O or TVT-A) was not associated with the success rate (odds ratio, 3.21; 95% confidence interval, 0.59-17.40; *P*=0.175).

Conclusion
TVT-A surgery is comparable with TVT-O in terms of high success rate and low frequency of complications, including bladder injury and groin pain.

Keywords: Stress urinary incontinence; Midurethral sling; Tension-free vaginal Tape; Transobturator tape

Introduction

Stress urinary incontinence (SUI) is defined by the International Continence Society (ICS) as involuntary leakage of urine during effort, exertion, sneezing, or coughing, and is the most common subtype of urinary incontinence [1,2]. The prevalence of SUI depends on its definition, and several previous studies have reported that approximately 23.8-40.8% of Korean women are affected [3,4]. SUI not only decreases the quality of life, leading to depression and social isolation if severe [5], but also has financial and social costs.

Although there are non-surgical treatments for SUI, such as

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behavioral therapy, biofeedback, and medications [6], many patients report dissatisfaction with non-surgical SUI therapies because of the cost, discomfort, inconvenience, lack of efficacy, or related complications, such as urinary tract infection [7]. Therefore, surgery is considered the gold standard treatment for SUI [8].

In 1996, tension-free vaginal tape (TVT) was first introduced by Ulmsten et al. [9]. However, retropubic TVT has complications such as bladder perforation and injuries to the blood vessels and nerves. Mid-urethral sling surgery, introduced thereafter, uses either "outside-in" trans-obturator vaginal tape [10] or "inside-out" transobturator vaginal tape (TVT-obturator®, TVT-O) [11]. The "inside-out" method avoids damage to the urinary tract, does not require cystoscopy, and the duration of the procedure is shorter than that of the "outside-in" method [11]. Although these methods have been proven to have a similar efficacy to the retropubic method, with a low incidence of complications during surgery [12], they might be associated with nerve damage that can induce leg and groin pain.

The TVT-abbrevo® (TVT-A) method, which uses a small polypropylene mesh (12 cm), has been widely used since its introduction [13]. Because the mesh is shorter in length, surgical complications can be reduced due to reduced dissection and a minimal length of mesh passing through the adductor muscles [14,15]. At the same time, the mesh is still placed between the obturator membrane and under the mid-urethra, allowing the mid-urethra to maintain the same tension-free support as with TVT-O [14,15]. However, studies comparing TVT-A with classical surgery are limited [16,17]. Therefore, this retrospective study aimed to compare the efficacy, postoperative satisfaction, and incidence of complications between TVT-A and TVT-O.

Materials and methods

This retrospective study included 213 patients who underwent TVT-O or TVT-A surgery at the Obstetrics and Gynecology Department at the Asan Medical Center between January 2010 and December 2019. SUI was defined as involuntary urination or leakage during effort, exertion, sneezing, or coughing [1]. The medical history of all patients was recorded, and they underwent a physical examination, including a pelvic examination, a bladder diary, urodynamic studies (UDS), a Q-tip test, urinalysis, and urine culture. UDS were conducted according to ICS standards. The exclusion criteria were a history of pelvic malignancy or pelvic radiation treatments, intrinsic urethral sphincter deficiency (ISD), detrusor overactivity incontinence observed on UDS, symptoms of overactive bladder (OAB), and bacteriuria on urine culture. In order to eliminate confounding factors affecting treatment outcomes, we also excluded patients who underwent concomitant surgery.

We recorded the clinical characteristics of the patients, including age, parity, body mass index (BMI), menstrual status, underlying diagnoses, and a history of pelvic organ surgery with or without anti-incontinence surgery and concomitant

Table 1. Comparison of the baseline characteristics

Variable	TVT-O (n=64)	TVT-A (n=79)	*P*-value
Age (yr)	54.53±7.72	57.33±9.04	0.052
BMI (kg/m^2)	23.47±3.09	24.93±3.47	0.010
Parity	2.17±1.02	2.37±1.21	0.305
Post-menopausal	43 (67.2)	57 (72.2)	0.520
Taking MHT	9/43 (20.9)	10/57 (17.5)	0.669
Urethral hypermobility	36/41 (87.8)	63/72 (87.5)	0.962
Previous pelvic surgery		.	
Previous incontinence operation	5 (7.8)	12 (15.2)	0.175
Pervious hysterectomy	11 (17.2)	20 (25.3)	0.241

Values are presented as mean±standard deviation or number (%).
TVT-O, tension-free vaginal tape-obturator®; TVT-A, tension-free vaginal tape-Abbrevo; BMI, body mass index; MHT, menopausal hormone therapy.

surgery. For patients who had previously undergone hysterectomy, menopause was determined by the presence of associated symptoms. We defined urethral hypermobility as a Q-tip angle of >30°.

Primary outcomes were the peri- and postoperative complications of TVT-O and TVT-A. We obtained the following variables: duration of surgery, estimated blood loss (EBL), any complications during surgery, postoperative fever, hematoma, and hematuria immediately after the surgery. Patients were asked to visit the outpatient clinic 2 weeks, 3 months, and 6 months after surgery, and symptoms related to the surgery including groin pain, mesh exposure, vesicovaginal fistula (VVF), and urinary retention were recorded. We used the TVT-O system (Gynecare; Ethicon, Somerville, MA, USA) or the TVT-A system (Gynecare; Ethicon); all other surgical procedures were the same.

The secondary outcome was the success rate of TVT-O and TVT-A. Patients were divided into three categories based on their responses to a questionnaire: cure (no SUI episodes), improvement (improved, but still had one or more SUI episodes within 6 months), no improvement (same or more SUI symptoms as preoperatively, or a recurrence). Significant and moderate improvements were considered to be a success. Urgency urinary incontinence was ruled out in patients complaining of persistent or recurrent symptoms.

Statistical analyses were conducted using SPSS version 21 (IBM, Armonk, NY, USA). The unpaired *t*-test for continuous variables was used for comparisons between groups. The chi-squared test and Fisher's exact test were used for the categorical variables. Univariate logistic regression analysis was performed to identify the independent factors associated with surgical success. The Institutional Review Board of the Asan Medical Center approved the study (protocol number 2020-0843), and the requirement for informed consent was waived because of the retrospective nature of the study.

Table 2. Intra- and peri-operative outcomes of TVT-O and TVT-A

Variable	TVT-O (n=64)	TVT-A (n=79)	*P*-value
Duration of surgery (min)	31.7±11.7	30.2±10.2	0.4201
Estimated blood loss (mL)	13.0±12.8	9.7±10.4	0.0957
Fever	0	0	-
Hematuria	0	0	-
Vulva hematoma	0	0	-
Bladder injury	0	0	-

Values are presented as mean±standard deviation or number.
TVT-O, tension-free vaginal tape-obturator®; TVT-A, tension-free vaginal tape-Abbrevo.

Results

Of 213 patients who had undergone TVT-O or TVT-A during the study period, we excluded 24 patients who had previously undergone surgery for malignancy, 41 patients who had TVT-O or TVT-A combined with other operations, two that were diagnosed with OAB, and three that were diagnosed with ISD. Finally, 64 and 79 patients were included in the TVT-O and TVT-A groups, respectively.

Table 1 shows the basic characteristics of the two groups. The average age of the patients was 54.53±7.72 years (range, 36-78) in the TVT-O group and 57.33±9.04 years (range, 41-78) in the TVT-A group (*P*=0.052). BMI was higher in the TVT-A group than in the TVT-O group (24.93±3.47 vs. 23.47±3.09, *P*=0.010). With the exception of the above variables, there were no significant differences in any other characteristics known to affect the symptoms of SUI.

There were no significant differences in the duration of

Table 3. Surgical complications at 2 weeks, 3 months, and 6 months after surgery

Variable	2 weeks			3 months			6 months		
	TVT-O (n=64)	TVT-A (n=78)	*P*-value	TVT-O (n=58)	TVT-A (n=72)	*P*-value	TVT-O (n=47)	TVT-A (n=56)	*P*-value
Groin pain	8 (12.5)	8 (10.3)	0.791	0 (0.0)	1 (1.4)	0.999	0 (0.0)	0 (0.0)	0.999
Urinary retention	3 (4.7)	4 (5.1)	0.999	1 (1.7)	1 (1.4)	0.999	0 (0.0)	2 (3.6)	0.499
Mesh exposure	1 (1.6)	0 (0.0)	0.451	0 (0.0)	0 (0.0)	0.999	1 (2.1)	0 (0.0)	0.456
VVF	0 (0.0)	0 (0.0)	0.999	0 (0.0)	0 (0.0)	0.999	0 (0.0)	0 (0.0)	0.999

Values are presented as number (%).
TVT-O, tension-free vaginal tape-obturator®; TVT-A, tension-free vaginal tape-Abbrevo; VVF, vesicovaginal fistula.

surgery or EBL between the groups. Further, there were no postoperative complications such as fever, hematuria, or hematoma of the vulva during the period of hospitalization in either group (Table 2).

Table 3 shows the results of the patients' follow-up at the outpatient clinic 2 weeks, 3 months, and 6 months after surgery to assess postoperative complications. In the TVT-O group, 64, 58, and 47 patients were checked after 2 weeks, 3 months, and 6 months, respectively, while 78, 72, and 56 patients were checked in the TVT-A group at the same time points. The incidence of groin pain and postoperative urinary retention was not significantly different between the groups. However, two patients in the TVT-O group developed mesh exposure, one at 2 weeks and the other at 6 months postoperatively. Six months later, no VVF developed in either group.

Six months after surgery, 66.0% (n=31) of patients in the TVT-O group and 42.9% (n=24) of patients in the TVT-A group reported that their symptoms were cured (*P*=0.019). In addition, 25.5% (n=12) of patients in the TVT-O group and 53.6% (n=30) of patients in the TVT-A group showed improvement (*P*=0.005). In conclusion, the success (cure and improvement) rate was greater than 90% in both groups (Table 4).

To evaluate the confounding factors of the success of surgery at 6 months, we classified the patients into two groups: success (n=97) and failure (n=6) (Table 5). In the univariate logistic analysis, the type of TVT (TVT-O or TVT-A) was not associated with surgical success (odds ratio [OR], 3.21; 95% confidence interval [CI], 0.59-17.40; *P*=0.175). In addition, other factors such as age, BMI, parity, menopause, and the use of menopausal hormone therapy (MHT) were not significantly different (*P*>0.5).

Table 4. Satisfaction level after 6 months of surgery

Variable	TVT-O (n=47)	TVT-A (n=56)	*P*-value
Cure	31 (66.0)	24 (42.9)	0.019
Improvement	12 (25.5)	30 (53.6)	0.005
No improvement	4 (8.5)	2 (3.6)	0.408

Values are presented as number (%).
TVT-O, tension-free vaginal tape-obturator®; TVT-A, tension-free vaginal tape-Abbrevo.

Table 5. Univariable logistic regression analysis of factors associated with post-operative success at 6 months

Level	Success (n=97)	Failure (n=6)	OR (95% CI)	*P*-value
Type of TVT				
TVT-O	43 (44.3)	4 (66.7)	Ref.	
TVT-A	54 (55.7)	2 (33.3)	3.21 (0.59, 17.40)	0.175
Age				
<60 years	70 (72.1)	4 (66.7)	Ref.	
≥60 years	27 (27.8)	2 (33.3)	0.98 (0.18, 5.35)	0.980
BMI				
<25 kg/m^2	61 (62.9)	4 (66.7)	Ref.	
≥25 kg/m^2	36 (37.1)	2 (33.3)	1.50 (0.28, 8.14)	0.638
Parity	2.20±1.04	2.14±0.90	1.05 (0.49, 2.27)	0.891
Menopause				
0	32 (33.0)	2 (33.3)	Ref.	
1	65 (67.0)	4 (66.7)	1.57 (0.33, 7.46)	0.569
Menopause_MHT				
Premenopause	32 (33.0)	2 (33.3)	Ref.	
Menopause without MHT	51 (52.6)	3 (42.9)	1.64 (0.31, 8.66)	0.557
Menopause with MHT	14 (14.4)	1 (14.3)	1.35 (0.13, 14.20)	0.800

Values are presented as mean±standard deviation or number (%) unless otherwise indicated.
OR, odds ratio; CI, confidence interval; TVT; tension-free vaginal tape; TVT-O, TVT-obturator®; TVT-A, tension-free vaginal tape-Abbrevo; Ref., reference; BMI, body mass index; MHT, menopausal hormone therapy.

Discussion

In this study, both TVT-A and TVT-O surgeries led to a high success rate. There were a few reported perioperative complications such as EBL, fever, and hematoma, and the duration of the surgeries was similar. Postoperative complications, including groin pain, urinary retention, and mesh exposure, were rare, and their incidence was not significantly different between the groups.

TVT-O has the advantage of a shorter operation time and lesser bladder damage compared with previous surgical methods of SUI, such as retropubic TVT or Burch's colposuspension [11,18]. However, post-surgical groin pain is a common problem with TVT-O, and TVT-A can be an alternative. The obturator nerve that passes from the lumbar spinal nerves to the thigh passes through the obturator foramen. During surgery, the helical passers pass though the obturator foramen, which can lead to groin or medial thigh pain if the nerve bundle is damaged [18,19]. Previous studies found that TVT-A surgery significantly reduced immediate postoperative groin pain compared with TVT-O surgery; however, there was no difference after 6 weeks (TVT-O vs. TVT-A: 14% vs. 6%, *P*=0.32) [16,20]. In our study, there were more patients with groin pain in the TVT-A group 2 weeks after surgery. However, for both operations, the rate of postoperative groin pain was comparable with that in previous studies, and there was no significant difference between the two groups (TVT-O vs. TVT-A: 12.5% vs. 10.3%, *P*=0.791). In addition, similar to previous studies, groin pain decreased over time, with no significant difference between the groups. Although this study has the limitation of failing to evaluate immediate postoperative pain, it is considered that both procedures are effective for SUI surgery with less groin pain after surgery.

A randomized trial including 158 patients reported complications such as mesh exposure and urinary retention after both types of surgery (mesh exposure TVT-A vs. TVT-O: 2% vs. 1%, urinary retention TVT-A vs. TVT-O: 0% vs. 1%) [16]. Unlike previous studies, our study did not observe any mesh exposure in the TVT-A group. There were two patients with mesh exposure in the TVT-O group. One of the patients who developed mesh exposure 6 months after surgery underwent a second surgery to remove the mesh a year after the onset of symptoms due to their persistence. The number of patients with urinary retention was low in both groups (two patients in the TVT-A group and no patients in the TVT-O group at 6 months after surgery). In addition, there were no cases of VVF in either group. Therefore, the TVT-A and TVT-O procedures are considered safe for SUI with minimal surgical complications.

As reported in several previous studies, both TVT-A and TVT-O showed a comparable high success rate [20,21]. Canel et al. [20] found that there was no significant difference in the success rate (no reported SUI) at 6 weeks and 1 year of follow-up (TVT-O vs. TVT-A: success rate at 6 weeks after surgery, 80% vs. 86%, *P*=0.59; success rate at 1 year after surgery, 78% vs. 88%, *P*=0.29). In addition, subjective improvement (Patient Global Impression of Improvement score, PGI-I score) was also high for both techniques at the 1-year follow-up (PGI-I score [very satisfied], TVT-O vs. TVT-A: 66% vs. 68%, *P*=0.59). Only 10% of patients had persistent SUI (no improvement) [20]. Likewise, our study showed a low rate of "no improvement" at the 6-month follow-up (TVT-O vs. TVT-A: 8.5% vs. 3.6%, *P*=0.408). Over 90% of the patients who underwent TVT-A and TVT-O surgeries had improved SUI symptoms. However, there were more patients who reported a "cure" in the TVT-O than in the TVT-A group (TVT-O vs. TVT-A: 66.0% vs. 42.9%, *P*=0.019). The reason for this difference may be that our study did not use validated questionnaires, and there was no objective assessment of the degree of improvement.

Several previous studies have reported that the results of the mid-urethral sling surgery are poor among elderly patients [22,23]. Rechberger et al. [22] reported that both BMI and menopausal status were not correlated with the surgical outcome after 18 months, and increasing age was the only risk factor for failure (OR, 1.64; 95% CI, 1.10-2.46; *P*=0.016). The most recent study of TVT outcomes in elderly patients also found that age >75 years was a risk factor for decreasing cure rates, while BMI, parity, and menopausal status were not statistically significant [23]. However, at the 13-year follow-up after TVT, no independent risk factors affected the long-term success rate [24]. The relatively short follow-up period limits the interpretation of these results, but our study found that there were no variables (including type of TVT) associated with postoperative success.

This study has some limitations. First, the study was conducted retrospectively. Second, the postoperative improvement level was not assessed through validated questionnaires or objective measures such as a cough stress test. Third, the follow-up duration was relatively short to measure postop-

erative complications or recurrence. Fourth, this study did not evaluate groin pain immediately after the procedure, and it did not apply a validated scale such as the Visual Analog Scale for assessing groin pain. However, compared with previously published studies analyzing the surgical complications of TVT-O and TVT-A, our study was conducted on a relatively large number of patients, and more than 90% of the surgeries were performed by a single surgeon, which could reduce bias due to inter-surgeon variation.

Thus, TVT-A surgery is comparable with TVT-O in terms of a high success rate and a low frequency of complications, and it can be an alternative surgical treatment option for SUI depending on the preference of the surgeon.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

Ethical approval

Ethical clearance was obtained from the Institutional Review Board of the Asan Medical Center (protocol number 2020-0843). The study was performed in accordance with the principles of the Declaration of Helsinki

Patient consent

Written informed consent and the use of images from patients are not required for the publication.

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