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Voiding Dysfunction

Randomized Comparative Study of the U- and H-Type Approaches of the TVT-Secur Procedure for the Treatment of Female Stress Urinary Incontinence: One-Year Follow-Up

Jung Jun Kim, Young-Suk Lee, Kyu-Sung Lee

Department of Urology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea

Purpose: We compared outcomes of the U- and H-type approaches of the tension-free vaginal tape (TVT)-Secur procedure for the treatment of female stress urinary incontinence (SUI).

Materials and Methods: From March 2007 to July 2008, 115 women with SUI underwent TVT-Secur by a single surgeon. Patients were randomly assigned to either the U- or the H-type approach. After 12 months, postoperative changes in the Sandvik questionnaire, incontinence quality of life questionnaire (I-QoL), Bristol female lower urinary tract symptoms-scored form (BFLUTS-SF), and postoperative patient satisfaction were evaluated. Cure was regarded as no leakage on the Sandvik questionnaire. Complications were also evaluated.

Results: Of 115 women, 53 were treated with the U approach, and 62 women were treated with the H approach. At 12 months, 88.7% of those treated with the U approach and 87.1% of those treated with the H approach were cured (p=0.796). The I-QoL and filling, incontinence, sexual function, and QoL sum (BFLUTS-SF) scores were improved with both approaches, and there were no significant differences in the degree of improvement between approaches. Approximately 83.7% and 82.9% of the women treated with the U and H approaches, respectively, were satisfied with the outcome (p=0.858). There were 3 cases of intra-operative vaginal wall perforation in the H-type group. Immediate postoperative retention was observed in 2 women in the U-type group and 1 woman in the H-type group. One woman in the U-type group underwent tape releasing and cutting procedures for persistent large post-void residuals.

Conclusions: The U- and the H-type approaches of the TVT-Secur procedure provided comparable effectiveness for the treatment of female SUI.

Key Words: *Comparative study; Stress urinary incontinence; Therapy*

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Corresponding Author:
Kyu-Sung Lee
Department of Urology, Samsung Medical Center, Sungkyunkwan University School of Medicine, 50, Irwon-dong, Gangnam-gu, Seoul 135-710, Korea
TEL: +82-2-3410-3554
FAX: +82-2-3410-3027
E-mail: ksleedr@skku.edu

INTRODUCTION

Urinary incontinence affects up to 50% of women, resulting in a significant medical, social, and economic burden [1,2]. The annual direct costs of incontinence in the United States were estimated to be more than $16 billion [3]. Among women with incontinence, 50% to 80% are identified as having stress urinary incontinence (SUI), or involuntary leakage of urine resulting from physical exertion or sneezing and coughing. [4,5]. Similar to its frequency in Western countries, about 37.8% of Korean adult women suffer from SUI [6]. Although the initial treatment of stress incontinence is often nonsurgical (behavioral therapy, pelvic-floor exercises, or incontinence devices), surgical treatment is considered for patients who are bothered by persistent symptoms. An estimated 4% to 10% of women in the United States undergo surgery intended to restore continence, and this rate has increased steadily during the past 20 years [7].

At present, one of the most successful treatments for SUI is provided by surgery. Burch corposuspension was once the standard technique, but tension-free vaginal tape (TVT) is now the gold standard. TVT is a minimally invasive procedure with a cure rate comparable to Burch cor-

posuspension in an appropriate randomized control study [8,9]. However, TVT has the risk of serious complications associated with the 'blind' course of the needle through the retropubic space. Therefore, bladder perforation as well as vascular and bowel injuries are occasionally reported [10-12]. For obviation of needle passage through the retropubic space, the trans-obturator sling was introduced. The trans-obturator sling procedure demonstrated a comparable cure rate but fewer complications associated with needle passage through the retropubic space [13,14]. However, the trans-obturator sling can induce entrapment of the obturator nerve, and groin and upper thigh pain occasionally occur [15]. Furthermore, there are reports of nerve and vascular injuries as well as fasciitis [16]. Therefore, further improvement of the surgical methods for the treatment of SUI is needed.

The TVT-Secur system was developed to reduce the invasiveness of the surgical procedures and to avoid passing the needle through the retropubic or obturator regions. The advantages of this technique are related to the short course of the needles, which minimizes the risk of vascular, nerve, or visceral injury. The prosthetic implant is placed under the midurethra and can be fixed in the hammock (H) position into the obturator internus muscle or in the U-shaped position into the connective tissue of the urogenital diaphragm behind the pubic bone. Some concerns may arise regarding the strength of the fixation point and the tensioning maneuver. Comparative studies of the surgical outcome between approaches are lacking.

Herein, we conducted a prospective, randomized, comparative study to compare effectiveness and safety between the H and U approaches of the TVT-Secur procedure for the treatment of female SUI.

MATERIALS AND METHODS

This was a 12-month, randomized trial involving one experienced surgeon at a single medical center. Participants received detailed information about the study procedure and provided written consent before study entry. Consenting patients were randomly allocated to either the U-type or the H-type method immediately.

Women who were 18 years old or older and presented with urodynamic SUI for at least 3 months were selected for this study. Patients with a history of prior anti-incontinence surgery or ≥stage 2 pelvic organ prolapse were excluded. Baseline measures included patient demographics, detailed medical and surgical history, and obstetric and gynecological history. All women underwent a physical examination for urethral hypermobility, as measured by the Q-tip test, and pelvic-organ prolapse. Preoperatively, we assayed women by a urodynamic study, Sandvik questionnaire, incontinence quality of life questionnaire (I-QoL), Bristol female lower urinary tract symptoms-scored form (BFLUTS-SF) questionnaire, incontinence visual analogue scale (I-VAS), 3-day voiding diary, and uroflowmetry. Just after the decision of surgery, informed consent was gained. At the 12-month follow-up, changes in the I-QoL questionnaire, BFLUTS-SF questionnaire, I-VAS, 3-day voiding diary, and uroflowmetry were assessed; complications were also assessed. Patients' perception of treatment benefit, satisfaction, and willingness to undergo retreatment or recommend treatment were also evaluated. Cure was defined as no leakage during stress after surgery at the 12-month postoperative visit.

The primary endpoint was the difference in the cure rate of SUI between the H- and U-type approaches. The secondary endpoints included differences in 1) postoperative changes in I-QoL, BFLUTS-SF, I-VAS, uroflowmetry, and voiding diary; 2) patients' perception of treatment benefit, satisfaction, and willingness to undergo retreatment or recommend treatment; 3) perioperative parameters (operative time, bleeding amount, and immediate postoperative pain VAS); and 4) return to normal activities. Overall cure rate and complications were also evaluated. Our institutional review board approved this study, and written informed consent was obtained from all participants before enrollment.

1. Surgical procedure

Random allocation to either the U or the H approach was performed after obtaining informed consent. All operations were conducted at a day care surgery center by the same experienced surgeon. Under a combination of local anesthesia and light sedation, patients were positioned in the dorsal lithotomy position. After infiltrating mixed normal saline with lidocaine and 1:200,000 epinephrine into the anterior vaginal wall, an approximately 1.5 cm midline vertical vaginal incision was made from 1 cm below the external urethral meatus, and paraurethral dissections were processed bilaterally. For the U-type procedure, the inserter was grasped without the protective cover and using the needle holder, and the inserter was introduced into the previously dissected paraurethral incision orienting the inserter to 45° from the sagittal midline and toward the ipsilateral shoulder. The inserter was advanced upward until the back edge of the pubic bone was reached, keeping the inserter tip against the backside of the pubic bone. The needle driver was disconnected from the first inserter and was connected to the second inserter after removing the protective cover. The second inserter and device were placed in the back side of the pubic bone in the same manner. After disconnecting the needle holder from the second inserter, tension was adjusted. After the final adjustment, the release wire was pulled and the inserters were removed. For the H approach, dissection was made laterally, towards the ischiopubic ramus and parallel to the floor on both sides, and the inserter and device were positioned firmly into the obturator internus muscle. Cystoscopy was performed only in patients undergoing the U approach. Urethral catheters were not used, and patients were discharged after several instances of self-voiding.

RESULTS

From March 2007 to July 2008, 115 women with SUI underwent the TVT-Secur procedure. Of those, 53 underwent the U-type surgery, and 62 underwent the H-type surgery. Initially, 133 women were enrolled and randomly allocated

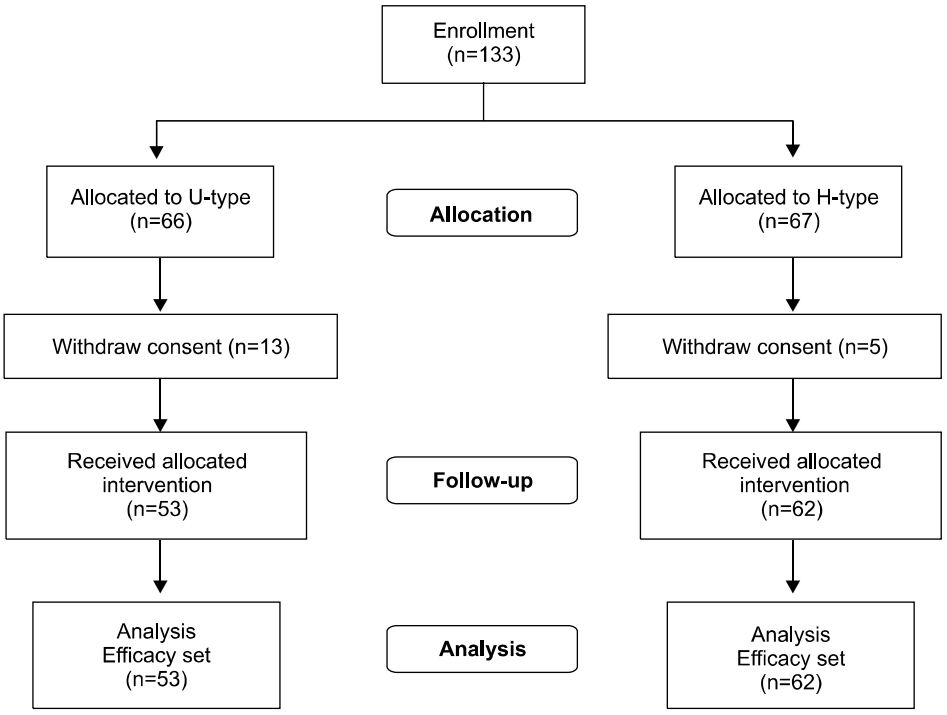

FIG. 1. Participants' diagram.

TABLE 1. Patients' baseline characteristics

	Overall (n=115)	U type (n=53)	H type (n=62)	p-value
Age (years)	55.96±8.98	55.21±9.34	56.6±8.68	0.410[a]
BMI (kg/m^2)	23.50±2.77	23.76±3.07	23.28±2.50	0.400[a]
Parity (times)	2.94±1.42	2.66±1.13	3.18±1.60	0.104[a]
Menopause	34 (29.82%)	17 (32.08%)	17 (27.87%)	0.624[b]
Prior hysterectomy	8 (6.96%)	4 (7.55%)	4 (6.45%)	1.000[c]
Symptom duration (months)	62.37±80.80	52.57±70.57	70.57±89.70	0.055[a]
Symptom grade				0.916[a]
I	39	18	21	
II	66	30	36	
III	10	5	5	
Incontinence VAS	6.65±2.13	6.61±2.15	6.69±2.14	0.869[a]
Urodynamic parameters				
ALPP (cm H_2O)	96.95±22.88	92.92±19.98	100.38±24.73	0.020[a]
MUCP (cm H_2O)	44.12±12.37	43.84±13.28	44.37±11.63	0.827[a]
DO (n, %)	9 (8.0%)	5 (9.6%)	4 (6.6%)	0.7302

BMI: body mass index, VAS: visual analogue scale, ALPP: abdominal leak point pressure, MUCP: maximal urethral closing pressure, DO: detrusor overactivity, [a]: wilcoxon two-sample test, [b]: chi-square test, [c]: Fisher's exact test

TABLE 2. Perioperative parameters

	Overall (n=115)	U type (n=53)	H type (n=62)	p-value
Operative time (min)	14.04±5.73	14.77±6.35	13.42±5.13	0.114[a]
Intraoperative bleeding (ml)	61.85±61.02	56.45±45.31	66.36±71.63	0.645[a]
Postoperative pain at recovery room (VAS)	2.13±1.87	2.18±2.00	2.09±1.77	0.926[a]

VAS: visual analogue scale, [a]: Wilcoxon 2-sample test

TABLE 3. Changes in outcome measures; I-QoL, BFLUTS-SF, incontinence VAS, voiding diary, and uroflowmetry parameters

	Overall		p-value	U type		p-value	H type		p-value	p-value U vs. H
	Preoperative	Postoperative		Preoperative	Postoperative		Preoperative	Postoperative		
I-QoL scores										
Total	41.33±21.88	71.28±17.47	<0.0001	39.32±21.32	70.56±16.43	<0.0001	43.04±22.38	71.89±18.42	<0.0001	0.6070
Avoidance and limiting behavior	46.96±22.74	77.19±18.89	<0.0001	44.42±22.72	75.63±18.44	<0.0001	49.13±22.67	78.52±19.31	<0.0001	0.7551
Psychosocial impacts	48.33±26.77	75.88±20.53	<0.0001	46.34±26.08	77.88±17.12	<0.0001	50.04±27.44	78.01±20.66	<0.0001	0.4139
Social embarrassment	38.13±27.21	83.24±23.13	<0.0001	36.04±26.01	82.35±22.70	<0.0001	39.92±28.29	84.00±23.65	<0.0001	0.7216
BFLUTS scores										
FS	4.98±2.67	2.89±2.18	<0.0001	4.87±2.63	2.80±1.95	<0.0001	5.08±2.72	2.97±2.37	<0.0001	0.4693
VS	1.78±2.45	1.58±2.29	0.491	1.75±2.66	1.84±2.64	0.826	1.81±2.28	1.36±1.94	0.242	0.1733
IS	8.28±3.84	2.07±2.94	<0.0001	9.00±3.72	1.60±2.42	<0.0001	7.66±3.87	2.47±3.28	<0.0001	0.0210
Sex	1.18±1.47	0.32±0.88	<0.0001	1.30±1.54	0.20±0.45	<0.0001	1.08±1.41	0.42±1.12	<0.0001	0.3822
QoL	7.34±4.38	2.07±3.30	<0.0001	7.87±4.55	1.98±3.31	<0.0001	6.89±4.22	2.15±3.32	<0.0001	0.2857
Urodynamic parameters										
Qmax (ml/s)	23.94±9.70	20.11±9.97	0.182	22.65±7.49	17.74±9.12	0.111	25.05±11.20	22.14±10.42	0.947	0.2048
Postvoid residual urine (ml)	17.66±25.79	32.77±37.78	0.016	15.19±19.89	24.00±23.35	0.348	19.80±29.99	40.29±46.04	0.022	0.3035
Voiding diary										
Micturation	8.49±2.86	7.47±2.49	<0.0001	8.49±2.63	7.59±2.48	0.022	8.48±3.08	7.35±2.52	0.001	0.8280
Nocturia	0.76±0.81	0.87±0.85	0.794	0.72±0.82	0.98±0.97	0.288	0.80±0.81	0.78±0.73	0.592	0.1740
Urgency episode	2.68±3.51	1.96±2.77	0.035	2.54±3.25	2.42±3.24	0.457	2.79±3.74	1.55±2.23	0.029	0.3234
Urgency scale	2.09±0.99	1.87±1.07	0.062	2.07±1.00	1.85±1.18	0.415	2.11±0.98	1.89±0.96	0.117	0.8817
incontinence VAS	6.65±2.13	1.08±2.34	<0.0001	6.61±2.15	0.95±2.41	<0.0001	6.69±2.14	1.20±2.31	<0.0001	0.4354

I-QoL: incontinence quality of life, BFLUTS-SF: bristol female lower urinary tract symptoms-scored form, VAS: visual analogue scale, FS: filling symptoms, VS: voiding symptoms, IS: incontinence symptoms, Sex: sexual function, Qmax: maximal flow rate

to either the U-type (n=66) or the H-type (n=67) procedure. Of those, 13 women in the U-type group and 5 women in the H-type group withdrew informed consent and did not undergo surgery (Fig. 1).

The mean age was 55.21±9.34 years in those receiving the U-type surgery and 56.6±8.68 years in those undergoing the H-type approach (p= 0.410). There were no significant differences in preoperative patient characteristics or perioperative parameters between the U-type and H-type approaches (Table 1, 2).

Cure rates were 88.7% (47/53) for the U-type approach and 87.1% (54/62) for the H-type approach (p=0.796), with an overall cure rate of 87.8% after 12 months postoperatively. The I-QoL (total and all subscale scores), filling, incontinence, sexual function, and QoL sum (BFLUTS-SF), and incontinence VAS were significantly improved with both approaches, but the degree of improvement did not differ significantly between the two approaches (Table 3). Regarding the voiding diary, micturition episodes were reduced with both approaches, but urgency episodes decreased significantly with only the H-type approach (Table 3). The maximal flow rate did not change with either approach, but post-void residuals increased in women treated with the H method (Table 3). Approximately 82.9% of women treated with the U-type approach and 84.3% of those treated with the H-type method reported that they were satisfied with the surgical outcome (p=0.858). A total of 80.5% of those treated with the U-type method and 86.3% of those treated with the H-type approach reported a benefit from the surgery (p=0.455). About 87.8% and 88.0% treated with the U-type and the H-type approaches, respectively, reported that they would recommend the surgery to others who had SUI (p=0.442). Also, 87.8% and 86.3% treated with the U-type and with the H-type methods reported that they would undergo the same surgery if they had been in same condition (p=0.800).

Regarding intra-operative parameters, the mean duration of the operation was 14.8±6.3 min for the U-type approach and 13.4±5.1 min for the H-type approach (p=0.114). The mean amount of blood loss was 56.4±45.3 ml for the U-type approach and 66.4±71.6 ml for the H-type approach (p=0.645). Immediate postoperative pain VAS was 2.2±2.0 for the U-type approach and 2.1±1.8 for the H-type approach (p=0.926). The time required for patients to return to normal activities was not significantly different between the approaches (Table 4). There were no patient complaints about dyspareunia or loss of libido after either type of procedure.

There were 3 cases of intra-operative vaginal wall perforations during the H-type approach. All 3 cases were immediately repaired, and the wound healed without infection or erosion. Immediate postoperative retention was observed in 2 women treated with the U-type approach and in 1 woman treated with the H-type method. Retention was resolved after temporary drainage without voiding symptoms. One woman had tape release and additional cutting procedures for persistent and large amounts of residual urine. Overall, 4 women underwent additional midurethral sling procedures for persistent urine leakage. In detail, transobturator tape (TOT) was applied for 3 women as an additional sling procedure and TVT was applied for 1 woman.

DISCUSSION

Our study demonstrated that there was no significant difference in the cure rate between the U-type and the H-type methods of TVT-Secur, with an approximately 88% overall cure rate after 1 year of follow-up, compared with previous studies reporting 1-year cure rates of 91% for TVT [17], 92% for TOT, and 86% for TVT-obturator (TVT-O) procedures [18]. To our knowledge, no comparative studies between TVT-Secur and other midurethral sling procedures such as TVT and TOT have been performed. Also, although there are some reports on TVT-Secur, no prospective comparative study of the U and H methods has been carried out. In our study, both types of surgery demonstrated comparable cure rates and patient-reported outcomes at the 1-year follow-up. Our study demonstrated a comparable cure rate with the other sling methods, including TVT, the gold standard treatment for female SUI. A few studies have reported unfavorable outcomes for TVT-Secur [19-21]. Recently, however, a prospective study reported a 1-year cure rate as high as 93.5% [22]. In addition, MiniArc, other types of midurethral slings with single-incision systems, have resulted in up to 91% 1-year cure rates [23].

An important point for obtaining continence is the disconnection of the inserter from the mesh. This entails a gentle twist of the handle while gently pushing the device into the patient's body. This maintains the ideal tension of the mesh, which should be left abutting the urethra, forcing the periurethral tissues to protrude slightly through the mesh

TABLE 4. Comparison of required time for return to normal activity between the U- and H-type approaches

Days	Overall (n=115)	U type (n=53)	H type (n=62)	p-value
Time to house work	6.22±10.95	7.18±12.15	5.43±9.89	0.624[a]
Time to job	8.03±8.98	9.33±9.69	6.64±8.27	0.207[a]
Time to social activity	12.64±18.46	14.33±20.31	11.41±17.17	0.347[a]
Time to hobby	12.77±13.85	14.84±15.11	11.08±12.67	0.442[a]
Time to sexual activity	39.30±14.56	38.96±15.31	39.56±14.20	0.885[a]

[a]: Wilcoxon two-sample test

pores. Otherwise, the mesh will not be firmly attached to the connective tissue and will fail to provide adequate tension to the urethra. Thus, surgeons need experience in removing the inserters without loosening the mesh.

TVT-Secur is an 8 cm long polypropylene mesh with the absorbable end able to be fixed to the obturator internus internal fascia that can be inserted through a single 1.5 cm vaginal incision. The extension of the dissection required to create a passage for the sling is very limited. Because neither sutures nor inserting needles are needed, the risk of internal injury inherent to the blind passage of inserting needles is hypothetically minimized. Because mortalities have been reported after midurethral slings associated with perineal fasciitis [16] as well as vascular and bowl injury [10-12], safety must be considered when choosing the type of midurethral sling. In our study, 6 cases of complication were reported. There were no cases of bladder perforation, which occurs in up to 11% of TVT procedures [24]. Nor were there any cases of vessel injury, which usually results from the blind course of the needles and occurs in up to 4.0% of those treated with TVT [25]. Furthermore, no patient suffered from postoperative persistent groin or thigh pain due to obturator nerve entrapment by the mesh, which occurs in up to 14.3% of those treated with the trans-obsturator sling series [26].

The technique for placing the TVT-Secur can be rapidly learned by the average surgeon qualified to treat SUI. However, caution is required when placing the TVT-Secur extremities in the fibrous attachment of the internal obturator muscle, because this might not be quickly achieved by inexperienced surgeons. No space should be left between the urethra and the device. The TVT-Secur needle dimension requires a wider tunnel, and surgeons probably need some experience with the procedures to find it. The operator must be careful to avoid vaginal perforation. In this study, there were 3 cases of intra-operative vaginal wall perforation with the H-type approach. Neuman reported a 4% incidence of vaginal perforation in their first 100 cases [22]. TVT-Secur, especially the H-type, requires a wider tunnel to prevent dragging of the vaginal submucosal connective tissue when placing the end of the device into the fibrous tissue of the internal obturator muscle. Otherwise, the needle can perforate the vaginal wall. Neuman also reported a 10% incidence of vaginal tape protrusion, a 5% incidence of tape removal, a 2% incidence of bladder outlet obstruction, and a 1% incidence of paravesical hematoma [22]. Therefore, a surgeon must receive adequate training before attempting this surgery.

Changes in post-void residuals were significantly larger with the H-type approach than with the U-type approach. TVT induces urethral obstruction more frequently than do trans-obturator procedures, as evidenced by ultrasonographic and urodynamic findings [27,28]. Currently, it is unclear why the H-type approach resulted in significantly larger post-void residuals in our study than the U-type approach; clinically, however, the increase is thought to be insignificant. Furthermore, of the 3 patients with immediate postoperative urinary retention, none needed additional treatment for persistent large post-void residuals or voiding symptoms after removal of the temporary urethral catheter.

Urgency episodes were significantly reduced only with the H-type approach. Generally, studies comparing TVT and TOT reported no difference in *de novo* frequency and urgency [26,27]. However, the effectiveness on overactive bladder symptoms remains controversial. Interestingly, midurethral sling procedures are effective in improving preexisting overactive bladder symptoms in half of the patients with mixed incontinence [28,29]. Contact with urine in the proximal urethra can induce a reflex contraction of the detrusor muscle [30]. Thus, eliminating urinary leakage may decrease this reflex after anti-incontinence surgery. At present, improvement in overactive bladder symptoms, including urgency and *de novo* urgency, after TVT-Secur need further study.

Statistically considered sample size calculation for randomized controlled trials was not applied for the design of this study. For the calculation of an optimistic sample size, the investigator must have some information on both the variability of response to therapy and the assumed degree of effectiveness of therapy. But, because only a few reports provided information about the variability and effectiveness of each subtype of TVT-Secur before our study, statistically considered sample size calculation was not applicable for this study.

At baseline, the abdominal leak point pressure (ALPP) of the H-type approach group was significantly higher than that of the U-type group. But, because the absolute difference in mean value was just 7.46 cmH_2O and the proportion of intrinsic sphincter deficiency (ISD, ALPP $<$ 60 cmH_2O) between the U-type (0.37%) and H-type (0.48%) groups was not significantly different (p=0.87), the difference in ALPP may be clinically insignificant. However, this unbalanced baseline characteristic could be a prognostic factor having a negative effect on the U group. If random allocation had been more balanced and clinically significant effect-size and power had been calculated, the surgical outcome of the U-type approach could have been superior to that of the H-type.

At this time, we cannot explain the exact reasons for persistent urine leakage after TVT-Secur. All 4 women who underwent additional midurethral sling because of persistent SUI after TVT-Secur were cured. Therefore, one possible explanation for failure is suboptimal urethral tension of TVT-Secur.

The goal of a minimally invasive surgical procedure should be to provide an acceptable cure rate that is comparable to that of standard methods as well as a relatively low incidence of complications. In the context of the acceptable cure rate and low rate of complications compared with TVT and TOT, our study demonstrates that with relatively short-term follow-up, both the U-type and the H-type approaches of the TVT-Secur procedure are equally effective and safe for the treatment of female SUI.

CONCLUSIONS

Both the U-type and the H-type approaches of the TVT-Secur system are effective procedures in terms of cure rate and patient-reported outcomes for the treatment of female SUI with 1 year of follow-up. There were no severe complications related to either approach. Studies are needed to establish the long-term outcomes of the procedure.

Conflicts of Interest

The authors have nothing to disclose.

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