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Voiding Dysfunction

One-Year Surgical Outcomes and Quality of Life after Minimally Invasive Sling Procedures for the Treatment of Female Stress Urinary Incontinence: TVT SECUR® vs. CureMesh®

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Purpose: We compared the efficacy and safety of two minimally invasive sling procedures used to treat female stress urinary incontinence (SUI), tension-free vaginal tape (TVT) SECUR® and CureMesh®, and assessed the 1-year surgical outcomes.

Materials and Methods: Sixty women with SUI were assigned to undergo either the TVT SECUR (n=38) or CureMesh (n=22) procedures between April 2007 and June 2008. Patients were monitored via outpatient visits at 1 month, 3 months, and 1 year after surgery. The efficacy of these procedures was evaluated by the cough test or by a urodynamic study. At these postoperative visits, the patients also completed several questionnaires, including incontinence quality of life, patient's perception of urgency severity, the scored form of the Bristol Female Lower Urinary Tract Symptoms, visual analog scale, and questions about perceived benefit, satisfaction, and willingness to undergo the same operation again. The objective cure rate was defined as no leakage during the cough test with a full bladder. The subjective cure rate was evaluated by self-assessment of goal achievement performed 1 year postoperatively.

Results: The two groups were similar in preoperative characteristics and urodynamic parameters. The objective cure rates were similar between TVT SECUR and CureMesh (68.4% vs. 77.3%). All respondents reported improvement after surgery. There were no intra-operative complications.

Conclusions: Our results showed that the TVT SECUR and CureMesh procedures are both safe and simple to perform and have no significant differences in efficacy. Comparative studies with long-term follow-up are warranted to determine the true efficacy of these procedures.

Key Words: *Minimally invasive surgical procedures; Stress urinary incontinence; Treatment outcome*

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INTRODUCTION

Stress urinary incontinence (SUI) accounts for over 80% of female urinary incontinence and consists of involuntary leakage of urine with effort, exertion, sneezing, coughing, laughing, exercising, or any maneuver that causes increased intra-abdominal pressure [1,2]. In South Korea, about 21% of middle-aged women are known to have SUI that deteriorates their quality of life [3].

Surgery is one of the most effective treatments for SUI. Currently, the tension-free vaginal tape (TVT) procedure, a modified sling procedure first described by Ulmsten et al in 1996, is the most widely used [4] and has a high cure rate of 80-100% [5,6] and long-term success rate of 78.9-95.2% [7-10]. However, the TVT procedure has reported complications that include bladder perforation, postoperative urinary retention, retropubic hematoma, and pain [5,7]. To minimize some of these complications, such as bladder or intestinal perforation, the transobturator tape (TOT) procedure, a technique working through the obturator foramen, was developed by Delorme et al [11,12].

Recently, a minimally invasive sling technique involving a single incision on the anterior vaginal wall was developed to reduce pelvic organ damage and pain. The TVT

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SECUR system (Gynecare, Ethicon, Somerville, NJ, USA) was first used in 2006 [13], and the MiniArc™ single-incision sling (American Medical System, Minnetonka, MN, USA) was introduced in 2007. Another domestic monofilament polypropylene mesh similar to MiniArc called CureMesh (HueMedion, Namyangju, South Korea) has also been used. To date, however, there are few domestic reports related to these procedures. For this reason, we compared the efficacy and safety of two procedures (TVT SECUR system and CureMesh) through a 1-year follow-up study.

MATERIALS AND METHODS

In this prospective, nonrandomized study, subjects were patients diagnosed with female SUI who underwent the TVT SECUR procedure (40 patients) or the CureMesh procedure (22 patients) from April 2007 to June 2008. Through preoperative physical examination and urodynamic studies, patients with pelvic organ prolapse, suspected intrinsic sphincter deficiency, or suspected urinary obstruction were excluded. A total of 60 patients, 38 patients in the TVT SECUR group and 22 patients in the CureMesh group, who were followed up for 1 year or longer were included. All operations were carried out under mask inhalation anesthesia by a single surgeon. In cases in the TVT SECUR group, the "U position" or "Hammock position" was used. The inserter tip was oriented to 45° from the sagittal plane toward the ipsilateral shoulder in the "U position," similar to the traditional TVT route. The inserter tip was oriented at an angle of 45° from the midline toward the ischiopubic ramus and the tip was approximately in the 3 and 9 o'clock positions in the "Hammock position," similar to the obturator foramen approach [13]. In cases in the CureMesh group, the tape was positioned similarly to the "Hammock position" approach. The Foley catheter was removed the morning of postoperative day 1. Timed voiding or clean intermittent self-catheterization (CIC), if necessary, were used in patients who failed to void, in those with a post-void residual (PVR) greater than 150 ml, or in those with bladder outlet obstruction symptoms.

Preoperatively, all patients underwent history taking, pelvic examination, 3-day voiding diary, urinalysis, urine culture, Q-tip test, full bladder standing stress test, 1-hour pad test, and urodynamic studies including uroflowmetry. Patients also filled out several questionnaires, such as the incontinence quality of life (I-QoL), patient's perception of urgency severity (PPUS), visual analogue scale (VAS) for incontinence, Self-assessment/Sandvik questions, and the scored form of the Bristol Female Lower Urinary Tract Symptoms questionnaire ($BFLUTS_{SF}$), prior to the operation and 1 year after the operation. Uroflowmetry and PVR urine tests were carried out to assess the cure rate and the complication rate, respectively. Some patients' questionnaires were completed by telephone interview. Questions on self-assessment of goal achievement and patient benefit, satisfaction, and willingness to have the operation again (BSW) were asked especially to evaluate the patients' subjective satisfaction postoperatively. The full bladder standing stress test by coughing was carried out to assess the objective cure rate.

The objective surgical outcomes were evaluated by the Stamey classification. Cure was defined as the absence of any episodes of involuntary urine leakage during stressful activities and the stress cough test. Improvement was defined as a significant reduction in urine leakage, such that it did not require further treatment [14].

Recurrence of urinary incontinence was confirmed by urine leakage in the standing stress test with a full bladder. Also, after showing the patients their pre-treatment goals, subjective satisfaction was rated as satisfactory with greater than 4 points or more in goal attainment scores, as unchanged with 3 points, and as dissatisfactory with 2 points or less on the self-assessment of goal achievement questionnaire.

Statistical analysis was performed with PC-SPSS version 12.0 (SPSS, Inc., Chicago, IL, USA) using paired Student's t-test, chi-square test, and Wilcoxon rank sum test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The average follow-up period was 18.4±2.9 months for the TVT SECUR group and 17.8±1.8 months for the CureMesh group (p=0.086). There were no significant differences in preoperative clinical findings between the two groups (Table 1).

One-year objective success rates were 86.8% in the TVT SECUR group (68.4% cured, 18.4% improved, and 13.2% failed) and 90.9% in the CureMesh group (77.3% cured, 13.6% improved, and 9.1% failed). Patients' subjective satisfaction scores of the operation were 68.4% and 77.3% satisfactory, 10.5% and 9.1% unchanged, and 21.1% and 13.6% dissatisfactory, respectively, but showed no statistical significance (Table 2).

Between the two groups, the average operation time was shorter in the CureMesh group, and the duration of indwelling Foley catheter use showed no difference (Table 3). However, there were three cases (7.9%) with a PVR of more than 150 ml on postoperative day 1 in the TVT SECUR group; two of those resolved with timed voiding only, and the other one recovered via timed voiding and CIC for 4 days.

Four (10.5%) cases of *de novo* urgency occurred in the TVT SECUR group and two (9.1%) in the CureMesh group; however, there was no statistical significance in the difference between the two groups (Table 3). Among them, four improved within 3 months following administration of anti-cholinergics and two did not improve even with more than 12 months of medication. The two groups had no major complications such as intra-operative bladder perforation, hemorrhage requiring transfusion, or postoperative retropubic hematoma. Complications such as vaginal erosion were not found at the 1-year postoperative physical exami-

TABLE 1. Clinical characteristics of patients treated with the TVT SECUR and CureMesh procedures

	TVT SECUR (n=38)	CureMesh (n=22)	p-value
Age (years)	52.0±7.6	50.4±6.9	0.421
Follow-up period (months)	18.4±2.9	17.8±1.8	0.086
No. of parity	2.2±0.9	2.1±0.5	0.535
Postmenopausal	21 (55.3)	11 (50.0)	0.455
Previous pelvic surgery	11 (28.9)	4 (18.2)	0.541
BMI (kg/m^2)	24.4±2.9	25.6±4.0	0.199
Positive stress test (%)	32 (84.2)	17 (77.3)	0.499
Q-tip test ($>30^{o}$)	33 (86.8)	16 (72.7)	0.176
Pad test (g)	12.0±14.9	9.9±17.1	0.606
Preoperative storage symptoms			
Frequency (>8/day)	23 (60.5)	17 (77.3)	0.260
Nocturia (≥1/night)	8 (21.2)	8 (36.4)	0.159
Urgency	28 (73.7)	13 (59.1)	0.350
Urge incontinence	15 (39.5)	10 (45.5)	0.595
Preoperative symptom/QoL score			
Symptom	16.3±8.2	16.2±7.5	0.961
QoL	4.8±1.2	4.5±0.9	0.241
Preoperative urodynamic parameters			
Detrusor overactivity	7 (18.4)	4 (18.2)	0.601
Qmax (ml/s)	31.9±11.5	30.7±9.9	0.679
Voided volume (ml)	366.4±85.8	368.9±101.0	0.917
PVR (ml)	7.7±12.5	8.3±13.2	0.856
Pdet at Qmax (cmH_2O)	35.2±14.6	32.4±9.9	0.473
MUCP (cmH_2O)	72.2±25.2	81.4±24.6	0.171
VLPP (cmH_2O)	104.2±12.6	102.7±11.9	0.646

Values are given as Mean±SD or number (%), TVT: tension-free vaginal tape, BMI: body mass index, QoL: quality of life, Qmax: maximal flow rate, PVR: post void residual, MUCP: maximal urethral closure pressure, VLPP: Valsalva leak point pressure

TABLE 2. Comparison of clinical outcomes of patients treated with TVT SECUR and CureMesh

	TVT SECUR (n=38)	CureMesh (n=22)	p-value
Objective cure rates			
Cure	26 (68.4)	17 (77.3)	0.463
Improvement	7 (18.4)	3 (13.6)	0.632
Failure	5 (13.2)	2 (9.1)	0.636
Satisfaction			
Satisfied	26 (68.4)	17 (77.3)	0.463
Tolerable	4 (10.5)	2 (9.1)	0.858
Fair	8 (21.1)	3 (13.6)	0.474

Values are given as number (%), TVT: tension-free vaginal tape

nation (Table 3). There were five cases (13.1%) of recurrence of SUI in the TVT SECUR group and two cases (9.1%) in the CureMesh group. All recurrences were cured by re-operation with the TOT procedure on average 4.2 months after surgery.

In the 1-year follow-up uroflowmetry, the maximum urine flow rate (Qmax) of the CureMesh group significantly decreased from 31.0 ml/s to 26.1 ml/s, but the values were within the normal range (Table 4). Urinary storage symptoms such as daytime frequency, nocturia, urgency, and urge incontinence were all significantly improved in the TVT SECUR group, and only nocturia and urgency symptoms were significantly improved in the CureMesh group (Table 4). Also, in both groups, postoperative questionnaires, such as I-QoL, PPUS, VAS for incontinence, Self-assessment/Sandvik questions, and $BFLUTS_{SF}$, showed significant improvements in all aspects (Table 5). In the questionnaire about the patient's willingness to repeat the operation, 31 patients (93.9%) in the TVT SECUR group and 17 patients (85.0%) in the CureMesh group responded positively to undergoing surgery. For recommending surgery, 31 patients (93.9%) and 20 patients (90.9%), respectively, responded positively to willingness to recommend the procedure to another person.

DISCUSSION

The tension-free mid-urethral sling procedure, the gold standard of treatment for female SUI, is based on the integral theory proposed by Petros and Ulmsten in 1993 [15]. The TVT procedure, introduced by Ulmsten et al in 1996, has spread worldwide as the first-generation sling procedure, and it is still the most universally used owing to its high efficacy and safety [4,16]. However, in a large-scale study involving 1455 patients from 38 hospitals performing TVT procedures, major surgical complications such as

TABLE 3. Comparison of the intraoperative and postoperative parameters of patients treated with TVT SECUR and CureMesh

	TVT SECUR (n=38)	CureMesh (n=22)	p-value
Operation time (min)	5.3±1.3	3.8±1.1	<0.001
Total anesthesia duration (min)	25.7±6.0	25.2±6.1	0.784
Hospital stay after operation (hours)	31.2±15.8	34.6±14.4	0.418
Perioperative complications			
Groin pain	1 (2.6)	0	NS
Vaginal wall penetration	0	0	NS
Bladder perforation	0	0	NS
Hb loss (g/dl)	1.13±0.89	1.45±0.53	0.134
Postoperative complications			
Vaginal erosion	0	0	NS
Urethral erosion	0	0	NS
Paravesical hematoma	0	0	NS
Urinary infection	1 (2.6)	0	NS
Dyspareunia	0	0	NS
Postoperative voiding difficulty			
PVR>150 ml[a]	3 (7.9)	0 (0)	0.188
Postoperative storage symptoms[b]			
Frequency (>8/day)	3 (7.9)	2 (9.1)	0.826
Nocturia (≥1/night)	2 (5.3)	4 (18.2)	0.093
Urgency	7 (18.4)	4 (18.2)	0.804
Urge incontinence	6 (15.8)	5 (22.7)	0.657
De novo urgency	4 (10.5)	2 (9.1)	0.908

Values are given as number (%), TVT: tension-free vaginal tape, NS: not significant, Hb: hemoglobin, PVR: post void residual. [a]: at first postoperative day, [b]: at one year after surgery

TABLE 4. Changes in uroflowmetry parameters and storage symptoms before and after surgery

	TVT Secur (n=33)			CureMesh (n=20)		
	Preoperative	Postoperative	p-value	Preoperative	Postoperative	p-value
Uroflowmetry parameters						
Qmax (m/s)	31.4±11.9	29.5±14.2	0.350	31.0±10.0	26.1±11.4	0.006
Voided volume (ml)	365.6±76.9	268.2±169.5	0.003	375.3±98.8	277.0±117.7	0.006
PVR (ml)	7.9±13.2	10.6±20.2	0.376	9.4±14.6	9.5±12.0	0.983
Storage symptoms						
Frequency (times/day)	8.6±3.5	7.6±1.9	0.018	8.6±2.9	8.6±2.2	0.524
Nocturia (times/night)	0.8±1.0	0.3±0.5	0.003	1.0±1.1	0.5±0.8	0.019
Urgency	28 (73.7)	7 (18.4)	<0.001	13 (59.1)	4 (18.2)	0.006
Urge incontinence	15 (39.5)	6 (15.8)	0.019	10 (45.5)	5 (22.7)	0.101

Values are given as Mean±SD or number (%), TVT: tension-free vaginal tape, Qmax: maximal flow rate, PVR: post void residual. Recurred patients were excepted in this data

bladder perforation, abdominal organ injuries, massive hemorrhage (>200 ml), vascular injuries, nerve injuries, and hematoma were reported [17]. Some studies have reported that this procedure has a higher rate of complications and a longer recovery period than do current colposuspension procedures [18,19]. The second-generation sling procedures were developed to reduce major complications such as bladder perforation and to eliminate the need for intra-operative cystoscopy. Delorme first described the TVT-obturator (TVT-O) procedure in 2001, which is performed through the obturator foramen, and de Leval presented the inside-out form of the procedure in 2003 [11,12]. However, although complications such as adjacent organ injuries, obturator nerve injuries, and pain are decreased for the TVT-O and the TOT procedures, such complications are still reported [20]. The TVT SECUR procedure, first introduced in 2006, is minimally invasive compared with previous procedures and was developed to minimize pelvic organ damage or vascular injuries because it does not involve needle penetration of the retropubic space or the obturator foramen. The minimally invasive, single-incision sling operation, MiniArc-Minisling (similar to CureMesh®) was introduced in 2007 as a third-generation sling procedure, along with the TVT SECUR procedure. Both tips of the tape

TABLE 5. Changes in scores of several questionnaires after surgery to treat female stress urinary incontinence

	All patients				TVT SECUR				CureMesh			
	Preoperative	Postoperative	p-value	n	Preoperative	Postoperative	p-value	n	Preoperative	Postoperative	p-value	n
I-QoL	71.4±17.7	49.6±47.7	0.006	40	72.1±18.9	92.5±17.4	<0.001	29	65.0±17.8	93.8±22.3	0.046[a]	11
PPUS	2.0±0.8	2.6±0.7	0.001	31	2.0±0.8	2.6±0.7	0.001	31	1.8±0.7	2.4±0.8	0.004	20
VAS	6.1±2.0	2.0±1.9	<0.001	33	6.3±2.0	1.7±2.3	<0.001	33	6.1±2.2	1.9±2.1	<0.001	21
Self-Assessment	1.0±0.1	1.7±0.5	<0.001	55	1.0±0.2	1.7±0.4	<0.001	35	1.0±0.0	1.6±0.5	<0.001	20
Sandvik Questions 1	3.6±0.6	2.4±0.9	0.001		3.6±0.7	2.4±0.9	0.03		3.6±0.5	2.3±1.0	0.002	
Sandvik Questions 2	1.8±0.8	1.2±0.5	0.013		1.8±0.9	1.3±0.7	0.104		1.7±0.9	1.1±0.3	0.095	
$BFLUTS_{SF}$	22.7±10.1	5.8±7.3	<0.001	47	23.7±11.5	8.0±7.5	<0.001	26	21.5±8.1	3.0±6.2	<0.001	21

TVT: tension-free vaginal tape, I-QoL: incontinence quality of life questionnaire, PPUS: patient's perception of urgency severity, VAS: visual analogue scale, $BFLUTS_{SF}$: Scored Form of the Bristol Female Lower Urinary Tract Symptoms questionnaire, [a]: Wilcoxon's signed rank test

are self-fixating, and the procedures can be performed with a single incision on the anterior vaginal wall. However, several complications have been reported, such as unintended tape removal at the time of inserter removal, vaginal wall perforation, or tape extrusion, but these have been decreasing in frequency with increasing experience with the procedures [21]. In our study, there were no complications other than two cases of inguinal pain and postoperative urinary tract infection.

Currently, there are few studies on the efficacy of minimally invasive, single-incision sling procedures. Examining short-term follow-up results (an average of 5-10 weeks), seven abstracts reported in the 2007 International Urogynecology Association (IUGA) on the TVT SECUR procedure showed a mean objective cure rate of 80.3% (range, 69-88%) with a mean objective recurrence rate of 19.7% (range, 3-31%), with low rates of complications [13]. In addition, a 1-year follow-up study of the TVT SECUR procedure by telephone interview reported higher objective cure rates in the last 46 subjects (93.5%) than in the first 44 subjects (88.6%) [21]. Another 1-year study reported an objective cure rate of 78% and a subjective cure rate of 81% after the TVT SECUR procedure [22]. Among the 107 patients who received TVT SECUR procedures, 71% were cured and 14% were improved after 15 months [23]. In addition, 83.1% and 77.6% of 97 patients who received MiniArc-Sling procedures showed no urine leakage in a cough provocative test at 6 weeks and 12 months after surgery, respectively, with significant improvements in 69.1% of the patients' quality of life [24]. According to a comparative study of the TVT SECUR and MiniArc-Sling procedures, the objective cure rate was 80.4% and 90.2%, respectively, but the average follow-up period differed at 11 months and 3.5 months for each group, respectively [25]. In our study, the cure rates for the TVT SECUR group and the CureMesh group were 68.4% and 77.3%, respectively, and improvements in symptoms were 18.4% and 13.6%, respectively, showing similar results to previous studies and no significant differences between the two groups. All patients with recurrence were operated on in the initial phase and the recurrence was thought to be due to loosening of the fastening of the tape during inserter removal, although the tape was not removed with the inserter. A decrease in the urine flow rate in the uroflowmetry test in the CureMesh group was probably the result of hard fastening of the tape during the procedure, based on our experiences of past patient recurrences. Therefore, it was suggested that these procedures have a certain learning curve. Furthermore, in the CureMesh group, the average operation time was shorter than in the TVT SECUR group. Among the two minimally invasive sling procedures, our primary experience was with the TVT SECUR procedure, and our experience with the CureMesh procedure came later. This consecutive experience seems to reemphasize the importance of the learning curve.

Acute urinary retention, one of the most common complications that occur after SUI procedures, is known to occur

in 2.3-10.0% of patients after TVT procedures [26]. Urinary retention is reported to occur in 0.9-8.0% after the TVT SECUR and MiniArc-MiniSling procedures [13,16,21-24]. In our study, uroflowmetry was performed on patients who complained of voiding difficulty after surgery, and there were 3 cases (5%) with voiding difficulty, which was defined as less than 15 m/s of maximal urine flow rate or a PVR of more than 150 ml of residual urine.

The occurrence of *de novo* urgency after the TVT SECUR and MiniArc procedures has been reported at various rates, ranging from 5.6% to 36.8% [13,22-24]. We also observed *de novo* urgency in 10% of the patients in this study, but most improved with the administration of anticholinergics. In addition, symptoms such as frequency, urgency, and urge incontinence after midurethral sling procedures in female SUI patients with overactive bladder accompanied by detrusor overactivity improved in 23.5-63.1% of patients [27-29]. In our study, postoperative symptoms such as daytime frequency, nocturia, urgency, and urge incontinence were improved in 56.0-73.2% of the patients.

It is important that surgical outcomes be evaluated according to patient expectations and satisfaction. Recently, research in the field of SUI surgery reflects a similar trend of using patient expectations, goal selection and achievement, and QoL measures in determining surgical outcomes. Significant improvement was reported on the International Consultation on Incontinence Short Form (ICIQ-$_{SF}$) and the Women Irritative Prostate Symptoms Score (W-IPSS) after the TVT SECUR procedure [21]. However, some investigators have reported that there was no change in the ICIQ-$_{SF}$ in the 3-month short-term follow-up of patients who underwent the TVT SECUR and MiniArc-Minisling procedures [24]. In our study, not all patients completed the questionnaires, but the I-QoL, PPUS, VAS, Self-assessment/Sandvik questions, and BFLUTS$_{SF}$ all showed significant improvements at 1 year after surgery. Also, the patients' subjective satisfaction after reviewing the treatment goals made before treatment was relatively low at about 68.4% and 77.3% for the TVT SECUR group and the CureMesh group, respectively. The relatively low figure can probably be attributed to the fact that the patients had set treatment goals related to urine storage symptoms, such as frequency, urgency, and nocturia, that would not necessarily be reduced by these procedures. Therefore, it is necessary to make patients aware of the range of symptoms treatable by a given procedure by precisely explaining the nature of the disease and the potential outcomes of surgery. On the other hand, the BSW survey showed that 93.9% and 85.0% of patients would be willing to undergo surgery again, and 93.9% and 90.9% of patients would recommend surgery to others for the TVT SECUR and CureMesh procedures, respectively. These high figures reflect a high satisfaction rating in these patients.

CONCLUSIONS

In a 1-year follow-up comparison, the two minimally invasive sling procedures, TVT SECUR and CureMesh, showed no significant differences in efficacy or safety. Our findings demonstrate that these procedures are safe, have shorter operation times, and are more convenient than conventional procedures. Although these procedures have a lower cure rate than do current TVT or TOT procedures, efficacy can be improved with increasing proficiency of the surgeon. Long-term follow-up studies, including comparative studies with current procedures, are required to define efficacy.

Conflicts of Interest

The authors have nothing to disclose.

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