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RANDOMIZED, COMPARATIVE STUDY OF THE U- AND H-TYPE APPROACHES OF THE TVT-SECUR® PROCEDURE FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE: TWO-YEAR FOLLOW-UP

Hypothesis / aims of study

Single incision sling system, tension-free vaginal tape (TVT)-Secur® was developed with 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 that minimizes the risk of vascular, nerve, or visceral injury. The prosthetic implant is placed under the mid-urethra 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. Early results of single incision slings reported that cure rates were 66.6-75% from several studies. However, there was little data from long-term studies. We performed the follow-up at 2-year after the TVT-Secur® procedure for the treatment of female stress urinary incontinence (SUI).

Study design, materials and methods

From March 2007 to July 2008, 115 women with SUI underwent TVT-Secur® (Gynecare® Inc, Menlo Park, CA, USA) by a single surgeon. Patients were randomly assigned to either the U- or the H-type approach and followed-up at 12 months and 24 months after the procedure. 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, 90 patients were followed at 24 months after the operation. 41 were treated with the U approach, and 49 women were treated with the H approach. Mean age of total patients was 56±9 years and mean duration of SUI was 62.4±80.8 months (U-type : 52.6 months, H-type : 70.6 months) There were no significant differences in the preoperative patient characteristics and perioperative parameters between U- and H-type types approaches. At 12 months after the operation, overall cure rate was 87.8%. Eighty-nine percent (47/53) of those treated with the U approach and 87.1% (54/62) of those treated with the H approach were cured (p=0.796). At 24 months, 81.1% of total 90 patients (73/90) were cured, 85.1% (34/41) of those treated with the U approach and 79.6% (39/49) of those treated with the H approach were cured. (p=0.687) There was no difference according to the type of procedure. (p=0.687) Seventy five % of total patients continued their effects of operation till 24 months the same as their effect at 12 months after the operation. Seventy-seven percent of total patients stated they had benefit from the operation. Seventy-seven percent of the patients were satisfied with the treatment and 81%of all patients stated that they would undergo the procedure again under the same circumstances. Eighty-four percent of the patients would recommend this treatment to a friend with the same condition. The I-QoL and filling, incontinence, sexual function, and QoL sum (BFLUTS-SF) scores were improved with both approaches at 24 months and there were no significant differences in the degree of improvement between 12 months and 24 months. (Table)

Interpretation of results

Our results support that a minimally invasive surgical procedure, TVT-Secur® could be one of the effective and safe methods for the treatment of female SUI with an acceptable cure rate and low incidence of complications. This study could provide us more confident results from relatively long-term follow-up than previous randomized studies.

Concluding message

The U- and the H-type approaches of the TVT-Secur® procedure provided comparable effectiveness for the treatment of female SUI at 24 months after the operation.

Table. Changes in outcome measures after the operation with TVT-Secur® ; I-QoL, BFLUTS, incontinence VAS

	Overall			U-type			H-type		
	Preop	1yr	2yr	Preop	1yr	2yr	Preop	1yr	2yr
I-QOL scores									
Total	41.3±21.9	71.3±17.5	97.1±21.2	39.3±21.3	70.6±16.4	96.9±18.9	43.0±22.4	71.9±18.4	97.3±23.6
Avo/lim behavior	47.0±22.7	77.2±18.9	85.6±21.9	44.4±22.7	75.6±18.4	84.1±22.9	49.1±22.7	78.5±19.3	86.8±21.2
PI	48.3±26.8	75.9±20.5	86.7±20.5	46.3±26.1	77.9±17.1	87.8±19.3	50.0±27.4	78.0±20.7	85.8±21.8
SE	38.1±27.2	83.2±23.1	83.2±26.1	36.0±26.0	82.4±22.7	84.6±24.9	39.9±28.3	84.0±23.7	81.9±27.5

BFLUTS scores									
FS	4.98±2.67	2.89±2.18	3.38±2.23	4.87±2.63	2.80±1.95	3.40±2.27	5.08±2.72	2.97±2.37	3.37±2.24
VS	1.78±2.45	1.58±2.29	2.04±2.51	1.75±2.66	1.84±2.64	2.24±2.49	1.81±2.28	1.36±1.94	1.85±2.57
IS	8.28±3.84	2.07±2.94	2.10±3.14	9.00±3.72	1.60±2.42	2.28±3.65	7.66±3.87	2.47±3.28	1.93±2.64
Sex	1.18±1.47	0.32±0.88	0.19±0.56	1.30±1.54	0.20±0.45	0.16±0.55	1.08±1.41	0.42±1.12	0.22±0.58
QoL	7.34±4.38	2.07±3.30	2.04±3.73	7.87±4.55	1.98±3.31	2.56±4.33	6.89±4.22	2.15±3.32	1.56±3.07
I-VAS	6.65±2.13	1.08±2.13	1.73±2.71	6.61±2.15	0.76±1.79	1.37±2.73	6.69±2.14	0.6±1.09	1.96±2.73

I-QoL : incontinence quality of life, BFLUTS: Bristol female lower urinary tract symptoms, VAS: visual analogue scale, Avo/lim behavior: avoidance and limiting behavior, PI: psychosocial impacts, SE: social embarrassment, FS: filling symptoms, VS: voiding symptoms, IS: incontinence symptoms, Sex: sexual function, QoL: quality of life

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Samsung Medical Center IRB**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**