

ONE-YEAR SURGICAL OUTCOMES OF MINIMALLY INVASIVE SLING PROCEDURES FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE: NEEDLELESS VS. TVT SECUR

Hypothesis / aims of study

Recently various minimal invasive surgical treatments for stress urinary incontinence have been introduced. We compared the efficacy of two minimally invasive slings using single incision of vaginal wall procedure used to treat female stress urinary incontinence, Needleless^R and TVT Secur^R procedure. The aim of this study is conducted to compare the results of both surgical procedures after 1 year of operation.

Study design, materials and methods

Eighty women with SUI were assigned to undergo either the TVT Secur^R (n=40) or Needleless^R (n=40) procedure from April 2007 and February 2011, prospectively. All female patients performed urodynamic study, and were confirmed urinary leakage during filling cystometry study. Pre- and postoperative evaluation includes the score form of the Bristol Female Lower Urinary Tract Symptom-Short Form (BFLUTS-SF), Incontinence quality of life (I-QOL), Sandvik questionnaire, and voiding diary. Patients who had urinary tract infection, pelvic organ prolapse, neurogenic bladder and bladder stone were excluded. Finally, 38 patients in the TVT Secur^R group and 38 patients in the Needleless^R group who were followed up for 1 year after operation. Cure was regarded as no leakage on the Sandvik questionnaire.

Results

The mean age was 54.7±8.7 years for Needleless^R group and 52.0±7.6 years for TVT Secur^R group. There were no statistically differences in body mass index, number of parity, Staemy grade of incontinence and urodynamic parameters between two groups. However, menopause status patients were more in Needleless^R group. The average operation time was 7.5±2.2 minutes for Needleless^R group and 6.7±6.5 minutes for TVT Secur^R group. Of 38 women with Needleless^R, 31 patients were cured (81.6%) and of 38 women with TVT Secur^R, 26 patients were cured (68.4%). Pre- and postoperative evaluation of I-QOL, BFLUTS-SF showed statistically improved after operation in both groups.

Interpretation of results

In this study, Needleless^R group were resulted in higher cure rate than TVT Secur^R group although there was no statistical significance in cure rate between two groups. Postoperative patients satisfaction for results was similar between both groups.

Concluding message

Needleless^R and TVT Secur^R procedures were both effective for treatment of stress urinary incontinence. Long-term follow up study including comparative studies with current procedure are required to define efficacy.

Table 1. Patients baseline characteristics

	Needleless (n=38)	TVT secur (n=38)	p-value
Age (yrs)	54.7 ± 8.7	52.0 ± 7.6	0.424
BMI (kg/m ²)	24.7 ± 3.0	24.4 ± 2.9	0.648
Parity (times)	2.2 ± 0.7	2.2 ± 0.9	0.115
Menopause (n, %)	30 (78.9)	21 (55.3)	<0.001
Stamey grade			0.114
Grade I	14 (36.8)	22 (57.9)	
Grade II	18 (47.4)	11 (28.9)	
Grade III	6 (15.8)	5 (13.2)	
Incontinence VAS	5.4 ± 1.6	6.3 ± 2.0	0.315
Urodynamic parameters			
ALPP (cmH ₂ O)	105.2 ± 11.4	104.2 ± 12.6	0.534
MUCP (cmH ₂ O)	89.1 ± 21.0	72.2 ± 25.2	0.110
DO (n,%)	4 (11.1)	7 (18.4)	0.304

Table 2 Comparison of clinical outcomes of patients treated with Needleless and TVT secur

	Needleless (n=38)	TVT secur (n=38)
Cure	31 (81.6)	26 (68.4)
Improved	3 (7.9)	7 (18.4)
Failure	4 (10.5)	5 (13.2)

Table 3. Changes in outcomes measures; uroflowmetry parameters, I-QOL, BFLUTS-SF, and incontinence VAS

	Needleless (n=38)			TVT Secur (n=38)		
	preoperative	postoperative	p-value	preoperative	postoperative	p-value
I-QOL scores						
Total	64.7±28.6	86.1±12.9	< 0.001	72.1±18.9	92.5±17.4	< 0.001
BFLUTS scores						
FS	4.9±2.5	1.8±2.3	< 0.001	5.0±3.2	3.0±2.0	0.007
VS	2.1±2.4	0.9±1.3	0.003	2.9±2.4	2.0±2.2	0.037
IS	6.6±3.7	1.5±2.5	< 0.001	6.7±3.4	2.2±2.4	< 0.001
Sex	0.9±1.3	0.1±0.4	0.001	1.7±2.2	0.3±0.5	0.008
QoL	5.0±4.3	1.2±2.3	< 0.001	6.3±4.1	2.3±2.4	0.001
Uroflowmetry parameters						
Q _{max} (ml/s)	22.6±9.1	20.9±8.5	0.13	31.0±10.0	26.1±11.4	0.006
PVR (ml)	10.1±20.1	14.0±25.0	0.374	9.4±14.6	9.5±12.0	0.983

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Cheil General Hospital Institutional Review Board **Helsinki:** Yes **Informed Consent:** Yes