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EFFICACY OF NEEDLELESS® SLING DEVICES FOR STRESS URINARY INCONTINENCE TREATMENT; PROSPECTIVE, MULTICENTRE STUDY

Hypothesis / aims of study

Numerous options for the surgical treatment of stress urinary incontinence were exist. Currently, minimal invasive surgical treatment using single incision of vaginal wall was introduced and used in the treatment for stress urinary incontinence. Needleless® sling devices for stress urinary incontinence surgery have been introduced in the last few years. We report 12-months outcomes of the Needleless® sling for stress urinary incontinence in women.

Study design, materials and methods

We performed a multicentre (3 centres), prospective, single arm study to evaluate clinical and patient reported outcomes on the use of the Needleless® sling for stress urinary incontinence. Preoperative and postoperative 6 months and 12 months evaluation included a standing stress test, the Sandvik questionnaire, the Incontinence Quality of Life (I-QOL) questionnaire, the Bristol Female Lower Urinary Tract Symptoms-short form (BFLUTS-SF) and Incontinence visual analogue scale. Patients' satisfaction and complications were evaluated. Objective and subjective cures were defined as no leakage on the stress test and responses on the Sandvik questionnaire, respectively.

Results

A total of 128 women with a mean age of 56.1 ± 9.14 years were enrolled in the study. At 12 months, 108 patients were available for analysis. Mean duration of surgery, estimated blood loss and length of hospital stay were 13.8 ± 8.76 minutes, 24.6 ± 18.56 ml and 1.8 ± 1.48 days. At discharge from hospital the mean visual analogue pain scale was 1.6 ± 1.52. The objective and subjective cure rate were 82.4%, 74.1%, respectively. I-QOL questionnaire, BFLUTS-SF and Incontinence visual analogue scale showed a statistically significant improvement compared to preoperation. Adverse events included hematoma (1.8%), temporary urinary retention (1.8%), dyspareunia (0.9%), foreign sensation (0.9%) and de novo urgency (0.9%).

Interpretation of results

Postoperative outcome is significantly improved compared with preoperative status. Cure rate of Needleless® sling operation for stress urinary incontinence was 82.4% objectively. Adverse event of Needleless® sling operation was not significant.

Concluding message

Clinical results of this study suggest that the Needleless® sling could be considered as one of minimally invasive sling material improving quality of life in women with stress urinary incontinence. It demonstrated excellent patient tolerability with minimal pain, early return to normal activity and low morbidity. But, this minimally invasive technique still needs to be studied in larger prospective, randomized, comparative trials.

Table 1. Baseline characteristics

	N=108
Age (yrs)	56 (37-77)
Symptom periods (yrs)	5.7 (0.25-40)
Parity (times)	2.47 (0-5)
BMI (kg/m^2)	24.4 (18.4-35.5)
ALPP (cm/H_2O)	92.77(35-149)
MUCP (cm/H_2O)	60.77(18-137)
MFR (ml/sec)	23.39(5-46)
PVR (ml)	9.56(0-87)

Table 2. Changes in outcome measures after midurethral sling using Needleless®

	pre OP	post Op 12mos	p-value
I-QOL			
Avo/Lim	55.6 ± 27.5	82.7 ± 19.2	<0.001
Psychosocial impacts	58.4 ± 30.5	87.4 ± 17.5	<0.001
Social embarrassment	47.3 ± 30.7	82.9 ± 19.4	<0.001
BFLUTS scores			
Filling sum	5.07 ± 2.93	2.57 ± 2.49	<0.001
Voiding sum	2.16 ± 2.69	1.45 ± 2.07	<0.013
Incontinence sum	6.52 ± 3.99	1.00 ± 2.54	<0.001
Sexual function score	1.17 ± 1.51	0.26 ± 0.61	<0.001
QoL score	6.03 ± 4.30	1.57 ± 2.46	<0.001

Table 3. Success rate of Needleless®

		Objective		
		Complete dry	Incontinence	
Subjective	Complete dry	81	0	75%
	Incontinence	8	19	25%
		82.4%	26.6%	100%

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