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EFFICACY AND SAFETY OF TRANSOBTURATOR ADJUSTABLE TAPE (TOA) FOR THE SURGICAL TREATMENT OF PATIENTS WITH SEVERE STRESS URINARY INCONTINENCE (SUI), OR COMBINED SUI AND VOIDING DYSFUNCTION

Hypothesis / aims of study

Despite of the proven efficacy of the midurethral sling (MUS) procedure for the treatment of female stress urinary incontinence (SUI), there remains concern about postoperative persistent incontinence or obstructive symptoms in women with severe incontinence or voiding dysfunction (VD). A.M.I TOA System (Agency for Medical Innovations, Austria) is invented to readjust the tension of tape postoperatively. We conducted this study to evaluate the efficacy and safety of the MUS using TOA for women with severe SUI, or combined SUI and VD.

Study design, materials and methods

This study was conducted as a prospective and multicenter study. Women with severe SUI (ALPP $\leq$ 60cmH_2O, or Stamey symptom grade III/III), or combined SUI and VD (maximum flow rate (MFR) < 12ml/sec with voided volume $\geq$ 100ml, or postvoid residuals (PVR) > 150ml) underwent MUS using TOA System. At 1 day after surgery, tension might be reduced or increased according to the results of stress test and uroflowmetry (UFM). In case of persistent SUI, the mesh was tightened. On the other side, in case of voiding dysfunction (PVR>100mL or maximaum flow rate<10mL/s), the mesh was released. At 6 months after surgery, changes in the Sandvik questionnaire, ICIQ-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS), Incontinence Impact Questionnaire-7 (IIQ-7), and UFM parameters were evaluated. Patients' satisfaction and complication were also assessed. Cure was defined as 'no leakage' on the Sandvik questionnaire.

Results

Mean age of total 65 patients was 57.3±9.3, mean number of delivery was 2.7±0.9, and mean ALPP (abdominal leak point pressure) was 63.3±28.7cmH_2O. Nineteen patients had voiding difficulty, 35 patients had severe stress incontinence, and 11 patients had both condition. Therefore, 30 (46.1%) women had VD and 46 (70.8%) had severe SUI. Tension adjustment was needed in 27 (41.5%) women (reduction; 14, increase; 13). Complete cure rate of SUI was 84.4% and the satisfaction of the operation was 85.5%. Total ICIQ-FLUTS score except voiding symptom were improved significantly. Also, the score of IIQ-7 and Sandvik were improved significantly. The postoperative maximum flow rate and the amount of post voiding residual in the patient with combined VD and SUI were not significantly changed compared to preoperative results (Table). There was no significant intraoperative complication. One case of persistent voiding dysfunction after operation and a case of wound infection were detected. Tape cut was done in the former case and tape removal was done in the latter case.

Interpretation of results

The fact that 41% of patients with severe SUI patient or combined SUI and voiding dysfunction were required to adjust the tension of the tape means the possibility of high failure rate of the treatment using conventional transobturator tape. And because of the high complete cure rate and a few complication events even in the patients with severe SUI symptoms, midurethral sling using TOA could be a good treatment option for those patients. Furthermore, concerning TOA technique improved the SUI symptoms at the same time it did not aggravate the voiding symptoms and parameters in the combined VD and SUI patients, this technique could be a preferable technique especially for the combined SUI patients with voiding symptoms.

Concluding message

Considering approximately 41% of women with severe SUI or combined SUI with VD needed tension adjustment after MUS procedure, TOA system can be an effective modality for the treatment of SUI in women with risks of postoperative persistent SUI or obstructive symptoms.

Table. Changes in outcome measures between baseline and postoperative 6 months; ICIQ-FLUTS, IIQ-7, Sandvik severity index and uroflowmetry parameters

	Baseline	6 months	p-value
ICIQ-FLUTS			
Combined symptom score	19.3 ± 8.4	8.1 ± 7.6	<0.0001*
Filling sum	6.5 ± 3.0	3.2 ± 2.6	<0.0001*
Voiding sum	3.1 ± 3.4	2.5 ± 3.1	0.2680*
Incontinence sum	9.7 ± 4.6	2.4 ± 3.7	<0.0001*
Sexual function sum	2.0 ± 1.9	0.5 ± 1.1	<0.0001
QoL sum	9.8 ± 4.6	3.0 ± 4.5	<0.0001
IIQ-7	57.9 ± 26.3	14.2 ± 25.5	<0.0001
Sandvik severity index (n=64)			<0.0001
no	0	54	
mild	1	1	

moderate	11	7	
severe	26	1	
very severe	26	1	
Uroflowmetry (n=30)†			
MFR (ml/sec)	14.5 ± 8.2	17.8 ± 10.7	0.4274 *
MFR<12 ml/sec	13 (52.0%)	11 (44%)	1.0000*
PVR (ml)	28.6 ± 41.4	47.8 ± 83.2	1.0000*
PVR > 150 ml	0	3 (12%)	

* Bonferroni correction, † for women with voiding dysfunction

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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)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**Because it is a usual procedure.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**