

## TRANS-OBTURATOR MID-URETHRAL SLING IN FEMALE MIXED URINARY INCONTINENCE

### Hypothesis / aims of study

Mixed urinary incontinence (MUI) is defined as the complaint of involuntary loss of urine associated with urgency as well as with efforts or physical exertion or on sneezing or coughing.

Some authors have suggested that urethral dysfunction has a central role in MUI. The latest and most fascinating theory on the pathogenesis of MUI suggests stress urinary incontinence (SUI) as the origin of the disease: during increased intra-abdominal pressure, in the presence of bladder neck incompetence, urine enters the proximal urethra provoking an involuntary detrusor contraction through an urethro-detrusorial reflex. Following this theory, mid-urethral slings have been proposed in patients with MUI.

Primary objective of this study was to evaluate, at a mean follow-up of 59 months, the subjective and objective outcomes on continence using a trans-obturator mid-urethral sling (TOT) in patients with MUI. Secondary objective was to determine the impact on Quality of Life (QoL) as well as which factors potentially influence the success of the procedure.

### Study design, materials and methods

This is a prospective, single-arm, observational study on female patients with MUI and predominant SUI conducted at a high-volume urogynaecological centre between April 2008 to December 2011. SUI was diagnosed using both the Cough Stress Test and urodynamics. All patients had unsuccessfully undergone pelvic floor training and antimuscarinic therapy. The study was approved by the ethical committee of the institution. All patients provided informed consent to participate in our study. All patients underwent surgical insertion of a trans-obturator mid-urethral sling (Monarc®). Post-operative work-ups were planned for 6 months, 1 year and then annually. The post-operative assessment was carried out by different authors to those who operated. The correction of SUI was evaluated objectively using the standardised Cough Stress Test (CST) and the 1-hour PAD test. The subjective cure rates for both SUI and UUI were evaluated using ICIQ-SF and the Patient Global Impression of Improvement (PGI-I). The King's Health questionnaire was used to evaluate Quality of Life (QoL). For the overall results, we defined patients as 'dry' when they had no urinary leakage and no use of pads; as 'improved' with at least a 50% reduction in use of pads and a declaration of "satisfaction with the results of the operation"; as 'failed' in all other cases.

Statistical analysis: the McNemar chi-square test, the paired t-test for continuous parametric variables, and the Fisher exact test ( $p < 0.05$  statistically significant). A logistic regression model and odds ratios (with 95 percent confidence intervals) were used to assess the independent prognostic value of six variables for the outcome. A  $p$  value of  $< 0.05$ , using the Chi-square test, was considered statistically significant.

### Results

Eighty six consecutive patients with MUI that met all the study criteria were included and evaluated. Mean age was 60 years, mean BMI 27.07, median parity 2; 64 patients were post-menopausal. The mean follow-up was 59 months (36-84 months). We evaluated the results for SUI and UUI separately. We had an objective cure rate for SUI in 83.7% (72 patients) and a subjective cure rate of 81.5% (75 patients). UUI disappeared in 64 patients (74.4%). The overall continence rate (for SUI and UUI together) was 62.3% (57 patients). The analysis of urodynamic data showed a statistically significant increase of Detrusor pressure at maximum flow ( $p = 0.02$ ) and a significant reduction of Maximum flow ( $p = 0.03$ ) (Table 2). No obstruction, according to Blaivas and Groutz nomogram, was observed. Using a univariate analysis, we looked at the performance of 6 variables (age, parity, body mass index, menopausal status, pre-op. detrusor overactivity and pre-op PdetQmax) and we found no significant risk factor for failure (Table 3). The King's Health Questionnaire indicated a statistically significant improvement in QoL in all domains.

### Interpretation of results

In our study transobturator mid-urethral slings correct SUI in 83.7% of the sample, and UUI in 74.4%, with an overall correction of incontinence in 62.3%. According to the univariate analysis, we did not find clinical or urodynamic parameter correlated with the outcome.

Our data seem to confirm the theory that, in some patients, MUI could be mainly due to an urethral rather than to a detrusorial dysfunction. This hypothesis could be confirmed by the lack of pre-operative response to the antimuscarinic drugs in our sample, considering that these drugs act on the detrusorial component of incontinence.

### Concluding message

Our study demonstrates that transobturator mid-urethral slings can be used effectively in patients with MUI with 87.2% of patients satisfied of the results of the operation, as confirmed by PGI-I. More studies are needed to identify pre-operative selection criteria that could be predictive of the outcome of surgical treatment in patients with MUI.

Table 1 – PGI-I values

Very much better	60 patients (69.8%)
Much better	15 patients (17.4%)
A little better	6 patients (6.9%)
No difference	4 patients (6.9%)
A little worse	1 patients (1.2%)
Much worse	0
Very much worse	0
Total	86 patients

Table 2- Pre- and post-operatively urodynamic data

	Pre-op	Post-op	P
Cystometric capacity	mean 398.2 (222-593ml)	mean 370 (237-520ml)	0.22§
Detrusor overactivity	68 patients (79.1%)	63 patients (73.3%)	0.87*
PdetQmax	mean 16.2 (1-46 cmH2O)	mean 25.3 (9-57 cmH2O)	0.02§
Qmax	mean 25.3 (9-57ml/sec)	mean 18.4 (7-28ml/sec)	0.03§
Urodynamic SUI	86 patients (100%)	14 patients (16.3%)	0.0000*

Table 3- Univariate logistic regression

Variables	Cure rate	Failure rate	p value*	Odds ratio
Age (years)			0.114	0.474
36-59	27/57 (47.4%)	10/29 (34.5%)		
>60	30/57 (52.6%)	19/29 (65.5%)		
Parity			0,547	0.730
0-2	18/57 (31.6%)	7/29 (70.6%)		
3	39/57 (68.4%)	22/29 (29.4%)		
Body mass index			0.234	2.100
21-29 kg/m2	40/57 (70.2%)	24/29 (82.8%)		
>30 kg/m2	17/57 (29.8%)	5/29 (17.2%)		
Menopause			0.082	0,347
yes	39/57 (68.4%)	25/29(86.2%)		
not	18/57 (31.6%)	4/29 (13.8%)		
PdetQmax			0.876	0.917
<20 cmH2l	49/57 (85.9%)	21/29 (82.4%)		
>20 cmH2O	8/57 (14.1%)	8/29 (27.6%)		
DO			0.113	0.338
yes	42/57 (73.7%)	26/29 (89.7%)		
not	15/57 (26.3%)	3/29 (10.3%)		

\*Chi-square test

Disclosures

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