

RANDOMIZED CONTROL STUDY OF MONARC® VS. TENSION-FREE VAGINAL TAPE OBTURATOR (TVT-O®) IN THE TREATMENT OF FEMALE URINARY INCONTINENCE IN : COMPARISON OF MEDIUMTERM CURE RATE

Hypothesis / aims of study

Trans-obturator approaches of midurethral sling (MUS) surgery are one of the most commonly performed operation for female stress urinary incontinence in the world. However, the results of randomized clinical trial of trans-obturator MUS surgery (Monarc vs. TVT-O) for the treatment of female urinary incontinence were reported very few. In this study, we compared the 3 years follow-up cure rate of the these two procedures.

Study design, materials and methods

From January 2007 to February 2010, 100 patients who was performed the Monarc (Group A: 50) and TVT-O (Group B: 50) were included in study and analyzed retrospectively. The mean follow-up duration of both groups was 36 months. Pre-operative and post-operative evaluations included physical examination, uroflowmetry and postvoid residual (PVR) measurement, involuntary urine loss with physical activity and urinary symptoms. Patient satisfaction after treatment was rated as very satisfied, satisfied, so-so, and dissatisfied. Very satisfied and satisfied considered as satisfied rate. Cure of female urinary incontinence was defined as the statement of the patient who did not experience any loss of urine upon physical activity.

Results

There were no significant difference in the pre-operative patients' characteristics, post-operative complication and success rate between the two groups. The cure rate of group A and B were 86.0% and 84.0% (Table 1). And patient's satisfaction (very satisfied, satisfied) rate of group A and B were 82.0% and 80.0% (Table 2). In terms of uroflowmetry and post-void residual (PVR), the mean post-operative PVR in group A and B were 23.45ml and 23.98ml. And mean post-operative maximal flow rate (MFR, ml/sec) in group A and B were 22.9ml/sec and 22.1ml/sec (Table 3).

Table 1. Comparison of subjective cure rate between Monarc and TVT-O

	Monarc	TVT-O
No incontinence (%)	43(86)	42(84)
Improved (%)	5(10)	4(8)
Unchanged (%)	2(4)	4(8)
Total	50	50

Table 2. Comparison of uroflowmetry and post-void residual urine between Monarc and TVT-O

	Pre-operation	Post-operation
Monarc		
MFR(ml/sec)	17.7	22.9
Post-voided residual(ml)	17.2	23.5
TVT-O		
MFR(ml/sec)	22.2	22.1
Post-voided residual(ml)	56.0	24.0

Table 3. Patient's Satisfaction between Monarc and TVT-O

	Monarc	TVT-O
Very satisfied (%)	23 (46)	25 (50)
Satisfied (%)	18 (36)	15 (30)
So-so (%)	8 (16)	6 (12)
Unsatisfied (%)	1 (2)	4 (8)
Total	50	50

Interpretation of results

There's no statistically differences in the cure rate, patient's satisfaction between Monarc and TVT-O group. Two methods were effective in the control of female stress urinary incontinence and uroflow and residual urine did not change significantly.

Concluding message

The Monarc and TVT-O were equally efficient treatment of female urinary incontinece, with maintenance of high cure rates for 3 years.

References

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Specify source of funding or grant	No
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?	No
This study did not require ethics committee approval because	Because this study was prepared by the analysis of the patients records
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes