708

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SIX MONTH DATA FROM THE TRANSOBTURATOR HAMMOCK PROCEDURE FOR FEMALE STRESS URINARY INCONTINENCE: A PROSPECTIVE STUDY IN 8 COUNTRIES.

Hypothesis / aims of study

The transobturator approach to sub-urethral sling placement offers unique advantages when compared to other types of SUI (stress urinary incontinence) procedures. This large prospective study confirms intra-operative safety and surgical utility of the transobturator approach and evaluates effectiveness and patient quality of life (QoL).

Study design, materials and methods

Between January and September 2003, 146 patients were implanted with the Monarc™ Subfascial Hammock in a prospective, multi-center study at 15 sites in Europe, Canada, and Australia. Intra-op and post-operative complications were monitored to evaluate safety. Effectiveness was evaluated objectively by cough stress test, and one-hour pad weight test. Subjective effectiveness was evaluated by two patient-completed QoL questionnaires: Urogenital Distress Inventory Short Form (UDI-6) and the Incontinence Impact Questionnaire Short Form (IIQ-7). Patients will be followed for 24 months.

Results

The mean age of the 146 females implanted was 56.8 years, with 9.4 years (mean) of incontinence. An average of 3.4 pads were used per day pre-operatively. Data on 107 patients included pre-operative VLPP levels at a mean value of 68.9 cm/H_20. Mean operative time was 20.4 minutes skin-to-skin with a mean time of 9.0 minutes required for the sling portion only. Mean blood loss was 35.8 mls. Most (97.9%) had no intra-operative complications. Patients were able to void without a catheter within 10.1 hours post-operatively. There were no incidences of vascular, bowel, or bladder perforations.

Pad use per day dropped from a pre-operative mean of 3.4 pads/day to mean values of 0.5 pads/day at 4/6 weeks, 3 month, and 6 month post-operative visits.

The cough stress test showed a significant conversion from positive to negative at all post-operative visits currently evaluated.

Cough Stress Test	Pre-Op		4-6 Weeks		3 Months		6 Months	
Variable	n	%	n	%	n	%	n	%
Negative	8	5.7	118	90.8	101	91	77	91.7
Positive	132	94.3	12	9.2	10	9	7	8.3
Totals	140	100	130	100	111	100	84	100

Post-operative QoL questionnaire responses for both the UDI-6 and IIQ-7 showed significant improvements in quality of life when compared to baseline responses.

QoL Scores	UDI-6*				IIQ-7			
	Pre-Op	4-6 Wks	3 Months	6 Months	Pre-Op	4-6 Wks	3 Months	6 Months
n	147	134	117	85	145	133	117	85
Mean	47.0	12.5	11.6	13.2	53.4	9.9	7.8	8.8
Range	20-100	0-80	0-73	0-67	0-100	0-100	0-100	0-81

*Due to translation difficulties by patients in one country, the visual analog scale question was excluded from the UDI-6 analysis for all patients across all visits.

A total of 42 possible device-related complications were reported in 20/146 patients (13.7%). Specific complications included:

UTI's	9 (6.1%)	Urge symptoms	7 (4.8%)
Increased residual urine	5 (3.4%)	Groin pain	3 (2.1%)
Recurrent incontinence	3 (2.1%)	Urinary retention	3 (2.1%)
Cystitis symptoms	2 (1.4%)	Acute urinary retention	2 (1.4%)
Urge incontinence	2 (1.4%)	Vaginal erosion	2 (1.4%)

Device malfunction, dyspareunia, vaginal discharge, and vaginal infection were each reported in 1/146 patients (0.7%). 11/20 patients reported multiple adverse events; 9/20 patients reported single adverse events.
Surgical revisions occurred in 5/146 patients (3.4%) to release sling tension or remove slings; three due to continued urinary incontinence, one due to retention, and one due to vaginal erosion.

Interpretation of results

Objectively, patients enrolled showed a significant decrease in number of pads used per day as well as pad weights collected during the one-hour pad weight test. Subjectively, patients also reported significant quality of life improvements as noted in responses to UDI-6 and IIQ-7 questionnaires. There were no reports of intra-operative bladder or bowel perforations or vascular injuries.

Concluding message

The Monarc Subfascial Hammock is a safe, effective procedure for sub-urethral sling placement. These early results need to be verified by continued long-term evaluations.

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