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ONE-YEAR COMBINED RESULTS FROM TWO PROSPECTIVE STUDIES ON THE MONARC TRANSOBTURATOR SLING

Hypothesis / aims of study
The transobturator sling has emerged as an alternative treatment for female stress urinary incontinence. We report 1 year follow-up data of two prospective studies at 24 sites in 9 countries in Europe, Australia, and North America assessing the safety and evaluating efficacy of the Monarc™ Subfascial Hammock (American Medical Systems, Inc., Minnetonka, MN, U.S.A.) for female stress urinary incontinence.
Study design, materials and methods
262 female subjects with confirmed SUI were enrolled between January 2003 and May 2004 in two prospective studies with similar protocols, and implanted with the Monarc, a tension-free polypropylene suburethral sling. All sites gained Ethics Committee approval, and all patients signed informed consents. Pre-operative objective evaluation included urodynamic testing (UDT), cough-stress test, and one-hour pad test. Subjective evaluation included quality of life questionnaires (QOL), the UDI-6 and IIQ-7. Procedural data were gathered and concomitant repairs were allowed. The pre-op evaluations (minus UDT) were repeated at 4-8 weeks and 6, 12 and 24 months post-operation. Adverse Events (AE) were reported across all evaluations.
Results
262 patients underwent the Monarc procedure. The average study patient was 56.8 years old (30-88 years) and had experienced SUI for an average of 7.7 years (<1-55 years). Mean operative time for sling placement was 12.4minutes (<5-19 minutes). Mean blood loss was 36 ml (0-490 ml) and mean time to urinate without a catheter was 12.9 hours (0-144 hours). 88.2% of patients went home with out a catheter.

To date, 167 patients have completed 1 year follow-up with an objective cure rate of 91.8% (as defined by a negative Cough Stress Test). Average urine loss on the One-Hour Pad Weight Test decreased from 50.5g pre-op to 8.4g at 1 year. The number of incontinence pads used per day decreased from 2.7pads (0-16pads) to 0.6 pads (0-8pads).

Global Scores for both the UDI-6 and IIQ-7 showed significant improvement at 1 year:

Evaluation	**Pre-op**	**1 Year**	**Wilcoxon's Signed-Rank Test**
UDI-6 (Global Score)	65.3	15.3	p<0.001
IIQ-7 (Global Score)	47.6	8.8	p<0.001

100 patients reported urge symptoms pre-operatively; 48 had urge symptoms resolve following the procedure. De-novo urge symptoms occurred in 34 (12.9%) patients. A McNemar Test of these data show that patients were significantly more likely to be cured of urge symptoms than they were to developing de novo urge (p<0.001).

82 device-related complications were reported in 41(15.6%) patients. The most common device-related adverse events included: 34 (12.9%) de novo urge, 15 (5.7%) UTI/cystitis, 8 (3.1%) increased residual urine, 6 (2.3%) urinary retention, 6 (2.3%) sling extrusion, 5 (1.9%) pain (4 groin, 1 abdominal), 4 (1.5%) vaginal infection and 1 (0.4%) urethral trauma. 13 (5%) patients had surgical revisions: 9 (3.4%) recurrent incontinence, 2 (0.8%) sling extrusion, 1 (0.4%) urinary incontinence/sling extrusion/malposition of the sling, and 1 (0.4%) retention.

Interpretation of results

The transobturator approach is safe and effective for treating stress urinary incontinence. Objective cure rate was 91.8% (negative cough stress test at 12 months post-op) and significant improvement was shown across post-op evaluations. There were no bladder, bowel, or vascular perforations reported. Patients were significantly more likely to be cured of any pre-operative urge symptoms than they were to develop de novo urge.

Concluding message

Results are promising at one-year follow-up. Return to normal voiding was rapid with minimal voiding dysfunction. Long-term follow-up data are necessary; subjects will be followed through 2 years.

FUNDING: American Medical Systems