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2 YEAR FOLLOW-UP DATA ON 147 PATIENTS IMPLANTED WITH THE MONARC TRANSOBTURATOR SLING FOR TREATMENT OF STRESS URINARY INCONTINENCE

Hypothesis / aims of study
Suburethral slings are now a standard treatment for women with stress urinary incontinence (SUI). Over the past several years physician have begun using a transobturator approach to place these slings. We are reporting on 2 year follow-up data from a study on the Monarc Sling.

Study design, materials and methods
Female subjects were enrolled between January 2003 and January 2004 in an ethics committee approved prospective multi-center study in 8 countries. 147 patients were implanted with the Monarc™ Subfascial Hammock (American Medical Systems, Minnetonka, MN), a tension-free sub-urethral polypropylene sling. All had confirmed SUI. 2 Year follow-up objective evaluation included cough-stress test and one-hour pad test; subjective evaluation included two quality of life questionnaires (QOL), the short forms of the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7). Adverse Events (AE) were reported across all evaluations.

Results
Mean age was 56.7 years (31-82 years) and average time with incontinence was 9.4 years (<1-55 years). 147 subjects underwent the Monarc procedure, with an average op time of 9 minutes. Blood loss was minimal (average 37 ml). Average time to urinate without a catheter was 10 hours, and almost all patients (145/146, 99.3%) went home without a catheter.

122 subjects have completed 2-year follow-up with an objective cure rate of 87.6% as defined by a negative cough-stress test. Urine loss during the pad test decreased from 68.7g pre-op to 9.4g at 2 years post-op. Mean pad use/day decreased from 3.4 pads (0-16 pads) pre-op to 0.6 pads (0-8 pads) 2 years post-op. Improvements in global QOL scores were statistically significant ($p<0.001$). 101/122 (82.8%) patients subjectively rated themselves as either completely dry or substantially continent/requiring no protection; physician subjective evaluation of cure was 100/122 (82.0%).

Of the 68/147 (46.3%) patients who reported pre-op urge symptoms, 33/122 (27%) reported no urge symptoms at 2 years. 13/122 (8.9%) subjects developed de novo urge. There were no incidences of vascular, bowel, or bladder perforations and no haematomas reported. There were 53 device related Adverse Events reported in 26 (17.6%) patients: 11 (7.4%) UTI, 8 (5.4%) urgency, 2 (1.4%) de novo urge incontinence, 8 (5.4%) incomplete emptying { 2 instances of acute retention in the same patient (1.4%)}, 7 (3.4%) pain (3 groin, 2 dyspareunia, 1 inguinal, 1 bladder), 4 (2.7%) recurrent incontinence, 3 (2.0%) sling exposure/extrusion, and 1 (0.7%) each of the following: Bladder emptying disorder, cystitis, urethral obstruction, urethral trauma, vaginal discharge, vaginal scar tissue, vaginal infection, and disrupted surgery (patient anatomy did not allow for needle pass) where an alternative ligature carrier was used to place the Monarc sling.

Interpretation of results
The transobturator approach is an effective method for treating stress urinary incontinence. 87.6% of patients in this study had a negative cough stress test at 2 year post-op. At the same time, this approach is safe – of the 147 patients implanted, zero had bladder, bowel, or vascular perforations. Significant improvement was shown across all pre- versus post-op measurements.

Concluding message
Both objective and subjective data demonstrate that the Monarc transobturator approach is a safe and effective method for treatment of SUI.

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HUMAN SUBJECTS: This study was approved by the Each site had their own EC approval. Prof. De Ridder's was Faculteit Geneeskunde, Commissie Voor Medische Ethiek/Klinisch Onderzoek and followed the Declaration of Helsinki Informed consent was obtained from the patients.