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PRELIMINARY PROCEDURAL AND SAFETY DATA FROM THE UNITED STATES CLINICAL STUDY ON THE AMS MONARC™ SUBFASCIAL HAMMOCK

Hypothesis / aims of study

In recent years, sub-urethral sling placement has become a standard treatment for Stress Urinary Incontinence (SUI). A United States clinical trial was launched in July 2003. The goals of the study were to show reduced morbidity in vascular/bladder/bowel injuries that are related to the retropubic approach, examine the neurological effects of passing the Monarc needles through the obturator foramen, and determine subjective and objective efficacy of the Monarc Subfascial Hammock.

Study design, materials and methods

Pre-operative urodynamics, and pre and post-op Q-Tip Test, Cough Stress Test, One-hour pad test, 3-day voiding diaries, Quality of Life Questionnaires and a Motor, Sensory and Pelvic Exam were performed. Physicians and subjects assessed degree of continence attained post-operatively. Intra-operative data included concomitant repairs, operative time, blood loss, cystoscopy results, time to void without catheter and complications. Subjects will be followed at 4-6 Weeks, 6 Months and 12 Months.

During the Motor, Sensory and Pelvic Exam, the physician performed a general pelvic examination, noting any abnormalities or prolapse conditions. For the sensory portion, a bilateral light touch and pinprick exam was done of the mons, labia, perianal area, and medial thigh. The patient was asked to assess pain and tenderness using the visual analogue scale (0=No Pain, 10=Worst Possible Pain) with palpation of the adductor muscle/proximal tendon, passive abduction, resistance adduction, passive external rotation of the hip, resistance internal rotation of the hip, and assessment of gait.

Results

Between July 2003 and March 2004, 47 patients were implanted with the Monarc hammock. Mean operative time was calculated for three circumstances:

Circumstance	Number of Patients	Mean Op time (minutes)	Range (minutes)
Monarc procedure only	37	14.7	5-30
Monarc procedure + concomitant repairs	5	31.4	12-70
Patients Implanted at teaching hospital (residents participating in procedure)	5	36	23-39

Average blood loss was 32.8 ml (2-150ml). Intraoperative cystoscopy was performed on 46 patients (98%) and no bladder perforations were reported. Mean time to void without catheter was 10.8 hours (0-32 Hr) and 43 patients (91.5%) went home without a catheter.

39 patients completed 4-6 week follow-up visits. Both physician and patient assessments of the level of continence attained reported 33 (85%) patients being substantially or totally continent.

There were 7 adverse events (AEs) reported in 3 patients (6.4% of total patients). Two of the AEs were device-related: One patient reported musculoskeletal pain, which is ongoing and is being treated with medication. One patient reported urinary retention; the patient was catheterized and the event resolved in two days. The same patient also reported dehydration, increased chronic cough, post-op abdominal pain (all of which have resolved). The physician feels that these AEs were due to the concomitant repairs performed during Monarc placement surgery and are not device related. Two patients reported two additional

non-device related events: atrial fibrillation (treated with medication, resolved) and bacterial vaginosis (treated with antibiotics, ongoing).
1/47 patients (2.1%) failed the procedure; the sling was removed, and another procedure was performed.

The Motor, Sensory, and Pelvic Exam Results

Exercise	**Pre-Operative (n=47)**				**4-8 Weeks (n=35)**			
	Left	Left	Right	Right	Left	Left	Right	Right
Average Pain/Tenderness Average Range of Motion	Pain or Tenderness	ROM (degrees)	Pain or Tenderness	ROM (degrees)	Pain or Tenderness	ROM (degrees)	Pain or Tenderness	ROM (degrees)
Palpation of adductor muscle + proximal tendon	0	N/A	0	N/A	0	N/A	0	N/A
Passive abduction	0.2	45.1°	0.0	44.7°	0	44.5°	0.1	45.1°
Resistance adduction	0	N/A	0	N/A	0	N/A	0.1	N/A
Passive external rotation of hip	0.1	43.3°	0.0	43.6°	0	44.2°	0	44.2°
Resistance internal rotation of hip	0.8	N/A	0.0	N/A	0	N/A	0	N/A
Assessment of Gait	0.2	N/A	0	N/A	0	N/A	0	N/A

ROM=Range of Motion

Interpretation of results

There were no vascular, bladder or bowel injuries reported, and no intra-operative complications. Blood loss was minimal and most patients went home without a catheter. It appears that neurological function and range of motion is not affected by passing needles through the obturator foramen. By mimicking the natural position of the pubourethral ligament, we believe we reduce the post-operative risk of urinary retention.

Concluding message

By avoiding the vessels and nerves of the retropubic space, the Monarc offers a relatively quick procedure that proves to be safe and effective. These initial results show that the transobturator approach may be safer than the traditional retropubic approach to the tension free mid-urethral sling. Further follow-up is needed.

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