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A META-ANALYSIS OF THE INTRA-OPERATIVE SAFETY AND EFFECTIVENESS OF THE TRANSOBTURATOR HAMMOCK SEEN IN RESULTS OF TWO PROSPECTIVE STUDIES IN 9 COUNTRIES WITH 204 PATIENTS

Hypothesis / aims of study

For years, women with urinary incontinence have had the treatment option of a minimally invasive procedure that placed tension-free vaginal tape sub-urethrally with a relatively high degree of success. However, while rare, bladder and bowel perforations, as well as vascular injuries are possibilities with this treatment modality due to the blind passage of needles through the retropubic space. To address this concern, a new surgical approach which passes the needles through the trans-obturator foramen while still placing polypropylene mesh sub-urethrally has been introduced.

We are reporting on a meta-analysis of a combined sample of 204 women in 9 countries in Europe, Australia, and North America who participated in two studies on the efficacy and safety of the Monarc Subfascial Hammock Sling System (American Medical Systems).

Study design, materials and methods

Common data points between two studies with similar protocols were analyzed. Improvement rates were measured pre- and post-op by: physician and patient report, quality of life measures (IIQ-7 and the UDI-6), pad use per day, cough stress test, and finally, one-hour pad weight test. The follow-up range in the smaller study (taking place in the U.S. only) is 4-8 weeks, 6 months, and 12 months. The follow-up range in the larger study (the remaining 8 countries) is 4-6 weeks, 3 months, 6 months, 12 months and 24 months.

204 women (mean age of 56.5 years) enrolled in the study between January 2003 and March 2004; operative data was gathered on 193 of these participants. Most had some form of stress incontinence: 145/204 (71.1%) had stress and 54/204 (26.5%) had mixed incontinence. Of the remaining participants, 2/204 (1.0%) had urge incontinence and 3 (1.5%) were unreported. Incontinence was present for an average of 8.4 years, and pad use was reported as 3.0 pads/day (mean).

Pre-operative diagnostics tests consisted of the cough stress test and the one-hour pad weight test. Of the 200 women who took the cough stress test, 181 (90.5%) tested positive. Among the 191 women who consented to the one-hour pad weight test, the average pad weight gain was 57.2g.

Results

The mean operative time for sling placement only was 10.6 minutes. Blood loss was minimal (mean of 35ml), and the time to urinate without a catheter was 10.3 hours. The majority of patients, 180/193 or 93.3% (with 8/193 or 4.1% unreported) went home without a catheter.

Positive results on the cough stress test dropped from 181/200 (90.5%) pre-op to 7/77 (8.2%) at 6 months. Pad use per day dropped from 8.4 pads/day pre-operatively to 0.5 pads/day at the 4-8 week and 6 month follow-up. Physician and patient assessment of continence, defined as completely dry or substantially continent, was 90.6% and 89.6% respectively at 4-8 weeks, and 85.7% and 82.5% respectively at 6 months.

44 complications that could possibly have been related to the device were reported in 22 patients (22/193, or 11.4% of patients).

Specific complications included:

UTI's	9 (4.7%)	Urge symptoms	7 (3.6%)
Increased residual urine	5 (2.6%)	Urinary retention	4 (2.1%)
Recurrent incontinence	3 (1.6%)	Groin pain	3 (1.6%)
Cystitis symptoms	2 (1.0%)	Acute urinary retention	2 (1.0%)
Urge incontinence	2 (1.0%)	Vaginal erosion	2 (1.0%)

Device malfunction, dyspareunia, vaginal discharge, vaginal infection, and musculoskeletal pain were each reported in 1/193 patients (0.5%).

6/193 patients (3.1%) had surgical revisions to release sling tension, remove slings, or replace the sling; four due to continual urinary incontinence, one due to retention, and one due to vaginal erosion.

Interpretation of results

The transobturator approach was designed to address concerns of intra-operative injuries which have been reported with sling treatments passed through the retropubic space. Of the 193 patients for whom we have intra-operative data, zero had bladder, bowel, or vascular perforations. Both objective and subjective criteria points gathered post-operatively showed improvement; these included pad use per day, cough stress test, one-hour pad weight test, and physician and patient assessment.

Concluding message

This important meta-analysis combines data from Australia, Belgium, Canada, France, Germany, Italy, Spain, the United Kingdom, and the United States and represents the largest prospective study to date on the transobturator procedure. The Monarc Subfascial Hammock appears to be a safe, effective procedure for sub-urethral sling placement.

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