Transobturator Sling: Combined Analysis of 1 Year Follow-Up in 9 Countries with 266 Patients

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Summary. Monarc's outside-to-in transobturator approach avoids the retropubic space and may reduce the risk of injury to bladder, bowel and other major vessels.[1,2,3]. Its proprietary needles are designed to move away from the obturator canal.

Method. 272 women with SUI were enrolled in two prospective single-arm studies and data were collected at baseline and follow-up visits at 4-8 weeks, 6, 12, 18 and 24 months.

Results. To date, 169 patients have completed their one-year follow-up. Objective cure rate at one year was 91.8% (negative cough stress test).

Introduction

Many treatments of female stress urinary incontinence (SUI) have been developed over the years, with varying degrees of success. A recent approach, the transobturator placement of slings, has been steadily gaining a following as a safe, effective, and quick treatment of SUI.

The trocars pass through the obturator foramina; avoiding the retropubic space completely and limiting the blind passage of the needles to a couple of cm. The efficacy and expediency of this approach has been shown in various published articles and abstracts. [1,2,3]

The data presented here is the combined data from two prospective studies on a commercially available transobturator sling, the Monarc Transobturator Sling (AMS, Minnetonka, MN, USA). A total of 266 patients in 9 countries were treated under similar protocols and were followed out to one-year.

Method

272 women (56.8 years, SD = 11.7) with SUI for an average of 7.7 years (SD = 8.6) were enrolled in two prospective, single-arm studies with similar protocols. Data was collected at baseline and follow-up visits at 4-8 weeks, 6, 12, 18, and 24 months post-op. Concomitant repairs were allowed. IRB/ethics committee approval was obtained, and all patients completed the informed consent process prior to enrollment. QoL measures (IIQ-7 and UDI-6), pad usage, physician and patient report, cough stress test, the one-hour pad weight test, and the presence or absence of urge symptoms were collected at each visit.

Procedure

The physician empties the bladder and makes a 1.5 cm midurethral vaginal incision (see Figure 1).

The vaginal epithelium is dissected. A fingertip is inserted in the incision site, while one palpates the medial edge of ischiopubic ramus with the contralateral hand (see Figure 2).

At the level of the clitoris and below the insertion of the adductor longus tendon, a small stab incision is made. This is the insertion point for the Monarc needle tip. The needle is passed through the obturator foramen and rotated around the descending ischiopubic ramus (see Figure 3). The needle

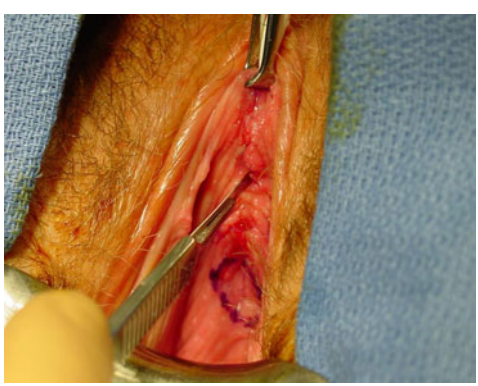

Fig. 1

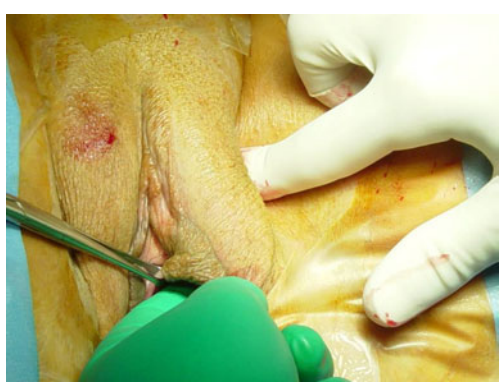

Fig. 2

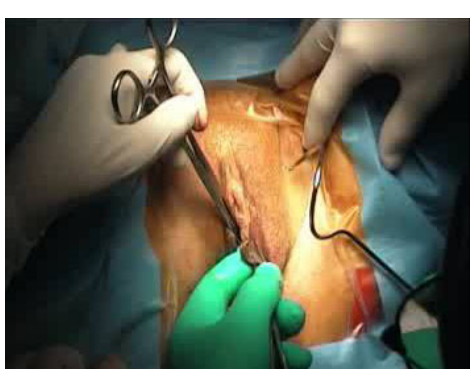

Fig. 3

tip is received with the contralateral fingertip of the surgeon and remains on the fingertip until its exit out of the midurethra incision.

The mesh is connected to the needle and retracted. All steps are repeated on the patient's contralateral side. The mesh tension is set. At last, the mesh is cut at subcutaneous level and skin and vaginal incisions are closed.

Results

Operative data was gathered on 262 of these participants, and to date, 169 have completed their one-year follow-up.

The mean operative time for sling placement only was 12.4 minutes. Blood loss was minimal (mean of 36 ml) and mean time to urinate without a catheter was 12.9 hours. Objective cure rate at one year was 91.8% (negative cough stress test).

At the 12 month follow-up, pad use dropped to 0.6 pads/day, compared to 2.7 pads/day pre-operatively. Average urine loss on the One-Hour Pad Weight Test decreased from 50.5g pre-op to 8.4g at 1 year ($p < 0.001$).

Physician and patient assessment of continence at follow-up, defined as completely dry or substantially continent, was 86.1% and 81.6%, respectively. Patients' quality of life was also significantly improved, with the UDI-6 dropping from an average of 65.3 pre-operatively to 15.3 at follow-up, and the IIQ-7 dropping from an average of 47.6 pre-operatively to 8.8 at follow-up.

Urge symptoms resolved in 27.5% of patients following the procedure. De-novo urge symptoms occurred in 10.6% of patients (17/161).

82 complications that could possibly have been related to the device were reported in 41 patients (41/262, or 15.6% of patients). Specific device-related complications are listed in Table 1.

13/262 patients (5.0%) had surgical revisions: 9/262 (3.4%) due to recurrent urinary incontinence alone, 2/262 (0.8%) due to sling extrusion alone, 1/262 (0.4%) due to a combination of recurrent urinary incontinence, sling extrusion, and malposition of the sling, and 1/262 (0.4%) due to a combination of the sling being too tight and retention.

Table 1.

Complication	# (% of pts)
UTIs/Cystitis	15 (5.7%)
Urge Symptoms	14 (5.3%)
Recurrent Incontinence	9 (3.4%)
Elevated PVR	8 (3.1%)
Erosion/Extrusion	6 (2.3%)
Pain (Groin)	4 (1.5%)
Urge Incontinence	4 (1.5%)
Vaginal Infection	4 (1.5%)
Retention	3 (2.3%)
Pain (Abdominal)	2 (0.8%)

Conclusions

The transobturator approach is a safe and effective method for treating stress urinary incontinence, with a 91.8% objective cure rate in this study (negative cough test at 12 months post-op). There were no major complications reported including no bladder, bowel, or vascular perforations.

Patients were significantly more likely to be cured of any pre-operative urge symptoms than they were to develop de-novo urge symptoms.

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