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SHORT-TERM EXPERIENCE WITH USE OF TRANSOBTURATOR (MONARC®) SUBURETHRAL SLING.

Hypothesis / aims of study

The treatment of urinary stress incontinence (USI) has been deeply transformed by the introduction in 1996 of the Tensionfree Vaginal Tape (TVT), which involves the placement of a synthetic polypropylene tape under the mid urethra. However, serious complications such as bowel and major vessel injury have been described and are caused by the passage of the trocars in the retropubic area. Recently, a new way of insertion of suburethral slings through the obturator foramen has been described with a supposedly reduced risk of serious complications and a similar efficacy to treat USI. The aim of this study was to prospectively evaluate the impact of the Monarc® (American Medical Systems) transobturator tape, which is inserted from outside-in through the obturator foramen with a specifically designed device.

Study design, materials and methods

This is a prospective multicentric study including 182 patients who underwent a Monarc procedure in 8 different hospitals between February 2003 and November 2004. 138 patients had urodynamically proven stress incontinence, including 21 with low closure pressure urethra, 14 had mixed incontinence and 1 patient had voiding difficulty. 100 patients had a Monarc insertion without any associated procedure. Patients' satisfaction was assessed with a visual analogic scale (VAS) at 6 weeks and 6 months after surgery. The question asked to the patients was: In a scale from 0 to 100, 0 being the worst and 100 the best, how satisfied are you by the operation? Objective assessment of the quality of life was obtained with the Incontinence Impact Questionnaire—short form (IIQ-7) and the Urogenital Distress Inventory—short form (UDI-6) before the operation and 6 months after. Sexual function was assessed with the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, short form (PISQ-12) before and 6 months after the operation. Objective evaluation of the urine losses was performed with a 24 hours pad test before and 6 months after the operation.

Results

Among the 100 patients who underwent a Monarc procedure only, the operative time was 19.7 +/- 6.0 min. 69 patients had a general anesthesia, 13 had a spinal and 13 had a local analgesia and sedation. Hospital stay was 24.2 +/- 16.5 hours. 78% of patients had no postoperative catheter. Mean catheterisation time was 10.9 +/- 5.5 hours. All patients had a control cystoscopy and no bladder or urethral perforation was diagnosed. 3 patients had a vaginal perforation that was recognised and repaired during the operation. 2 patients had a significant (> 500 ml) haemorrhage that did not require transfusion. Postoperatively, 1 patient developed new onset voiding difficulty needing loosening of the tape on day 4 and one patient needed division of tape at 6 months. 1 patient complained of persisting leg pain and 1 patient developed significant bruising of the inner thigh.

At 6 weeks, the mean VAS score was 84.9 ± -25.6 and did not change significantly to 80.1 ± -32.4 at 6 months (p>0.5). Pre operative IIQ-7 score was 8.9 ± -5.5 and improved significantly to 2.1 ± -4.5 at 6 months (p<0.0001). Similarly, the UDI-6 score improved from 8.2 ± -3.8 to 3.0 ± -3.6 (p=0.0001). Sexual function was unchanged from 17.6 ± -5.9 to 15.1 ± -3.3 (p=0.08). The 24 hours pad test showed an improvement, although not significant (p>0.5), from 52.4 ± -7.8 (Median: 26) to $28.2 \pm -6.1.5$ (Median: 0).

Interpretation of results

The Monarc® procedure is a safe procedure and can be performed alone or in association with other pelvic floor operations. When performed alone, it is a short procedure that can be performed under general, spinal or local analgesia. Postoperative catheterisation can generally be avoided unless the procedure is performed under spinal analgesia. Hospital stay is short and the complication rate is low. Satisfaction rate is high and maintained at 6 months follow up. Quality of life is significantly improved as measured by two validated questionnaires. Sexual function is not affected by this procedure.

Concluding message

Monarc® is a safe and efficient procedure. Prospective randomised trials comparing the Monarc® to the TVT are warranted before this procedure becomes a new gold standard in the treatment of USI.