

TRANS-OBTURATOR TAPE (T.O.T.®) FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE : A MULTICENTRIC PROSPECTIVE STUDY**Hypothesis / aims of study**

The aim of this tracker study was to confirm with a large number of patients that T.O.T.® is a simple and safe mini-invasive treatment for female stress urinary incontinence.

Study design, materials and methods

441 consecutive patients with Stress Urinary Incontinence (SUI) were recruited by 9 centres from November 2001 to January 2004. All these patients underwent the T.O.T.® procedure (Uratape® or Obtape®, non-elastic polypropylene tapes) previously described by E.Delorme (1). 233 patients had Uratape®, and 208 Obtape®. Inclusion criteria were: SUI, urethral hypermobility with or without previous surgery, and with or without associated prolapse. The pre-operative evaluation included: history, physical examination, urodynamic testing and residual. Post-operatively, physical examination, uroflowmetry and residual were evaluated. Peri and post operative complications were also recorded on the case report form.

Mean age was 58 years (29-88), and mean parity 2.3 (0-8). 273/441 (61.9%) patients were post-menopause. 115/441 (26%) patients had a prior hysterectomy, and 55/442 (12.5%) were previously operated for genital prolapse. 69/441 (15.6%) had recurrent stress incontinence, 64 had been operated once and 5 patients twice before T.O.T.® as described in Table 1.

Table 1

	N=74
Burch	35
Marshall-Marchetti	2
TVT	24
Stamey, Pereyra	6
Uratape	2
Other	5

T.O.T.® was combined with genital prolapse repair in 66 cases (14.9%). 267 patients were operated under general, 131 under spinal and 43 under local anaesthesia. Cure was defined as the absence of subjective complaint of urine leakage, and the absence of leakage on cough stress test.

215/441 (48.7%) patients had pure stress urinary incontinence, 78/441 (17.7%) reported also symptoms of urgency, and 133/441 (30.2%) had mixed incontinence. 20/441 (4.5%) patients had urethral closure pressure <20 cm of water. Among the 441 patients, 292 patients had at least 3 months follow-up.

Peri-operative outcome will be described on the total (441) population and efficacy in the 292 patients with at least 3 months follow-up.

Results

Peri-operative complications occurred in 13/441 cases (2.9%). 2 bladder perforations, 4 urethral perforations and lateral vaginal perforations occurred. It is important to point out that no vascular, nerve or bowel complication occurred in this important series. The post-operative retention rate was 9/441 (2%) treated in 3 cases by surgical release of the tape, by dilatation in 2 cases and intermittent self-catheterisation in 4 cases (lasting for 1 week to 3 months). 12/441 complained about transient pain (2.7%). In 4/12 cases it was related to the position during surgery, (lumbago, and sciatica) and in 8/12 cases it was due to the surgery. The mean follow up for the sub-group of 292 patients was 12 months (3 - 29). 244/292 (83.6%) were completely dry, 27/292 (9.2%) were improved and 21/292 (7.2%) were considered as failure.

Among the 155 patients suffering from urgency (64/292) or urge incontinence (91/292), the urgency disappeared in 77 (49.6%) patients, improved in 41 (26.5%), and remained identical

in 30 (19.4%) and got worse for 7 patients (4.5%). 2/137 patients (8.7%) complained from *de novo* urgency.

Median vaginal extrusion of the tape occurred in 13 cases with Uratape® and in 1 case with Obtape®.

We observed also 3 lateral exposures of the polypropylene 1 to 3 months after anti-incontinence surgery. These cases were due to a lateral perforation of the sulcus during surgery due a too superficial positioning of the tape.

Interpretation of results

The rate of vaginal extrusion observed with Uratape® (5.6%) is certainly due to the silicon part under the urethra. With Obtape® (100% polypropylene) this rate (1.9%) decreased dramatically, and is in some cases related to a perforation of the sulcus of the vagina. Nevertheless, this rate is comparable to what has been already published with other polypropylene tapes. (2)

Concluding message

This tracker study shows encouraging results for in SUI in terms of peri-operative complications, effectiveness and post-operative retention. These results have to be confirmed with furthermore evaluations.

References

1. E Delorme et al. Transobturator urethral suspension: a minimally invasive procedure to treat female stress urinary incontinence. *Prog Urol* 2001;11:1306-13. *Article in french*
2. J Wang et al. Tissue reaction of suburethral vaginal wall to polypropylene (prolene) tape after continence taping procedures: a case control pilot study. *Intern.Gynecol Journal* October 28-31,2003