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TRANSOBTURATOR TAPE (T.O.T.) FOR SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE: EFFICACY AND COMPLICATIONS

Hypothesis / aims of study

The purpose of this study was to assess the efficacy and the complications of surgical procedure with urethral support with transobturator tape (TOT) in a population of 160 incontinent patients suffering from stress urinary incontinence (SUI) with urethral hypermobility.

Study design, materials and methods

From June 2002 to June 2005, 160 consecutive patients with proven stress urinary incontinence underwent the TOT procedure. Mean age of women was 60 ± 10 (range 39-83). In all subjects, we used a non-elastic, non-woven, non-knitted, thermally bonded polypropylene mesh.

From June 2002 to January 2004 we inserted a tape with a 15 mm central silicone coated section (Uratape) and from February 2004 onwards we inserted a kind of tape with the same peculiarity but without the silicone coated midportion (Obtape). The tape was inserted without tension in a horizontal plane under the mid-urethra between the two obturator foramina.

All patients were assessed before and after surgery by clinical urogynecological evaluation, urodynamic examination and by rating the perceived quality of life through a Visual Analog Scale (VAS 1-10). Preexisting obstruction and hypocontractile detrusor were considered as exclusion criteria. Urinary tract infection was excluded in all subjects before any clinical evaluation. Patients were informed about the risks and carefully monitored for obstruction symptoms after surgery. In cases where impaired bladder emptying or severe irritative symptoms occurred, conservative management was used. This management includes alpha-lytic therapy, self-catheterization, continuous bladder drainage, and anticholinergic therapy.

The mean postoperative follow-up was 24 months (range 6-31 months). Patients were considered successfully cured when absence of subjective complaint of urine leakage was remarked, when wearing protection was no longer necessary, when the cough stress test performed with a full bladder showed no urine loss. Patients were considered improved when they reported a decrease of stress urinary incontinence episodes, when they judged that their condition improved and used less protection. The remaining cases were considered failures.

<u>Results</u>

All patients returned for postoperative evaluation. One-hundred thirty-two out of 160 (82.5%) were completely cured, 26 out of 160 improved (16.3%) and 2 out of 160 (1.2%) remained unchanged. No intra-operative complications, specifically bleeding, bladder, nerve, bowel and vascular injuries, were recorded; neither tape-related urethral erosion nor residual pain occurred after the operation. Twenty-two patients experienced urine retention which resolved within one week after catheter removal and alpha-lytic therapy. Ten patients underwent a second surgery: 2 for tape resection to treat obstruction, and 8 for complete tape removal to treat vaginal erosion. Seven patients (4.4%) developed "de novo" overactive bladder symptoms.

Interpretation of results

Among the 160 women who underwent to sub-urethral sling procedure for urinary stress incontinence using transobturator approach there were no intraoperative or perioperative complications. The effectiveness we had with TOT is similar to that described by other authors using TVT [1]. However, we did not observe the knew TVT-related complications (bladder, nerve or vascular injury), nor severe bleeding.

Tape resection has been necessary in two subjects. These two events were probably caused by incorrect tape adjustment and occurred during the early learning period when we adjusted the tape tension by intra-surgery stress test. At present, we perform tape adjustment leaving an adequate space between the tape and the midurethra to prevent obstruction without stress test.

We observed approximately a 5% rate of vaginal erosion (8 cases). This percentage is one of the lowest rates reported in literature [2]. The different knitting and pore size of polypropylene meshes seems to have a relation with vaginal erosion. Apparently woven or knitted polypropylene mesh with larger pores cause less erosion than nonwoven, nonknitted mesh. All erosions, except one, occurred in patients treated with Uratape procedure. We could speculate that the central suburethral silicone coated section can be a predisposing factor of bacterial colonization that, in turn, could lead to the erosion. All tapes were removed vaginally as thoroughly as possible. Unexpectedly all patients remained continent after tape removal, probably because of a periurethral fibrosis process.

We found interesting the significant correlation between vaginal erosion and the precocious onset (and the presumably increased frequency) of sexual activity after surgery.

Concluding message

The present study confirms the results obtained by the instigator of the technique, E. Delorme, and allows us to consider TOT as an effective and safe technique for the treatment of female stress urinary incontinence.

The transobturator approach does not involve risks of bladder, bowel, vascular or nervous injuries and intraoperative cystoscopy is not necessary. Therefore this surgical procedure is time-saving.

References

- 1. Obstet Gynecol 2004 Dec; 104(6): 1259-62.
- 2. J Urol 2005 May; 173(5): 1637-30.
- 3. European Urology 2004; 45(2): 203-7.

DISCLOSURES: NONE CLINICAL TRIAL REGISTRATION: trials registry.

This clinical trial has not yet been registered in a public clinical

HUMAN SUBJECTS: This study did not need ethical approval because it is an observational study and did not follow the Declaration of Helsinki - with approval by the ethics committee - in the sense that it is an observational study Informed consent was not obtained from the patients.