Original article

Efficacy and safety of transobturator polypropylene hernia mesh (TOT) for female urinary stress incontinence: mean and large follow-up (7 years)

LEONEL BRIOZZO, FERNANDA NOZAR, VERÓNICA FIOL, SOLEDAD BOTTARO, FERNANDA GÓMEZ

Department of Obstetrics and Gynecology, University of Uruguay, School of Medicine, Montevideo, Uruguay

Abstract: *Objectives:* to evaluate the efficacy and safety of transobturator tape in the treatment of female stress urinary incontinence (SUI). To assess the level of satisfaction with the technique. *Methods:* prospective study. Population: 60 patients who underwent TOT procedure from February 2002 to October 2004. Patients were assessed in five temporary sections, up to February 2011. Inclusion criteria: incontinence as a subjective symptom, stress incontinence on physical examination and urodynamic test that confirmed it. Technique: recyclable needles and simple polypropylene mesh instead of commercials kits. *Results:* no vascular, nervous, neither digestive injury was registered. One case of bladder injury. Primary outcomes: 56,7% of the patients are asymptomatic, 25% better and 18,3% do not refer changes. 71,7% are very satisfied, 13,3% mild satisfied and 13,3% unsatisfied. *Conclusions*: the results confirm the effectiveness of TOT in treating female SUI with a low complication rate. The effectiveness of the technique decreases with time.

Key words: Female urinary stress incontinence; TOT.

INTRODUCTION

In 1994 DeLancey proposed the "hammock hypothesis", which states that "increases in urethral closure pressure during a cough probably arise because the urethra is compressed against a hammock-like supporting layer".[1,2,3]

Since Petros and Ulmsten`s concept (1996), minimal invasive surgery using a mid-urethral support without tension (tension free vaginal tape-TVT-technique) has been widespread.[4] TVT has been shown to be effective with a cure rate of incontinence of more than 80%, thus eventually becoming the reference standard technique. The most frequent TVT complications are a consequence of penetrating retropubic space. Therefore, the transobturator tape (TOT) technique has been developed as an alternative to the TVT. Both procedures were designed to reproduce the natural suspension of urethral fascia using a polypropylene mesh. TOT was first described by Delorme in 2001, and consists in placing a tape between the two obturator foramen, thus creating a hammock that should support the urethra, as in the TVT technique.[5,6,7]

Stress incontinence is a condition that can be objectively diagnosed by urodynamic examination, but it is also a subjective symptom. Therefore, the cure has to be defined as absence of subjective complaint of urine leakage.

This prospective study shows the results with a minimum 3-year follow-up on efficacy and safety of TOT.

OBJECTIVES

To evaluate the efficacy and safety of transobturator polypropylene hernia mesh in the treatment of female stress urinary incontinence. To assess the level of satisfaction with the technique.

PATIENTS AND METHODS

From February 2002 to October 2004, 60 patients with stress incontinence from different centers in Montevideo, Uruguay, underwent a TOT with a polypropylene mesh and participated in a prospective study. The inclusion criteria were incontinence as a subjective symptom and visible stress incontinence after physical examination. Before surgery all patients had undergone an urodynamic study that confirmed stress incontinence. The excluded criteria were urinary infection, and severe detrusor instability (no inhibited detrusor contractions major to 40 cm H_2O). Characteristics of patients are presented in Table 1. All surgeries were performed by the same surgeons who had training on TOT and the TOT technique was the same in all cases. All different surgeries performed are presented in Table 2.

The TOT technique consisted in:

– 1.5 mm. anterior vaginal incision, 1 cm below the urethral meathus.

– Paraurethral dissection toward ischiopubic ramus.

– Bilateral genitofemoral incision on a horizontal line that passes through the clitoral hood.

– Passage of the needle from the genitofemoral incision towards the obturator foramen, oriented to the paraurethral space.

– Polypropylene mesh is manual prepared and fixed to the needle. The needle is directed towards the genitofemoral incision.

– Insertion of a Foley catheter and instillation of 300 cc of physiological saline solution. If maximum vesical capacity is over 400 cc, this volume should be instilled.

– The patient is requested to perform the Valsalva maneuver and the tension free tape is adjusted under the mid-urethra.

TABLE 1. – Patients characteristics (N = 60).

Age (yr)	57.9 (27-88)
Parity	2.6 (range:0-9)
Menopausal	38 (63,3%)
Previous incontinence surgery (Kelly-Marion, Burch)	8 (13,3%)
Previous hysterectomy	3 (5%)
Previous prolapse surgery	1 (1,7%)
Cystocele (I or II stage)	56 (93,3%)
Pure stress incontinence	55 (92%)
Mixed	5 (8%)
Urethral hypermobility	52 (86,7%)

TABLE 2. – Concurrent surgery.

TOT only	24
Vaginal hysterectomy	2
Abdominal hysterectomy	3
Vaginal hysterectomy, anterior and posterior colporrhaphy	15
Posterior colporrhaphy	11
Sacro spinous suspensions	11

– Vaginal closure performed with a slow absorption thread running suture.

Removal of Foley catheter after effect of regional anesthesia.

Perioperative hazards (including hemorrhage and bladder or urethral perforation) and postoperative hazards (including urinary retention, urgency, pain and other adverse effects) were evaluated.

The patients were assessed in five temporary sections: October 2005, October 2006, October 2007, October 2008 and February 2011. The evaluation was done by a professional who didn´t participate in the surgery, and was by an adaptation of the Incontinence Impact Questionnaire-short form IIQ-7[8] that was done by telephonic questionnaire. Cure was defined as the absence of subjective complaint of urine leakage and absence of leakage on cough stress testing. Improvement was defined as patients reporting a decrease in stress incontinence. Failure was defined as unchanged or aggravated symptoms.

RESULTS

All patients were evaluated at the end with a minimum 6 year follow-up (range of 6 to 9 years). Neither vascular complications nor nervous or digestive complications appeared during the procedure. One case of bladder rupture was registered, taking into consideration that this patient had a grade 3 anterior cystocele repaired.

Concerning postoperative complications, only one case of urinary retention was registered. In this case, the Foley catheter was kept in place during 3 days and myotonic drugs were prescribed, with good response to treatment. 7% of cases presented urinary urgency postoperatively, which cleared up over time.

Some patients experienced postoperative pain at the passage of the mesh which was treated with analgesics. In one case obturator pain appeared when exercising after 3 years of surgery. No infectious complications showed up.

Results referring to urinary incontinence are shown in Table 3. Between 6 to 9 years follow-up, 56,7% of patients were completely cured, 25% showed improvement and 18,3% showed unchanged symptoms. Concerning satisfaction at the end of the study, 71,7% of the population is very satisfied, 13,3% mild satisfied and 13,3% unsatisfied.

An important outcome to evaluate was the extrusion of the mesh, as our technique uses handmade tapes. We observed two cases (3,3%) of vaginal erosion and mesh extrusion, one at two months, and one after four years of monitoring. Only the second case required removal.

DISCUSSION

TVT has become the gold standard for treatment of stress urinary incontinence, after demonstrating a similar effectiveness to Burch.[9-11] Although the effectiveness of TVT is not discussed, this technique has reported major vascular injuries, associated with 4% to 9% of bladder rupture.[9,10,12,13] On the other hand, TVT requires intraoperatory cystoscopy. TOT is proven to be a safer technique, considering that no major vascular injuries have been reported and neither are they expected, as a result of the anatomic approach of the technique. In this analysis there is a clear decrease in the risk of bladder rupture with TOT, demonstrated as well in other series.[14-19] These results were what as expected because during TOT there is no access to Retzius space, and also the TOT needle is always kept under the level of the levator any muscle.

Previous studies with TOT have reported urethral erosions, which were not observed in the present study.[8,17] In this study no vascular or nervous injuries were detected in using TOT. Postoperative urinary dysfunctions caused by TOT, are significantly reduced in comparison with other suburethral slings. This fact may be in part explained by the horizontal position of the sling that reduces the possibilities of urethral compression. Results concerning the cure and improvement of urinary incontinence with TOT are acceptable. However, in this population it was observed a decrease in efficacy over time. It is possible that the tissue deteriorates with time. On the other hand there may be an anatomical explanation, the pubourethral ligaments descend vertically, and the TOT creates a horizontal neoligament. It would be important to make an analysis of undercurrent variables, such as the status of the striated urethral sphincter, urethral mobility, the context of surgery performed, etc. In this way, it would be possible to make more accurate conclusions. Finally, the TOT technique is easy to learn, reproducible and our modifications of the technique described are inexpensive.

CONCLUSIONS

The results presented in this study show TOT as an effective technique but the effectiveness decreases with time. Moreover, it is a safe procedure with a low rate of complications. An increase in studies and longer evaluation periods will definitely provide us with more information to evaluate the efficacy of this new anti-incontinence technique.

REFERENCES

1. DeLancey JO. Functional anatomy of the female lower urinary tract and pelvic floor. Ciba Found Symp 1990; 151: 57-69; discussion 69-76.
2. DeLancey JO. Structural support of the urethra as it relates to stress urinary incontinence: the hammock hypothesis. Am J Obstet Gynecol 1994; 170: 1713-20; discussion 1720-3.
3. Delancey JO. Fascial and muscular abnormalities in women with urethral hypermobility and anterior vaginal wall prolapse. Am J Obstet Gynecol 2002; 187: 93-8.
4. Ulstem U, Petros P. Intravaginal slingplasty (IVS): an ambulatory surgical procedure for treatment of female urinary incontinence. Scand J Urol Nephrol 1995; 29: 75-82.
5. Delorme E. Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol 2001; 11: 1306-13.

TABLE 3. – Cure rate at five temporary sections. N: 60.

	Oct 2005	Oct 2006	Oct 2007	May 2008	Feb 2011
Cured	91,7	88,3	85	66,7	56,7
Improved	6,7	11,7	15	26,7	25
Failed	1,6			6,6	18,3

Cured: absence of subjective complaint of urine leakage and absence of leakage in cough stress testing.
Improved: decrease of stress incontinence.
Failed: unchanged or aggravated symptoms.

6. Dargent D, Bretones S, George P, Mellier G. Insertion of a sub-urethral sling through the obturating membrane for treatment of female urinary incontinence. Gynecol Obstet Fertil 2002; 30: 576-82.
7. Mellier G, Benayed B, Bretones S, Pasquier JC. Suburethral tape via the obturator route: is the TOT a simplification of the TVT? Int Urogynecol J Pelvic Floor Dysfunct 2004; 15(4): 227-32.
8. Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. Neurourol Urodynam 1995; 14: 131-9.
9. Meschia M, Pifarotti P, Bernasconi F, Guercio E, Maffiolini M, Magatti F, et al. Tension-free vaginal tape: analysis of outcomes and complications in 404 stress incontinent women. Int Urogynecol J Pelvic Floor Dysfunct 2001; 12:S24-7.
10. Paraiso MF, Walters MD, Karram MM, Barber MD. Laparoscopic Burch colposuspension versus tension-free vaginal tape: a randomized trial. Obstet Gynecol 2004; 104:1249-58.
11. Ward KL, Hilton P. A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. Am J Obstet Gynecol 2004; 190:324-31.
12. Agostini A, Bretelle F, Franchi F, Roger V, Cravello L, Blanc B. Immediate complications of tension-free vaginal tape (TVT): results of a French survey. Eur J Obstet Gynecol Reprod Biol 2006;124:237-9.
13. Karram MM, Segal JL, Vassallo BJ, Kleeman SD. Complications and untoward effects of the tension-free vaginal tape procedure. Obstet Gynecol 2003;101:929-32.
14. Barber M, Gustilo-Ashby A, Grace Chen C, Kaplan P, Paraíso M, Walters M. Perioperative complications and adverse events of the MONARC transobturator tape, compared with the tension-free vaginal tape. Am J Obstetrics and Gynecology 2006; 195: 1820–5.
15. Grise P, Droupy S, Saussine C, Ballanger P, Monneins F, Hermieu JF, Serment G, Costa P. Transobturator tape sling for female stress incontinence with polypropylene tape and outside-in procedure: prospective study with 1 year of minimal follow-up and review of Transobturator tape sling. Adult Urology 2006; 68: 759-763.
16. Giberti C, Gallo F, Cortese P, Schenone M. Transobturator tape for treatment of female stress urinary incontinence: objective and subjective results after a mean follow-up of two years. Adult Urology 2007; 69: 703-707.
17. Minaglia S, Ozel B, Klutke C, et al. Bladder injury during transobturator sling. Urology 2004; 64: 376e1–376e2,.
18. Dargent D, Bretones S, George P, et al. Insertion of a sub-urethral sling through the obturating membrane for treatment of female urinary incontinence. Gynecol Obstet Fértil 2002; 30: 576–582.
19. Fischer A, Fink T, Zachmann S, Eickenbusch U. Comparison of retropubic and outside-in transobturator sling systems for the cure of female genuine stress urinary incontinence. Eur Urol 2005; 48:799-804.

Correspondence to:
FERNANDA NOZAR
Avda. Italia 2545/201.
CP: 11600. Montevideo, Uruguay.
Email: fernandanozar@gmail.com