

TOT does not affect the urethral sphincter innervation: a pilot study

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Received: 30 September 2010 / Accepted: 14 January 2011 / Published online: 11 February 2011
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Abstract

Introduction and hypothesis To exclude a neuromuscular denervation damage due to prosthetic mini-invasive surgery using transobturator tape (TOT) by pre and postoperative electromyography (EMG) of the striated urethral sphincter. **Methods** Seventeen women with SUI were enrolled by urogynecologic and urodynamic examination. Each of them underwent EMG of striated urethral sphincter performed by 25-mm concentric needle that was put in as far as 5 mm inside internal urethral sphincter. Amplitude and duration of EMG potentials were measured during caught, maximal contraction, and at rest. Four months after TOT treatment women underwent EMG.

Results The mean amplitude of EMG potentials does not show significant statistical differences between pre- and post-TOT ($P=NS$). The duration of potentials, instead,

changed between pre and posttreatment only during the maximal contraction test ($P\leq 0.05$).

Conclusions TOT prosthesis surgery, avoiding denervation and devascularization of pelvic structures does not produce damage of the urethral sphincter.

Keywords Electromyography · TOT · Urethral sphincter · Stress urinary incontinence

Introduction

Urinary incontinence exerts a huge influence on women's quality of life. Many surgical procedures have been described for the treatment of stress urinary incontinence (SUI) [1]. In the past decade, sling surgery has become the main technique for the management of female SUI [2, 3] characterized by very high efficacy, safety, and minimal invasiveness. Ulmsten and Petros were the first to describe the tension-free vaginal tape (TVT) operation to treat women affected by SUI [4]. Although the TVT procedure is safe and efficacious, complications such as bladder, bowel, and blood vessel injury have been reported. The most promising innovation in minimally invasive surgery for SUI has been the transobturator tape (TOT) described by Delorme [5, 6]. The non-elastic polypropylene tape is inserted without tension in a horizontal plane underneath the middle of the urethra from one obturator foramen to the other. The lateral ends of the tape are tunneled percutaneously through a tunneling device, preserving the retropubic space [7]. The TOT approach avoids the risks of bladder, intestinal, and vascular injuries [8, 9]. Anatomic studies performed on cadavers have definitively showed the safety of the tape passage using TOT [10]. However, the presence

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of a foreign body such as polypropylene tape provokes a reaction that compromises the anterior vaginal wall, which is a rich neurovascular area [11]. The pudendal nerve, which has its important sensitive termination in the area of pubocervical fascia surrounding the urethra, could undergo detrimental fibrosis after an anti-incontinence procedure. During pelvic surgery, every effort should be made to avoid injury to the intrapelvic somatic nerve originating from the pudendal nerve. This somatic nerve, lying along the lateral border of the mid-urethra up to the endopelvic fascia, has its terminal branch in the urethral sphincter [11]. It is an important structure of continence [12]. Thus, mini-invasive sling procedures should have the objective of restoring both anatomy and function, respecting anatomical structures of the pelvic floor [13]. The high cure rate of these techniques is 90% for the TOT procedure [6] and, owing to its safety, it is considered the best approach to treat female SUI [14]. However, to date, no evidence has shown the direct effect of TOT procedures on the suburethral neuromuscular structures.

Our prospective pilot study focused on possible neuromuscular damage of the urethral sphincter after TOT surgery. Therefore, elementary EMG of the matter muscle was used before and 4 months after TOT procedure.

Materials and methods

The prospective study was performed at the Urogynecologic Service of the Department of Obstetrics and Gynaecology, and Radiologic Sciences and at the Department of Neurosciences, Azienda Ospedaliero-Universitaria Policlinico, University of Catania School of Medicine, Catania, Italy. The institutional ethical committee of the department approved the study. All the subjects provided written informed consent before entering the study, which was conducted in accordance with the Declaration of Helsinki. The study was not advertised and no remuneration was offered. Twenty-three consecutive women, ranging in age from 45 to 67 years, affected by clinical SUI were screened in the prospective study. A single operator performed the clinical and instrumental diagnostic procedures to enroll the women affected by SUI. Each patient underwent a complete pre-surgery urogynecologic workup, including urodynamic assessment, micturition urethrocytography, pelvic organ prolapse quantification, stress test on supine and orthostatic position, and urine culture. Women with uterine or bladder prolapse, previous vaginal surgery, or neuropathy were excluded from the study. Each subject underwent EMG of the urethral sphincter. EMG is a technique for evaluating and recording the electrical activity produced by skeletal muscles [15]. It detects the electrical potential generated by muscle cells when these cells are electrically or neurolog-

ically activated. The signals can be analyzed to detect medical abnormalities, activation level, and recruitment order or to analyze the biomechanics of movement. There are two kinds of EMG in general use: surface EMG and intramuscular (needle and fine-wire) EMG. To perform intramuscular EMG, a needle electrode is inserted through the skin into the muscle tissue. Normal muscles at rest make certain, normal electrical sounds when the needle is inserted into them. Abnormal spontaneous activity might indicate some nerve or muscle damage. Usually, skeletal muscles do not have activity at rest. During contraction, a large number of fibers are recruited and this results in an interference trace at EMG. In the sphincter muscles, instead, there is periodic activity at rest due to tonic contraction that becomes an interference trace during maximal contraction.

EMG was performed by a 25 mm length, 0.46 mm diameter concentric needle (Medelec Elite Disposable Concentric Needle Electrodes, Neurocare, Madison, WI, USA) with a recording area of 0.07 mm, that was put in as far as 5 mm inside the internal urethral sphincter to reach the highest concentration of stripped muscular fibres. EMG data were obtained at pre-stress test and during caught and maximal voluntary contraction of perineal muscles.

The EMG data were analyzed by Medelec Synergy N2 Software (Healthcare, Madison, WI, USA).

The electric activity was quantified by mean rectified voltage to value amplitude and duration of electric potentials.

Four months after TOT surgery, patients underwent urodynamic assessment and stress test on supine and orthostatic position to evaluate the success of the operation. The EMG of urethral sphincter was repeated to evaluate if the TOT surgery had caused neuromuscular damage.

Statistical analysis was performed using a software package for Windows 95 (Grantz SA, Primer of Biostatistics, McGraw-Hill, NY, 1997). A two-sided *t* test for the sample by analysis of variance was used to compare the EMG and clinical data before and after TOT surgery.

The scores are presented as the mean \pm SD. The result was statistically significant at $P < 0.05$.

Results

After urodynamic evaluation, four women were excluded due to genitourinary prolapse and two due to previous vaginal surgery. Finally, 17 women (mean age 55 years), having a mean parity of 2.6, were enrolled in the study. They underwent TOT procedure according to the technique of Delorme [16].

The mean operative time was 15 min in day-surgery hospitalization. The day after surgery post-void residual

urine volume before discharge was measured; it was less than 100 ml for each patient.

At the urogynecologic examination performed 4 weeks after TOT, the stress test was negative, urethral hypermobility was reduced and sling exposure was not observed. Only one woman was affected by infection of the wound, but it rapidly resolved after antibiotic treatment. Sixteen women (94.1%) were objectively cured at follow-up.

Four months after TOT, the women underwent urethral sphincter EMG. There was no statistically significant difference in amplitude values at baseline and post-TOT ($P>0.05$). The duration of potentials, instead, changed between pre and posttreatment only during the maximal contraction test ($P<0.05$) but this is not enough to suppose denervation of urethral sphincter because it could derive from different maximal contraction of the perineal muscles.

Data show that TOT surgery does not provoke damage of urethral sphincter because it does not cut the terminal branches of the pudendal nerve, neither because the minimal denervation is quickly followed by reinnervation within 4 months (Tables 1 and 2).

Discussion

This was the first prospective study evaluating the effects of TOT on the periurethral innervation area using EMG that is usually used to evaluate muscular tone of limbs in cases of myopathies and neurologic diseases. Some authors investigated the function of the urethral sphincter through electromyography after anti-incontinence surgery, such as the Burch procedure and sling apposition; however, without a comparison with preoperative data. [17].

The anatomy of the urethral sphincter was well described by Karam et al. They dissected ten cadavers of female fetuses and analysed them through a three-dimensional reconstruction based on immunohistochemical studies. The proximal third of the urethral sphincter consists of circular smooth muscle, the middle third consists of two circular layers of smooth and striated muscle fibers, and the distal third consists of a circular layer of smooth muscle fibers surrounded by an omega-shaped layer of striated muscle fibers. In the proximal third of the urethral sphincter,

Table 1 Pre- and post-TOT EMG amplitude data, before and during cough and maximal contraction

Amplitude	pre-TOT	post-TOT	<i>P</i> value
Basal trace	271.93±82.57	271.92±81.71	NS
Cough	351.8±172.05	339.57±173.34	NS
Maximal contraction	437.33±302.53	432.47±282.29	NS

TOT transobturator tape NS not significant

Table 2 Pre- and post-TOT EMG duration data, before and during cough and maximal contraction

Duration	pre-TOT	post-TOT	<i>P</i> value
Basal trace	7.44±1.29	7.71±1.38	NS
Cough	10.08±1.90	9.79±1.86	NS
Maximal contraction	12.43±2.75	11.61±2.95	<0.05

TOT transobturator tape NS not significant

myelinated fibers were identified running with unmyelinated fibers from the pelvic plexus. These fibers were closely related to the lateral and anterior walls of the vagina. Unmyelinated fibers entered the smooth muscle part of the sphincter at 4 o'clock and at 8 o'clock. Most myelinated fibers entered the sphincter at 3 o'clock and at 9 o'clock [18].

Even if the TOT is a blind procedure, the blind track is situated in the thigh away from any vital structures (femoral vessels, great saphenous vein, and branch of the obturator nerve as it leaves the obturator canal).

On the basis of our study, TOT was associated with similar electromyographic findings at baseline and postoperatively. TOT does not cause denervation because of less contact area with urethra and fascia, similar to the horizontal position of the sling. The TVT procedure consists of a more vertical orientation of the sling but an electromyographic comparison between these two procedures does not exist in literature. However, some years ago we studied the clitoral blood flow changes before and after the two techniques in order to determine if vascular damage is provoked by this mini-invasive surgery. In the TVT group, both the PSV (peak systolic velocity) and PI (pulsatility index) decreased and RI (resistance index) increased with respect to the baseline values ($P<0.05$). In contrast, the color Doppler ultrasound measurements obtained from the TOT group were similar to those obtained at baseline ($P=NS$) [19]. However, we are still studying the effect of TVT procedure on innervation.

All these studies show that the transobturator approach reduces anatomic and functional risks caused by sling passage to correct SUI. To support this theory we published the results of the correction of cystocele by the double transobturator technique [20]. The prosthetic procedure did not influence clitoral blood flow. In fact, color Doppler measurement showed that the mean PI, PSV, and RI were not significantly lower to those obtained at pretreatment. The double transobturator tension-free approach considerably improved quality of life and sexual function.

On the basis of our results, EMG appears to be useful in measuring the integrity of innervation of the urethral sphincter. We used it before and after TOT surgery for SUI. Our data could add new information on the safety of

this technique and on the anatomic and functional preservation of neuromuscular perineal structures. For these reasons and because of the high cure rate of this surgical technique, we believe that TOT surgery is the gold standard therapy in SUI. The clinical relevance of the current investigation is to effort our previous result by using TOT. In fact, women did not undergo either changes of clitoral blood flow (19) nor denervation. Consequently, treatment with TOT could be able to preserve the clitoral sensitivity. One limit of our study depends on the small number of women recruited for EMG.

Therefore, additional studies are needed to investigate this aspect.

Conflict of interest None.

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