

Correction of female SUI by trans-obturator tape: technique and results. Our experience

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SUMMARY: Correction of female SUI by trans-obturator tape: technique and results. Our experience

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Aim. The aim of our study was the assessment of safety and efficacy of a minimally invasive approach in treatment of female stress urinary incontinence (SUI), placing a trans-obturator tape, in order to support the mid-urethra and to correct the SUI.

Materials and methods. Our study was a retrospective observational one. Our experience is based on the analysis of 29 patients enrolled between January 2009 and October 2011, suffering from SUI with urethral hypermobility. The primary outcome is the complete bladder continence, measured by anamnestic and physical examination with stress test. Other analyzed variables were mean time of surgery and mean time of hospitalization. The follow-up visits were planned at 3 and 6 months after surgery. At each visit, patients underwent anamnestic and physical examination with stress test. Statistical analysis was performed with SPSS 18.0. All data are presented as mean \pm standard deviation (SD) (range) or absolute frequency (percentage).

Results. Mean time of surgery was 25.8 \pm 5 minutes (range 20-45 minutes) and mean hospitalization time was 3.1 \pm 1 days (range 2-6 days). There were no bladder perforations or substantial blood loss. There were not observed cases of hematuria, fever or urinary retention during postoperative period.

There was one case of laceration of bladder neck, repaired during surgery.

After 3 months of follow-up all patients were continent.

After 6 months of follow-up, 24 out of 29 patients (82.8%) had no urinary losses; 3 out of 29 (10.3%) reported improvements, but with persistence of a lower degree of incontinence, occasionally requiring use of pads.

Other 2 patients (6.9%), who previously suffered from mixed incontinence, showed, after treatment, principally UUI symptoms (Urge Urinary Incontinence).

RIASSUNTO: Correzione della IUS femminile per via trans-otturatoria: note di tecnica e risultati. La nostra esperienza

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Scopo. Scopo del nostro lavoro è la valutazione della sicurezza e dell'efficacia di un approccio mini-invasivo nel trattamento dell'incontinenza urinaria da stress (IUS) nella donna, con impianto di una sling per via trans-otturatoria, in grado di sostenere l'uretra media e di correggere la IUS.

Materiali e metodi. Il nostro è uno studio retrospettivo osservazionale. La nostra esperienza si basa sull'analisi di 29 pazienti giunte alla nostra osservazione tra gennaio 2009 e ottobre 2011, affette da IUS con ipermobilità uretrale. L'outcome primario è la continenza vescicale completa, misurata tramite anamnesi ed esame obiettivo con stress test. Altre variabili analizzate sono state il tempo medio di operazione e il tempo medio di ospedalizzazione. Il follow-up ha previsto visite a 3 e 6 mesi dall'intervento. Ad ogni visita le pazienti sono state sottoposte ad anamnesi ed esame obiettivo con stress test.

L'analisi statistica è stata condotta con SPSS 18.0. Tutti i dati sono riportati come media \pm deviazione standard (DS) (range) o frequenza assoluta (percentuale).

Risultati. La durata media dell'intervento è stata di 25,8 \pm 5 minuti (range 20-45 minuti) e la degenza media è stata 3,1 \pm 1 giorni (range 2-6 giorni). Non sono state osservate perforazioni vescicali o cospicue perdite ematiche. Non sono state osservate in fase post-operatoria ematuria, iperpiressia o ritenzione urinaria.

In un caso si è avuta la lacerazione del collo vescicale, riparata in corso di intervento.

Alla visita di follow-up dopo 3 mesi tutte le pazienti risultavano continenti.

Alla visita di follow-up dopo 6 mesi, 24 su 29 pazienti (82,8%) non presentavano perdite urinarie; 3 su 29 (10,3%) riportavano un miglioramento, con persistenza di un minor grado di incontinenza, che richiedeva l'uso occasionale di assorbenti.

Altre 2 pazienti (6,9%), che in precedenza soffrivano di incontinenza mista, manifestavano, dopo trattamento, principalmente sintomi da IUU (incontinenza urinaria da urgenza).

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Conclusions. *The trans-obturator approach is undoubtedly an effective and safe surgical option to be taken into account when we move towards a surgical correction of SUI. The short hospitalization time allows a rapid recovery of bladder motility and spontaneous micturition, with reduced or absent bladder irritative symptoms.*

Further results will be available after a longer period of follow-up, with urodynamic examination, ultrasound evaluation and randomized controlled trials.

Conclusioni. *L'approccio trans-otturatorio è senza dubbio un'opzione chirurgica sicura ed efficace da prendere in considerazione qualora ci si avvia verso una correzione chirurgica della IUS.*

Il ricovero ospedaliero breve consente una rapida ripresa della motilità vescicale e della minzione, con ridotti o assenti sintomi irritativi vescicali.

Ulteriori risultati saranno disponibili al compimento di un maggiore periodo di follow-up con esami urodinamici, valutazioni ecografiche e studi randomizzati e controllati.

KEY WORDS: Female SUI - Suburethral sling - Polypropylene - Tension-free - TOT.
IUS femminile - *Sling* sottouretrale - Polipropilene - *Tension-free* - TOT.

Introduction

Urinary incontinence is defined by ICS (International Continence Society) as "any involuntary loss of urine that is a social or hygienic problem for the individual" (1).

The prevalence of this disease is difficult to estimate for two reasons: first, because of the difficulty in defining grade, quantity and frequency of urine loss as to represent a defined pathological condition and, not least, the elevated drop-out index for personal reasons, which clearly cause an underestimation of the pathological phenomenon. However, the prevalence of female urinary incontinence is assessed between 13.1 and 70.9% of the population, with rates increasing with age (2).

There are several types of urinary incontinence: stress, urge, mixed, overflow, reflux, functional, nocturnal enuresis, whose physiopathological bases are different.

SUI is undoubtedly the most common type, with rates assessing from 13 to 50%, increasing with elderly (2), and occurs when different factors and conditions (laughing, sneezing, coughing, leading weights, climbing stairs and make efforts in general) increase the intra-abdominal and then bladder pressure, resulting in urine loss.

The most common cause of female SUI is the urethral hypermobility due to loss of function of mechanical support given by the pelvic floor. This situation occurs much more frequently in women than in men, because of the higher stress which this anatomical region is subjected to: pregnancy and natural childbirth, dystocical birth, pelvic surgery, hypoestrogenism, menopause; other causes can be connective tissue diseases or neurological disorders.

With regard to the diagnosis, medical history is very important, as the amount of urine loss and frequency of incontinence episodes, precipitating factors or elements associated with this event, any uri-

nary symptoms (dysuria, frequency or urgency), medications, coexisting intestinal diseases or prolapse of pelvic organs, obstetric history, recent and remote pathological history, especially diabetes, connective tissue disorders, neurological disorders and respiratory problems. Routine investigations are also urine analysis (to exclude urinary infections) and physical examination (to assess the presence of prolapse and urine loss following Valsalva manoeuvre). Other tests may be performed as tip-test, voiding diaries, assessment of post-void residual, cystoscopy, cystourethrography and urodynamic studies.

Management of female SUI may be pharmacological (duloxetine, alpha-adrenergic agonists, estrogens), physical (pelvic floor rehabilitation exercises, electrical stimulation, biofeedback), or surgical (neck urethral suspension, periurethral bulking, artificial urethral sphincter or suburethral slings by transvaginal or trans-obturator approach).

The aim of our study was to investigate the results through a trans-obturator surgical approach (TOT, Trans-Obturator Tape).

Materials and methods

Our study was a retrospective observational one. Our experience is based on analysis of 29 patients enrolled between January 2009 and October 2011, suffering from SUI with urethral hypermobility. The anamnestic aspects of our patients are presented in Tables 1 and 2.

We excluded from the study patients with UUI (urge urinary incontinence) or urogenital prolapse (cystocele maximum of 1 degree).

Pre-operative evaluations include anamnesis and voiding diary, physical examination with stress test, urine analysis with urine culture, complete urodynamic examination and ultrasound examination of the urinary tract.

TABLE 1 - HISTORICAL FEATURES OF THE PATIENTS. DATA ARE PRESENTED AS ABSOLUTE FREQUENCY (PERCENTAGE).

Menopause	16 (55,17%)
HRT* in menopause	
• yes	6 (20,7%)
• no	10 (34,5%)
Type of UI	
• SUI	21 (72,4%)
• MUI**	8 (27,6%)
Sexual activity	18 (62%)
Previous pelvic surgery	
• Hysterectomy	4 (13,8%)
• TVT or Burch	5 (17,2%)
Positive Q-tip test	5 (17,2%)

* HRT: Hormone Replacement Therapy

** MUI: mixed urinary incontinence

TABLE 2 - HISTORICAL FEATURES OF PATIENTS AND OUTCOMES. DATA ARE PRESENTED AS MEAN ± SD.

		Age	Operative Time (min)	Recovery (days)	Parity	Height	Weight	BMI *
N	Valid	29	29	29	29	29	29	29
	Missing	0	0	0	0	0	0	0
Mean		54,72	25,90	3,14	2,41	1,6003	65,86	25,38
Median		54,00	24,00	3,00	2,00	1,6000	66,00	26,00
Mode		40 ^a	23 ^a	3	2	1,53 ^a	65	24
Std. Deviation		9,273	5,002	1,026	,780	,05603	3,281	2,665
Minimum		39	20	2	1	1,52	57	20
Maximum		72	45	6	4	1,70	72	29

* BMI: body mass index

All study participants signed an informed consent. We used a non elastic polypropylene sling, tension-free positioned under the mid-urethra and laterally extended behind the ischio-pubic branch to come out from the skin at level of the inguinal fold after passing the foramen, the membrane and the obturator muscle.

Patients were considered cured of SUI if they had a negative cough stress test result and there were no reports of urine leakage during stress; patients were also considered to have improved, if they had no leakage on the cough stress test, but may have occasional urine leakage during stress. However, this oc-

casional leakage did not influence daily activities or require any further surgical or pharmacological treatment. In patients who did not meet these criteria, treatment was considered to have failed.

Other analyzed variables were mean time of surgery and mean time of hospitalization.

At discharge, a physical examination with stress test was performed to assess continence as well as pelvic ultrasound control.

The follow-up visits were planned at 3 and 6 months after surgery.

At each visit, patients underwent historical and physical examination with stress test.

Statistical analysis was performed with SPSS 18.0. All data are presented as mean \pm standard deviation (SD) or absolute frequency (percentage).

Technique

The surgical procedure is performed through vagino-perineal approach with the patient catheterized in the lithotomy position.

We are used to infiltrate, when the patient's conditions permit, the anterior vaginal wall with a vasoconstrictor solution (adrenaline 2:1000), in order to reduce bleeding and to facilitate the plans' separation.

Through a median longitudinal incision of the anterior vaginal wall, starting 1 cm from the urethral tubercle, we exposed Halban's fascia, we made an incision and through a progressive smooth dissection we created a tunnel in paravaginal space protecting the urethra and the bladder neck.

When the tip of the operator's finger reaches the inner face of the obturator foramen passing behind the ischio-pubic branch, the tunnel is fully defined.

To identify the point of access to the obturator foramen, anatomical element of crucial importance in the trans-obturator approach, we identified the point in which the inguinal fold crosses the transverse line passing through the base of the clitoris and corresponding to the infero-medial margin of the obturator foramen. This is the point of maximum distance from vascular and nerve formations passing this structure (3 cm).

Exactly in the point identified by the intersection of the two lines indicated above, we performed a tiny skin incision of 0.5-1 cm, bilaterally.

A tunneler needle was introduced in the skin incision, crossing the obturator foramen and, under guidance of the operator's finger placed in the paraurethral tunnel, it came out into the vagina.

Our experience has shown that the perpendicular of the tangent of the ischio-pubic branch is the easier and the safer direction to insert the tunneler through the tunnel.

It is important to remember that the passage of the needle is never blindly, but it is always accompanied by the operator's finger.

When the tunneler's tip comes into the vagina, the extreme lateral of the sling is inserted into the eye so that: 1) it is placed under the mid-urethra, 2) it is extended behind the ischio-pubic branch, 3) it comes out from the skin for easy retraction of tunneler.

At this point the procedure is repeated contralaterally.

Generally, at the end of the procedure we execute a stress test after the bladder was filled up (250 ml),

firstly with the released sling and then after placing it.

We considered that, in respect of a tension-free system, it is necessary to leave 3-4 mm between sling and urethra.

Usually we place a Foley catheter, and then we proceed to suture the vaginal wall and the skin incisions. The procedure ends with the apposition of the vaginal plug and with the prescription of antibiotics.

Results

In our technique, the mean duration of surgery was 25.8 ± 5 minutes (range 20-45), with a mean hospital stay of 3.1 ± 1 days (range 2-6).

There were no bladder perforations or substantial blood loss. There were not hematuria, fever or urinary retention during postoperative period.

There was one case of laceration of the bladder neck, repaired during surgery.

After 3 months of follow-up, all patients were continent.

After 6 months of follow-up, 24 out of 29 patients (82.8%) had no urinary losses; 3 out of 29 (10.3%) reported improvements, but with persistence of a lower degree of incontinence, occasionally requiring use of pads.

Other 2 patients (6.9%), which previously suffered from mixed incontinence, showed after treatment principally UII symptoms (Table 3).

Discussion

The choice of surgery for the treatment of SUI is almost always considered only after that other remedies, pharmacological, physical or rehabilitative, have not had the desired effect (3).

In the last 15-20 years there have been significant advances in the surgical treatment of female SUI. On the basis of the integral theory of the pelvic floor, there are series of musculo-aponeurotic structures that cooperate to maintain continence (4).

According to this theory, the sub-urethral and sub-vesical pelvic structures act as mechanic support, and in case of damage to these structures, there can be LUTS (Lower Urinary Tract Symptoms).

Surgical procedure, involving the insertion of sub-urethral slings, has the purpose of restoring the mechanism of support that tissues and anatomical structures have lost for various reasons.

The first employed technique for that purpose is TVT (Tension-free Vaginal Tape). This involves the insertion of a sling surgically placed in the retro-pubic space through the vagina.

TABLE 3 - PRIMARY OUTCOME: FULL BLADDER CONTINENCE. RESULTS OF FOLLOW-UP. DATA ARE PRESENTED AS ABSOLUTE FREQUENCY (PERCENTAGE).

	Cured	Improved	Not cured
3 months follow-up	29 (100%)	0	0
6 months follow-up	24 (82,8%)	3 (10,3%)	2 (6,9%)

Delorme in 2001 was the first to introduce the trans-obturator surgical approach (TOT, Trans Obturator Tape) for the insertion of sub-urethral slings (5).

TOT differs from TVT because cutaneous incisions are at level of groins and no longer in the pubic area.

The initial technique by Delorme provided an “out to in” direction to introduce the sling, that is, from thigh to vagina. De Leval in 2003 introduced a change to this technique, proposing the “in to out” approach (TVT-O, Tension-free Vaginal Tape - Obturator) (6).

In our study we applied the technique firstly described and performed by Delorme.

Both techniques seem to have good results with regards to the therapeutic outcome, and lower rates of post-surgical complications than those reported with TVT (7, 8).

The implant technique via trans-obturator was developed considering that the auxiliary procedures (such as cystoscopy), necessary in case of TVT, have biological impact and significant costs, and that bladder, intestinal and vascular lesions should be avoided in total safety. Furthermore, propylene tape, positioned via trans-obturator underneath mid-urethra, reproduces the natural transversal strip of suspension of the urethra saving the retropubic space, which instead is involved by other surgical techniques.

The principal rationale of this technique compared to previous responds to the surgeons’ need to seek as much as possible to avoid direct access to retropubic structures, that mostly exposes to risk of vascular-nerve injury, as well as to the urogenital structures.

Another important advantage of the trans-obturator approach is that, being not possible to over-tighten the tape, and having this a slightly different position compared to trans-vaginal approach, the urinary retention by mechanical obstruction recurs much more rarely than it can happen with TVT (9-11).

Chae et al. reported a cure rate of 87.8% with TOT at one year follow-up; in the study by Chen et al., instead, the percentage of recovered reaches 91.1%. Nerli et al., obtained cure in 88.8% of pa-

tients and an improvement in 11.2%. Finally, Park et al. show a cure rate of 91.4% and an improvement of 2.9% at one year of follow-up (12-15).

Retrospective analysis that we conducted shows that overall we got a global improvement in 93.1% of patients, of which 82.8% had complete healing and maintaining of urinary continence even at 6-month follow-up, so that it can be considered as complete therapeutic success, while 10.3% is considered as an improvement compared to the pre-operative conditions, on the basis of a subjective evaluation reported by patients.

Our data are in analogy with the experience of Magon et al., for which the cure rate is 93.2%, or even of Khan et al., who have had a cumulative success rate of 92% (9, 10).

Mean operative time, 25.8 ± 5 minutes (20-45), is located in a very good average compared to data from literature. In his experience, Khan et al. reported an operative time of 24 ± 3.8 min, whereas Nerli et al. showed instead a time of 18.4 ± 1.85 minutes. Ito et al. reported TOT in their study in a mean operative time of 31 ± 8.3 minutes, and Chen et al., instead, reported times of 20 ± 13.5 minutes. Oh et al. reported an operative time of 22.7 ± 2.3 minutes (10, 13, 14, 16, 17).

With regard to the mean hospital stay, Chen et al. reported a mean time of 2.3 ± 0.8 days, whereas Ito et al. referred times of 3.3 ± 0.7 days. Finally, Khan et al. showed mean time of hospitalization of 6 ± 2.4 days (10, 13, 17).

The mean hospital stay in our case was found to be 3.1 ± 1 days (2-6), demonstrating that both the ability and the relative simplicity of the surgical technique used, such as the paucity of post-operative complications, allow rapid discharge, with lower costs and rapid functional recovery for patients.

Conclusions

This technique is certainly an optimal therapeutic choice for female SUI, as it is executable in spinal anesthesia with hyperbaric marcaina or local anaesthesia with xylocaine 2%. Short hospitalization allows rapid recovery of bladder motility and micturi-

tion, with absent or reduced bladder irritative symptoms. Agility in the technique and the high degree of patient satisfaction are very indicative of a technique based on valid pathophysiological and anatomical

assumptions. Further results will be available after a longer period of follow-up, with urodynamic examination, ultrasound evaluation and randomized controlled trials.

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