Full Length Research Paper

An evaluation of the outcome and quality of life after TOT-surgery

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TransObturatorTape (TOT) is a surgical technique for the correction of stress urinary incontinence (SUI). We report our experience about clinical outcomes and quality of life of patients who underwent TOT. We collected clinical and instrumental data about 27 patients who underwent TOT during 2006-2007, and investigated their quality of life using the King's Health Questionnaire (KHQ). We analysed data by R (version2.7.0), considering significant p<0.05.Mean age at surgery was 62.81years (range 39-83), mean BMI was 29.31kg/mq (±7.74). 85.19% of patients were in menopause (73.91% spontaneous). Mean parity was 2.19 (±1.11) and only two women were nulliparous. 44.44% of patients had at least one previous gynaecological intervention (34.62% hysterectomy). Relapse prevalence was 44.44%, correlated with higher (worse) KHQ scores (p<0.05), and affected especially women with a mixed urinary incontinence (MUI) (p0.09) or with a coexistent genital prolapse (p<0.05). TOT improved women quality of life, independently by relapse or by the presence of a MUI (p<0.05). Previous gynaecological interventions, and in particular hysterectomy followed by SUI, resulted protective against symptom relapse.TOT does not resolve urge component in case of MUI and may cause urge incontinence after SUI correction. Anyway, women quality of life results strongly improved by TOT, even in case of relapse.

Keywords: Transobturator tape technique, hysterectomy, genital prolapse, stress urinary incontinence, quality of life.

INTRODUCTION

Stress urinary incontinence (SUI) is defined as the complaint of involuntary leakage of urine during an effort or an exertion or during sneezing or coughing. SUI not only affects older women but also young and physically active women with a strong impact on their quality of life. In older women SUI is frequently associated with urge

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ABREVIATIONS

TOT: Transobturator tape
TVT: Tension-free vaginal tape technique
SUI: Stress urinary incontinence
UUI: Urge urinary incontinence
MUI: Mixed urinary incontinence
KHQ: King's Health Questionnaire
UCP: Urethral Closure Pressure

urinary incontinence (UUI), or hyperactive bladder symptoms (Cervigni and Natale, 1999; Viktrup and Moller, 2004). In particular, the association of SUI with UUI is defined mixed urinary incontinence (MUI). In this paper, the definitions about pelvic floor symptoms are based on the last International Continence Society consensus (Abrams et al., 2003).

A good position of the sphincteric unit is very important for the urinary continence mechanism. When the abdominal pressure increases, a pressure increase inside the bladder is generated but, if the sphincteric unit is intra-abdominally correctly located, a pressure increase to the sphincteric unit also appears. As a consequence, the increase of Urethral Closure Pressure (UCP) prevents the loss of urine but, if the sphincteric unit is not in the correct position, an increase of abdominal pressure does not cause the augmentation of UCP and it is not possible to prevent the urine leakage (Cervigni and Natale, 1999).

The treatment of SUI is one of the most controversial aspects of the pelvic floor surgery. In the last decades, a

lot of surgical procedures have been developed, with abdominal or vaginal approach. For SUI the goal of pelvic surgery is to ensure the good position of the sphincteric unit (Cervigni and Natale, 1999), with a mini-invasive approach, the possibility of a day-surgery or a short recovery, and the less trauma and pain after surgery as possible.

Ulmsten and Petros described the concept of mid-urethral support without tension and developed the tension-free vaginal tape technique (TVT) (Giberti et al., 2007; Ulmsten et al., 1996; Petros and Ulmsten, 1993); this was the first mini-invasive technique with vaginal approach. In 2001, Delorme developed the Trans-Obturator-Tape (TOT) technique, where the tape placed between the two obturator foramen creates an hammock supporting the urethra (Delorme et al., 2004; Delorme, 2001); the objective of this procedure is to maintain the same position and efficacy as TVT while reducing the complications related to the penetration in the retropubic space (Charalambous et al., 2008).

The aim of our study was to evaluate the outcome and the quality of life after TOT-surgery in 27 patients treated with this approach from January 2006 to December 2007 in the Clinic of Obstetrics and Gynaecology of the University Hospital of Udine.

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MATERIALS AND METHODS

We studied retrospectively 27 women affected by SUI or MUI, who underwent the TOT-procedure in our Clinic from January 2006 to December 2007, 22 of which completed the follow up.

Inclusion criteria were the execution of the procedure at least 6 months before the follow up evaluation, the instrumental confirmation of urinary incontinence by urodynamic investigation, and no previous mesh surgery.

Every woman was subjected to a pre-operative evaluation that included: medical anamnesis, urogynaecologic examination, functional tests (cough-test, Q-tip-test and pad-test), transvaginal ultrasonography, and urodynamic investigation. The purpose of such evaluation was to define the type and the severity of urinary incontinence, its impact on the quality of life, the simultaneous presence of other pelvic floor alterations, and the eventual presence of corrigible risk factors such as an elevated BMI or a chronic cough.

Urodynamic investigation consisted in urethrocystometry, urethral pressure profiles and urine flow measurements with Valsalva Leak Point Pressure definition. At the end of pre-operative evaluation women with SUI and some cases of MUI were considered eligible for TOT-surgery.

The TOT-approach was performed under spinal anaesthesia with the patient in lithotomy position. A Foley catheter was intra-operatively inserted to empty the bladder. The surgical technique was based on Delorme description, consisting in a sagittal incision in the vaginal wall and a bilateral para-urethral dissection of vagina in the direction of ischio-pubic ramus, followed by two little cutaneous incisions in the inferior internal part of the obturator foramen. A helical tunneller was used from the outside entrance point to the vaginal incision using the index finger to guide its passage and to protect the urethra. The tape used, called Monarc-tape, is a knitted polypropylene mesh, very flexible and extensible. A tension-free adjustment was made to the tape under the mid

Urethra. Vaginal and cutaneous closure were performed by using respectively a slow absorption suture and a fast absorption one. No cystoscopy was made during the procedure.

After at least 7 month from the intervention a post-operative evaluation was performed. The patients did not repeated uro-gynaecologic examination, transvaginal ultrasonography and urodynamic investigation, but were only analysed again from a subjective point of view, using the Italian version of King's Health Questionnaire for urinary incontinence, composed by 21 questions about the urinary incontinence impact on the quality of life, including daily activities, physical activities, social activities and sexual intercourse.

Statistical analysis was performed using R (version 2.7.0) and considering significant a $p < 0.05$. T-test or Wilcoxon test were used for continuous variables, Chi-square test and Fischer exact test for categorical ones. Also a multivariate logistic regression was performed.

RESULTS

Mean age at surgery was 62.81 years (±10.7) with a range varying between 39 and 83 years of age. Mean BMI was 29.31kg/mq (±7.74). Chronic cough affected three women. Twenty three patients (85.19%) were in menopause, which was spontaneous in the 73.91% (17/23) of cases; the average age at menopause was 49.77 years (±6.31). Only two women in menopause used hormonal therapy for a short period.

Taking in consideration the reproductive history, twenty five patients had at least one pregnancy with spontaneous delivery, with a mean of 2.19 pregnancies each (±1.11), with no significant notes about neonatal weight, labour phase duration or trauma during delivery; the remaining two patients were nulliparous.

The average time between symptoms development and surgical intervention was 6.96 years (±7.12). Twenty one women had a pure SUI and six a MUI. Concomitant disorders of the pelvic floor, such as hysterocele, cystocele, rectum prolapse and vaginal defect, were present in eight women.

Nineteen women required only a urinary incontinence correction; eight women needed also a treatment of concomitant pelvic floor defects, for example transvaginal hysterectomy and vaginal wall reconstruction. No intra-operative complications happened, such as vessels or nervous lesions, nor bowel or urinary structures lesions. The median hospitalization time was 5.07 days (±1.04); longer recoveries were related to SUI with a concomitant pelvic floor defect. During hospitalization no complication happened.

The follow up time varied between 7 and 29 months, with a mean follow up of 18 months, and a mean age at follow up of 64.37 years (±10.7). In the 54.55% (12/22) of evaluated patients there was a relapse after surgery.

Median value of the King's Health Questionnaire score was 66.66 (25-162.5). Satisfaction judgments about TOT were so divided: 44.45% very good, 14.82% good, 11.11% discrete, 3.70% poor, 7.41% very poor (figure 1);

Women Satisfaction
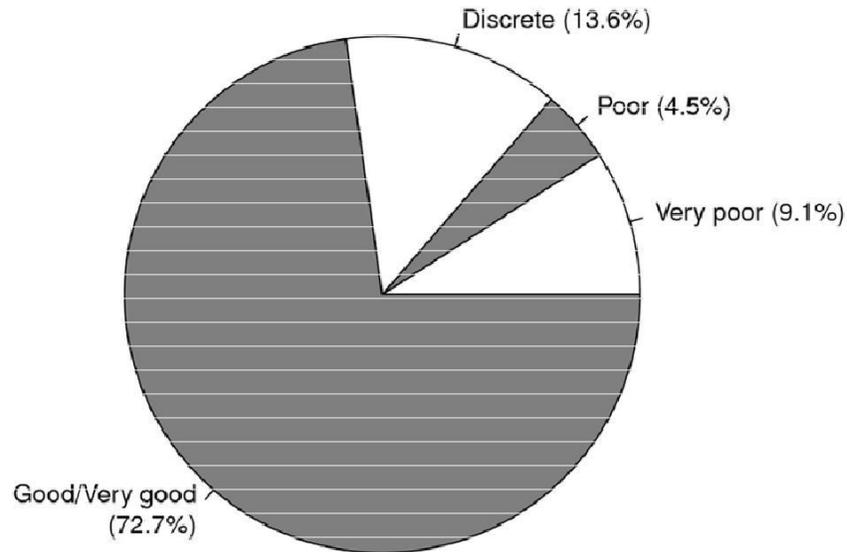
Figure 1. Women satisfaction after surgery. In this graphic we considered only the total amount of women who answered to this question.

Would you repeat the intervention?
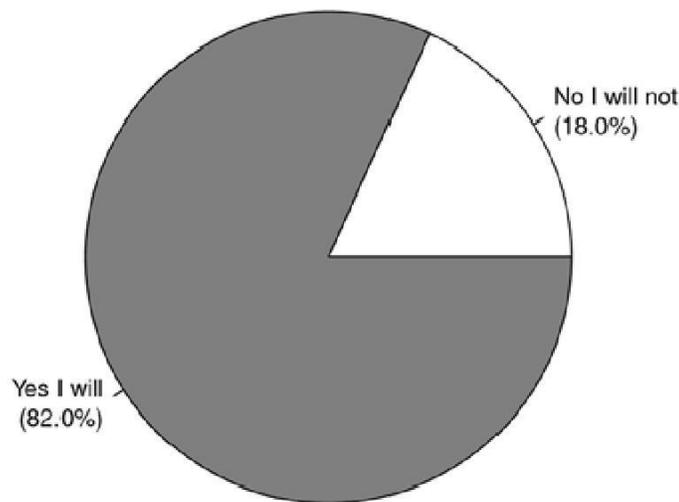
Figure 2. The prevalence of women that would repeat the intervention again because they were satisfied by the improvement of the symptoms

18.52% did not answer.
The 81.81% of patients would repeat the surgery if necessary (figure 2).

Some clinical symptoms (such as chronic cough, type of urinary incontinence, urgency, enuresis, etc.) have been evaluated before and after surgery and their prevalence is synthesized in table 1.

Table 2 summarizes the differences between women with a relapse and those without. Relapse prevalence was 44.44% (12/27), correlated with higher (worse) KHQ

Table 1. Symptoms before and after intervention. Prevalences and Chi-square test.

	Before-TOT	After-TOT	p
Chronic cough	11.11% (3/27)	9.09% (2/22)	0.816
SUI	92.59% (25/27)	31.82% (7/22)	<0.05
UI	62.96% (17/27)	50% (11/22)	0.362
Urgency	74.07% (20/27)	54.55% (12/22)	0.153
Enuresis	25% (6/24)	4.55% 1/22	0.054
Strangury	13.04% 3/23	9.09% (2/229	0.673
Dysuria	22.73% (5/22)	13.64% (3/22)	0.434
Hesitancy	13.64% (3/22)	27.27% (6/22)	0.262
Pelvic burden	37.5% (9/24)	9.09% (2/22)	<0.05
Intermittent stream	13.04% (3/23	31.82% (7/22)	0.130
Pelvic pain	9.09% (2/22)	9.09% (2/22)	1.000
Dyspareunia	6.53% (1/16)	0.00% (0/14)	0.341
Stypsis	33.33% (9/27)	45.45% (10/22)	0.386
Use of pads	79.17% (19/24)	40.91% (9/22)	<0.05
Vaginal discharge	79.17% (19/24)	40.91% (9/22)	<0.05
IVU	15.79% (3/19)	4.55% (1/22)	0.226
Absent bladder sensation	8.7% (2/23	4.55% 1/22)	0.577
Wet sensation	34.78% (8/23)	18.18% (4/22)	0.208

Table 2. Monovariate analysis in cases with relapse. Prevalences and chi-square test, *prevalences and Fischer exact test, **Average value (standard deviation).

	Relapse	No relapse	p	
Average age at surgical time	63.33 (±7.88)	62.2 (±11.18)	0.791	**
Menopause	91.67% (11/12)	90% (9/10)	0.892	
Age at menopause	51.4 (±4.43)	49.56 (±3.97)	0.352	**
Time between symptoms' start and surgery (years)	6.61 (±8.56)	8.95 (±5.98)	0.461	**
Hospitalization (days)	5.08 (±1.24)	5 (±0.67)	0.843	**
King's Health Questionnaire score	207.64 (±165.06)	27.5 (±14.19)	<0.05	**
BMI	31.65 (±9.15)	26.45 (±4.57)	0.120	**
Parity	2.08 (±1.16)	1.9 (±0.88)	0.678	**
Operative delivery	9.09% (1/11)	0% (0/9)	0.350	
Previous gynecological surgery	36.36% (4/11)	70% (7/10)	0.123	
Previous hysterctomy	18.18% (2/11)	60% (6/10)	0.080	**
Previous gynecological neoplasias	9.09% (1/11)	20% (2/10)	0.476	
MUI	41.67% (5/12)	10% (1/10)	0.097	
Anterior vaginal wall prolaps	41.67% (5/12)	0% (0/10)	<0.05	
Uterus prolaps	33.33% (4/12)	0% (0/10)	0.096	**
Vaginal hysterectomy associated with TOT	33.33% (4/12)	0% (0/10)	0.096	**
Anterior vaginal wall reconstruction	33.33% (4/12)	0% (0/10)	0.096	**
Genital prolapse surgically treated	50% (6/12)	0% (0/10)	<0.05	

scores (207.64 ±165.06 vs 27.50 ±14.19; p<0.05), and affected especially women with MUI (p 0.09) or with a coexistent genital prolapse by monovariate analysis (p<0.05).

By multivariate logistic regression, the previous hysterectomy followed by SUI resulted to be protective for symptoms relapse after intervention (OR 0.09; IC95% 0.01–0.99; p<0.05), while the following factors resulted to

Table 3. Median and interquartile range of King's Health Questionnaire scores in the patients who relapsed, and patients who not relapsed (p Wilcoxon test).

	Relapse	No relapse	p
General Health Perceptions	50 (25-50)	25 (25-25)	<0.05
Incontinence Impact	33.33 (33.33-33.33)	0 (0-0)	<0.05
Role limitations	16.67 (0-16.67)	0 (0-0)	<0.05
Physical limitations	25 (0-37.5)	0 (0-0)	<0.05
Social limitations	8.34 (0-36.11)	0 (0-0)	<0.05
Personal relationships	0 (0-0)	0 (0-8.33)	0.529
Emotions	0 (0-11.11)	0 (0-0)	0.056
Sleep / energy	0 (0-16.67)	0 (0-0)	0.055
Severity measures	33.33 (25-43.75)	0 (0-0)	<0.05

have no influence on relapse: age at the intervention, vaginal hysterectomy associated with TOT, parity, grade and localisation of genital prolapse, months of follow up.

Table 3 shows that King's Health Questionnaire score, in the complex and in the majority of its components, was worse in women with a relapse than in those without. Anyway, TOT improved women quality of life, independently by relapse or by the presence of a MUI (p<0.05). In fact, by multivariate logistic regression, the women satisfaction was positivetly influenced by lower BMI (p<0.05), whereas the following factors showed no significant influence on women satisfaction: age at intervention, vaginal hysterctomy or vaginal wall reconstruction associate with TOT, pad-test before intervention, previous hysterectomy, previous gynaecological surgery, parity, grade and localisation of genital prolapse, months of follow up, recurrence after intervention.

DISCUSSION

As already stated in many international studies, also in our population, we came across several risk factors that were more recurrent than in the normal population. Age and menopause with oestrogen deficiency compete in urinary incontinence pathogenesis; this problem is more frequent in elder women, even if it is not an exclusive condition of elderly and menopause. In our study, mean age at surgical time was 62.81 years, and 81.19% of women was in menopause at surgical time; for 66.67% of them symptoms started or became more important with menopause (Mancuso, 2005; Hextall, 2000; Larson et al., 1997; Sultana and Walters, 1994; Nygaard and Heit, 2004).

Pregnancy and vaginal delivery are common risk factors for SUI, as they can cause a nervous damage (Fornell et al., 2004; Delorme, 2001; Handa et al., 1996). All considered women were multiparous, with a mean number of babies of 2.19, and without any history of difficult labour or macrosomial babies.

Gynaecological surgery, for example hysterectomy, can cause pelvic floor alterations and urinary incontinence (Mancuso, 2005). Twelve of our patients had a previous gynaecological intervention, represented by hysterectomy in 9 cases, and after surgery symptoms started for 4 women and were worsened for one other.

In addition, overweight and obesity play an important role in the pathogenesis of SUI, causing an elevation of intra-abdominal pressure (Townsend et al., 2007; Fornell et al., 2004). Our average BMI was 29.31 Kg/mq (first degree of overweight); only eight women had a normal weight while two had a BMI greater than 40 Kg/mq.

Another recognized risk factor for SUI is the chronic cough, but in our population only three women reported a chronic cough, which is actually an insufficient number to reach any statistical significance.

Women normally do not speak benevolently of this problem, and a lot of them consider it a normal consequence of age and menopause. The percentage of women that apply to a specialist is only a minimal part of all women affected by this problem (Viktrup and Moller, 2004) . In our population, mean time between symptoms onset and surgical intervention was about 7 years.

Taking in consideration surgical complications, no vascular or nervous injuries, nor urinary tract or bowel damages, nor anaesthesia complications was reported during the 27 TOT procedures. Postoperative tape tension reduction was never needed. The median hospitalization time was 5 days, being longer recoveries related to SUI with a concomitant pelvic floor defect. Although, our experience is limited to a small number of patients, TOT-technique resulted to be simple and safe and the learning curve of our surgeon was good from the beginning (Charalambous et al., 2008; Giberti et al.,

2007; Juma and Brito, 2007; Krauth et al., 2005; Rou-meguére et al., 2005; Costa et al., 2004).

The main late-onset complications reported by the literature are the tape rejection and the symptom relapse. Tape rejection was more frequent in the past due to its relation with the used materials; the Monarc-tape we used is made of polypropylene, which reduces such a risk (Bader et al., 2006; Huebner et al., 2006; Falconer et al., 2001). No cases of tape rejection with vaginal erosion arose among our patients.

Twelve of the twenty two patients evaluated had a relapse; seven of them had a pure SUI and five a MUI. Two of the seven patients presenting pure SUI and three of the five with MUI experienced also a concurrent pelvic floor disorder treated in the same surgical time. Pelvic organ prolapse and urinary incontinence are often present at the same time (Buchsbaum, 2006). Therefore, by the presence of any pelvic floor disorder, it is important to examine the patient as well as for urinary continence, and when the patient comes for a problem of continence, it is important to study also her pelvic floor dynamics. Managing one aspect cannot abstract from the treatment of the other one (Latini and Kreder, 2005), but unfortunately a simultaneous treatment of a pelvic floor problem can worsen the outcome of TOT -approach for the cure of SUI (Clark et al., 2003) . Also in our study this association was observed, even if without any statistical significance.

Regarding the type of incontinence reported after surgery, the majority of women with a relapse had urgency symptoms, and only in some cases had a real urge incontinence. Only two women presented once more a pure SUI with symptoms that can be assimilated to the ones present before surgery; three women had only occasionally SUI.

The five women who experienced a problem of MUI, resolved the SUI component, but in the postoperative period they complained about the persistence of urgency. The onset of de novo urgency symptoms could be caused by modifications of periurethral collagen and the formation of fibroid scar around the mesh; the material used for the tape influenced the degree of these 2 events. In addition, the hormonal status seemed to play an important role in urgency. The onset of these symptoms is lower with TOT-technique than with TVT, because the tunneler does not go through the retropubic space, and so can not damage the periurethral nerve, which is involved in urge incontinence pathogenesis (Giberti et al., 2007; Falconer et al., 2001).

In table 3, questions 1 and 2 of the KHQ concern the comprehensive health condition and the impact of urinary incontinence on women's quality of life. The mean score for the first question was quite elevated because of the mean age and the many concurrent health problems of our population, for which urinary incontinence did probably not represent the most important one. The main restrictions suffered by the patients were the unfeasability of physical activities or long trips and the limitations in social activities. It was difficult to accept pad use or water intake restriction. As a consequence, urinary incontinence was not perceived as a great problem at home, but it became so out of the domestic walls and by relating with new people and new situations. In this case, women became uncomfortable and unsure, started not to go out and preferred staying at home (Lifford et al., 2008; Coyne et al., 2003).

In our population, urinary incontinence did not represent a limitation for sexual intercourse, but that was related to the sexual inactivity of the women studied. Depression or anxiety and sleep disturbances were not identified by patients as relevant problems.

The overall judgment of TOT was good and more than 80% of patients would repeat the surgery if necessary, even though that the 55% of women had a relapse. A possible explanation to this incongruity is that symptoms presented after surgery were not so disabling as before; and symptoms decrease was a good result for patients, while significantly improving their quality of life (Giberti et al., 2007).

In the postoperative period, seven women had SUI, four of them had only an occasional loss of urine during intra-abdominal pressure increase, three had frequently episodes of urine loss during stress, and for 2 of these had symptoms which were equal to those before surgery. Moreover, urgency was constantly present in every case of relapse.

After TOT the prevalence of SUI was significantly lower (p<0.05), while no significant difference there was for UUI (p=0.362). Therefore, TOT is a good treatment for SUI and, even if it does not completely resolve the problem, it improves significantly the symptoms perception; on the contrary, it is not effective for the treatment of urgency and urge incontinence. Urge incontinence affected 17 women before TOT, having 6 of them a MUI. After surgery, urge incontinence was present in 11 patients, but only for 3 of them was a chronic problem. Five of the women with MUI had a relapse, but for them TOT was the solution for the stress component of their problem and only urge incontinence overstayed.

Twenty of the studied women reported urgency before TOT, and 12 of 22 women also after TOT. It is important not to confuse urgency with urge incontinence because urgency does not always generate in a problem of incontinence. Urgency showed no statistically significant difference between pre-TOT and post-TOT (p=0.153).

Enuresis, pelvic burden, pads use and vaginal loss were statistically more prevalent before TOT than after it (p<0.05). Pelvic burden was a problem for nine patients before surgery, who had a concurrent pelvic floor defect; in five of them the pelvic floor alteration was so important that it was corrected in the same time of TOT. Pelvic burden was postoperatively reported in only two patients: for one it was a new problem and for the other the persistence of a minimal problem.

Pads were used by nineteen patients before and nine after TOT. Women that used pads, required less pads after TOT than before surgery. However, they often used them for personal security in special occasions such as when they were out of home (Giberti et al., 2007; Roumeguére et al., 2005).

Regarding other evaluated symptoms, such as pelviperineal pain, dyspareunia (pain during sexual intercourse), urinary tract infections, stranguria, dysuria and other miction problems, no significant differences were found between pre- and post-TOT.

Dividing post-TOT population into 2 sub-populations, based on the eventual relapse, two symptoms were significantly more prevalent in the population with a relapse, that is to say anterior vaginal wall prolapse and surgically-treated genital prolapse.

Considering our study aim, to evaluate the outcome and the quality of life in patients undergoing TOT-surgery for SUI correction, TOT resulted to be very appreciated by women in terms of mini-invasivity, short hospitalization, fast recovery and satisfying outcome. The main limitations of our study are the small sample number and the retrospective design of the study.

In conclusion, TOT does not resolve urge component in case of MUI and may cause urge incontinence after SUI correction. Anyway, the women quality of life results strongly improved by TOT, in case of complete resolution as well as in case of symptoms reduction by the presence of a relapse. Therefore, TOT results to be an optimal approach for the treatment of SUI and, in selected cases of MUI.

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