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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Safety and efficacy of surgical transobturator tape in the treatment of stress urinary incontinence in women – three years of follow-up

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SUMMARY

Introduction/Objective Stress urinary incontinence (SUI) is defined as the complaint of involuntary loss of urine in effort or physical exertion, or on sneezing or coughing. It is a common clinical condition affecting 50% of middle-aged and elderly women. Mid-urethral slings (MUSs) are the gold standard in the treatment of SUI.

The aim of this study was to investigate the success rate and complications of surgical treatment of SUI in women with transobturator tape (TOT) within the three years of follow-up.

Methods From January 2011 until January 2018, 86 women with predominantly SUI were operated by TOT procedure. In 61.6% of patients SUI was confirmed by preoperative urodynamic examination (cystometry, uroflowmetry, urethral presser profile) and in 38.4% of patients by clinical examination of stress test (cough provocation). All patients were invited for a follow-up examination six, 12, 24, and 36 months after surgery. The result of the operation is defined as cured, improved or without success.

Results The average age was 55 (32–72) years. The most common complications were tape erosion (3.5%), incision bleeding (2.3%), transient leg pain (3.5%), dyspareunia (2.3%), vaginal erosion (3.5%) and de novo urge (5.8%). After three years of follow-up, 82.6% patients were cured.

Conclusion TOT is a safe, effective and successful procedure with 82.6% of cured patients during a three-year follow-up.

Keywords: urinary incontinence; stress; trans-obturator tape; suburethral slings

INTRODUCTION

The International Urogynecological Association and the International Continence Society define stress urinary incontinence (SUI) as the complaint of involuntary loss of urine in effort or physical exertion, or on sneezing or coughing [1]. It is a common clinical condition affecting 50% of middle-aged and elderly women [2]. SUI negatively interferes with the quality of life and mental health [3].

In order to maintain urinary continence, it is very important that there is a synergy between the structures that make up the pelvic floor, the sympathetic and parasympathetic nervous systems and the motor fibers of the pudendal nerves. Involuntary loss of urine may occur as a result of an alteration in one or more components due to the inability of the urethra to counteract the increase in abdominal pressure. Predisposing factors for SUI are age, parity (especially with vaginal delivery) and obesity due to their influence on the weakening of pelvic floor structures, leading to urethral hypermobility. Parity can additionally lead to SUI through its effects on urethral and bladder innervation, triggered by the stretching or compression of nerves during the passage of the fetus through the birth canal [4].

Because of its safety and efficacy [5, 6], a surgical treatment is the method of choice, when conservative therapy fails. Until the introduction of mid-urethral slings (MUSs), the gold standard surgical treatment of SUI was the Burch retropubic urethropexy or Marshall-Marchetti-Krantz procedure through the retropubic routine [7]. Nowadays, the gold standard in the treatment of SUI is MUSs [8]. Since the report by Ulmsten and Petros in 1995, the tension-free vaginal tape (TVT) technique, thanks to its advantages such as shorter postoperative stay, minimal surgical trauma and long-term high sucess rate, has been the most commonly used surgical treatment for SUI [9]. Despite the fact that this technique has reached high success rates in the mid and long term, important complications, such as retropubic hematomas, bladder perforation and voiding dysfunction have also been described [9].

In 2001 a new technique was described, trying to reduce these complications, involving the placement of a synthetic mesh under the middle urethra through the transobturator route from the thigh to the vagina (transobturator tape outside-in [TOT]). De Leval presented a modification to the technique, in 2003, suggesting insertion of the mesh toward the opposite direction, from the vagina to the

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thigh (transobturator tape inside-out [TVT-O]) [10]. Both slings, TOT and TVT-O have shown high curative rate and lower number of complications [11, 12, 13]. Nevertheless, several researchers point at thigh and groin pain as the main complications.

The purpose of this study was to investigate the success rate and complications of surgical treatment of SUI in women with TOT outside-in technique with three years of follow-up.

METHODS

This was a retrospective study and presents the surgical results of treatment of SUI in women with monofilament polypropylene tape tension-free by transobturator approach, technique outside-in, in the period from January 2011 to January 2018 in a tertiary referral center at the Clinic for Gynecology and Obstetrics, Clinical Center of Vojvodina in Novi Sad, Serbia. This study was approved on February 21, 2019 under number 00-187/1 by Ethics Committee of the University of Novi Sad, Faculty of Medicine, Serbia.

A total of 86 women, who had SUI or mixed urinary incontinence, with a predominantly stress component, underwent surgery. The exemption criteria were the absence of urodynamic changes associated with the SUI, findings indicating infravesical obstruction and detrusor overactivity, coagulopathy, pregnancy, history of sensitivity of a foreign body (i.e., polypropylene), acute cystitis, vulvovaginitis, previous surgery to treat SUI and history of pelvic radiotherapy treatment.

In the preoperative preparation, a detailed anamnesis, previous medical history, clinical urogynecological examination, laboratory analyzes, negative urine culture findings, provocative cough tests were taken.

In our study, we used clinical and functional terminology that is in accordance with the standardization of the International Society for Continence. Urinary stress incontinence was confirmed by preoperative urodynamic examination (cystometry, uroflowmetry, urethral presser profile) or clinical examination of stress test (cough provocation) with full bladder in standing and lying position. Two surgeons, trained in urogynecological surgery, performed all operations according to the original Delorme technique (TOT outside-in) using monofilament polypropylene tape. Patients underwent surgery under general or spinal anesthesia. The Foley catheter was removed on the first postoperative day. The patients were discharged home in 1–4 days. Before surgery, all patients signed written consent for surgery and postoperative follow-up. All patients were invited for a follow-up examination six, 12, 24, and 36 months after surgery, which consisted of asking the patients about postoperative satisfaction, gynecological examination, urine and urine culture analysis and performing provocative cough tests with a full bladder in standing and lying down. The result of the operation is defined as cured, improved or without success. Cure was defined as the absence of subjective complaint of urine leakage, and the absence leakage on cough stress testing. Patients were considered improved when they had a decrease of stress incontinence. Other cases were considered as without success.

RESULTS

A total of 86 women, who suffered from SUI or mixed urinary incontinence, with a predominantly stress component, underwent surgery by placing a monofilament polypropylene tape tension-free by transobturator approach, technique outside-in. Preoperative urodynamic examination (cystometry, uroflowmetry, urethral presser profile) was performed in a total of 53 (61.6%) patients. These were 21 patients who suffered from SUI, eight patients with history of previous abdominal hysterectomy, three patients with history of previous vaginal hysterectomy as well as 14 patients who had mixed urinary incontinence and seven patients who had initial anterior vaginal wall prolapse (Figure 1). In 33 (38.4%) patients, who were not subjected to urodynamic examination, SUI was confirmed by a clinical trial of a stress test (cough provocation) with a full bladder in standing and lying position.

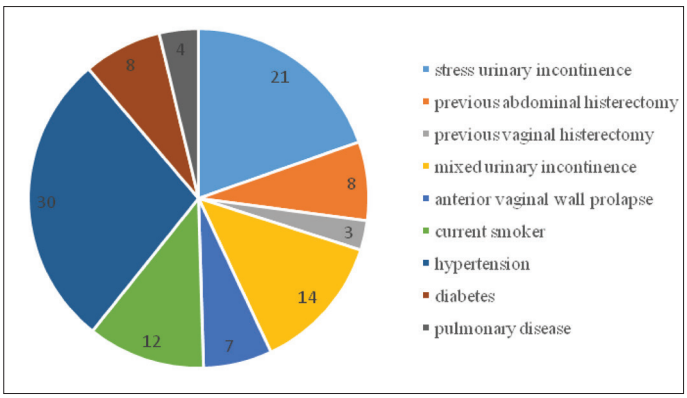

Figure 1. Graphic representation of comorbidities of patients

All patients in the preoperative preparation had a positive cough test and a negative urine culture.

The age of the patients ranged 33–72 years, with an average of 55 years. 12 patients (14%) were current smokers. More than a quarter, 30 (35%) patients had hypertension. Almost 10% (eight) of patients had diabetes, while four patients (5%) had pulmonary disease (Figure 1).

The length of hospitalization was 1–4 days. The urinary catheter was removed on the first postoperative day. 69 patients (80%) underwent surgery in general anesthesia and 17 patients (20%) under spinal anesthesia. Complications such as tape erosion occurred in three patients (3.5%), incision bleeding in two patients (2.3%), transient leg pain in three patients (3.5%) and dyspareunia in two patients (2.3%). No perforations of the bladder or urethra were observed, as well as intestines or blood vessels. Vaginal erosion occurred in three patients (3.5%). Erosion occurred in

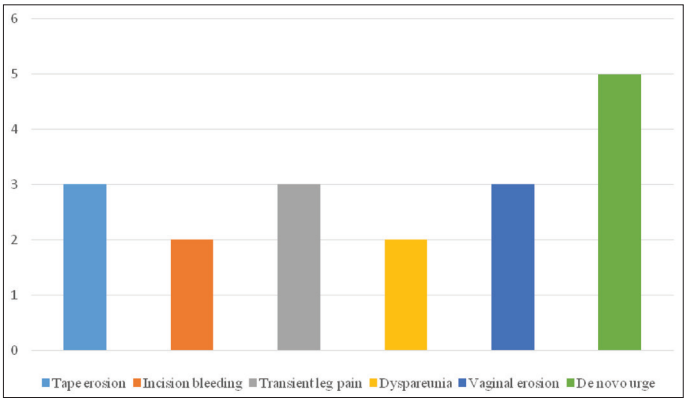

Figure 2. Graphical representation of the type and frequency of complications

two patients six months after surgery, and in one patient 12 months after surgery. In two patients, the solution was achieved by repeated sutures, and in one patient the tape was cut. Transient leg pain occurred in three patients and lasted less than 10 days. Bleeding from the incision site was treated conservatively (tamponade) and resolved during the first postoperative day. Dyspareunia, which manifested as a late complication in both patients, occurred one year after the operation. One patient underwent conservative treatment, the other had a tape cut. In five patients (5.8%) de novo urgency was registered as a late complication (Figure 2).

Table 1. Results of realistic valuation of cure determined on the basis of postoperative assessment

Period after surgery (months)	Objective cure rate n (%)		
	Cured	Improved	Without success
6	80 (93%)	/	6 (7%)
12	77 (89.5%)	(1.2%)	8 (9.3%)
24	73 (84.9%)	4 (4.6%)	9 (10.5%)
36	71 (82.6%)	(6.9%)	9 (10.5%)

In our study, 71 (82.6%) patients who underwent surgery with the TOT outside-in technique, after three years of follow-up, were cured (Table 1).

DISCUSSION

SUI is a widespread, global disease that affects women around the world and is often underestimated. Most frequently it occurs among middle-aged and elderly women, as shown by the results of our study in which the average age of women was 55 years [2].

There are several advantages, such as minimal morbidity, short operation time, rapid convalescence, and long-term efficacy that make MUSs considered the gold standard for treating SUI [6, 7, 10].

TOT is an effective and safe method for treating SUI and is the method of choice in many centers [14]. Nevertheless, the reports show different success rates for the procedure [15]. In the current study, TOT was very successful because more than three-quarters of patients 71 (82.6%) were relieved of symptoms after the three-year follow-up.

Synthetic MUSs is the first-line surgical procedure for SUI according to the 2017 position statement from the European Urogynaecological Association with a success rate of > 80% [16] what we also proved in our research using only polypropylene tape with a success rate of 82.6% and improvement rate of 6.9% after three years of follow-up. One year after surgery, the success rate in our study was observed in 89.5% of patients, improvement in 1.2% of patients, while 8.9% of patients reported no success after the treatment. After two years, success rate was 84.9%, improvement was observed in 4.6% of patients, while 10.5% of patients were without success after the treatment. The results of our research are correlated with literature data in several studies [3, 11, 16].

In ours, as in other studies, patients were operated under general or under spinal anesthesia. The anesthesiologists made a decision whether to use general or spinal anesthesia taking into account the patient's condition and comorbidities. The type of anesthesia had no effect on the outcome of the operation although it was previously thought that the use of spinal anesthesia was important to achieve the adequate tensioning of the sling and control of continence performing the cough test during the procedure [17].

Delorme described TOT procedure in the attempt to minimize TVT complications such as bladder perforation, retropubic hematomas and voiding dysfunction. However, there are still complications, and the most common intraoperative complications are bladder and vaginal perforations and hemorrhage [10]. There were no significant intraoperative complications in our study, as evidenced by Abrar et al. [18] who conducted a cross-sectional study of 162 patients who underwent surgery for SUI with Burch colposuspension (n = 40), tension free vaginal tape (TVT) (n = 59) or TOT (n = 63), from 2006 to 2014 at the Aga Khan University Hospital in Karachi.

Tape erosion is directly associated with biomechanical properties, wound healing, local factors as infection and also surgical technique. Tape erosion occurred in only three patients (3.5%), which correlated with the results of various studies [19].

After TOT surgery, transient leg pain which lasted for less than 10 days, occurred in three patients (3.5%) and it is in accordance with the existing literature where it is stated that the incidence of leg pain reach up to 15.5% [20].

In our study dyspareunia is manifested as a late complication in two patients (2.3%) and occurred a year after the operation, which indicates that this rate was almost ten times lower than that of Karakeçi et al. [20]. One patient underwent conservative treatment, while the other had the tape cut.

Individual factors, as well as surgical technique and sling material are significant contributing factors to the development of vaginal erosion. Vaginal erosion can also

occur as a result of inadequate suturation of the vaginal incision, infection, rejection of the sling material, early sexual intercourse and vaginal perforation. A study by Afflar et al. reported that 3.3% of the patients who underwent the TOT operation, developed vaginal erosion complication what is almost exactly the same rate as in our study 3.5% [21]. Erosion occurred in two patients six months after the surgery, and in one patient 12 months after the surgery. The solution was achieved by repeated sutures in two patients and in one patient the tape was cut.

As a complication, de novo urge incontinence effects the life quality negatively but occurs rarely after the TOT operations and it proves that TOT operation has a minimal obstructive effect. Rougmeguere et al. as well as Krauth et al. reported de novo urge incontinence rate as 2.5% and 5.2% after three months follow-up. In the study of Afflar et al. de novo urge incontinence rate in the TOT group was low (4.2%). Göynümer et al. established de novo urge incontinence in 3% of the cases [21]. In our study, in the medium-term follow-up, in five patients (5.8%) de novo urge incontinence occurred as a late complication and this rate was similar with the literature [21].

Gynecological surgeries and procedures significantly increased the risk for de novo urge incontinence, so that eight patients with the history of previous abdominal hysterectomy and six patients with the history of previous vaginal hysterectomy in our study had twice the risk of developing de novo urge incontinence. In one patient with a history of previous vaginal hysterectomy and diagnosed SUI, there was no successful outcome treated at the first follow up after six months. The second patient was continental even after the third year of follow-up with the appearance of urge incontinence one year after the operation. The third patient was continental and subjectively satisfied after the third year of follow-up.

The surgeon's experience is essential for the success of a surgical procedure so that the low complication rate and the high success rate of surgical treatment in this study can be explained by the adequate surgical training and experience of the surgeons who performed the operations [22].

CONCLUSION

Our study confirms that TOT is a safe procedure in the short and medium term with very few intraoperative, early and late postoperative complications. It is also an effective and successful procedure in the treatment of SUI with 82.6% of cured and 6.9% of improved patients during a three-year follow-up. Further evaluation of the procedure requires studies with a longer follow-up.

Conflict of interest: None declared

REFERENCES

1. Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/ International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Int Urogynecol J. 2010;21(1):5–26.
2. Nambiar A, Cody JD, Jeffery ST, Aluko P. Single-incision sling operations for urinary incontinence in women. Cochrane Database Syst Rev. 2017;7:CD008709.
3. Maturana AP, Palos CC, Ghersel FR, Fernandes CE, Oliveira E. Randomized controlled trial comparing mini-sling with transobturator sling for the treatment of stress urinary incontinence. Int Urogynecol J. 2020;31(9):1925–31.
4. Alas AN, Chinthakanan O, Espaillat L, Plowright L, Davila GW, Aguilar VC. De novo stress urinary incontinence after pelvic organ prolapse surgery in women without occult incontinence. Int Urogynecol J. 2017;28(4):583–90.
5. Morling JR, McAllister DA, Agur W, Fischbacher CM, Glazener CM, Guerrero K, et al. Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997–2016: a population-based cohort study. Lancet. 2017;389(10069):629–40.
6. Gurol-Urganci I, Geary RS, Mamza JB, Duckett J, El-Hamamsy D, Dolan L, et al. Long-term rate of mesh sling removal following midurethral mesh sling insertion among women with stress urinary incontinence. JAMA. 2018;320(16):1659–69.
7. Luo Z, Jiao B, Zhao H, Liu H, Lai S, Zhang G. Contasure-needleless single incision slings versus transobturator slings (TOT/TVT-O) for female patients with stress urinary incontinence: a systematic review and meta-analysis. BMC Urol. 2020;20(1):51.
8. Ford AA, Rogerson L, Cody JD, Ogah J. Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev. 2017;7:CD006375.
9. Capobianco G, Madonia M, Morelli S, Dessole F, De Vita D, Cherchi PL, et al. Management of female stress urinary incontinence: A care pathway and update. Maturitas. 2018;109:32–8.
10. Oliveira LM, Dias MM, Martins SB, Haddad JM, Girão MJBC, Castro RA. Surgical Treatment for Stress Urinary Incontinence in Women: A Systematic Review and Meta-analysis. Rev Bras Ginecol Obstet. 2018;40(8):477–90.
11. Palos CC, Maturana AP, Ghersel FR, Fernandes CE, Oliveira E. Prospective and randomized clinical trial comparing transobturator versus retropubic sling in terms of efficacy and safety. Int Urogynecol J. 2018;29(1):29–35.
12. Tammaa A, Aigmüller T, Hanzal E, Umek W, Kropshofer S, Lang PFJ, et al. Retropubic versus transobturator tension-free vaginal tape (TVT vs TVT-O): five-year results of the Austrian randomized trial. Neurourol Urodyn. 2018;37(1):331–8.
13. Celada P, Cañete P, Ortiz Murillo E, Tarín JJ, Cano A. Effectiveness and quality of life 10 years after transobturator suburethral tape surgery for stress urinary incontinence. J Obstet Gynaecol Res. 2018;44(3):518–23.
14. Huser M, Hudecek R, Belkov I, Horvath I, Jarkovský J, Tvarozek S, et al. Long Term Safety and Efficacy of Single-Incision Sling versus Mid-Urethral Sling in the Treatment of Stress Urinary Incontinence. Authorea. Mar 17, 2020.
15. Bayrak O, Seckiner I, Urgun G, Sen H, Ozcan C, Erturhan S. Transobturator midurethral slings versus single-incision slings for stress incontinence in overweight patients. Int Braz J Urol. 2015;41(4):714–21.
16. Chapple CR, Cruz F, Deffieux X, Milani AL, Arlandis S, Artibani W, et al. Consensus statement of the European Urology Association and the European Urogynaecological Association on the use of implanted materials for treating pelvic organ prolapse and stress urinary incontinence. Eur Urol. 2017;72(3):424–31.
17. Košević B, Nikolić I, Bančević V, Marić P, Jovanović M, Stamenković D, et al. Surgical outcome of the transobturator tape procedure for management of female urinary incontinence: A single center experience. Vojnosanit Pregl. 2020;77(12):1304–8.
18. Abrar S, Razzak L, Mohsin R. The practice of Burch Colposuspension versus Mid Urethral Slings for the treatment of Stress Urinary Incontinence in developing country. Pak J Med Sci. 2021;37(5):1359–64.

19. Hong IK, Kim HC, Kim JJ, Kim JY, Lee KW. The Rate of Mesh Erosion after Modified Transobturator Tape (Canal Transobturator Tape) Surgery: Analysis of 5 years' Outcome and Influencing Factors. Urol Int. 2019;103(4):482–7.
20. Karakeçi A, Eftal TC, Keleş A, Gölbaşı C, Onur R. Single-incision midurethral sling shows less pain and similar success rate in a short-term follow-up compared to the transobturator tape method in the treatment of stress urinary incontinence. Turk J Urol. 2019;46(1):63–8.
21. Taner CE, Okay G. Early complications of the transobturator tape and mini sling procedure. J Turk Soc Obstet Gynecol. 2014;11(1):14–20.
22. Kershaw V, Nicholson R, Ballard P, Khunda A, Puthuraya S, Gouk E. Outcome of surgical management for midurethral sling complications: a multicentre retrospective cohort study. Int Urogynecol J. 2020;31(2):329–36.

Сигурност и ефикасност хируршке трансобтураторне траке у лечењу стресне уринарне инконтиненције код жена – трогодишње праћење

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САЖЕТАК

Увод/Циљ Стресна уринарна инконтиненција (СУИ) дефинише се као невољно испуштање мокраће приликом напора, физичког напрезања, кијања или кашљања. То је често клиничко стање које захвата 50% жена средње и старије животне доби. Субуретрални слингови су златни стандард у третману СУИ.

Циљ ове студије је био да истражи стопу успешности и компликација хируршког третмана СУИ код жена трансобтураторном траком (ТОТ) унутар трогодишњег праћења.

Методе У периоду од јануара 2011. до јануара 2018. године, 86 жена са предоминантном СУИ оперисане су процедуром ТОТ. Код 61,6% болесница СУИ је преоперативно потврђена уродинамским испитивањем (цистометрија, урофлоуметрија, профил уретралног притиска), а код 38,4% болесница клиничким испитивањем теста осетљивости на кашаљ. Све болеснице су позване на контролни гинеколошки преглед шест, 12, 24 и 36 месеци после операције. Резултат операције је дефинисан као излечен, побољшан или без успеха.

Резултати Просечна старост болесница је била 55 година (32–72). Најчешће компликације су биле ерозија траке (3,5%), крварење из места инцизије (2,3%), пролазна бол у нози (3,5%), диспареунија (2,3%), ерозија вагине (3,5%) и *de novo* хитност (5,8%). После трогодишњег праћења 82,6% болесница је било излечено.

Закључак ТОТ је сигурна, ефикасна и успешна процедура са 82,6% излечених болесница током трогодишњег праћења.

Кључне речи: уринарна инконтиненција; стрес; трансобтураторна трака; субуретрални слингови