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Comparison of Transobturator Tape and Mini-Sling Tissue Fixation in Female Patients Who Had Stress Urinary Incontinence

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation;

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Abstract

Background. Urinary incontinence is a significant medico-social problem and its incidence increases up to 70% in the postmenopausal period.

Objectives. We aimed to compare the efficacy and safety of transobturator adjustable tape (TOT) and mini sling in female urinary incontinence.

Material and Methods. A total of 69 patients were included in the study. Single surgeon applied TOT (n = 56 with ISD) or 13 mini sling (n = 13 with ISD). Patients were considered to have ISD identified by a Valsalva leak point pressure (VLPP) measurement < 60 cm H_2O with a volume of 150 mL in the bladder or by a maximum urethral closure pressure (MUCP) measurement < 20 cm H_2O with a volume of 200 mL in the bladder. The mean follow-up period was 25 months for TOT group and 24 months for mini sling group (p = 0.72).

Results. The cough test was negative in 48 of TOT group (86%) and 11 of mini sling group (84.6%). ICIQ-SF scores for the median value decreased from 14 (11–21) preoperatively to 3 (0–9) postoperatively (p < 0.05) in the TOT group, and 15 (12–23) preoperatively to 4 (0–10) postoperatively (p < 0.05) in the mini sling group. The difference in the decrease of the score between two groups was not statistically significant (p = 0.42). There was not any significant complication to note. The mean hospital stay for TOT group was 2.1 days (1–5), and 1.4 days (1–3) for mini sling group (p = 0.12). Operation time was was significantly lower in mini-sling group than TOT group (11.6 vs. 18.4, p < 0.01).

Conclusion. Both TOT and mini-sling procedures are successful and safe procedures in the treatment of female stress urinary incontinence with ISD (Adv Clin Exp Med 2015, 24, 5, 851–855).

Key words: urinary incontinence, TOT, mini sling, cystocele.

Stress Urinary Incontinence

Stress urinary incontinence (SUI) is determined as leakage of urine with any activity like laughing, coughing, and exercise. Up to 30% of women experience symptoms of urinary incontinence during their lifetimes [1, 2]. Laparoscopic Burch colposuspension has been described by Vancaillie et al. and accepted as the gold standard for SUI [3]. Petros et al. reported the first intravaginal suburethral slingoplasty operation [4]. In 1996, Ulmsten et al. performed midurethral retropubic sling

named TVT and since then, treatment modalities have been dramatically changed [5]. Although TVT is less invasive than Burch operation, some complications such as vascular, bladder, and small bowel injuries are reported [6, 7]. A midurethral approach was performed *via* transobturator route (TOT) by Delorme [8]. The complications seen in TVT were decreased with TOT. However, TOT found to be useless to treat intrinsic sphincter deficiency (ISD). Also, other complications which are specific to TOT like obturator nerve injury and bladder damage are increased. A current multicentric study

852 K. Zengin et al.

demonstrated that there was no difference between TOT and TVT in terms of efficacy [9]. Postoperative quality of life was similar in both groups.

In 2005, a mini-sling tissue fixation operation (TFS) has been introduced by Petros et al. for treatment of SUI [10]. Retropubic or obturator space was not used in this procedure and a cystoscopy was also not needed. Besides, there is minimal post-operative pain with a mini-sling. There are few studies comparing TOT with mini-sling operations. We aimed to compare the efficacy and complication rates of TOT and mini-sling procedures.

Material and Methods

A total 69 patients with SUI who were planned for TOT or mini-sling operations were enrolled to this study. Inclusion criteria were SUI with VLPP < 60, and being unresponsive to conservative management. Exclusion criteria were overflow incontinence, history of genitourinary surgery and genital prolapsus. An informed consent form was obtained from all patients and the study was approved by an ethical committee. The preoperative evaluation included history, physical examination, voiding diary, cough test, ICIQ-SF questionnaire (Turkish version), cystoscopy, and urodynamic examination [11]. Patients were considered to have ISD identified by a Valsalva leak point pressure (VLPP) measurement < 60 cm H₂O with a volume of 150 mL in the bladder or by a maximum urethral closure pressure (MUCP) measurement < 20 cm H₂O with a volume of 200 mL in the bladder. All operations were performed between October 2010 and December 2012 by the same surgeon under spinal anesthesia.

The patients were examined at 3, 6 and 12 months after the surgery and later annually. The primary endpoint of the study was to detect objective cure rate, subjective cure rate, and failure rate through 2-year following SUI surgery. Objective cure was described as having a negative cough stress pad test (CSPT) and measuring a bladder volume of 150 cc or greater. Subjective cure was described when the CSPT was positive but bladder volume is less than 150 cc. The operation was accepted as failure, if incontinence continued. The secondary endpoint was to determine the operation time and postoperative complications. Patients were followed up to 26 months.

Surgical Technique

Women were placed in a dorsal lithotomy position with legs fixed in stirrups. Spinal anesthesia was used in all cases. TOT was performed by using standard outside-in method. A monofilament



Fig. 1. The monofilament tape used in TOT operation

tape (Safyre T, Promedon, Argentina) was utilized (Fig. 1). The tape was inserted in this method starting in the groin, following the obturator foramen and placed in the periurethral space prepared by the surgeon. The mini-sling operation was performed as described by Petros et al. [8]. An adjustable sling (TFS Surgical, Adelaide, Australia) was used for the mini-sling operation.

Statistical Analysis

Shapiro-Wilk's and Levene's tests were used to test the normality and variance homogeneity of the data. Values are expressed as frequencies and percentages, mean ± standard deviation or median and 25th–75th percentiles. To compare parametric continuous variables, Student's *t*-test was used; to compare nonparametric continuous variables, the Mann-Whitney *U*-test was used. Categorical data was compared by Chi-square distribution. Statistical analyses were performed using the statistical package SPSS, v. 15.0 (SPSS Inc., Chicago IL, USA); a value of p < 0.05 was used to define statistical significance.

Results

Sixty nine women were included into the study. Age, body mass index (BMI), parity, duration of SUI, hormon replacement therapy (HRT) status, and birth pattern were similar in both groups (Table 1). Mean hospital stay was shorter in mini-sling group (1.4 day) than TOT group (2.1 day) but, the difference was not statistically significant (p < 0.12). Operation time was significantly lower in mini-sling group than TOT group (11.6 vs. 18.4, p < 0.01). In both groups, there were no bladder injury or wound infection. Two patients in TOT group reported urinary retention (Table 2).

ICIQ-SF scores for the median value decreased from 14 (11–21) preoperatively to 3 (0–9) postoperatively (p < 0.05) in the TOT group, and 15 (12–23) preoperatively to 4 (0–10) postoperatively (p < 0.05) in the mini sling group (Table 3).

TOT and Mini-Sling in SUI 853

Table 1. Characteristics of the patients

	TOT group (n = 56)	Mini-sling group (n = 13)	p
Age (year)	60.2 ± 7.67	58.4 ± 6.91	0.46
BMI	31.2 ± 4.12	30.6 ± 3.95	0.29
Parity	3.01 ± 1.67	2.86 ± 1.44	0.35
Duration of SUI (year)	7.51 ± 2.48	6.89 ± 2.33	0.12
Using HRT (%)	18 (32.1)	4 (30.7)	0.31
Birth pattern vaginal (%) non-vaginal (%)	38 (67.8) 18 (32.2)	8 (61.5) 5 (38.5)	0.57

BMI – body mass index, HRT – hormone replacement therapy.

Table 2. Operative data and postoperative complications

	TOT group (n = 56)	Mini-sling group (n = 13)	p
Operative data			
mean hospital stay (day)	2.1 ± 0.81	1.4 ± 0.52	0.12
operation time (min)	18.41 ± 5.43	11.6 ± 4.21	0.01
bladder injury	0	0	n/a
wound infection	0	0	n/a
urinary retention (%)	2 (3.5%)	0	0.56
Cure rate (%)			
objective cure rate (%)	85.7%	84.6%	0.92
subjective cure rate (%)	5.3%	7.7%	0.48
failure rate (%)	9%	7.7%	0.69

min – minute, n/a – not applicable.

Table 3. Mean ICIQ-SF values of the patients

	TOT group (n = 56)	Mini-sling group (n = 13)	p
ICIQ-SF value			0.05
prepoerative	14 ± 4.5	15 ± 5.6	
postoperative	3 ± 1.1	4 ± 1.3	

Table 4. Patients' cure rates according to the operations

	TOT group (n = 56)	Mini-sling group (n = 13)	p
Objective cure rate (%)	48 (85.7)	11 (84.6)	0.05
Subjective cure rate (%)	3 (5.3)	1 (7.7)	0.48
Failure (%)	5 (9)	1 (7.7)	0.69

The difference in the decrease of the scores between two groups was not statistically significant (p = 0.42). The objective cure rate, subjective cure rate and failure rate in TOT group were 85.7%,

5.3%, and 9%, respectively. The objective cure rate, subjective cure rate and failure rate in mini-sling group were 84.6%, 7.7%, and 7.7%, respectively (Table 4). However, there was no statistically

854 K. Zengin et al.

significant difference between the two groups according to the patients' cure rate.

There was no significant complication to note in the mini-sling group. The two urinary retention patients seen in TOT group which were recovered with three days' long catheterization.

Discussion

In this study, we aimed to compare the efficacy and safety of transobturator adjustable tape (TOT) and mini-sling in female SUI with intrinsic sphincter deficiency (ISD). Our study has shown that both TOT and mini-sling procedures are successful and safe procedures in the treatment of female SUI with ISD. There were no significant differences between groups by means of complications and hospital stay.

In our study, study groups were homogenous. Inclusion and exclusion criteria helped to maintain the equivalence of the groups. The patient population was similar. All the cases were performed under spinal anesthesia with a non-stretch tape. The operation was carried out by the same surgeon. Preoperative and postoperative evaluation was achieved by another person.

Our study suggests that the cure rate was similar at the end of a 2-year follow-up in TOT and mini-sling groups 85.7% vs. 84.6%, respectively. Our results were in contradiction with the study of Sivaslioglu et al. [12]. They reported with their 3-year follow-up study that TFS was superior than TOT in terms of objective cure rate (90% vs. 84%) but the difference was not statistically significant. Two years later, the same authors published their

5-year follow-up data [13]. At the end of five years, they demonstrated that the objective cure rate were 83% and 75% in TFS and TOT groups, respectively. Moreover, this difference was found to be significant (p = 0.029).

Although a lot of theories have been introduced, there is conflict about the real mechanism of SUI. Hammock theory is the most recognized one and based on distal urethral closure. According to this theory, distal urethra is closed like a vaginal hammock to support the continence during straining [14]. TOT is a tension free sling procedure and, since it is first described in 2001 by Delorme, thousands of operations have been achieved all over the world. The most accepted benefits of TOT were not to pass retropubic area like transvaginal tape procedure (TVT), and have a low urge incontinence rate [15]. As well as these advantages, TOT is related with some possible complications. The complications such as bladder injury, vascular injury are due to blind needle passage. Performing a mini sling operation is somehow easier than TOT. Oliveira et al. also mentioned that operative technique is simplier [16]. There is no report about life threatening complications of mini-sling. Although, the operation time was shorter for the mini-sling group in our study, there was no statistically significant difference between the two groups by means of complications.

In our study, both TOT and mini-sling operations were found to be equally effective for the treatment of SUI. In spite of the equivalent efficacy, mini-sling is promising, because of a shorter operation time. Hence, mini-sling operation was first introduced in 2005, large randomized controlled trials comparing TOT and mini-sling are required.

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TOT and Mini-Sling in SUI 855

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