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The Comparison of Short Term Results of Transobturatour Tape and Single Incision Midurethral Sling Procedures

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Abstract

Objectives: We aimed to evaluate the efficacy of transobturator tape (TOT) and single incision mini sling (SIMS) procedures in the treatment of stress urinary incontinence (SUI).

Materials and Methods: The data of 32 patients who underwent TOT(Promedon®) or SIMS (Ophira®) operations related to SUI between January 2010 - August 2012 were retrospectively evaluated. The sample divided in two groups according to the operation type. The demographical features, preoperative, perioperative, and postoperative data were analysed and compared between two groups to evaluate the efficacy of the operations in SUI. All patients were assessed with a detailed history, physcical examination, cough test, Q-tip test, ultrasonography, postvoiding residual measurement, cystometry and UDI-6, IIQ-7 questionares. Postoperatively, the patients without any incontinence on cough test or sistometry were defined as the success.

Results: The parameters of age, menapousal status, number of vaginal delivery, and body mass index were similar in two groups. The mean operation time was significantly shorter in SIMS group (16±3 vs 27±5, $p<0.05$). Postoperative succes was not different between two groups (88% , %80 respectively, $p>0.05$). Postoperative UDI-6 and IIQ-7 scores were 3.5 ± 3.4 vs 3.8 ± 4.8 and 4.4 ± 4.2 vs 5.1 ± 5,6 respectively, and they were similar ($p>0.05$ in both). In addition, the improvement in these scores were not statistically significant between two groups ($p>0.05$ in both).

Conclusion: SIMS procedure is safe and as effective as TOT with shorter operation time in the surgical teratment of female SUI.

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Introduction:

Stress urinary incontinence (SUI) is defined as the leakage of urine without any detrusor contractions, and the pirimary symptom is urine leakage during some actions, such as coughing, that increases the intraabdominal pressure (1). SUI can simultaneously be presented with detrusor overactivity, intrinsic sphincter deficiency (ISD), and/or pelvic organ prolapse. These concomittant disorders make the management of SUI difficult. Since the definition of the integral theory of Petros and Ulmsten, the data of physiopathological mechanism of SUI has increased and continuously improved over the last two decades. The major disorder that causes to SUI is associated with a structural defect in the pelvic structure. Thus the surgical treatment modalities take the greatest place in the management of SUI (2).

Midurethral slings (MUS), which contained 3 different types, have been the mainstay in treatment of SUI over the last decade. Initially, Ulmsten et al. defined transvaginal tape (TVT) operation, which was a prototype, minimally invasive intravaginal suburethral sling operation and accepted worldwide as the standard surgical treatment for SUI (3, 4). Although TVT had reported high cure rate with minimal postoperative pain and residual urine in an acceptable range, severe complications including visceral (bowel) and vessel (iliac vessels) injuries have been described(4, 5, 6, 7). As an alternative to TVT, Delorme created a new MUS technique that was called transobturator tape (TOT). TOT significantly decreased the complications of TVT with an equivalent cure rate (8). Nevertheless, it was not as an effective treatment for ISD, and the blind passage of needles through the obturator foramen might also cause some different complications, such as obturator vessel injury, groin pain, and bladder perforation (7- 9). Some meta-analyses showed that there was no significant difference between the success rates of TVT and TOT (10- 12). Although TOT had low complications rates, the occurrence of limited number of complications leaded to the creation of a recent, more minimally invasive technique, which was initially described in 2006 and most commonly called as single incision mini sling (SIMS). In this technique, a ‘‘suburethral hammock’’ similar to the other techniques is provided by implanting a shorter sling through a small vaginal incision under local anesthesia. This treatment can also be performed in out-patient clinic. Because of its technique, the complications of TOT related to the blind passage of the needle through the obturator foramen can be avoided, thus the morbidity can be decreased (13, 14). In the clincial practice, although different types of SIMSs, such as TVT-Secur and MiniArc, are commonly used, the efficacy of SIMS compared with classical MUS is still contraversial (15- 18).

In the present study, we analysed the short term results of TOT and SIMS applications, and compared the results with the aim of evaluating the efficacy of both techniques in the treatment of SUI.

Material & Methods:

The data of 32 patients who had the diagnosis of SUI and underwent MUS operations including TOT and SIMS between January 2010 - August 2012 were retrospectively evaluated. The sample were divided in two groups according to the surgical procedure. While group 1 included 17 patients who underwent TOT operation (Promedon®) , group 2 contained 15 patients with the surgery of SIMS operation (Ophira®). The patients who were with the diagnosis of pure stress incontinence, had an incontinence surgery icluding TOT (Promedon®) or SIMS (Ophira®), and had no other disorders at urodynamic testing were included in the study. A hystory of previous major pelvic surgiries such as major gynecologic operations, urodynamically proved detrusor overactivity were the exclusion criterias. Previous to the surgery, all patients were assessed with a detailed medical history, physical examination, stress test, Q-type test, urinary ultrasonography, postvoiding residual urine measurement (PVR), cystometry, and UDI-6 and IIQ-7 questionares. All data were recorded.

All patients were preoperatively informed about the procedures. At the operation day, a second generation of cephalosporine was

applied to provide infection prophylaxia (Cephazoline 1 gr, IV infusion). The cases were prepared in lithotomy position under spinal anesthesia. The surgical area was cleaned, and a foley catheter was inserted in. TOT operation was performed as Delorme described (8). Surgical technique of Ophira® mini sling system: A vertical 1-cm lenght vaginal incision was performed at 1 cm from the urethral meatus. Minimal dissection was performed laterally towards the ascending ramus of the ischiopubic bone, preserving the endopelvic fascia. For insertion of the implant, first, the retractable insertion guide is connected to the multipoint fixation arm and is introduced towards the obturator internus muscle, one centimeter above the vaginal fornix, guided by surgeons' index finger. When the centering mark of the implant is slightly underneath the right flap of the vaginal incision, the trigger at the handle is deploid to release in place the fixation arm. The same procedure repeated on the other side. Tape tension adjusted and operation was finished. At postoperative period, foley catheter was removed at postoperative first day. Subsequently, when the urination was realized, the patient was discharged at the same day. The cases of not having any urine leakage at stress test or no pathological findings at urodynamic testing were accepted as the success of the procedure. At the follow up period, PVR measurement was performed at postoperative 1st and 7th days. Subsequently, the analyses of PVR measurement, stress test, cystometry, UDI-6 and IIQ-7 questionnaires were executed at postoperative 1st and 6th moths, and then annually. All data were also collected. The preoperative, perioperative, and postoperative data in two groups were statistically compared. Statistical analyses were performed with SPSS version 18.0, and the data were displayed as mean $\pm$ standard deviation (SD) (range). Mann-Whitney U and chi-square tests were used for statistical comparisons. A 5% level of significance was used for all statistical testing. A p value <0.05 was considered significant.

Results:

We had 17 patients in TOT group and 15 patients in SIMS (Ophira®) group. The two groups were similiar in terms of age, body mass index, number of vaginal delivery, menopausal status, incontinence type, preoperative UDI – 6 and IIQ – 7 scores ($p>0.05$). This data were clearly demonstrated in table 1. (Table 1) Postoperative succes rate was smiliar in two groups, and it was found 88% in TOT group and %80 in SIMS group on 12th month ($p>0.05$). The mean operaton time was significantly shorter in SIMS group (16 ± 3 vs 27 ± 5, $p<0.05$). Postoperative UDI-6 and IIQ-7 scores were determined 3.5 ± 3.4 vs 3.8 ± 4.8 and 4.4 ± 4.2 vs 5.1 ± 5.6, respectively. These results were not significantly different between two groups ($p>0.05$ in both). In addition, the improvement in these scores were also not statistically significant between two groups ($p>0.05$ in both). These findings were shown in table 2. (Table 2) Vaginal lasseration, which was occurred related to the trocar passage and determined in operative period, was detected in 2 patients in only TOT group. These patients were treated by the primary closure of the laseration with 3.0 polyglactin sutures at the same session with TOT. No additional complication was detected in the follow-up period of these patients. Vaginal extrusion was detected in one patient in TOT group during the investigation of dyspareunia at 3rd month of the surgery. It was treated by the trimming of exposed component of the mesh under spinal anesthesia and the primary closure of vaginal wall. Groin pain was occurred in one patient in TOT group, but no objective cause could found in this patient as a result of the neurological consultation. Temporary urinary obstruction was ocurred in 2 patients in TOT group and 1 patient in SIMS group. No additional surgical intervention was required in these patients, and the disorder was treated by just temporary urethral catheterization during following 2-3 days. Postoperative PVR volume and was 60 ± 15 in group 1 and 60 ± 10 ml in group 2, respectively. Postoperative PVR values were similar between two groups ($p> 0.005$). Although, de novo urgency was observed in 4 patients in TOT group and 2 patients in SIMS group, the anticholinergic treatmet

was reiquired only in 2 of these patients. The urgency in other 4 patients was spontaneously improved in the follow-up.

Discussion:

Colposuspension has been considered gold standard intervention in surgical treatment of female stres urinary incontinence for decades. However, after the minimally invasive procedures of TVT and TOT were described more than two decades ago, tension free MUSs replaced colposuspensions (2,4,8). Evolution was not stopped, and the clinicians have been tried to make the procedures more easier and effective with low complications and high patients' pleasure.

The effectiveness of SIMS for female SUI has been contraversial. SIMS were concluded that as effective as the other MUS procedures in female SUI in short term by EAU guidelines with level of evidence 1b (19). In our study, the absolute dryness rate (the success rate) was obtained in 88% in TOT group and 80% in SIMS groups at the 12th month of the follow-up. It was seen that the success rate of two operations were similar. ($p>0.05$) On the other hand, in a recent meta-analysis, Fattah-Abdel et al reported that SIMS were associated with inferior objective and subjective cure rates on the short term follow up and higher re-operation rates in comparison with standart MUS procedures (20). Five of 9 randomised studies regarding TVT-Secur in this metaanalysis showed that early efficacy was reported as low as 60% (21). In a recent prospective randomized, evaluator-blinded, multicenter study authors reported that both subjective and objective cure rates were significantly lower for TVT Secur than for TVT one year after the surgery (22). Similar to our study, Palma et al reported good results with Ophira® that were comparable with the previously reported TOT results in the literature (23). Furthermore, Sereles et al reported that 95% of patients were dry on the basis of subjective and objective assessment with Solyx® single incision system that was performed by transobturatour route at a mean follow-up of 6.5 months (range, 5-8 months) (24).

The primary goal of SIMS procedures was to maintain the support of mid-urethra by using short macroporous polypropylene meshes with various modifications to fixe the meshes to the retropubic tissues, endopelvic fascia or obturator fascia. In Ophira®, there are multiple fixation arms like a pine tree, and this may provide the primary and stable fixation of the sling. In addition, an invivo biomechanical study in Winstar rats showed that Ophira® mini sling system presented the best primary fixation in comparison with TVT Secur®, Tissue fixation system®, Zipper sling®, T device, and type 1 polypropilen mesh as a control at the end of 30 days after the surgery (25). Thus, we supposed that this data might help us to explain why Ophira® mini sling system works better than TVT secur.

The previous literature reported that SIMS had several benefits including decreased operation time, early return to daily activities, and significantly less groin and/or leg pain (20,26). Similiar to the literature, our study revealed that the operation time was significantly lower in SIMS than TOT group (16 ± 3 vs 27 ± 5, $p<0,05$). Groin pain is a potential problem in TOT procedure, and it is more common in inside to outside approach (11). In our study, while only one patient in TOT group was suffered from groin pain, there was no case in SIMS group. Obturator nerve injuries related to the operation have been reported less than 1% in the literature (27,28), a clear etiology of groin pain in this patient could not be determined. Therefore, although it was thouht that it might be associated with neurological condition, no neurological reason was determined by neurological consultation and radiological imaging in this patient.

In the present study, 2 cases of vaginal lasseration were determined in 2 patients in only TOT group, this complication was succesfully managed by the primary closure of the laseration at the same session with TOT. After the treatment, no additional problem was observed in the follow-up period of these patients. Vaginal extrusion that was seen in one patient and treated by removing of exposed part of the mesh and

the primary closure of vaginal wall was the other complication in TOT group. Nevertheless, no complications, such as vaginal extrusion or lasseration, were not observed in SIMS group. Inadequate closure of vaginal wall, infection, mesh rejection and unrecognised vaginal injury during trocar passage were listed for the risk factors of extrusion in the literature (29). In our limited experience in SIMS, we supposed that minimally disection of tissues and short trocar passage lenght might avoid vaginal extrusion related to the vaginal lasseration.

Conclusion :

Although we had a small number of patients and short follow-up period, our findings showed that Ophira® mini sling systems provided a comparable and efficient succes rates with standart TOT procedures. Furthermore, it was determined that SIMS (Ophira®) had also less complication rates and operation time. Therefore, we supposed that SIMS (Ophira®) operation, which was found as effective as TOT, could be used for the treament of SUI in similar effectivity with TOT.

Conflict of interest statement:

The authors declared that they had no financial conflicts of interest or other interests that may influence the manuscript.

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Table 1. Pre operative patients' characteristics and assesments

	TOT (n:17)	SIMS (n:15)	P value
Age[a]	57.7 ± 7.4	52.8 ± 12.5	> 0.05[*]
Body-Mass Index[a]	31.7 ± 4.7	31.1 ± 5.6	> 0.05[*]
Number of vaginal delivery[b]	3 (2-6)	3 (2-6)	> 0.05[*]
	14	11	> 0.05[**]
Post menopause (n)	6	7	> 0.05[**]
Mixt incontinence	8	6	> 0.05[**]
Preoperative UDI 6[a]	15.5 ± 1.4	13.0 ± 1.9	> 0.05[*]
Preoperative IIQ 7[a]	16.6 ± 1.3	14.8 ± 1.8	> 0.05[*]

[*]Mann Whitney U test, [**]chi square test, [a]mean±SD, [b]median (range)

Table 2. Intra / post - operative assesments and complications.

	TOT (n:17)	SIMS (n:15)	P value
Operation time (minute)[a]	27 ± 5	16 ± 3	< 0.05[**]
Postoperative dryness	15	12	< 0.05[*]
Postoperative postvoiding residual volume (ml)	60 ± 15	60 ± 10	> 0.05[**]
Improve of UDI-6 scores[a]	12.0 ± 3.4	8.2 ± 5.3	> 0.05[**]
Improve of IIQ-7 scores[a]	12.1 ± 4.0	8.5 ± 6.2	> 0.05[**]
Postoperative UDI-6 [a]	3.5 ± 3.4	3.8 ± 4.8	> 0.05[**]
Postoperative IIQ-7[a]	4.4 ± 4.2	5.1 ± 5.6	> 0.05[**]
Complications			
Vaginal extrusion	1	-	
Urethral erosion	-	-	
Bladder injury	-	-	
Vaginal laseration	2	-	
Groin/leg pain	1	-	
Urinary obstruction	2	1	
Denove urgency	4	2	

[*]chi square test, [**]Mann-Whitney U test, [a]mean±SD,

References:

1. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U et al. Standard- isation Sub-committee of the International Continence Society. The standardisation of terminology of lower urinary tract dysfunction: report from the Standardization Sub-committee of the International Continence Society. Neurourol Urodyn. 2002;21(2):167-178.

2. Petros PE and Ulmsten UI. An integral theory of female urinary incontinence. Experimental and clinical considerations. Acta Obstet Gynecol Scand Suppl 1990;153:7-31.

3. Fong ED, Nitti VW. Review article: Mid-urethral synthetic slings for female stress urinary incontinence. BJU Int 2010;106(5):596–608.

4. Ulmsten U, Henriksson L, Johnson P, Varhos G: An ambula- tory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 1996;7(2):81-5; discussion 85-6.

5. Ward KL, Hilton P, Browning J. A randomized trial of colposuspension and tension free vaginal tape for primary genuine stress incontinence. BJOG 2008;115:226–33.

6. Nilsson CG, Palva K, Rezapour M, Falconer C. Eleven years prospective follow-up of TVT procedure for treatment of stress urinary incontinence. Int Urogynecol J 2008;19(8):1043–7.

7. Petros PE, Richardson PA. Midurethral Tissue Fixation System sling -- a 'micromethod' for cure of stress incontinence -- pre- liminary report. Aust N Z J Obstet Gynaecol. 2005;45(5):372-5.

8. Delorme E. Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol 2001;11(6):1306-13.

9. Palma P, Riccetto C, Dambros M, Fraga R. Pre pubic sparc: A promising alternative for selected cases of USI. Revista Urología Panamericana. 2003;15(3):19-21.

10. Sung VW, SchleinitzMD,Rardin CR,Ward RM,Myers DL. Comparison of retropubic vs transobturator approach to midurethral slings: a systematic review and meta-analysis. Am J Obstet Gynecol 2007;197(1):3–11.

11. Latthe P, Foon R, Toozs-Hobson P. Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. BJOG 2007;114(5):522–31.

12. Novara G, Artibani W, Barber MD, Chapple CR, Costantini E, Ficarra V et al. Updated systematic review and meta-analysis of the comparative data on colposuspension, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol 2010;58(2): 218–38.

13. Urwin GH, Heaton SR. The MiniArc (TM) single incision sling system for female stress urinary incontinence: early results. BJU Int. 2008;101(1):26.

14. Kennelly M, Moore R, Keil K, Nguyen J, Lukban J. Short term assessment of MiniArc (TM) sling for the treatment of female stress urinary incontinence. Int Urogynecol J. 2008;19:S24.

15. Molden SM, Lucente VR. New minimally invasive slings: TVT Secur. Curr Urol Rep 2008;9(5):358–61.

16. Moore RD, Mitchell GK, Miklos JR. Single center. Retrospective study of the technique, safety, and 12-month efficacy of the MiniArcTM single-incision sling: a new minimally invasive procedure for treatment of female SUI. Surg Technol Int 2009;18:175–81.

17. Meschia M, Barbacini P, Baccichet R, et al. Short-term outcomes with the AjustTM system: a new single incision sling for the treatment of stress urinary incontinence. Int J Urogynaecol 2011;22:177–82.

18. Jiménez Calvo J, Hualde Alfaro A, Raigoso Ortega O, Cebrian Lo- stal JL, Alvarez Bandres S, Jiménez Parra J, et al. Our experience with mini tapes (TVT Secur and MiniArc) in the surgery for stress urinary incontinence. Actas Urol Esp. 2008;32(10): 1013-8.

19. Lucas MG, Bedretdinova D, Bosch JLHR, Burkhard F, Cruz F, Nambiar AK et al. Guidelines on urinary incontinence. Uroweb 2013. Available at: http://www.uroweb.org/gls/pdf/16052013Urinary_Incontinence_LR.pdf

20. Abdel-Fattah M, Ford JA, Lim CP, Madhuvrata P. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: a meta-analysis of effectiveness and complications. Eur Urol. 2011; 60(3): 468-480.

21. Red Alinsod.Recent Advances in Tape Slings for Female Urinary Stress Incontinence Rev Obstet Gynecol. 2009; 2(1):46-50.

22. Andrada Hamer M, Larsson PG, Teleman P, Bergqvist CE, Persson J. One-year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur. Int Urogynecol J. 2013; 24(2):223-229.

23. Palma P, Riccetto C, Bronzatto E, et al. Efficacy of Ophira mini sling system for stress urinary incontinence: midterm follow up of 176 patients in a multicenter international clinical trial. Scientific Programme, 41st Annual Meeting of the International Continence Society (ICS), 29 August - 2 September 2011, Glasgow, UK. Neurourol Urodyn 2011; 30: 830-1, abstract no. 22 Avaliable at: http://www.icsoffice.org/Abstracts/Publish/106/000022.pdf

24. Serels S, Douso M, Short G. Preliminary findings with the Solyx single-incision sling system in female stress urinary incontinence. Int Urogynecol J. 2010;21(5):557-561.

25. Palma P, Siniscalchi RT, Maciel LC, Bigozzi MA, Dal Fabbro I, Riccetto C. Primary fixation of mini slings: a comparative biomechanical study in vivo. Int Braz J Urol. 2012; 38(2):258-266

26. Cox A, Herschorn S, Lee L. Surgical management of female SUI: Is there a gold standard? Nat Rev Urol. 2013;10(2):78-89.

27. Barber MD, Gustilo-Ashby AM, Chen CC, Kaplan P, Paraiso MF, Walters MD. Perioperative complications and adverse events of the MONARC transobturator tape, compared with the tension-free vaginal tape. Am J Obstet Gynecol 2006;195(6):1820 - 1825.

28. Karram MM, Segal JL, Vassallo BJ, Kleeman SD. Complications and untoward effects of the tension-free vaginal tape procedure. Obstet Gynecol 2003;101(5): 929 – 93.

29. Daneshgari F, Kong W, Swartz M. Complications of mid urethral slings: Important outcomes for future clinical trials. J Urol 2008;180(5):1890-1897.