Comparison of Transobturator Tape Surgery Using Commercial and Hand Made Slings in Women with Stress Urinary Incontinence

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Purpose: To compare the complications and success rates of hand-made sling with commercial sling used in transobturator tape (TOT) surgery.

Materials and Methods: From 2008 to 2010, hand-made slings were used in TOT surgery, whereas commercial slings were used from 2010 to 2013 in our clinic. Overall 102 patients were included in the study. Patients were categorized into 2 groups: group 1 had hand-made (polypropylene monofilament) slings, while group 2 had commercial slings (polypropylene monofilament). We retrospectively reviewed 1-year follow-up results of the whole cohort. Ages, body mass indexes, menopausal status, operation time, cost of sling, success of operation and complications were recorded. All these data were compared between the 2 groups.

Results: There were 41 patients (54.29 ± 9.88 years) in group 1 and 61 patients (52.82 ± 9.85 years) in group 2. Menopausal status and body mass index (28.1 vs. 29.2 kg/m^2 respectively) were similar for both groups. Previous history of incontinence or pelvic organ prolapse surgery (P = .046), mean duration of the procedure (P = .001), and vaginal extrusion rate (P = .016) were significantly lower in group 2. The cost of the sling was higher in group 2 than in group 1. There was no significant difference in success of operation between the groups (P = .319).

Conclusion: According to our results, hand-made mesh is a viable option in TOT surgery with similar efficacy, but surgeons should be careful in terms of vaginal extrusion.

Keywords: suburethral slings; urinary incontinence; stress; surgery; treatment outcome; urologic surgical procedures; adverse effects.

INTRODUCTION

Stress urinary incontinence (SUI) is the urine leakage through the urethra resulting from increased abdominal pressure and urethral occlusion mechanism dysfunction in the absence of detrusor muscle contraction.[1] The prevalence of SUI increases with age and reaches 45% at 60 years of age.[2] Since SUI is a common problem, many surgical techniques have been described for management, including conventional open surgeries and minimally invasive techniques that use organic or synthetic materials to support the mid-urethra, known as slings. Suburethral slings have become the preferred technique for the treatment of SUI.[3] In 2001, Delorme[4] described a new method of tension-free mid-urethral tape, referred to as the transobturator tape (TOT), in which the tape is introduced through the obturator foramen and the retropubic space is not violated. With mid-urethral sling techniques, a number of synthetic materials were developed and impressive reductions in surgical morbidity have been achieved. The use of synthetic meshes reduced operating time and eliminated the possibility of morbidity at the autologous graft harvest site.[5] The characteristics of different meshes differ in terms of their fibers, weave, porosity and flexibility. These properties affect tissues response and the capacity for incorporation into the host's tissues or for fighting infection; however, the cost of the meshes used in the TOT procedure is expensive, especially in developing countries.

The objective of this study was to compare low-cost, hand-made polypropylene slings with the more expensive commercial slings in SUI management.

MATERIALS AND METHODS

From 2008 to 2010, hand-made slings (Covidien Ilc, 15 Hamsphire Street, Mansfield, MA, USA) were used in TOT surgeries in our clinic. Commercial slings were used for the same purpose in from 2010 to 2013. A total of 135 patients underwent the TOT procedure during the study period; however, 21 patients were lost during the follow-up and 12 patients did not complete the 12-month follow-up period. The remaining 102 women who underwent TOT surgery with the complaint of pure SUI or mixed SUI in that period were retrospectively evaluated. One-year follow-up data of all patients were recorded. Medical history, demographic characteristics, body mass indexes (BMI), and menopausal status of patients were recorded. Physical examination, urinalysis and urodynamic evaluations were performed on all patients preoperatively.

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Table 1. Demographic and clinical characteristics of patients who underwent sling procedures using hand-made or commercial slings.

Variables	Group 1	Group 2	*P* Value
No. of patients	41	61	_____
Mean age (years) (SD)	54.29 (9.88)	52.82 (9.85)	.537
Mean BMI (kg/m^2) (SD)	28.1 (3.7)	29.2 (4.52)	.210
Mixed UI *	15 (36.6)	17 (27.9)	.237
Pure SUI *	26 (63.4)	44 (72.1)	
Premenopausal *	15 (36.6)	30 (49.2)	.209
Postmenopausal *	26 (63.4)	31 (50.8)	
Previous UI or POP surgery *	11 (26.8)	7 (11.5)	.046
Mean duration of surgery (min)	40.6	30.9	.001

Abbreviations: BMI, body mass index; SD, standard deviation; UI, urinary incontinence; SUI, stress urinary incontinence; POP, pelvic organ prolapse.
* Data are presented as no. (%).

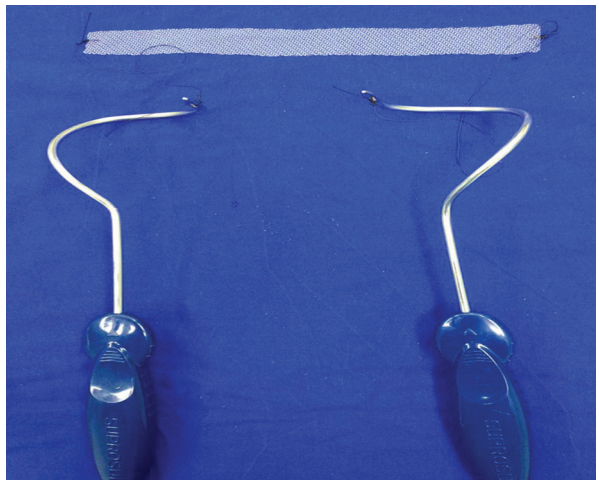

Figure. Demonstration of hand-made sling with two silk sutures and introducers.

Urodynamic analysis was performed as described in the International Continence Society (ICS) guidelines with 2 lumens 8 F urethral catheters, one lumen for infusion of fluid and the other for bladder pressure measurement, and a 4.5 F rectal catheter. The Valsalva maneuver was used to provoke SUI. Patients with confirmed SUI via physical examination and urodynamic studies underwent the TOT procedure. Before the operation, all patients were evaluated with ultrasonography, but none had bladder lithiasis or any other bladder pathology.

Before 2010, commercial slings were not covered by the general health insurance of Turkey. Thus, use of hand-made slings was emphasized in an informed consent form that was routinely received before the operation from all group 1 patients. Placement of the sling to the mid-urethra was done by a single surgeon (CO) in the outside-in manner as described previously by Delorme.[4] As antibiotic prophylaxis, cefazolin (1 gr) was intravenously administered 30 minutes before the procedure. The time taken for the surgical procedure and the cost of slings were also recorded and noted for every patient. Group 1 was treated with a hand-made sling consisting of a polypropylene monofilament mesh measuring 15 cm in width and 30 cm in length. The cost of this sling was 45 US dollars. Initially, we divided this large sling into 15 pieces 1 cm in width and 30 cm in length in sterile condition. We used one piece in the operation and the remaining 14 pieces were packaged separately and re-sterilized using the ethylene technique. Thus, we used a single sling in 15 patients, corresponding to a cost of 3 US dollars per patient in group 1. In contrast, in group 2, the commercial Betamix® BSS Vaginal Tape System (Betatech Medical Corporation, Istanbul, Turkey) (http://www.betatechmedical.com) was used. The cost of this sling was 300 US dollars per patient. Both types were monofilament polypropylene macroporous slings.

We prepared a hand-made sling after passing silk sutures through both edges of the mesh. Other sites of the silk sutures were passed through holes at the end of the introducers (**Figure**). We used specially-designed introducers for group 1. The vaginal mucosa was closed with continuous 2.0 absorbable polyglactin 910 sutures material. The urethral catheters were removed and patients were discharged at postoperative day 1. After removal of urethral catheters, post-void residual volumes were measured in all patients. Less than 100 mL residual urine was accepted as normal and considered as absence of urethral obstruction.

Exclusion criteria included history of major pelvic surgery, radiation therapy to the pelvis, chronic retention, and pure intrinsic sphincter deficiency. Patients with active urinary infections were treated and then included

Table 2. Comparison of complication rates between two study groups.*

Complications	Group 1 (n = 41)	Group 2 (n = 61)	Grade**	*P* Value***
Vaginal extrusion	6 (14.6)	1 (1.6)	Grade 3	.016
Bladder Pprforation	0 (0)	1 (1.6)	Grade 3	.598
De novo urgency	2 (4.9)	0 (0)	Grade 2	.159
UTI	1 (2.4)	2 (3.3)	Grade 2	.647
Obstruction	1 (2.4)	1 (1.6)	Grade 2	.645

Abbreviation: UTI, urinary tract infection.
* Data are presented as no. (%).
** According to Clavien-Dindo classification of surgical complications grade
*** Fisher's exact test.

Table 3. Comparison of operation success rates between two study groups.*

Surgical Outcome	Group 1 (n = 41)	Group 2 (n = 61)	*P* Value
Successful	31 (75.6)	51 (83.6)	.319
Improvement	4 (9.8)	5 (8.2)	.525
Failed	6 (14.6)	5 (8.2)	.304

* Data are presented as no. (%).

in the study. All patients were assessed at the 30th day and 3, 6, and 12 months after surgery. Pre, early post-, and late post-operative complications were recorded. All complications were graded according to the 2004 Clavien–Dindo grading system.[6] The follow-up visit included a detailed medical interview, clinical examination, urine analysis and post-void residual volume determination. At follow-up visits, they were specifically asked about the relief of symptoms for which they underwent surgery. The cure of SUI was defined as no urine leakage at cough test (negative stress test) and not reporting any event of urinary incontinence. Only 1 or 2 episodes of SUI were accepted as relief of symptoms. Patients who did not meet these criteria were considered to have "failed" treatment. At the first follow-up visit, the patients who had negative stress test but had urgency or urge incontinence were treated with anticholinergic treatment for 12 weeks and then re-evaluated in terms of incontinence. We repeated the stress test at the following visit and evaluated in terms of urgency and urge incontinence. Our cure criteria were applied to these patients after that.

Statistical Analysis

All collected data were entered and analyzed using the Statistical Package for the Social Science (SPSS Inc, Chicago, Illinois, USA) version 17.0. The independent sample t-test, Fisher's exact, and chi-squared tests were used. Statistical significance was set at a *P* value < .05.

RESULTS

Retrospective analysis identified 102 patients achieving minimum 12-month follow-up; 41 (40.2%) patients in group 1 and 61 (59.8%) patients in group 2. Mean ages, BMIs, urodynamic proven SUI, and mixed urinary incontinence rates were similar in both groups (**Table 1**). Overall, 32 (31.4%) patients had urodynamic proven mixed type incontinence, whereas, at follow-up, 24 (23.5%) patients had urge incontinence and needed anticholinergic treatment (*P* = .027). There was a significant decrease in terms of overactive bladder symptoms, which did not depend on the type of sling used (*P* = .570).

There was no significant difference between the groups regarding menopausal status. Mean operative time was higher in group 1. Medical history of incontinence or pelvic organ prolapse surgery (POP) was significantly higher in group 2 (**Table 1**).

Bladder perforation was seen in only one patient and, after closure of the bladder, we performed the obturator sling procedure. Her urethral catheter was removed at postoperative day 7. There was a need for urethral catheter post-surgery due to obstruction in 2 patients, 1 in group 1 and the other in group 2. After 2 weeks, catheters were removed and were no longer required.

Vaginal extrusion occurred more often in group 1 than in group 2 (**Table 2**). Overall, the vaginal extrusion rate was 6.8% (n = 7) and all were seen in the first 6 months of follow-up. All patients were treated initially with topical estrogen cream and then with partial removal of the extruded sling. Even with partial removal of the sling and re-approximation of the vaginal mucosa, continence was maintained in 6 patients, all of which were in group 1; however, the patient in group 2 was incontinent before and after partial removal of the sling. De novo urgency and urinary tract infection (UTI) occurred in 2 and 3 patients, respectively without statistically significance, all of them were managed successfully with conservative treatments. There was not any other early or late postoperative complication. All complications are summarized in **Table 2**.

We accepted no episode of incontinence as success of the operation. Partial improvement was defined as 1 or 2 episodes of incontinence per day. At the end of the study, there was no significant difference between the groups in terms of success of operation (*P* = .319) (**Table 3**). Furthermore, we achieved the same result among patients with pure stress incontinence after exclusion of 32 patients (15 in group 1, 17 in group 2) who had mixed-type incontinence (*P* = .477).

DISCUSSION

Sub-urethral synthetic slings, like TOT, have been described as the most popular surgery for management of female SUI.[7] Some types of materials, such as alloplastic, autologous and synthetic, were described as sub-urethral slings.[3] Natalin and colleagues compared the autologous and synthetic sling materials in terms of success rate and bladder outlet obstruction;[8] the authors found similar success rates for both sling materials, though, bladder outlet obstruction was common in the autologous sling group. Mustafa and Wadie defined a new technique for placement of an in situ anterior vaginal wall sling in 11 patients.[9] The authors used this autologous sling with a good success rate and low incidence of complications. The perfect graft material has not yet been created. Polypropylene, monofilament mesh with a large pore size (Type 1 mesh) is the ideal mesh for the sling procedures.[10] Both types of slings that we used in the procedures were Type 1. Synthetic sling materials are commonly used in the treatment of SUI, but synthetic sling materials are much more expensive and increase the cost of surgery. In this study, we used 2 types of synthetic slings; low-cost hand-made slings and expensive commercial slings to support the mid-urethra for the management of SUI.

Rechberger and colleagues reported that successful surgical SUI management did not depend on the BMIs of patients.[11] In contrast, age and menopausal status affected the success rate of operation. They found that TOT surgery appears to be more effective in premenopausal women than in postmenopausal. They also reported that age has an unfavorable effect on the

success of the operation. In our study, there was not a statistically significant difference between the 2 groups in terms of age, menopausal status, or BMI of patients; these data were similar for the 2 groups.

In the literature, mean operative time ranged from 16-51 minutes.[12,13] Our operation time was measured from the opening to the closing of the vaginal wall. There was a significantly shorter operative time in group 2, likely due to the time spent preparing the hand-made sling. On the other hand, operation times of both groups were in the range described in the literature.

Although bladder perforation is a common complication that is seen in tension-free vaginal tape (TVT), the TOT technique reduces this risk by avoiding violation of the retropubic space. However, needles may injure the bladder. In the literature, bladder perforation during the TOT procedure was between 0-1.52%.[14,15] Abdel-Fettah and colleagues compared the outside-in (n = 241) and inside-out techniques (n = 148) in terms of bladder and urethral injuries.[16] They reported 2 (0.5%) bladder and 2 (0.5%) urethral injuries, all of which were outside-in TOT group with no significant difference between techniques. We report only 1 (0.9%) case of bladder perforation during the procedure without significance between the groups. In terms of postoperative complications, de novo urgency and UTI were seen in 3 and 2 patients, respectively, without statistically significance. It is known that the TOT procedure results in high chronic groin pain,[17] however, none of our patients complained of chronic groin pain at the end of the follow-up.

Vaginal extrusion refers to fnding exposed sling material in the vaginal canal postoperatively. Conservative treatment, including the application of topical estrogen creams, may manage the small extrusions; however, larger extrusions should be managed with removal of all infected materials and re-approximation of the vaginal mucosa with a combination of appropriate antibiotics. Some patients with large extrusions may benefit from excision and removal of the extruded portion of the sling and closure of the vaginal wall. Reported rates of vaginal mesh extrusion change from 0 to 13.8% in transobturator slings.[18,19] Our overall vaginal extrusion rate is (6.8%) in the acceptable range in the literature. The vaginal extrusion rate was significantly high in the hand-made group. Ignjatovic and colleagues used self-created and commercial slings in 67 and 47 patients, respectively.[20] They reported vaginal extrusion in 1.4% and 4.2% of the self-created and commercial groups, respectively. Brito and colleagues used hand-made slings in 19 patients and commercial slings in 20 patients.[13] They did not observe any evidence of erosion of the urinary system or vaginal extrusion. However, they used the TVT technique, in contrast to us. Long and colleagues reported that the vaginal extrusion rate is higher in the TOT procedure compared with TVT, but it was not statistically significant.[17] Furthermore, it does not explain the higher vaginal extrusion rate of the hand-made group compared with the commercial group in our study. Aside from this, we did not see any urethral or bladder erosion of the sling. Overall, our success rate was 80.4% (n = 82). Patients had no episode of incontinence after the procedure until the last follow-up visit. There was no difference between the hand-made and commercial groups in success rate. Furthermore, the study that compared the hand-made and commercial slings reported that success rate does not depend on the type of sling used.[13] In our study, we confirmed the results of Brito and colleagues. The main different outcome of these 2 studies was the vaginal extrusion rate. They did not report any case of vaginal extrusion, whereas we found 7 cases, which was significantly high, in the hand-made group. Furthermore, we did not clarify any complication after the 6th month of follow-up; all vaginal extrusions were seen in the first 6-month period after the procedure. It was most likely the result of re-sterilization of hand-made slings. The other most probable cause might be the significantly high medical history of previous incontinence or POP surgery in group 1. Extrusion of material may also be related to infection or the physical properties of the implanted material. Nevertheless, no additional factors could be established as the reason for higher vaginal extrusion in the hand-made group.

More recently, a study was performed to compare self-cutting slings (n = 67) with commercial slings (n = 47).[20] In this prospective study, the authors compared the two groups and concluded that self-cut slings do not have inferior results in terms of success rate and complication rate. We confirmed this result in our retrospective study. Our results also support the use of hand-made slings with a similar success rate to commercially-available slings. The main difference between the 2 studies is the vaginal extrusion rate. Although other complications were statistically similar between the 2 groups, vaginal extrusion was higher in the hand-made group in the present study.

The present study is not free of limitations. The main limitation in our study was the low number of patients in both groups. The retrospective character of the present study was another limitation. Another limitation was the high number of mixed UI in whole cohort; however, after exclusion of the 32 patients who had mixed UI, the difference in success rates between the 2 groups remained insignificant. On the other hand, we only evaluated the 1-year follow-up result of our study, but the 1-year follow-up period may be short to make a final comparison.

CONCLUSION

In conclusion, use of hand-made slings is a reasonable option in the management of SUI. However, hand-made slings' cost may increase when the cost of erosions and sterilization are added, leading to underestimation of the cost for group 1. In addition, physicians should be careful, in terms of vaginal extrusion, when they use hand-made slings. Significant vaginal extrusion necessitates an evaluation of the medicolegal aspects of hand-made slings. Further studies with a larger number of patients and long-term follow-up results should be carried out to elucidate these results.

CONFLICT OF INTEREST

None declared.

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