

SUCCESS OF CUSTOMMADE TRANSOBTURATOR SLINGS PREPARED FROM CONVENTIONAL POLYPROPYLENE MESH IN THE TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN

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Abstract:

Objective: To observe the outcome of the transobturator tape, using custommade slings prepared from conventional polypropylene mesh in women in management of SUI.

Materials and Methods: This prospective observational study was carried out from June 2010 to April 2015 among 35 patients who underwent the TOT procedure using handmade (polypropylene monofilament) slings; and complete at least the 12 month follow up period. Medical history, demographic characteristics, body mass indexes (BMI), menopausal status of patients, operation time, cost of sling, success of operation and complications were recorded. Before the operation, all patients were confirmed SUI through physical examination, urinalysis, urodynamic studies and ultrasonography. Placement of the sling to the midurethra was done in manner as described by Delorme. All the data were analyzed.

Results: There were 35 patients with mean age 51.23 ± 5.63 years, BMI 26.14 ± 3.70 kg/m². Twenty of the patients post were menopausal. The cost of the sling was 1200 BDT (15 USD). The success rate of TOT 12 months after surgery and at the last follow up was 91.5% and 88.6% respectively. Postoperative obstruction was noted in 2 patients, vaginal extrusion occurred in one case, de novo urgency and urinary tract infection (UTI) occurred in 2 patients. All of them were managed successfully with conservative treatments. There was no other early or late postoperative complication. There was significant improvement of the QoL and statistically no significant decrease in the Q max during the follow up period.

Conclusion: Custommade mesh is a reasonable option in TOT surgery with good efficacy and cost effectiveness and complication like vaginal extrusion is also minimum.

Keywords: Suburethral slings; Stress urinary incontinence; Treatment outcome; Urologic surgical procedures; Adverse effects.

Bangladesh J. Urol. 2015; 18(2): 49-55

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]. SUI has a significant impact on the quality of life for many

women, although estimates of prevalence vary widely due to inconsistencies in the definitions of SUI and differences in populations' studied[2]. The prevalence of SUI increases with age and reaches 45% at 60 years of age[3].

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

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materials to support the mid-urethra, known as slings. Suburethral slings have become the preferred technique for the treatment of SUI[4]. In 2001, Delorme[5] 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. The published data reported the TOT success rate ranging from 80.5% to 96%[6]. 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[7]. The characteristics of different meshes differ in terms of their fibers, weave, porosity and flexibility. These properties affect tissue 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 like Bangladesh. The objective of this study was to observe the success, complications and tolerance of the transobturator tape using handmade slings prepared from conventional polypropylene mesh in women in management of SUI.

Materials and Methods

This was a prospective observational study among the Bangladeshi patients from June 2010 to April 2015. A total of 35 patients underwent the TOT procedure during the study period and complete at least 12 months follow up. Medical history, demographic characteristics, body mass indexes (BMI), and menopausal status of patients were recorded. Before the operation, all patients were confirmed as SUI via physical examination, urinalysis, urodynamic studies along with ultrasonography. Urodynamic analysis was performed as described in the International Continence Society (ICS) guidelines. Use of handmade slings was accepted by all patients plotted in informed consent forms taken before the operation. Placement of the sling to the mid-urethra was done by a single surgeon under spinal anaesthesia in the 'outside in' manner as described previously by Delorme.⁵ Ceftriaxone (1 gm) and gentamycin (80 mg) were administered intravenously 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. All patients were treated with a custommade sling consisting of a polypropylene monofilament mesh measuring 1.5 cm in width and 15 cm in length. The cost of this sling was 1200 BDT (15 US dollars). In contrast, the commercial Betamix® BSS

Vaginal Tape System cost was 27,000 BDT (350 US dollars). Both types were monofilament polypropylene macroporous slings. We prepared a custommade sling after passing 1/0 polypropylene thread through both edges of the mesh that makes it 35 cm in length approximately. Other sites of the 1/0 polypropylene thread were passed through holes at the end of the TOT needle (Figure).

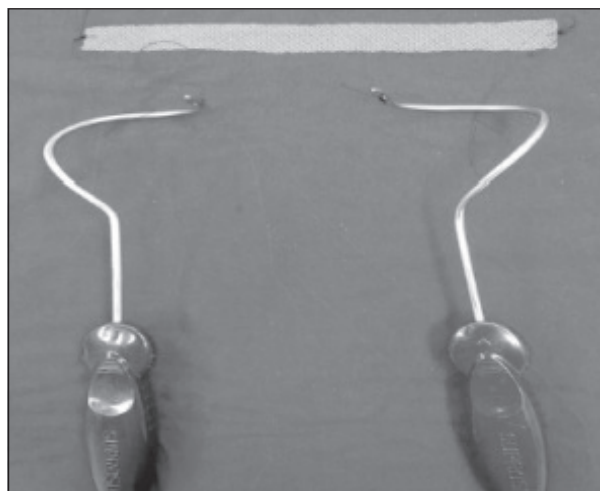


Figure: Demonstration of handmade sling with two polypropylene thread and TOT needle.

The vaginal mucosa was closed with absorbable 2/0 polyglactin interrupted sutures, followed by vaginal packing. The urethral catheters were removed and patients were discharged at 2nd postoperative day. 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. All patients were given extensive advice at the time of discharge which specifically stressed to avoid squatting and intercourse for 4 weeks. 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 in the study. All patients were assessed at 3, 6, and 12 months then yearly after surgery. Pre, early post, and late post operative complications were recorded. All complications were graded according to the 2004 Clavien– Dindo grading system[8]. Quality-of-life (QOL) of the studied patients was assessed according to QOL questionnaire by McConnell 1994 (appendix). The follow up visit included a detailed medical interview, clinical examination, urine analysis, uroflowmetry 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 improvement 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. Then the criteria of cure were applied to these patients.

All collected data were entered and analyzed using the Statistical Package for the Social Science (SPSS Inc, Chicago, Illinois, USA) version 20.0. The independent sample t-test, Fisher’s exact, and chi-squared tests were used. Statistical significance was set at a P value < 0.05.

Results:

This prospective study included 35 patients achieving minimum 12 months follow up. Mean age, BMI, menopausal status and duration of surgery is demonstrated in Table-I.

Table-I

Demographic and clinical characteristics of patients who underwent TOT procedures using handmade slings

Variables	N
Mean age (years) ±SD*	51.23±5.63
Mean BMI* (kg/m2) ±SD*	26.14±3.70
Premenopausal *	15
Postmenopausal *	20
Mean duration of surgery (min)	40.6

* BMI, body mass index; SD, standard deviation;

Table-III

Patient’s quality-of-life (QOL)

	Quality of life	Paired t test		
	Range	Mean±SD	t	p value
Preoperative	4-6	5.6±.604	Comparison with preoperative	
After 12 months	0-2	0.23±.547	34.911	0.000
At the last FU	0-2	0.29±.572	34.931	0.000

SD: Standard deviation,

The success rate of TOT after 12 months postoperatively and at the last follow up (FU) was 91.5% and 88.6% respectively. We accepted no episode of incontinence as success of the operation. Improved 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 =0 .939) (Table-II).

Table-II

The success rate of the procedure at 12 months and at the last follow up

	Success rate (%)		Chi-square	
	12 months	at the last FU	χ ²	P value
Cured	32 (91.5%)	31 (88.6%)	0.124	0.939
Improved	03 (08.6%)	03 (08.6%)		
Failed	0 (0%)	01 (02.9%)		

FU, follow up;

There was a need for urethral re-catheter postoperatively in 2 patients. After 1 week, catheters were removed and were no longer required. Vaginal extrusion occurred in one case and was treated with partial removal of the sling and re-approximation of the vaginal mucosa; continence was maintained. *De novo* urgency and urinary tract infection (UTI) occurred in 2 patients, all of them were managed successfully with conservative treatments. There was no other early or late postoperative complication.

Table-III compares the QOL of the studied patient preoperatively, 12 months postoperatively and at the last follow up showing significant and sustainable improvement of the QOL.

Uroflowmetry was performed in all patients that show no statistically significant decrease in the Q max during the follow up shown in Table IV.

Table-IV
Evaluation of maximal flow rate

	Q max (ml/sec)	Paired <i>t</i> test		
	Range	Mean±SD	<i>t</i>	<i>p</i> value
Preoperative	23 – 36	29.37±3.144	Comparison with preoperative	
After 12 months	21 – 33	28.17±2.864	2.550	0.015
At the last FU	20 – 31	24.17±3.129	9.135	0.000

Appendix
Quality of life questionnaire

Delighted	Pleased	Mostly satisfied	Mixed (satisfied and un satisfied)	Mostly dissatisfied	Unappy	Terrible
0	1	2	3	3	5	6

If you were to spend the rest of your life with your urinary condition just the way it is now, would you feel about that ?

Discussion:

The main goal of the surgical treatment of SUI is to restore a perfect continence with minimal morbidity. Sub-urethral synthetic slings, like TOT, have been described as the most popular surgery for management of female SUI[9]. Some types of materials, such as alloplastic, autologous and synthetic, were described as sub-urethral slings[4]. Natalin and colleagues compared the autologous and synthetic sling materials in terms of success rate and bladder outlet obstruction;[10] 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[11]. 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[12]. 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 low cost handmade polypropylene, monofilament mesh 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[13]. 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 in terms of age, menopausal status, or BMI of patients. In the literature, mean operative time ranged from 16-51 minutes[14-15]. Our operation time was measured from the opening to the closing of the vaginal wall, it were in the range described in the literature but commercially available sling placement could be of shorter duration due to the time spent preparing the hand-made sling in our study.

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%[16,17]. Abdel-Fettah and colleagues compared the outside-in (n = 241) and inside-out techniques (n = 148) in terms of bladder and urethral injuries[18]. 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 none of bladder perforation during the procedure. In the present study, 2 (5.7%) patient developed postoperative urinary retention. There was no significant difference in the mean Q max and postvoid residual urine measured preoperatively, at

12 months postoperatively and at the last follow up (58 months). In the study done by Cheng and Liu, they concluded that the severity of obstructive symptoms and postvoid residual volumes at 5 years were not improved compared with 1 year after the procedure ($P = 0.10$ and $P = 0.33$ respectively)[19]. Morey *et al.* stated that the position of the transobturator sling replaces the damaged pubourethral ligament with a permanent mesh tape that provides the support needed to prevent leakage. The angle of the TOT sling is much less acute than TVT, therefore not only is this more anatomic and natural, it also makes sense that there are fewer problems with urinary dysfunction such as urinary obstruction[20].

In terms of postoperative complications, *de novo* urgency and UTI were seen in one patient, without statistically significance. It is known that the TOT procedure results in high chronic groin pain[21], however, none of our patients complained of chronic groin pain in the follow up. Vaginal extrusion refers to finding 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[22-23]. Our vaginal extrusion is only one (2.9%) in the acceptable range in the literature. Ignjatovic and colleagues used self-created and commercial slings in 67 and 47 patients, respectively[24]. They reported vaginal extrusion in 1.4% and 4.2% of the self-created and commercial groups, respectively. Brito and colleagues used handmade slings in 19 patients and commercial slings in 20 patients[25]. 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[21]. Aside from this, we did not see any urethral or bladder erosion of the sling.

Overall, our success rate was 88.6% ($n = 35$). Patients had no episode of incontinence after the procedure until the last follow up visit. Furthermore, the study that compared the handmade and commercial slings reported

that success rate does not depend on the type of sling used[15]. In our study, we confirmed the results of Brito and colleagues. The main difference in outcome of these 2 studies was the vaginal extrusion rate. They did not report any case of vaginal extrusion, whereas we found one in the handmade sling. Furthermore, we did not clarify any complication after the 6th month of follow up; the vaginal extrusion was seen in the first 12 month period after the procedure. The most probable cause might be the significantly high medical history of previous incontinence. 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 handmade sling. Our results also support the use of handmade slings with a similar success rate to commercially available slings.

In the present study, there is a significant improvement in the QOL score among the treated patients during the early and late follow-up, which is comparable to studies done by Schierlitz et al. and Ballester et al.[25,26] Furthermore Cheng and Liu in their study on 103 women with SUI treated with TOT found that, incontinence severity degree and QOL scale scores were largely improved after the operation ($P < 0.001$) while no difference was found between years 1 and 5 ($P = 0.11$ and $P = 0.09$ respectively).[19]

The present study is not free of limitations. The main limitation in our study was the low number of patients.

Conclusion:

Use of custommade slings is a reasonable option in the management of SUI. However, custommade slings' cost may increase when the cost of erosions are added. But in developing countries careful application of the sling in expert hand can minimize erosion and other complications of the procedure and may be recommended as an acceptable approach in management of large number of SUI patients. Further studies with the larger number of patients and long-term follow up should be carried out for elucidation of the results and standardization of the procedure.

Conflict of Interest: None declared

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Abbreviation:

QoL : Quality of Life

SUI : Stress Urinary incontinence

TOT: Transobturator tape

TVT : Tension free vaginal trape