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Transvaginal subfascial synthetic sling – "A novel technique" versus trans-obturator mid-urethral sling in female stress urinary incontinence: A comparative study

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Abstract

Background: To assess the treatment outcome and overall efficacy of the novel technique of a *transvaginal subfascial synthetic sling (TVSS)* in comparison to the standard trans-obturator tape (TOT-O) mid-urethral sling for female stress urinary incontinence (SUI).

Materials and methods: The study included 206 female SUI patients managed at our institution between March 2015 and December 2019. The patients were randomly distributed into 2 comparable groups (Group A as TOT-O and Group B as TVSS) with respect to age, trouble due to SUI assessed with respect to degree of incontinence (number of episodes and diapers used per day), and body mass index ($\leq$40 kg/m^2), with 100 patients in the TOT-O group as group A and 106 patients in TVSS as group B. Preoperative variables related to the number of incontinent episodes and diapers usage were equal in both groups. The procedure was done under spinal anesthesia and results were assessed in terms of improvement in SUI as the primary outcome, any sexual dysfunction, complications, and overall satisfaction as secondary outcomes.

Results: Symptomatic improvement after the procedure was seen in all patients with complete resolution of symptoms in 91 patients (91.%) in the TOT-O group (group A) versus 96 patients (90.56%) in the TVSS (group B). Postoperative complications included urinary retention in 6% versus 5.6%, increased day time urinary frequency in 8% versus 6.6%, urge incontinence in 4% versus 2.8%, and groin/thigh pain in 12% versus 0.9%, respectively. Mesh incision was done in 1 (1%) versus none (0%), and local mesh excision for mesh erosion in 2 (2%) versus 1 (0.9%) at 3 months after the procedure in the TOT-O group and the TVSS group, respectively. The *p* value and Chi-Square test with respect to the clinical profile and satisfaction with respect to complete resolution of symptoms was calculated using Open EPI software which were insignificant. Sexual function (SF) was assessed using the Brief Index of SF for Women questionnaire. All the patients were satisfied with respect to SF at 6 months of follow-up.

Conclusions: The *TVSS* as a novel technique for female SUI is less invasive, simpler to learn, with less postoperative pain with resolution of SUI, rapid recovery, and good personal satisfaction compared to the standard TOT-O in procedure.

Keywords: Stress urinary incontinence; *Trans-obturator tape "outside-in"*; *Transvaginal subfascial sling*; Voiding dysfunction

1. Introduction

Stress urinary incontinence (SUI) is a disease that is closely related to the quality of life. The mid-urethral sling operations as retropubic tension-free vaginal tape (TVT) were reported by Ulmsten and Petros[1] and the trans-obturator tape (TOT) by Delorme.[2] The pathogenic factors for SUI include age, body mass index (BMI), menopause, and it is also closely related to the number of child births and life style.[3] The International Continence Society defines SUI as the complaint of involuntary urine leakage with effort, exertion, sneezing, or coughing resulting from hypermobility of the urethra and functional insufficiency of the urethral sphincter.[4] The mid-urethral sling operations became the most popular procedures and showed exponential growth in many cases. This operation is still evolving in materials and techniques.[5] Theoretically, the mid-urethral sling involves a suburethral support mechanism.[6,7] These procedures produce dynamic urethral compression under stress.[5] Failures are as low as 5.7% for the trans-obturator and 7.8% for the retropubic procedures. Perioperative complications are only 0.8% for trans-obturator and 5.5% for retropubic procedures.[8] TOT involve the risk of groin and leg pain. Even though tension-free TVT and TVT-O/TOT have similar efficiency, many patients choose TVT to avoid leg and groin pain.

The idea of the "*Transvaginal Subfasial Sling (TVSS)*" as a novel technique for resolution of SUI was conceived, as in our few initial cases the TOT needle had inadvertently became superficial to the Ischiopubic Rami which we came to know after doing perineum ultrasonography in patients who presented with groin discomfort, which revealed that the mesh was lying superficial to

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the obturator membrane not piercing the obturator foramen. On follow-up groin discomfort was settled by conservative treatment, along with complete resolution of SUI.

This technique for treatment of SUI has not been reported in the literature. Using the technique and principles of the "standard trans-obturator outside-in" we describe a new, simple, minimally invasive, easy to learn technique which we term the *"Transvaginal Subfasial Sling (TVSS)."* In order to determine the efficacy and outcome of TVSS with respect to continence and perioperative complication, a comparative study between TVT and TVSS was carried out at our center.

2. Materials and methods

2.1. Sample size

For a margin of error at 10% and confidence level of the study at 90%, a minimum of 59 patients (calculated using Raosoft sample size calculator and based on similar previous studies that reported 4–35%) will be diagnosed with SUI were required for the study. Sample size justification: the study used (Brawley et al., 2012).[9]

2.2. Formula for calculating the sample size

$$n = z^2 \times p(1-p)/e^2$$

where **n** is sample size, **z** is the z score, **e** is the margin of error, and **p** is the population proportion.

$$n = (1.64 \times 1.64) \times (0.35 \times [1-0.35])/(0.1 \times 0.1) = 58.24$$

The total number of patients who were qualified for the below mentioned inclusion criteria with at least 6 months of follow-up until the end of study were taken for this study.

2.3. Inclusion criteria

(1) All patients with SUI;
(2) Patients with mixed urinary incontinence only after urgency incontinence was settled with medical therapy;
(3) BMI $\leq 40\,kg/m^2$.

2.4. Exclusion criteria

(1) Patients with mixed urinary incontinence with predominant urgency incontinence;
(2) BMI $\geq 40\,kg/m^2$;
(3) Patients with concomitant pelvic organ prolapse;
(4) Patients who had a low-pressure and a low-mobility urethra were excluded from the study.

2.5. Patients and ethical elements

The Ethics Committee of the hospital approved the study with the Ethical approval number of IEC SKIMS 75U, and all patients provided written informed consent for participation in the study. Registration in the clinical trials registry sites was not done.

The study included 206 female patients with SUI managed at our institution between March 2015 and December 2019. The preoperative evaluation included a detailed history, baseline investigations (complete blood count, kidney function test, liver function test, urine examination, and urine culture), cystoscopic examination and stress test, and uroflometry with an estimation of residual urine was done in all cases to assess for the flow pattern pre- and postoperatively. The stress test was done lying down during bladder filling for cystoscopic examination. Additionally, patient subjective feeling of leakage of urine on stress maneuvers with daily use of diapers was considered. All patients had a positive stress test. Lower urinary tract imaging (ultrasonography with postvoid residual urine [PVRU] estimation) and urodynamic evaluation were done in selected cases (especially in those patients with predominant urge incontinence and doubtful history). Patients with concomitant pelvic organ prolapse which was assessed by a gynaecologist[10] and those with urodynamic study documented detrusor over activity were excluded from the study. The urethral catheter was removed on the 1st postoperative day in the hospital and both groups were assessed for the continence and the patients were counselled. Postprocedure results were assessed in terms of improvement/resolution of stress incontinence by performing a stress test (standing) in both groups, pain was assessed using a visual analogue scale, any other complication, and overall satisfaction in terms of continence of patients in both groups. Follow-up evaluations were done at 1, 3, 6, and 12 months postoperatively in both groups. On each follow-up, the history regarding improvement in urinary continence, any postoperative pain, and sexual dysfunction were determined.[10,11] The stress test was performed in both groups. All patients underwent uroflometry and ultrasonography for residual urine at the 1 month follow-up.

2.6. Surgical technique

All procedures were performed under spinal anesthesia. The patient was placed in the dorsal lithotomy position. The lower abdomen and genitalia were prepared with diluted Savlon and betadine and drapped in a sterile fashion. A 16 Fr Foley's catheter was placed in the urethra, and the mid-urethra was identified. The safe entry point for the TOT needle is the intersection point of the perpendicular line from the insertion of Adductor longus and the horizontal line from tip of the clitoris as for standard TOT (Fig. 1). The point at which these lines intersect corresponds to the entry of the TOT needle. An Allis clamp was used to grasp the anterior vaginal wall and a 2-cm vertical incision was made 1 cm proximal to the external urethral meatus. A suburethral tunnel was created in the anterior vaginal wall after hydrodissection.

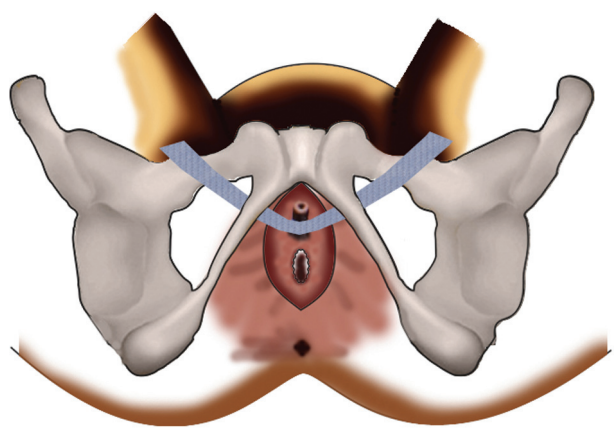

Figure 1. Diagrammatic representation of standard TOT-O outside-in procedure through the obturator membrane (bilateral thin arrows piercing through the obturator membrane and thick white arrows pointing to the Ischiopubic Rami). TOT = trans-obturator tape.

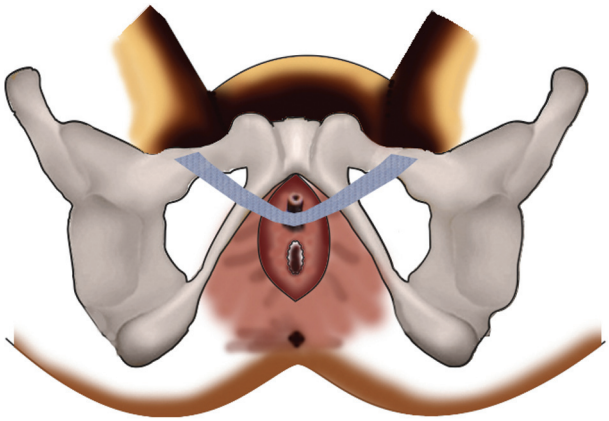

Figure 2. Diagrammatic representation of the TVSS superficial to the Ischiopubic Rami (bilateral thin arrows not piercing the obturator membrane and superfascia thick white arrows pointing to Ischiopubic Rami).

The Ischiopubic Ramus was felt with the index finger. Standard TOT surgery begins with dissection in the vesicovaginal space. This dissection is carried out lateral to the urethra until the inferior border of the Ischiopubic Rami and Pubic symphysis can be easily palpated. Normally in the standard TOT-O procedure, a trocar must traverse the obturator internus muscle, obturator membrane, and obturator externus muscle as it goes through the obturator foramen. Lateral to the obturator foramen are the adductor muscles (gracilis and adductor brevis muscles) of the thigh (Corton, 2013),[12] while in TVSS, the needle device is introduced from the outside with a finger acting as a guide so that the tip of needle passes superficial to the corresponding Ischiopubic Ramus (Fig. 2). The tip of the TOT needle is brought out through the incision in the vaginal wall and the thread of 1 end of the synthetic mesh is fed through the eye of the TOT needle and then the needle is withdrawn through the same superficial path to the Ischiopubic Rami to the original incision in the groin, and the procedure is repeated on the other side. There is no difference in the instruments and mesh material used in this procedure and they are the same as those used in TOT (helical needle passer and polypropylene mesh). A 2 cm × 39.8 cm nonabsorbable undyed monofilament polypropylene mesh sling was used in our study. The sling was adjusted with scissors so that it would lie under the mid-urethra with minimal tension. As the procedures were performed under spinal anesthesia, the patients were instructed to strain by coughing after filling the bladder with 300 mL saline to determine whether the tightness of the sling needed adjustment. Both ends of the sling were cut beneath the skin incision in the groin. The anterior vaginal wall incision was closed using vicryl 4–0 sutures. Sterile dressings were applied on skin incisions in the groin. Betadine soaked gauze was kept in the vagina.

2.7. Postoperative care

Patients were instructed to spontaneously void after catheter removal and use betadine vaginal pessaries for 1 week. All patients were discharged on the 1st postoperative day with PVRU estimation. Patients who could not void and those with PVRU of more than 100 mL were taught selfcleaning intermittent catheterization before being discharged. Patients were advised to start normal daily routine activities after discharge from the hospital, maintain local hygiene, avoid straining, lifting heavy weights for 3 to 4 weeks, and avoiding sexual activity for 4 to 6 weeks postoperatively. Patients with prior urgency were advised to take anticholinergics for 3 months postoperatively.

3. Results

The study included 206 female SUI patients managed at our institution between March 2015 and December 2019. The study was a nonblinded study and patients were randomly distributed into 2 groups using a simple randomization technique.[13] Group A included 100 patients in which TOT was done and group B included 106 patients in which TVSS was performed. Both groups were comparable with respect to age, degree of SUI, trouble due to SUI assessed with respect to degree of incontinence, and BMI ($\leq$40 kg/m^2). Patients with a BMI $\geq$ 40 kg/m^2 were advised to follow a weight reduction program and were included in the study only when the BMI was $\leq$40 kg/m^2, and those patients who had a low-pressure and a low-mobility urethra were excluded from the study.

The mean age of the patients was 43.5 years (Table 1). All patients were multiparous. The mean operative time was 34 minutes (30–45 minutes) in the TOT group and 28 minutes (25–30 minutes) in the TVSS group and the mean follow-up was 12 months in both groups. Symptomatic improvement (Table 2) after the procedure was seen in all patients in both groups with complete resolution of symptoms (subjective and objective improvement) in 91 patients (91.0%) in the TOT group versus 96 patients (90.56%) in the TVSS group. Objective improvement was assessed by a stress test lying down and standing. Eight patients (8%) in the TOT group and 10 (9.4%) in the TVSS group had some degree of SUI. Postoperative complications (Table 2) included urinary retention in 6 (6%) versus 6 (5.6%), increased day time frequency of urination in 8 (8%) versus 7 (6.6%) patients, urge incontinence in 4 (4%) versus 3 (2.8%) patients, groin/thigh pain in 12 (10%) versus 1 (0.9%), mesh incision in 1

Table 1

Clinical profile of the patients (n = 206).

Age in years	Group A (TOT, n = 100)	Group B (TVSS, n = 106)	*p* value/Chi Square test
25–35	5 (5%)	6	$p = 0.974/\chi^2 = 5.99$
35–45	65 (65%)	69	
>45	30 (30%)	31	
Symptomatology			
Predominant stress incontinence	88 (88%)	92 (86.7%)	$p = 0.794/\chi^2 = 3.84$
Stress a/w urge incontinence	12 (12%)	14 (13.2%)	

a/w = associated with; TOT = trans-obturator tape; TVSS = Transvaginal Subfascial Synthetic Sling.

Table 2
Results of the study.

Satisfaction	Group A (TOT, n = 100)	Group B (TVSS, n = 106)	*p* value/Chi Square test
Satisfactory with complete resolution of SUI	92 (92%)	96 (90.5%)	$p = 0.715/\chi^2 = 3.84$
Unsatisfactory with Partial resolution of SUI	8 (8%)	10 (9.4%)	

	Group A (TOT, n = 100)	Group B (TVSS, n = 106)
Complications		
Intraoperative	Nil	Nil
Postoperative		
SIEV	2 (2%)	Nil
De novo urge incontinence	Nil	Nil
Mesh perforation	Nil	Nil
Mesh exposure	2 (2%)	1 (0.9%)
Mesh incision	2 (2%)	Nil
Groin/thigh pain	16 (16%)	1 (0.9%)
Need for CIC	8 (8%)	6 (5.6%)

CIC = continuous intermittent catheterization; Nil = zero; SIEV = symptoms of incomplete evacuation of bladder; SUI = stress urinary incontinence; TOT = trans-obturator tape; TVSS = transvaginal subfacial sling.

(1%) versus none (0%), mesh erosion in 2 (2%) versus 1 (0.9%) at 3 months after the procedure in TOT and TVSS, respectively.

Mesh incision (Table 2) was done in 1 patient in the TOT group and none in the TVSS group and mesh erosion in 2 in the TOT group and 1 in the TVSS group. Postoperative groin/thigh pain was managed by oral analgesics and mesh erosion which persisted after local estrogen cream application was excised under local anesthesia. None of our treated patient developed *de novo* urge incontinence. However patients with preoperatively mixed urinary incontinence were treated with oral anticholinergic medications and had the procedure only when urgency incontinence was settled and medication was continued postoperatively for a period of 2 to 3 months.

Results (*p* value and Chi-Square test) with respect to the clinical profile of the patients and satisfaction with respect to complete resolution of SUI was calculated using Open EPI software which were insignificant and sexual function (SF) was assessed using the Brief Index of SF for Women questionnaire. All the patients were satisfied with respect to SF at 6 months of follow-up. Overall, 93.3% of the patients were satisfied with the procedure.

4. Discussion

The female urethra lies under the pubic symphysis and the pubourethral ligaments suspend the anterior urethral wall to the pubic arch. In case of valsalva or stress maneuvers, the posterior wall of the urethra slides away from the anterior urethral wall, which in turn opens the bladder neck and proximal urethra resulting in SUI. Urethral slings are currently the procedure of choice for the surgical correction of female SUI. A variety of materials and techniques have been used for sling placement. Unlike pubovaginal slings, the mid-urethral sling is loosely placed at the midportion of the urethra. Currently, a soft, loosely woven, polypropylene monofilament mesh is used with a pore size exceeding 75 μm which permits passage of macrophages and has excellent host tissue ingrowth, thereby promoting organized fibrosis and reinforcement of the sphinteric mechanism through improved urethral support and improving continence.

We propose a novel technique (Fig. 2) called as *Transvaginal Subfascial Sling* (TVSS) for the surgical correction of female SUI which is based on the concept that organized fibrosis due to mesh is enough to prevent the movement of the posterior urethral wall during stress or valsalva maneuvers in order to prevent SUI. In our technique, the sling is loosely placed at the mid-urethra *superfascia corresponding to the Ischiopubic Rami*. A comparison between TVT and the novel operation (TVSS) is feasible, but in our centre the majority of the procedures for SUI are done by the TOT-O procedure. This is a novel technique not reported in the literature for female SUI. Using the technique and principles of the standard trans-obturator route, we describe a new, simple, minimally invasive, easy to learn technique which we term the "Transvaginal Subfasial Sling (TVSS)." The placement method has an impact on some complications of mesh insertion. The location of fixation and trocar placement largely contribute to pain complications of the mesh in urologic surgery and may significantly vary (Hinoul et al., 2007).[14] Retropubic sling arms can incorporate the urethra, bladder muscularis, levator musculature, and obturator muscle when a trocar is passed close to the pubic bone, rectus muscle, or lumbar nerve branches in their trajectory. However since in TVSS mesh lies superficial to the Ischiopubic Rami, there is less incidence of postoperative pain in our study (12% vs. 0.9% in the TVSS group vs. the TOT group, respectively).

In our study the majority of the patients were in the age group of 35 to 45 years and the predominant symptom was SUI with troublesome symptoms associated with poor esteem. The majority of the patients were satisfied at 12 months post-operation. Symptomatic improvement after the procedure was seen in all patients with complete resolution of symptoms in 91 patients (91.%) in TOT group versus 96 patients (90.5%) in TVSS group with results being comparable to the study by Tincello et al.[15] with a continence rate of 87.2% at a follow-up of 12 months. Wang et al.[16] made a comparison of 3 mid-urethral tension-free tapes (TVT, TVT-O, and TVT-Secur) in the treatment of female SUI and concluded that TVT-O is easy to operate and safe compared to other mid-urethral tension-free tapes. The aim of this novel technique was to assess the effectiveness of TVSS in stress incontinence in the female population. The resolution of stress incontinence and patient satisfaction was accepted as the functional success. However, there needs to be more comparative studies of TVSS with the standard procedure for stress incontinence in females as a procedure of choice. This was a randomized surgical trial of the standard technique for a TOT procedure versus a modified

technique, TVSS that avoids having to transit the obturator membrane. The major advantage of the modification is a much lower incidence of groin/thigh pain (12% vs. 0.9%), yet maintaining similar success and satisfaction rates. All patients underwent the procedure under spinal anesthesia as many patients were apprehensive about the procedure under local anesthesia. Moreover, if a redo procedure is done, it can be done without any apprehension about the surrounding structures, as the tape has not pierced the obturator membrane. However, in our case series none of our patients required removal of the sling. Patients with persistent groin/thigh pain can be treated with removal if the pain does not subsides on conservative management. To our knowledge, no such technique is described in the literature. The technique is quite simple, easy to reproduce with no need to traverse the obturator membrane thereby avoiding any injury to the neurovascular bundle/anomalous vessels in the obturator canal and is associated with less postoperative pain and similar postoperative outcome as TOT.

5. Conclusion

The TVSS as novel technique for female SUI as it is less invasive, simpler to learn, has less postoperative pain with resolution of SUI, has rapid recovery, and good personal satisfaction compared to the standard TOT outside-in procedure. Moreover a redo procedure is easier to do without apprehension of injury to the surrounding structures.

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None.

Statement of ethics

The Ethics Committee of the hospital approved the study with the Ethical approval number of IEC SKIMS 75U, and all patients provided written informed consent for participation in the study. All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of interest statement

The author declares no conflicts of interest.

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Author contributions

Abdul Rouf Khawaja: Project development, manuscript writing;
Malik Abdul Rouf: Data collection;
Farzana Bashir Khan: Data collection;
Arif Hamid Bhat: Project development;
Yaser Ahmad Dar: Data collection;
Sajad Ahmad Malik: Project development;
Mohammad Saleem Wani: Project development, manuscript editing.

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