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Original Article

To evaluate the safety and efficacy of the TVT-Secur procedure in the treatment of stress urinary incontinence in women

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ABSTRACT

Background: The prevalence of stress urinary incontinence (SUI) in the middle-aged Indian women is around 16%. The use of transvaginal tapes (TVTs) has revolutionised the surgical management of SUI. Patients who undergo placement of the tape via the transobturator route often complain of persistent thigh pain at the site of trocar insertion. The use of minimally invasive tapes with a single suburethral incision reduces surgical trauma by eliminating thigh incisions, while maintaining the cure achieved by conventional TVTs. The study was conducted to test the efficacy and safety of minimally invasive TVT-Secur tape placement for treatment of SUI in women.

Methods: 20 women with stress incontinence were implanted with TVT-Secur tapes and followed up for a year.

Results: The objective cure rate of SUI was 85% at the end of a year. The improvement in the patient satisfaction and Incontinence-specific QOL scores, of both Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7), was statistically significant at 95% and 99% confidence levels. There were no complaints of thigh pain; however, there were intraoperative complications in the form of bladder perforation in 5% ($n = 1$), urethral injury in 5% ($n = 1$) and urethral tape exposure in 10% ($n = 2$), at 3 months requiring tape sectioning.

Conclusions: These cure rates and complications are comparable to the standard TVT implantations at the end of a year, without thigh pain; however, a greater number of patients and a longer follow-up is required to see whether the long-term cure is maintained or not, before recommending the same as a standard of treatment.

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Introduction

Urinary incontinence affects almost 30% of females aged 30–60 years, with stress urinary incontinence (SUI) comprising the maximum number of female patients seeking treatment.¹ The surgical treatment of SUI, in the last two decades, has progressed from open surgical to a laparoscopic approach, and conventional colposuspension has been replaced by standard mid-urethral slings (SMUS). Complications of SMUS have decreased with the introduction of the transobturator approach.

The need for the development of third-generation single-incision mini-slings (SIMS) arose as a result of persistent thigh pain in patients who underwent implantation of the SMUS via transobturator route.² These SIMS, after suburethral insertion, maintain the mid-urethral elevation, by anchoring their ends in the obturator internus muscle, via removable introducers. The TVT-Secur (Gynecare, Ethicon, Somerville, NJ) tape is a SIMS, without any exit wounds in the thigh.

The objective of the study was to evaluate the safety and efficacy of the use of TVT-Secur tape, as a treatment for SUI, in this population of Indian women.

Material and methods

In this single-arm observational study, between January 2010 and September 2010, a total of 20 female patients were implanted with TVT-Secur tapes.

Ethical clearance for study was obtained. All patients signed informed consent.

The diagnosis of SUI was confirmed by a typical history, a demonstrable leakage in lying or standing position on physical examination, Q tip test for demonstration of urethral hypermobility, cystoscopy and vaginal examination to exclude significant prolapse requiring intervention. An anal tone evaluation to rule out neurogenic causes and assessment of perineal body clinically completed the clinical examination. Ultrasonography of the urinary system and documentation of the post-void residual urine were also done. Urodynamic testing was done on selected cases who had associated urge

incontinence as per the recommendations of the update panel of the American Urological Association (AUA).³

Besides baseline demographic data, Incontinence-specific Quality of Life (I-QOL) scores were calculated using self-administered questions using Urogenital Distress Inventory-6 (UDI-6), and Incontinence Impact Questionnaire-7 (IIQ-7),⁴ both at the beginning of the study and at the end of a year.

Hospital outcomes, including surgical complications, were documented. All patients attended follow-up visits, which included history taking and examination at 2 weeks, 6 weeks and 6 months. All patients were examined again at 12 months and cure was documented, using a standing stress test. The I-QOL questionnaire was also repeated.

Inclusion criteria

Pre-menopausal female patients who had completed their family and did not wish to have any more children, or post-menopausal patients with symptoms, with objectively proven stress incontinence or stress predominant mixed incontinence confirmed on urodynamic testing and had consented for surgery.

Exclusion criteria

Female patients who have had prior anti-incontinence surgery or requiring concomitant vaginal surgery, or those patients with clinically demonstrable intrinsic sphincter deficiency (ISD) with urodynamic leak point pressure (LPP) less than 60 cm water, those with an active urinary tract infection (UTI) or vaginal infection at time of surgery and patients having a post-void residual volume of greater than 100 ml on ultrasonography were also excluded.

Technical literature

TVT-Secur is an 8 cm long polypropylene mesh with special absorption fixation tips providing mechanical attachment prior to the long-term integration of the mesh. It is provided with attached inserters, which are pushed by the needle drivers from behind, and inserters subsequently removed (Figs. 1–3).

Fig. 1 – TVT-Secur when removed from the pack.
With kind permission from Prof. Menahem Neuman.

Fig. 2 – TVT-Secur after removal of inserters.
With kind permission from Prof. Menahem Neuman.

Fig. 3 – Actual size of the TVT-Secur.
With kind permission from Prof. Menahem Neuman.

Operative details (Hammock technique)

The patient, under spinal anaesthesia, was placed in Lithotomy position and catheterised. A 1.5-cm sagittal sub-urethral anterior vaginal wall incision was made and undermined bilaterally paraurethrally towards the ischiopubic ramus. The tape mounted on inserters was pushed by needle driver straight into the obturator internus muscle, while hugging the bone, and stopped when it entered the obturator internus

Fig. 4 – Frontal view.
With kind permission from Prof. Menahem Neuman.

muscle. The needle driver was then disconnected from the first inserter, and connected to the contralateral inserter, after ensuring absence of twist in the tape. The drivers were then disconnected and inserters removed after adjustment of the tape (Fig. 4). The vaginal incision was then closed, and vaginal packing done. The urethral catheter was removed the next morning.

Results

The mean age of study subjects was 50.5 years (range 34–70 years). Majority (65%) did not have any co-morbidity. The remaining 7 (35%) study subjects had diabetes (2), hypertension (3), hypothyroidism (1) and lymphedema (1). Majority (65%) of females were P₂ (Para 2). Parity status of remaining subjects was P₁ (01), P₃ (05) and P₄ (01). Only three cases had both stress and urge incontinence. The average time for reporting from onset of the problem was 5.02 years (range 1–20 years). The common reason for delay in reporting was lack of awareness. The median scores preoperatively for IIQ-7 and UDI-6 scores were 51.5 and 68.7, respectively. Complications documented during the study are depicted in Table 1. There was a statistically significant difference in scores of patients pre- and postoperatively for IIQ-7 and UDI-6 scores (Wilcoxon sign rank test, $p < 0.05$) (Tables 2 and 3).

Table 1 – Postoperative complications in study subjects as per IUGA/ICS CTS nomenclature.

S. no.	Patient no.	Description of complication	CTS classification	Remedial measures
1	3	Small intraoperative bladder perforation	4AT1S1	Procedure abandoned. Injury healed on conservative method
2	5	Intraoperative urethral exposure	4AT1S1	Reimplantation with no sequelae
3	2	Midline tape exposure less than 1 cm occurring within a period of 6 months, with discharge and dyspareunia	2CcT2S1	Sectioning of the tape and coverage with vaginal flap
4	12	Midline tape exposure less than 1 cm occurring within a period of 6 months, with discharge and dyspareunia	2CcT2S1	Sectioning of the tape and coverage with vaginal flap

Table 2 – Pre- and postoperative UDI-6 scores of patients.

Patient	UDI score before	UDI score after
1.	62	10
2.	50	42
3.	30	10
4.	30	6
5.	75	15
6.	33	9
7.	42	10
8.	63	15
9.	63	9
10.	57	19
11.	50	10
12.	30	10
13.	50	15
14.	72	20
15.	80	20
16.	37	14
17.	62	16
18.	55	15
19.	28	14
20.	62	16

$n_1 = 20$, $n_2 = 20$.

Wilcoxon sign rank test, U test, p value <0.000 (two tailed).

Table 3 – Pre- and postoperative IIQ-7 scores of patients.

Patient	IIQ score before	IIQ score after
1.	58	8
2.	65	15
3.	33	15
4.	35	8
5.	94	24
6.	40	12
7.	96	25
8.	95	15
9.	94	20
10.	85	15
11.	76	17
12.	50	15
13.	99	25
14.	43	15
15.	80	18
16.	80	14
17.	62	18
18.	90	3
19.	15	3
20.	85	13

$n_1 = 20$, $n_2 = 20$.

Wilcoxon sign rank test, p value <0.000 (two tailed).

All patients were operated under spinal anaesthesia, under appropriate antibiotic cover. The average timing of the surgical procedure was 30 min, which ranged from 20 to 40 min.

Intraoperative complications

None of the patients had any intraoperative bleeding. A bladder perforation and a minor urethral injury were seen in 2 patients, respectively. Intraoperative bladder injury caused by the sharp trocar required abandoning of the procedure. The injury was cystoscopically confirmed and managed conservatively with indwelling catheter placement for a period of 2

weeks, with complete healing. The patient with urethral injury was noted to have small circumference, and submucosal visualisation of a portion of the tape on cystoscopy. Since there was no transgression of the urethral mucosa, the tape was divided suburethrally, removed and another fresh tape applied in the correct plane during same anaesthesia. Both patients manifested their injury with immediate hematuria, noticeable in the tubing of the urobag. Other patients with minor complications included a minor forniceal injury, repaired on table uneventfully. In an extremely obese patient, with truncal obesity, the introducer was initially misdirected superficial to the inferior pubic ramus, rather than deep to it, which was corrected. All these errors occurred during the initial part of the learning curve, and were not seen subsequently. The patient with iatrogenic bladder injury was reimplanted, after a period of 6 months, successfully.

Post-removal of the catheter, all patients reported improvement in the symptoms of SUI. None of the patients developed urinary retention. The dysuria and urgency present in the initial 24 h improved within a period of 48 h. The reduction in stream after the procedure was minimal although not quantifiable. At 2 weeks of follow-up, all except a single patient continued to have control of stress incontinence, with variable low-grade irritative and obstructive lower urinary tract symptoms (LUTS). Prominence of the region of the scar over the anterior vaginal wall was noted by many patients. Clinical examination revealed healing suburethral wounds. Upon review at 6 weeks, except for a single patient, the rest maintained improvement from stress incontinence. The incontinence did not improve completely in the patient who had undergone implantation after healing of the bladder injury. All three patients with preoperative-associated urge incontinence had significant reduction in this symptom, whereas de novo urge incontinence was seen in one patient.

At follow-up after 6 months, 2 patients came with symptoms of perineal discomfort, bloody vaginal discharge and severe dyspareunia, with hispareunia. Clinical examination indicated midline subcentrimetric vaginal tape exposure. Initially, management was by antibiotics for local infection, and both patients underwent subsequent, limited tape sectioning and coverage by partially mobilised vaginal flaps followed by healing; however, their SUI returned, albeit with lesser intensity. A summary of the complications as per the CTS system⁵ is given in Table 2.

Follow-up after a year allowed the rest of the patients to continue with the gains obtained for stress incontinence, without the appearance of any fresh complications. The IIQ-7 and UDI-6 Inventory at the end of a year were indicative of a reduction of the scores, which were statistically significant. The postop IIQ-7 and UDI-6 scores ranged from 6 to 42 (mean 14.8) and from 8 to 23 (mean 15.4), respectively.

Statistical analysis

All patients from January 2010 to September 2010 were included in the study. The median scores (UDI-6 and IIQ-7) of patients were calculated before and after surgery using Wilcoxon sign rank test. Post hoc power calculation was done, which was found to be more than 95%. Hence, sample size of 20 was considered adequate for the study.

Discussion

We had a heterogeneous population of patients, presenting with symptoms of SUI.

Objective cure rates

Due to a single patient having persistent SUI, post-surgery, our objective cure rate was 95% at 03 months. This patient probably had ISD, instead of urethral hypermobility alone. This cure rate fell down to 85% at the end of a year, due to vaginal tape exposure, requiring sectioning of the tape in 2 patients. Other centres implanting TVT-Secur have published cure rates of 77.2% at 4 months as by Mossa et al.,⁶ to 78–81% by Meschia et al.⁷ and Walsh,⁸ and to 87.1% by Kim et al.⁹ Even lower cure rates of 68.2% at one year have been reported by Joo et al.¹⁰ Han et al.¹¹ on the other hand have cited that the overall success rate after TVT-Secur implantation was maintained over a period of 3 years although the cure rate fell down to 72.9%. Cure rates with other mini-slings like Mini-Arc have ranged between 80 and 92% at the end of one year, as per the studies by Annett et al.¹² and by Daneshgari et al.¹³

The improvement in the patient satisfaction and Incontinence specific QOL scores, as measured by Mann–Whitney *U* test of both UDI-6 and IIQ-7, was statistically significant at 95% and 99% confidence levels.

Intraoperative complications

The cause of the bladder perforation was inadequate lateral directed force on the inserter, thus highlighting the importance of applying correct technique to the introduction of sharp-edged trocars. This bladder injury and another partial urethral injury were amenable to conservative treatment. The literature does not mention the mechanism of injury to urinary bladder in series using TVT-Secur. Both patients had appearance of sudden hematuria in the previously clear urine in the catheter tubing. This may be used as an indirect marker of injury, for the beginners, and a close watch for this sign should be kept during the surgery for the rest of the patients.

The rate of intraoperative complications was higher when compared with no injury to (1%) in the literature as noted by Walsh.⁸ These complications could be attributed to the complex mechanism of introduction and manoeuvres of disengaging the metallic inserters, which occurred in the initial part of the learning curve.

Two patients who presented with vaginal discharge, dyspareunia and hispareunia, and were detected to have vaginal tape exposures, were treated initially using antibiotics and oestrogen creams, as in a study reflecting management of erosions by Kaelin-Gambirasio et al.¹⁴ In the absence of improvement, in both patients, the central part of the tape had to be excised to control exposure and infection.

Besides the type of tape with the biomaterial used, exposures have been found to be higher in diabetics as in the study by Chen et al.¹⁵ The cause of erosion can be possibly attributed to the presence of NIDDM in one patient. Although the polypropylene used in the tape is Type 1 macroporous

monofilamentous mesh with pore size of greater than 75 microns, the cause in the second patient could not be pinpointed. Plication of the pubocervical fascia between the urethral mucosa and the tape, as proposed by Chen et al.¹⁵ and Sivaslioglu et al.,¹⁶ has been considered as a possible measure to reduce the incidence of erosions.

De novo urgency was seen in a single patient (5%), comparing favourably with the report of 6.2% in the literature.¹¹

Obstructive LUTS

None of the patients developed acute urinary retention, but transient reduction in the urinary stream was seen in a single patient, who improved subsequently. This is much less than the reported incidence of 5–7%, and obstructive LUTS following retropubic sling surgery.

None of the patients had reports of thigh pain, as there were no exit points. The literature reports a thigh pain odds ratio of 8.3² for thigh pain when comparing TVT-O to retropubic approach.

Conclusions

The objective cure rate was 85% at the end of a year, with statistically significant improvement in Incontinence-specific QOL scores. None of the patients had postoperative thigh pain.

Conflicts of interest

The authors have none to declare.

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