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MANAGEMENT OF STRESS URINARY INCONTINENCE IN WOMEN : SINGLE INCISION DEVICE (TVT SECUR) VERSUS RETROPUBIC TENSION-FREE VAGINAL TAPE DEVICE (TVT), A RANDOMIZED CLINICAL TRIAL IN TERTIARY CARE CENTRE

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ABSTRACT

Purpose: We aim to present our experience to compare the effectiveness of the new TVT Secur sling device to that of the established retropubic TVT device at 12 months postoperatively, with the primary outcome being objective "cure" (urine leakage less than 1 g) measured using a standardized pad test.

Materials and Methods: Our study was designed as a parallel group randomized trial with follow up of participants at one year postoperatively. From January 2016 to Mar 2018, 74 stress urinary incontinent patients who underwent retropubic procedure using either a TVT Secur sling device ("TVT Secur Group") or the TVT tension-free vaginal tape device ("TVT Group") were followed up 12 months after the surgery. Outcome in the form of objective and subjective cure, complication and adverse events, incontinence related quality of life, sexual function and satisfaction with surgical outcomes were analysed.

Results: Forty women were randomly allocated to the TVT Secur Group and 34 to the TVT Group. A total of 68 (92%) were followed up at 12 months. Duration of operation was similar for both groups (TVT Secur Group median 18 minutes versus TVT Group median 21 minutes). Of women in the TVT Secur Group who had a pad test, 27/33 (82%) were "cured", compared to 25/28 (89%) in the TVT Group.

Conclusion: The TVT Secur device improves patient outcomes and ease of use for surgeons, often by simplifying procedures while reducing operating room time. Our small randomized trial did not find statistically significant differences in outcomes (cure, adverse events, or quality of life) between women allocated to having a TVT Secur versus those allocated to having an established TVT procedure for stress urinary incontinence. Our experience also highlights the need for more larger trial, so that surgeons and their patients are confident in the effectiveness and safety of TVT Secur device

KEYWORDS

Stress urinary incontinence, TVT Secur, TVT

INTRODUCTION

Urogynecologists have for several years been concerned about the introduction of new Gynecare TVT Secur sling device into clinical practice without new evidence of safety or effectiveness [1,2, 3]. At a meeting of the Western Society for Pelvic Medicine in 2007, the surgeons decided that a trial of TVT Secur was a research priority, given the lack of new clinical evidence to support its adoption into practice. There is no concrete data from India. The objective of our randomized trial was to compare the effectiveness of the new TVT Secur sling device to that of the established retropubic TVT device at 12 months postoperatively, with the primary outcome being objective "cure" (urine leakage less than 1 g) measured using a standardized pad test.

METHODS

Our study was designed as a parallel group randomized trial with follow up of participant s at one year postoperatively.

SETTINGS

The study was conducted by two participating surgeons (one uro-gynaecologist and one general obstetrician/gynaecologists) in two centres: one tertiary care Army Hospital, Pune, and other tertiary care hospital in Civil, Pune. Both participating surgeons had at least 8 years' experience of incontinence surgery using TVT slings. The study was approved by the ethics committees of each participating site.

PARTICIPANTS

Women electing for surgical management of stress urinary incontinence (SUI) were eligible to participate in the trial if they leaked urine with increased abdominal pressure [4, 5], and were suitable for either type of surgery. Women were excluded if they had previous incontinence surgery; required concurrent pelvic organ prolapse surgery; had primary complaint of overactive bladder or incontinence caused only by bladder overflow; intended to have further children; had Alzheimer's or Parkinson's disease, progressive neurological disease such as multiple sclerosis, or were immunocompromized, or would be unavailable for follow-up. Patients agreeing to join the study provided written informed consent.

BASELINE

Participants were asked to complete a questionnaire including incontinence-related quality of life measures: Urogenital Distress Inventory (UDI-6), a six item measure of urogenital distress, and Incontinence Impact Questionnaire (IIQ-7), a seven-item measure of incontinence effect [6] and a 12-item sexual function questionnaire, the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12, (PISQ-12) [7]. Patient characteristics including obstetrical history and menopausal status were extracted from patient charts.

RANDOMISATION

Consenting patients were randomly allocated 1:1 to receive a retropubic procedure using either a TVT Secur sling device ("TVT Secur Group") or the TVT tension-free vaginal tape device ("TVT Group"). The randomisation list was generated by the study analyst using proc plan procedure in SAS (SAS Institute Inc., Cary, NC, USA) using permuted block randomisation. Neither the surgical team nor the patient knew the next treatment allocation. The patient allocation was notified a few days before surgery to ensure that the appropriate device was available in the operating room: surgeons were unaware of group of allocation until day of surgery.

INTERVENTIONS

Ethicon Gynecare sling devices were used: either the TVT Secur device (using "U" technique, akin to retropubic placement) or the TVT device. All procedures were carried out according to the usual practice of participating surgeons, consistent with the recommendations of the device manufacturer. Preoperative urodynamic testing was used at the clinician's discretion [5]. Anaesthesia included general, regional or local anaesthesia with sedation, depending on the choice of surgeon, anaesthesiologist and patient. Intraoperative cystoscopy was carried out at the end of the procedure for all patients. Where possible the operations were planned as day procedures, with postoperative home care. If necessary for clinical or logistical reasons, women were admitted to the hospital. Surgical details including type of anaesthesia, length of operation, length of time in hospital (hours) and any intra- or post-operative complications (including any difficulty experienced with the procedure) were extracted from patient charts, verified as necessary by surgeon.

If women required re-operation for incontinence during the 12 months following surgery, the appropriate procedure was left to the surgeon's discretion.

OUTCOMES

Outcomes were measured at 12 months following surgery. All

participating women were invited for outpatient follow-up. Chart data on outcomes were recorded. Women who were unable to attend clinic follow-up were asked to complete questionnaires including subjective outcome. Women were not informed which device they had received.

Objective cure (primary outcome)

Objective evidence of SUI was obtained using a standardized pad test at 12 months after surgery. Women undertaking the test had retrograde bladder filling with 300 ml of sterile water and wore pre-weighed pads while they undertook the standardized physical activities of the 1-hour pad test [4]. Women were considered "cured" if the pad weight gain was less than 1 g over the test period, a definition of cure used in other studies of surgery for SUI [8–10].

Complications and adverse events

Complications were identified from hospital and routine 6-week follow-up charts. At the 12 month follow-up, a physician carried out an examination of operative wounds and a digital vaginal exam to palpate for tape erosion. Women were also asked to recall any problems they believed they experienced as a result of surgery.

Subjective evidence of cure

Subjective cure at 12 months after surgery was defined as either no experience of "lost or leaked urine when you coughed, laughed, sneezed, lifted, exercised, etc.", or if urine loss has been "a small problem" or "no problem at all" over the past seven days.

Incontinence-related quality of life

All women were asked at 12 months to complete UDI-6 and IIQ-7 [6]. Each measure produces a single score of 0 (no distress for UDI-6, no impact for IIQ-7) to 100 (maximum distress or impact). Both measures were developed for incontinence trials, have been independently validated [11–13], are widely used [14] and endorsed by the International Consultation on Incontinence (ICI) [15].

Sexual function

At 12 months, women were asked if they had returned to usual sexual activity. Sexual function was measured using PISQ-12, which produces a single score of 0 (poor function) to 48 (excellent function) [7] and is recommended by ICI for measuring sexual function in patients with incontinence [15].

Satisfaction with surgical outcome

Women were asked whether the outcome of surgery had met expectations and whether they would recommend the surgery to someone else.

Sample size

Our study was designed, With assumptions of 80% power, significance level of 0.05, and a drop-out rate of 7% (based on follow-up in previous randomized trial [8]), we estimated that a sample of 40 patients per group would be required (total 80). Recruitment was estimated to take around a year.

Analysis

Analysis was undertaken following the intention-to-treat principle: women were analysed in the surgical group to which they were randomized even if they received another procedure. A single analysis was planned, when all women had completed 12 month follow-up. Data entry and management were carried out using Access (Microsoft, Redmond, WA), and analyses were carried out using SAS v9.3 (SAS Institute Inc., Cary, NC, USA). All complications were reviewed by a urogyneacologist . Descriptive statistics (means, standard deviations, proportions) were calculated for baseline data. Primary analysis compared the proportions of patients in the TVT Secur Group versus the TVT Group who demonstrated cure on the 1-hour pad test at 12 months following surgery, using Fisher Exact Test: relative risk (RR) and 95% confidence interval (CI) were also calculated. Analyses of secondary outcomes used similar tests to compare binomial outcomes for the two groups. Differences between groups for time, quality of life and sexual function scores were compared using the Mann–Whitney U-test. Changes in UDI-6, IIQ-7 and PISQ-12 scores were compared between groups using t-tests. Imputation was not used for missing data, and missing values were excluded from all statistical tests and RRs. Results are reported according to the CONSORT Statement for parallel group randomized trials [16].

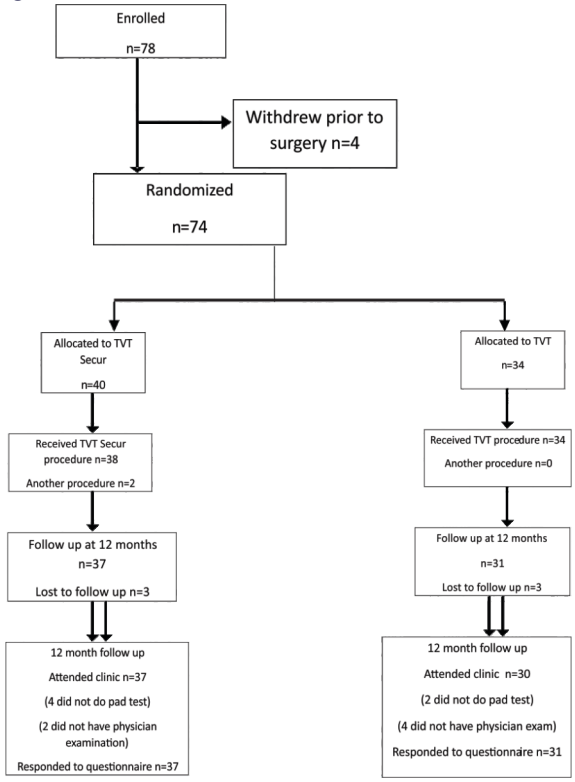
Approvals

Ethics approval was received from the research ethics boards responsible for each of the participating hospitals.

RESULTS

Four women consented to join the study but eventually chose not to have surgery and were not randomized. Seventy-four women were randomized into the study. Women had their surgery between Jan 2016 and March 2018. Forty women were randomly allocated to the TVT Secur Group and 34 to the TVT Group. A total of 68 (92%) were followed up at 12 months.

Figure 1.



Baseline data are presented in **Table 1.** Operative details and hospital stay are described in **Table 2.** All but two women in the TVT Secur Group had the procedure as allocated: one woman had a transobturator tape device because the random allocation was unavailable in the OR; another woman had the TVT Secur device replaced by a transobturator tape device at the index surgery when the intraoperative cough test found significant SUI. Two subjects (one in each group) had a Novasure endometrial ablation, and one TVT Group patient also had a hysteroscopy, dilatation and curettage at the same time as their SUI procedure. Other operative complications were as follows: in one TVT Secur Group patient, urine continued to leak after the device arms were tightened as much as considered safe but no action was taken to replace the tape; and in another TVT Secur Group patient, after a button hole was formed in the left vagina fornix, the device was repositioned and the button hole repaired. One of the TVT Group patients had a bladder perforation, and one had ≥ 200 ml blood loss. Duration of operation was similar for both groups (TVT Secur Group median 18 minutes versus TVT Group median 21 minutes). Similar numbers of women were admitted to hospital (two (5%) TVT Secur Group versus three (9%) TVT Group patients) mainly for logistic reasons (e.g. time of operation was too late to start home care)

Table 1. Patients Characteristics at baseline

Characteristics	TVT Secur Group	TVT Group
	n=40	n=34
Mean Age (years)	52.4 (SD12.3)	47.2 (SD10.8)
Median BMI	27.2(IQR7.1)	27.8(IQR7.8)
Current Smoking	5(13%)	6(18%)

Constipation	7(18%)	11(32%)
Nulliparous	2(5%)	2(6%)
No Vaginal Deliveries	4(10%)	4(12%)
Post Menopausal	18(45%)	11(32%)
Currently on Hormone replacement treatment	11(28%)	5(15%)
Questionnaire findings		
Median UDI-6 Score	39(IQR25)	39(IQR22)
Median IIQ-7 Score	33(IQR 29)	36(IQR24)
Median PISQ-12 Score	36(IQR9)	37(IQR9)
Stress UI symptoms in past 7 days		
No,or yes but no problem or small problem	20(50%)	17(50%)
Yes, a big problem	19(48%)	17(50%)
Yes, unknown how much problem	1(3%)	0(0%)
Urge UI symptoms in past 7 days		
No,or yes but no problem or small problem	32(80%)	31(91%)
Yes, a big problem	7(18%)	3(9%)
Unknown/Yes, unknown how much problem	1(3%)	0(0%)
Night time awakening to void in past 7 days		
No,or yes but no problem or small problem	35(88%)	33(97%)
Yes, a big problem	2(5%)	1(3%)
Unknown/Yes, unknown how much problem	3(8%)	0(0%)

Notes:SD-Standard deviation; BMI-Body Mass Index; IQR-inter-quartile range; NA- Not applicable

Table 2. Operative and Hospital details

Charateristics	**TVT Secur Group**	**TVT Group**	**Statistical test result**
	n=40	**n=34**	
Median operation time(Procedure start to closure, mins)	18(IQR11)	21(IQR12)	M-Wp=0.23
Type of anaesthesia	FEp=0.56		
Local only	19(48%)	16(47%)	
General only	19(48%)	18(53%)	
Spinal	2(5%)	0(0%)	
Complications	FEp>0.99		
Yes	3(8%)	2(6%)	
No	36(92%)	31(94%)	
Unknown	1	1	
Hospital admission	FEp=0.66		
Not admitted	38(95%)	31(91%)	
Planned	2(5%)	3(9%)	

Notes: IQR-inter-quartile range; M-W_ Mann-Whitney U-test; FE-Fisher Exact Test.

The primary outcome, objective cure at 12 months postoperatively, was measured using a pad test in 33 women in the TVT Secur Group and 28 in the TVT Group (Table 3). Of women in the TVT Secur Group who had a pad test, 27/33 (82%) were "cured", compared to 25/28 (89%) in the TVT Group (relative risk 0.92, 95% CI 0.75 to 1.13). Other pelvic procedures were reported for 4 (11%) women in the TVT Secur Group, only one of which was linked to the SUI procedure: an excision of the vaginal mesh for an extrusion in the patient whose button hole was repaired. No additional pelvic floor procedures were reported for the TVT Group. At follow-up, other complications during the 12 month postoperative period were reported by three women in the TVT Secur Group, who reported worsening of nocturia, pain in the groin, and development of leakage following the tape excision for an erosion (respectively): one woman in the TVT Group reported an occasional burning sensation under the urethra. On vaginal examination, the majority of women had normal palpation, but the surgical tape was palpable (non-tender) for seven (21%) women in the TVT Secur Group and two (8%) in the TVT Group.

Table 3. Twelve month Follow up

Charateristics	**TVT Secur n=37**	**TVT n=30**	**Fischer exact test results***	**RR(95%CI)**
Pad Test (Primary Outcome)	P=0.49	0.92		
<1gm	27(82%)	25(89%)		(0.75-1.13)
≥1gm	6(19%)	3(11%)		
Pad test not done	4	2		
Complications since hospital discharge	P=0.13	0.89(0.79-1.00)		
Additional pelvic procedures	31(89%)	26(100%)		
No	4(11%)	0(0%)		
yes	2	4		
unknown	1(2%)	0(0%)		
Vaginal Examination			P=0.27	0.85
Normal Palpation	26(79%)	24(92%)		(0.69-1.05)
Tape palpable but non-tender	7(21%)	2(8%)		
Unknown not done	4	4		
Bimanual examination			P=0.50	0.94
Normal	32(94%)	25(100%)		(0.87-1.02)
Abnormal	2(6%)	0(0%)		
Unknown/ not done	3	5		

Notes: * Tests exclude women did not have test or exam or whose status is unknown.

Questionnaires were completed by 37/40 (93%) women in the TVT Secur Group and 31/34 (91%) in the TVT Group (Table 4). Incontinence symptoms did not differ between groups: subjective cure (no or little problem with stress incontinence symptoms) was reported by women 35 (95%) in the TVT Secur Group, and 29 (97%) in the TVT Group. Quality of life had improved for both groups as reported using UDI-6 and IIQ-7 but did not differ between groups: mean decrease in UDI-6 score of 28 for the TVT Secur Group and 27 for the TVT Group; mean decrease in IIQ-7 score of 25 for both groups. The majority of women reported the surgery met their expectations (26 (70%) versus 28 (90%), p = 0.069), and would recommend the surgery to someone else with similar symptoms (34 (92%) versus 30 (97%), p > 0.99). Sexual activity was reported at baseline and 12 months by 22 women in the TVT Secur Group and 26 in the TVT Group: PISQ-12 scores improved by median 4 points in both groups (t-test p = 0.77).

Table 4. Twelve month follow-up questionnaire results

Charateristics	TVT Secur group n=37	TVT group n=31	Statistical results	RR(95%CI)
Stress UI symptoms in past 7 days			FEp>0.99	0.98
No,or Yes but no problem or small problem	35(95%)	29(97%)		(0.88-1.08)
Yes a big problem	2(5%)	1(3%)		
Unknown/Yes, unknown how much problem	0	1		
Urge UI symptoms in past 7 days			FEp=0.59	1.04
No, or Yes but no problem or small problem	36(97%)	29(94%)		(0.93-1.16)
Yes, a big problem	1(3%)	2(6%)		
Night Time awakening to void in past 7 days			FEp=0.50	0.95(0.88-1.02)
No,, or Yes but no problem or small problem	35(95%)	31(100%)		
Yes a big problem	2(5%)	0(0%)		
Median UDI-6 scotre	11(IQR17)	0(IQR11)	M-Wp=0.22	N/A
Mean change from baseline	-28(SD21)	-27(SD20)	t-test p=0.84	N/A
Median IIQ-7 Score	0(IQR14)	0(IQR14)	M-Wp=0.71	N/A
Mean change from baseline	-25(SD27)	-25(SD18)	t-test p=0.88	N/A

Notes: * Tests exclude women did not have test or exam or whose status is unknown.

DISCUSSION

Main findings

Our trial compare the outcomes of TVT Secur using the U-method with outcomes following the established TVT in women with stress urinary incontinence without other pelvic floor surgical procedures, and no additional unpublished trials of this design are registered. The two tape devices are designed to place the tape in the same position in relation to the urethra, and therefore our study provides a direct comparison between the devices. At 12 months postoperatively we did not find statistically significant differences in outcome between groups for cure defined as pad test leakage of <1 g (82% TVT Secur versus 89% TVT), or subjective cure defined as no or small problem caused by leakage in the past week (95% TVT Secur versus 97% TVT). Nor did we find differences between groups for incontinence-related quality of life or adverse effects following surgery.

Comparison of the findings with published literature

Only one randomized trial has been published to date directly describing the outcome of TVT Secur U technique to that following TVT [17]. This large trial, by Barber and colleagues, compared outcomes a year postoperatively, differing from our trial in including women with pelvic organ prolapse or other pelvic floor problems. Among the 263 subjects randomized, 65% had concomitant surgery (hysterectomy, pelvic organ prolapse surgery or colpolcleisis) [17]. Barber and colleagues' trial did not include an objective outcome measure, rather reporting on subjective cure (a composite of subjective report of Incontinence Severity Impact [18] and absence of other incontinence treatments) at 12 months. The study found that 57% of women were cured among the TVT Secur group, versus 61% of the TVT group (TVT Secur was not found inferior to TVT), but significantly more patients in the TVT Secur group reported severe symptoms (16% versus 5%, p = 0.025). The lower success rates in Barber's study (compared to our cure rates of 82% and 89%) is likely as a result of the difference in outcome definition compared to ours, and may also have been influenced by the concomitant surgery. In Barber's study, over 90% in each group would choose the same procedure again, and women in both groups demonstrated improvements from baseline UDI-6 and IIQ-7 scores that were similar to the changes experienced by the women in our study.

One other published randomized trial compared TVT Secur (using the hammock (H) technique that places the tape in a position replicating an obturator tape) to TVT, recruiting 125 women, less than half of the planned 280 patients [19, 20]. Recruitment was stopped early because of a significantly lower cure rate at 2 months, and concern about three severe adverse events in the TVT Secur group (a tape erosion into the urethra, a tape placed inside the bladder, and bleeding from the corona mortis) [19]. Follow-up at one year after surgery found that TVT Secur produced significantly poorer outcomes than TVT, with fewer women having no leakage on cough test (71% TVT Secur (H) versus 94% TVT, p = 0.01), no pad test leakage (58% TVT Secur (H) versus 94% TVT, p = 0.05), and subjective cure (80% TVT Secur (H) versus 98% TVT, p = 0.03) [20]. The authors suggested that despite careful training in the TVT Secur H technique, their adverse findings for TVT Secur might have been the result of the TVT Secur being more clinician-dependent and less "forgiving", requiring extremely careful placement of the "one chance only" device [19]. Another randomized trial compared TVT Secur outcome to TVT and TVT-O (obturator tape), finding TVT Secur was least effective at one year after surgery (subjective cure 68% TVT Secur, 94% TVT, 92% TVT-O, p = 0.005) [21]. Several other randomized trials reported on outcome of TVT Secur (U or H approach) compared to transobturator tape devices, finding lower objective and/or subjective cure rates than transobturator tape procedures [22–26] or that TVT Secur was not inferior to transobturator tape procedures [27–30]. As a result of their findings, trial authors were generally critical of TVT Secur.

Strengths and limitations

The main strengths of our study are that it compared outcomes for women a year following TVT Secur and TVT, without concomitant pelvic floor surgery. We were able to obtain outcome data for 92% of women recruited, indicating the high level of commitment of the participating centres. The study was carried out in a variety of hospital settings to increase the generalizability of the findings. A further strength was that most of the outcomes were patient-reported by subjects who were not made aware which device had been implanted, and whose potential preferences or biases for one or other device would not affect their perception of outcome. The primary outcome, urine leakage measured during a standardized pad test was undertaken by unblinded but independent outcome assessors, research nurses who were not involved in patient care.

The principal limitation of our study was that it has small number with only 74 patients randomized. With so few patients in our study, there is a risk that we were unable to identify a real difference between outcomes for the two groups: lack of statistically significant differences in outcome in our study could be as a result of type II error. In a study of this size, only large differences in outcome between groups would be found to be statistically significant. None the less, the findings from our two centre trial add to the available evidence of effectiveness of TVT Secur compared to TVT that will be of interest to physicians who used TVT Secur and women who had one of these devices implanted. The more larger randomized trial is needed to have concrete evidence of the efficacy of the device used to treat the stress urinary incontinence.

CONCLUSION

The TVT Secur device improves patient outcomes and ease of use for surgeons, often by simplifying procedures while reducing operating

room time. Our small randomized trial did not find statistically significant differences in outcomes (cure, adverse events, or quality of life) between women allocated to having a TVT Secur versus those allocated to having an established TVT procedure for stress urinary incontinence. Our experience also highlights the need for more larger trial, so that surgeons and their patients are confident in the effectiveness and safety of TVT Secur device.

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Abbreviations

H: Hammock technique for TVT Secur placement, akin to obturator tape placement
ICI: International consultation on incontinence
IIQ-7: 7 item incontinence impact questionnaire
PISQ-12: 12 item pelvic organ prolapse/urinary incontinence sexual questionnaire
SUI: Stress urinary incontinence
TVT: Tension-free vaginal tape
U: Technique for TVT secur placement, akin to retropubic tape placement
UDI-6: 6 item urogenital distress inventory.

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