

# Comparison of the classic TVT and TVT-Secur

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## Summary

**Background and aims:** Tension-free vaginal tape (TVT) is a well-established surgical procedure for the treatment of female stress urinary incontinence (SUI) and TVT-Secur was designed to reduce the undesired complications and to minimize the operative procedure as much as possible. **Aim:** To present the authors' experience in using the classic TVT and TVT-Secur and to evaluate and compare complications and short- and long-term results. **Materials and Methods:** A retrospective study and analysis of 230 patients presented with SUI at King Abdulaziz University Hospital (KAUH) and United Doctor Hospital (UDH) from March 1, 2007 until July 3, 2010. Classical TVT and TVT-Secur with or without associated operation were performed. All patients were controlled at six months and complications, as well as objective results, have been reported. The study was approved by ethical committee of KAUH. **Results:** All patients with SUI admitted to KAUH and UDH for sub-urethral tape were analyzed (230 patients); 149 had classical TVT and 81 had TVT-Secur. Their age ranged from 30 years to 73 years with a mean of 49.8 years and std of 9.4. Their parity ranged from two to 15 with a mean of 6.2 and std of 2.4. One hundred eighty patients had SUI and 50 patients had mixed incontinence. The type of anesthesia used was general anesthesia in 69.6% (160) of cases and regional anesthesia in form of epidural or spine in 30.4% (70) of cases. Operative complications revealed a bladder perforation in 3.5% (eight) of cases and 2.2% had bleeding of more than 200 ml, and 53 patients which contribute to 23% had retention and required a catheter for 48 hours or more. After three months, it was observed that erosion of the mesh occurred in three cases. Fourteen cases (7%) continue to have SUI failure rate. **Conclusion:** The classical TVT and TVT-Secur were found to be very effective, easy, and safe procedures and with excellent results.

**Key words:** TVT; TVT; Secure urinary stress incontinence; Sling procedures.

## Introduction

Urinary incontinence is involuntary leakage of urine [1]. It is a common problem among adult women; the overall prevalence of 40% and between six to ten percent of women with severe incontinence. It is well-known that urinary incontinence is more common in women than in men [2]. Stress urinary incontinence (SUI), being the most common type of urinary incontinence in women, is due to insufficient strength of the pelvic floor muscles. It is defined as the complaint of involuntary leakage of small amount of urine as a result of increased intra-abdominal pressure and thus increased pressure on the bladder due to effort, exertion, sneezing or coughing [1-3].

Tension-free vaginal tape (TVT) is a well-established surgical procedure for the treatment of female SUI. It was first described by Ulmsten in 1996, which is based on a mid-urethral tape support, which is accepted as effective and safe surgical technique [4-6].

Bladder penetration, urinary outlet obstruction, potential bowel penetration, intraoperative bleeding, and post-operative infections are known complications of the classical TVT [5-13].

TVT-Secur was designed to reduce the undesired complications and to minimize the operative procedure as much as possible. This device is composed of an eight-cm long polypropylene mesh and is introduced by a metallic inserter, while no exit skin cuts are required [5].

The aim is to present the authors' experience of using a minimally invasive sub-urethral tape in form of either the classic TVT, and TVT-Secur and to evaluate and compare complications and short- and long-term results.

## Materials and Methods

A retrospective study of 230 patients suffering from SUI had TVT or TVT-Secur procedures performed at King Abdulaziz University Hospital (KAUH) and United Doctor Hospital (UDH) from March 1, 2007 until July 3, 2010 were analyzed and studied.

Inclusion criteria were: urinary incontinence symptoms with no intrinsic sphincteric deficiency, based on subjective complaints, objective clinical signs, and confirmed in some cases with urodynamic diagnosis including cystometry, uroflowmetry, and stress test. An age of at least 30 years and patients desiring surgical correction of SUI. The exclusion criteria were: post-void residual volume > 100 cc and desired future childbearing. History of bleeding diathesis or current anti-coagulation therapy, current genitourinary fistula or urethral diverticulum, reversible cause of incontinence (i.e. drug effect), and contraindication to surgery.

All the procedures were performed after receiving consents from the patients, informing them that tape would be positioned to elevate the bladder. The type of operation and whether TVT or TVT-Secur was to be utilized were selected according to the surgeon's preference and experience. All patients were given prophylactic antibiotics and were subjected to an iodine antiseptic vaginal wash prior to commencement of the operation.

The mode of anesthesia depended on patient request and the surgeon's preference. Foley catheter was placed in all cases

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and cystoscopy was performed in all patients that underwent classical TVT but not TVT-Secur. Patients presenting with significant cystocele or rectocele were managed with anterior or posterior colporrhaphies (anterior and posterior) as required.

Intraoperative and postoperative complications were recorded. All patients were personally contacted through interview after six months of the operation and then before writing this paper. Failure was defined as persistent complaints of SUI reported by the patients and then clinically confirmed that it conditioned the quality of life. Minimal residual leakage, not deteriorating the patient's quality of life as reported by the patients, was not considered as therapeutic failure. The study was approved by ethical committee of KAUH.

The Statistical Package for the Social Sciences (SPSS) 15.0 software was used to analyze data using t-test, chi-square test, and K independent sample (Kruskal-Wallis Test) were used when appropriate. A *p* value of < 0.05 was considered to be statistically significant.

## Results

Out of 230 patients, 149 had classical TVT and 81 had TVT-Secur and their age ranged from 30 to 73 years, with a mean of 49.8 years and std of 9.4. Their parity ranged from two to 15 with a mean of 6.2 and std of 2.4.

One hundred eighty patients had SUI and 50 had mixed incontinence. Thirty percent of patients had past medical history in form of hypertension and diabetes and 23.5% had past surgical history. Fifty-eight patients (25.2%) had urinary tract infection treated with antibiotics. Out of 230 patients 175 patients (76.1%) had a confirmed diagnosis of either SUI or mixed by urodynamic testing.

One hundred sixty patients (69.6%) out of 230 had the procedure performed under spinal or epidural anesthesia and 70 patients (30.4%) had it under general anesthesia.

Table 1 shows the comparisons of the age in years and parity which was not statistically significant. The operative time in minutes, hospital stay in days, and the number of days needed to keep the catheter between the two groups of patients who had classical TVT and those who had TVT-Secur using t-test were statistically significant (*p* = 0.001).

One hundred forty-eight patients had either classical TVT or TVT-Secur without concomitant gynecological surgery and 54 patients underwent anterior and posterior repair and only 28 patients underwent posterior repair Table 2.

Out of 230 patients, 161 had no complications and 53 patients had voiding difficulties that required prolonged catheterization; most of this type of complication occurred in the group who had classical TVT. The frequency of complications were not statistically significant with (*p* = value 0.05) between the group who had Classical TVT and TVT-Secur but the type of complication were different (Table 3).

The complications were more common in patients who had concomitant surgery than patients who had TVT alone and this was statistically significant (*p* = 0.001) Table 4.

Table 1. — Age, parity, duration of operation, hospital stay, catheterization in TVT and TVT-Secur groups.

Variable	Type of operation	Number	Mean	Std. deviation	<i>p</i>
Age (years)	TVT	149	50.8	9.9	0.03*
	TVT Secur	81	48.1	8.3	
Parity	TVT	149	6.1	2.4	0.9*
	TVT Secur	81	6.2	2.5	
Duration of operation (min)	TVT	149	70.8	21.5	0.001**
	TVT Secur	81	51.4	13.7	
Hospital stay (days)	TVT	149	4.8	2.8	0.001**
	TVT Secur	81	2.5	1.2	
Catheterization (days)	TVT	149	4.0	5.9	0.001**
	TVT Secur	81	1.1	0.8	

\*Statistically not significant; \*\*Statistically significant.

Table 2. — Classical TVT and TVT-Secur and concomitant surgery.

	Classical TVT	TVT-Secur	Total
Procedure only	97	51	148
With anterior and posterior repair	40	14	54
With posterior repair	12	16	28
Total	149	81	230

Table 3. — Complication in classic TVT and TVT-Secur.

	No	Classical TVT	TVT-Secur	%
No complications	161	100	61	70
Voiding problem, urinary retention	53	38	15	23
Bladder perforation	8	8	0	3.5
Retropubic hematoma, bleeding	5	2	3	2.2
Tape "mesh" erosions of vaginal wall	3	1	2	1.3
Total	230	149	81	100
				0.51*

\*Not significant.

Table 4. — Complication in relation to concomitant procedure.

	Procedure only	A & P repair	Post. repair	
No complications	113	26	22	161
Voiding problem (urinary retention)	19	28	6	53
Bladder perforation	8	0	0	8
Retropubic hematoma, bleeding	0	2	3	5
Tape (mesh) erosions of vaginal wall	0	1	2	3
Total	140	57	33	230

A & P repair = anterior and posterior repair; post. repair = posterior repair; *p* value 0.001: statistically significant.

## Discussion

The mid-urethral slings like TVT, TVT-Obturator (TVT-O), and TVT-Secur became very popular procedures among surgeons specializing in female pelvic reconstructive techniques and had gained experience in treating SUI. These procedures are simple and have excellent results.

The experience at the present institution suggest that TVT And TVT-Secur are easy to master and minimally invasive with respect to tissue handling. It had been reported by Rackley *et al.*, that complications and surgical outcomes were similar to the present results and found that patient selection was important to minimize the potential morbidity, avoid patient's mortality, and produce a high-rate of durable success [14].

Neuman reported the complications and early follow-up of TVT and TVT-Secur. TVT-Secur was associated with early safety and efficacy problems. Intraoperative complications associated with the TVT, such as bladder penetration and postoperative complications, such as thigh pain and bladder outlet obstruction, may be reduced with TVT-Secur [15]. He also reported a comparison of two anti-incontinence operations: TVT and the TVT-O. The surgeons' learning curves of these two minimally invasive surgical procedures for the treatment of female SUI was comparable. The safety and cost-effectiveness of TVT are well-established. TVT-O, was designed to overcome some of TVT-related operative complications. TVT-O patients seem to have less intraoperative and postoperative complications than the TVT patients. However, long-term comparative data collection is required prior to drawing solid conclusions concerning the superiority of one of these two operative techniques [16].

Tommaselli *et al.*, in their study to reduce complications of transobturator TVT, single-incision devices were introduced in the last years. A comparison between TVT-O and TVT-Secur techniques in terms of efficacy and safety, showed no differences in terms of cure rate between the two groups (81.6% vs 83.8%). Complication rate in the TVT-secur group was lower (8.1%) than in the TVT-O group (15.8%), but not significant. So both techniques seem to be effective and safe, with a low incidence of complications in both groups [17].

In another study by Oliveira *et al.* to evaluate the short-term surgical complications and results of a TVT system and TVT-Secur, in the treatment of SUI, it concluded that TVT-Secur is a simple and safe treatment for female SUI, but before recommending this sling as a first choice for treating SUI, TVT-Secur must pass the test of time and comparative studies with conventional slings [18].

## Conclusion

The classical TVT and TVT Secur were found to be very effective, easy, and safe procedures and with excellent results. The complications were found to be more in patients who had concomitant surgery of the TVT.

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