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## **Clinical and Quality-of-Life (QoL) outcomes in women treated by Tension Free Vaginal Tape (TVT)**

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### **Abstract**

**Objectives:** To assess subjective success rates, complications and impact on quality of life (QoL) in women treated by Tension Free Vaginal Tape for urinary incontinence.

**Methods:** A retrospective cohort analysis was made on 30 consecutive women undergoing TVT procedure alone or as concomitant to other pelvic surgical procedures, from June 2004 to October 2007. All the Patients were evaluated by history, clinical examination with POP-Q (pelvic organ prolapse-quantification) scoring for uterovaginal prolapse and urodynamic testing. Improvement of health -related QoL (quality of life) was assessed by incontinence impact questionnaire-short form (IIQ-7) and urogenital distress inventory -short form (UDI-6). The success of surgery was evaluated by asking whether the incontinence was cured, improved or had no change after the operation. Data was computed and analyzed by using SPSS version 13.

**Results:** Concomitant surgery was performed in 14 (46.6%) cases. Median age was 47 years and duration of follow up was 14 months (range 4-37 months). Eight (26.6%) women had mixed Urinary Incontinence with Detrusor Overactivity. Previous pelvic surgery like MMK (Marshall-Marchetti-Krantz along with TAH (total abdominal hysterectomy) was found in 5 (16.6%) cases. Complications were listed as per-operative, short term and long-term. Among the short term complications Bladder perforation was seen in 2 cases (6.7%) and overt urinary retention in 2 cases (6.7%). Long-term complications as voiding dysfunction occurred in only 1 (3.3%) case. Symptoms were labeled as completely cured in 27 (90%) patients, significantly improved in 2 (6.6%) and one with mixed incontinence regarded as having worsening of urge symptoms and dysuria.

**Conclusion:** A median follow up of 14 months showed that our surgical results of TVT alone or with concomitant surgery were similar to internationally published results and TVT can be safely performed with concomitant procedures (JPMA 59:274; 2009).

### **Introduction**

Stress incontinence is a symptom or sign indicating that the woman has involuntary urine loss associated with exertion. Urodynamic stress incontinence (previously known as genuine stress incontinence) is a solely urodynamic diagnosis which occurs when an incompetent urethra allows leakage of urine in the absence of a detrusor contraction.<sup>1</sup>

Rapid progress has been achieved in stress urinary incontinence treatment after the description of minimally invasive sling Tension free tape (TVT) in 1995 by Ulmsten,<sup>2</sup> because of minimal morbidity and high initially success rate and more than one million procedures have been performed worldwide. The starting point for development of the TVT procedure was the introduction of new pathophysiological concepts of female stress urinary incontinence, known as the "integral theory", by Petros and Ulmsten and Hammock hypothesis by De Lancey.<sup>3,4</sup> Both of these new hypothesis shared the common concept that strong supportive sub

urethral tissue was essential for maintaining an adequate continence mechanism in women. Restoration of the sub urethral supportive tissue and increasing the urethral resistance under stress condition were achieved by a specific prolene tape in this procedure. High success rates reported in mid and long-term studies has popularized this procedure, and TVT-type procedures are gradually becoming the new gold standard treatment for female stress urinary incontinence.<sup>5</sup>

The objectives of this retrospective study were to assess subjective success rates, complications, and impact on patient's quality of life (QoL) before and after the surgical procedure in our setup.

### **Patients and Methods**

A retrospective cohort analysis was conducted on 30 patients who had Tension free vaginal Tape alone or in combination with other pelvic surgeries at Aga Khan University Hospital, Karachi from June 2004 to October 2007.

The initial pre-operative evaluation included a history, clinical examination with POP-Q (pelvic organ prolapse-quantification) scoring for uterovaginal prolapse and urodynamic testing.<sup>1</sup> All of the above had an objective assessment of symptoms by stress test and urodynamic stress incontinence. All the women had a negative urine culture before the urodynamic testing and eight women with concomitant urinary urge incontinence gave a 24 hours record of urinary diary as well. Urodynamic stress incontinence was seen as observation of urinary leak with rise of valsalva leak point pressure > 60 cm water in 25 women (urethral hyper mobility) while five women showed a low leak point pressure <60 cm water (Intrinsic sphincter defect). Detrusor over activity was also recorded in 8 women (mixed UI).

Improvement of health-related QoL was assessed by incontinence impact questionnaire-short form (IIQ-7) and urogenital distress inventory -short form (UDI-6).<sup>6</sup> Response to each item were originally rated between 0 (not affected at all) and 3 (greatly affected). Post operatively IIQ-7 and UDI-6 were re-evaluated along with objective assessment by stress test at each follow up visit. Patients were advised to have visits after one, 4, 8 and 12 weeks. Women having more than 3 months duration of surgery and no further follow up visits and were interviewed by Telephone.

### Criteria for Cure:

The success of surgery was evaluated by asking whether the incontinence was cured, improved or had no change after the operation. We also questioned if urinary urgency worsened or appeared de-novo after the procedure.

Voiding dysfunction was defined as having dysuria and inability to void or post void residual >200 ml requiring a Foleys catheter or intermittent self catheterization at discharge from hospital. Postoperatively the patients were regarded as cured if they had negative stress test results and if QoL had improved  $\geq 90\%$ . To be regarded as improved the patient had to have a  $\geq 75$  improved QoL. Data analysis was performed using statistical program SPSS version 14. Descriptive statistics were presented as a percentage of the total numbers.

### Results

Patient characteristics are shown in Table 1. All the patients were assessed by POP-Q scoring for uterovaginal prolapse and 16 patients had minor degree of prolapse (stage 1 and 2) while 6 patients had major degree of prolapse (stage 3 and 4). Median duration of follow up was 14 months (4-37). TVT alone patients were discharged after 24 hours of surgery and mean duration of stay with concomitant surgery was 3 days. Fifteen women were menopausal and 10 were using local application of estrogen vaginal cream.

Table 2 shows the types of surgery performed.

Concomitant surgery was performed in 14 women (70%). These procedures included: posterior vaginal repair,<sup>9</sup> vaginal sacropexy<sup>1</sup> and vaginal hysterectomy with anterior and posterior vaginal repair<sup>1</sup> and with pelvic floor repair.<sup>3</sup>

Complications are shown in Table 3. Bladder perforation occurred in two patients. Urinary retention occurred in 2 cases.

All the patients received only prophylactic antibiotic but one patient with concomitant surgery developed acute UTI and was treated by therapeutic antibiotics. Long term follow up showed voiding dysfunction in only one patient.

No patient so far complained of de-novo urinary urgency and with median follow up for 16 months (range 4-

**Table 1: Patient characteristics. (n=30).**

Age (years)	47 (30-74)
Parity	4 (2-9)
BMI	30(23-40)
Menopausal	50%
Urge symptoms (pre-operative)	36.7%
Duration of incontinence symptoms (years)	5.5(1-20)
Follow -up time (months)	14(4-37)
Previous pelvic surgery	5(16.6%)
Recurrent UTI	3(10%)
POP-Q stage 0	8(26.6%)
POP-Q stage 1	7(23.3%)
POP-Q stage 2	9(30%)
POP-Q stage 3	2(6.7%)
POP-Q stage 4	4(13%)

\*Values are given as median (range) or percent.

37months) no patient has shown any signs of tape infection /erosion or tape rejection. All of the patients had a negative stress test soon after surgery and during subsequent visits. During the first 3 months post-operatively results and QoL had improved  $\geq 90\%$  in 27 patients (90%) and  $\geq 75\%$  in 2 patients (6.6%) while in one patient (3.3%) there was voiding dysfunction which persisted after 6 months of surgery.

### Discussion

Several reports have been published claiming that TVT (tension free vaginal tape) is a safe and effective treatment for female urinary incontinence.<sup>7,8</sup>

**Table 2: Types of surgery performed (n=30).**

Variable	n	%
TVT surgery alone	16	53.3%
TVT and Posterior repair	9	30.3%
TVT, Vaginal hysterectomy and pelvic Floor repair	3	10.0%
Vaginal hysterectomy and anterior and posterior repair	1	3.3%
TVT and Sacropexy repair	1	3.3%

TVT = Tension Free Vaginal Tape.

Our objective success rate by stress test and subjective success rates by IIQ-7 scoring at 4, 8 and 12 weeks showed > 90% improvement in symptoms in 27 (90%) patients and >

**Table 3: Procedures Complications.**

Complications	n	%
I. Per-operative		
Haemorrhage	0	0
Bladder perforation	2.0	6.7%
II. Short term complications	2	6.7%
Urinary retention UTI	1	3.3%
Voiding dysfunction (dysuria with retention)		
III. Long term complications		
Voiding dysfunction	1	3.3%
De-novo urgency	0	0%
Urethral and vaginal erosions	0	0%

75% improvement in symptoms in 2 (6.6%) patients while in one patient (3.3%) there was long term voiding dysfunction. There is no local study for comparison; the Ward/Hilton trial<sup>9</sup> measured both objective and subjective cure at 6 months, one year and 2 year. Subjective cure of stress incontinence amongst those assessed at 6 months was 65%, the rates for objective cure varied between 65 and 95% and all the patients were subjected to urodynamic testing post-operatively.<sup>9</sup> Using both the subjective and objective assessment criteria, the long-term results after 5 years by Nilsson et al showed 84.7% patients as completely cured, 10.6% had significantly improved and 4.7% were regarded as failures.<sup>10</sup>

Bladder perforation rate has been reported to be between 1.1 and 15% after TVT procedures.<sup>11</sup> No consensus exists on concomitant surgery as being a risk factor for postoperative urinary retention and bladder perforation.<sup>11</sup>

Bladder perforation occurred in only 2 (6.7%) patients. One patient had TVT and posterior repair, with Body Mass Index of 40 and hence obesity can be considered as another risk factor for bladder perforation. Another patient had only TVT but she had previous two Caesarean Sections and one difficult abdominal hysterectomy. The results of the studies regarding previous pelvic surgery as a risk factor for bladder perforation are conflicting<sup>12,13</sup> as the numbers are relatively very small, and it is not possible to derive any meaningful results regarding these risk factors.

The coexisting rate of stress urinary incontinence in patients having a prolapse is as high as 63%.<sup>14</sup> We performed 14 TVT procedures in combination with hysterectomy, hysteropexy and posterior colporrhaphy and pelvic floor repair.

Short-term voiding disorder is described in 4% to 11 % of women and retention requiring transaction of tape occurs in 1% to 2.8%.<sup>15</sup> A multi-institutional review has shown urinary retention (>24 hours after) in 19.7% of women<sup>16</sup> while a retrospective controlled study by Tayrac et al showed urinary retention in 46.2% of patients having concomitant surgery with TVT within first seven days and in 11.5% after the first week.<sup>17</sup> The cure rate for stress urinary incontinence with TVT and concomitant surgery was 96.2%.

Long-term voiding dysfunctions like urgency and dysuria persisted for >12 weeks in one patient with history of Marshal Marchetti Krantz surgery in the past. She was diagnosed as having mixed urinary incontinence and recurrent UTI as well. The incidence of mixed UI ranges from 30% to 50%. Duckett and Tamilselvi have shown subjective cure of urge symptoms in 63% women of mixed UI following TVT while overactive bladder symptoms persisted in 37%.<sup>18</sup> For post-operative overactive bladder symptoms prior to anti-incontinence surgery and old age were found to be possible risk factors.<sup>11</sup>

A relatively low rate of complications is an important advantage of the TVT-type procedure. The incidence of intraoperative blood loss of over 200 cc was reported as 1.9%, major vessel injury, 0.07% and vaginal haematoma 0.07%.<sup>19</sup> Fortunately we did not encounter any case of intra-operative haemorrhage or post-operative vaginal haematoma and this could be related to the use of general or regional anaesthesia. Wang, in his article has commented that a possibility with light sedation is that some patients can become agitated and not cooperate with the surgeon during trocar insertion, in which case persistent attempts to pass the trocar could result in bladder perforation or even a laceration of the external iliac vessels.<sup>20</sup>

After TVT procedure, 4.1, 0.8 and 0.7% of the patients had urinary tract infection, wound infection of abdominal incision and defective healing of vaginal incision, respectively.<sup>21</sup> One of our patient (3.3%) after TVT and vaginal hysterectomy developed urinary tract infection and Tayrac et al have reported postoperative urinary infection in 11.5% in patients with concomitant surgery vs 4.5% in patients with TVT alone ( $p>0.05$ ).<sup>17</sup>

None of our patients developed mesh infection or showed urethral and vaginal erosions over a median follow up of 14 months (range 4-37 months) and this could be due to relatively younger age group, median age 47 (range 30-74 years).

## Conclusion

Although we have a small and short term data but our results are comparable to those published by Western countries. Our results indicate that TVT is a safe and effective

treatment for stress urinary incontinence and concomitant surgeries can be safely performed. The women in the study had a median age of 47 years and hence no age-related complications like mesh infection, erosion and De novo urgency were observed. All patients were assessed objectively and subjectively for urinary incontinence pre-operatively but post-operatively only subjective was done. The objective assessment was made by cough test. A prospective study with post-operative objective assessment by urodynamic testing is warranted.

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