

A RANDOMIZED CONTROL TRIAL OF TENSION-FREE VAGINAL TAPE VS PUBOVAGINAL SLING: CURE RATES AND QOL IMPROVEMENT

Aims of Study

Because of simplicity and minimally surgical invasiveness the tension-free vaginal tape (TVT) procedure now becomes one of the most popular surgeries for stress urinary incontinence (SUI). Through a randomized control trial of the tension-free vaginal tape surgery in comparison with pubovaginal sling (PVS) operation, we report cure rates and improvement of quality of life (QoL).

Materials and Methods

A total of 60 women suffered from SUI were randomly assigned to either the TVT (31 women) or PVS (29 women), and were followed up 3, 12 and 24 months later. Patients characteristics prior to surgery such as age, urodynamic parameters, and QoL scores are not significantly different between the groups ($p>0.05$). Objective cure was defined as the complete absence of leak during a cough stress test at 250 to 300 ml of water in the bladder. Uebersax's short forms [1] assessed how much women were bothered or affected by the symptoms related to urinary incontinence before and after surgery. Scores of incontinence impact questionnaires (IIQ-7) and urogenital distress inventories (UDI-6) were transformed to a scale of 100 where a high score is consistent with a woman's severely affected well-being. The TVT operation was performed under local anesthesia. The PVS utilized the rectus fascia of 6x1 cm which was sutured with a 1-0 polypropylene thread. This suture was tied over the abdominal rectus muscle without any tension.

Results

Cumulative continence rates, QoL and maximum flow rates (MFR) for the 2 operations are tabulated in Table. An objective cure rate at 24 months was 70.3% for the TVT and 48.3% for the PVS ($p>0.05$). Surgical complications were encountered in 9 women of the TVT arm and in 7 of the PVS arm, but the complications were not serious and could be conservatively managed. Four women necessitated revision surgery one week later in the latter group because of difficulty in urination and post-void residue being more than 100 ml.

Before surgery QoL scores ranged from 30 to 40 of 100 points in both IIQ-7 and UDI-6 which later improved significantly ($p<0.01$) in both groups and remained so for the rest of follow up periods. MFR significantly decreased following both surgeries but gradually recovered to 20.5 and 22.5 ml/sec 24 months later, respectively. Dyspareunia was complained of by 21% of women in the TVT and 6% in the PVS arm ($p>0.05$) where 17 women in the former and 13 in the latter were sexually inactive. Twenty-five women (81%) in the TVT and 20 (69%) in the PVS were either much satisfied or satisfied with the surgical outcome ($p>0.05$). De novo urge incontinence developed in 2 of 31 women (6.5%) in the TVT and 2 of 29 (6.9%) in the PVS, two of whom have been on anti-cholinergic medication.

Interpretation of Results

Surgical outcomes of the TVT have been reported from 42.5% to 90.4%. A Nordic multicenter study reported a 5-year cure rate of 84.7%. Our 2-year cumulative data of 70.3% is located in the middle of these data. The cure rate of the PVS (48.3%) was much disappointed. It is not surprising to find that no tension sometimes causes difficulty in urination or retention for some weeks because of inability of the detrusor muscle to adapt to the new continence mechanism where urethral resistance was surgically increased.

The Nordic study confirmed that the QoL assessed in a visual analogue scale improved from 75 out of 100 points prior to the TVT to 0 after surgery. Vassallo et al. [2] and Pang et al. [3] assessed IIQ-7 and UDI-6 of women who were treated with the TVT surgery, and found that the TVT resulted in significant improvement of QoL after a follow up of 22 and 12 months, respectively, which was in accord with our observation.

Concluding Message

The TVT is superior to the PVS in a 2-year cumulative cure rate although the statistical difference was insignificant. Parameters of IIQ-7 and UDI-6 improved significantly after surgery in both groups. It is concluded that the TVT is a safe and reliable procedure with less operative complications as a surgical treatment of SUI.

References

1. Short forms to assess life quality and symptom distress for urinary incontinence in women: the incontinence impact questionnaire and the urogenital distress inventory. *Neurourol Urodyn* 14: 131-9, 1995.
2. Tension-free vaginal tape: a quality-of-life assessment. *Obstet Gynecol* 100: 518-24, 2002.
3. One-year urodynamic outcome and quality of life in patients with concomitant tension-free vaginal tape during pelvic floor reconstruction surgery for genitourinary prolapse and urodynamic stress incontinence. *Int Urogynecol J* 14: 256-60, 2003.

	Pre-op	3 mo	12 mo	24 mo
Cure rates (TVT)		93.5%	90.3%	70.3%
(PVS)		93.5%	65.5%	48.3%
IIQ-7 (TVT)	31.9	7.7	5.1	5.4
(PVS)	39.5	8.1	13.3	9.3
UDI-6 (TVT)	35.5	9.7	10.1	10.3
(PVS)	36.4	9.5	11.6	9.2
MFR (TVT)	27.1 ml/s	18.3 ml/s	18.3 ml/s	20.5 ml/s
(PVS)	30.1 ml/s	19.8 ml/s	23.9 ml/s	22.5 ml/s