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A RANDOMISED CONTROL TRIAL OF TENSION-FREE VAGINAL TAPE IN COMPARISON WITH PUBOVAGINAL SLING IN THE TREATMENT OF STRESS INCONTINENCE

Aims of Study

Tension-free vaginal tape (TVT) surgery was reported in 1995 (1). A 5-year follow-up study (2) found that subjective and objective cure was observed in 85% of 72 patients with 5% failure. The real value of TVT needs to be assessed by randomised control trials and so far there are only 2 such studies. One study (3) randomised 344 women to either TVT or colposuspension and observed that objective cure rates were 68% in the former and 57% in the latter. The other (4) allocated 68 patients to TVT and 74 to porcine dermal sling, and authors obtained the subjective cure rate of 85% in the former and 89% in the latter. Our aim is to evaluate surgical outcomes of TVT compared to pubovaginal sling (PVS) operation in a prospective randomised manner.

Methods

A total of 61 women were recruited for surgical trials in our clinic from September 1999 to October 2002. Of the patients 4 withdrew from the study and 57 women were available for the present assessment. Twenty-nine women were randomly assigned to tension-free vaginal tape procedure and 28 to pubovaginal sling operation. The women attended the clinic 3, 12 and 24 months after operation. Objective cure was consistent with complete continence in response to strong coughs 3 to 4 times in a row in a lithotomy position with intravesical water of 250 to 300ml. Subjective assessment was based on a questionnaire that asked women presence of incontinence and provided 5 answers, i.e., complete continence, only slight leakage with strong physical exercises, improved but still lose urine, no change, or got worse. Either the first or second answer was regarded as subjective cure. A follow-up period ranged from 3 to 24 months with 54% of women having completed a 24-month visit.

While the vaginal tape procedure was carried out under local anesthesia, the pubovaginal sling operation was performed under epidural anesthesia by supporting the bladder neck with the rectus fascia of a 5 cm in length. Both ends of the fascia were sutured and elongated with non-absorbable threads. Continence rates were assessed by Kaplan-Meier survival analysis with log rank statistical significance at $p<0.05$.

Results

Patients' characteristics of 2 groups are comparable (Table). All women were urodynamically diagnosed as having either stress incontinence (54 patients) or mixed incontinence (3 patients). Concomitant surgery was performed in 6 women in the TVT group and 5 in the PVS group: anterior and/or posterior colporrhaphy in 6, vaginal hysterectomy in 2, and Le Fort operation, tube ligation, incision of the external orifice 1 each. Intraoperative complications occurred in 11 patients, injury to the urethra or bladder in 6 women of the TVT arm and in 5 of the PVS arm. Revision surgery was required 7 days after surgery in 4 women of the PVS because of residue more than 100ml. Neither wound infection nor tape erosion were encountered.

Kaplan-Meier cumulative objective cure rates were 68.4% for the TVT and 45.7% for the PVS at 24 months where difference was not statistically significant (P=0.072) (Fig. 1). The subjective cure rates were much better, namely 85.9% for the TVT and 71.8% for the PVS (P=0.186) (Fig. 2). Objective and subjective cure rates of vaginal tape are very similar with those reported by Ward and Hilton (3) and Arunkalaivanan and Barrington (4), respectively.

Conclusions

The most crucial surgical step is how to support the mid-urethra or bladder neck with minimal or no tension in both surgeries. It is likely that low objective cure of the PVS is attributed to repeated assaults of pressure rises and downward movements of the bladder neck that, in turn, stretched the rectus fascia or jeopardized suture points at each end of the fascia. On the

other hand, the vaginal tape does not become loose or elongate because the mid-urethra is rather immobile and fixed beneath the pubic bone resulting in the higher cure rate.

In conclusion the tension-free vaginal tape is promising because of less surgical invasiveness, less postoperative complications and objective cure at 2 years being comparable with pubovaginal sling.

References

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Table. Characteristics of 57 patients.

Group	Age	60-min pad-test (g/hr)	Intrinsic sphincter deficiency
TVT (n=29)	32-91(m=59)	0.2-75.5 (m=22.2)	16 women (55%)
PVS (n=28)	30-75 (m=54)	1.3-139.1 (m=28.4)	15 women (54%)

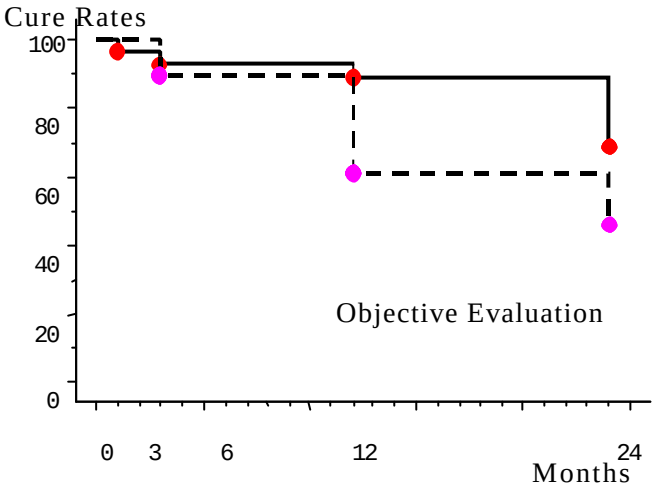

Fig. 1. Objective cumulative cure rates at 24 months were 68.4% for TVT (straight line) and 45.7% for PVS (dotted line).

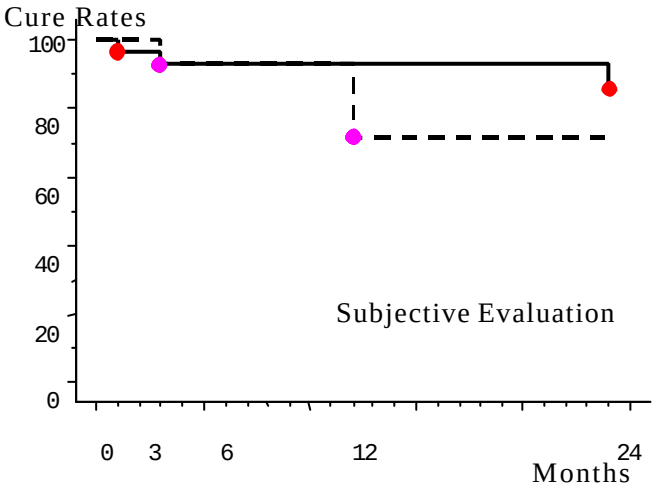

Fig. 2. Subjective cumulative cure rates at 24 months were 85.9% for TVT (straight line) and 71.8% for PVS (dotted line).