Multifilament tape resulted in similar cure rate of stress incontinence as monofilament tape, but less urinary retention

Rechberger T, Rzeźniczuk K, Skorupski P, Adamiak A, Tomaszewski J, Baranowski W, Jakowicki JA. A randomized comparison between monofilament and multifilament tapes for stress incontinence surgery. Int Urogynecol J 2003; 14: 432–436.

OBJECTIVE To compare the efficacy and safety of two types of polypropylene mesh tape for treatment of stress urinary incontinence: multifilament (non-elastic) tape in the intravaginal slingplasty (IVS) procedure and monofilament (elastic) tape in the tension-free vaginal tape (TVT) procedure.

DESIGN Randomized, assessor-blind, controlled trial. Allocation was computer-generated and carried out by a third party. The study had sufficient power to detect an absolute difference of 12% in cure rate.

SETTING University hospital in Poland.

SUBJECTS A total of 100 women, aged 34–79 (mean 55) years, with stress urinary incontinence confirmed by cough provocation tests and a urodynamic profile. Women with intrinsic sphincter deficiency, or other gynecological disorders, such as myoma or severe uterine or vaginal prolapse, were excluded. Fifty-seven percent of women were postmenopausal and 26% had had previous gynecological surgery. Mean body mass index was 29 (range 20–46) kg/m^2.

INTERVENTION Randomization allocated 50 women to undergo the IVS procedure with multifilament tape and another 50 women to undergo the TVT procedure with monofilament tape. The two procedures, performed under spinal anesthesia, were identical except for the delivery instruments and the tape. The tape was positioned without tension at the midurethra. The women were examined periodically for up to 18 months.

MAIN OUTCOME MEASURES Cure rate (cough tests negative and subjective absence of leakage), intraoperative and postoperative complications.

MAIN RESULTS After a median duration of follow-up of 14 months, complete cure of stress incontinence was achieved by 40/50 women (80%) in the multifilament tape group, compared to 44/50 (88%) in the monofilament tape group (p=0.28, relative risk (RR) 0.9, 95% CI 0.7–1.1)*. The remaining women showed significant improvement in symptoms, except for one woman in each group for whom the treatment failed. The incidence of urinary retention was significantly lower in the multifilament group than the monofilament group (4 vs 18%, p=0.03, RR 0.22, CI 0.06–0.85*), as was the prolonged duration of hospital stay for women with this complication (mean 3 vs 7 days, p=0.03). There was no significant difference between groups in the frequencies of other complications, such as bladder perforation (8 vs 4%), massive bleeding at the bladder neck (2 vs 4%), or de novo urgency (8 vs 16%).

CONCLUSION The use of a multifilament tape in the IVS procedure resulted in a similar cure rate of stress urinary incontinence, compared to the monofilament tape in the TVT procedure, with less risk of postoperative urinary retention.

*Calculated from data in article.

1361-259X/$ - see front matter
doi:10.1016/j.ebobgyn.2004.04.001

Commentary

The tension-free vaginal tape (TVT) was the first midurethral tape procedure to gain widespread acceptance for the treatment of stress urinary incontinence, after prospective observational studies demonstrated high success rates[1] and randomized trials demonstrated objective cure rates similar to those with retropubic urethropexy.[2] Presently, surgeons are facing numerous alternatives to TVT, involving different mesh materials, different delivery systems, or both. Introduction of these procedures is often based on demonstration of technical equivalency of the device, rather than on adequately powered outcomes trials. The vast majority of published data are based solely on the TVT experience, and outcomes associated with TVT should not be assumed for other devices that have been significantly modified, without the insight of clinical trials.

Potential differences in sling performance were highlighted by Deitz et al, who found lowest initial stiffness and resistance to deformation under tension for the prolene TVT mesh.[3] The stiffer and more tightly woven multifilament intravaginal slingplasty (IVS) demonstrated linear behavior and less plastic deformation while under tension. IVS is also characterized by a narrower pore size, interstices between the multifilament elements, and is narrower, compared with TVT (8 vs. 12 mm). The present authors have introduced the first randomized trial of two midurethral slings, examining subjective and objective outcomes in women undergoing TVT or IVS procedures.

The primary strength of this study is its prospective, randomized design. Exclusion criteria were appropriate, including intrinsic sphincteric deficiency and stage III/IV pelvic organ prolapse. Inclusion criteria could have been improved by specifying which subjects had urethral hypermobility at baseline; any differences between the two groups should have been reported.

One important methodological issue relates to the observation time, which ranged from 4 to 18 months (median 13.5). It was not specified whether the duration of follow-up was equal between groups, and the wide range suggests that the analysis includes subjects followed for a significantly shorter period than the planned 18 months. It is unclear how differential follow-up might have influenced the results; ideally, it should have been addressed using life table analysis. Second, postoperative multichannel urodynamics would have improved the measurement of, not only SUI outcome, but also detrusor overactivity (resolution and de novo rates) and voiding function, outcomes which may affect patient satisfaction. The authors measured objective success by cough testing with a 'comfortably full bladder', a volume which can be significantly confounded by the presence of detrusor overactivity. Finally, although the clinical success of TVT has been shown not to correlate with Q-tip angle,[4] this measure would have been useful for analyzing urinary retention and assessing for overtightening of the sling in these instances.

The authors highlighted the increased frequency and prolonged duration of immediate postoperative urinary retention in the TVT recipients, compared to IVS recipients. Reduced urinary flow and voiding dysfunction after TVT have been reported elsewhere.[5] Conceivably, higher rates of retention could reflect more pronounced 'gripping' of the TVT tape edges into surrounding tissues. Whether this feature could reduce the TVT's risk of migration, and contribute to its long-term success, remains unclear. Despite the statistical significance of the urinary retention finding, its *clinical significance* must be placed in the context of long-term outcomes. It is important to recognize the trend towards higher total cure rate for TVT within this cohort (88 vs. 80%, NS).

Another theoretical disadvantage of multifilament mesh concerns its smaller pore size and interstices. 'Type I' mesh, such as TVT, should freely admit macrophages, conferring low infectious risk. In contrast, when pore sizes are $< 10\ \mu m$, macrophages may be unable to access bacteria. Multifilament components in Type I mesh have thus been cited as a potential risk factor for infection.[6] Because low infection and erosion rates have been remarkable aspects of the TVT experience to date, newer materials should be carefully assessed in this regard.

Understanding the relative merits of available mesh materials, and determining the 'best' sling procedure, will require longer-term follow-up with consideration of objective and subjective outcomes. This first randomized trial represents an important step. As new alternatives to TVT emerge, further prospective trials will be invaluable for understanding their advantages and pitfalls.

Roger P. Goldberg MD, MPH
Northwestern University, Evanston, IL, USA

Literature cited

1. Nilsson CG, Kuuva N, Falconer C, et al. Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2001; 12(Suppl 2): S5–S8.
2. Ward K, Hilton P. Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. BMJ 2002; 325: 67–70.
3. Dietz HP, Vancaillie P, Svehla M, et al. Mechanical properties of urogynecologic implant materials. Int Urogynecol J Pelvic Floor Dysfunct 2003; 14: 239–243.
4. Lukacz ES, Luber KM, Nager CW. The effects of the tension-free vaginal tape on proximal urethral position: a prospective, longitudinal evaluation. Int Urogynecol J Pelvic Floor Dysfunct 2003; 14: 179–184.
5. Wang KH, Wang KH, Neimark M, Davila GW. Voiding dysfunction following TVT procedure. Int Urogynecol J Pelvic Floor Dysfunct 2002; 13: 353–357.
6. Cosson M, Debodinance P, Boukerrou M, et al. Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J Pelvic Floor Dysfunct 2003; 14: 169–178.