Tension-free vaginal tape for treatment of urinary stress incontinence

Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence

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Executive summary

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Executive summary

Description of the service

Tension-free vaginal tape (TVT™) is a minimal access surgical sling procedure for treating stress urinary incontinence in women. The tape is passed beneath the urethra, aiming to restore the urethra to its normal position. TVT is placed with minimal tension and support is thought to be achieved by causing a tissue reaction with a subsequent collagen scar. TVT is generally reserved for women whose symptoms have not been alleviated by conservative management, such as pelvic floor muscle training.

Epidemiology and background

The prevalence of urinary incontinence is difficult to estimate owing to variations in definitions of incontinence, populations sampled and study methodologies used. It is also thought that under-reporting may mask the true magnitude of the problem. Estimates of the overall prevalence of any incontinence have varied between 10 and 52% of adult women, and of severe incontinence between 3 and 17%. A surgical intervention may be suggested where conservative interventions fail or cease to control stress urinary incontinence or in cases where they are unsuitable. The four main types of operations for female incontinence for the last 3 years in England and Wales were TVT, colposuspension, traditional suburethral sling procedures and injectable agents. In 2000–01 there were just over 8000 primary operations performed in England, with the majority being colposuspension (46%) and TVT (34%). Similar percentages were seen in Wales: colposuspension (38%) and TVT (25%).

This review assesses the effectiveness and cost-effectiveness of TVT in comparison with other surgical procedures, particularly colposuspension. The primary outcomes were subjective cure rates and quality of life, at least 24 months after the procedure. Short-term outcomes relating to the perioperative period (such as complications and resource use) were also assessed. Studies of women with symptoms of stress incontinence were considered, whether or not it had been demonstrated by urodynamics and whether or not it was combined with other symptoms such as urge incontinence. Where the data allowed, the following subgroups were considered: women undergoing a secondary intervention (after failed previous surgery), women with co-existing prolapse, and women with mixed symptoms of incontinence.

Methods

A search of electronic databases and websites between 1966 and 2002 was conducted to identify potentially relevant papers. Reference lists of relevant articles and abstracts of a limited number of conference proceedings titles were searched and selected experts in the field were contacted. Full-text papers were obtained for all potentially relevant studies and formally assessed for content relevance and methodological quality by two researchers independently. Details of study designs, participants, interventions and prespecified outcomes were recorded.

A systematic review of existing economic evaluations comparing TVT with any of the comparators was conducted. The identified studies were critically appraised and their results summarised.

A Markov model comparing TVT with the comparators was developed using the results of the review of effectiveness and data on resource use and costs from previously conducted studies. The Markov model was used to estimate costs and quality-adjusted life-years (QALYs) for up to 10 years following surgery and it incorporated a probabilistic analysis and also sensitivity analysis around key assumptions of the model.

Number and quality of studies

Eighty-two published studies related to TVT met the inclusion criteria. There were five randomised controlled trials, nine non-randomised comparative studies, two population-based registries, 17 case series with more than 2 years of follow-up and 49 case series with less than 2 years of follow-up. Additional data about the comparators were drawn from six pre-existing systematic reviews. ▶

Summary of benefits

TVT is less invasive than colposuspension and traditional sling procedures. It is usually performed under regional or local anaesthesia rather than general anaesthesia, and is followed by a shorter stay in hospital.

The principal operative complication is bladder perforation, occurring in around one in 25 procedures. This does not appear to carry any long-term risk provided that it is recognised at the time of the operation. Other traumatic injuries, such as to a major vessel or nerve, can occur but are rare. In the longer term, the main concern is complications associated with the use of the tape, particularly erosion into the vagina or urinary tract. Current evidence suggests that these occur only rarely, but it is too soon to judge this reliably.

Most assessment has been in the form of description of case series. These show 2-year subjective 'cure' rates (variously measured) of 74–95%, with between 3 and 16% additional women improved but not cured. Only limited quality of life data are available from case series, but again they suggested significant improvement following TVT. The data from the case series must be treated with caution as bias may have been introduced because of the way in which cases were selected for inclusion and the lack of controls.

Judging how well TVT performs in comparison with other surgical procedures for stress incontinence is difficult because there are few randomised controlled trials (RCTs). Confidence intervals (CIs) around the estimates are therefore wide. In comparison with open colposuspension, at 6 months and based on one trial involving 316 women, the estimated relative cure rate is 9% lower after TVT [relative risk (RR) 0.91; 95% CI 0.78 to 1.07] with an absolute difference of –6% (95% CI –17 to 5%). **[Confidential information removed.]** Differential withdrawals and losses to follow-up in the trial that contributes most of the data complicate interpretation. The conclusions depend on what assumptions are made about these women.

Laparoscopic colposuspension and traditional slings have broadly similar cure rates to TVT and open colposuspension based on limited data from direct comparisons with TVT and from systematic reviews. Injectable agents appear to have lower cure rates.

There are currently no RCT data beyond 2 years post-surgery. Although the case series with more than 4 years of follow-up suggest sustained cure rates, there are only three such studies, and they include only around 300 women. Long-term continence rates are therefore currently not known reliably, nor are the effects of TVT on the outcome of future problems such as prolapse and recurrent stress incontinence.

Costs

Collection of cost data focused on direct health service costs, in respect of theatre costs, inpatient costs and outpatient costs. The estimated total cost of the procedures was £1114 for TVT, £1317 for colposuspension, £1340 for traditional slings, £1317 for laparoscopic colposuspension and £1305 for injectable agents. After 5 years of follow-up the cost would be £1494–1559 for TVT, £1654–1936 for colposuspension and £1626–1908 for traditional slings. Similar estimates were not derived for laparoscopic colposuspension and injectable agents.

Cost per QALY

The economic model suggested that on average TVT dominates open colposuspension: 5 years after surgery TVT was associated with a lower mean cost (£267) and the same or more QALYs (+0.00048). In the stochastic analysis, the likelihood of TVT being considered cost-effective was 100% if decision-makers were unwilling to pay for additional QALYs. If a decision-maker was prepared to pay up to £20,000 for an additional QALY, there was about a 95% chance that TVT is cost-effective; at £30,000 and £40,000 the probabilities were approximately 93% and 85%, respectively.

TVT was more likely to be considered cost-effective compared with the other surgical procedures based on the assumptions that traditional slings have the same effectiveness as open colposuspension and are also more costly; that laparoscopic colposuspension has the same or lower effectiveness as open colposuspension and similar costs; and that injectable agents are less effective than TVT but of greater cost.

Sensitivity analyses

Using plausible assumptions about the relative effectiveness of TVT compared with open colposuspension (particularly about withdrawals from trials) and changing assumptions about retreatment rates led to a reduction in the ▶

likelihood of TVT being cost-effective: if a decision-maker was prepared to pay up to £20,000 for an additional QALY, then there is about an 88% chance that TVT is cost-effective; at £30,000 and £40,000 the probabilities are approximately 78 and 70%, respectively.

Increasing the absolute probability of cure following TVT reduced the likelihood that TVT would be considered cost-effective. This reflected the assumption that the relative risk is independent of the level of absolute risk and the absence of data to test this. Increasing the effectiveness of a secondary colposuspension increased the incremental cost per QALY and hence decreased the probability of TVT being cost-effective. Changes in the estimated costs of treatment and the probability of having a retreatment had only minor effects on the cost-effectiveness of TVT in two further sensitivity analyses.

Limitations of the calculation (assumptions made)

Varying the assumptions about withdrawals in the major trial of TVT versus open colposuspension had a large impact on estimates of relative effectiveness and cost-effectiveness. There were very few comparative studies with other operations. There were also very few data about TVT's performance after 2 years. TVT's longer term performance in respect of continence and safety is not known and the assumptions used (based on data up to 2 years) may not be reliable. Estimates of cost depend on assumptions about length of hospital stay and the costs of inpatient care.

Other important issues regarding implementation

Increased adoption of TVT will require additional surgeons proficient in the technique. Operative complications may in part reflect learning. Appropriate training will be required in both the technical aspects of the procedure and the choice of women suitable for TVT.

Notes on the generalisability of the findings

This review has only considered TVT for women whose incontinence is currently managed surgically. Its scope did not include TVT for women who at present are managed conservatively. TVT is one of a number of variants of less invasive sling procedures for urinary incontinence. No comparative data were identified that compared other variants with TVT or the other comparator operations.

Need for further research

Understanding of the place of TVT in clinical practice would be enhanced by unbiased assessments of longer term performance from follow-up of controlled trials or population-based registries; more data from methodologically sound RCTs using standard outcome measures; a surveillance system to detect longer term complications, if any, associated with the use of tape; and rigorous evaluation before extending the use of TVT to women who are currently managed non-surgically.

Publication

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