Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of tension-free vaginal tape (TVT), a minimal access surgical sling procedure, to treat stress urinary incontinence in women.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised women with stress urinary incontinence, whether or not it had been demonstrated by urodynamics or other symptoms such as urge incontinence.

Setting
The setting was secondary care. The study was conducted in the UK.

Dates to which data relate
The effectiveness evidence related to studies reported in the systematic review (Chapter 3) of the report, and to studies between 1996 and 2003 for those included in the economic evaluation. The cost data related principally to studies published between 1996 and 2003. The price year was 2001.

Source of effectiveness data
The effectiveness data were derived from a systematic review of the literature, which was augmented by assumptions made by the authors or clinical experts.

Modelling
A Markov model, with cycle length 1 year, was used to assess the cost-effectiveness of TVT relative to the chosen comparators. The model (Data 4, TreeAge Inc.) incorporated both temporal and logical sequences of treatment and their consequences for the patient. The deterministic model had a time period of 10 years, while the probabilistic version used various time periods. The four health states used were cured or dry, failed but proceeding to retreatment, permanent state of incontinence, and death. Generic complications were also incorporated into the model. The model was probabilistic and used a Monte Carlo simulation to assess the likelihood of TVT being cost-effective for various values of decision-makers' willingness-to-pay for an extra quality-adjusted life-year (QALY).
Outcomes assessed in the review
The input parameters used for modelling, which were derived from the literature, were:

- the success rates of each procedure,
- the probabilities of specific events used to generate costs (such as complications),
- the probabilities of retreatment,
- quality of life (QoL), and
- mortality rates (for open surgery only).

Study designs and other criteria for inclusion in the review
The systematic review included randomised controlled trials, non-randomised comparative studies, population-based registries, and case-series. Other systematic reviews were also included.

Sources searched to identify primary studies
The cure rates for TVT were derived from the systematic review (see Chapter 3 of the HTA report for full details). The authors also utilised data from the industry submission associated with the HTA.

Criteria used to ensure the validity of primary studies
Full details were given in Chapter 3 of the HTA report.

Methods used to judge relevance and validity, and for extracting data
Full details were given in Chapter 3 of the HTA report.

Number of primary studies included
Approximately four primary studies plus relevant studies from the systematic review (as reported in Chapter 3) were used for modelling purposes.

Methods of combining primary studies
Either a meta-analysis (for data derived from the systematic review) was used or parameters were derived from individual studies.

Investigation of differences between primary studies
Full details were given in Chapter 3 of the HTA report.

Results of the review
The cure rates with TVT versus open colposuspension were 65% (year 1) and 60% (year 2). The relative risk (RR) of cure was 0.91 (95% confidence interval, CI: 0.78 - 1.07).

Adjusting for withdrawals, the cure rates with TVT were 68% (year 1) and 64% (year 2), and the RR of cure was 0.87 (95% CI: 0.76 - 1.01).

The death rate from open surgery was 0.0005.

The effectiveness of retreatment colposuspension was 78.4%.
The baseline estimate of QoL for stress incontinence was 0.78 (measured using the EQ-5D UK population tariffs).

Six months after surgery, QoL was 0.806 for the TVT group and 0.794 for the colposuspension group.

QoL associated with a cure was 0.82.

QoL was 0.8 for incontinent women and 0.85 for continent women.

The authors indicated that confidential information relating to efficacy data in their models was removed from the report.

**Methods used to derive estimates of effectiveness**

Where data were unavailable in the literature, the authors sought estimates and assumptions from clinical experts or, in some cases, other literature.

**Estimates of effectiveness and key assumptions**

The authors assumed that 75% of women whose first treatment failed would seek retreatment, 30% of women whose first retreatment failed would seek second retreatment, and no patients would seek a third retreatment.

If women failed to achieve a cure, QoL was estimated to be 0.78.

The effectiveness of traditional slings was assumed to be the same as open colposuspension, while laparoscopic colposuspension was assumed to have the same effectiveness as either TVT or open colposuspension. Injectable agents were assumed to have poorer cure rates than TVT.

**Measure of benefits used in the economic analysis**

Although a number of short-term outcomes were assessed, the primary benefit measure used was the QALY. Estimates were derived from the literature and from expert assumptions (as reported above). A discount rate of 1.5% was applied, which was consistent with HTA guidelines at the time of the study.

**Direct costs**

The costs and the quantities were not reported separately. A discount rate was appropriately applied at 6%, in accordance with HTA guidelines at the time of the study. The resource data were identified from the literature, manufacturers' reports, and from experts in the field. The unit costs were obtained from sources such as manufacturers' price lists and NHS Reference costs. The total direct costs included in the analysis covered operations, hospital wards and follow-up. The operation costs were for consumables, theatre and staff. The hospital ward costs were for inpatient stay, tests and investigations, medications, staff and postoperative costs. The follow-up costs were for outpatient appointments and staff. The costs of complications were assumed to have been incorporated into the average cost of the procedures. The price year was 2001.

**Statistical analysis of costs**

Uncertainty in the cost data was dealt with in the sensitivity analyses.

**Indirect Costs**

The indirect costs were not assessed.

**Currency**

UK pounds sterling (£).
Sensitivity analysis
The model solutions were both deterministic and probabilistic. Parameters that were varied included the cost of different procedures (theatre time and length of stay), and the ranges were derived from the systematic review. High and low values were used for cure rate and retreatment probabilities, with ranges for these parameters again being derived from the systematic review. The sensitivity analysis utilised CIs for costs and QALYs based on the industry submission that was included in the study, and extrapolated from 6 months to 1 year to match the Markov cycle. In the probabilistic analysis, triangular distributions were employed in conjunction with Monte Carlo simulations based on minimum, maximum and mid point values.

Estimated benefits used in the economic analysis
The study reported extensive results for both deterministic and stochastic results. Only the stochastic results for TVT versus open colposuspension are given here (other comparators are reported in the 'Synthesis of Costs and Benefits' section).

The difference in QALYs (based on CIs) was -0.008 to 0.01 for model 1 at 5 years and -0.010 to 0.009 for model 2 at 5 years, in favour of open colposuspension.

Cost results
The study reported extensive results for both deterministic and stochastic results. Only the stochastic results for TVT versus open colposuspension are given here (other comparators are reported in the 'Synthesis of Costs and Benefits' section).

TVT was expected to be less costly than open colposuspension for all estimates and follow-ups considered.

The difference in costs (based on CIs) was -382 to -157 for model 1 at 5 years and -373 to -134 for model 2 at 5 years, both in favour of TVT.

Synthesis of costs and benefits
Incremental costs per QALY were presented as a series of cost-effectiveness acceptability curves (CEACs). Most of the estimates showed a lower cost and lower effect for TVT in comparison with open colposuspension.

The CEACs indicated that if a decision-maker were unwilling to pay anything extra for an additional QALY then TVT would be preferred because of its lower cost.

If the decision-maker were willing to pay up to 30,000 per extra QALY, there would be a 92% chance that TVT was cost-effective relative to open colposuspension (model 1).

TVT was more likely to dominate colposuspension for the baseline models than for models adjusted for withdrawals.

For TVT versus laparoscopic colposuspension, the modelling showed that similar results to open colposuspension would be found. The results for TVT versus traditional slings showed that, for models 1 and 2 at 2 years, TVT is likely to be cost-effective, even at willingness-to-pay values of 30,000 per additional QALY. The results for TVT versus injectable agents showed that TVT would be the dominant strategy (more effective, less costly).

The results of the deterministic and stochastic sensitivity analyses were extensively reported. The results were generally similar to the industry submission associated with this HTA.

Authors' conclusions
The authors concluded "taken as a whole the additional economic modelling indicates that TVT (tension-free vaginal tape) relative to open colposuspension might be cost-effective and could be the dominant option". In the adjusted analyses, however, TVT was less likely to be considered cost-effective. The results of TVT versus other comparators were not as robust as they could have been with the benefit of more reliable and directly comparative data (versus
CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear and was well supported by the authors. You should determine which technologies are applicable to your own setting.

Validity of estimate of measure of effectiveness
The validity of some estimates used in the modelling will be high given that they were derived from the systematic review. However, several parameters were based on estimates and assumptions where no directly comparable data for other comparators were available. To address these limitations, the authors undertook extensive sensitivity analyses. For example they sought to eliminate potential bias caused by women withdrawing from open colposuspension, as a result of their less severe incontinence, by building two models that assumed that those who withdrew before surgery were cured. The validity of extrapolating the results to much longer time periods casts some doubts on the consistency of the findings over time.

Validity of estimate of measure of benefit
The use of QALYs clearly helps with the comparability of the study’s results with other health care programmes. A number of assumptions were made in the derivation of QALY results from the model.

Validity of estimate of costs
The costing appropriately reflected the chosen perspective (the UK NHS). The authors recognised the lack of reliable cost data for the comparator technologies, and the values actually used were the same as those used in the industry submission. The application of extensive sensitivity analyses did, to some extent, help to overcome these limitations. The sources of the cost data were described, although, where several choices were cited, the final choice was not always clear. A summary table showing each resource, its unit costs and the selected source(s) would have helped make the costing more transparent. The price year was stated, which will help with the generalisability of the results. Extensive sensitivity analyses were conducted, which increase the validity of the results.

Other issues
The authors compared their results with the industry submission associated with this HTA, and found the deterministic results to be broadly similar. However, as the authors noted, the follow-up period was only 6 months with the industry submission, and the modelling considered much longer timeframes. As part of the review of other economic evaluations, the findings of other relevant studies were summarised. The authors noted the high number of assumptions that were required to facilitate their modelling, and these clearly have an impact on the credibility of the study’s findings. Whilst the available data allowed TVT to be compared with open colposuspension, comparisons with other comparators were somewhat constrained.

Implications of the study
The findings, in terms of clinical practice, tended to support TVT as a cost-effective technology. However, the large number of caveats and high number of assumptions introduced into the modelling mean that the validity of the results is weaker than it might have been. The authors noted the lack of long-term data on the effectiveness of TVT versus other comparators, which would benefit from further research.

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