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) for the treatment of female stress urinary incontinence (SUI).

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised a hypothetical cohort of women affected by SUI and for whom surgical procedures had failed or were not suitable. Pregnant women or those who planned to have children were excluded.

Setting
The setting was a hospital. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and some resource use data were derived from studies published between 1996 and 2003. The price year was 2001.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of published studies and authors' assumptions.

Modelling
A Markov model was constructed to examine the clinical and economic impact of TVT in comparison with alternative surgical treatments. The time horizon of the model was 10 years. Women could move between health states on the basis of probability values derived from the literature. After their initial surgery, patients moved into one of the following states:

cured or dry (continent) by subjective measures;

failed but proceeding to re-treatment (as patients can be offered a repeat procedure if their initial one fails);

permanent state of incontinence (resorting to containment management of their incontinence by using pads); and

death.
All-cause mortality was not included in the model. The re-treatment strategy was open COLP, which could be performed up to two times. If a third procedure failed, the women remained incontinent.

Outcomes assessed in the review
The outcomes estimated from the literature were:

- the probability of death with open COLP;
- the rate of re-treatment with open COLP;
- utilities values associated with cure and incontinence (derived using the EQ-5D);
- the cure rates with TVT (estimated using actually collected data or adjustment for withdrawals pre-surgery) and the other interventions;
- the average length of stay with TVT, open COLP, traditional slings, injectables, and laparoscopic COLP; and
- theatre time with TVT, open COLP, traditional slings, and laparoscopic COLP.

Study designs and other criteria for inclusion in the review
A systematic review of the literature was undertaken to identify relevant studies. Three types of studies were included in the review. These were randomised trials, non-randomised comparative trials, and case series.

Sources searched to identify primary studies
The main source of evidence was the Cochrane Incontinence Review Group's registers of trials. Other relevant studies were identified by searching several electronic databases and contacting experts in the field.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
Eight primary studies provided the evidence.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The probability of death with open COLP was 0.0005.

The rate of re-treatment with open COLP was 0.78.
The utilities values were 0.82 with cure and 0.78 with incontinence.

The cure rates with TVT were 0.65 when estimated using actually collected data and 0.68 when adjusted for withdrawals pre-surgery.

Traditional slings would perform the same as open COLP, laparoscopic COLP would perform the same as open COLP or possibly worse, and injectables had poorer cure rates.

The average length of stay was 2.9 days with TVT, 7.1 days with open COLP, 7.2 days with traditional slings, 2 days with injectables, and 4.6 days with laparoscopic COLP.

Theatre time was 30 minutes with TVT, 52.4 minutes with open COLP, 45.6 minutes with traditional slings, and 60 minutes with laparoscopic COLP.

Methods used to derive estimates of effectiveness
The authors made some assumptions to derive model inputs when no published evidence was available.

Estimates of effectiveness and key assumptions
The proportion of women opting for re-treatment after failure of operation was 0.75 for the first re-treatment, 0.30 for the second and 0 for the third. The cure rate of re-treatment open COLP was lower than that of open COLP performed as first-line surgical option.

Measure of benefits used in the economic analysis
The summary benefit measure used was the number of quality-adjusted life-years (QALYs). This was calculated by combining survival and quality-of-life data using the decision model. The utility values were obtained from the literature and based on the EQ-5D. Discounting was carried out at an annual rate of 1.5%.

Direct costs
Discounting was relevant since the costs were incurred during a 10-year timeframe. An annual discount rate of 6% was applied. The economic evaluation comprised all direct medical costs associated with the interventions under evaluation. A detailed breakdown of the cost items was not provided, and the costs were not presented separately from the quantities of resources used. Only the total estimated costs for each procedure were provided. The cost/resource boundary of the NHS was adopted. Resource use was estimated from published estimates. The costs came from manufacturers’ prices and NHS reference costs. Some cost estimates were derived from published studies. The price year was 2001.

Statistical analysis of costs
The costs were treated deterministically in the base-case, but triangular probability distributions were assigned to some categories of costs in the probabilistic analysis.

Indirect Costs
The indirect costs were not considered in the economic evaluation.

Currency
UK pounds sterling (€).
Univariate sensitivity analyses were performed to examine the impact of variations in some model assumptions on the results of the analysis. In particular, it was assumed that re-treatment open COLP was as effective as first-line open COLP. In addition, the proportion of women opting for re-treatment after initial treatment had failed was varied, the costs for TVT and open COLP were changed (using average theatre times and hospital length of stay in England and Wales), and the cure rates for TVT were increased. A probabilistic sensitivity analysis was carried out, in which model inputs were varied simultaneously in order to determine cost-effectiveness acceptability curves.

**Estimated benefits used in the economic analysis**
The estimated difference in QALYs between open COLP and TVT depended on the time-horizon used in the model. The difference was 0.002748 in year 1, 0.001986 in year 2, 0.001255 in year 3, 0.000428 in year 4, -0.00048 in year 5, -0.00144 in year 6, -0.00351 in year 8, and -0.00569 in year 10. Therefore, TVT led to gains in QALYs after the fourth year.

**Cost results**
The estimated procedural costs were 1,058 for TVT, 1,301 for open COLP, 1,340 for traditional sling, 1,305 for injectables (excluding theatre costs), and 1,317 for laparoscopic COLP.

The estimated difference in costs between open COLP and TVT depended on the time horizon used in the model. It was 243 in year 1, 254 in year 2, 258 in year 3, 261 in year 4, 267 in year 5, 271 in year 6, 273 in year 8, and 274 in year 10. Thus, TVT was cheaper than open COLP at any time.

**Synthesis of costs and benefits**
Incremental cost-utility ratios were calculated to combine the costs and benefits of the treatment strategies. Since open COLP was generally less expensive than any of the other comparators (with the exception of TVT) and had at least as good or better effectiveness, TVT was compared with open COLP only.

The incremental analysis showed that the incremental cost per QALY with open COLP relative to TVT was 88,450 in year 1, 127,753 in year 2, 205,532 in year 3, and 611,087 in year 4. From year 5 to year 10 TVT dominated open COLP, which was both less effective and more expensive.

The probabilistic sensitivity analysis showed that TVT was always less expensive than open COLP. The cost-effectiveness acceptability curve suggested that if the decision-maker was unwilling to pay anything extra for additional QALYs, then TVT should be the preferred strategy because of its lower costs. If the decision-maker was willing to pay up to 30,000 per additional QALY, there was an 86% chance that TVT was cost-effective relative to open COLP.

The univariate sensitivity analysis showed that if re-treatment open COLP was as effective as first-line open COLP, then TVT was never dominant. Further, if 85% of women opted for re-treatment (it was 75% in the base-case model), then TVT was dominant from the fourth year, while if the probability was reduced to 40%, TVT dominated only from the seventh year. Changes in the costs had only a minor impact on the base-case results. When the cure rate of TVT increased to 90%, then the probability that TVT was cost-effective was nearly 100% if the decision-maker was unwilling to pay anything for an additional QALY, but it decreased to 50% if the decision-maker was willing to pay 50,000 for an additional QALY.

**Authors' conclusions**
Tension-free vaginal tape (TVT) was likely to represent a cost-effective alternative to open colposuspension (COLP), from approximately 5 years, for the treatment of female stress urinary incontinence (SUI). The adoption of a longer timeframe suggested that TVT dominated open COLP. The remaining surgical options were ruled out due to the higher costs and at least comparable effectiveness.

**CRD COMMENTARY - Selection of comparators**
The selection of the comparators reflected all possible surgical treatment options for female SUI. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a systematic review of the literature. The authors reported the search method and the types of studies included. However, limited information on the methods and conduct of the review (i.e. the methods used to extract and combine the primary estimates, and the comparability of the primary studies) was provided. The issue of uncertainty was addressed in the sensitivity analysis. Some assumptions were also made. The model results relied on one key assumption, the efficacy of re-treatment open COLP.

Validity of estimate of measure of benefit
The use of QALYs as the summary benefit measures was appropriate as it incorporated the impact of the interventions on survival and quality of life. The utility values were derived from published studies. QALYs are comparable with the benefits of other health care interventions. Discounting was applied, as recommended in UK guidelines.

Validity of estimate of costs
The authors stated explicitly which perspective was adopted in the study and only the direct medical costs were included in the analysis. The information on the cost categories considered in the study was limited, as a breakdown of the cost items was not reported. Some costs were presented using macro-categories because they were derived from published studies. Similarly, the resource use data came from published evidence. This reduces the possibility of replicating the cost analysis. The costs were treated stochastically in the sensitivity analysis and some economic estimates were varied in the sensitivity analysis. The price year was reported, which enhances the possibility of reflating the results of the analysis in other settings.

Other issues
The authors made only a few comparisons of their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. The authors noted some limitations of their study. For example, the use of assumptions and the lack of data on direct comparisons between TVT and comparators other than open COLP. In addition, the process of extrapolation to the long term introduced further uncertainty. The study referred to women with SUI for whom non-surgical treatment had been unsuccessful, but the authors pointed out that some women currently being treated non-surgically could be considered eligible for TVT.

Implications of the study
The study results supported the use of TVT for the treatment of female SUI in women who had failed previous non-surgical options. However, further research is needed to reliably define the long-term clinical and economic outcomes of TVT in comparison with open COLP.

Source of funding
The UK NHS R&D Health Technology Assessment Programme commissioned and funded the review on behalf of the National Institute for Clinical Excellence. Core funding provided by the Chief Scientist Office of the Scottish Executive Health Department.

Bibliographic details

PubMedID
Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Cost-Benefit Analysis; Female; Humans; Prostheses and Implants /economics; Quality-Adjusted Life Years; Urinary Incontinence, Stress /economics /surgery; Urologic Surgical Procedures /economics /methods; Vagina /surgery

AccessionNumber
22004008421

Date bibliographic record published
31/07/2005

Date abstract record published
31/07/2005