A cost-utility analysis of tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence

Manca A, Sculpher M J, Ward K, Hilton P

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
Two alternative primary treatments for urodynamic stress incontinence were examined. These were colposuspension (COLP) and tension-free vaginal tape (TFVT).

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised women with urodynamic stress incontinence. Women were excluded if they had detrusor overactivity, vaginal prolapse requiring treatment, or had prior surgery for prolapse or incontinence. They were also excluded if they had a major degree of voiding dysfunction (defined at cystometry as a voiding pressure greater than 50 cm H2O, maximum flow less than 15 mL/second and residual urine volume greater than 100 mL), neurological disease, or were allergic to local anaesthetic.

Setting
The setting of the study was urogynaecology, general gynaecology and urology outpatient clinics. The economic study was carried out in the UK and the Republic of Ireland.

Dates to which data relate
The effectiveness and resource use data were gathered between May 1998 and August 1999 (recruitment period), then assessed for the subsequent 6 months (follow-up period). The prices used in the economic evaluation referred to 1999-2000 values.

Source of effectiveness data
The effectiveness evidence was derived from a single published study, the details and methods of which were published elsewhere (see Other Publications of Related Interest).

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that considered in the effectiveness analysis.

Study sample
Power calculations were performed in the preliminary phase of the study. Assuming a 90% cure rate and a 10% difference in the cure rate between procedures, a sample of 197 patients in each group was required to detect a statistically significant difference in the main outcome measure with 80% power (262 patients to achieve 90% power). A sample of 344 women, who were recruited from outpatient clinics once surgery had been selected for their stress incontinence, was enrolled in the study. There were 175 women (median age: 50 years; interquartile range: 42 - 56) in the TFVT group and 169 women (median age: 50 years; interquartile range: 45 - 59) in the COLP group. Only 170 women in the TFVT group and 146 in the COLP group received the treatment. The remaining patients withdrew consent, declined surgery, or were ineligible for the trial.

Study design
This was a multicentre, prospective, randomised clinical trial, which was carried out in 14 centres (both university teaching hospitals and district general hospitals). Blinding was not possible due to the apparent differences in the procedures performed. The patients were randomised using a telephone system and a computer-generated procedure. The women were grouped into blocks of four and six participants. The length of follow-up was 6 months. The patients were initially contacted 6 weeks after surgery through a postal questionnaire and then after 6 months for clinical examination, symptom review and urodynamic tests. Some loss to follow-up occurred before the end of the follow-up period. The final data were available for 152 women in the TFVT group and 127 patients in the COLP group.

Analysis of effectiveness
The basis for the clinical study was intention to treat. The primary outcome measure was the cure rate, based on a negative stress test on urodynamic testing combined with a negative 1-hour pad test. The secondary health outcomes were subjective cure of incontinence and the development of voiding problems, urge symptoms, and vaginal prolapse. These were estimated using the SF-36 questionnaire (incontinence) and the Bristol female lower urinary tract symptoms questionnaire (voiding, urge and prolapse), respectively. The study groups appear to have been comparable at baseline in terms of their age and clinical characteristics. Comparability was also observed between those who remained in and those who withdrew from the study.

Effectiveness results
The cure rate was 66% in the TFVT group and 57% in the COLP group, (p=0.099; 95% confidence interval, CI, for the difference: -4.7% - 21.3%).

Improvements in most secondary outcomes were observed in both groups. There were no statistically significant differences.

After 6 months, TFVT patients experienced greater improvements than COLP women for some dimensions of the SF-36 scores (role emotional, energy/vitality, mental health and social functioning. However, the change in the overall index did not reach statistical significance.

Clinical conclusions
The two procedures were comparable in terms of cure rates and most clinical outcomes. However, the patients' perceptions of their own health improved in the TFVT group.

Measure of benefits used in the economic analysis
The summary benefit measure was the quality-adjusted life-years (QALYs). These were estimated using the health status assessment obtained from the sample of women who were included in the effectiveness study. Data were missing for 53 patients in the TFVT group and for 49 women in the COLP group. These patients were therefore excluded from the base-case analysis.

Direct costs
Discounting was not relevant since the costs per patient were incurred during 6 months. The unit costs and the quantities of resources used were presented separately and a breakdown of the cost items was provided. The health services included in the economic evaluation were ward ‘hotel’ services, theatre, anaesthetic room, recovery area, overheads, key consumables (TFVT and staple gun), outpatient and day-case visits, and general practitioner visits. Drug, treatment of complications, and staff expenses were included in each cost category reported above.

The cost/resource boundary of the UK NHS was adopted. Resource use was estimated from actual data, which were collected using case report forms completed by clinical staff on the same group of women as those enrolled in the effectiveness study. As in the analysis of the QALYs, missing data were excluded from the base-case analysis. The unit costs came from the British National Formulary, a survey of three UK hospitals, PSSRU, the Chartered Institute of Public Finance and Accountancy, and official doctors’ remunerations. Value-added tax was included when appropriate. The costs were estimated using 1999 - 2000 prices. The costs were updated to 1999 - 2000 values by considering health service inflation.

Statistical analysis of costs
The skewed distribution of the resource use data was accounted for by using non-parametric bootstrap (based on 2.5 and 97.5 centiles). The costs were presented as mean (and median) values +/- standard distribution and interquartile ranges. The 95% CIs were also presented for differential costs.

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

Currency
UK pounds sterling (£).

Sensitivity analysis
To deal with incomplete cost and utility data, the missing values were imputed using a multivariate multiple imputation procedure and the analysis was carried out on the whole sample of women included in the effectiveness study. Another sensitivity analysis was performed to assess the impact of the length of hospital stay and cost of inpatient stay on the estimated cost-effectiveness ratio. It appears that a univariate analysis has been carried out.

Estimated benefits used in the economic analysis
The mean QALYs gained per patient were 0.397 (median 0.42; interquartile range: 0.35 - 0.45) in the TFVT group and 0.387 (median 0.40; interquartile range: 0.35 - 0.44) in the COLP group. The difference in QALY (TFVT minus COLP) was 0.010 (95% CI: -0.010 - 0.030). When missing values were imputed and considered in the sample of patients, the difference in QALY was 0.012 (95% CI: -0.006 - 0.029).

Cost results
The mean total costs per patient were 1,058 (+/- 935) (95% CI: 839 - 1,100) in the TFVT group and 1,301 (+/- 1,195) (95% CI: 1,050 - 1,449) in the COLP group. The difference in cost (TFVT minus COLP) was -243 (95% CI: -341 - -201). When missing values were imputed, the difference in cost was -242 (95% CI: -340 - -183).

Synthesis of costs and benefits
On the basis of the point estimates of costs and QALYs, TFVT dominated COLP, which was both more costly and less effective. However, some uncertainty exists in the point estimates, mainly on the QALY side. The acceptability curve, used to deal with the issue of uncertainty, suggested that the probability that TFVT was less costly than COLP was 100%. Also, that the probability of TFVT being more cost-effective was 94.6% when the decision-maker was willing to pay at least 30,000 per QALY.
The sensitivity analysis showed that TFVT was more likely to be cost-effective as long as the differential inpatient length of stay for women in the TFVT group was no more than one day higher than for those who underwent COLP. When missing data were imputed, similar conclusions were reached. Variations in the cost of inpatient stay had no impact on the base-case results.

Authors’ conclusions
Over a 6-month postoperative period, tension-free vaginal tape (TFVT) proved to be a cost-effective alternative to colposuspension (COLP) for the primary treatment of urodynamic stress incontinence. This conclusion should be corroborated using long-term data.

CRD COMMENTARY - Selection of comparators
The authors justified the choice of the comparators. COLP was selected since it was a common approach for the primary treatment of urodynamic stress incontinence, while TFVT represented a recently developed intervention. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a randomised trial, which was appropriate for the study question. Aspects of the study further enhanced its internal validity. First, power calculations were performed to enrol an appropriate number of patients. Second, the analysis of the clinical study was conducted on an intention to treat basis. Third, the study groups were comparable at baseline. Fourth, the study sample was likely to have been representative of the study population. Finally, a multicentre design was adopted, with patients recruited from different institutions. Blinding was not feasible, both for logistic reasons (for assessors) and due to differences in the procedures (for patients). The follow-up period might have been too short to detect future changes in stress incontinence.

Validity of estimate of measure of benefit
The use of QALYs as the summary benefit measure appears to have been appropriate to capture the effect of the study interventions on health status. Discounting was not applied since the benefits were achieved in the short term. The health utilities were obtained using a standardised approach, which was accurately described. The use of QALYs permits the benefits of the current interventions to be compared with those associated with other health care technologies. The clinical importance of the QALY difference between the intervention and comparator (0.012) may be open to question. This is important in view of the non significant difference in clinical effects between the groups.

Validity of estimate of costs
The authors explicitly reported the perspective adopted in the study and provided a detailed breakdown of the cost categories. It appears that all the relevant cost items have been included in the economic evaluation. The inclusion of the indirect costs would have been helpful if a societal perspective were to be considered (although correspondence with the author confirms that the perspective adopted was appropriate for the study's guidelines). The reference years for the costs were reported, as were details on the unit costs and resource use. This enhances the replication of the study and assists reflation exercises in other settings. The costs were treated stochastically and sensitivity analyses on the main cost drivers were performed. Therefore, the robustness of the cost analysis was ensured. The source of the cost data was reported for every cost category. The costs were updated to reflect the inflation rate, but the method used was not reported. Overall, the validity of the cost analysis was high.

Other issues
The results were not compared with those of other published studies. The authors did not address the issue of the generalisability of the study results to other settings, but considered the variability in the cost data by performing sensitivity analyses in which the cost of inpatient stay was varied to reflect rates observed across UK. The authors also added that the performance of COLP was not standardised among the units involved in the effectiveness study and that this would enhance the generalisability of the results. The study referred to women with urodynamic stress incontinence.
and this was reflected in the conclusions of the analysis. The cost-effectiveness of the study interventions was expressed as an acceptability curve, in which the value for money of the technology was considered as a function of the decision-maker's willingness to pay for an extra QALY. This represents a strength of the study.

**Implications of the study**
The study results suggested that TFVT is associated with a high probability of being cost-effective, while it is cheaper than COLP under all scenarios considered in the study. If the decision-maker is willing to pay 30,000 for an extra QALY gained, then the probability that TFVT is more cost-effective than COLP will be higher than 80%. Further research should investigate the role played by laparoscopic COLP, as only open COLP was used in the present study.

**Source of funding**
Supported by Ethicon.

**Bibliographic details**

**PubMedID**
12628263

**Other publications of related interest**

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Cost-Benefit Analysis; Female; Follow-Up Studies; Humans; Polypropylenes /economics; Quality of Life; Quality-Adjusted Life Years; Surgical Mesh /economics; Suture Techniques; Treatment Outcome; Urinary Incontinence, Stress /economics /surgery; Vagina /surgery

**AccessionNumber**
22003000628

**Date bibliographic record published**
31/07/2004

**Date abstract record published**
31/07/2004