A cost-effectiveness analysis of tension-free vaginal tape versus laparoscopic mesh colposuspension for primary female 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 study examined the use of tension-free vaginal tape (TVT) and laparoscopic mesh colposuspension (LC) as primary operative treatments for stress urinary incontinence (SUI). The TVT procedure was carried out under local anaesthesia and, if needed, intravenous analgesics were administered. The LC procedure involved an extraperitoneal mesh colposuspension. The surgical procedures are described in more detail in other studies (Valpas et al. 2003 and 2004, see 'Other Publications of Related Interest' below for bibliographic details).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women with urodynamically confirmed SUI with a positive stress test result.

Setting
The setting was secondary care. The economic study was carried out in Finland.

Dates to which data relate
The effectiveness evidence and resources used data were collected between 1999 and 2001. The price year was 2000.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The cost data were collected prospectively on the same patient sample as that used in the effectiveness study.

Study sample
Assuming a cure rate for TVT of 95%, a cure rate for LC of 80%, and an acceptable Type I error of 5% and Type II error of 20%, a sample size of 176 was required. In the event, 128 women were recruited. After randomisation 7 women did not take part. Four of these women refused to undergo the operation, two did not accept the results of randomisation, and one was operated on in a hospital not participating in the study. There were 70 women in the TVT group and 51 in the LC group.
Study design
The study was based on a randomised controlled trial that was carried out in four university hospitals and two central hospitals. Randomisation was carried out by means of a computer-generated randomisation list. Block randomisation (40 women per centre) was used for each participating hospital. The duration of follow-up was 1 year. There appears to have been no loss to follow-up.

Analysis of effectiveness
The analysis was conducted on an intention to treat basis. The primary health outcomes were negative stress tests and 48-hour pad test (<8 g/48 hours) results. A secondary outcome was health-related quality of life (HRQoL), measured by means of a visual analogue scale (VAS) and a validated questionnaire (the Urinary Incontinence Severity Score, UISS) assessing the inconvenience caused by urinary incontinence. The UISS is an incontinence-specific HRQoL measure in which a score of 0 means no inconvenience at all, while 20 represents maximal inconvenience resulting from urinary incontinence. A score of 0 on the VAS indicated no inconvenience, while a score of 10 indicated maximum inconvenience. No details of the demographic comparability of the groups at baseline were provided, although this might have been reported in an earlier study (Valpas et al. 2003). The groups were generally shown to be relatively similar in terms of the outcome measures at baseline. The exception was the 48-hour pad test in which the TVT group performed slightly worse.

Effectiveness results
Sixty (85.7%) of the participants in the TVT group and 29 in the LC group had a negative stress test in the year following the intervention, compared with 0 in each group at baseline (95% confidence interval, CI, for change between the groups: 12.7 to 43.9).

For the 48-hour pad test (g/48 hour), there was a 79.5 g reduction (from 82.5) in the TVT group and a 56 g reduction (from 68.4) in the LC group (95% CI for change between the groups: -2.8 to 30.4).

The UISS decreased by 10.7 (from 11.8) in the TVT group and 8.8 (from 11.6) in the LC group (95% CI for change between the groups: 0.27 to 2.94).

The VAS showed a reduction of 6.3 (from 7.1) in the TVT group and a reduction of 4.4 (from 6.8) in the LC group (95% CI for change between the groups: 0.65 to 2.07).

Clinical conclusions
The results in the TVT group were significantly better than those in the LC group as measured by the stress test, VAS and UISS.

Measure of benefits used in the economic analysis
There was no summary measure of benefit. In effect, a cost-consequences analysis was performed.

Direct costs
The unit costs and the resource quantities were reported separately. The direct costs included in the analysis were the costs of the treatment in each treatment arm and other hospital costs. The costs of treatment were divided into surgical procedural costs and time-dependent costs. Surgical procedural costs included the basic cost for use of the operating theatre. Time-dependent costs were salaries for the operating theatre staff during preparation of the patient for surgery, salaries for the operating team, and salaries for the staff from the time spent before the patient was moved to the recovery area. The unit cost estimates were based on those in a hospital in Finland. Discounting was not performed, but it was not necessary given that that length of follow-up was only 1 year. The price year was 2000.

Statistical analysis of costs
A statistical analysis of the costs was not performed.

**Indirect Costs**
The indirect cost included in the analysis was the unit productivity costs of absence from work. This was based on the national average salaries of women in similar age groups to those included in the study. The unit costs of sick leave and the amount of sick leave were reported separately for both procedures.

**Currency**
Euros (EUR).

**Sensitivity analysis**
Sensitivity analysis was carried out using a "bootstrap" approach to assess the variability of the cost-effectiveness estimates. It evaluated the following changes in assumptions: both groups of women stayed in the hospital for 24 hours; the cost of sick leave was left out of the analysis; and, instead of an extraperitoneal approach with mesh and tackers, the costs of an intraperitoneal approach with sutures were evaluated.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total cost was EUR 2,081.4 for the TVT procedure and EUR 3,261.5 for the LC procedure.

**Synthesis of costs and benefits**
The TVT procedure was found to dominate the LC procedure over the 1 year' follow-up as it had lower costs and higher mean improvements with the VAS, UISS and 48-hour pad test results.

The bootstrap replications of mean differences in the costs and effectiveness showed that, in more than 99% of cases, LC was more costly and resulted in poorer outcomes (in terms of the UISS and VAS) than the TVT procedure.

**Authors' conclusions**
Over a follow-up period of 1 year, the tension-free vaginal tape (TVT) procedure was more cost-effective than laparoscopic colposuspension (LC) as a primary treatment for female stress urinary incontinence (SUI).

**CRD COMMENTARY - Selection of comparators**
Although neither of the health technologies used in the economic analysis was explicitly stated to be the comparator, both technologies appear to have represented current practice in the authors' setting. You should decide if they represent current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a multi-centre randomised controlled trial, which was appropriate for the study question. The patient groups were shown to be broadly comparable at analysis. To fully assess the quality and validity of the effectiveness data, the reader is referred to the parent study (Valpas et al. 2003).

**Validity of estimate of measure of benefit**
There was no summary measure of benefit so, in effect, a cost-consequences analysis was performed.
Validity of estimate of costs
The study perspective was not explicitly stated, although the inclusion of productivity costs would seem to indicate that it was societal. It is therefore not possible to say whether all the categories of costs have been included. All the categories of costs relevant to the hospital have been included. However, some categories of costs relevant to a societal perspective, such as travel costs, have not been included, although these costs might have been assumed to be common to both alternatives. The costs and the quantities were reported separately, which increases the generalisability of the results. Some of the costs were subjected to sensitivity analysis. Discounting was not performed, but it was not necessary given the relatively short duration of follow-up. The price year was reported.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was addressed. The authors do not appear to have presented their results selectively. The study enrolled women with SUI and this was reflected in the authors’ conclusions. The authors reported a further limitation of their study, the fact that fewer women were recruited than were required by the sample size calculation.

Implications of the study
The authors suggested that, over a follow-up period of 1 year, the TVT procedure is more cost-effective than LC as a primary treatment for female SUI.

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None stated.

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Other publications of related interest
Because readers are likely to encounter and assess individual publications, NHS EED abstracts reflect the original publication as it is written, as a stand-alone paper. Where NHS EED abstractors are able to identify positively that a publication is significantly linked to or informed by other publications, these will be referenced in the text of the abstract and their bibliographic details recorded here for information.


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MeSH
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