

# HERU Briefing Paper

HEALTH ECONOMICS RESEARCH UNIT

Briefing paper for the NHS

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## ECONOMIC EVALUATION OF TENSION FREE VAGINAL TAPE (TVT)<sup>TM</sup> FOR STRESS URINARY INCONTINENCE

1. Although less costly TVT appears to have similar effectiveness to other operations for surgical treatment of stress incontinence

2. The principal source of evidence has limited follow-up and was not able to provide sufficient information on the long-term effectiveness of TVT.

3. Information on the longer-term performance of TVT is still needed.

### Key Messages

## Background

Tension-free vaginal tape (TVT) is a minimal access surgical sling procedure for treating stress urinary incontinence (SUI) in women. The tape is passed beneath the urethra in order to restore the urethra to its normal position. Minimal tension is used, and the support is thought to be achieved by causing a tissue

reaction with a subsequent collagen scar. TVT, along with other surgical interventions, is generally reserved for women whose symptoms have not been alleviated by conservative management, such as pelvic floor muscle training.

This briefing paper is based on work performed in collaboration with the Health Services Research Unit (HSRU) at the University of Aberdeen

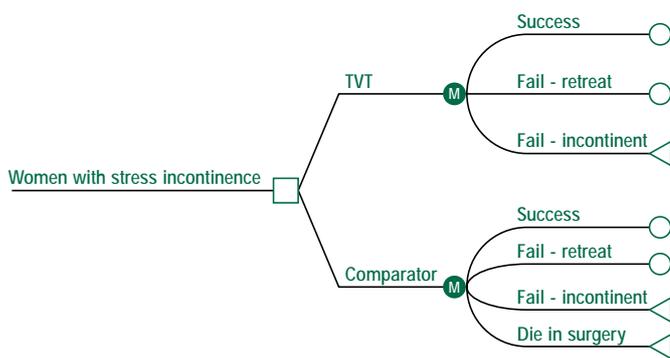


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# Methods

Economic evaluation based on a Markov model was used to assess the cost-effectiveness of TVT relative to the standard surgical procedures currently used for SUI (a simplified version is shown in Figure 1). The surgical interventions compared with TVT were open abdominal retropubic colposuspension, laparoscopic retropubic colposuspension; traditional suburethral sling procedures; and periuritheral injectables.

**Figure 1: Simplified Markov Model for TVT versus comparators**



The Markov model incorporated both the temporal and logical sequences of treatment, including the events that follow from the procedure and the outcomes for the patient. The model provided estimates of total NHS costs and patient outcomes

from the use of TVT and other procedures for the treatment of stress incontinence over five years. An assessment of the likelihood that TVT would be considered cost-effective at various values for decision-makers willingness to pay for an additional quality adjusted life year (QALY) was made using Monte Carlo simulation.

## Probabilities

Because the model assessed future costs and benefits information was required on the rates at which events such as retreatment and mortality occurred with the different interventions. These rates were derived from a systematic review and they allowed probabilities to be estimated which varied by procedure and over time to the extent supported by the data. One of the principal probabilities was the cure rate (Table 1). Two estimates are presented; Model 1 is based precisely on the data reported and Model 2 allows for the differential withdrawal from treatments that occurred after treatment allocation but before treatment was received in the major trial (Manca et al 2003). The estimates of relative cure are potentially biased without this adjustment (HTA monograph).

**Table 1 TVT cure rates and relative risk rates in comparison with open Burch colposuspension derived from published evidence on effectiveness**

Scenario		1 year (n/N)	1 year (n/N)
Model 1: Baseline	Cure rates for TVT*	0.65 (158/245)	0.65 (158/245)
	Relative risk**	0.91 (95% CI 0.78 to 1.07)	
Model 2: Adjusting for withdrawals pre-surgery	Cure rates for TVT‡	0.68 (186/273)	0.68 (186/273)
	Relative risk**	0.87 (95% CI 0.76 to 1.07)	

\* Pooled estimates of TVT and Burch colposuspension arms of Ward trial; \*\* estimated from 6 month data, ‡ assuming the 5 women in the TVT arm and the 23 in the colposuspension are those that withdrew before allocated treatment was received were cured. † Relative rates based on meta-analysis of data from Liapis and Ward.

## Outcomes

Published evidence on quality of life for women with stress incontinence was very limited. Quality of life was assessed using the SF-36 and the EQ-5D and one disease specific measure - the BFLUTS questionnaire. Values of 0.80 and 0.85 were used for incontinent and continent women, respectively, for the deterministic analysis. Therefore, in the analysis differences in QALYs between treatments were driven solely by differences in cure rates. Future benefits were discounted at rate of 1.5%.

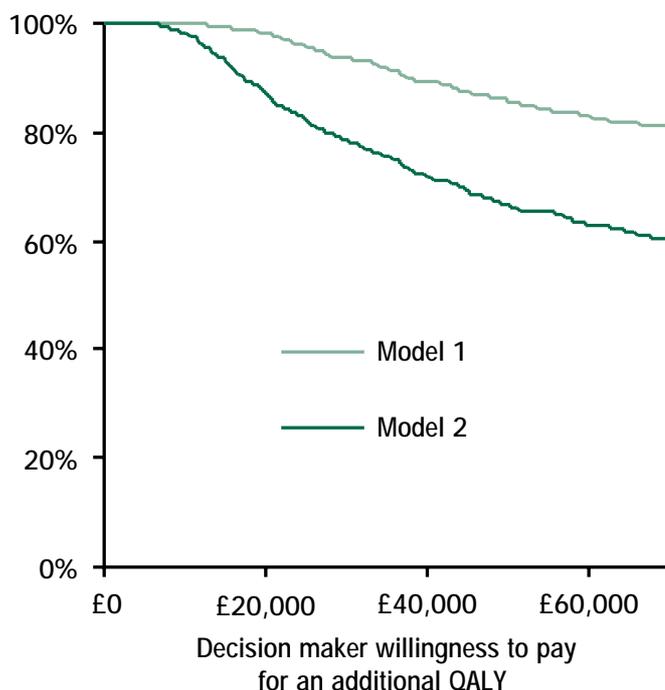
## Costs

Resource and cost data were identified from existing studies, relevant literature such as reports from manufacturers, and advice from experts in this field. Costs were measured in pounds Sterling (£) for the year 2001. As is standard in economic evaluation future costs were discounted in this case using the recommended 6% per annum rate.

# Results

In model 1 the total cost up to 5 years following a TVT (£1569) was less than that of colposuspension (£2007). Using mean estimates of cure, TVT was initially less effective than colposuspension in terms of QALYs but over time the cumulative QALYs from TVT exceeded those of colposuspension making TVT dominant.

**Figure 2: Cost-effectiveness acceptability curves for TVT versus open colposuspension for models 1 and 2 for five years follow-up**



The incremental costs per QALY ratios are presented as a series of cost-effectiveness acceptability curves in Figure 2. The curves show the probability that TVT would be considered cost-effective for different threshold values of society's willingness to pay for an additional QALY. For example, if the decision maker was willing to pay up to £30,000 there is roughly a 92% chance that in Model 1 TVT is cost-effective relative to colposuspension. In order to illustrate the impact of the differential follow-up a cost-effectiveness acceptability curve has also been shown for model 2. Under Model 2 TVT is less likely to be considered cost-effective.

Fewer data were available with which to make the other comparisons so the results are tentative. Nevertheless comparing TVT to laparoscopic colposuspension would give similar results to the open colposuspension. In comparison with traditional slings TVT is likely to be considered cost-effective even when the incremental cost per QALY is as high as £30,000. In comparison with injectables the available evidence suggested that injectables were more costly (£1305) and were likely to have a much poorer cure rate. Therefore, TVT would be considered more efficient.

# Implications/Conclusions

Taken at face value, this review of the effectiveness and cost-effectiveness of TVT suggests that TVT's effectiveness is near that of the current standard operation, open colposuspension, that its short-term risks are no greater, and that under most assumptions, it is likely to be considered cost-effective. These conclusions should be treated cautiously. The most compelling reason for this is the limited information on long-term performance of TVT (the maximum follow-up in RCTs is only to two years). At present, it is not known whether the high 'cure' rates will be sustained or that TVT will have no

unanticipated long-term complications related to the use of tape, such as erosion into the vagina or urinary tract.

The current evidence base supporting the use of TVT is incomplete; worldwide TVT has been performed in at least 230,000 women, data are available for only around 470 women participating in five RCTs of TVT. Other data provide strong evidence of efficacy (TVT can improve or cure incontinence) but RCTs are needed to better understand how well TVT compares with current standard practice.

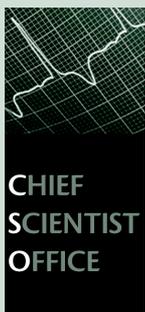
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## For further details about this study see:

Cody J, Wyness L, Wallace S, Glazener C, Kilonzo M, Stearns S, McCormack K, Vale L, Grant A, Systematic Review of the clinical effectiveness and cost effectiveness of tension free vaginal tape (TVT) for the treatment of urinary stress incontinence. Health Technology Assessment 2003 Vol 7 (forthcoming). The executive summary and full report can be downloaded from the NHS R&D HTA Programme website <http://www.hta.nhsweb.nhs.uk>.

This briefing paper describes work conducted by the Economic Evaluation Programme for the NHS Research and Development Health Technology

Assessment Programme, on behalf of the National Institute of Clinical Excellence. Further information about this topic may be obtained by contacting Luke Vale at HERU, University of Aberdeen, Foresterhill, Aberdeen AB25 2ZD (Tel: 01224 551127); Fax: (01224 662994); e mail [l.vale@abdn.ac.uk](mailto:l.vale@abdn.ac.uk). For general information about HERU please contact Anne Bews at the above address or visit our Web site at <http://www.abdn.ac.uk/heru>. The Health Economics Research Unit (HERU) is core funded by the Chief Scientist Office of the Scottish Executive Health Department.



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