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A COST UTILITY ANALYSIS OF TRANS-OBTURATOR TAPE COMPARED WITH TENSION-FREE VAGINAL TAPE IN THE SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE

Hypothesis / aims of study
We conducted a cost utility analysis, alongside a randomized controlled trial (RCT) [1], to evaluate the use of trans-obturator tape (TOT) compared with tension-free vaginal tape (TVT) in the surgical treatment of stress urinary incontinence (SUI) in women. We hypothesized that the TOT intervention would be cost-effective compared with TVT, from the public payer perspective.

Study design, materials and methods
Resource utilization and quality of life data were collected on 194 patients who gave written consent to join the RCT and were randomized to TOT or TVT procedures. Subjects were followed for one year from the date of surgery. The trial resource use data were supplemented using health region and provincial health department data for resource use and costs. Resource use was valued with unit costs adjusted to 2007 Canadian dollars. Utility scores derived from patient responses to the 15D questionnaire were used to calculate quality adjusted life years (QALYs). Statistical comparisons were carried out between TOT and TVT groups.

Results
Our RCT [1] found that incontinence cure rate (cure defined as <1g urine leaked during standardized pad test), did not differ significantly between groups (81% for the TOT group 77% for the TVT group, RR 1.05, 95% CI 0.90; 1.23), but more women in the TOT group had tapes that were palpable on vaginal exam at 12 month postoperatively compared with the TVT group (80% versus 27%, RR 0.22, 95% CI 0.13; 0.37). Quality of life improved significantly from baseline in both groups (30 point improvement in IIQ-7 score, both groups).

The economic evaluation found no difference in average QALYs between groups (0.91 for the TOT group 0.90 for the TVT group, difference 0.00, 95% CI -0.02; 0.01). There were non significant trends for lower costs over the 12 month follow-up period in the TOT group for surgical, inpatient, outpatient and physician costs. The total cost/patient over the 12 month period for the TOT group was $5435, and for the TVT group was $6568: this represented a non-significant difference in total costs of $1133 (95% CI -2793; 442).

Interpretation of results
Health care costs over the fist 12 months after surgery were not significantly different for the TOT group compared to the TVT group. However, longer term assessment is needed to determine if the palpable tapes lead to vaginal erosion and treatment, and thus to additional health care costs following TOT.

Concluding message
Until long-term follow-up and economic data are available from this and other trials, TVT should remain the mid-urethral sling procedure of choice.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ClinicalTrials.gov NCT00234754**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**University of Calgary Conjoint Health Research Ethics Board (Ethics ID 18421)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**