

Systematic review and economic modelling of effectiveness and cost utility of surgical treatments for men with benign prostatic enlargement

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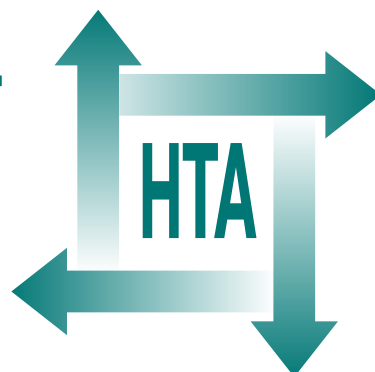
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Executive summary

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Executive summary

Background

Benign prostatic enlargement (BPE) commonly causes older men to have difficulty passing urine. If non-surgical management does not alleviate symptoms satisfactorily, the standard treatment is transurethral resection of the prostate (TURP). TURP requires an anaesthetic and a stay in hospital and sometimes has unwanted effects. Consequently, newer procedures using alternative energy sources have been developed. Some do not require a general anaesthetic, are carried out in outpatient settings and have fewer adverse effects. However, there is uncertainty about their clinical effectiveness and cost-effectiveness. This review aimed to:

- determine the clinical effectiveness of alternative procedures
- model estimates of cost and cost utility
- rank the clinical effectiveness and risk profile of newer procedures in terms of benefits, risks and cost-effectiveness
- identify areas for future research.

Description of proposed interventions

Surgery for BPE can be divided into 'minimally invasive' and 'tissue ablativ' treatments. Minimally invasive procedures include transurethral microwave therapy (TUMT), transurethral needle ablation (TUNA), transurethral ethanol ablation of the prostate (TEAP) and transurethral laser coagulation. Tissue ablativ procedures are as invasive as TURP and include laser prostatectomy, laser vaporisation, transurethral vaporisation of the prostate (TUVVP), transurethral vaporesection of the prostate (TUVRP), and bipolar TURP, TUVVP and TUVRP. Although the ablativ techniques are grouped together for the purposes of this review, there are differences in the method of ablation of the prostate with some techniques using vaporisation (e.g. TUVVP) compared with those using resection [e.g. holmium laser enucleation of the prostate (HoLEP)].

Methods

Clinical effectiveness

Electronic searches of 13 databases were conducted to identify randomised controlled trials (RCTs) of surgical interventions for BPE. Selected conference proceedings were hand searched, websites consulted and reference lists scanned.

Two reviewers independently assessed study quality and extracted data. The International Prostate Symptom Score/American Urological Association (IPSS/AUA) symptom score was the primary outcome; other outcomes included quality of life, peak urine flow rate and adverse effects.

Cost-effectiveness

A Markov model was produced reflecting likely care pathways. Parameter estimates were derived from the systematic review of clinical effectiveness, a review of previous economic evaluations and other UK relevant sources.

Results

A total of 156 reports describing 88 RCTs were included. The majority had fewer than 100 participants (range 12–234).

TURP provided a consistent, high level of long-term symptom improvement. Improvements in quality of life and flow rate were also observed. Minimally invasive procedures result in less improvement in symptoms and flow rate. Ablative procedures give similar symptom and quality of life improvements to TURP. HoLEP additionally resulted in greater improvement in flow rate. In terms of effectiveness, HoLEP appears to be unique amongst the newer technologies in offering an advantage over TURP, currently confined to urodynamic outcomes, which may not be of importance to patients, although long-term follow-up data are lacking. Severe blood loss was more common following TURP. The rate of incontinence was similar across all interventions other than for TUNA and laser coagulation, which reported lower rates. Acute retention and need for reoperation

was more common with newer technologies, especially the minimally invasive interventions.

The economic model suggested that minimally invasive procedures (represented by TUMT) were unlikely to be considered cost-effective compared with TURP. Strategies involving TUMT with TURP as a second procedure as necessary were more costly but had a similar effectiveness to TURP. Of the other ablative procedures, TUVF was less costly than TURP (and also the least costly single treatment considered) but less effective. HoLEP was estimated to be more effective and less costly than a single TURP but less effective than a strategy involving repeating TURP if necessary. However, the base-case analysis suggested an 80% chance that a strategy of TUVF, followed by HoLEP if required, would be the cost-effective strategy at a threshold of £20,000 per quality-adjusted life-year (QALY). At an approximately £50,000 threshold, on average, TUVF, followed by TURP as required, would be cost-effective, although considerable uncertainty surrounds this finding.

Sensitivity analyses

All changes found in the sensitivity analyses were intuitively sensible and their possible impact depended on society's willingness to pay for a QALY.

Limitations of the calculations (assumptions made)

The main limitations relate to the quantity and quality of the data available, in the context of multiple comparisons. Many trials were under-reported or poorly reported; much of the information available was in a form that was unsuitable for meta-analysis. Obtaining cost estimates was not always straightforward and costing under all resource categories was not possible.

Conclusions

For the NHS, increased use of TUVF and/or HoLEP would lead to an increased requirement for training, which may be costly; in addition, it would take time to establish an adequate level of

provision. In the absence of strong evidence in favour of newer methods, TURP remains both clinically effective and cost-effective. The use of minimally invasive technologies in the NHS is not appropriate until a more effective and/or less costly technology is available.

Need for further research

1. For men who might currently be managed medically, a systematic review including modelling to determine how many years of medical treatment are necessary to offset the cost of treatment with a minimally invasive or ablative intervention in the first instance.
2. Better research into the true costs of the different interventions as a critical driver of economic evaluations.
3. Consensus work in partnership with governing bodies such as the British Association of Urological Surgeons to agree parameters for conducting future trials, such as standardising definitions and reporting of outcome measures.
4. For men judged to need ablative therapy, is there an alternative to TURP that is more effective, safe or cost-effective? A well-conducted head-to-head trial of treatment strategies – TUVF followed by either TURP or HoLEP, versus HoLEP, versus TURP × 2 – would be the most desirable to establish the gold standard. Such a trial should take prostate size into account and should include direct measures of utility. Newer technologies could then be compared against this gold standard and, given the rapid developments in this area, a tracker trial approach may be appropriate.
5. Trials of different strategies aimed at improving outcomes and minimising adverse effects after TURP, particularly bleeding.

Publication

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NIHR Health Technology Assessment Programme

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The research reported in this issue of the journal was commissioned by the HTA Programme as project number 04/38/03. The contractual start date was in July 2005. The draft report began editorial review in December 2006 and was accepted for publication in March 2008. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.

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