A clinical outcomes and cost analysis comparing photoselective vaporization of the prostate to alternative minimally invasive therapies and transurethral prostate resection for the treatment of benign prostatic hyperplasia

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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 procedural options for the treatment of benign prostatic hyperplasia (BPH). Options included photoselective vaporisation of the prostate (PVP), microwave thermotherapy (TUMT), transurethral needle ablation (TUNA), interstitial laser coagulation (ILC) and transurethral resection (TURP). TUMT was stratified into three interventions based on the American Urological Association (AUA) Clinical Guidelines for the Management of BPH. The three alternative TUMT interventions were identified as Prostatron Version 2.0, Prostatron Version 2.5 and Targis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The hypothetical patient population was assumed to have lower urinary tract symptoms indicative of BPH and to be suitable for treatment with one of the seven procedural options included in the analysis.

Setting
The hypothetical setting was assumed to differ according to the intervention. It was assumed that PVP procedures were performed in a hospital outpatient setting, that TUNA and TUMT services were performed in a primary care setting, that ILC was performed in a variety of settings including a freestanding ambulatory surgery centre, and that TURP procedures were performed in a hospital inpatient (secondary care) setting. The hypothetical setting related to the USA.

Dates to which data relate
The effectiveness data related to 1996 to 2005, whereas the resource use data related to 1999 to 2005. The price year was 2005.

Source of effectiveness data
The clinical data relating to treatment included the probability of adverse events and the rate of change in clinical outcome scores. These included the American Urological Association/International Prostate Symptom Score (AUASSI/I-PSS), maximum uroflowmetry rate (QMAX) and quality of life (QOL) score. The adverse events included in the model were incontinence, urinary tract infection, impotence/erectile dysfunction, dysuria/irritative voiding, bladder neck stenosis/stricture, urinary retention, haematuria and re-operation.

Modelling
A deterministic Markov model with a 2-year time horizon and monthly cycles was developed. A decision tree was presented in the paper as a simplified schematic of the model structure. The model included eight adverse events associated with the procedural interventions. These and the probabilities of each adverse event were reported, but the authors did not present the input data used for the mortality risk and other clinical outcomes. The authors assumed that only one adverse event could occur per patient over the 2-year follow-up, and that only one instance of re-treatment occurred. The model was analysed by patient level simulation where 10,000 patients were entered into the model, one at a time.

Sources searched to identify primary studies
The probability of adverse events and rates of change in clinical outcome score were obtained from the AUA Clinical Guidelines for the Management of BPH for TURP, TUNA and TUMT, and from a meta-analysis based on a literature review for PVP and ILC since they were not included in the guidelines.

Methods used to judge relevance and validity, and for extracting data
The authors reviewed the literature to identify clinical trials that involved PVP or ILC. They did not report the methods of the review, which identified 25 clinical trials. The authors reported that the meta-analysis was based on an approach described in the AUA guidelines methodology in order to ensure consistency between the clinical data for each intervention. The baseline values for AUASS/I-PSS, QMAX and QOL were assumed to be the same for all procedural interventions.

Measure of benefits used in the economic analysis
There was no summary measure of benefit. The main outcomes of the model were average scores for AUASS/I-PSS, QMAX and QOL. These were not well described, but they all appear to have measured negative clinical outcomes. This means that a decrease in the scores actually represents an improvement in the health of the patient. The percentage decrease in the scores from baseline was reported for each score at 6, 12 and 24 months.

Direct costs
The study included the costs to a third-party payer, specifically Medicare. The direct costs covered the initial intervention (which varied in setting), routine follow-up care related to BPH, the treatment of adverse events and procedural re-treatment. The costs of pharmacological treatments were excluded from the analysis. The authors assumed that the cost per adverse event would be the same for all treatments. The costs were derived from Medicare claims data. The authors did not apply discounting, which was inappropriate given the 2-year time horizon. All costs were inflated to 2005 using the medical care component of the Consumer Price Index. The authors reported the average cost of each adverse event, the average cost of each initial procedure (weighted according to the setting in the case of ILC), and the expected cost per patient as estimated in the economic model.

Statistical analysis of costs
The authors conducted a deterministic analysis and did not undertake any statistical analysis of the costs.

Indirect Costs
The indirect costs were not included in the analysis, which was consistent with the perspective adopted.

Currency
US dollars ($).

Sensitivity analysis
The authors performed several one-way sensitivity analyses to test the robustness of the model results to different
parameter values. A threshold analysis was used to determine the re-treatment rate at which the cost of PVP would be equal to that of TURP. In addition, an extreme case analysis was conducted in which parameter values were varied to the maximum observed or feasible.

**Estimated benefits used in the economic analysis**
There were too many results to report in this abstract. PVP resulted in the largest benefit in all clinical outcome measures, followed by TURP. The remaining five interventions would be ranked differently according to the clinical outcome measure selected. The numbers of adverse events were not reported as these were used simply to obtain an estimate of the costs.

**Cost results**
The expected cost per patient over 2 years was:

- $3,589 for PVP,
- $4,754 for ILC,
- $4,927 for TUNA,
- $6,179 for TURP,
- $5,461 for TUMT Prostatron Version 2.0,
- $5,488 for TUMT Prostatron Version 2.5, and
- $5,699 for TUMT Targis.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant.

**Authors' conclusions**
Photoselective vaporisation of the prostate (PVP) is a clinically efficacious and cost-effective treatment for benign prostatic hyperplasia (BPH) when compared with alternative minimally invasive options and transurethral resection of the prostate (TURP).

**CRD COMMENTARY - Selection of comparators**
The authors justified their choice of the comparators by stating that the procedural options for BPH had not previously been compared simultaneously. You should decide whether the alternatives compared are relevant in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence was derived from a set of published guidelines for TURP, TUNA and TUMT. The authors conducted a meta-analysis using the same methods as used in the published guidelines to obtain corresponding estimates for PVP and ILC. They did not describe the methods used for the review of the literature or the meta-analysis. The authors stated that the review did not allow a standardisation of data across studies as a mix of study types was included. The review combined data from prospective studies, retrospective studies and from cohorts with different patient characteristics. This might have allowed several sources of bias to be incorporated in the estimates of effectiveness. The effectiveness evidence for PVP and ILC was based on more recent evidence than that reviewed in the published guidelines. It was unclear why the authors did not update the meta-analysis for all comparators. The authors did not describe the outcomes in sufficient detail (QOL in particular), which made the table reporting the results very confusing.
Validity of estimate of measure of benefit
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed.

Validity of estimate of costs
The analysis of the costs was performed from the perspective of a third-party payer, specifically Medicare in the USA. The authors excluded the cost of pharmacological interventions for BPH as these were not relevant to the study question. They also assumed that the cost per adverse event would be the same for all procedural interventions. All relevant costs appear to have been included in the analysis. Medicare reimbursement rates were used to determine costs, thus the results may not be generalisable to other third-party payers or other countries. The authors did not discount the costs in spite of the 2-year time horizon. The cost data were adequately reported and the price year was stated.

Other issues
The authors did not compare their results with the findings from other studies, stating that there were no published studies comparing the procedural options for BPH. The issue of generalisability to other settings was not addressed. The authors do not appear to have reported their results selectively, nor did they provide sufficient detail about the uncertainty around the input parameters. The authors' conclusions are dependent on the validity of the underlying model structure and assumptions, which may not be strong enough to support firm conclusions.

Implications of the study
The authors did not make any recommendations for further research.

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