# Randomised evaluation of alternative electrosurgical modalities to treat bladder outflow obstruction in men with benign prostatic hyperplasia

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## Executive summary

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# Executive summary

## Objectives

To compare and evaluate the clinical and cost-effectiveness of transurethral vaporisation of the prostate (TUVP), a new electrosurgical modality, with the standard treatment, transurethral resection of the prostate (TURP).

## Design

A multicentre randomised controlled trial of pragmatic design with associated economic evaluation using cost minimisation.

## Setting

Patients were recruited from four centres in south-east England.

## Participants

Between March 1997 and August 1999, 235 men were recruited across the four participating centres. All patients had previously been assessed as requiring surgery for lower urinary tract symptoms deemed to be due to benign prostatic hypertrophy. Patients with clinical evidence of prostatic cancer, those unfit for surgery and those who had had previous prostatic surgery were excluded. Forty-five patients recruited were in urinary retention.

## Interventions

Randomisation was performed by a sealed envelope system provided by the data monitoring team at PROTO. Symptomatic and retention patients were randomised separately to ensure an even distribution in each arm. Patients were randomised as close as possible to the time of their operation.

TURP was performed and subsequent management conducted according to the usual practice of the clinical team. TUVP was performed with the most promising available equipment using a technique described in the literature. Postoperative management after TUVP was left to the ward team, who were not necessarily informed to which treatment arm the patient had been allocated.

For the purpose of the study, patients were assessed clinically, by questionnaire and investigation at baseline, 2 months and 6 months after randomisation. A long-term follow-up postal questionnaire was sent to each patient at 2 years.

For the economic evaluation, direct costs from the NHS viewpoint were collected.

## Main outcome measures

The International Prostate Symptom Score (IPSS) was used as the primary outcome measure. Patients in retention were allocated an IPSS related to the period immediately before retention occurred. A reduction of IPSS of $\geq 5$ was taken as a satisfactory outcome. The IPSS quality of life (QoL) question provided disease-specific information about QoL.

The following were used as secondary outcome measures:

- urinary flow rate – two free flow rates with voided volume of >150 ml at each visit
- post-void urinary volume assessed by transabdominal ultrasound – two measurements at each visit
- prostate volume by transrectal ultrasound – at baseline and 6 months only
- pressure-flow urodynamics in the standing position using the medium fill rate technique
- questionnaires – SF-36, EuroQol and a sexual function section based on the International Incontinence Society – 'Benign Prostatic Hyperplasia' (ICS-BPH) questionnaire.

Blood was taken for measurement of full blood count and urea and electrolytes at baseline and at 24 hours. Adverse events were recorded on the Data Collection Form (DCF) during the hospital

stay. At follow-up visits, any adverse event that had occurred since last contact with the study team was recorded, as were any visits to the district nurse, GP or any hospital.

## Results

### Effectiveness

TURP and TUVP were both effective in producing a clinically important reduction in IPSS and positive change in the IPSS QoL question. The success rate for relief of symptoms, defined as a >5 reduction in IPSS at 6 months was 85% for TURP and 74% for TUVP. Neither the success of the treatment nor the change in aggregated IPSS was significantly different between the groups. The improvement was sustained to 24 months after treatment with no significant difference between the groups. The effectiveness of both treatments was also equivalent when assessed through improvement in objective measures of urinary tract function, reduction in prostate size and the change in health questions of SF-36.

There was no change from baseline for other domains of SF-36 or EuroQoL.

### Adverse events

For the purposes of this study, an adverse event was defined as any undesirable experience that the patient had, whether considered procedure-related or not.

The absolute incidence of adverse events was similar between the two groups. The incidence of severe or prolonged bleeding was less with TUVP, as evidenced by the need for blood transfusion and the drop in haemoglobin level 24 hours postoperatively.

### Resource use

TURP and TUVP are broadly equivalent in direct NHS resource use. In particular, staff costs, theatre usage and capital equipment costs are the same. This study did not show any significant difference in inpatient stay or use of outpatient resources between the groups. The disposable electrodes used for TUVP are more expensive than reusable TURP electrodes.

## Conclusions

The study's primary conclusions were as follows:

- TURP and TUVP are equivalently effective in improving the symptoms of benign prostatic enlargement.
- The improvement in symptoms lasts for at least 2 years.
- TUVP is associated with less morbidity due to haemorrhage than TURP.
- Reduction in bleeding after transurethral surgery to the prostate is not associated with a significant reduction in hospital stay when patients are managed by staff who are accustomed to managing patients after TURP.
- Replacement of TURP by TUVP would not produce a significant cost benefit to the NHS unless a reduction hospital inpatient stay of at least 1 day could be secured.

## Recommendations for future research

The following areas of further research are recommended for consideration:

- Further research is necessary to determine why patients stay in hospital after transurethral surgery to the prostate and how a reduction in the length of stay can be achieved.
- A much larger observational study/audit is required to assess the incidence of infrequently occurring adverse events after TUVP. Until the results are available, TUVP should not replace TURP in the NHS.
- The patients in this study should be followed for a longer period to establish whether the durability of improvement is similar to 5 years and beyond.

## Publication

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The HTA programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, consumer groups and professional bodies such as Royal Colleges and NHS Trusts.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 94/04/09. As 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.

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