

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

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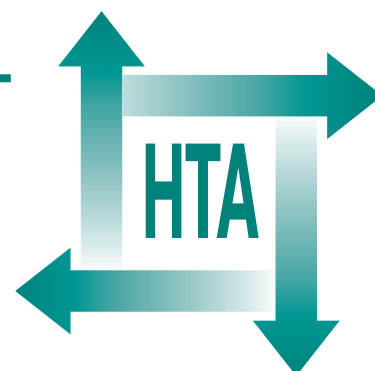
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Executive summary

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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 ≥ 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 TUVF 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 TUVF. 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 TUVF, as evidenced by the need for blood transfusion and the drop in haemoglobin level 24 hours postoperatively.

Resource use

TURP and TUVF 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 TUVF are more expensive than reusable TURP electrodes.

Conclusions

The study's primary conclusions were as follows:

- TURP and TUVF are equivalently effective in improving the symptoms of benign prostatic enlargement.
- The improvement in symptoms lasts for at least 2 years.
- TUVF 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 TUVF 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 TUVF. Until the results are available, TUVF 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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NHS R&D HTA Programme

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the 'National Knowledge Service' that is being developed to improve the evidence of clinical practice throughout the NHS.

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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.

Research suggestions are carefully considered by panels of independent experts (including consumers) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or designing a trial to produce new evidence where none currently exists.

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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.

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