Cost effectiveness of microwave thermotherapy in patients with benign prostatic hyperplasia. Part I: methods

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
Microwave thermotherapy in patients with benign prostatic hyperplasia.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised a hypothetical cohort of 10,000 65-year-old men with moderate to severe BPH symptoms. Patients had an American Urology Association symptom score greater than 14 and less than 30 and no clinical conditions precluding the use of any of the three treatment alternatives. Patients with prostate cancer and other serious comorbidities were excluded from the analysis.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
Effectiveness and resource use data were collected from studies published between 1988 and 1999. Cost data were taken from sources published between 1996 and 1999. The price year was 1999.

Source of effectiveness data
Effectiveness data were derived from a literature review and expert opinion.

Modelling
A 5-year Markov decision analytic model was used to determine the cost-effectiveness of transurethral microwave thermotherapy compared with medical therapy and TURP for a cohort of 65-year-old men with moderate to severe BPH symptoms.

Outcomes assessed in the review
The review assessed health states, short-term clinical events, long-term outcomes, and utility weights associated with the three treatment options. The outcomes assessed included rates of remission, temporary and permanent adverse events, retreatment, and mortality.
Study designs and other criteria for inclusion in the review
Some effectiveness estimates were obtained from a multicentre, prospective, randomised controlled trial, others from published reports.

Sources searched to identify primary studies
MEDLINE was searched from 1966 to present. The search was limited to articles in English and excluded review articles, letters, and editorials. The reference lists from the retrieved articles were also reviewed.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Summary statistics from individual studies were used.

Number of primary studies included
At least eighteen primary studies were included.

Methods of combining primary studies
A narrative method was used.

Investigation of differences between primary studies
Not stated.

Results of the review
The probabilities of remission ranged from 0.23 to 0.5 with thermotherapy, from 0.295 to 0.4 with medical therapy, and from 0.1 to 0.7 with TURP.

The probability of worsening BPH symptoms was 0.02 with thermotherapy, 0 with medical therapy, and 0.05 with TURP.

The probability of death was 0 with thermotherapy and 0.0005 with medical therapy.

The probabilities of temporary adverse events (urinary retention, incontinence, epididymitis) ranged from 0.02 to 0.08 with thermotherapy and from 0.02 to 0.75 with TURP.

With medical therapy, probabilities of ejaculatory dysfunction, erectile dysfunction, and myocardial infarction were 0.06, 0.1, and 0.01, respectively.

The probabilities of haemorrhage requiring transfusion and requiring surgical repair were 0.12 and 0.02, respectively, with TURP.

The probabilities of myocardial infarction, urethral stricture, severe UTI, and deep vein thrombosis were 0.01, 0.04, 0.01, and 0.02, respectively, with TURP.

The probabilities of permanent adverse events (incontinence, ejaculatory or erectile dysfunction) ranged from 0.01 to 0.73 with TURP.

Utility values for significant remission, moderate remission, no remission, and worsening of BPH symptoms without an adverse event were 99.1, 97.1, 94.4, and 87.3, respectively, in non-risk-adverse patients.
Utility values for significant remission, moderate remission, no remission, and worsening of BPH symptoms without an adverse event were 100, 99.8, 98.2, and 97.0, respectively, in risk-adverse patients.

Methods used to derive estimates of effectiveness
Effectiveness estimates were also derived by consulting a multispecialty clinical panel, including two urologists, a general internist, and a nurse practitioner and were also based on authors' assumptions.

Estimates of effectiveness and key assumptions
The probabilities of retreatment ranged from 0.05 to 0.5 with thermotherapy, from 0.05 to 0.5 with medical therapy, and from 0.0 to 0.85 with TURP.

The authors made the following assumptions. That men who undergo any of the treatments will require retreatment if their symptoms either do not improve within 2 months after treatment or degenerate over time. That men treated with TURP can undergo retreatment up to three times and that men treated with thermotherapy or medical therapy can only be retreated twice. Finally, patients with moderate-to-severe BPH symptoms after the initial treatment may enter into a watchful waiting health state.

Measure of benefits used in the economic analysis
Quality-adjusted life months (QALM) were used as the measure of benefit. Utility estimates were obtained by interviewing 13 patients with moderate-to-severe BPH symptoms using the standard gamble technique. The standard gamble was administered to patients by a trained interviewer using a pilot-tested script. Preferences were recorded using standardised answer sheets. Benefits were discounted at an annual rate of 3%.

Direct costs
Direct costs were discounted at an annual rate of 3%. Quantities and costs were reported separately. Direct costs were the treatment costs of TURP, medical therapy, and thermotherapy, costs of treating adverse events, and costs based on response to therapy. The quantity/cost boundary adopted was that of society. Costs were taken from the national Medicare reimbursement schedules. Laboratory test costs were taken from the Clinical Laboratory Information Act Fee Schedule. Drug costs were estimated from the Drug Topics Red Book. Professional fees for anaesthesiology services were taken from the Medicare Fee Schedule for Anaesthesiology. Costs for thermotherapy were derived from a large medical centre in Seattle, Washington. The price year was 1999.

Statistical analysis of costs
No statistical analyses of costs were reported.

Indirect Costs
Indirect costs of lost productivity and intangible costs of pain and suffering related to BPH morbidity were characterised in the health state descriptions and were incorporated in the utility values.

Currency
US dollars ($).

Sensitivity analysis
One-way sensitivity analyses were conducted on initial success, durability, costs, utilities, adverse effects, discount rate, and time horizon.
Estimated benefits used in the economic analysis
The number of QALMs gained were 53.29 by medical therapy, 53.52 by thermotherapy, and 51.81 by TURP.

Cost results
Total costs were $6,294 for medical therapy, $7,035 for thermotherapy, and $7,334 for TURP.

Synthesis of costs and benefits
For the non-risk-adverse patients, thermotherapy was dominant over TURP. The incremental cost per QALY gained of thermotherapy over medical therapy was $38,664. The cost-effectiveness results in the risk-adverse patients were similar to those in the non-risk-adverse patients. The incremental cost per QALY gained of thermotherapy over medical therapy was sensitive to the initial success rates and the durability associated with thermotherapy and medical therapy.

Authors' conclusions
From a societal perspective, thermotherapy appears to be a reasonable and cost-effective alternative to both medical and surgical treatment. However, the actual treatment decision should be based on multiple factors, only one of which is cost-effectiveness.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparators used, namely that they represented traditional strategies. You, as a user of the database, should decide if these health technologies are relevant to your setting.

Validity of estimate of measure of effectiveness
The authors undertook a literature review to derive effectiveness estimates that seemed appropriate, although they did not state that a systematic review of the literature had been undertaken. Additional effectiveness estimates were, appropriately, based on expert opinion. The validity of the results was enhanced by sensitivity analyses to account for variability in the estimates. The authors based their analysis on a number of assumptions, for which no justification was presented. Effectiveness data used in the five-year model were based on three-year data for thermotherapy.

Validity of estimate of measure of benefit
The estimation of benefits was modelled. The instrument used to derive health benefits, the standard gamble preference measurement technique, was appropriate. Utility values were based on the experience of a small number of patients who have BPH.

Validity of estimate of costs
Good features of the cost analysis were that all relevant direct cost categories were included, indirect costs were incorporated in utility values and the validity of cost results was enhanced by appropriate sensitivity analyses. Furthermore, quantities and costs were reported separately, which enhances the generalisability of the results. Finally, the price year was reported, which would make reflation exercises in other settings possible. However, charges were not converted into costs and, hence, true opportunity costs were not estimated.

Other issues
The authors made appropriate comparisons of their findings with those from other studies but the issue of generalisability to other settings was not addressed. The authors did not present their results selectively. The study considered 65-year-old men with moderate-to-severe BPH symptoms and this was reflected in the authors' conclusions.

Implications of the study
The authors suggested that from a societal perspective, thermotherapy appears to be a reasonable and cost-effective alternative to both medical and surgical treatment. However, the actual treatment decision should be based on multiple factors, only one of which is cost-effectiveness.

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