A double-blind randomized controlled trial and economic evaluation of transurethral resection vs contact laser vaporization for benign prostatic enlargement: a 3-year follow-up

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
Contact laser prostatectomy in the treatment of benign prostatic hyperplasia. The prostate is vaporised using an SLT MD60 Nd: YAG machine, with a 600 Micro metre fibre with a semi-rigid distal end incorporating a 6-mm sapphire-tipped round probe. The irrigation fluid used during laser treatment was normal saline.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients presenting for TURP. The exclusion criteria were as follows: patients who had undergone previous surgery or instrumentation for benign prostatic enlargement (BPE), had known prostate cancer, were unable to understand sufficient English to complete the questionnaires or were unable to give informed consent.

Setting
Hospital and community. The economic analysis was carried out in Oxford, UK.

Dates to which data relate
Effectiveness and resource use data corresponded to patients enrolled in the study between January 1993 and January 1995. The price year was 1997.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

Link between effectiveness and cost data
Costing was conducted prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were used to determine the sample size (although they appear to have been retrospective); the sample size of 150 selected would detect a difference of 5 in the American Urologic Association (AUA) symptom score, with a double-sided alpha of 0.05 and a beta of 0.1; the study was judged to have adequate power to detect a moderate to large change in symptoms. In total 152 patients were randomly assigned to TURP or contact laser prostatectomy. Four patients were excluded after randomisation in the laser group as a consequence of the decision to
perform a retropubic prostatectomy or urethrotomy rather than an endoscopic prostatectomy. As a result, 148 patients were treated: 72 by contact laser (median age 70 years, range: 51-95) and 76 by conventional TURP (median age 71 years, range: 47-84). Surgery was performed by 5 surgeons, all operators having limited experience with the laser procedure before the study.

Study design
This was a double-blind randomised controlled trial, carried out in a single centre. The duration of the follow-up was 3 years. Besides four being lost to follow-up immediately after randomisation in the laser arm, the number of patients lost to follow-up at 1, 2, and 3 years were 14, 25, and 29, respectively, in the laser arm versus 12, 23, and 32 in the TURP arm of the study. Randomisation was performed using restricted randomisation balanced to 10, and sealed envelopes kept in the operating theatre. The patient, ward and medical staff (other than the operating surgeon) were unaware of the treatment received.

Analysis of effectiveness
The principle used in the analysis of effectiveness was stated to have been intention to treat. The primary outcome measure was the AUA symptom score. Secondary outcome measures were peak urinary flow rate, treatment-related complications, and re-operation rate. The study groups were comparable in terms of prostate volume and prostate urethral length. The relationship between re-operation events and operator experience was assessed using the chi-squared test for trend.

Effectiveness results
The effectiveness results were as follows:

The mean (SD) AUA score after 1 year in the laser group was 8.7 (6.5) from 19.9 (7.7) at baseline versus 5.8 (5.4) from 19.4 (6.5) at baseline in the TURP group, (p=0.006).

The mean (SD) AUA score after 2 year in the laser group was 7.8 (6.6) versus 5.7 (6) in the TURP group, (p=0.018).

The corresponding values after 3 years were 8.9 (6.6) in the laser group and 6.5 (6.5) in the TURP group, (p=0.001).

The mean (SD) peak urinary flow rate (mL/s) at 1 year in the laser group was 17.1 (13.2) from the baseline value of 11.8 (4.5) versus 21.2 (12.4) from the baseline value of 11.4 (5) in the TURP group, (NS).

The mean (SD) peak urinary flow rate (mL/s) at 2 year in the laser group was 14.2 (7.4) versus 15.9 (8.0) in the TURP group, (NS).

The corresponding values after 3 years were 13.4 (7.3) in the laser group and 12.7 (6.4) in the TURP group, (NS).

Regarding the complications, it was reported that perioperative blood loss and transfusion requirements significantly favoured the laser treatment (median blood loss 39 mL versus 200 mL).

One patient treated by laser developed a scrotal abscess, while the urethral stricture rate and urinary tract infection rate was slightly higher in the TURP group.

The mean duration of catheterisation was less in the laser arm (1 day versus 2 days), although the need for re-catheterisation was higher; 17 patients in the laser arm failed to void when the urethral catheter was removed (28%), compared with eight in the TURP arm (12%), (p<0.05).

At 3 years, 13 of the laser patients (18%) and seven of the TURP patients (9%) had undergone re-operation.

Clinical conclusions
There were no clinically significant differences between TURP and contact laser prostatectomy in the mean change in
symptom scores and flow rates. There were distinct perioperative advantages in favour of the contact laser treatment, but some disadvantages in terms of re-catheterisation and re-operation rates.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported. Since it was judged that there was no clinically significant difference between TURP and contact laser prostatectomy in the mean change in symptom scores and flow rates the economic study was reduced to a cost-minimisation analysis.

Direct costs
Costs were not discounted despite a three-year time frame considered for the study incorporating complications and re-operations. Resource use quantities were reported separately from the costs. Cost items were reported separately. The cost analysis covered the cost of theatre (overheads and consumables), hotel services, community services (including out-patient visits, GP consultations, and practice and district nurse visits), laser and capital services, and re-operations. The perspective adopted in the cost analysis was that of the National Health Service (NHS). The volumes of resources used by each patient were recorded during the study. Unit costs were calculated based on the opportunity cost of all resources using the cost of each resource item using 1996 market prices or costs obtained from the hospital or national statistics. The NHS hospital and community price index was used to adjust cost data to 1997 prices. The full economic methodology of this study was reported elsewhere in a paper published in 1996. The price year was 1997.

Statistical analysis of costs
95% confidence intervals (CIs) were calculated for the differences in the cost items and in total costs. The type of statistical test performed was not reported.

Indirect Costs
Not included.

Currency
UK pounds sterling ( ).

Sensitivity analysis
A one-way sensitivity analysis was conducted on the laser in-patient stay to assess the possible impacts on the cost difference between the two procedures.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The mean total cost for the laser group was 1,252.2 versus 971.4 in the TURP group, resulting in a difference of 280.8 (95% CI: 192.3 - 369.3). Sensitivity analysis showed that reducing the laser in-patient stay to 1.5 days would decrease the base-case difference to -50 (95% CI: -122 - 22) in favour of the laser procedure.

Synthesis of costs and benefits
Costs and benefits were not combined since the economic study proceeded on a cost-minimisation basis.
Authors' conclusions
Contact laser prostatectomy is a valid treatment for benign prostatic hypertrophy. The performance of contact laser prostatectomy as day-case surgery would have cost advantages to the National Health Service.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator (TURP). It was the conventional method used in the context in question. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results is likely to be high due to the double-blind randomised nature of the study design, and sample size determination through power calculations. Although it was claimed that the effectiveness analysis was based on intention-to-treat analysis, this appears not to be justified given the primary clinical outcome being based on less than the full sample size in each study group. The study patients were found to be comparable in terms of prostate volume and prostate urethral length. The relationship between re-operation events and operator experience was assessed using the chi-squared test for trend. It was speculated that the higher failure rate in the laser group might be due to the fact that the technique was new and the surgeons had limited experience with it before the study; careful patient selection and increased surgical experience may reduce the re-operation rate. The study sample appears to have been representative of the study population. The authors' clinical conclusions do not appear to be fully justified given the different outcome measures, indicating different results regarding the effectiveness of the two procedures involved; adopting a composite measure could have given an unequivocal result and reduced the role of subjective assessments which are prone to bias.

Validity of estimate of measure of benefit
The analysis of benefits was based on therapeutic equivalence of treatment alternatives. The economic analysis therefore included only costs.

Validity of estimate of costs
Good attributes of the cost analysis were that: resource use quantities were reported separately from the costs, adequate details of methods of cost estimation were given, the price year and the perspective adopted were specified, and statistical analyses were performed on resource use or cost data. However, discounting may have been appropriate for the chosen time frame, and the effects of alternative procedures on indirect costs were not addressed.

Other issues
The authors' conclusion appears to be justified given the randomised nature of the study design and the sensitivity analyses performed. The issue of generalisability to other settings was not addressed in the sensitivity analysis, although appropriate comparisons were made with other studies. The degree to which the study sample was representative of the study population was not discussed.

Implications of the study
There are plausible circumstances in which the costs of the laser treatment could be similar or even less than conventional TURP (the laser in-patient stay of 1.5 days). The adoption of day-case laser surgery as a treatment option is already a reality in Oxford, and this, together with the satisfactory outcome in terms of symptomatic relief, and equally importantly the lack of haemorrhage during and after surgery, makes contact laser surgery an important option in the management of the study population.

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Other publications of related interest

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