Systematic review of minimally invasive techniques for relief of bladder outflow obstruction: update and re-appraisal

Authors' objectives
To compare the safety and efficacy of minimally invasive laser prostatectomy techniques and minimally invasive non-laser thermal prostatectomy techniques against transurethral resection of the prostate (TURP), the current benchmark treatment. Comparisons would also be made, where possible, between different laser techniques and different treatment regimens within the one laser or thermal technique.

Searching
MEDLINE (from 1984 to December 1999), Current Contents (from 1993 to December 1999), EMBASE (from 1974 to December 1999) and the Cochrane Library (from 1966 to December 1999) were searched without language restrictions. The search terms were listed. Foreign language papers were not translated because their abstracts did not offer any significantly different or more extensive results than those reported in the English language papers. Only full papers (not abstract) were included in the review.

Study selection
Study designs of evaluations included in the review
RCTs, controlled clinical trials, case series and case reports were eligible for inclusion.

Specific interventions included in the review
Studies that compared visual laser ablation of the prostate (VLAP), interstitial laser coagulation (ILC) or laser contact vaporisation (LCV), high-intensity focused ultrasound of the prostate (HIFU), transurethral electrovaporisation of the prostate (TUVP), transurethral microwave therapy (TUMT), or transurethral needle ablation of the prostate (TUNA) to TURP or to each other were eligible for inclusion in the review. Comparisons of different treatment regimens within the one laser or thermal intervention were also eligible for inclusion.

Placebo-controlled trials were not included. Studies of holmium laser resection of the prostate and transurethral ultrasound-guided laser-induced prostatectomy were excluded. Combinations of laser techniques with each other were excluded, as were combinations of laser techniques with other techniques (e.g. bladder neck incision or TUIP) unless data for these patients could be separated from the pooled results. Case series detailing TUVP were excluded because there were randomised controlled trials (RCTs) available. The assessment of TUMT was limited to studies using the Prostatron device in conjunction with Prostasoft software, and case series of TUMT were only included if they had a minimum follow-up of two years.

Participants included in the review
Studies of patients with bladder outflow obstruction and non-malignant enlargement of the prostate were eligible for inclusion in the review.

Outcomes assessed in the review
Safety and efficacy outcomes were eligible for inclusion in the review. For safety, the question was whether any of the laser or thermal procedures were more or less likely to cause injury or harm to the patient in comparison with TURP; a range of major and minor post-operative complications were assessed. For efficacy, the question was whether any of the laser or thermal procedures produced equivalent clinical outcomes in comparison with TURP; subjective and objective urodynamic parameters, peri-operative treatment data and reoperation rate were among those assessed. To be eligible for inclusion, the studies were required to report at least pre-operative measurements of symptom score and urine flow, to have a minimum follow-up period of one year and information on at least one of the following outcomes: subjective or objective symptom improvement and post-operative morbidity or mortality. Articles were excluded if they reported only preliminary and incomplete patient data sets.
How were decisions on the relevance of primary studies made?
Two reviewers selected the studies and decisions were reached by consensus.

Assessment of study quality
The authors appear to have assessed aspects of validity such as allocation concealment, sample size, follow-up period, handling of withdrawals, patient selection criteria and blinding. The level of evidence of the included studies was also assessed, based on their study design. The authors do not state how the validity assessment was performed.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction. Data were extracted on the sample size, maximum follow-up, loss to follow-up and outcomes.

Methods of synthesis
How were the studies combined?
Where there was no significant heterogeneity, a fixed-effect model was used to calculate the pooled relative risks and 95% confidence intervals for RCTs of each intervention versus TURP, otherwise a random-effects model was used. In the review of thermal techniques, weighted mean differences and 95% confidence intervals were calculated and standardised mean differences were used to compare symptom scores, peak urinary flow rate and post void residual volume. Continuous data were not pooled in the review of laser techniques because one of the larger studies did not provide these data. Only data from clinically homogeneous RCTs with similar allocation concealment were pooled. The findings from other study designs were summarised narratively.

How were differences between studies investigated?
Chi-squared tests were used to assess statistical heterogeneity, with a p-value of less than 0.1 used to indicate significant heterogeneity. Only RCTs with comparable outcomes, inclusion criteria, treatment regimen and follow-up period, and similar allocation concealment, were pooled.

Results of the review
Fourteen studies (n=1,365) were included in the review of laser techniques: 6 RCTs (n=396), 3 controlled studies (n=408) and 5 case series (n=504). Thirty studies (n=4,080) were included in the review of thermal techniques: 9 RCTs (n=775), 1 controlled study (n=57) and 20 case series (n=3,248).

Review of laser techniques: the small sample size and poor quality of many studies meant that no definitive conclusion could be made as to the safety and efficacy of VLAP, ILC or LCV in comparison with TURP. There was limited evidence to suggest that safety outcomes favoured VLAP, ILC and LCV, whereas effectiveness outcomes favoured TURP. All three laser techniques achieved comparable improvements in symptom score, maximum urinary flow rate and post void residual urine volume, but LCV appeared to be safer than VLAP and ILC.

Review of thermal techniques: the small sample size and poor quality of many studies meant that no definitive conclusion could be made about the safety and efficacy of HIFU, TUMT or TUNA in comparison with TURP. Current evidence suggested that safety outcomes favoured HIFU, TUMT and TUNA, while effectiveness outcomes favoured TURP. A meta-analysis of TURP versus TUVP trials showed a similar degree of symptomatic relief for both treatments over a 1- to 2-year period, but with less morbidity in the TUVP group.

The results for each outcome were reported in the report.

Authors' conclusions
The evidence-base for VLAP, ILC, HIFU, TUMT, TUNA and LCV is inadequate and a controlled clinical trial of ILC should be conducted. An audit of VLAP and LCV should be undertaken.
TUVP is a suitable alternative to TURP for certain patient groups.

**CRD commentary**

The review was split into two parts: a review of minimally invasive laser techniques versus TURP, and a review of minimally invasive non-laser techniques versus TURP. The two reviews had similar methodologies and were presented together as a single report. However, because no attempt had been made to amalgamate their contents, it was difficult to get an overview of laser and thermal techniques versus TURP.

Both reviews used explicit detailed inclusion criteria and undertook reasonably comprehensive literature searches without language restrictions. However, there does not appear to have been any attempts to locate unpublished or additional material, which might mean that some studies have been missed. The validity assessment appeared (from the 'Methods' section of each review) to be restricted to a level of evidence assessment based on study design. However, from the text it is apparent that the authors took account of other aspects such as allocation concealment, handling of withdrawals and blinding in their analysis, but it is not clear how this was done. Some details of the review process were missing, such as how many reviewers extracted the data.

Details of the included studies were presented, but there were few details relating to the participants. Only clinically homogeneous RCTs were included in the meta-analysis, but other study designs were added in a narrative synthesis; it is not clear how much weight was given to these more biased study designs in comparison with the RCT evidence. The authors' conclusions appear to follow from the results presented, but should be treated with caution due to the limitations highlighted.

**Implications of the review for practice and research**

**Practice:** The authors state that VLAP and ILC are contraindicated in patients with large prostates and/or median lobe enlargement. ILC is considered inappropriate for patients with complete urinary retention. The authors state that TUVP is appropriate for widespread use, with the caveat that it may be contraindicated in patients with large prostates or those wishing to preserve erectile function.

**Research:** The authors state that future studies should include more meaningful urodynamic parameters to ascertain the effectiveness of thermal techniques, VLAP and ILC in the treatment of bladder outflow obstruction. Recommendations include a controlled clinical trial of ILC (ideally a RCT) and further controlled comparisons of HIFU, TUMT and TUNA with TURP, untreated controls and medical treatment. An audit of VLAP and LCV was also recommended.

**Bibliographic details**


**Other publications of related interest**


**Indexing Status**

Subject indexing assigned by CRD

**MeSH**

Electrocoagulation /methods; Hyperthermia, Induced /methods; Male; Microwaves /therapeutic use; Prostatectomy /methods; Prostatic Hyperplasia /surgery; Ultrasonic Therapy /methods
Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.