



Australian Safety
and Efficacy
Register of New
Interventional
Procedures –
Surgical

Executive summary

Holmium Laser Prostatectomy for Benign Prostatic Hyperplasia

(Adapted from the report of the Review Group by Dr R. Tooher)

Objective

The objective of this review was to assess the safety and efficacy of holmium laser prostatectomy, both holmium laser resection of the prostate (HoLRP) and holmium laser enucleation of the prostate (HoLEP), in comparison with transurethral resection of the prostate (TURP) - the current standard treatment for benign prostatic hyperplasia (BPH).

Methods

Databases (OVID PreMEDLINE, OVID MEDLINE, Current Contents, Cochrane Library, EMBASE, UK National Research Register, NIH Clinical Trials.Gov, PubMed, Science Citation Index, SIGLE and the HTA Database) were searched up to, and including, August 2002. Studies were included if they dealt with benign prostatic hyperplasia and contained data on at least one of the specified outcomes. Studies that utilised combination laser therapy (using neodymium and holmium laser) were excluded from the review. The comparator procedure was the current gold standard treatment for BPH, transurethral resection of the prostate (TURP). Where appropriate, data from RCTs were statistically pooled and relative risks (RR) or weighted mean differences (WMD), with 95% confidence intervals, were calculated. Where it was thought to add to the interpretation of results, RR and WMD were calculated for single RCTs. Large, well conducted TURP case series were also retrieved as benchmark information; these were derived from randomised controlled trials of more than 50 patients where the comparator was not one of the holmium laser prostatectomy techniques. The specified outcomes were perioperative, short-term and long-term morbidity and mortality rates, urodynamic outcome, symptom relief and cost effectiveness.

Results

Studies that compared the use of HoLRP or HoLEP with TURP in the treatment of BPH were limited in number. Three randomised controlled trials comparing HoLRP and TURP and two comparing HoLEP and TURP were identified. There was also one uncontrolled comparative study comparing each of the holmium techniques with TURP. The remainder of the evidence was in the form of case series (Level IV evidence). There were 13 HoLRP case series and 10 HoLEP case series. The available evidence-base was relatively weak with only one of the five RCTs considered to be of good quality. The other RCTs identified were hampered by poor reporting of methodological details particularly methods of randomisation, allocation concealment and blinding. In general the evidence-base was weakened by significant losses to follow-up and short follow-up periods.

In terms of the primary safety issue from a clinical perspective – blood loss – both of the holmium laser procedures (HoLRP and HoLEP) were found to be superior to TURP in terms of a number of key indicators (transfusion rates, postoperative bladder irrigation, and duration of catheterisation and length of hospital stay), although blood loss itself was not often reported due to measurement difficulties. There did not appear to be a difference between the holmium laser procedures and TURP for rates of stricture or urinary tract infection. However, for other safety outcomes, such as mortality and rates of

perforation, it was difficult to make any firm conclusions due to a lack of high quality data. In terms of efficacy, the holmium laser procedures appear to be equivalent to TURP for symptom relief. TURP was found to be superior to the holmium laser procedures in terms of operative times and retrieved more tissue than HoLRP. The addition of the mechanical morcellator in the HoLEP technique appeared to result in more tissue being retrieved than in TURP. Both the holmium laser techniques and TURP were found to retrieve adequate tissue for postoperative histology to detect undiagnosed prostate cancer. The lack of long-term follow-up in the majority of holmium laser studies meant that no conclusion could be drawn about the long-term durability of the procedures in comparison to TURP. Cost-effectiveness was addressed in one RCT comparing HoLRP and TURP, which suggested that HoLRP may be more cost-effective than TURP. However, longer term follow-up and studies in other settings would be required to determine whether this finding can be generalised.

Conclusion and recommendations

Classifications

Evidence rating – On balance, the evidence-base was rated as average. However, for some outcomes the evidence base was poor and as a result no conclusive findings could be determined for these outcomes.

Safety – The holmium laser procedures are considered at least as safe as TURP in terms of blood loss, rates of stricture and urinary tract infection. In terms of other safety indicators, such as mortality, rates of perforation, and other complications, the relative safety of the holmium laser procedures could not be determined.

Efficacy – The holmium laser procedures appear to be at least as efficacious as TURP in the short term but long-term efficacy could not be determined.

Recommendations

Additional high-quality randomised controlled trials would strengthen the evidence base for the holmium laser procedures. However, at this stage, the priority for research should probably focus on providing long-term follow-up and addressing problems with losses to follow-up which threatened the validity of many of the included studies.

Centres considering introducing the holmium laser procedures should ensure that surgeons have adequate experience in transurethral resection techniques and preferably previous experience in laparoscopic and laser surgery. An appropriate program of supervised training could best be developed by the Urological Society of Australasia.

Review Group Membership

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Important note The information contained in this report is a distillation of the best available evidence located at the time the searches were completed as stated in the protocol. Please consult with your medical practitioner if you have further questions relating to the information provided, as the clinical context may vary from patient to patient.

For further information about ASERNIP-S

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