NICE National Institute for Health and Care Excellence

NICE guidance

Transperineal laser ablation for treating lower urinary tract symptoms of benign prostatic hyperplasia

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg798

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

People who cannot have TURP or other transurethral procedures

1.1 Transperineal laser ablation (TPLA) can be used to treat lower urinary tract symptoms of benign prostatic hyperplasia in the NHS while more evidence is generated, in people who cannot have transurethral resection of the prostate (TURP) or other transurethral procedures. It can only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wanting to do this procedure should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).

- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

People who can have TURP or other transurethral procedures

1.4 More research is needed on TPLA to treat lower urinary tract symptoms of benign prostatic hyperplasia in people who can have TURP or other transurethral procedures, before it can be used in the NHS.

1.5 This procedure should only be done as part of a formal research study and a research ethics committee needs to have approved its use.

What evidence generation and research is needed

1.6 Evidence generation and more research is needed on:

- patient selection
- longer-term outcomes, including reintervention rates.

Why the committee made these recommendations

There is not enough good-quality evidence on the safety and efficacy of this procedure. Most of the evidence is from small observational studies with short follow up. There are no major safety concerns and the procedure appears to improve symptoms, but more evidence is needed.

Benign prostatic hyperplasia is a common condition, particularly in older people. It is

unclear whether this procedure works as well as other surgical procedures, but there may be fewer side effects. There are some people who cannot have transurethral procedures who could benefit from this procedure, so it can be used with special arrangements for these people. It should be used only in research when a transurethral procedure is an alternative.

2 The condition, current treatments and procedure

The condition

2.1 Benign prostatic hyperplasia, also known as benign prostatic obstruction or benign prostatic enlargement, is a common condition that affects older people with a prostate. Stromal and epithelial cells increase in number, causing the prostate to get bigger. It usually occurs in the periurethral region of the prostate, with large discrete nodules compressing the urethra. Symptoms include hesitancy during urination, interrupted or decreased urine stream (volume and flow rate), nocturia, incomplete voiding and urinary retention.

Current treatments

2.2 Mild symptoms are usually managed conservatively. Drugs may also be offered, such as alpha-adrenoceptor blockers and 5 alpha-reductase inhibitors. If other treatments have not worked, surgical options include transurethral resection of the prostate (TURP), transurethral vaporisation, holmium laser enucleation, insertion of prostatic urethral lift implants, prostatic artery embolisation or prostatectomy (see NICE's guideline on lower urinary tract symptoms in men). Potential complications of some of these surgical procedures include bleeding, infection, urethral strictures, incontinence and sexual dysfunction. Many of these procedures require general anaesthetic, regional anaesthetic or sedation.

The procedure

2.3 The procedure uses a percutaneous transperineal approach to ablate the prostate with laser energy. The aim is to reduce the prostate volume, leading to reduced urinary tract symptoms.

2.4 The procedure can be done as a day-case procedure under local, regional or general anaesthesia. Continuous saline irrigation of the urethra and bladder is done with a catheter in place during the entire procedure. The person having the procedure is placed in a lithotomy position. Transrectal ultrasound guidance and real-time monitoring is done using a device to pre-visualise and verify the positioning of the needles to best fit the volume and the shape of the prostate. Then one or two 21-gauge introducer needles per lobe (depending on the basal volume and shape of the prostatic gland) are inserted transperineally into the prostatic tissue. A laser fibre is then introduced through the needle.

2.5 Low powers (3 to 5 watts) and low laser light energy (up to 1800 J per fibre and illumination) are delivered from the diode laser system for several minutes to heat and destroy the prostate tissue around the tip of the fibre, according to a standard protocol. If needed, more illuminations can be done to treat a larger area. The maximum volume treated in a session and the extent of the ablation vary according to the prostatic volume, anatomy and surgeon preference.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 2 randomised controlled trials, 2 systematic reviews (1 of which also included 1 of the randomised controlled trials), and 7 prospective case series. It is presented in the summary of key evidence section in the interventional procedures overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduction in lower urinary tract symptoms, and preservation of sexual function, including ejaculatory function.

3.3 The professional experts and the committee considered the key safety outcomes to be: damage to adjacent structures, need for reintervention, urinary incontinence and urinary retention.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The upper size limit for a prostate to be treated using this procedure is unknown. There are uncertainties about its use in median lobes and it may be contraindicated in people with heavily calcified prostates.

3.6 People who have the procedure in the UK may need temporary catheterisation afterwards. There have been reports of some people who do not need catheterisation.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.