NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

Benign prostatic hyperplasia (also known as benign prostate enlargement) is a non-cancerous enlarged prostate. It can block or narrow the tube (urethra) that urine passes through to leave the body, causing lower urinary tract symptoms, such as urination problems. In this procedure, optical fibres are inserted into the skin between the anus and scrotum (transperineal) and guided to the target area using ultrasound imaging. The fibres then deliver laser energy to the prostate. The heat from the laser destroys some of the prostate tissue (ablation), making it smaller. The aim is to increase the flow of urine and reduce the lower urinary tract symptoms.

NICE is looking at transperineal laser ablation for treating lower urinary tract symptoms of benign prostatic hyperplasia.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

Issue date: July 2024

- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 21 August 2024

Target date for publication of guidance: December 2024

1 Draft 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. Using transrectal ultrasound guidance and real-time monitoring using a dedicated software planning tool, 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, a second illumination 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 9 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), 4 prospective case series and 1 retrospective 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 Most people who have the procedure in the UK have had temporary catheterisation afterwards, but there have been reports of some people who do not need catheterisation.

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Chair, interventional procedures advisory committee
July 2024

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