# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Transurethral water vapour ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia

Benign prostatic hyperplasia is a non-cancerous enlargement of the prostate. It can block or narrow the tube (urethra) that urine passes through to leave the body, causing urination problems. During this procedure, heated water vapour is injected into the prostate using a probe that is passed up the urethra. The heat from the vapour destroys some of the prostate tissue, reducing its size.

The National Institute for Health and Care Excellence (NICE) is looking at transurethral water vapour ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

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

# This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the <u>Interventional Procedures Programme process</u> <u>guide</u>.

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Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

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

Closing date for comments: 19/04/2018

Target date for publication of guidance: July 2018

# 1 Draft recommendations

- 1.1 Current evidence on the safety and efficacy of transurethral water vapour ablation for urinary tract symptoms caused by benign prostatic hyperplasia is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
- 1.2 This procedure should only be done by a urologist with specific training in the procedure, who should carry out their initial procedures with an experienced mentor.

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# 2 The condition, current treatments and procedure

#### The condition

2.1 Lower urinary tract symptoms caused by benign prostatic hyperplasia commonly affect men over 50. Stromal and epithelial cells increase in number, causing the prostate to increase in size. It often occurs in the periurethral region of the prostate, with large discrete nodules compressing the urethra. Symptoms include hesitancy during micturition, 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 used, such as alpha blockers and 5-alpha-reductase inhibitors. If other treatments have not worked, then surgical options include transurethral resection of the prostate (TURP), transurethral vaporisation, holmium laser enucleation, prostatic artery embolisation or prostatectomy (see the NICE guideline on lower urinary tract symptoms in men). Insertion of prostatic urethral lift implants has been introduced more recently as an alternative treatment for lower urinary tract symptoms caused by benign prostatic hyperplasia. Potential complications of surgical procedures include bleeding, infection, urethral strictures, incontinence and sexual dysfunction.

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#### The procedure

- 2.3 Transurethral water vapour ablation is usually done as day-case surgery using local anaesthetic, and sometimes sedation. A device similar to a rigid cystoscope is advanced into the prostatic urethra. Under direct visualisation, a retractable needle is inserted into the prostate and water vapour (at a temperature of about 103 degrees centigrade) is delivered for 8 to 10 seconds. At the same time, saline irrigation is used to cool and protect the surface of the urethra. Conductive heat transfer disrupts cell membranes in the prostate, leading to rapid cell death. The needle is retracted and repositioned several times so that thermoablation can be repeated in different areas of the gland, including the median lobe. The aim is to reduce the size of the prostate, leading to improvement in lower urinary tract symptoms 1 to 3 months after treatment, without impairing sexual function.
- 2.4 Patients may have to take antibiotics and have a urinary catheter for some days after the procedure. Some activities, including sexual intercourse, should be avoided for up to 1 month.

# 3 Committee considerations

#### The evidence

3.1 To inform the committee, 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 8 sources, which was discussed by the committee. The evidence included 1 randomised control trial (reported with 1, 2 and 3 years of follow-up in 4 publications) and

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2 case series (1 of which was reported in 3 publications), and is presented in table 2 of the <u>interventional procedures overview</u>.

- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: improvement of lower urinary tract symptoms, urinary flow rate, and quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: bleeding, infection, disorders of sexual function, and need for re-intervention.

#### Committee comments

- 1.3 The committee was advised that the procedure may also be effective in the treatment of patients with an enlarged median prostatic lobe.
- 3.4 Patients may need a urinary catheter for several days after the procedure.

Tom Clutton-Brock Chairman, interventional procedures advisory committee February, 2018

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