NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transurethral water-jet 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. In this procedure, a probe is passed up the urethra (transurethral) and into the bladder. Then a high-speed jet of water is injected through the probe into the prostate. This destroys some of the prostate tissue (ablation), making the urethra wider. The aim is to increase the flow of urine.

This is a review of NICE's interventional procedures guidance on transurethral water jet ablation for lower urinary tract symptoms caused by 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

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- 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: 24 May 2023

Target date for publication of guidance: September 2023

1 Draft recommendations

1.1 Transurethral water-jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia (BPH) may be used if standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.

1.2 For auditing the outcomes of this procedure, enter the main efficacy and safety outcomes (see sections 3.2 and 3.3) into NICE's interventional procedure outcomes audit tool (for use at local discretion).

Why the committee made these recommendations

There is a lot of good quality evidence that the procedure improves lower urinary tract symptoms caused by BPH and is safe enough to use with standard arrangements.

2 The condition, current treatments and procedure

The condition

2.1 Benign prostatic hyperplasia (BPH) 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 often happens 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 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.

The procedure

2.3 Transurethral water-jet ablation for lower urinary tract symptoms caused by BPH uses a specialised system that combines image guidance and robotics for the targeted heat-free removal of prostate tissue.

2.4 The procedure is usually done under general or spinal anaesthesia. Transrectal ultrasound is used throughout the procedure. A handpiece with an integrated cystoscope and ablation probe is inserted through the urethra and into the bladder. When it is correctly positioned, planning software is used to create a personalised treatment plan. A high-speed jet of saline is then delivered to the prostate at various flow rates, to give targeted and controlled tissue removal, according to the treatment plan. The ablated tissue is aspirated through ports in the handpiece and can be used for histological analysis. Several methods are used to control bleeding, including cautery, a balloon catheter in the bladder (with or without bladder neck traction) and a balloon catheter in the prostatic fossa. The average resection time is about 3 to 5 minutes. After the procedure, a 3-way Foley catheter is placed through the penis into the urethra and the bladder is

continuously irrigated. The catheter is removed before discharge from hospital, usually on the day after the procedure.

2.5 The possible advantages of the procedure include a shorter resection time compared with other endoscopic methods, and the potential to preserve sexual function. The procedure does not use heat to ablate the prostate tissue, which removes the risk of complications from thermal injury.

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 1 pooled analysis of 4 trials, 1 randomised controlled trial (described in 2 publications and also included in the pooled analysis), 1 prospective multicentre single-arm trial (also included in the pooled analysis), 1 retrospective cohort study, 1 retrospective non-randomised comparative study, 2 retrospective case series, and a report from the US Food and Drug Administration Manufacturer and User Facility Device Experience database. The evidence is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in table 5 of the 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: bleeding, 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 Most of the evidence was from small- to medium-sized prostates.

3.6 The procedure has evolved over time. Additional electrosurgery at the end of the procedure is now commonly used to reduce the risk of bleeding.

3.7 The committee was told that this procedure may produce less sexual dysfunction than some of the other procedures used to treat lower urinary tract symptoms caused by benign prostatic hyperplasia.

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Chair, interventional procedures advisory committee
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