



Transurethral water-jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia

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www.nice.org.uk/guidance/ipg770

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.

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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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG629.

1 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, the main efficacy and safety outcomes identified in this guidance (see sections 3.2 and 3.3) can be entered into MICE'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-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.

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 removal of prostate tissue.
- 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. 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.

A possible advantage of the procedure is 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 11 sources, which was discussed by the committee. The evidence included 1 systematic review, 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 (described in 2 publications and 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.
- 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.

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- 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.
- Patient commentary was sought but none was received.

Committee comments

- 3.5 Most of the published evidence was from people with small- to mediumsized prostates, but there is emerging evidence from people with larger 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 cause 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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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.