NICE National Institute for Health and Care Excellence

NICE guidance

Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia

HealthTech guidance

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www.nice.org.uk/guidance/htg639

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.

Contents

This guidance replaces IPG641 and IPG737.

1 Recommendations

1.1 Evidence on the safety and efficacy of prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE guidance page.

1.2 Clinicians wanting to do prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- 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 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.

1.4 Patient selection should be done by a team experienced in managing benign

prostatic hyperplasia. The procedure should only be done by clinicians with specific training in the technique.

1.5 Further research could include registry data or randomised controlled trials using a suitable comparator. It should report details of patient selection, including size of prostate, and longer-term outcomes, including the need for reintervention.

2 The condition, current treatments and procedure

The condition

2.1 Lower urinary tract symptoms caused by benign prostatic hyperplasia commonly affect men aged over 50. Benign prostatic hyperplasia results from an increased number of stromal and epithelial cells. These cells are typically 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 NICE's guideline on lower urinary tract symptoms in men describes current treatment options. Mild symptoms are usually managed conservatively. Medicines such as alpha blockers and 5-alpha-reductase inhibitors may also be used. If other treatments have not worked, there are several possible surgical options, including transurethral resection of the prostate, transurethral vaporisation, holmium laser enucleation, prostatic urethral lift implant insertion, prostatic artery embolisation and prostatectomy. Potential complications of some of these surgical procedures include bleeding, infection, urethral strictures, incontinence and sexual dysfunction.

The procedure

2.3 The aim of prostatic urethral temporary implant insertion is to relieve symptoms of benign prostatic hyperplasia by creating new channels in the urethra to increase the flow of urine. The aim of using a temporary implant is to avoid complications from an implant left in place long term.

2.4 Local anaesthesia or light sedation is used. A folded device made from nitinol is deployed into the bladder under direct visualisation using a cystoscope. The device is opened in the bladder and retracted into the prostatic urethra. Over the following days, the pressure applied by struts in the device creates areas of ischaemia in the prostatic urethra and bladder neck. This makes new longitudinal channels through which urine can flow. After 5 to 7 days, lidocaine gel and a flexible silicone extraction catheter are inserted into the urethra and the device is removed. Insertion of the device is usually done as a day-case procedure and removal is done as a day-case or outpatient procedure.

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 4 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial and 3 single-arm trials. It is presented in the summary of key evidence section in the overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved quality of life, reduced lower urinary tract symptoms, improved urinary flow, reduced postvoid residual volume and preservation of sexual function.

3.3 The professional experts and the committee considered the key safety outcomes to be: bleeding, pain, infection and need for reintervention.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that:

- there is only 1 device for this procedure and the technology is evolving
- there was a sizeable placebo effect associated with the procedure in 1 study
- the procedure is associated with expected, short-term, mild, transient and self-resolving complications.

3.6 The committee was informed that the procedure may provide more benefit for people with smaller prostates and well-functioning bladders.

3.7 The committee was informed that preservation of sexual function may be a benefit of this procedure.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 737 has been migrated to HealthTech guidance 639. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.