NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Prostatic urethral temporary implant insertion 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, local anaesthesia or light sedation is used and a tiny wire device (implant) is inserted into the urethra. It expands to create new permanent channels in the lining of the urethra. It stays in place for 5 to 7 days and is then removed. The aim is to increase the flow of urine.

This is a review of NICE's interventional procedures guidance on prostatic urethral temporary implant insertion 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

- 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: 25 April 2022

Target date for publication of guidance: September 2022

1 Draft recommendations

1.1 Evidence on the safety of prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia shows well-recognised complications in the short term. Evidence on its efficacy 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 interventional procedures 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 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.

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. 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 inserted into the prostatic urethra under direct visualisation using a cystoscope. The device is opened in the 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 and removal of the device are both done as day-case procedures.

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 interventional procedures 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 and reduced postvoid residual volume.

3.3 The professional experts and the committee considered the key safety outcomes to be: bleeding, pain, infection, urinary incontinence 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
- was a sizeable placebo effect associated with the procedure in some of the studies.

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

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Chair, interventional procedures advisory committee

March 2022

ISBN: