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, a tiny wire device 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.

The National Institute for Health and Care Excellence (NICE) is looking at prostatic urethral temporary implant insertion 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 Interventional Procedures Programme process guide.

Issue date: [month year]

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: 18th October 2018

Target date for publication of guidance: January 2019

1 Draft recommendations

1.1 Current 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 in the context of research.

1.2 Further research, preferably in the form of randomised controlled trials, should report details of patient selection (including prostate size and the amount of median lobe enlargement), improvement in lower urinary tract symptoms in the short-term and long-term, re-intervention rates, and outcome measures of sexual function using established methods.

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, there are a range of surgical options that may be considered including transurethral resection of the prostate (TURP), transurethral vaporisation, holmium laser enucleation, insertion of prostatic urethral lift implants, prostatic artery embolisation or prostatectomy (see the NICE 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 Prostatic urethral temporary implant insertion aims to relieve symptoms of benign prostatic hyperplasia by creating new channels in the urethra that increase the flow of urine, without having the complications of an implant left in situ.

2.4 Using local anaesthesia or light sedation, a folded device made from nitinol is inserted into the prostatic urethra with a cystoscope under direct visualisation. The device opens 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 a day case procedure and take about 5 minutes.

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 2 sources, which was discussed by the committee. The evidence included 1 prospective case series that was reported with 1-year and 3-year follow-up in 2 publications, and is presented in table 2 of the interventional procedures overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: improvement in lower urinary tract symptoms, quality of life, improved urinary flow rate and preservation of sexual function.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: bleeding, infection, disorders of sexual function, need for re-intervention and urinary retention.

Committee comments

3.4 The committee was informed that this procedure does not necessarily prevent the need for later transurethral resection of the prostate (TURP) or make it more difficult to do.

3.5 The committee was informed that the procedure may not be suitable for small, or primarily bladder neck, prostatic enlargement.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

September 2018

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