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

Interventional procedures guidance
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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. However, 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.

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.

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.

1 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, ideally 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, 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 3 sources, which was discussed by the committee. The evidence included 2 prospective case series including 1 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.

3.4 Patient commentary was sought but none was received.

Committee comments

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

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation