NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Prostate artery embolisation for benign prostatic hyperplasia

Benign prostatic hyperplasia (BPH) is a non-cancerous enlargement of the prostate. It can block or narrow the tube that urine passes through to leave the body, causing urination problems. In this procedure, using X-ray guidance, a thin tube called a catheter is inserted into an artery in the groin. It is guided into the blood vessels that supply the prostate. Small particles are then injected into these vessels. This reduces the prostate's blood supply, with the aim of shrinking it.

The National Institute for Health and Care Excellence (NICE) is looking at prostate artery embolisation for 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.

Issue date: December 2017

For further details, see the Interventional Procedures Programme process guide.

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: 22 January 2018

Target date for publication of guidance: April 2018

1 Draft recommendations

1.1 Current evidence on the safety and efficacy of prostate artery embolisation for benign prostatic hyperplasia is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection should be done by a urologist and an interventional radiologist.

1.3 This technically demanding procedure should only be done by an interventional radiologist with specific training and expertise in prostatic artery embolisation.

2 The condition, current treatments and procedure

The condition

2.1 Benign prostatic hyperplasia is common in older men. 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, then surgical options include transurethral resection of the prostate, transurethral vaporisation of the prostate, holmium laser enucleation of the prostate or prostatectomy (see the NICE guideline on lower urinary tract symptoms in men). Insertion of prostatic urethral lift implants has been introduced more recently as an alternative treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. Potential complications of surgical procedures include bleeding, infection, strictures, incontinence and sexual dysfunction.

The procedure

2.3 Prostate artery embolisation for benign prostate hyperplasia is usually done using local anaesthesia. Under x-ray guidance, the prostate is approached through the left or right femoral artery. Super-selective catheterisation of the small prostatic arteries is done using fine microcatheters through the internal iliac and vesical arteries. Embolisation involves the introduction of microparticles to completely block the prostatic vessels. Embolisation agents include polyvinyl alcohol (PVA) and other newer synthetic biocompatible materials.

2.4 The aim of prostate artery embolisation is to reduce the prostate's blood supply, causing some of it to undergo necrosis and shrink. It is common for patients to experience pelvic pain during and after the procedure. This does not usually last more than 1 to 3 days. The potential benefits of prostate artery embolisation compared with surgery include fewer complications and avoiding a general anaesthetic.

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 9 sources, which was discussed by the committee. The evidence included 1 systematic review, 2 randomised controlled trials (also included in the systematic review), 1 non-randomised comparative study (also included in the systematic review), 2 case series, and 3 case reports, and is

presented in table 2 of the interventional procedures overview. It also considered data provided by the UK-ROPE register. Other relevant literature is listed in the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: quality of life, urinary symptoms as measured by the International Prostate Symptom Score, and improvement in urodynamics.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: inadvertent embolisation of other sites, urinary retention, prostatic bleeding (haematuria and haematospermia), groin haematoma, pain, and retrograde ejaculation.

3.4 This guidance is a review of NICE's interventional procedures guidance on prostate artery embolisation for benign prostatic hyperplasia.

Committee comments

3.5 The evidence showed a relatively high incidence of urinary retention after the procedure.

3.6 The committee was informed that this procedure involves extensive imaging, which may result in significant radiation exposure.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
December 2017

ISBN: