NICE National Institute for Health and Care Excellence

NICE guidance

Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to 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, 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.

1 Recommendations

1.1 Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 During the consent process clinicians should, in particular, advise patients about the range of possible treatment options and the possible need for further procedures if symptoms recur.

1.3 The procedure should only be carried out by clinicians with specific training in the insertion of prostatic urethral lift implants.

1.4 NICE encourages further research and publication of results from consecutive case series of patients having this procedure. Details of patient selection should be clearly documented. Reported outcomes should include the effects of the procedure on symptoms and quality of life, the duration of benefits, and the need for further procedures. All complications should be reported. NICE may review this procedure in the light of longer-term outcomes.

2 Indications and current treatments

2.1 Benign prostatic hyperplasia is a common condition that affects older men. It is characterised by an increase in the size of the prostate, which is caused by an increased number of stromal and epithelial cells. Benign prostatic hyperplasia can cause lower urinary tract symptoms including hesitancy during micturition, interrupted or decreased urine stream, nocturia, incomplete voiding and urinary retention.

2.2 Mild symptoms are usually managed conservatively. Drugs such as alpha blockers and 5-alpha-reductase inhibitors can be used. If symptoms are more severe, then surgical treatments may be used including transurethral resection of the prostate (TURP), transurethral vaporisation of the prostate, or holmium laser enucleation of the prostate (see NICE's guideline on lower urinary tract symptoms in men: management).

3 The procedure

3.1 The aim of insertion of prostatic urethral lift implants for lower urinary tract symptoms secondary to benign prostatic hyperplasia is to secure the prostatic lobes in retracted positions such that the lumen of the urethra is increased. The procedure is designed to cause less tissue injury than surgical resection or thermal ablation, and it is claimed to reduce the risk of complications such as sexual dysfunction and incontinence.

3.2 The procedure is undertaken transurethrally with the patient under local or general anaesthesia. A pre-loaded delivery device is passed through a rigid sheath under cystoscopic visualisation. The delivery device is used to compress one lateral lobe of the prostate in an anterolateral direction towards the prostatic capsule. A needle is then advanced through the lobe and capsule, and a monofilament implant with 2 end pieces is deployed. One end of the implant is anchored in the urethra and the other on the outer surface of the prostatic capsule, retracting the prostatic lobe away from the urethral lumen. Multiple implants are usually inserted during the same procedure.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

4.1 In a randomised controlled trial (RCT) of 206 patients comparing 140 patients treated by prostatic urethral lift against 66 patients treated by a sham procedure there was a significant difference in mean change in American Urological Association Symptom Index (AUASI) score (scores range from 0 to 35; higher score indicating greater severity) at 3-month follow-up. The mean score decreased by 11 points at follow-up from a baseline score of 22 in patients treated by prostatic urethral lift and by 6 points at follow-up from a baseline score of 24 in patients treated by the sham procedure (p=0.003 difference between the groups).

4.2 A case series of 64 patients reported a significant improvement in International Prostate Symptom Score (scale 0 to 35; higher score indicating more severe symptoms) at follow-up intervals from 2 weeks to 24 months. The mean score improved from 22 at baseline to 13 at 2-year follow-up (n=33; p<0.001).

4.3 The RCT of 206 patients reported a significant difference in change in AUASI quality-of-life scores (scale 0 to 5; higher score indicating lower quality of life) at 3 months. The mean quality-of-life score decreased from 5 to 2 in patients treated by prostatic urethral lift and from 5 to 4 in patients treated by the sham procedure (p<0.001 difference between the groups).

4.4 The case series of 64 patients reported Sexual Health Inventory for Men scores (scale assesses erectile dysfunction, with scores ranging from 1 to 25, with 1 being the most severe and 25 being healthy). There was a statistically significant improvement in score in 26 patients (for whom results were reported), from 18 at baseline to 20 at 1-year follow-up (p=0.01).

4.5 The RCT of 206 patients reported a significant improvement in mean urinary flow rate at 3 months. The mean improvement in urinary flow was 4 ml/s in patients treated by prostatic urethral lift and 2 ml/s in patients treated by the sham procedure (from 8 ml/s at baseline for both groups; p=0.005 difference between

the groups).

4.6 A case series of 19 patients reported a significant reduction in mean post-voiding residual volume, from 147 ml at baseline to 46 ml at 3-month follow-up (n=11; p=0.01).

4.7 The RCT of 206 patients reported retreatment at 1 year in 5% (7 out of 140) of patients treated by prostatic urethral lift. Five patients underwent further prostatic urethral lift treatment because of insufficient response and 2 patients were treated by transurethral prostate resection (TURP) or laser vaporisation (reasons for retreatment not reported). The case series of 64 patients reported that 20% (13 out of 64) of patients had further procedures. Four patients had TURP or photoselective vaporisation of the prostate within 7 months. Nine patients with symptomatic improvement after the initial procedure had TURP (n=4), photoselective vaporisation (n=4) or prostatic urethral lift (n=1; at a mean of 13 months after the procedure) because of recurrent lower urinary tract symptoms.

4.8 The specialist advisers listed key efficacy outcomes as symptom improvement, improvement in quality of life, reducing or stopping medical therapy, flow improvement, reduction in post-void residual volume and maintenance of sexual and ejaculatory function.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

5.1 Urinary tract infections (within 3 months of the procedure) were reported in 3% (4 out of 140) of patients treated by prostatic urethral lift and 2% (1 out of 66) of patients treated by a sham procedure in the randomised controlled trial of 206 patients (level of significance not reported).

5.2 Orchitis was reported in 3% (3 out of 102) of patients in a case series of 102 patients (duration and timing not reported).

5.3 Symptoms of prostatitis (penile and perineal discomfort, pain on erection and ejaculation) were reported in 1 patient in the case series of 64 patients (treated with antibiotics).

5.4 Urinary retention (within 30 days of the procedure) was reported in 16% (3 out of 19) of patients in the case series of 19 patients (reported as lasting median 3.5 days; no further details given).

5.5 Transient urge incontinence was reported in 8% (5 out of 64) of patients in the case series of 64 patients (resolved within 8 days).

5.6 Incomplete voiding (within 30 days of the procedure) was reported in 1 patient in the case series of 19 patients (lasting 42 days).

5.7 Erectile dysfunction was reported within 30 days of the procedure in 11% (2 out of 19) of patients in the case series of 19 patients. This spontaneously resolved after 23 days in 1 patient and 127 days in the other patient.

5.8 The specialist advisers listed bleeding, prostatic swelling and retention (needing catheterisation) as anecdotal adverse events. The specialist advisers considered vascular and rectal injury to be theoretical adverse events.

6 Committee comments

6.1 The Committee recognised that, in common with other treatment options, insertion of prostatic urethral lift implants is not likely to offer permanent relief of symptoms. Some patients may prefer it to other procedures that have a greater risk of causing sexual dysfunction. Certain patients may also prefer this procedure to prolonged drug therapy.

6.2 The Committee was advised that subsequent treatments are possible after this procedure.

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.