

Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in men

1 Guidance

- 1.1 Current evidence on the safety and efficacy of insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in men is not adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake this procedure should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG224publicinfo).
- 1.3 This procedure should only be undertaken by units that specialise in the investigation and treatment of post-prostatectomy incontinence and that can offer alternative treatments, including insertion of artificial urinary sphincters.
- 1.4 Clinicians undertaking insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in men should submit data on all patients to the British Association of Urological Surgeons registry (available from www.baus.org.uk).
- 1.5 Further publication of safety and efficacy outcomes would be useful. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

- 2.1.1 Stress urinary incontinence in men is characterised by the involuntary leakage of urine during exercise, coughing, sneezing or laughing. It is usually iatrogenic, and prostatectomy is the commonest iatrogenic cause.
- 2.1.2 Conservative treatments include pelvic floor muscle training, electrical stimulation and biofeedback. Surgical interventions include injection of bulking agents, insertion of a bulbar-urethral sling or implantation of an artificial urinary sphincter.

2.2 Outline of the procedure

- 2.2.1 The procedure is usually performed under local or regional anaesthesia, using cystoscopy and fluoroscopic or ultrasound imaging. Purpose-made introducers are used to insert two small silicone balloons percutaneously via a perineal approach. One balloon is positioned on each side of the urethra, close to the bladder neck. The balloons are filled with a mixture of water and contrast agent to enable the positioning to be confirmed by imaging. Each balloon is attached to a subcutaneous port sited in the scrotum. These ports can be used to alter the volume of fluid in each balloon postoperatively. Most patients require several such adjustments to achieve the best balance between leakage and difficulty in voiding.

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This guidance is written in the following context

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

2.3 Efficacy

- 2.3.1 All the evidence on efficacy is based on two case series – one of 117 patients and another of 23 patients. The case series of 117 patients with a mean follow-up of 13 months reported a significant decrease in the mean number of incontinence pads required daily, from six (range 1–24) at baseline to two (0–15, $n = 116$) at 3 months ($p < 0.001$). At 2 years ($n = 40$), the mean number of pads required per day was one, also significantly lower than at baseline ($p < 0.001$). In a second case series of 23 patients with a mean follow-up of 22 months, mean daily pad usage decreased significantly from 4.8 (standard deviation ± 1.7) at baseline to 1.8 (± 1.6) at final follow-up ($p < 0.05$).
- 2.3.2 The same case series of 23 patients reported significant improvements in quality of life, assessed using the I-QOL scale. The mean I-QOL score increased from 63.0 points at baseline to 82.6 points at final follow-up (mean duration 22 months; $p < 0.05$). In the larger study of 117 patients, the mean quality of life score increased from 34.7 points at baseline to 66.3 points 2 years after the procedure ($n = 40$; $p < 0.001$).
- 2.3.3 The larger case series, reporting symptomatic stress incontinence scores on the Stamey scale, found significant improvements compared with baseline at 3-month ($n = 116$), 12-month ($n = 63$), and 24-month ($n = 40$) follow-up (all $p < 0.001$). The smaller case series ($n = 23$) found a significant improvement in the mean Valsalva manoeuvre leak point pressure following the procedure, from 48.7 ± 25.4 cm H₂O at baseline to 84.1 ± 33.5 cm H₂O at final follow-up (mean follow-up of 22 months; $p < 0.05$). For more details, refer to the 'Sources of evidence' section.
- 2.3.4 The Specialist Advisers considered there to be uncertainties about the short- and long-term efficacy of the procedure.

2.4 Safety

- 2.4.1 Intraoperative urethral or bladder perforation occurred in 9% of patients in one case series (2/23) and 13% in the other (15/117). There were no complications related to blood loss during the procedure in either study. There was one case report of a rectal perforation due to the procedure.
- 2.4.2 In the large case series of 117 patients, 6% (13/231) of balloons migrated, causing erosion (not defined) (mean follow-up of 13 months), and in the

other case series, balloon migration (necessitating removal of the device) occurred in 13% (3/23) of patients (mean follow-up of 22 months). The latter study also reported that detrusor overactivity occurred in 9% (2/23) of patients. This was treated with anticholinergic medication.

- 2.4.3 Leakage of balloon fluid occurred in 10% (24/231) of balloons in one case series and 4% (1/23) of patients in the other case series (further details not stated). In the former, revisional procedures were required in 46% (54/117) of patients for a variety of indications. For more details, refer to the 'Sources of evidence' section.
- 2.4.4 The Specialist Advisers considered there to be uncertainties about the safety of the procedure. They stated that theoretical adverse events include injury to the urethra, bladder or rectum, urethral erosion, urethral stricture, device infection, bladder outlet obstruction, urinary retention, urinary tract infection, development of overactive bladder, and rupture or migration of the balloon.

3 Further information

- 3.1 The Institute has published interventional procedures guidance on insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women (www.nice.org.uk/IPG133).

Andrew Dillon
Chief Executive
July 2007

Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG224publicinfo

Sources of evidence

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

'Interventional procedure overview of insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in men', October 2006.

Available from: www.nice.org.uk/ip361overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1292. 'Understanding NICE guidance' can be obtained by quoting reference number N1293.

The distribution list for this guidance is available at www.nice.org.uk/IPG224distributionlist

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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