

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

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 women does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women 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. Use of the Institute's *Information for the public* is recommended.
 - Audit and review clinical outcomes of all patients having insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence.
- 1.3 Publication of safety and efficacy outcomes will 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 is the involuntary leakage of urine during exercise or certain movements such as coughing, sneezing and laughing. It is usually due to weak or damaged muscles and connective tissue in the pelvic floor, or to weakness of the urethral sphincter itself. It is estimated that 10–52% of adult women have some form of urinary incontinence.
- 2.1.2 Typically, first-line treatment is conservative and includes pelvic floor muscle training, electrical stimulation and biofeedback. Surgical alternatives include colposuspension, insertion of a tension-free vaginal tape, traditional suburethral slings and intramural urethral bulking procedures.

2.2 Outline of the procedure

- 2.2.1 Under local or regional anaesthesia, two small silicone balloons are inserted via a percutaneous perineal approach. Under radiological guidance, 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 radiologically. Each balloon is then attached to a subcutaneous port sited in the labium majorum. These ports can be used to alter the volume of fluid in the balloons postoperatively, thereby achieving continence without voiding difficulties.

Interventional Procedure Guidance 133

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. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health 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 health professionals and people using the NHS in England, Wales and Scotland.

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

2.3 Efficacy

- 2.3.1 All the data reviewed were from conference abstracts. A multicentre case series of 170 women reported that there was a statistically significant increase in the mean abdominal leak point pressure after the procedure (from 60.6 cm/H₂O to 86.2 cm/H₂O, $p = 0.003$). There was also a significant increase in the mean quality of life score, from 35 at baseline to 70 at 12 months ($p < 0.0001$). Of the 34% (58/170) of women followed up for 2 years, 83% (48/58) were dry or had significantly improved continence. For more details, refer to the Sources of evidence (see right).
- 2.3.2 The Specialist Advisors noted that there is a lack of data on long-term outcomes.

2.4 Safety

- 2.4.1 The most common adverse event was urinary tract infection, which affected 15% (25/170) of women in one study. Other complications included balloon dislocation in 13% (22/170), port erosion in 10% (17/170), bladder perforation in 8% (14/170), sexual discomfort in 2% (3/170) and urgency in 1% (2/170) of women. A second study reported that 5% (2/37) of women experienced urethral pain after the procedure. For more details, refer to the Sources of evidence.
- 2.4.2 The Specialist Advisors stated that potential adverse events include infection, erosion of the device into the vagina or urethra, urinary retention, urethral injury and urethral or vaginal pain.

3 Further information

- 3.1 NICE has issued guidance on tension-free vaginal tape (www.nice.org.uk/TA056) and transobturator foramen procedures (www.nice.org.uk/IPG107). NICE is also producing guidance on insertion of biological slings for stress urinary incontinence (www.nice.org.uk/ip_264) and intramural urethral bulking procedures for stress urinary incontinence (www.nice.org.uk/ip_262).

Andrew Dillon
Chief Executive
July 2005

Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. 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/IPG133publicinfo

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 women, December, 2004

Available from www.nice.org.uk/ip263overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0889. *Information for the public* can be obtained by quoting reference number N0890.

The distribution list for this guidance is available at www.nice.org.uk/IPG133distributionlist

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