

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Interventional procedure consultation document

**Extraurethral (non-circumferential)
retropubic adjustable compression devices
for stress urinary incontinence in women**

Stress urinary incontinence is when urine leaks out during exercise or when coughing, sneezing and laughing. It usually happens because the muscles and tissue that make up the pelvic floor have become weakened or damaged, most commonly because of pregnancy. This procedure involves placing 2 small silicone balloons under the bladder, through a cut in the skin behind the vagina. The balloons are placed on either side of the urethra (the tube that carries urine from the bladder). The balloons are filled with fluid and they support the bladder, reducing leaks but allowing the normal passage of urine. After the procedure, fluid can be added or removed from the balloons to get the best effect for the individual person.

The National Institute for Health and Care Excellence (NICE) is examining extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.
- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is 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 the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would 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 NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 22 December 2016

Target date for publication of guidance: March 2017

1 Draft recommendations

- 1.1 Current evidence on the safety and efficacy of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women is inadequate in quantity and
- IPCD: extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women

quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to insert extraurethral retropubic adjustable compression devices for stress urinary incontinence in women should:

- 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 NICE's [information for the public](#) is recommended.
- [Audit](#) and review clinical outcomes of all patients having extraurethral retropubic adjustable compression devices for stress urinary incontinence (see section 7.2).

1.3 All adverse events involving any medical devices used in this procedure should be reported to the [Medicines and Healthcare products Regulatory Agency](#).

1.4 Further research into this procedure should include detailed safety outcomes, long-term results and patient-reported outcome measures. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 Stress urinary incontinence is the involuntary leakage of urine during exercise or certain movements such as coughing, sneezing and laughing. In women, it is most commonly associated with previous pregnancy, with or without recognised obstetric trauma.

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

Previous urogynaecological surgery may also result in stress urinary incontinence.

- 2.2 A NICE clinical [guideline](#) describes recommendations for the management of urinary incontinence in women. Conventional treatment is conservative, and includes lifestyle changes such as weight loss and pelvic floor muscle training. Surgery is considered if these conservative measures do not help. Different types of surgery may be used including intramural bulking procedures, insertion of a synthetic tension-free vaginal tape, insertion of a transobturator tape or other sling procedures, and colposuspension. When previous surgery has failed, insertion of an artificial urinary sphincter may be needed.

3 The procedure

- 3.1 Extraurethral (non-circumferential) retropubic adjustable compression device insertion aims to prevent stress urinary incontinence by increasing urethral resistance and providing support to the bladder neck.
- 3.2 With the patient under local, regional or general anaesthesia, an incision is made in the perineum. Specially designed introducers are used to insert 2 small silicone balloons. Under radiological guidance the balloons are positioned on either side of the urethra, close to the bladder neck. The balloons are filled with a mixture of water and radiocontrast medium to enable the positioning to be confirmed. Each balloon is then attached to a subcutaneous port sited in the labia major. These ports can be used to add or remove fluid to the balloon postoperatively, thereby achieving the best balance between voiding and leakage.

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 [interventional procedure overview](#).

- 4.1 In a systematic review of 8 studies, the mean number of pads used per day reduced from a range of 4.1–5.4 at baseline to a range of 1.1–1.2 at 2-year follow-up. In a case series of 57 patients (also included in the systematic review), there was a statistically significant decrease in the mean number of pads used per day from 5.6(\pm 2.3) at baseline (n=57) to 0.4(\pm 0.8) at 72 month follow-up (n=29; p<0.001).
- 4.2 In a case series of 52 patients, 14% (7/52) of patients were fully continent and 25% (13/52) of patients reported more than 80% improvement at last follow-up (median 10.5 months); 19% (10/52) of patients were still having successive balloon inflations. In the case series of 57 patients, 62% of patients reported that they were fully continent at last follow-up (mean 72 months), 30% reported improvement of more than 50%, and 8% of patients reported no change or improvement of less than 50%. In a case series of 41 patients, 44% of patients were fully continent, 15% reported significant improvement, 29% reported slight improvement and 12% reported no change at last follow-up (mean 25 months).
- 4.3 In a case series of 162 patients (also included in the systematic review), 51% and 76% of patients were fully continent (<2 g on a provocative pad test) at 1 and 5 year follow-up respectively. The mean provocative pad weight decreased for 85% (107/126) of

patients, with a mean improvement from 49.6 g to 11.2 g ($p < 0.001$) at 1-year follow-up.

- 4.4 In the case series of 162 patients, the mean Incontinence Quality of Life (IQOL) score improved from 36.8 at baseline to 71.1 at 1 year and 74.3 at 5 year follow-up (p value not reported). In the same study, the mean Urogenital Distress Inventory (UDI) score improved from 60 at baseline to 37 at 1 year and 51 at 5 year follow-up. In the case series of 57 patients, there was a statistically significant improvement in the mean IQOL score from 27.2 at baseline to 65.9 at 1 year and 78.6 at 72-month follow-up ($p < 0.001$ for both).
- 4.5 In the case series of 57 patients, there was a statistically significant increase in the mean Valsalva leak point pressure from 51 cmH₂O at baseline to 86 cmH₂O at 12-month follow-up ($n=30$; $p < 0.01$). The mean urethral closure pressure increased from 47 cmH₂O at baseline to 51 cmH₂O at 12 month follow-up ($n=30$; p =not significant).
- 4.6 In the case series of 41 patients, explantation because of non-response was done in 15% (6/41) of patients.
- 4.7 The specialist advisers listed key efficacy outcomes as cure or Improvement in urinary incontinence as measured by subjective outcome measures (validated questionnaires), and objective measures (pad tests and urodynamics).

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

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

detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 Intraoperative urethral or bladder perforation was reported in 3–17% of patients in a systematic review of 8 studies. Haematoma within 30 days of the procedure (first implantation) was reported in 1 patient in a case series of 52 patients; this was treated by deflation of the balloons.
- 5.2 Urethral erosion was reported in 2–15% of patients and cutaneous erosion of the port was reported in 3–8% of patients, during the first year of follow-up, in the systematic review of 8 studies. Balloon migration during the first year was reported in 7–18% of patients in the same study and balloon dysfunction during the first year was reported in 0.6–6% of patients.
- 5.3 Device infection during the first year was reported in 0.6–9% of patients in the systematic review of 8 studies. Urinary tract infection was reported in 2% of patients in a case series of 162 patients.
- 5.4 Dysuria or acute urinary retention was reported in 2–7% of patients in the systematic review of 8 studies. De novo urgency during the first year of follow-up was reported in 11% of patients in 1 study included in the systematic review of 8 studies.
- 5.5 The device was explanted in 18% (28/153) of patients during the first year of follow-up in the case series of 162 patients. Of these, 50% (14/28) were reimplanted within 12 months. Reasons for explantation included port erosion, balloon migration, balloon erosion, worsening incontinence, pain, device failure, infection, and port migration. Balloons were removed in 21% (12/57) of patients (3 bilateral and 9 unilateral) in a case series of 57 patients.

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

- 5.6 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not describe any anecdotal adverse events. They considered that the following were theoretical adverse events: urethrovaginal fistula formation, urethral stricture, vaginal erosion, pelvic or genital pain, dyspareunia, development of overactive bladder, and urethral stenosis. One adviser noted that the procedure may make established techniques (as a secondary procedure) more technically difficult.

6 Committee comments

- 6.1 The committee was informed that the procedure is not in widespread use in the UK.
- 6.2 The committee noted that most patients have had previous procedures before insertion of extraurethral retropubic adjustable compression devices for stress urinary incontinence.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).
- 7.2 Patient commentary was not sought, because it was not possible to identify any patients who had been treated by this procedure in the UK.
- 7.3 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local

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

discretion). This tool will be available when the guidance is published.

- 7.4 This guidance is a review of NICE's interventional procedure guidance on [insertion of extraurethral \(non-circumferential\) retropubic adjustable compression devices for stress urinary incontinence in women](#).

Tom Clutton-Brock

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November, 2016