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NHS
National Institute for Health and Clinical Excellence

Intramural urethral bulking procedures for stress urinary incontinence in women

1 Guidance

1.1 Current evidence on the safety and short-term efficacy of intramural urethral bulking procedures for stress urinary incontinence is adequate to support the use of these procedures provided that normal arrangements are in place for clinical governance and for audit or research.

1.2 Clinicians should ensure that patients understand that the benefits of the procedures diminish in the long term and provide them with clear written information. In addition, use of the Institute's *Information for the public* is recommended.

1.3 Further publication of longer-term efficacy outcomes will be useful. Clinicians should submit data to the British Association of Urological Surgeons registry (available from www.baus.org.uk), or the British Society of Urogynaecologists registry (for further information contact BSUG@rcog.org.uk).

2 The procedure

2.1 Indications

2.1.1 Stress urinary incontinence is the involuntary leakage of urine during exercise or movements such as coughing, sneezing and laughing. It is usually caused by weak or damaged muscles and connective tissues of the pelvic floor, or by weakness of the urethral sphincter itself. It is estimated that 10–52% of adult women have some form of incontinence.

2.1.2 Typically, first-line treatment is conservative and includes pelvic floor muscle training, electrical stimulation and biofeedback. If the condition does not improve, surgical alternatives in women may include colposuspension, tension-free vaginal tape, transobturator foramen procedures or traditional suburethral slings.

2.2 Outline of the procedure

2.2.1 Intramural urethral bulking aims to augment the urethral wall and increase the urethral closure force. Several millilitres of bulking agent are injected into the submucosa of the proximal urethra just distal to the bladder neck. The injections are usually administered under local anaesthesia, either transurethrally or para-urethrally. Injections are undertaken either under vision using a cytoscope; or blindly, using a non-endoscopic implantation device.

2.2.2 A number of bulking agents are currently available.

2.3 Efficacy

2.3.1 A small randomised controlled trial reported that 53% (34/64) of patients treated by urethral bulking with collagen had no incontinence at 12 months, compared with 72% (39/54) treated with conventional open surgery.

2.3.2 One case series of patients treated with collagen reported that, after 12 months, 42% (38/90) had either no incontinence or an improvement in symptoms, as measured objectively using cystometry and abdominal leak point pressure. One case series of patients treated with silicone particles reported that 68% (69/102) had either no incontinence or marked improvement after a mean follow-up of 3 months. This proportion decreased to 48% (40/84) after a mean follow-up of 18 months. Four randomised controlled trials reported no difference in efficacy between different bulking agents. For more details, refer to the Sources of evidence.

2.3.3 The Specialist Advisors noted that efficacy may depend on patient selection, the bulking agent used and the injection technique.

Interventional Procedure Guidance 138

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.

NHS Quality Improvement Scotland

2.4 Safety

2.4.1 Five case series reported safety data on a total of 389 patients. The most commonly reported adverse events were urinary tract infection, affecting 1% (1/102) to 12% (11/90) of patients, and urinary retention, affecting 0% (0/40) to 11% (10/90) of patients. Other reported complications included abscess at the injection site, urgency of micturition and prolonged pain. For more details, refer to the Sources of evidence.

2.4.2 The Specialist Advisors stated that migration of the bulking agent, voiding difficulties, urinary tract infection and allergic reaction are potential adverse events. Haemorrhage was listed as a rare potential adverse event.

2.5 Other comments

2.5.1 The Committee noted that a variety of bulking agents may be used for these procedures which may have different risk and benefit profiles.

2.5.2 The Committee particularly noted that the benefits of these procedures diminish with time but that the procedure can be repeated.

3 Further information

3.1 NICE has issued guidance on tension-free vaginal tape for stress incontinence (www.nice.org.uk/TA056), transobturator foramen procedures for stress urinary incontinence (www.nice.org.uk/IPG107) and insertion of extraurethral (non-circumferential) retropubic adjustable compression devices (www.nice.org.uk/IPG133). NICE is also producing guidance on insertion of biological slings for stress urinary incontinence (www.nice.org.uk/ip_264).

Andrew Dillon
Chief Executive
November 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/IPG138publicinfo

Sources of evidence

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

Interventional procedure overview of intramural urethral bulking procedures for stress urinary incontinence in women, August 2004

Available from www.nice.org.uk/ip262overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0923. *Information for the public* can be obtained by quoting reference number N0924.

The distribution list for this guidance is available at www.nice.org.uk/IPG138distributionlist

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