

Intramural urethral bulking procedures for stress urinary incontinence in women

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. However, 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.

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.

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 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, or the British Society of Urogynaecologists registry (for further information contact the British Society of Urogynaecologists).

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 cystoscope; 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.

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](#) (replaced by NICE clinical guideline 40, '[Urinary incontinence: the management of urinary incontinence in women](#)'), [transobturator foramen procedures for stress urinary incontinence](#) and [insertion of extra-urethral \(non-circumferential\) retropubic adjustable compression devices](#). NICE is also producing guidance on insertion of biological slings for stress urinary incontinence [Now published as '[Insertion of biological slings for stress urinary incontinence](#)']].

Andrew Dillon
Chief Executive
November 2005

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.

Information for patients

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.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

23 January 2012: minor maintenance.

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and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).