NICE National Institute for Health and Care Excellence

NICE guidance

Intramural urethral bulking procedures for stress urinary incontinence in women

HealthTech 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, and specifically any special arrangements relating to the introduction of new interventional procedures. 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

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. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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.

Contents

This guidance replaces IPG138.

1 Recommendations

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 NICE'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 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 overview.

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 overview.

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

Sources of evidence

The evidence considered by the committee is in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 138 has been migrated to HealthTech guidance 86. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.