

Injectable bulking agents for faecal incontinence

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg210

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.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of injectable bulking agents for faecal incontinence does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research, which should take place in the context of a clinical trial or formal audit protocol that includes information on well-defined patient groups.
- 1.2 Clinicians wishing to inject bulking agents for the treatment of faecal incontinence 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. In addition, use of NICE's information for the public is recommended.
 - Audit and review clinical outcomes of all patients receiving injectable bulking agents for faecal incontinence (see section 3.1).
- 1.3 The procedure should only be performed in units specialising in the assessment and treatment of faecal incontinence. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

- 2.1.1 Faecal incontinence occurs when a person loses the ability to control their bowel movements and is unable to retain faeces in the rectum. It can be caused by a wide variety of conditions that affect either the anatomy or function of the anal sphincter. Perineal injury during childbirth is a common cause of faecal incontinence in women. Faecal incontinence can also be caused by neurological disorders such as spinal injury and multiple sclerosis, or it can result from anorectal surgery. Faecal incontinence is associated with considerable physical and social disability.
- 2.1.2 First-line treatment for faecal incontinence is usually conservative and includes antidiarrhoeal medication and pelvic floor muscle training. In patients for whom conservative treatments prove inadequate, alternatives include surgery to tighten the anal sphincter (overlapping sphincteroplasty), sacral nerve stimulation, creation of a new sphincter from other suitable muscles (for example, dynamic graciloplasty), implantation of an artificial sphincter or the creation of a permanent colostomy.

2.2 Outline of the procedure

- 2.2.1 Bulking agents are injected into the wall of the lower rectum in order to create one or more bulges, narrowing the opening through which stool will pass and thereby helping to retain it within the rectum. The procedure is usually performed under local anaesthesia. Several millilitres of bulking agent are injected into the submucosa just above the dentate line. Injections can be done via the anal canal or via a trans-sphincteric route, with or without ultrasound guidance. More than one injection may be given.
- 2.2.2 Several bulking agents are currently used, including collagen, silicone particles and carbon beads.

2.3 Efficacy

- 2.3.1 In the largest case series, 82 patients had significant improvements in continence scores compared with baseline at 6 months ($p < 0.001$), which was maintained at 12 months in a subset of 42 patients. Similar results were reported in a case series of 18 patients, who had a significant improvement in continence grading compared with baseline at 12 months ($p = 0.0002$). The authors noted that the improvement in continence score was significantly higher in patients who received injections at two or more sites. In another case series, 60% (6 out of 10) of patients reported improvement from baseline at 6 weeks after the procedure, although only 30% (3 out of 10) still reported some improvement at 6 months.
- 2.3.2 Two studies reported on quality of life and patient satisfaction after the procedure. In the case series of 18 patients, improvement compared with baseline was reported in patient satisfaction ($p = 0.053$) and in all quality-of-life scales ($p = 0.006$ to 0.059) at 12 months. In the second study of 82 patients, all quality-of-life domains, measured using a faecal incontinence scale, had improved compared with baseline at a median follow-up of 6 months. For more details, see the [overview](#).
- 2.3.3 The Specialist Advisers commented that there is a lack of good-quality data on the efficacy of this procedure. In particular, they noted that there is uncertainty about the duration of any possible benefits and whether repeat injections are needed to maintain this effect.

2.4 Safety

- 2.4.1 Few complications were reported in the studies. The most commonly reported complication was pain at the injection sites. In the largest case series, 7% (6 out of 82) of patients reported some pain following the procedure. In a smaller case series, half of the patients (5 out of 10) experienced pain or minor ulceration at the injection site or in the anal canal for up to 10 weeks after the procedure. Other complications included leakage of the bulking agent in 1 of 10 patients and, in a different study, passing of the bulking agent in 2 of 18 patients. For more details, see the [overview](#).

- 2.4.2 The Specialist Advisers listed infection, pain and leakage of the bulking agent along the injection track as the main complications of the procedure. Migration of the bulking agent, and rectovaginal fistula were also noted as possible complications.

2.5 Other comments

- 2.5.1 It was noted that a number of different agents may be used for this procedure, which makes interpretation of data difficult.
- 2.5.2 It was also noted that repeat injections can be undertaken if necessary.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and developed an [audit tool](#) (which is for use at local discretion).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described 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 decision made, and has been written with patient consent in mind.

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Endorsing organisation

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