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Injectable bulking agents for faecal incontinence

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NICE interventional procedure guidance 210

www.nice.org.uk/ipg210

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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 the Institute's [information for patients](#) ('Understanding NICE guidance') 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. The Institute 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% (6/10) of patients reported improvement from baseline at 6 weeks after the procedure, although only 30% (3/10) 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 ($p = 0.006$ – 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, refer to the 'Sources of evidence' section.
- 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% (6/82) of patients reported some pain following the procedure. In a smaller case series, half of the patients (5/10) 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, refer to the 'Sources of evidence' section.

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. The Institute has identified relevant audit criteria and developed an [audit tool](#) (which is for use at local discretion).

Andrew Dillon
Chief Executive
February 2007

Sources of evidence

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

['Interventional procedure overview of injectable bulking agents for faecal incontinence'](#), October 2006.

Information for patients

NICE has produced [information describing its guidance on this procedure for patients and their carers](#) ('Understanding NICE guidance'). 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](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

Changes since publication

16 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient 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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