

Understanding NICE guidance

Information for people who use NHS services

Treating faecal incontinence with injectable bulking agents

NICE 'interventional procedures guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.

This leaflet is about when and how injectable bulking agents can be used to treat people with faecal incontinence in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe faecal incontinence or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

What has NICE said?

There are still uncertainties over the safety of this procedure and how well it works. If a doctor wants to use injectable bulking agents for faecal incontinence, he or she should make sure that extra steps are taken to explain the uncertainty and the likely benefits and potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens after the procedure.

Further information on the safety of injectable bulking agents for faecal incontinence and how well the procedure works in different patient groups will be helpful. The procedure should only be used in units specialising in the assessment and treatment of faecal incontinence. NICE has encouraged doctors to consider asking patients to take part in a research study (called a clinical trial) or an audit (a formal examination of results) looking at injectable bulking agents for faecal incontinence. NICE may look at this procedure again if more information becomes available.

Other comments from NICE

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

This procedure may not be the only possible treatment for faecal incontinence. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Injectable bulking agents

The procedure is not described in detail here – please talk your doctor for a full description.

Faecal incontinence is when a person loses the ability to control their bowel movements. The procedure is carried out under local anaesthesia and involves injecting a material into the muscles around the anus (anal sphincter) with the aim of bulking the sides of the sphincter. Different materials are available to provide the extra strength, and these are called bulking agents.

What does this mean for me?

If your doctor has offered you injectable bulking agents for faecal incontinence, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at seven studies on this procedure.

How well does the procedure work?

In some studies a faecal incontinence score was used to assess how well the procedure works. In one study, 82 patients showed a significant benefit at 6 months, and this lasted for at least 12 months in 42 patients. A smaller study of 18 patients had similar results. A further study of 10 patients showed improvement in 6 out of 10 patients after 6 weeks although only 3 out of 10 patients still reported improvement after 6 months.

In the study of 18 patients, injections at two or more sites in the anus seemed to be associated with better faecal incontinence scores. Patients in

this study reported better quality of life and were more satisfied following the procedure. Similar improvements in quality of life were reported in the study of 82 patients after an average of 6 months.

The expert advisers commented that there is not enough good quality information on how well the procedure works. In particular they noted that it is uncertain how long the benefits last for and how many injections are needed to keep up the effect.

Risks and possible problems

Pain at the injection sites is the most commonly reported problem. In the study of 82 patients, 6 reported pain. In a smaller study, 5 out of 10 patients experienced pain or minor ulceration of the anus for up to 10 weeks after the procedure. Leakage of the bulking agent was noted in 1 out of 10 patients. In a different study, 2 out of 18 patients excreted (passed) the bulking agent.

The expert advisers listed infection, pain and leakage of the bulking agents as the main possible problems with the procedure. The potential for the bulking agent to move away from the site where it is injected and the development of an abnormal opening between the rectum and the vagina in women were also considered as possible risks.

More information about faecal incontinence

NHS Direct online (www.nhsdirect.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG210

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1210).