

Understanding NICE guidance

Information for people who use NHS services

Treating faecal incontinence using endoscopic radiofrequency (heat) therapy

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how using endoscopic radiofrequency (heat) therapy can be used in the NHS to treat people with faecal incontinence. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. 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.

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.

What has NICE said?

Although there is evidence to say that this procedure appears safe, there are still uncertainties about how well it works because there is only evidence about how well it works in the short term, based on a small number of patients. If a doctor wants to use the procedure to treat faecal incontinence, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the potential risks. 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 to the patient after the procedure.

The procedure should only be carried out in units that specialise in assessing and treating faecal incontinence that can offer a range of treatment options.

NICE has encouraged further research into how well this procedure works in the long term, how it affects quality of life and which patients could benefit, and may look at this procedure again if more information becomes available.

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.

Treating faecal incontinence using endoscopic radiofrequency (heat) therapy

The medical name for this procedure is 'endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence'.

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

Faecal incontinence is when a person loses the ability to control their bowel movements, resulting in leakage of faeces. Faecal incontinence has many different causes. It can be distressing and can severely affect everyday life.

Initial treatment for faecal incontinence usually includes dietary management and medication to stop diarrhoea. This may be followed by pelvic floor muscle training and anal sphincter training. If these treatments fail, surgery may be needed.

In this new procedure, heat energy is used to cause a degree of fibrosis (similar to scar tissue), so tightening the ring of muscle that forms the anal sphincter and helping to control bowel movements. It is intended to be less invasive than other surgical treatments. The procedure is carried out with the patient under sedation and using local anaesthetic.

What does this mean for me?

If your doctor has offered you this procedure, he or she should tell you that NICE has decided that although it appears safe there are uncertainties about how well it works. 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 procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

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 8 studies on this procedure.

How well does the procedure work?

Two studies involving 50 and 19 patients used a faecal incontinence quality of life questionnaire to assess lifestyle, coping, depression and embarrassment before and after the procedure. The study of 50 patients followed their progress for 6 months and the study of 19 followed patients' progress for 5 years. The two studies showed that patients' quality of life improved in the 4 areas, and that the improvements were maintained.

As well as quality of life, the study of 50 patients involved clinical checks looking at sphincter pressure, rectal sensation, nerve function and any problems with the sphincter, but found no differences after the procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that aims of the procedure are improved faecal continence and quality of life.

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

Risks and possible problems

In the study of 50 patients, anal ulcers formed in 2 patients 2–3 weeks after the treatment. For 1 patient this was mild and resolved, and continence was improved. For the other patient the ulceration caused anal pain, and continence was worse at 6 months after the treatment. This study also reported that 5 patients had anal pain after the procedure.

In 2 studies of 50 and 19 patients, a total of 7 patients had severe bleeding after the procedure, requiring stitches to control the bleeding.

In studies of 50 and 24 patients, a total of 2 patients reported constipation and 1 reported diarrhoea.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that possible complications include severe bleeding and narrowing of the anus.

More information about faecal incontinence

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on faecal incontinence, visit our website at www.nice.org.uk

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. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. 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 is about 'Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/IPG393

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2544). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.