

Understanding NICE guidance

Information for people who use NHS services

Surgical repair of anal fistula with a bioprosthetic plug

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 a bioprosthetic plug can be used to surgically repair anal fistula 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 anal fistula 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?

Although there are no major safety concerns about this procedure, there are still uncertainties about how well it works. If a doctor wants to use a bioprosthetic plug to surgically repair anal fistula, he or she should make sure that extra steps are taken to explain these uncertainties. 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.

NICE has also said that more information about the safety of this procedure and how well it works would be useful, and has encouraged doctors to work together to publish results about long-term results. NICE may look at this procedure again if more information becomes available.

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

Surgical repair of anal fistula with a bioprosthetic plug

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

An anal fistula is an abnormal connection between the anal canal (back passage) and the skin around the anus. A fistula usually results from a previous anal abscess that has not healed properly, but it can also be linked to other conditions such as Crohn's disease.

An anal fistula may cause symptoms such as pain or discomfort around the anus and leakage of blood or pus from the fistula.

Several different types of surgery may be performed to encourage healing.

In this procedure a specially designed 'plug' is inserted into the fistula and stitched in place. The aim is to seal off the fistula where it joins with the bowel while still allowing any pus to drain out as the fistula heals and new tissue grows.

The procedure is performed under general anaesthesia. The fistula tract is first cleaned. Then the surgeon pulls a cone-shaped plug into the inner opening of the fistula tract until it blocks it, and then the plug is stitched into place. The medical name for the plug is a bioprosthetic plug. Bioprosthetic means that it is made of a material that has come from an animal, usually a pig.

What does this mean for me?

If your doctor has offered you surgical repair of anal fistula with a bioprosthetic plug, 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 four studies on this procedure.

How well does the procedure work?

One study followed patients' progress for 14 weeks after the procedure. In this study, the procedure worked in 13 out of 15 patients. Another study which followed patients for 6 months showed that 15 out of 17 fistulae healed. Two further studies showed that the procedure worked in 30 out of 36 and 47 out of 55 fistulae when patients were followed up at around 12 months.

A similar treatment (in which the fistula was treated with a special glue to seal the opening) worked well in 4 out of 10 patients.

In a study following patients for 10 months after an operation to cut into the fistula to help it to heal, 31 out of 95 fistulae recurred.

The expert advisers said that they were uncertain about how well this procedure works in the long term and whether the fistula is likely to come back.

Risks and possible problems

None of the studies gave any information about safety of the procedure. The expert advisers did not think that there were any major safety worries.

More information about anal fistula

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/IPG221

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1271).