

Treating reflux with hydrogel implants

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 hydrogel implants can be used to treat people with reflux (also known as gastro-oesophageal disease or GORD) 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 reflux 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 page 7.

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.



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What has NICE said?

There is a limited amount of evidence about how well this procedure works in the short term and there are also concerns over the safety of this procedure. If a doctor wants to use hydrogel implants for reflux, 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 the 'Understanding NICE guidance' factsheet about this procedure and other written information as part of the discussion. There should also be special arrangements for monitoring what happens after the procedure.

This procedure may not be the only possible treatment for reflux.

Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Hydrogel implants for the treatment of reflux

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

Reflux is a common condition in which the stomach contents pass back up into the oesophagus (gullet) and make it inflamed. Reflux is caused by problems with the gastro-oesophageal sphincter muscle, which is the ring of muscle that normally closes the opening between the oesophagus and the stomach.

Symptoms of reflux include heartburn, chest pain, regurgitation or an acid taste in the mouth. Other symptoms can include difficulty with swallowing, and a cough or wheeze.

There are many different treatments for reflux including weight loss, dietary and lifestyle changes, medicines and a variety of operations.

Hydrogel implants are designed to narrow the opening of the oesophagus into the stomach to reduce reflux. Before the procedure, the patient is given a sedative to help them relax. A thin, flexible telescope called an endoscope is passed through the mouth and down the oesophagus to the gastro-oesophageal region so the surgeon can see what he or she is doing. A very fine tube is passed through the endoscope, and the hydrogel implants are inserted into the wall of the oesophagus. The implants absorb water and expand fully within 24 hours, making the entrance to the stomach narrower and helping prevent reflux.

What does this mean for me?

If your doctor has offered you hydrogel implants for the treatment of reflux, 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 two studies on this procedure.

How well does the procedure work?

Two studies used patient questionnaires to evaluate a range of symptoms associated with reflux. In the first study a total of 69 patients were involved. Heartburn-related quality of life, regurgitation, and general physical aspects of quality of life scores all improved when the patients were followed up 6 months after the procedure. A second study of nine patients reported that the patients' heartburn-related quality of life scores had also improved in the 6 months after the procedure.

In the study of 69 patients, 58% had an inflamed and irritated oesophagus before the procedure. Six months after the procedure, only 32% of patients reported it.

The two studies also measured the acid in the oesophagus. In the study of 69 patients, this information was only available for 45 patients, but of these 45, only 18 patients had a normal acid level 6 months after the procedure. The study of nine patients showed that only three of them had a normal acid level after the procedure.

The expert advisers were not sure whether the procedure has a long-lasting effect.

Risks and possible problems

Only the study of 69 patients had any evidence about the procedure's safety. One patient's pharynx (throat) was pierced while the tube was being inserted. They needed to stay in hospital for a week but did not need an operation to repair the problem.

The most common problem was that the implants started to come out of the wall into the oesophagus. This had happened in 15 out of 67 patients by 6 months after the procedure.

The expert advisers said another potential complication is movement of the implants.

More information about reflux

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/IPG222

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1273).

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