NICE National Institute for Health and Care Excellence

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Information for the public

Treating gastro-oesophageal reflux disease using an endoscope and electrical heat energy

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

This document is about when and how an endoscope and electrical heat energy can be used in the NHS to treat people with gastro-oesophageal reflux disease (GORD for short). It explains guidance (advice) from NICE (the National Institute for Health and Care Excellence).

This HealthTech 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 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 document 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 GORD or the procedure in detail – a member of your healthcare team should give you full information and advice about these. The document 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 8.

What has NICE said?

There is evidence that this procedure is safe enough in the short term but its long-term safety is uncertain. When it comes to how well it works, the procedure does seem to relieve symptoms of acid reflux but it's not clear exactly how it works.

If a doctor wants to use an endoscope and electrical heat energy for GORD, they should take extra steps to explain the uncertainty about how well it works and the risks of the procedure. The patient should be given this document and other written information. This should all happen before the patient decides whether to agree to the procedure. There should also be special arrangements for monitoring what happens to the patient after the procedure.

NICE said that more information would be useful on how well the procedure works (especially in the long term and compared with surgery), which patients should have it, and exactly how it works.

Other comments from NICE

NICE noted that it wasn't sure how this procedure works. It's possible that it works not by reducing reflux but by making the bottom end of the oesophagus (gullet) less sensitive, which could lead to complications later.

Treating gastro-oesophageal reflux disease using an endoscope and electrical heat energy

The medical name for this procedure is 'endoscopic radiofrequency ablation for gastro-oesophageal reflux disease'.

Radiofrequency ablation means heat energy is used.

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

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

Gastro-oesophageal reflux disease, or GORD for short, is a common condition in which the stomach contents flow back up into the oesophagus (food pipe or gullet). Symptoms include heartburn, chest pain, nausea and problems with breathing.

People with mild symptoms are advised to make lifestyle changes. Medication can reduce the acid level in the stomach. If these don't work, or cause side effects, surgery or other procedures may be offered.

In this procedure – endoscopic radiofrequency ablation – the patient is given a calming drug called a sedative. An endoscope (a small flexible telescope) is passed down the oesophagus so that the health professional can see what they are doing. A catheter containing a small balloon is passed through the endoscope to where the oesophagus meets the stomach. The balloon is inflated, so that tiny electrodes on the outside of the balloon come into close contact with the oesophagus. The electrodes are heated several times for about a minute at a time. This changes the tissues in the oesophagus. The aim is to reduce symptoms, although exactly how the procedure does this is not clear.

What does this mean for me?

If your doctor has offered to treat your GORD using an endoscope and electrical heat energy, 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 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

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

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?

Quality of life was measured in 20 studies of 896 patients who had endoscopic radiofrequency ablation. It was reported to have improved significantly 10–20 months after the procedure. Not all the studies used the same measure.

Three studies measured whether symptoms including heartburn improved after the procedure. A review of 9 studies that included 525 patients found that patients' heartburn had improved significantly 2 years after the procedure. A study of 22 patients found that symptoms improved significantly 3 months after treatment in patients who had endoscopic radiofrequency ablation, but not in those who had a sham procedure (a 'dummy' procedure that has no effect). When patients treated with the sham procedure were later given endoscopic radiofrequency ablation, their symptoms also improved significantly 3 months later. A study of 43 patients treated medically or by endoscopic radiofrequency ablation found that after 6 months 80% of patients treated with endoscopic radiofrequency ablation had symptoms fewer than 3 times a week, compared with only 40% of patients treated medically after 6 months. After 12 months this changed to 69% for the ablation group and 62% for the medical group.

Two studies looked at how much medication patients needed to take after having endoscopic radiofrequency ablation. In the study of 22 patients, it stayed the same 6 months after treatment. In the study of 43 patients, 3 patients out of the 23 who had endoscopic

radiofrequency ablation had stopped taking medicine altogether after 6 months and 4 had stopped by 12 months.

Four studies looked at how well endoscopic radiofrequency ablation reduced acid levels in the oesophagus.

In the first, a review of 364 patients in 11 studies, after 1 year the average amount of time patients had abnormally high levels of acid in their oesophagus had reduced from 10% to 7%. The second study, of 22 patients treated by either endoscopic radiofrequency ablation or a sham procedure, showed no difference after 3 and 6 months. In the third, all except 1 of 18 patients treated by endoscopic radiofrequency ablation still had abnormally high acid levels 6 months after treatment, compared with three-quarters of 12 patients treated medically. The fourth study compared endoscopic radiofrequency ablation with surgery in 126 patients. The amount of time patients had abnormally high levels of acid reduced from 11% to 9% 5 months after endoscopic radiofrequency ablation, and from 10% to 6% 8 months after surgery.

In a study of 43 patients treated medically or by endoscopic radiofrequency ablation, a similar number of patients in each group (around half) had oesophagitis (inflammation of the lining of the oesophagus caused by irritation by acid from the stomach) 6 months after treatment.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that long-term measurement of acidity levels (pH) and symptoms are important as well as quality of life and patients being able to stop or reduce medicine use.

Risks and possible problems

In one study of patients who had endoscopic radiofrequency ablation, 3 died and there were 22 ‘complications’ overall. However the study did not report what the complications were or how many procedures the deaths and complications related to.

Three patients had bleeding from the lining of their oesophagus and 2 patients had an injury to it in a study of 90 patients. They got better within a week of the procedure.

One patient in a study of 56 had problems with their stomach not emptying properly. It got better after 8 weeks.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that a possible rare complication was the oesophagus tearing. They also said that, in theory, there was an increased risk of oesophageal cancer in the long term because the patient might continue having reflux that goes unnoticed – although no cases of cancer have been recorded so far.

More information about gastro-oesophageal reflux disease

NHS Choices (www.nhs.uk) may be a good place to find out more.

For details of all NICE guidance on gastro-oesophageal reflux disease, visit our website at www.nice.org.uk

About NICE

NICE provides national guidance and advice to improve health and social care. Interventional procedures 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. HealthTech 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 document is about 'endoscopic radiofrequency ablation for gastro-oesophageal reflux disease'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/HTG318

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on Accessibility at the bottom of the NICE homepage to use this service.

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

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