

## Understanding NICE guidance

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Information for people who use NHS services

# Treating gastro-oesophageal reflux by stitching folds into the stomach reached through the mouth

*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 stitching folds into the stomach, reached through the mouth, can be used in the NHS to treat people with gastro-oesophageal reflux. 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 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 gastro-oesophageal 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 the back page.

## What has NICE said?

Although there are no major safety concerns for this procedure, there are still uncertainties about how well it works. There is some evidence that it reduces the need for medication in the short term, but the evidence for other improvements is inconsistent and there is no good evidence that it works as a long-term treatment to reduce acid in the oesophagus. If a doctor wants to use stitching folds in the stomach, reached through the mouth, for gastro-oesophageal reflux, they should make sure that extra steps are taken to explain the uncertainty about how well it works, particularly in the long term. 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.

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

## Stitching folds into the stomach reached through the mouth

The medical name for this procedure is 'endoluminal gastroplication for gastro-oesophageal reflux'.

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

Gastro-oesophageal reflux disease (shortened to GORD) happens because the ring of muscle at the bottom of the gullet (the tube that runs from the mouth to the stomach, also called the oesophagus) isn't working properly to keep the acid stomach contents in place. The stomach contents come back up the oesophagus towards or into the mouth – this is called reflux. The person feels a burning pain (called heartburn) and may also have chest pain, nausea and breathing difficulties.

Treatments for GORD include making changes to the person's lifestyle to prevent or reduce reflux and taking medicines to reduce acidity in the stomach. If these don't help, a surgical procedure may be offered to try to help stop the reflux.

With the patient under sedation or general anaesthesia, a flexible viewing tube (endoscope) is inserted through the mouth into the person's oesophagus. Working through this tube, the surgeon uses special instruments to stitch and fold the top of the stomach, just below where the oesophagus meets the stomach, to create a smaller opening. The aim is to reduce the amount of stomach contents re-entering the oesophagus.

## Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described here. NICE looked at 10 studies on this procedure.

## What does this mean for me?

If your doctor has offered you stitching folds in the stomach, reached through the mouth, for gastro-oesophageal reflux he or she should tell you that NICE has decided that although the procedure is safe there are uncertainties about how well it works, especially in the long term. 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?

## How well does the procedure work?

A study of 60 patients reported that half (50%) of those treated with the procedure had an improvement in their heartburn 3 months after the procedure, whereas only 6% who had a dummy procedure and 18% who had no treatment had an improvement.

In a study of 159 patients, 56% who had the procedure had improved quality of life 3 months after the procedure, compared with 19% who had a dummy procedure. In a study of 126 patients, those who had the procedure had less reflux, as did those who had an alternative procedure called radiofrequency ablation.

The study of 60 patients found that 3 months after treatment 13 out of 20 patients who had the procedure, 5 out of 20 who had the dummy procedure and 0 out of 17 who had no treatment took half the amount of medication or less than they did before 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 the aim of the procedure is to control reflux without needing further surgery.

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

## Risks and possible problems

A study of 86 patients reported that the oesophagus was torn and needed an operation to repair it in 2 patients.

Chest problems were reported in 2 studies. In 1 patient, air in the chest cavity caused the lungs to collapse after the viewing tube was removed. The patient required a chest drain, but was able to go home after 2 days. Another patient had temporary narrowing of the lung airways during the procedure and needed to have a breathing tube inserted.

Following the procedure, abdominal pain was reported in 9 out of 78 patients who had the procedure and 3 out of 81 who had the dummy procedure in the study of 159 patients. Other problems included vomiting, nausea and difficulty swallowing 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 possible problems include narrowing of the area between the stomach and the oesophagus, failure to control reflux, injury to surrounding tissues and organs, and the sensation of a lump or object in the throat.

## More information about GORD

NHS Choices ([www.nhs.uk](http://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 GORD, visit our website at [www.nice.org.uk](http://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](http://www.nice.org.uk/aboutguidance)*

*This leaflet is about 'Endoluminal gastroplication for gastro-oesophageal reflux disease'. This leaflet and the full guidance aimed at healthcare professionals are available at [www.nice.org.uk/guidance/IPG404](http://www.nice.org.uk/guidance/IPG404)*

*You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email [publications@nice.org.uk](mailto:publications@nice.org.uk) and quote reference N2609). 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.*