NICE National Institute for Health and Care Excellence

NICE guidance

Laparoscopic insertion of an inactive implant for gastro-oesophageal reflux disease

HealthTech guidance

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www.nice.org.uk/guidance/htg749

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations 4

People with IOM 4

People without IOM 5

What research is needed 5

2 The condition, current treatments and procedure 6

The condition 6

Current treatments 6

The procedure 6

3 Committee considerations 8

The evidence 8

Committee comments 8

Update information 10

This guidance replaces IPG803.

1 Recommendations

People with IOM

1.1 For people with ineffective oesophageal motility (IOM), laparoscopic insertion of an inactive implant can be used to treat gastro-oesophageal reflux disease in the NHS while more evidence is generated. It can only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wanting to do this procedure should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

People without IOM

1.4 For people without IOM, more research is needed on laparoscopic insertion of an inactive implant for gastro-oesophageal reflux disease before it can be used in the NHS.

1.5 This procedure should only be done as part of a formal research study and a research ethics committee needs to have approved its use.

What research is needed

1.6 More research, in the form of randomised controlled trials, registry studies or other suitably designed studies, is needed on:

- patient selection
- patient-reported outcomes, including validated health-related quality-of-life measures
- long-term outcomes.

Why the committee made these recommendations

The evidence suggests this procedure is as safe as other common laparoscopic procedures for gastro-oesophageal reflux disease. But the efficacy evidence is from small studies, so further research is needed on short- and long-term efficacy.

People with IOM could benefit from this procedure, because other laparoscopic treatment options are limited. So it can be used with special arrangements for these people.

Because the efficacy evidence for this procedure is limited, and other common laparoscopic procedures are available for people without IOM, this procedure should only be used in research for these people.

2 The condition, current treatments and procedure

The condition

2.1 Gastro-oesophageal reflux disease (GORD) is when acid and other contents from the stomach flow back (reflux) into the oesophagus (food pipe). This can cause symptoms such as heartburn, chest pain, hoarseness, difficulty swallowing, cough, wheezing and dental erosions, and can impair quality of life. GORD can occur when the lower oesophageal sphincter (LOS, the ring of muscle at the bottom of the oesophagus) does not work properly, or if the LOS moves above the diaphragm into the thoracic cavity. In some cases, part of the top of the stomach (the fundus) can also push up through the diaphragm. This is called a hiatus hernia.

Current treatments

2.2 The standard treatments for symptomatic GORD are lifestyle modification and drug therapy. If these do not work or are not appropriate, people could be offered surgery. One option is laparoscopic insertion of a magnetic ring at the gastro-oesophageal junction (NICE interventional procedures guidance 749). Another surgical option is laparoscopic fundoplication, a procedure that involves wrapping the top part of the stomach around the lower oesophagus (see the the NICE guideline on the investigation and management of gastro-oesophageal reflux disease and dyspepsia). For more complex cases, such as GORD with ineffective oesophageal motility, there are limited treatment options.

The procedure

2.3 The procedure involves placing an implant on the outside of the upper part of the stomach wall. The implant is made from medical-grade silicone and is considered

inactive because it does not move or release any chemical or biological substances. The aim is to keep the LOS in the abdominal cavity and maintain the angle between the stomach entrance and the LOS, to restore normal anatomy.

2.4 During the procedure, a section of the upper part of the stomach wall is attached to the LOS. Then, at the top of the stomach (fundus) and parallel to the oesophagus, the device is sewn into a pocket of the fundus wall (on the outside of the stomach) and sutured in place. This should be above the LOS.

2.5 This is a laparoscopic procedure done under general anaesthesia and includes repair of a hiatus hernia if present.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 6 sources, which was discussed by the committee. The evidence included 1 prospective observational study, 3 retrospective cohort studies, 2 retrospective chart reviews that did subgroup analyses of 1 of the retrospective cohort studies, and 1 follow-up analysis of the people included in the prospective observational study. It is presented in the summary of key evidence section in the overview. Other relevant literature is in table 5 of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be an improved health-related quality of life score (such as on the GastroEsophageal Reflux Disease Health Related Quality of Life [GERD-HRQL] scale), rate of odynophagia, protein pump inhibitor use, and 24-hour pH monitoring.

3.3 The professional experts and the committee considered the key safety outcomes to be: device erosion and Clavien–Dindo rating of surgical adverse events.

3.4 Six commentaries from people who have experienced this procedure were received, which were discussed by the committee.

Committee comments

3.5 The committee noted that this procedure does not encircle the oesophagus. So, it can be used as a treatment option for people with ineffective oesophageal motility. The committee also noted that this procedure may result in less bloating than other procedures.

3.6 The committee acknowledged that unpublished evidence on this procedure reports similar safety and efficacy outcomes to the published data.

3.7 The committee was informed that this procedure should be done by healthcare professionals with experience of laparoscopic techniques for anti-reflux surgery and specific training in this procedure.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 803 has been migrated to HealthTech guidance 749. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.