NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

Gastro-oesophageal reflux disease (GORD) is when stomach acid and other contents flow back (reflux) into the oesophagus (food pipe). 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 chest. This procedure involves placing an implant on the outside of the upper part of the stomach wall. The procedure is done using keyhole (laparoscopic) surgery. The implant is considered inactive because it does not move or release any chemical or biological substances. The aim is to keep the LOS in the right position, so that the stomach contents do not flow back into the oesophagus.

NICE is looking at laparoscopic insertion of an inactive implant for gastro-oesophageal reflux disease. NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 12 December 2024

Target date for publication of guidance: 17 April 2025

1 Draft recommendations

1.1 More research is needed on laparoscopic insertion of an inactive implant for gastro-oesophageal reflux disease before it can be used in the NHS.

1.2 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

1.3 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

There is evidence that this procedure works, but this is from small studies with limited follow-up. It is also unclear who would benefit most from this procedure. The short-term safety evidence suggests this procedure is as safe as other common laparoscopic procedures for gastro-oesophageal reflux disease. But, more research is needed on long-term safety. So, this procedure should only be used in research.

2 The condition, current treatments and procedure

The condition

2.1 Gastro-oesophageal reflux disease (GORD) is when stomach acid and other contents flow back (reflux) into the oesophagus (food pipe). This can cause symptoms such as heartburn, chest pain, hoarseness, difficult 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 (see NICE's interventional procedures guidance). Another surgical option is laparoscopic fundoplication, a procedure that involves wrapping the top part of the stomach around the lower oesophagus (see NICE's guideline on the investigation and management of gastro-oesophageal reflux disease and dyspepsia). For those with more complex cases, such as GORD with oesophageal motility disorders, 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 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.

For the device implant 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 fundus wall (on the outside of the stomach) and sutured in place. This should be above the LOS. The device is made from medical-grade silicone and is inactive.

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, 2 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 interventional procedures 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 GERD-HRQL), rate of odynophagia, protein pump inhibitor usage, and 24-hour pH monitoring.

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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 had this procedure were discussed by the committee.

Committee comments

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

3.6 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.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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