

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Endoluminal gastroplication for gastro-oesophageal reflux disease

Gastro-oesophageal reflux disease is when stomach acid and stomach contents flow back into the oesophagus because the ring of muscle around the top of the stomach is not working properly.

In this procedure a device with an endoscope (a thin, flexible tube with a camera on the end) is passed through the mouth and into the stomach. The device is used to wrap the upper portion of the stomach around the lower portion of the oesophagus and secure it, for example using multiple plastic fasteners. The aim is to prevent the stomach contents from flowing back into the oesophagus.

NICE is looking at endoluminal gastroplication for gastro-oesophageal reflux disease. This is a review of NICE's interventional procedures guidance on endoluminal gastroplication 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This document contains the [draft guidance for consultation](#).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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 21st October 2022

Target date for publication of guidance: March 2023

1 Draft recommendations

- 1.1 Evidence on the safety of endoluminal gastroplication for gastro-oesophageal reflux disease is adequate. However, evidence on its efficacy is inadequate in quality, particularly in terms of patient selection and long-term outcomes. Therefore, this procedure should only be used in the context of research. Find out [what only in research means on the NICE interventional procedures guidance page](#).
- 1.2 Further research should include suitably powered randomised controlled trials with details of patient selection, physiological measurements, and long-term outcomes.

2 The condition, current treatments and procedure

The condition

- 2.1 Gastro-oesophageal reflux disease (GORD) is a common condition caused by failure of the sphincter mechanism at the lower end of the oesophagus. Symptoms of GORD can be broadly grouped into those directly related to reflux episodes, such as heartburn, regurgitation and chest pain and nausea, and those symptoms caused by complications of reflux disease, including problems swallowing (dysphagia) and respiratory symptoms. Repeat episodes of GORD can damage the lining of the oesophagus and lead to oesophageal ulceration, oesophageal stricture, and Barrett's oesophagus.

Current treatments

- 2.2 [NICE's clinical guideline on the investigation and management of gastro-oesophageal reflux disease and dyspepsia in adults](#) makes recommendations for treatment. The standard treatments for

symptomatic GORD are lifestyle modification and drug therapy. Drug therapy includes acid-lowering agents such as H₂ receptor antagonists and proton pump inhibitors (PPIs). People with reflux symptoms that do not respond to medical treatment or develop intolerance to medication may have anti-reflux surgery.

- 2.3 Surgical or laparoscopic fundoplication surgery may be used, and minimally invasive treatments such as endoscopic radiofrequency ablation or endoscopic injection of bulking agents are available.

The procedure

- 2.4 Different devices have been used for this procedure and exact details of the technique vary. The procedure is usually done with the patient under general anaesthesia. An endoscopic fastening device is inserted through the mouth and into the stomach, along with an endoscope for constant visualisation. The device is used to attach the fundus to the anterior and left lateral wall of the distal oesophagus slightly above the oesophagogastric junction.
- 2.5 With 1 of the devices, polypropylene fasteners are delivered through apposed layers of oesophageal and fundus tissue to anchor the repair. About 20 fasteners are implanted during the procedure to create a full thickness, partial circumference, gastro-oesophageal fundoplication. The aim is to recreate a valve and form a barrier to reflux. Endoluminal gastroplication for gastro-oesophageal reflux disease aims to reduce the morbidity associated with open or laparoscopic fundoplication.

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 10

sources, which was discussed by the committee. The evidence included 2 systematic reviews (1 of which was done as part of a health technology assessment), 2 randomised controlled trials, 4 case series, and 2 case reports. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: improvement in reflux symptoms, improvement in quality of life, decreased medication usage, and rate of reintervention.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: oesophageal perforation, pleural effusion, pain, and bleeding.

Committee comments

- 3.4 The committee noted that there were several different devices available to do this procedure and techniques varied between devices. Most of the evidence came from a single device.
- 3.5 The committee was informed that some of the anchors used in this procedure may fall out over time.
- 3.6 This procedure was used in a wide variety of patient subgroups and it was unclear whether some subgroups may benefit more than others.
- 3.7 The committee noted that although complications were infrequent, these could be serious, such as oesophageal perforation.

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Chair, interventional procedures advisory committee

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