

Endoluminal gastroplication for gastro-oesophageal reflux disease

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg753

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.

This guidance replaces IPG404.

1 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 be used only in 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, 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 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 who develop intolerance to medication may have anti-reflux surgery.
- 2.3 Surgical or laparoscopic fundoplication 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 use, 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.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 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.
- 3.6 The committee was informed that some of the anchors used in this procedure may fall out over time.
- 3.7 This procedure was used in a wide variety of patient subgroups and it was unclear whether some subgroups may benefit more than others.
- 3.8 The committee noted that although complications were infrequent, these

could be serious, such as oesophageal perforation.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).