NICE guidance

Endoluminal gastroplication for gastro-oesophageal reflux disease

Interventional procedures guidance
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nice.org.uk/guidance/ipg404

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. However, 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.

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.

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 IPG115.

1 Guidance

This document replaces previous guidance on endoluminal gastroplication for gastro-oesophageal reflux disease (interventional procedure guidance 115).

1.1 The evidence on endoluminal gastroplication for gastro-oesophageal reflux disease (GORD) raises no major safety concerns. Evidence from a number of randomised controlled trials (RCTs) shows a degree of efficacy in terms of reduced medication requirement in the short term, but changes in other efficacy outcomes are inconsistent and there is no good evidence of sustained improvement in oesophageal pH measurements. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake endoluminal gastroplication for GORD should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's efficacy, particularly in the long term, and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/guidance/IPG404/publicinfo).
- Audit and review clinical outcomes of all patients having endoluminal gastroplication for GORD (see section 3.1).

1.3 Any further studies should include measurements of oesophageal pH and report long-term outcomes.

2 The procedure

2.1 Indications and current treatments

2.1.1 GORD is caused by failure of the sphincter mechanism in the lower oesophagus. Symptoms include heartburn, chest pain, nausea and respiratory difficulties. Complications include development of Barrett's oesophagus or oesophageal stricture.

2.1.2 Lifestyle modification and gastric acidity-lowering medication can help improve symptoms. For patients with symptoms that do not respond to conservative therapy, anti-reflux surgery (usually laparoscopic fundoplication) may be required.

2.2 Outline of the procedure

2.2.1 Endoluminal gastroplication for GORD is an endoscopic procedure that aims to avoid the need for surgical fundoplication.

2.2.2 With the patient under sedation or general anaesthesia, the procedure is carried out using a standard endoscope with an oesophageal overtube and an endoscopic suturing or fastening device. Multiple plications, or pleats, are made below the gastro-oesophageal junction with the aim of decreasing the reflux of stomach acid into the oesophagus.

2.2.3 A range of different devices are available for this procedure.

> Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview, available at www.nice.org.uk/guidance/IP/269/overview

2.3 Efficacy

2.3.1 An RCT of 60 patients comparing endoluminal gastroplication, sham procedure and no treatment reported improvement in mean heartburn score from baseline to 3-month follow-up of 50%, 6% and 18% respectively (gastroplication vs sham $p = 0.003$; sham vs no treatment p = not significant).

2.3.2 An RCT of 159 patients comparing endoluminal gastroplication with sham treatment reported improvement in GORD health-related quality of life score in 56% and 19% of patients respectively at 3-month follow-up ($p < 0.001$) (absolute figures not stated).

2.3.3 The RCT of 159 patients comparing endoluminal gastroplication with sham treatment reported a change in mean percentage of time exposed to acid reflux

(defined as pH < 4) from baseline to 3-month follow-up of 10% to 7%, and from 9% to 10% respectively (p = 0.01 for between-group comparisons).

2.3.4 A non-randomised controlled study of 126 patients treated by endoluminal gastroplication or radiofrequency ablation reported a decrease from baseline in mean percentage of time exposed to acid reflux (defined as pH < 4) of 10% to 6% (p = 0.05) and 11% to 9% (p > 0.9) respectively (significance between groups not stated; mean follow-up 6-months).

2.3.5 The RCT of 60 patients comparing endoluminal gastroplication, sham treatment and no treatment reported a decrease of 50% or more in proton pump inhibitor medication requirement in 65% (13/20), 25% (5/20) and 0% (0/17) of patients respectively at 3-month follow-up (gastroplication vs sham p = 0.011; sham vs no treatment p = 0.05).

2.3.6 The Specialist Advisers considered a key efficacy outcome to be control of acid reflux without further surgery.

2.4 Safety

2.4.1 Intraoperative perforation of the oesophagus in 2% (2/86) of patients was reported in a case series of 86; both were treated by surgical repair, with no clinical sequelae.

2.4.2 Bilateral pneumothorax following withdrawal of the endoscopic device was described in a case report. The patient was treated by temporary chest tube insertion and was discharged after 2 days. Intraoperative bronchospasm requiring intubation was reported in 1 patient in a case series of 85 patients.

2.4.3 Post-procedural epigastric pain was reported in 12% (9/78) of patients in the endoluminal gastroplication group and in 4% (3/81) of patients in the sham group in the RCT of 159 patients (p = 0.076).

2.4.4 The RCT of 159 patients comparing endoluminal gastroplication with sham treatment reported vomiting (5% [4/78] and 4% [3/81] respectively), nausea (8% [6/78] and 1% [1/81]), and dysphagia (3% [2/78] and 2% [2/81]) after the procedure (follow-up not stated).

2.4.5 The Specialist Advisers considered theoretical adverse effects to include stenosis of oesophageal junction, early failure to control reflux, injury to surrounding tissues and organs, and foreign body sensation.

2.5 Other comments

2.5.1 The Committee noted that different devices are available for this procedure and that outcomes may differ between them.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion), available from www.nice.org.uk/guidance/IPG404

3.2 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/guidance/IPG404/publicinfo

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation