NICE National Institute for Health and Care Excellence

NICE guidance

Endoscopic augmentation of the lower oesophageal sphincter using hydrogel implants for the treatment of gastro-oesophageal reflux disease

HealthTech guidance
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www.nice.org.uk/guidance/htg142

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

This guidance replaces IPG222.

1 Recommendations

1.1 There is limited evidence of short-term efficacy on endoscopic augmentation of the lower oesophageal sphincter using hydrogel implants for the treatment of gastro-oesophageal reflux disease (GORD). This evidence also raises concerns about the procedure's safety. Therefore, this procedure should not be used without special arrangements for consent and for audit.

1.2 Clinicians wishing to undertake endoscopic augmentation of the lower oesophageal sphincter using hydrogel implants for the treatment of GORD should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having endoscopic augmentation of the lower oesophageal sphincter using hydrogel implants for the treatment of GORD (see NICE's interventional procedure outcomes audit tool).

1.3 Any adverse events resulting from the procedure should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA).

2 The procedure

2.1 Indications

2.1.1 Gastro-oesophageal reflux disease (GORD) is caused by failure of the sphincter mechanism at the lower end of the oesophagus. It is commonly associated with hiatus hernia.

2.1.2 Symptoms of GORD include heartburn and retrosternal chest pain, regurgitation, waterbrash, respiratory symptoms, dysphagia and odynophagia (painful swallowing).

2.1.3 Mild symptoms of GORD can be managed with lifestyle modification and pharmacological therapy, which are effective in most patients. However, endoluminal gastroplication or antireflux surgery may be required for those with refractory symptoms or persistent oesophagitis.

2.2 Outline of the procedure

2.2.1 The procedure is usually carried out under sedation on an outpatient basis. The aim is to augment the lower oesophageal sphincter mechanism by implantation of one or more prostheses. An endoscope and implant delivery mechanism (comprising a needle, trocar, dilator and delivery sheath) are inserted into an overtube – a tubular device with a shelf or notch near its tip. The overtube is guided to the gastro-oesophageal junction and suction applied, pulling a fold of the oesophageal wall into the shelf of the overtube. Saline is injected into this fold to create a space within the submucosa, and a hydrogel prosthesis is implanted. Suction is released and the overtube is rotated to the next location on the oesophageal wall. The prosthesis absorbs water and expands fully within 24 hours, bulking out the oesophageal wall.

2.3 Efficacy

2.3.1 In one case series (n=69), GORD/heartburn-related quality-of-life (GORD-HRQL) scores improved significantly, from 24 at baseline (n=64) to 5 at 6 months (n=53; $p<0.05$). Regurgitation scores also improved, from 16 at baseline (n=55) to 2 at 6 months (n=49; $p<0.05$). Physical aspects of quality of life (as measured by the SF-36 Health Survey) improved significantly over 6 months (from 43 at baseline [n=60] to 52 at 6 months [n=57]; $p<0.05$), but the mental component of quality of life did not change significantly (from 49 at baseline [n=60] to 50 at 6 months [n=57]).

2.3.2 A case series of nine patients also reported improvement in mean GORD-HRQL score from 35.5 at baseline to 9.4 at 6-month follow-up ($p<0.01$).

2.3.3 In the case series of 69 patients oesophagitis was reported to be present at baseline in 58% of patients (39 out of 67) and at 6 months in 32% (17 out of 53).

2.3.4 In the case series of nine patients, acid exposure time of the distal oesophagus decreased in all patients but only reached normal levels (defined as below pH 4 for less than 4% of the time) in three. In the case series of 69 patients, acid exposure data were available for 45 patients. Only 40% of these (18 out of 45) had a normal pH level (using the same definition as above) at 6 months. For more details, see the overview.

2.3.5 The Specialist Advisers are uncertain whether the procedure has a long-lasting effect. They commented that few patients have shown a sustained reduction in objective measures of GORD, such as oesophageal acid exposure, after the procedure.

2.4 Safety

2.4.1 The case series of 69 patients reported safety outcomes. One patient's pharynx was perforated during overtube insertion, requiring a week of inpatient care, but surgical intervention was not required. In this case series the most common complication reported was erosion of the prosthesis into the oesophagus which occurred in 22% (15 out of 67) of patients by 6 months. For more details, see the

overview.

2.4.2 The Specialist Advisers listed potential complications as pharyngeal perforation, mucosal erosion and migration of the device.

3 Further information

3.1 NICE has issued a guideline on gastro-oesophageal reflux disease (GORD) and dyspepsia in adults and guidance on endoluminal gastroplication for GORD.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 222 has been migrated to HealthTech guidance 142. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.