

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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg222

1 Guidance

- 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 the Institute's [information for patients](#) ('Understanding NICE guidance') 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 section 3.1).

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 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 (39/67) and at 6 months in 32% (17/53).
- 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 (18/45) had a normal pH level (using the same definition as above) at 6 months. For more details, refer to the 'Sources of evidence' section.
- 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% (15/67) of patients by 6 months. For more details, refer to the 'Sources of evidence' section.
- 2.4.2 The Specialist Advisers listed potential complications as pharyngeal perforation, mucosal erosion and migration of the device.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. The Institute has identified relevant audit criteria and developed an [audit tool](#) (which is for use at local discretion).
- 3.2 NICE has issued a clinical guideline on [dyspepsia](#) and interventional procedures guidance on [endoluminal gastroplication for GORD](#).

Andrew Dillon
Chief Executive
June 2007

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of endoscopic augmentation of the lower oesophageal sphincter using hydrogel implants for the treatment of gastro-oesophageal reflux disease',

December 2006.

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.

4 Changes since publication

The guidance was considered for reassessment in June 2010 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please [contact us](#).

14 January 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into

account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

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