

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

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 (available from www.nice.org.uk/IPG222publicinfo).
 - 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 anti-reflux 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

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This guidance is written in the following context

This guidance represents the view of the Institute, which 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.

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This guidance is endorsed by NHS QIS for implementation by NHSScotland.

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), available from www.nice.org.uk/IPG222
- 3.2 NICE has issued a clinical guideline on dyspepsia (www.nice.org.uk/CG017) and interventional procedures guidance on endoluminal gastroplastication for GORD (www.nice.org.uk/IPG115).

Andrew Dillon
Chief Executive
June 2007

Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG222publicinfo

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.

Available from: www.nice.org.uk/ip387overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1272. 'Understanding NICE guidance' can be obtained by quoting reference number N1273.

The distribution list for this guidance is available at www.nice.org.uk/IPG222distributionlist

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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