

# Endoluminal gastroplication for gastro-oesophageal reflux disease

## 1 Guidance

- 1.1 Current evidence suggests that there are no major safety concerns associated with endoluminal gastroplication for gastro-oesophageal reflux disease (GORD). However, evidence of efficacy is not adequate for this procedure to be used without special arrangements for consent and for 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 understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's *Information for the public* is recommended.
  - Audit and review clinical outcomes of all patients having endoluminal gastroplication for GORD.
- 1.3 Publication of efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence.

## 2 The procedure

### 2.1 Indications

- 2.1.1 Gastro-oesophageal reflux disease (GORD) is a common condition and is 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 and waterbrash, and those symptoms caused by complications of reflux disease, including dysphagia and respiratory symptoms.

- 2.1.2 Lifestyle modifications and drug therapy are the standard treatment for patients with mild symptomatic GORD. Drug therapy includes antacids/alginates and acid-lowering agents such as H<sub>2</sub>-receptor antagonists and proton pump inhibitors (PPIs). Patients with reflux symptoms that do not respond to medical treatment may be treated with anti-reflux surgery. Minimally invasive treatments such as endoluminal gastroplication or injection therapy are possible alternatives to conventional open surgery.

### 2.2 Outline of the procedure

- 2.2.1 Endoluminal gastroplication for gastro-oesophageal reflux disease can be performed as an outpatient procedure. The procedure is done using a standard endoscope and an endoscopic sewing device. This creates plications, or pleats, at the lower oesophageal sphincter, intended to decrease the reflux of stomach acid into the oesophagus.

### 2.3 Efficacy

- 2.3.1 Data from a number of small studies indicate that patients may experience a degree of short-term symptom control following the procedure. In one study of 64 patients, heartburn severity and frequency were

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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. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

reported to have improved at 6 months, and the proportion of patients experiencing moderate to severe regurgitation decreased from 61% (39/64) to 8% (4/51).

- 2.3.2 In a case series of 64 patients, 24-hour pH monitoring showed that the total number of reflux episodes had significantly decreased at 3 and 6 months after the procedure. The mean percentage of time that the pH was less than 4 was not significantly decreased at 3 months compared with baseline levels. In the 29 patients followed up to 6 months, the mean time with pH less than 4 was 9% (SD 8.3) compared with 10% (SD 6.8) at baseline ( $p = 0.011$ ).
- 2.3.3 In a case series of 26 patients, quality of life significantly improved after the procedure. However, in 34 patients followed-up to 3 months, a randomised controlled trial found no significant benefit compared with a sham procedure.
- 2.3.4 Across all the studies reviewed, 80% (51/64) to 85% (22/26) of the enrolled patients had results reported at final follow-up. In three of the six studies included, outcome measures were poorly defined and often the durability of the procedure was not recorded. For more details, refer to the Sources of evidence.
- 2.3.5 The Specialist Advisors expressed concerns regarding the long-term efficacy of this procedure.

## 2.4 Safety

- 2.4.1 Complications following the procedure included abdominal or chest pain, sore throat and vomiting. These complications typically resolved within a few days of having the procedure.
- 2.4.2 More serious complications were uncommon. In the largest available study of 64 patients, 3% (2/64) of patients experienced mucosal tears and there was one case of oesophageal perforation. Two small case series of 15 and 34 cases reported no major complications,

and another study comparing endoluminal gastroplication with laparoscopic anti-reflux surgery did not include safety outcomes. For more details, refer to the Sources of evidence.

- 2.4.3 The Specialist Advisors had no major safety concerns. They stated that haemorrhage and perforation were potential complications.

## 2.5 Other comments

- 2.5.1 Initial experience with this technique in a small number of children has produced encouraging early results.

## 3 Further information

- 3.1 The Institute has issued a clinical guideline on managing dyspepsia in adults in primary care ([www.nice.org.uk/CG017](http://www.nice.org.uk/CG017)).

Andrew Dillon  
Chief Executive  
February 2005

## Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available, in English and Welsh, from [www.nice.org.uk/IPG115publicinfo](http://www.nice.org.uk/IPG115publicinfo)

## Sources of evidence

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

*Interventional procedures overview of endoluminal gastroplication for gastro-oesophageal reflux disease*, June 2004.

Available from: [www.nice.org.uk/IP269overview](http://www.nice.org.uk/IP269overview)

### Ordering information

Copies of this guidance can be obtained from the Department of Health Publications Order Line by telephoning 0870 1555 455 and quoting reference number N0822. *Information for the public* can be obtained by quoting reference number N0823 for the English version and N0824 for a version in English and Welsh.

The distribution list for this guidance is available at [www.nice.org.uk/IPG115distributionlist](http://www.nice.org.uk/IPG115distributionlist)

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