

# Endoscopic injection of bulking agents for gastro-oesophageal reflux disease

## 1 Guidance

- 1.1 Current evidence on the safety and efficacy of endoscopic injection of bulking agents for gastro-oesophageal reflux disease does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake endoscopic injection of bulking agents for gastro-oesophageal reflux disease should take the following action.
  - 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. Use of the Institute's *Information for the Public* is recommended.
  - Audit and review clinical outcomes of all patients having endoscopic injection of bulking agents for gastro-oesophageal reflux disease.
- 1.3 Publication of safety and 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 that can have a significant impact on the quality of life of an individual. It 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-2 antagonists and proton pump inhibitors (PPIs). Patients with volume reflux or symptoms that do not respond to medical treatment may be treated with anti-reflux surgery. Injection therapy may be considered as an alternative to surgery.

### 2.2 Outline of the procedure

- 2.2.1 The patient is sedated and given an injection of antibiotics. A needle catheter is then introduced through an endoscope and passed down the oesophagus into the gastro-oesophageal junction, so narrowing the lumen. This catheter is filled with a bio-compatible polymer and solvent and is used to inject or implant the polymer into the gastro-oesophageal junction. The injection is made

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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.

along the muscle layer or deep submucosal layer of the cardia. Multiple injections (often four) are performed in a circumferential manner around the oesophagus under fluoroscopic and endoscopic control.

## 2.3 Efficacy

- 2.3.1 Evidence of efficacy was based primarily on one uncontrolled study of 85 patients with GORD receiving chronic PPI therapy. This study reported that, at 12 months, 67% (57/85) of patients were no longer taking PPIs and that a further 9% (8/85) of patients had reduced PPI usage by 50% or more. Both heartburn and regurgitation symptom scores had improved at 12 months. Small reductions in acid reflux, as assessed by measuring oesophageal pH, were seen but no improvement in endoscopic grades was observed. Efficacy of treatment was related to the residual implant volume, and repeat treatments may be required to enhance this volume. For more details, refer to the Sources of evidence (see below).
- 2.3.2 The Specialist Advisors considered that this was a procedure at an early stage of development and that its efficacy was unknown.

## 2.4 Safety

- 2.4.1 Transient mild-to-moderate chest pain was the most commonly reported adverse event occurring after injection; the incidence in the studies ranged from 53% (8/15) to 92% (78/85). Other complications included dysphagia, fever and nausea. For more details, refer to the Sources of evidence (see below).
- 2.4.2 The Specialist Advisors had no major safety concerns.

## 2.5 Other comments

- 2.5.1 These recommendations were based on evidence presented to the Interventional Procedures Advisory Committee on the use of a bio-compatible polymer as a bulking agent. The Institute may review the procedure if further data become available.

Andrew Dillon  
Chief Executive  
April 2004

## Information for the Public

The Institute 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/IPG055publicinfo](http://www.nice.org.uk/IPG055publicinfo).

## Sources of evidence

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

*Interventional procedure overview of endoscopic injection of bulking agents for gastro-oesophageal reflux disease*, August 2003.

Available from: [www.nice.org.uk/ip226overview](http://www.nice.org.uk/ip226overview)

### Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0536. *Information for the Public* can be obtained by quoting reference number N0537 for the English version and N0538 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL [www.nice.org.uk/IPG055distributionlist](http://www.nice.org.uk/IPG055distributionlist)

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