

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

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg55](http://www.nice.org.uk/guidance/ipg55)

## 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.

# 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 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. NICE 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 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% of patients (57 of 85) were no longer taking PPIs and that a further 9% of patients (8 of 85) 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](#).

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 of 15) to 92% (78 of 85). Other complications included dysphagia, fever and nausea. For more details, refer to the sources of evidence.

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. NICE may review the procedure if further data become available.

# 3 Further information

## Sources of evidence

The evidence considered by the interventional procedures advisory committee is described in the [overview](#).

## Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

## 4 Update information

### Minor changes since publication

**January 2012:** Minor maintenance.

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## Endorsing organisation

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