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Endoscopic injection of bulking agents for gastro- oesophageal reflux disease

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NICE interventional procedure guidance 55

www.nice.org.uk/ipg55

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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/alginate 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% (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 section.
- 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 section.
- 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

3 Further information

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.

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

As part of NICE's work programme, the current guidance was considered for review but did not meet the review criteria as set out in the IP process guide. This guidance therefore remains current.

28 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](#). Information about the evidence it is based on is 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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