

Circumferential epithelial radiofrequency ablation for Barrett's oesophagus

1 Guidance

- 1.1 Evidence on the safety and efficacy of circumferential epithelial radiofrequency (RF) ablation for Barrett's oesophagus is currently inadequate. The evidence is limited in quantity and duration of follow-up and fails to justify the treatment of non-dysplastic Barrett's oesophagus. Therefore this procedure should only be used in the context of research.
- 1.2 Further research should specify clearly the grade of Barrett's oesophagus being treated and should include arrangements for long-term follow-up (for example, 5 years). The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

- 2.1.1 Barrett's oesophagus is a condition characterised by an abnormal lining (epithelium) of the oesophagus. It is associated with chronic gastro-oesophageal reflux disease (GORD). In some people Barrett's oesophagus may progress through a series of precancerous stages (dysplasia) to cancer. High-grade dysplasia is the histological stage that precedes cancer, but it is not possible to predict how soon such lesions will progress to cancer.
- 2.1.2 Oesophagectomy is the most radical treatment option for high-grade dysplasia in Barrett's oesophagus. Removal of the whole oesophagus takes away the risk of progression to cancer, but oesophagectomy is a major operation with potentially high morbidity and mortality. Furthermore, some patients are unfit for surgery or are reluctant to undergo this operation for a premalignant condition.

- 2.1.3 Less invasive treatments for high-grade dysplasia aim to remove the specialised columnar epithelium associated with Barrett's oesophagus and promote the regeneration of normal squamous epithelium. Treatments include laser ablation, endoscopic mucosal resection and photodynamic therapy. Follow-up by endoscopic surveillance is usually required to detect the development of further dysplastic changes and/or cancer.

2.2 Outline of the procedure

- 2.2.1 The aim of circumferential RF ablation is to destroy a thin layer of oesophageal epithelium around the lumen of the oesophagus for a length of a few centimetres.
- 2.2.2 The procedure is carried out under conscious sedation. Under endoscopic visualisation, a balloon-mounted coil measuring a few centimetres in length and attached to a probe is inserted into the oesophageal lumen and advanced to the level of the target area. The coil delivers a controlled emission of RF energy for a few seconds, which ablates a thin layer of epithelial tissue. Repeat treatments may be necessary if follow-up endoscopy shows residual Barrett's oesophagus.

2.3 Efficacy

- 2.3.1 A case series of 102 patients reported on dosimetry in 32 patients and effectiveness in 70 patients. Intention-to-treat analysis demonstrated a complete response to circumferential RF ablation (defined as 100% of biopsy samples reported negative for Barrett's oesophagus) in 59% (19/32) and 69% (48/70) of patients in the dosimetry and effectiveness phases of the study, respectively (12-month follow-up).

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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. Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

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

- 2.3.2 A second case series of seven patients treated after fundoplication for GORD reported that six patients (86%) had no residual Barrett's oesophagus on endoscopic examination at 3-month follow-up. For more details, refer to the 'Sources of evidence' section.
- 2.3.3 The Specialist Advisers stated that the benefit of the procedure is complete ablation of Barrett's oesophagus without the creation of strictures. Four Specialist Advisers noted the lack of long-term data. Key efficacy outcomes were considered to be complete ablation of Barrett's oesophagus with no stricture, visual and histological reversal of metaplasia, reduction in the presence of dysplasia and reduced incidence of carcinoma.

2.4 Safety

- 2.4.1 In the case series of 102 patients, 106 procedures were undertaken in the effectiveness phase (including 36 repeat treatments). Reported adverse events included nausea in 8% of patients (8/106) and fever in 2% (2/106). Mild bleeding, mucosal scarring, linear mucosal injury, airway obstruction and hypotension each occurred in 1% of patients (1/106). The latter two complications were thought to be related to the sedation used for the procedure. All adverse events were transient and resolved completely. There were no reports of strictures or buried glands in any of the 3007 biopsies taken during the study.
- 2.4.2 The case series of seven patients reported no procedure-related complications and no new or recurrent GORD-like symptoms at 3-month follow-up. For more details, refer to the 'Sources of evidence' section.
- 2.4.3 The Specialist Advisers identified stricture, perforation, pain, haemorrhage and buried malignancy beneath neo-squamous epithelium as adverse events. Theoretical adverse events included heat damage to the oesophageal wall and failure to completely ablate the targeted area of Barrett's oesophagus. Key safety outcomes were considered to be stricture formation, oesophageal perforation and requirement for blood transfusion.

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1432. 'Understanding NICE guidance' can be obtained by quoting reference number N1433.

The distribution list for this guidance is available at www.nice.org.uk/IPG244distributionlist

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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3 Further information

- 3.1 The Institute has issued interventional procedures guidance on photodynamic therapy for high-grade dysplasia in Barrett's oesophagus (www.nice.org.uk/IPG82) and thoracoscopically assisted oesophagectomy (www.nice.org.uk/IPG189).

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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/IPG244publicinfo

Sources of evidence

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

'Interventional procedure overview of circumferential epithelial radiofrequency ablation for Barrett's oesophagus', April 2007

Available from: www.nice.org.uk/ip397overview