Issue date: May 2010

NHS
National Institute for
Health and Clinical Excellence

# Epithelial radiofrequency ablation for Barrett's oesophagus

This document replaces previous guidance on circumferential epithelial radiofrequency ablation for Barrett's oesophagus (interventional procedure guidance 244).

## 1 Guidance

1.1 Current evidence on the efficacy of epithelial radiofrequency ablation (RFA) in patients with Barrett's oesophagus with high-grade dysplasia (HGD) is adequate, provided that patients are followed up in the long term. There are no major safety concerns. Therefore this procedure may be used in patients with Barrett's oesophagus with HGD provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Current evidence on the efficacy and safety of epithelial RFA in patients with Barrett's oesophagus with either low-grade dysplasia (LGD) or no dysplasia is inadequate in quality and quantity, and the balance of risks and benefits is not clear. Therefore, in these patients, this procedure should be used only with special arrangements for clinical governance, consent and audit or research.

1.3 Clinicians wishing to undertake epithelial RFA in patients with Barrett's oesophagus with either LGD or no dysplasia should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/guidance/IPG344/publicinfo).
- Audit and review clinical outcomes of patients with Barrett's oesophagus with LGD or no dysplasia having epithelial RFA (see section 3.1).

1.4 Patient selection for epithelial RFA for Barrett's oesophagus should be done by a multidisciplinary team experienced in the management of Barrett's oesophagus.

1.5 Epithelial RFA for Barrett's oesophagus should only be carried out by endoscopists with specific training in this procedure.

1.6 NICE encourages further research into epithelial RFA for Barrett's oesophagus. This should address the balance of risks and benefits of the procedure in patients with Barrett's oesophagus and either LGD or no dysplasia, and long-term outcomes in patients with Barrett's oesophagus of any histological type.

## 2 The procedure

### 2.1 Indications and current treatments

2.1.1 Barrett's oesophagus is a condition characterised by abnormal epithelium of the oesophagus. In some patients, Barrett's oesophagus may progress, through metaplasia and dysplasia, to oesophageal adenocarcinoma. Cancer risk is higher for patients with HGD (some of whom may already have developed early-stage cancer) and lower for patients with LGD or no dysplasia.

2.1.2 Patients with HGD are usually offered oesophagectomy, or frequent endoscopic surveillance and re-biopsy (with the aim of detecting neoplastic changes early). Endoscopic treatments that aim to remove or ablate abnormal epithelium have also been developed, including endoscopic mucosal resection and photodynamic therapy.

**Interventional procedure guidance 344**

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.

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.

NHS Quality Improvement Scotland

2.1.3 Patients with LGD or no dysplasia are usually offered regular endoscopic surveillance and re-biopsy (with the aim of detecting potential progression to HGD or cancer).

## 2.2 Outline of the procedure

2.2.1 The aim of RFA is to destroy the Barrett's epithelium in order to allow re-epithelialisation with squamous epithelium.

2.2.2 The procedure is carried out with the patient under conscious sedation, usually in an outpatient setting. Using endoscopic visualisation, an appropriately sized RFA probe is inserted into the oesophagus and advanced to the target area. Controlled pulses of RF energy are delivered to thermally ablate a thin epithelial layer in the affected areas. RFA is sometimes used after previous endoscopic mucosal resection.

2.2.3 If follow-up endoscopy and re-biopsy show residual Barrett's changes, repeat treatment sessions may be necessary.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview, available at www.nice.org.uk/IP397aoverview

## 2.3 Efficacy

2.3.1 A randomised controlled trial (RCT) of 127 patients (63 with HGD and 64 with LGD) treated by RFA or a sham procedure reported complete eradication of Barrett's oesophagus in 77% (65/84) and 2% (1/43) of patients respectively at 12-month follow-up ($p < 0.001$).

2.3.2 In the same RCT, among patients with HGD, fewer RFA-treated patients progressed to cancer at 12-month follow-up (2% [1/42]) compared with those in the sham group (19% [4/21]) ($p = 0.04$).

2.3.3 A register of 142 patients with HGD reported efficacy data on 92 patients with at least 1 follow-up endoscopy. At a median 1-year follow-up, HGD resolution had occurred in 90% (83/92) of patients; 80% (74/92) had no dysplasia (HGD or LGD) and 54% (50/92) had no Barrett's at all.

2.3.4 The Specialist Advisers listed key efficacy outcomes as eradication of metaplasia and dysplasia, relapse rate and reduction in development of cancer.

## 2.4 Safety

2.4.1 Oesophageal stricture was reported in 6% (5/84) of patients treated by RFA in the RCT of 127 patients (successfully treated by endoscopic dilatation) and 8 patients (denominator not stated) from a register of 106 patients treated by RFA (timing of events and management not stated).

2.4.2 Buried glandular mucosa detected on surveillance biopsy was reported in 15% (4/27) of patients 6–12 weeks after RFA (precise timing of detection not stated) in a case series of 27 patients. All were treated with additional RFA. One buried glandular mucosa was reported in neosquamous epithelium among 1475 biopsies (less than 1%) in a case series of 44 patients (subsequent treatment not described).

2.4.3 In the RCT of 127 patients, 1 patient developed new-onset chest pain and 1 patient developed chest discomfort and nausea. Both patients required overnight admission to hospital.

2.4.4 The Specialist Advisers listed anecdotal adverse events as dysphagia, minor bleeding, oesophageal perforation and pain (such as retrosternal pain).

# 3 Further information

3.1 This guidance requires that clinicians undertaking the procedure in patients with LGD or no dysphagia make special arrangements for audit. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion), available from www.nice.org.uk/guidance/IPG344

3.2 For related NICE guidance see www.nice.org.uk

## 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. See www.nice.org.uk/guidance/IPG344/publicinfo

**Ordering printed copies**
Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N2178 for this guidance or N2179 for the 'Understanding NICE guidance'.



**National Institute for Health and Clinical Excellence**
MidCity Place, 71 High Holborn, London WC1V 6NA; www.nice.org.uk

ISBN 978-1-84936-245-0
N2178 1P 3.6k May 10