

Epithelial radiofrequency ablation for Barrett's oesophagus

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg344

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.

This guidance replaces IPG82 and IPG244.

This guidance is partially replaced by IPG496.

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- 1.2 This recommendation has been updated and replaced by [NICE's interventional procedures guidance on endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia](#).
- 1.3 This recommendation has been updated and replaced by [NICE's interventional procedures guidance on endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia](#).
- 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 low-grade dysplasia (LGD) or no dysplasia, and long-term outcomes in patients with Barrett's oesophagus of any histological type. This recommendation has been partially updated by [NICE's interventional procedures guidance on endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia](#).

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 high-grade dysplasia (HGD; some of whom may already have developed early-stage cancer) and lower for patients with low-grade dysplasia (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.
- 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 radiofrequency ablation (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.

2.3 Efficacy

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](#).

- 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 out of 84) and 2% (1 out of 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 out of 42]) compared with those in the sham group (19% [4 out of 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 out of 92) of patients; 80% (74 out of 92) had no dysplasia (HGD or LGD) and 54% (50 out of 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 out of 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 out of 27) of patients 6 to 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 1,475 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 low-grade dysplasia (LGD) or no dysphagia to make special arrangements for audit. NICE has identified relevant audit criteria and developed an [audit tool](#) (which is for use at local discretion).
- 3.2 This guidance should be read in conjunction with [NICE's guideline on Barrett's oesophagus and stage 1 oesophageal adenocarcinoma: monitoring and management](#).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is

described in the [overview](#).

Information for patients

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

4 Update section

Minor changes since publication

24 July 2014: This guidance has been partially updated by [NICE's interventional procedures guidance on endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia](#).

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Endorsing organisation

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