

# Endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg496](http://www.nice.org.uk/guidance/ipg496)

## 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 partially replaces IPG344.

# 1 Recommendations

- 1.1 Current evidence on the efficacy of endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia 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 low-grade dysplasia with normal arrangements for clinical governance, consent and audit or research.
- 1.2 Current evidence on the efficacy and safety of endoscopic radiofrequency ablation for Barrett's oesophagus with no dysplasia is limited in quality and quantity. Therefore, this procedure should only be used in patients with no dysplasia in the context of research.
- 1.3 Patient selection for endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia should be done by a multidisciplinary team experienced in managing Barrett's oesophagus, as described in the [British Society of Gastroenterology guidelines](#).
- 1.4 Endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia should only be done by endoscopists experienced in treating Barrett's oesophagus, as described in the British Society of Gastroenterology guidelines.

- 1.5 Clinicians should enter details of all patients undergoing endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia onto the [UK National HALO Patient Registry](#), and review clinical outcomes locally.
- 1.6 NICE encourages further research into endoscopic radiofrequency ablation for Barrett's oesophagus with no dysplasia. Studies should define clearly the policies used for histological diagnosis. Outcomes should include complete resolution of Barrett's oesophagus, change and progression to low-grade dysplasia, high-grade dysplasia or cancer. All complications should be reported, particularly development of strictures. Comparative studies against surveillance would be useful.

## 2 Indications and current treatments

- 2.1 Barrett's oesophagus is a precancerous condition characterised by abnormal replacement of the squamous epithelium of the lower oesophagus by a type of columnar epithelium resembling that in the stomach and intestine.
- 2.2 In some patients, Barrett's oesophagus may progress through a series of stages to oesophageal adenocarcinoma – a cancer with a poor prognosis. These intermediate stages are graded into low-grade and high-grade dysplasia according to the degree of abnormal cellular architecture.
- 2.3 The risk of progression to oesophageal adenocarcinoma for anyone with Barrett's oesophagus is difficult to predict accurately. In general, the risk of cancer is highest for patients with high-grade dysplasia, lower for patients with low-grade dysplasia, and lowest for patients with no dysplasia (also referred to as "intestinal metaplasia", a change from epithelium that is normal for this site but with no evidence of dysplasia). Accurate classification of Barrett's oesophagus into these distinct histopathological types is difficult; there is the possibility of diagnostic misclassification because of biopsy sampling error and subjective biopsy interpretation. Strategies for addressing this include multiple biopsy sampling, diagnosis on at least 2 occasions, confirmation by 2 specialist histopathological experts and confirmation by an independent pathologist external to the original institution each time, all in the context of a multidisciplinary team.

- 2.4 The main risk factor for developing Barrett's oesophagus is a history of reflux of acid and/or bile into the oesophagus. Reflux commonly produces symptoms of heartburn but it can be asymptomatic.
- 2.5 The management of Barrett's oesophagus is determined by the dysplasia status. In Barrett's oesophagus with no dysplasia or low-grade dysplasia, periodic endoscopic surveillance and repeat biopsies may be considered with the aim of early detection of progression to high-grade dysplasia or cancer. If high-grade dysplasia or early cancer (carcinoma in situ) is detected, then treatment is recommended. If the disease is superficial (confined to the mucosa), treatment can usually be done endoscopically.
- 2.6 Endoscopic treatments for Barrett's oesophagus aim to destroy the Barrett's epithelium, leaving a surface that is subsequently replaced with a normal squamous epithelium. If the Barrett's epithelium is flat, then it can be ablated using one of several possible modalities such as photodynamic therapy, argon plasma coagulation, laser ablation, cryotherapy or multipolar electrocoagulation. If there are visible abnormalities, such as nodules or ulcers, then those areas are usually removed by endoscopic resection.

## 3 The procedure

- 3.1 The procedure is usually carried out with the patient under conscious sedation, in an outpatient setting. Using endoscopic visualisation, an appropriately sized radiofrequency ablation probe attached to the endoscope is inserted into the oesophagus, and advanced to the target area. Controlled pulses of radiofrequency energy are delivered, which cause thermal ablation of a thin layer of epithelium in the affected areas. A circumferential ablation catheter is usually used for primary treatment, whereas a focal ablation catheter can be used for remaining patches of Barrett's epithelium in any subsequent treatments. Radiofrequency ablation can also be used after doing endoscopic resection to remove larger, superficial abnormal areas. If follow-up high-definition endoscopy and re-biopsy show residual Barrett's changes, repeat treatment can be done using radiofrequency ablation.

## 4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#).

### Low-grade dysplasia

- 4.1 A randomised controlled trial of 127 patients with non-nodular dysplastic Barrett's oesophagus (64 with low-grade dysplasia and 63 with high-grade dysplasia) compared radiofrequency ablation plus endoscopic surveillance against endoscopic surveillance alone (sham procedure). Among patients with low-grade dysplasia (n=64; 42 treated by radiofrequency ablation, 22 treated by sham procedure), complete eradication of dysplasia was reported in 91% (38 of 42) of patients treated by radiofrequency ablation, compared with 23% (5 of 22) treated by sham procedure at 12-month follow-up. Patients randomised to the sham procedure were offered crossover to radiofrequency ablation after 12 months. After crossover, complete eradication of all dysplasia and intestinal metaplasia was reported in 98% (51 of 52) of patients with low-grade dysplasia at 2-year follow-up. At 3-year follow-up, dysplasia was eradicated in 100% (32 of 32) of patients.
- 4.2 A randomised controlled trial of 136 patients with low-grade dysplasia comparing radiofrequency ablation (n=68) against endoscopic surveillance (control, n=68) reported that the low-grade dysplasia treated by radiofrequency ablation was less likely to progress to adenocarcinoma (2% [1 of 68] compared with 9% [6 of 68],  $p=0.03$ ) and less likely to progress to high-grade dysplasia or adenocarcinoma (2% [1 of 68] compared with 27% [18 of 68],  $p<0.001$ ) at 3-year follow-up. At the end of the treatment, complete eradication of dysplasia and intestinal metaplasia occurred in 93% (63 of 68) and 88% (60 of 68) of patients respectively in the radiofrequency ablation group (data not given for the control group). During follow-up, complete eradication of dysplasia and metaplasia was maintained in 98% (62 of 63) and 90% (54 of 60) of patients respectively compared with 28% (19 of 68) ( $p<0.001$ ) and 0% ( $p<0.001$ ) of patients respectively in the control group.

- 4.3 The randomised controlled trial of 127 patients reported less progression from low-grade dysplasia to high-grade dysplasia in patients treated by radiofrequency ablation (5% [2 of 42]) compared with those treated by sham procedure (14% [3 of 22],  $p=0.33$ ) at 12-month follow-up.

## No dysplasia

- 4.4 A case series of 102 patients with non-dysplastic Barrett's oesophagus (32 in a dosimetry phase I study and 70 in an effectiveness phase II study) reported complete eradication of intestinal metaplasia in 59% (19 of 32) of patients in the dosimetry phase and 69% (48 of 69) of patients in the effectiveness phase at 12-month follow-up. In the effectiveness phase study at 30-month follow-up, after additional focal ablation in patients with endoscopic and histological evidence of intestinal metaplasia at 12-month biopsy, complete eradication of intestinal metaplasia was reported in 97% (60 of 61) of patients. At 5-year follow-up, complete eradication of intestinal metaplasia was reported in 92% (46 of 50) of patients, while 8% (4 of 50) of patients had intestinal metaplasia that was treated with 'single salvage focal ablation' 1 month after biopsy (complete eradication of intestinal metaplasia was reported at subsequent 2-month biopsy).
- 4.5 The specialist advisers listed key efficacy outcomes as eradication of dysplasia, prevention of progression to cancer, eradication of intestinal metaplasia, eradication of Barrett's oesophagus and quality of life.

## 5 Safety

This section describes 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 [interventional procedure overview](#).

- 5.1 Gastrointestinal haemorrhage was reported in 1 patient being treated by antiplatelet therapy for heart disease in the radiofrequency ablation group in a randomised controlled trial of 127 patients. This was treated endoscopically.

- 5.2 Perforation of the oesophagus (measuring 1.5 cm) within the proximal radiofrequency ablation field (noted 6 weeks postoperatively because of a report of 'a food impaction') was reported in 1 patient in a case series of 10 patients. Further details were not reported.
- 5.3 Oesophageal strictures were reported in 12% (8 of 68) of patients treated by radiofrequency ablation (time of occurrence not reported) in a randomised controlled trial of 136 patients: these were all successfully treated by endoscopic dilatation (in median of 1 session).
- 5.4 Erosive oesophagitis (transient and resolved completely) was reported in 6% (3 of 50) of patients at 5-year follow-up in a case series of 70 patients.
- 5.5 Overnight hospitalisation for new chest pain was reported in 1 patient (8 days after radiofrequency ablation) in the radiofrequency ablation group in the randomised controlled trial of 127 patients (outcome not reported). Chest pain (transient and resolved spontaneously) was reported in 8% (9 of 106) of procedures in the case series of 70 patients.
- 5.6 Fever (transient and resolved completely) was reported in 2% (2 of 106) of procedures undertaken in the case series of 70 patients.
- 5.7 The specialist advisers listed additional adverse events as dysphagia and oesophageal laceration.

## 6 Committee comments

- 6.1 The committee noted the difficulties in reliable diagnosis of low-grade dysplasia and was advised about the benefits of consensus reporting of histology.

## 7 Further information

- 7.1 This guidance is a partial review of [NICE's interventional procedures guidance on epithelial radiofrequency ablation for Barrett's oesophagus](#). It applies only to

Barrett's oesophagus with low-grade or no dysplasia. The sections in IPG344 relating to Barrett's oesophagus with high-grade dysplasia continue to apply.

## 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.

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## Endorsing organisation

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