NICE National Institute for Health and Care Excellence

NICE guidance

Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease

HealthTech guidance
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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.

Contents

This guidance replaces IPG292 and IPG461.

1 Recommendations

1.1 The evidence on the safety of endoscopic radiofrequency ablation for gastro-oesophageal reflux disease (GORD) is adequate in the short and medium term but there is uncertainty about longer-term outcomes. With regard to efficacy, there is evidence of symptomatic relief but objective evidence on reduction of reflux is inconclusive. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake endoscopic radiofrequency ablation for GORD should take the following actions.

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients 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 the public is recommended.
- Audit and review clinical outcomes of all patients having endoscopic radiofrequency ablation for GORD (see section 7.1).

1.3 Future review of the guidance might consider evidence from research that includes objective outcome measures such as oesophageal pH, long-term follow-up data, comparison with Nissen fundoplication, information about patient selection and further insight into the mechanism of action of the procedure.

2 Indications and current treatments

2.1 Gastro-oesophageal reflux disease is a common problem caused by disturbance of sphincter function at the lower end of the oesophagus. Symptoms include heartburn, regurgitation, chest pain, nausea, respiratory difficulties and dysphagia. If untreated, complications such as Barrett's oesophagus or oesophageal stricture can develop.

2.2 Lifestyle modification and gastric acidity-lowering medication can help to improve symptoms. Patients who have refractory symptoms, who develop complications despite medication or who develop intolerance to medication may be considered for anti-reflux surgery. Most commonly this is laparoscopic fundoplication but alternative endoscopic techniques have also been used.

3 The procedure

3.1 The aim of endoscopic radiofrequency ablation for gastro-oesophageal reflux disease is to reduce symptoms. The mechanism of action is unclear.

3.2 The procedure is usually performed with the patient under sedation. The distance to the gastro-oesophageal junction is measured endoscopically and a guidewire with a flexible tip is passed through the endoscope and left in the stomach; the endoscope is removed. A specially designed radiofrequency balloon catheter, consisting of an inflatable balloon-basket with 4 electrode needle sheaths, is inserted through the mouth over the guidewire and advanced to the gastro-oesophageal junction. The balloon is inflated to the diameter of the oesophagus and the electrodes are deployed to penetrate through the mucosa and deliver radiofrequency energy to the musculature of the lower oesophageal sphincter and the gastric cardia. Several cycles of approximately 1 minute of radiofrequency energy are delivered. These cause changes in the tissues of the lower oesophagus, but the precise mechanism of action of radiofrequency energy on the oesophagogastric junction remains a subject of debate (see section 6.1).

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 overview.

4.1 A systematic review of 20 studies including 1,441 patients reported oesophageal acid exposure from 11 studies (364 patients). The mean percentage of time that the pH was less than 4 decreased from 10% at baseline to 7% (p=0.0003) at mean 12-month follow-up. A crossover randomised controlled trial (RCT) of 22 patients comparing endoscopic radiofrequency ablation against sham reported that there were no significant changes in oesophageal acid exposure at 3- or 6-month follow-up. An RCT of 43 patients reported abnormal oesophageal acid exposure in 94% (17 out of 18) of patients treated by radiofrequency ablation and in 75% (9 out of 12) of patients treated with proton pump inhibitors (PPIs) alone at 6-month follow-up (p=0.27).

4.2 A non-randomised comparative study of 126 patients treated by radiofrequency ablation or endoluminal full-thickness plication reported that the percentage of time the pH was less than 4 reduced from 11% at baseline to 9% at mean 5-month follow-up (not significant) and from 10% at baseline to 6% at mean 8-month follow-up (p=0.05), respectively.

4.3 The RCT of 43 patients reported oesophagitis (diagnosed by endoscopy) in 53% (10 out of 19) of patients treated by radiofrequency ablation and 54% (7 out of 13) of patients treated with PPIs alone at 6-month follow-up (p=0.97).

4.4 The systematic review of 20 studies including 1,441 patients reported the mean gastro-oesophageal reflux disease health-related quality of life score in 9 studies (433 patients), which improved from 26.1 at baseline to 9.3 after treatment (p=0.0001, mean follow-up 20 months). In the same review, 6 studies with 299 patients reported that the mean SF-36 (physical) score improved from 36 to 46 points at mean 10-month follow-up (p=0.0001). Five studies (264 patients) reported that the mean SF-36 (mental) score improved from 47 to 55 at mean 10-month follow-up (p=0.0015).

4.5 The systematic review of 20 studies reported a pooled heartburn score from 9 studies (525 patients) of 3.6 at baseline and 1.2 at mean 24-month follow-up ($p=0.0001$; lower scores indicate less severe symptoms). The crossover RCT of 22 patients comparing radiofrequency ablation against sham reported a significant improvement in symptom score at 3 months compared with baseline in the active treatment group (from 14.7 to 8.3; $p<0.005$) but not in the sham group (from 16.1 to 15.6; not significant). When patients in the sham group were subsequently treated by radiofrequency ablation, the symptom score significantly improved to 7.2 ($p<0.05$) at 3-month follow-up. The RCT of 43 patients treated by endoscopic radiofrequency ablation or PPIs alone reported symptoms fewer than 3 times a week in 80% (16 out of 20) and 40% (6 out of 15) of patients respectively at 6-month follow-up ($p=0.01$). At 12-month follow-up, 69% (11 out of 20) of patients in the radiofrequency ablation group had symptoms fewer than 3 times a week compared with 62% (8 out of 14) of patients in the control group ($p=0.71$). There were no statistically significant differences in the individual symptom scores.

4.6 The crossover RCT of 22 patients reported no significant change in medication use from baseline in either group at 6-month follow-up. The RCT of 43 patients reported that 13% (3 out of 23) and 17% (4 out of 23) of patients in the radiofrequency ablation group at 6 and 12 months respectively were able to stop PPIs completely compared with none of the control patients.

4.7 The specialist advisers listed key efficacy outcomes as long-term objective evidence (pH studies), long-term symptomatic control, quality of life and decreasing or stopping PPIs.

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 overview.

5.1 One case series reported 3 deaths and 22 complications overall (not otherwise defined) in patients treated by radiofrequency ablation for gastro-oesophageal reflux disease (number of procedures to which these events relate not known).

5.2 Mucosal bleeding was reported in 3% (3 out of 90) of patients in a case series of 90 patients. Superficial mucosal injury was reported in 2% (2 out of 90) of patients in the same study. All these complications resolved within 1 week of the procedure.

5.3 Prolonged gastroparesis was reported in 1 patient in a case series of 56 patients: this resolved within 8 weeks.

5.4 The specialist advisers stated that oesophageal perforation is an adverse event which, although rare, is generally acknowledged. The specialist advisers advised of a theoretical risk of developing oesophageal cancer which they considered might be a consequence of long-term unrecognised reflux.

6 Committee comments

6.1 The Committee was advised that the mechanism of action of endoscopic radiofrequency ablation for gastro-oesophageal reflux disease is a subject of continuing debate. It noted concern on the part of some specialists about the possibility that symptoms may improve as a result of denervation caused by the procedure; if that were the case then failure to recognise and treat reflux might lead to complications in the long term.

7 Further information

7.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 461 has been migrated to HealthTech guidance 318. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.