

Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg461

This guidance replaces IPG292.

1 Recommendations

This document replaces previous guidance on endoscopic radiofrequency ablation for gastro-oesophageal reflux disease (interventional procedure guidance 292).

- 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 1441 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% (17/18) of patients treated by radiofrequency ablation and in 75% (9/12) 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% (10/19) of patients treated by radiofrequency ablation and 54% (7/13) of patients treated with PPIs alone at 6-month follow-up ($p=0.97$).
- 4.4 The systematic review of 20 studies including 1441 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% (16/20) and 40% (6/15) of patients respectively at 6-month follow-up ($p=0.01$). At 12-month follow-up, 69% (11/20) of patients in the radiofrequency ablation group had symptoms fewer than 3 times a week compared with 62% (8/14) 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% (3/23) and 17% (4/23) 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% (3/90) of patients in a case series of 90 patients. Superficial mucosal injury was reported in 2% (2/90) 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).
- 7.2 For related NICE guidance see the [NICE website](#).

Information for patients

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

About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedures guidance process](#).

It updates and replaces NICE interventional procedure guidance 292.

We have produced a [summary of this guidance for patients and carers](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

Changes after publication

August 2013: Minor maintenance

Your responsibility

This guidance represents the views of NICE and 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.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their 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.

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Endorsing organisation

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

Accreditation

