

Endoscopic radiofrequency ablation for squamous dysplasia of the oesophagus

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg497

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.

1 Recommendations

- 1.1 Current evidence on the efficacy of endoscopic radiofrequency ablation for squamous dysplasia of the oesophagus is inadequate in quality and quantity. With regard to safety, there are well-recognised complications, particularly oesophageal strictures. 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 squamous dysplasia of the oesophagus should take the following actions.
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainties about the procedure's safety and efficacy, inform them about alternative treatment options and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- 1.3 Patient selection for endoscopic radiofrequency ablation for squamous dysplasia of the oesophagus should be done by a multidisciplinary team experienced in the management of oesophageal dysplasia.
- 1.4 Endoscopic radiofrequency ablation for squamous dysplasia of the oesophagus should only be done by endoscopists experienced in treating oesophageal dysplasia.
- 1.5 NICE encourages further research into endoscopic radiofrequency

ablation for squamous dysplasia of the oesophagus, including observational data collection. Studies should clearly define patient selection. Outcomes should include completeness of ablation, resolution of squamous dysplasia, progression to cancer and quality of life. All complications should be reported, particularly development of oesophageal strictures.

- 1.6 Clinicians should enter details about all patients undergoing endoscopic radiofrequency ablation for squamous dysplasia of the oesophagus onto the [UK National HALO patient register](#), and review clinical outcomes locally.

2 Indications and current treatments

- 2.1 Squamous dysplasia of the oesophagus consists of flat premalignant epithelial lesions that may progress to squamous cell carcinoma. The World Health Organization's (WHO) histologic classification of gastrointestinal tumours refers to squamous dysplasia as squamous intra-epithelial neoplasia (defined as non-invasive cytological or architectural alterations that may lead to development of invasive cancer) and categorises it as either low- or high-grade. Low-grade squamous dysplasia is associated with a low risk of progression to invasive squamous cell carcinoma, whereas high-grade intra-epithelial neoplasia carries a higher risk of progression.
- 2.2 Squamous cancer of the oesophagus can be treated by surgery (oesophagectomy) or chemoradiotherapy or a combination of these methods. When the disease is detected at an early pre-invasive stage such as carcinoma in situ or high-grade dysplasia, then endoscopic treatment is possible. Methods include removal by endoscopic mucosal resection or endoscopic submucosal dissection, and ablation using photodynamic therapy, argon plasma coagulation, laser ablation, cryotherapy or multipolar electrocoagulation.

3 The procedure

- 3.1 The aim of endoscopic radiofrequency ablation is to destroy squamous

dysplasia in order to allow re-epithelialisation with normal squamous epithelium.

- 3.2 The procedure is usually carried out with the patient under conscious sedation, in an outpatient setting. The area of squamous dysplasia is visualised using an endoscope. Spraying the oesophageal lining with Lugol's iodine identifies areas of dysplasia that can otherwise be difficult to find. 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 cells 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 squamous dysplasia in any subsequent treatments. Radiofrequency ablation can also be used after doing endoscopic mucosal resection to remove larger, superficial abnormal areas. If follow-up high resolution endoscopy and re-biopsy show residual 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](#).

- 4.1 A case series of 29 patients (18 with moderate-grade squamous intra-epithelial neoplasia, 10 with high-grade squamous intra-epithelial neoplasia and 1 with early squamous cell carcinoma) treated by radiofrequency ablation reported complete response (defined as absence of disease from any biopsy in the treatment area) in 86% (25/29) of patients at 3 months and 97% (28/29) of patients at 12-month follow-up.
- 4.2 A case series of 20 patients (12 with squamous high-grade dysplasia and 8 with early squamous cell carcinoma confined to the mucosa) treated by radiofrequency ablation reported that in 50% (10/20) of patients, there was complete reversal of dysplasia at 12 months after a median of 1 treatment. Of these patients, 80% (8/10) remained free of dysplasia at a

median follow-up of 24 months.

- 4.3 The case series of 20 patients reported that 20% (2/10) of patients had a recurrence after initial successful radiofrequency ablation. In 1 patient this progressed to invasive cancer. The other patient had multifocal low-grade dysplasia and after 4 further radiofrequency ablation procedures still had low-grade dysplasia at 41-month follow-up.
- 4.4 The case series of 29 patients reported that there was no neoplastic progression (defined as detection of early oesophageal cell neoplasia of a more severe histological grade) at 12-month follow-up.
- 4.5 The case series of 20 patients reported that in 30% (6/20) of patients, dysplasia progressed to invasive squamous cell cancer (defined as infiltration into the submucosal layer or beyond) at 1-year follow-up.
- 4.6 The specialist advisers listed key efficacy outcomes as eradication of squamous dysplasia and reduction in development of squamous carcinoma of the oesophagus.

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 In a case series of 13 patients, 1 patient (with a narrowed oesophagus after endoscopic mucosal resection) had an oesophageal perforation and a mediastinal abscess that developed 2 days after dilation for stenosis, done 12 days after radiofrequency ablation. This was managed with a covered stent and percutaneous drainage. After removal of the stent, a further stenosis was observed that was treated by repeated dilatation, corticosteroid injection and incisional therapy.
- 5.2 Oesophageal strictures were reported after circumferential radiofrequency ablation in 20% (4/20) and 14% (4/29) of patients in a case series of 20 patients and a case series of 29 patients respectively. Two strictures (both related to endoscopic mucosal resection) were

reported in 2 patients in the case series of 13 patients. All strictures in all these series resolved after 1 or more endoscopic dilations.

- 5.3 Mucosal laceration after sizing was reported in 1 patient in the case series of 29 patients and in 1 patient in the case series of 20 patients. Mucosal laceration (at the endoscopic resection scar) was reported in 2 patients in the case series of 13 patients. None of these lacerations needed treatment.
- 5.4 Submucosal haematoma (asymptomatic and needing no intervention) was reported in 1 patient in the case series of 13 patients.
- 5.5 The specialist advisers listed additional adverse events as complications of sedation, odynophagia, dysphagia, and chest and back pain.

6 Committee comments

- 6.1 The Committee noted contrasting outcomes in the available studies and was advised about the heterogeneous patient populations included in previous research.
- 6.2 The Committee noted that many patients presenting with squamous dysplasia of the oesophagus are frail and that other treatment options (including oesophagectomy and chemoradiotherapy) may be unsuitable or pose high risks for them.
- 6.3 The Committee noted that the risk of oesophageal strictures after endoscopic radiofrequency ablation is higher for squamous dysplasia than it is for Barrett's oesophagus with low-grade dysplasia or no dysplasia, due to the nature of the underlying pathology.

7 Further information

- 7.1 For related NICE guidance see the [NICE website](#).

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](#).