

Endoscopic submucosal dissection of oesophageal dysplasia and neoplasia

Interventional procedures 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.

1 Guidance

- 1.1 Current evidence on the efficacy of endoscopic submucosal dissection (ESD) in patients with oesophageal adenocarcinoma or high-grade dysplasia in Barrett's oesophagus is limited in quantity and there are safety concerns specifically regarding the risk of oesophageal perforation. Therefore, in these patients, the procedure should only be used in the context of research.
- 1.2 Current evidence on the efficacy of ESD in patients with oesophageal squamous carcinoma or squamous dysplasia is limited. This evidence is mostly from Japan where the epidemiology of oesophageal cancer is different from the UK. There are safety concerns specifically regarding the risk of oesophageal perforation. Therefore, in these patients, the procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.3 Clinicians wishing to undertake ESD for oesophageal squamous carcinoma or squamous dysplasia should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients and their carers 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 ESD for oesophageal squamous carcinoma or squamous dysplasia (see section 3.1).
- 1.4 Patient selection should be carried out by an upper gastrointestinal cancer

multidisciplinary team.

- 1.5 The procedure is technically challenging and should be carried out only by clinicians with specific training in the technique.
- 1.6 NICE encourages further research into the procedure. Studies should define clearly the type, grade and stage of cancer or dysplasia being treated. Efficacy outcomes should include adequacy of resection and the proportion of patients free from local recurrence. Safety outcomes should include perforation and stricture, and the consequences of these complications.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Malignant or premalignant changes in the oesophagus may take the form of either squamous cell carcinoma or adenocarcinoma, or their respective premalignant (dysplastic) forms. In the UK, approximately two thirds of all oesophageal cancers are adenocarcinomas and one third are squamous carcinomas.
- 2.1.2 Depending on the type and stage of cancer or dysplasia, current treatment options include oesophagectomy, chemotherapy, radiotherapy, ablative procedures such as radiofrequency ablation, and endoscopic mucosal resection (EMR). The latter usually removes lesions piecemeal, in contrast to endoscopic submucosal dissection (ESD) which aims to remove lesions intact and with a margin of healthy tissue.

2.2 Outline of the procedure

- 2.2.1 ESD is usually preceded by diagnostic endoscopy, biopsy and imaging. The procedure is done with the patient under sedation or general anaesthesia. Under endoscopic visualisation, the submucosa is injected with saline to help lift the

lesion. This fluid may contain pigment to help delineate the lesion, and adrenaline to reduce bleeding. A circumferential mucosal incision is made with an electrocautery knife around the lesion. Submucosal dissection is then carried out, parallel to the muscle layer, and the lesion is removed. A transparent hood can be used to retract the already dissected part of the lesion out of the visual field. Thermocoagulation is used to achieve haemostasis. Endoscopic clips can be used for larger vessels or to manage perforation.

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 comparative case series of 136 patients treated by ESD or by 1 of 2 different EMR techniques, reported en-bloc resection rates of 100% (31 out of 31) for ESD, and 87% (59 out of 68) and 71% (51 out of 72) for the two EMR procedures ($p < 0.05$). A comparative case series of 77 patients treated by ESD or EMR reported en-bloc resection in 91% (29 out of 32) and 11% (5 out of 46) of lesions respectively. Case series of 84 and 43 patients (including 107 and 58 neoplastic or dysplastic squamous lesions, respectively) reported en-bloc resection of all lesions in both series, and R0 resection (both lateral and basal margins free) in 88% (94 out of 107) and 78% (45 out of 58) of lesions respectively.
- 2.3.2 The comparative case series of 77 patients treated by ESD or EMR reported local recurrence in 4% (1 out of 26) and 25% (11 out of 44) of patients respectively (follow-up and significance not stated).
- 2.3.3 The Specialist Advisers listed key efficacy outcomes as adequacy of cancer treatment (complete resection with clear margins on histology) and survival.

2.4 Safety

- 2.4.1 Perforation during ESD causing pneumomediastinum was reported in 5% (4 out of

84) of patients in the case series of 84 patients and 1 patient in the comparative case series of 136 patients (all successfully treated by antibiotics). Perforation with pneumomediastinum was reported in 7% (4 out of 58) of lesion dissections in the case series of 43 patients: all were successfully treated by endoscopic clipping with the pneumomediastinum resolving spontaneously within a week.

- 2.4.2 Pneumomediastinum was reported in 6% (6 out of 102) of cases in the series of 102, all successfully treated with antibiotics, fasting and intravenous infusion.
- 2.4.3 Oesophageal stricture was reported in 16% (9 out of 58) of lesion dissections in the case series of 43 patients, all successfully treated by balloon dilatation.
- 2.4.4 In case series of 102 cases and 65 patients, oesophageal stenosis requiring balloon dilatation during follow-up was reported in 7% (7 out of 102) of cases (mean follow-up 21 months) and 17% (11 out of 65) of patients (follow-up of up to 47 months) respectively.
- 2.4.5 The Specialist Advisers considered possible adverse events to be aspiration pneumonia, uncontrollable bleeding and the need for emergency oesophagectomy.

2.5 Other comments

- 2.5.1 The Committee considered that ESD could be suitable for a national register.

3 Further information

- 3.1 This guidance requires that clinicians undertaking endoscopic submucosal dissection (ESD) for oesophageal squamous carcinoma or squamous dysplasia make special arrangements for audit. NICE has identified relevant [audit criteria](#) and has developed an [audit tool](#) (which is for use at local discretion).

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.

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Endorsing organisation

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