

Endoscopic submucosal dissection of lower gastrointestinal lesions

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 endoscopic submucosal dissection (ESD) of lower gastrointestinal lesions shows that it is efficacious, but evidence on long-term survival when used to treat malignant lesions is limited in quantity. There are some concerns about safety with regard to the risk of perforation and bleeding. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake ESD of lower gastrointestinal lesions should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy in relation to the risks of perforation and bleeding, and that conversion to open surgery may be necessary. Patients should be provided 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 of lower gastrointestinal lesions (see section 3.1).
- 1.3 ESD of lower gastrointestinal lesions is a technically challenging procedure and should only be carried out by clinicians with specific training in the technique. The Joint Advisory Group on Gastrointestinal Endoscopy intends to prepare training standards on this procedure.
- 1.4 Patient selection should be carried out either by a colorectal surgeon or by both a

colorectal surgeon and an endoscopist who are experienced in this technique.

- 1.5 NICE encourages further research into ESD of lower gastrointestinal lesions. There should be clear documentation of the incidence of complications including perforation, haemorrhage and need for open surgery (with the reasons for this), rates of complete resection, and long-term outcomes including local recurrence and survival.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Colorectal lesions may be benign, premalignant or malignant. Patients may be asymptomatic or may present with blood in the stool, change in bowel habit, abdominal pain or unexplained weight loss.
- 2.1.2 Lower gastrointestinal lesions may be investigated radiologically and/or endoscopically. Treatment normally involves resection of the lesions, which may be performed endoscopically or surgically. Current management of small colorectal lesions usually involves snare polypectomy or endoscopic mucosal resection (EMR). EMR usually removes lesions in small pieces, while endoscopic submucosal dissection (ESD) aims to resect lesions intact.

2.2 Outline of the procedure

- 2.2.1 In ESD, an electrocautery knife is used to resect the lesion in one piece (en bloc), aiming to reduce the risk of recurrence and to allow a more accurate histopathological assessment.
- 2.2.2 The procedure is performed with the patient under sedation (usually) or general anaesthesia. Lesions are visualised at colonoscopy and the submucosa injected with fluid to raise the lesion.

2.2.3 A circumferential mucosal incision is made initially around the lesion with the electrocautery knife. Submucosal dissection is then performed under endoscopic visualisation, parallel to the muscle layer. Diathermy coagulation is used to achieve haemostasis, but endoscopic clips may also be required to control bleeding and/or treat small perforations.

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 systematic review of 14 studies including 1,314 patients reported rates of en bloc lesion resection of 85% and complete cure (en bloc resection with histologically clear margins) of 75% (follow-up not stated).
- 2.3.2 A non-randomised comparative study of 536 lesions (number of patients not stated) reported higher rates of en bloc resection in patients treated by ESD (99%, 463 out of 468) compared with those treated by 'simplified' ESD using a snare (91%, 40 out of 44) and those treated by small incision EMR (83%, 20 out of 24; $p < 0.004$ for both comparisons with ESD).
- 2.3.3 Case series of 400 (405 lesions) and 278 (292 lesions) patients, reported en bloc resection rates of 87% (352 out of 405) and 90% (263 out of 292) of lesions respectively. Case series of 278, 42 and 35 patients reported en bloc resection with completely free margins in 15% (44 out of 292) of lesions, and 74% (31 out of 42) and 63% (22 out of 35) of patients respectively.
- 2.3.4 The case series of 278 patients reported recurrent rectal intramucosal cancer in 3% (1 out of 38) of lesions with incomplete resection that were followed-up for a median of 36 months (cancer was successfully removed).
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as one-piece resection rate, complete resection rate with clear margins, endoscopic cure rate, clinical cure rate and avoidance of bowel resection.

2.4 Safety

- 2.4.1 The non-randomised comparative study of 536 lesions reported perforation in 1% (7 out of 468), 5% (2 out of 44) and 0% (0 out of 24) of patients treated by ESD, 'simplified' ESD using a snare, and small incision EMR respectively (no further details provided). The case series of 400 patients reported colonic wall perforation in 3% (14 out of 405) of patients: all were detected intraprocedurally; all were managed successfully with endoscopic clips insertion; and 1 required surgical repair. In a case series of 186 patients (200 lesions) a perforation rate of 6% (12 out of 200) was reported: 11 of the perforations were detected intraprocedurally and 1 was detected 2 days later (requiring surgical repair).
- 2.4.2 The case series of 186 patients reported rectal bleeding, prompting emergency colonoscopy for application of endoscopic clips in 1% (2 out of 200) of lesions. One bleed occurred on the day of the procedure and the other occurred 10 days later.
- 2.4.3 Acute intestinal obstruction 18 hours after the procedure was reported in a case report of 1 patient (treated by aggressive fluid resuscitation and colonoscopic decompression).
- 2.4.4 The Specialist Advisers considered theoretical adverse events to include conversion of a curable cancer to an incurable cancer because of perforation.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant [audit criteria](#) and developed [audit support](#) (which is for use at local discretion) for this guidance.

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](#).