NICE guidance

Endoscopic submucosal dissection of gastric lesions

Interventional procedures guidance
Published: 27 October 2010

www.nice.org.uk/guidance/ipg360

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 safety and efficacy of endoscopic submucosal dissection (ESD) of gastric lesions shows that it is efficacious in achieving complete resection in a high proportion of cases, but evidence of long-term survival following treatment of malignant lesions is limited in quantity. There are safety concerns regarding the risks 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 gastric lesions should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy in relation to treating malignant lesions; and the risks of perforation, bleeding, and possible conversion to open surgery. 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 gastric lesions (see section 3.1).

1.3 Patient selection should be carried out by an upper gastrointestinal cancer multidisciplinary team.

1.4 This 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 for this procedure.

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

2 The procedure

2.1 Indications and current treatments

2.1.1 Gastric lesions include benign, dysplastic, and malignant tumours. Patients may be asymptomatic or experience loss of appetite and weight, anaemia and abdominal discomfort or pain.

2.1.2 Current treatment options for small gastric lesions are snare polypectomy (for protruding lesions) or endoscopic mucosal resection (EMR; for 'flat' lesions). EMR usually removes lesions piecemeal; in contrast, endoscopic submucosal dissection (ESD) aims to remove lesions intact and with a margin of healthy tissue.

2.2 Outline of the procedure

2.2.1 Endoscopic submucosal dissection aims to remove lesions without the need for open abdominal surgery. It is usually preceded by diagnostic endoscopy, biopsy and imaging investigations.

2.2.2 The procedure is carried out with the patient under sedation or general anaesthesia. Using endoscopic visualisation, the submucosa is injected with saline to help lift the lesion. This fluid may contain a pigment to help define 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, aiming to remove the lesion intact and with a healthy margin of tissue. A transparent hood may be used to retract

the already dissected part of the lesion out of the visual field. Haemostasis is achieved by electrocautery. Endoscopic clips may 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 non-randomised comparative study of 900 malignant lesions (patient numbers not stated) reported significantly greater complete resection rates of 95% (544 out of 572) for ESD versus 64% (210 out of 328) for EMR, and curative (with tumour-free margins) resection rates of 83% (473 out of 572) versus 59% (195 out of 328) respectively; $p<0.05$ for both comparisons.

2.3.2 A non-randomised comparative study of 896 patients (1,020 malignant lesions) reported significantly greater complete en-bloc resection rates for non-ulcerated lesions of 93% (157 out of 169) for ESD compared with 43% (343 out of 790) for EMR, and histologically clear margin resection rates of 93% (157 out of 169) versus 25% (194 out of 790) respectively ($p<0.01$).

2.3.3 A case series of 59 premalignant or malignant lesions (patient numbers not stated) reported en-bloc resection by ESD in 86% (44 out of 51) and free-margin complete resection in 73% (37 out of 51) of lesions.

2.3.4 The non-randomised comparative study of 900 lesions reported no recurrence among ESD-treated lesions and recurrence in 4% (13 out of 328) of EMR-treated lesions ($p<0.05$).

2.3.5 The non-randomised comparative study of 896 patients reported no recurrence in ESD-treated patients at a mean 19.4-month follow-up, and recurrence rates of 3% (10 out of 347) in ESD-treated patients and 4% (21 out of 478) in EMR-treated patients during 83.2-month follow-up.

2.3.6 The case series of 59 lesions reported local recurrence in 5 patients treated by

piecemeal ESD at up to 8-month follow-up.

2.3.7 The Specialist Advisers listed key efficacy outcomes as en-bloc and curative resection rates, recurrence rate and survival.

2.4 Safety

2.4.1 Two non-randomised studies – 1 of 900 lesions and the other of 346 patients – reported perforation in 4% (20 out of 572) and 5% (11 out of 243) of ESD-treated lesions or patients, and 2% (5 out of 328) and 2% (2 out of 103) of EMR-treated lesions or patients respectively (differences reported as not significant). In the study of 346 patients, 3 perforations in ESD-treated patients and 1 in an EMR-treated patient were detected intraprocedurally but the others were recognised post-procedurally (timing not stated). All perforations following ESD were managed non-surgically with a combination of endoscopic clipping, fasting, nasogastric tube drainage and antibiotics.

2.4.2 A non-randomised study of 655 patients (714 lesions) reported that perforations were significantly more frequent in ESD-treated patients than in EMR-treated patients (4% [11 out of 303] versus 1% [5 out of 411] of lesions; $p<0.05$). All patients were managed endoscopically (not otherwise described).

2.4.3 The Specialist Advisers listed bleeding as an anecdotal adverse event and considered the theoretical risk of perforation leading to tumour seeding.

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 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).

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.

ISBN: 978-1-4731-6354-6

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.