NICE guidance

Endoscopic mucosal resection and endoscopic submucosal dissection of non-ampullary duodenal 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 The evidence on efficacy of endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) of non-ampullary duodenal lesions is limited in quantity and there are safety concerns regarding the risks of perforation and bleeding. Therefore, these procedures should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake EMR and ESD of non-ampullary duodenal lesions should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about these procedures' 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 EMR and ESD of non-ampullary duodenal lesions (see section 3.1).

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

1.4 Both EMR and ESD of non-ampullary duodenal lesions are technically challenging procedures and should be carried out only by clinicians with specific training and

expertise in the use of EMR and ESD in other parts of the gastrointestinal tract (where lesions are more common). The Joint Advisory Group on Gastrointestinal Endoscopy intends to prepare training standards on these procedures.

1.5 NICE encourages further research into EMR and ESD of non-ampullary duodenal 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 Duodenal lesions (benign, dysplastic or neoplastic) are rare. Symptoms include nausea and vomiting, loss of appetite and weight, anaemia and abdominal pain. Lesions in people who have inherited polyposis syndromes may be identified through regular surveillance examinations.

2.1.2 Current treatment of malignant lesions may require major surgery (Whipple procedure). Endoscopic treatments such as snare polypectomy and argon plasma coagulation (APC) have been used for smaller lesions.

2.2 Outline of the procedure

2.2.1 Both procedures aim to remove lesions without the need for open abdominal surgery. They are usually preceded by diagnostic endoscopy, biopsy and imaging investigations.

2.2.2 Both endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) are 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 pigment to help define the

lesion, and adrenaline to reduce bleeding. In EMR, lesions are usually removed piecemeal with a snare. In ESD, submucosal dissection is performed with an electrocautery knife, parallel to the muscle layer, aiming to remove the lesion intact and with clear margins. 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 Case series of 27 and 23 patients reported complete resection in 85% (23 out of 27) and 86% (18 out of 21) of EMR-treated patients respectively. A case series of 14 patients reported that all 9 ESD-treated lesions were resected en bloc and 5 of the 6 EMR-treated lesions were resected en bloc.

2.3.2 The case series of 23 patients (21 EMR-treated patients) reported no local recurrences among 8 lesions removed en bloc at a median 13-month follow-up. Among 13 lesions removed piecemeal, 38% (5 out of 13) of lesions had remnant adenoma at a median follow-up of 10 months; all were treated successfully with snare resection and/or APC.

2.3.3 Case series of 13 EMR-treated patients, 4 ESD-treated patients and 3 EMR-treated patients reported no deaths or recurrences at mean follow-up of between 18 and 51.7 months.

2.3.4 The Specialist Advisers listed key efficacy outcomes as complete removal and recurrence rates, recovery period and mortality.

2.4 Safety

2.4.1 Perforation was reported in 2 ESD-treated patients and another 2 ESD-treated patients (successfully managed conservatively) in case series of 14 and 4 patients respectively.

2.4.2 Bleeding was reported in 33% (9 out of 27) of patients in the case series of 27 EMR-treated patients (within a larger series of 92 patients treated with EMR of different gastrointestinal organs). Among the 92 patients, 22 developed bleeding, 73% (16 out of 22) of whom developed it early (within 24 hours of EMR treatment). Among those who bled early, 88% (14 out of 16) were treated with endoscopic clip placement, snare ligation, electrocoagulation and/or injection therapy; 2 of the 6 patients who bled later than 24 hours required endoscopic management. Blood transfusion was required in 14% (3 out of 22) of patients.

2.4.3 Post-procedural bleeding was reported in 2 of 9 ESD-treated patients and 1 of 5 EMR-treated patients in the case series of 14 patients; all were successfully treated using endoscopic clips. The case series of 23 and 13 patients reported that 1 patient in each series developed bleeding after EMR (1 occurred up to 48 hours after EMR); both were successfully treated using endoscopic clips.

2.4.4 The Specialist Advisers considered theoretical adverse events to include delayed haemorrhage, perforation, bleeding and pain. They stated that the risks of perforation and bleeding are higher when these procedures are used in the duodenum than in other parts of the gastrointestinal tract.

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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.