

Endoscopic full thickness removal of non-lifting colonic polyps

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg580

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 The evidence on endoscopic full thickness removal of non-lifting colonic polyps raises some major safety concerns. Current evidence on efficacy is inadequate in quantity and quality. Therefore, this procedure should not be used unless there are special arrangements for clinical governance, consent, and audit or research.
- 1.2 Clinicians wishing to do endoscopic full thickness removal of non-lifting colonic polyps should:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients 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 endoscopic full thickness removal of non-lifting colonic polyps (see section 6.1).
- 1.3 Patient selection should be done by a polyp and early colorectal cancer multidisciplinary team. Only clinicians with specific training should do this procedure.
- 1.4 NICE encourages further research and data collection on endoscopic full thickness removal of non-lifting colonic polyps and may update the guidance on publication of further evidence. This should include safety and efficacy outcomes such as perforation, bleeding, the need for immediate re-intervention, inadequate resection and longer-term follow-up of patients found to have malignant disease.

2 Indications and current treatments

- 2.1 Colonic polyps are mucosal lesions that project into the lumen of the large bowel. Most colonic polyps cause no symptoms, but they may cause rectal bleeding, mucus in stools, abdominal pain and, rarely, diarrhoea or constipation. There is a significant risk that, after several years, polyps may develop into bowel cancer if left untreated.
- 2.2 Benign polyps and those with very early signs of malignancy can often be successfully removed by endoscopic polypectomy, or endoscopic mucosal or submucosal resection. However, polyps that are non-lifting usually involve deeper layers of the bowel wall because of either invasion by malignant cells or scarring from previous attempts at removal. Trying to remove these polyps by standard techniques risks incomplete resection of invasive disease and bowel perforation.

3 The procedure

- 3.1 Full thickness endoscopic bowel excision uses a full thickness resection device. This comprises a modified snare to remove the polyp and deeper layers of the bowel wall, and a clasp device that closes the full thickness of the bowel wall to prevent perforation. The device is attached to the end of a standard endoscope and advanced through the colon until the polyp is identified. The polyp is grasped at its centre and slowly pulled into the cap of the device. An 'over-the-scope' clip is released, closing the site of a potential defect in the bowel wall. A snare is simultaneously placed around the polyp, which is retrieved for histological analysis after the clip is deployed. After removal of the polyp, the colonoscope is re-inserted and the surgical site is examined for signs of haemorrhage and to check that the clip has closed the bowel wall.
- 3.2 The procedure is usually done with the patient under sedation but sometimes general anaesthesia is needed.

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 In a case series of 25 patients treated by endoscopic full thickness removal (EFTR) for colonic polyps, there was technical success in 83% (20/24). In a case series of 17 patients (10 with colonic lesions) treated by EFTR, there was technical success in 90% (9/10).
- 4.2 In the case series of 25 patients, there was complete resection (no microscopic residual tumour) in 75% (18/24). In the same study, residual polyps were present in 16% (4/25) of patients. In the case series of 17 patients, there was complete resection in 100% (9/9) of those with colonic lesions.
- 4.3 In the case series of 25 patients, there was full thickness resection of the lesion in 88% (21/24). In the case series of 17 patients, there was full thickness resection in 100% (9/9) of those with colonic lesions.
- 4.4 In the case series of 25 patients, local recurrence of the lesion at follow-up was reported in 4% (1/25).
- 4.5 The specialist advisers listed the following efficacy outcomes: histological confirmation of complete removal of the lesion, successful full thickness resection, avoidance of surgery, standardised reporting of lesion histology and documented audit of complications.

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 Minor bleeding was reported in 4% (1/25) of patients treated by endoscopic full thickness resection (EFTR) for colonic polyps in a case series of 25 patients. Bleeding was reported in 3% (5/180) of patients treated by EFTR in an unpublished case series of 180 patients with low gastrointestinal tract polyps. Bleeding was reported in 5% (4/87) of patients treated by EFTR whose data was

recorded in an unpublished registry of 87 patients with gastrointestinal polyps.

- 5.2 Bowel perforation was reported in 3% (5/180) of patients in the unpublished case series of 180 patients. Perforation was reported in 6% (5/87) of patients and anastomotic leak needing surgery was reported in 1% (1/87) of patients in the unpublished registry of 87 patients.
- 5.3 In the case series of 25 patients, 8% (2/24) of patients had subsequent surgical resection after the diagnosis of high-risk adenocarcinoma. However, histology of the surgical specimen revealed EFTR had completely removed the tumour in the initial resection. Further surgery after EFTR of lesions in the lower gastrointestinal tract was done in 7% (13/180) of patients in the unpublished case series of 180 patients. The reasons for surgery included the presence of high-risk T1-carcinoma in 5% (9/180) of patients, incomplete resection in less than 1% (1/180), perforation in 1% (2/180)] and appendicitis in less than 1% (1/180).
- 5.4 Postpolypectomy syndrome was reported in 8% (2/25) of patients in the case series of 25 patients. Postpolypectomy syndrome was reported in 2% (4/180) of patients in the unpublished case series of 180 patients.
- 5.5 Infection was reported in 8% (2/25) of patients in the case series of 25 patients. Appendicitis was reported in 1% (2/180) of patients in the unpublished case series of 180 patients.
- 5.6 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: inability to capture the polyp in the snare at resection (necessitating the use of a standard snare). They did not identify any theoretical adverse events that had not previously been reported.

6 Further information

- 6.1 This guidance requires that clinicians doing 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).

6.2 Patient commentary was sought but none was received.

Information for patients

NICE has produced information on this procedure for patients and carers ([information for the public](#)). 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](#).