NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Endoscopic full thickness removal of non-lifting colonic adenomas

Colonic adenomas (polyps) are small growths in the wall of the large bowel. Non-lifting polyps are deep in the wall, so are difficult to remove, and are also more likely to become cancerous if left untreated. In endoscopic full thickness removal, a special device is passed through a colonoscope (a thin, flexible tube with a camera on the end that is inserted through the anus into the large bowel) and used to remove the polyp and seal the bowel wall closed afterwards. The aim is to remove polyps in deeper layers of the bowel without causing bowel damage.

The National Institute for Health and Care Excellence (NICE) is examining endoscopic full thickness removal of non-lifting colonic adenomas and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about endoscopic full thickness removal of non-lifting colonic adenomas.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.
- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 27 February 2017

Target date for publication of guidance: May 2017

1 Draft recommendations

1.1 The evidence on endoscopic full thickness removal of non-lifting colonic adenomas 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 adenomas 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 *[[URL to be added at publication]]* is recommended.
- Audit and review clinical outcomes of all patients having endoscopic full thickness removal of non-lifting colonic adenomas (see section 6.1).

1.3 Patient selection should be done by a polyp and early colorectal cancer multidisciplinary team. The procedure should be done by a clinician with specific training in it.

1.4 NICE encourages further research and data collection on endoscopic full thickness removal of non-lifting colonic adenomas 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 adenomas (polyps) are mucosal lesions that project into the lumen of the large bowel. Most colonic adenomas cause no symptoms, but they may cause rectal bleeding, mucus in stools, abdominal pain and, rarely, diarrhoea or constipation. There is a small risk that, after several years, adenomas may develop into bowel cancer if left untreated.

2.2 Benign adenomas and those with very early signs of malignancy can often be successfully removed by endoscopic polypectomy, or endoscopic mucosal or submucosal resection. However, adenomas that are non-lifting usually involve deeper layers of the bowel wall because of either invasion by malignant cells or scaring from previous attempts at removal. Trying to remove these adenomas 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 adenoma 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 adenoma is identified. The adenoma 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 adenoma, which is retrieved for histological analysis after the clip is deployed. 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 adenomas, 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 adenomas 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 adenomas 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 gastro-intestinal tract adenomas. 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 adenomas.

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 gastro-intestinal tract was done in 7% (13/180) of patients in the unpublished case series of 180 patients. The reasons for surgery included the diagnosis after resection 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 adenoma 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 is developing an audit tool (which is for use at local discretion). This tool will be available when the guidance is published.

6.2 Patient commentary was sought but none was received.

6.3 For related NICE guidance, see the NICE website.

Tom Clutton-Brock
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