NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach

Gastrointestinal stromal tumours are a type of cancer that can develop in the wall of the digestive tract, usually in the stomach or small bowel. In this procedure, an endoscope (a thin, flexible tube with a camera on the end) is inserted through the mouth into the stomach. The tumour is pulled up into the tube using forceps (tongs). A clip is released and a snare is then placed over the tumour. The snare cuts out the tumour and some surrounding tissue (full thickness) and the clip is left in place, to close the hole in the stomach. The aim is to remove the tumour without the need for open surgery.

NICE is looking at endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

Issue date: October 2021

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 18 November 2021

Target date for publication of guidance: February 2022

1 Draft recommendations

1.1 Evidence on the safety and efficacy of endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Further research should ideally be randomised controlled trials or registry studies. It should report patient selection, tumour type, size and anatomical position, and long-term outcomes (such as tumour recurrence).

1.3 Patient selection should be done by a multidisciplinary team.

1.4 This procedure should only be done in specialist centres by interventional upper gastrointestinal endoscopists with specific training in this procedure.

2 The condition, current treatments and procedure

The condition

2.1 Gastrointestinal stromal tumours are a type of soft tissue sarcoma formed from abnormal cells in the tissues of the gastrointestinal tract. Gastrointestinal stromal tumours are most common in the stomach and small intestine but they can develop anywhere along the length of the gastrointestinal tract.

2.2 The grade of gastrointestinal stromal tumour is based on the mitotic rate. There are 2 grades: G1 (low grade – the cancer cells have a low mitotic rate, they are growing slowly and less likely to spread)

and G2 (high grade – the cancer cells have a high mitotic rate, they are growing faster and more likely to spread).

Current treatments

2.3 The choice of treatment for gastrointestinal stromal tumours depends on several factors, including the location, size and mitotic rate of the tumour, whether the tumour is metastatic, recurrent or refractory, and the patient's overall health. The standard treatments include surgery (open, laparoscopic, robotic or endoscopic surgery), targeted therapy using drugs or other substances, watchful waiting and supportive care.

The procedure

2.4 This procedure uses a full thickness resection device, which allow endoscopic full thickness resection with a single-step clip-and-cut technique. For example, one device comprises a modified snare to remove the tumour and deeper layers of the stomach wall, and a clasp device that closes the full thickness of the stomach wall.

2.5 The device is attached to the end of an endoscope and advanced through the mouth and the oesophagus to the stomach. Gradual dilation may be needed to help the device pass through the upper and lower oesophageal sphincters. The tumour is grasped at its centre and slowly pulled into the cap of the device completely. A clip is released, closing the site of a potential defect in the stomach wall. A snare simultaneously encloses the tumour and cuts it away, then it is retrieved for histological analysis.

2.6 After the tumour is removed, the endoscope is re-inserted and the surgical site is examined for signs of haemorrhage and to check that the clip has closed the stomach wall. The procedure is usually done with the patient under sedation, but sometimes general anaesthesia is needed.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 3 sources, which was discussed by the committee. The evidence included 1 case series and 2 case reports. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be complete resection of the tumour and less need for further procedures.

3.3 The professional experts and the committee considered the key safety outcomes to be bleeding, perforation and incomplete resection.

3.4 One patient organisation submission was received and discussed by the committee. Patient commentary was sought but none was received.

Committee comments

3.5 The committee was informed that this procedure is used for tumours that are under 15 mm in size.

3.6 This procedure is used for curative resection of gastrointestinal stromal tumours and for diagnosis.

3.7 This procedure is used for conditions other than gastrointestinal stromal tumours.

NICE interventional procedures consultation document, October 2021

Tom Clutton-Brock

Chair, interventional procedures advisory committee

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