



Endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach

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www.nice.org.uk/guidance/ipg717

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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 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.

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

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 person'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

- This procedure uses a full thickness resection device, which allows endoscopic resection with a single step, clip and cut technique. For example, 1 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.
- 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 reinserted 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.
- The professional experts and the committee considered the key efficacy outcomes to be complete resection of the tumour and less need for further procedures.
- The professional experts and the committee considered the key safety outcomes to be bleeding, perforation and incomplete resection.
- One patient organisation submission was received and discussed by the committee. Patient commentary was sought but none was received.

Committee comments

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

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.