

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of 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 placed over the tumour. The tumour and some surrounding tissue (full thickness) is cut out, 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.

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Abbreviations

Word or phrase	Abbreviation
Endoscopic full-thickness resection	EFTR
Esophagogastroduodenoscopy	EGD
Endoscopic mucosal resection	EMR
Endoscopic submucosal dissection	ESD
Endoscopic ultrasound	EUS
Gastrointestinal stromal tumour	GIST
Gastroduodenal full thickness resection device	FTRD
Over-the-scope clip	OTSC

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in March 2021 and updated in October 2021.

Procedure name

- Endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach.

Professional societies

- The Association of Endoscopic Surgeons of Great Britain and Ireland
- The Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland

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- The British Society of Gastroenterology.
- The Royal College of Surgeons.

Description of the procedure

Indications and current treatment

GISTs are a type of soft tissue sarcoma formed from abnormal cells in the tissues of the gastrointestinal tract. GISTs are most common in the stomach and small intestine but they can develop anywhere along the length of the gastrointestinal tract. The grade of GIST 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).

The choice of treatment for GISTs 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.

What the procedure involves

This procedure uses a FTRD, which allows EFTR 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. 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. 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.

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Efficacy summary

Technical success

In a case series of 29 patients with gastric subepithelial tumours (GIST, n=6; ectopic pancreas, n=10; lipoma, n=4; neuroendocrine tumour, n=3; leiomyoma, n=2; inflammatory fibroid polyp, n=2; myofibroblastic polyp, n=1; granulation tissue, n=1), technical success (macroscopically complete en bloc resection) was reported in 90% (26/29) of patients (Meier 2019). Of the 26 patients whose tumours were macroscopically completely resected, it was unclear how many patients had GISTs.

Histological margin of resection

In the case series of 29 patients with gastric subepithelial tumours, for the 6 patients with GISTs (less than 20 mm, mitotic index $\leq 5/50$ hpf [5 mitoses per 50 high-power fields]), R0 resection (histologically complete resection with negative lateral and deep resection margins) was reported in 3 GISTs, R1 (histologically incomplete resection with microscopic residual pathology at resection margins) in 3 GISTs and full-thickness resection (visibility of all layers of the gastric wall including serosa within the resection specimen) in 5 GISTs (Meier 2019).

In a case report of a patient with a GIST (0.8 x 0.8 cm and arising from the intersection of submucosal layer and muscularis layer without adjacent lymphadenopathy), histopathology showed fibrotic nodule with R0 resection, with the absence of muscularis propria (Fahmawi 2020).

In a case report of a patient with a GIST (15 mm), histopathology showed a low-grade G1 GIST (mitotic rate $1/5 \text{ mm}^2$) with negative lateral but positive deep resection margins (Perbtani 2020).

Recurrence

In the case series of 29 patients, no evidence of a residual or a recurrent lesion was found macroscopically in 23 patients (6 patients were lost to follow up, including 2 patients with GISTs) during a follow up of 3 months (Meier 2019). Additional biopsies from the resection site (26% [6/23]) showed no signs of a residual or a recurrent lesion.

In the single case report, no recurrence was described at 3 months postresection (Fahmawi 2020).

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Surgical intervention

In the case series of 29 patients, 1 of the 6 patients with GISTs had wedge resection at 8 weeks after R1 resection (12 mm, mitotic index 5/50 hpf; Meier 2019).

Safety summary

Minor periprocedural (oozing) bleedings on the resection site directly after resection were reported in 9 patients in the case series of 29 patients (Meier 2019). All events were not relevant to haemoglobin level or circulation parameters, and managed by immediate endoscopic intervention (coagulation or clip application). Of the 9 patients, it was unclear how many patients had GISTs.

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts 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 happened). For this procedure, professional experts listed the following anecdotal and theoretical adverse event: perforation with intra-abdominal sepsis.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach. The following databases were searched, covering the period from their start to 6 October 2021: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the [literature search strategy](#)). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The [inclusion criteria](#) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	<p>Clinical studies were included. Emphasis was placed on identifying good quality studies.</p> <p>Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study.</p> <p>Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.</p>
Patient	Patients with GISTs of the stomach.
Intervention/test	EFTR with FTRD
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 31 patients (of these, 8 patients had GISTs) from 1 case series (Meier 2019) and 2 case reports (Fahmawi 2020; Perbtani 2020).

Other studies that were considered to be relevant to the procedure but were not included in the main [summary of the key evidence](#) are listed in the [appendix](#).

Summary of key evidence on endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach

Study 1 Meier B (2019)

Study details

Study type	Case series (RESET)
Country	Germany (3 centres)
Recruitment period	2017 to 2018
Study population and number	n=29 (GIST, n=6; ectopic pancreas, n=10; lipoma, n=4; neuroendocrine tumour, n=3; leiomyoma, n=2; inflammatory fibroid polyp, n=2; myofibroblastic polyp, n=1; granulation tissue, n=1) Patients with gastric subepithelial tumours
Age and sex	Median 58 years (range 34 to 91); 58.6% (17/29) female; tumour size, median 11 mm (range 5 to 15)
Patient selection criteria	Inclusion criteria: patients with gastric subepithelial tumours and maximum tumour size of 15 mm (measured with EUS). Exclusion criteria: gastric subepithelial tumours more than 15 mm or with large extramural growth, signs of dissemination in EUS, criteria of lipoma in EUS, relevant oesophageal stenosis or diverticulum, pregnancy/nursing period, patients younger than 18 years, patients unable to sign informed consent.
Technique	Under deep sedation, EFTR was done and gastric FTRD (Ovesco Endoscopy AG, Tübingen, Germany) used.
Follow-up	3 months
Conflict of interest/source of funding	AM: a consultant for Ovesco Endoscopy. KC and AS: received lecture fees from Ovesco Endoscopy for FTRD training courses. Other authors: no conflicts of interest or financial ties to disclose.

Analysis

Follow-up issues: Patients were scheduled for endoscopic follow-up 3 months after the procedure and 6 patients were lost to follow up (2 patients could not be contacted anymore, 3 patients actively refused follow up and 1 patient died because of pulmonary embolisation). Of these 6 patients, 2 patients had GISTs.

Study design issues: This prospective, investigator-initiated, observational trial (NCT03096236) evaluated feasibility, efficacy and safety of clip-assisted EFTR for gastric subepithelial tumours using gastric FTRD in a prospective multicentre setting.

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Primary endpoint was technical success defined as complete macroscopic en bloc resection (judged by the endoscopist). Secondary endpoints were histologically complete R0 resection (tumour-free lateral and deep resection margins), histologically confirmed full-thickness resection (visibility of all layers of the gastric wall including serosa within the resection specimen), procedure-associated adverse events, procedure time and evidence of residual/recurrent lesion after 3 months.

All resections were performed by the same endoscopist at each centre. All endoscopists were highly experienced in EGD, EMR/ESD, OTSC-placement and EFTR with the FTRD.

Study population issues: Lesions were located in antrum (n=15), corpus (n=13) and fundus (n=1). The balloon was used in 24% (7/29) of patients to facilitate passage with gastric FTRD.

Key efficacy findings

Number of patients analysed: 29

Procedural data and histology

Target lesion reach with gastric FTRD	100% (n=29)
Balloon used	24% (n=7)
Procedural time (minutes), median/SD	30/14.4 (range 24 to 90)
Technical success	89.7% (n=26)
R0 resection	76% (n=22 [benign n=15; malignancy, n=7])
Full-thickness-resection	65.5% (n=19)

Risk stratification and resection status of GIST

Tumour size (mm)	Histology prior EFTR	Histology after EFTR	R0/FTR
8	GIST, Ki-67: 4%, mitotic index ? (unknown)	GIST, KI-67: 6%, mitotic index: 5/50 hpf	No/yes
13	Gastritis, submucosa not reached	GIST, KI-67: 3%, mitotic index: 0/50 hpf	Yes/yes
14	Not available	GIST, mitotic index: 3/50 hpf	Yes/yes
15	Not available	GIST, mitotic index: 2/50 hpf	Yes/yes
9	Gastritis, submucosa not reached	GIST, KI-67: 3%, mitotic index: 0/50 hpf	No/no
12	Gastritis, submucosa not reached	GIST, mitotic index: 5/50 hpf	No/yes

One patient (male, 44 years old, no comorbidities) had wedge resection at 8 weeks after R1 resection of a GIST (12 mm, mitotic index 5/50 hpf).

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Endoscopic 3-month follow up

3-month follow up	79.3% (n=23)
OTSC detached	78.3% (n=18)
OTSC in situ	21.7% (n=5)
Clip removed	40% (n=2)
Clip not removed	60% (n=3)
Signs of recurrency	0
Biopsy of resection site	26% (n=6)

Key safety findings

Procedure-related adverse events: 31% (n=9), all minor periprocedural bleedings on the resection site directly after resection and managed endoscopically with coagulation (78%) or application of hemoclips (22%). All patients were controlled endoscopically on the next day. No further bleeding was observed.

Study 2 Fahmawi Y (2020)

Study details

Study type	Case report
Country	US
Recruitment period	Not reported
Study population and number	n=1 Patient with GIST in the gastric body
Age and sex	49 years; female
Patient selection criteria	Not reported
Technique	Under general anaesthesia, EFTR was done and colonic FTRD (Ovesco Endoscopy AG, Tübingen, Germany) used.
Follow-up	3 months
Conflict of interest/source of funding	None

Analysis

Study design issues: This case report presented a novel technique for upper oesophagus dilation to facilitate a safe oral insertion of the colonic FTRD system for 1-step procedure EFTR.

Study population issues: The patient had a medical history of gastroesophageal reflux disease and obesity, and was referred to the study site for resection of suspected GIST. On EUS, the mass was hypoechoic measuring 0.8 x 0.8 cm and arising from the intersection of submucosal layer and muscularis layer without adjacent lymphadenopathy.

Key efficacy findings

Number of patients analysed: 1

Procedure time: 60 minutes

Histopathology: fibrotic nodule with complete resection (R0), with the absence of muscularis propria.

Endoscopy at 3 months after the procedure: no recurrence

Key safety findings

No intraprocedural, early or delayed complication.

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Study 3 Perbtani Y (2020)

Study details

Study type	Case report
Country	US
Recruitment period	Not reported
Study population and number	n=1 Patient with GIST in the fundus of the stomach
Age and sex	60 years; male
Patient selection criteria	Not reported
Technique	Under general anaesthesia, EFTR was done and FTRD used.
Follow-up	Not reported
Conflict of interest/source of funding	PVD: a consultant for Olympus, Lumendi, Boston Scientific, Cook Medical and Microtech. DY: a consultant for Steris, Boston Scientific, and Lumendi. All other authors disclosed no financial relationships.

Analysis

Study design issues: This case report presented the use of a FTRD device for the removal of a GIST in the stomach.

Study population issues: The patient who had EGD for gastroesophageal reflux symptoms was incidentally noted to have a 15 mm subepithelial lesion in the fundus of the stomach. EUS showed a hypoechoic lesion within the submucosa (layer 3). EUS-guided fine-needle biopsy results confirmed the subepithelial lesion to be a GIST.

Key efficacy findings

Number of patients analysed: 1

Histopathology: a low-grade G1 GIST (mitotic rate 1/5 mm²) with negative lateral but positive deep resection margins.

Key safety findings

Not reported.

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Validity and generalisability of the studies

- Studies were conducted in Germany (n=1) and US (n=2); there were no UK data.
- Of the included studies, 2 studies reported a follow up of 3 months and 1 did not report.
- A total of 31 patients were included, and of these, 8 patients had GISTs in the stomach.
- Two devices (gastric FTRD and colonic FTRD) were used and the colonic FTRD was off-label use for EFTR of GISTs in the stomach.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Endoscopic full thickness removal of non lifting colonic adenoma. NICE interventional procedures guidance 580 (2017). Available from www.nice.org.uk/guidance/IPG580
- Endoscopic submucosal dissection of gastric lesions. NICE interventional procedures guidance 360 (2010). Available from www.nice.org.uk/guidance/IPG360
- Endoscopic mucosal resection and endoscopic submucosal dissection of non-ampullary duodenal lesions (2010) NICE Interventional procedures guidance IPG359. Available from <https://www.nice.org.uk/guidance/ipg359>
- Endoscopic submucosal dissection of lower gastrointestinal lesions. NICE interventional procedures guidance 335 (2010). Available from www.nice.org.uk/guidance/IPG335
- Laparoscopic gastrectomy for cancer. NICE interventional procedures guidance 269 (2008). Available from www.nice.org.uk/guidance/IPG269
- Laparo-endogastric surgery. NICE interventional procedures guidance 25 (2003). Available from www.nice.org.uk/guidance/IPG25

NICE guidelines

- Dyspepsia: Managing dyspepsia in adults in primary care. NICE clinical guideline 17 (2004). Available from www.nice.org.uk/guidance/CG17
- Oesophago-gastric cancer: assessment and management in adults. NICE guideline NG83 (2018). Available from <https://www.nice.org.uk/guidance/ng83>

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. One professional expert questionnaire for endoscopic full thickness removal of

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gastrointestinal stromal tumours of the stomach was submitted and can be found on the [NICE website](#).

Patient organisation opinions

Patient organisation submissions for endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach were received and can be found on the [NICE website](#).

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Company engagement

A structured information request was sent to 1 company who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

The American Society for Gastrointestinal Endoscopy (ASGE) guideline (2015) on the role of endoscopy in the management of premalignant and malignant conditions of the stomach suggests resecting GISTs that are symptomatic or larger than 2 cm.

References

1. Meier B, Schmidt A, Glaser N et al. (2020) Endoscopic full-thickness resection of gastric subepithelial tumors with the gFTRD-system: a prospective pilot study (RESET trial). *Surgical endoscopy* 34(2): 853-60
2. Fahmawi Y, Krutika P, Kumar M et al. (2020) Overcoming the challenge of full-thickness resection of gastric lesions using a colonic full-thickness resection device. *ACG Case Reports Journal* 7(3): e00329
3. Perbtani Y, Gupte A, Draganov PV et al. (2020) Endoscopic full-thickness resection of a stomach gastrointestinal stromal tumor using a dedicated full-thickness resection device. *VideoGIE* 5(10): 470-2

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	06/10/2021	Issue 10 of 12, October 2021
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	06/10/2021	Issue 10 of 12, October 2021
International HTA database (INAHTA)	06/10/2021	-
MEDLINE (Ovid)	06/10/2021	1946 to October 05, 2021
MEDLINE In-Process (Ovid)	06/10/2021	1946 to October 05, 2021
MEDLINE Epubs ahead of print (Ovid)	06/10/2021	October 05, 2021
EMBASE (Ovid)	06/10/2021	1974 to 2021 October 05
EMBASE Conference (Ovid)	06/10/2021	1974 to 2021 October 05

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

Literature search strategy

Number	Search term
1	Stomach neoplasms/

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2	((gastric or stomach) adj4 (tumor* or tumour* or neoplas* or sarcoma* or cancer* or lesion* or carcinoma* or adenocarcinoma* or adenoma* or polyp* or growth* or mass*)).tw.
3	Gastric Mucosa/
4	((cardiac or gastric or pyloric) adj4 (mucosa* or gland*)).tw.
5	or/1-4
6	Gastrointestinal Stromal Tumors/
7	((Gastrointestinal or gastro-intestinal or GI or gastric) adj4 (stromal or submuco* or sub-muco* or subepithelial or sub-epithelial) adj4 (tumor* or tumour* or neoplas* or cancer* or lesion* or sarcoma*)).tw.
8	GIST*.tw.
9	or/6-8
10	Endoscopes, Gastrointestinal/ or Endoscopy, Gastrointestinal/
11	((endoscop* or endo) adj2 (full thick* or full-thick* or total wall or total-wall or deep wall or deep-wall) adj2 (remov* or resect* or excis* or surger* or procedure* or treat* or therap* or device* or probe)).tw.
12	((endoscop* or endo) adj2 (mucos* or mucus or submucos* or sub-mucos*) adj2 (remov* or resect* or excis* or surger* or procedure* or treat* or therap* or device* or probe)).tw.
13	(full* adj2 thick* adj2 (resect* or excis* or remov* or device* or probe)).tw.
14	(gFTRD or FTRD).tw.
15	(EFR or EFTR).tw.
16	OTSC.tw.
17	(over-the-scope or (over adj2 scope*)).tw.
18	((endoscop* or endo) adj4 clip*).tw.
19	or/10-18
20	5 and 9
21	19 and 20
22	animals/ not humans/

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23	21 not 22
24	limit 23 to english language

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the [summary of the key evidence](#). It is by no means an exhaustive list of potentially relevant studies.

Additional papers identified

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence section
Bauder M, Schmidt A and Caca K (2016) Non-exposure, device-assisted endoscopic full-thickness resection. <i>Gastrointestinal endoscopy clinics of North America</i> 26(2): 297-312	Review	Advancing the FTRD through the GI tract is more difficult compared with a standard colonoscope because of the rigid cap (outer diameter 21 mm) and the transparent sheath covering the whole length of the colonoscope. Further technical modifications (such as smaller cap size, more flexibility) could facilitate usage of the FTRD use in the upper GI tract.	Review article
Bisogni D, Manetti R, Talamucci L et al. (2019) Efficacy and safety of full-thickness resection device based on over-the-scope clip system for resecting of gastric lesions in selected patients. Case series from a referral centre for gastrointestinal diseases treatment	Case series n=3 (neuroendocrine tumour, n=1; recurrent adenocarcinoma, n=1; pre-pyloric lesion, n=1)	In this case series the R0-resection rate was 100% and at the current follow-up controls, no recurrence has been described. Unfortunately, the technical success rate is partially decreased due to the third case, in which a pyloric obstruction occurred.	It was unclear whether the patient with neuroendocrine tumour also had GIST.

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and literature overview. G Chir 40(6): 569-77			
Hajifathalian K, Ichkhanian Y, Dawod Q et al. (2020) Full-thickness resection device (FTRD) for treatment of upper gastrointestinal tract lesions: the first international experience. Endoscopy International Open 08: E1291-301	Case series n=56 (mesenchymal neoplasms including GIST, n=26; full-thickness biopsy, n=10; adenocarcinoma, n=5; NET, n=9; adenoma, n=6) FTRD located in oesophagus (n=1), cardia/fundus (n=11), stomach body (n=15), antrum (n=21) and duodenum (n=8)	The results suggest a high technical success rate and an acceptable histologically complete resection rate, with a low risk of AEs and early recurrence for FTRD resection of upper GI tract lesions.	Data on GISTs of the stomach were not reported separately.
Mori H, Kobara H, Nishiyama N et al. (2018) Current status and future perspectives of endoscopic full-thickness resection. Digestive endoscopy: official journal of the Japan Gastroenterological Endoscopy Society 30suppl1: 25-31	Review	Although the EFTR procedure is still developing and requires refinement, from a viewpoint of invasiveness, it is an excellent procedure compared to surgery of lesions in the digestive tract. Development of reliable closure devices and establishment of appropriate indications make EFTR more practical, and it would contribute to reduction of financial, physical and psychological burdens of patients with lesions involving the digestive tract wall.	Review article
Valli PV, Mertens J and Bauerfeind P (2018) Safe and	Case series n=60 (GIST, n=1)	After specific training, EFTR is a feasible, safe, and promising	It was unclear whether GIST was located in

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<p>successful resection of difficult GI lesions using a novel single-step full-thickness resection device (FTRD). Surgical Endoscopy 32(1): 289-299</p>		<p>all-in-one endoscopic resection technique. Data show that EFTR allows complete resection of lesions affecting layers of the gut wall beneath the mucosa with a low risk of adverse events. However, the preliminary results need to be confirmed in larger, controlled studies.</p>	<p>the stomach and data on GIST were not reported separately.</p>
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