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Usefulness of the thread-traction method in endoscopic full-thickness resection for gastric submucosal tumor: a comparative study

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Abstract

Background Endoscopic full-thickness resection (EFTR) has shown great prospects in treating gastric submucosal tumors (SMTs) from the muscularis propria. However, it is very difficult sometimes to ideally expose the tumor and gain adequate visualization for the dissection site. In the present study, we applied the thread-traction (TT) method to assist EFTR in treating gastric SMTs and investigated the feasibility and effectiveness of this strategy.

Methods A total of 28 patients were involved in the study. 13 patients were treated by TT-assisted EFTR (TT group) and the others by non-assisted EFTR (NA group). Data on clinical characteristics and therapeutic outcomes were collected for analysis.

Results The average tumor size was 1.6 ± 0.4 cm. En bloc resection rate was 92.9%. Histopathological evaluation indicated that 22 tumors were gastrointestinal stromal tumors (78.6%), all at low- or very low-risk, and 6 tumors were leiomyomas (21.4%). The total complication rate was 32.1%. All complications were managed intra-operatively or conservatively. Both the total procedure time and the perforation time were significantly shorter in patients of TT group than those of NA group (71.9 ± 30.5 vs. 107.5 ± 35.8 min, $P = 0.010$; 38.3 ± 22.0 vs. 68.6 ± 24.2 min, $P = 0.002$). The pain score evaluated by visual analogue system after operation was significantly lower in patients of TT group than those of NA group (4.5 ± 1.1 vs. 5.8 ± 1.4, $P = 0.014$). Although complication rate was lower in patients of TT group than those of NA group, the difference was not statistically significant (15.4% vs. 46.7%, $P = 0.114$). No residual or recurrent tumors were observed during a mean follow-up period of 17.9 ± 4.4 months.

Conclusions The TT method could effectively assist EFTR to shorten operation time and decrease the risk of complications.

Keywords Thread-traction · Endoscopic full-thickness resection · Submucosal tumor · Muscularis propria

Endoscopic full-thickness resection (EFTR) is a novel method that allows en bloc resection of gastric submucosal tumors (SMTs) originating from the muscularis propria (MP) [1]. Unlike endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD), which are currently the most applied methods in treating SMTs from superficial layers of the gastric wall and conserve the integrity of the MP layer, EFTR resects the tumor with the full-thickness of gastric wall and creates an iatrogenic perforation. The developments of endoscopic suturing strategies in recent years have made the closure of perforations not a worrisome problem [2–4]. EFTR has been demonstrated to be an effective and prospective minimally invasive treatment for patients with gastric SMTs [5].

However, the operation of EFTR is challenging and requires a high level of endoscopic skills and experiences. It is very difficult on some occasions to ideally expose the tumor and gain adequate visualization for the dissection site, especially when the tumor originates from the deep MP layer and has a tight adhesion with the serosa. Poor visualization may also add difficulties to sufficient preventive hemostasis.

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These make EFTR very time-consuming and increase the risk of complications. Another disadvantage of EFTR is the possibility that tumors presenting an extra-luminal growth pattern may fall into the peritoneal cavity during resection. Although several methods have been reported to ameliorate EFTR [5–8], they are more invasive or require specialized equipments which are limited regarding reproducibility and widespread applicability.

In the present study, we introduced an easily performed thread-traction (TT) method to assist EFTR and preliminarily evaluated the feasibility and effectiveness of this method in comparison with non-assisted EFTR in the treatment of gastric SMTs.

Materials and methods

Patients

This was a single-center, retrospective, cohort study. The study was approved by the Biomedical Ethics Committee of Changhai Hospital affiliated to Second Military Medical University (Shanghai, China) and informed written consents were obtained from all patients. Between July 2016 and Feb 2018, a total of 13 patients with gastric SMTs were treated by TT-assisted EFTR (TT group). Another 15 patients treated by non-assisted EFTR (NA group) were included as controls. Common gastroscopy, endoscopic ultrasonography (EUS), and contrast-enhanced computed tomography (CT) were conducted preoperatively to evaluate the tumor and exclude high-risk features of malignancy that were not amenable to endoscopic treatment [9].

Endoscopic procedure

All patients underwent EFTR under general anesthesia with intubation and under carbon dioxide insufflations. All EFTRs were performed by a single skilled endoscopist (FL) whose experiences included more than 800 ESDs for lesions of the upper and lower digestive tract. The EFTR procedure was regularly performed with a single-channel endoscope (GIF-Q260J; Olympus Optical, Tokyo, Japan) with a transparent cap attached. After identification of the lesions under white light, a sterilized solution of normal saline premixed with 1% indigo carmine and 1:10,000 epinephrine was injected into the submucosal layer on the lesion edge with an injection needle (NM-4L-1; Olympus) or the water-jet Hybrid knife (Erbe Elektromedizin Gmbh, Tübingen, Germany) without marking of the margin. The IT-2 knife (KD-611L; Olympus) and Hybrid knife were used either independently or in combination for the resection. The operation procedures were performed as follows: (1) circumferential incision around the tumor; (2) submucosal excavation as deep as the muscular layer around the tumor body; (3) when we suffered difficulties in the exposure of the dissection site between the tumor and the seromuscular layer, attempts by non-assisted EFTR were allowed for no longer than 5 min, or the thread-traction method would be conducted. The endoscope was withdrawn and a rotatable hemoclip with repeatable opening-closing function (ROCC-26-195; Micro-tech, Nanjing, China) was inserted through the endoscope accessory channel. A silk thread of approximately 1.5 m in length was tied to either claw of the hemoclip (Fig. 1). After subsequently re-insertion of the endoscope into the stomach, the hemoclip was anchored on the proximal edge of the resected mucosa so that the seromuscular layer under the tumor could be clearly visualized when traction was applied to the thread; (4) after the intra-luminal side of the tumor was fully revealed, an iatrogenic gastric perforation was created in the proximal seromuscular layer of the tumor with an Hybride knife; (5) a full-thickness incision around four-fifth of the circumference of the tumor was made by using an IT-2 knife; (6) removal of the tumor including the surrounding MP layer and serosa by using a snare; and (7) closure of gastric wall defects by the "purse-string suture" method. Porcine fibrin glue (YueLingJiao®; PuJi Medical Tech, Hangzhou, China) was sprayed onto the wound surface to prevent delayed bleeding, as we previously described [10]. A nasogastric tube was indwelled into the stomach at about 45–55 cm and confirmed in position by endoscopy. Continuous suction was applied for drainage of the gastric juice, maintenance of depressed tension of gastric wall and monitoring of possible hemorrhage. Figure 2 shows the procedure of a typical case of the TT method. All specimens were fixed by formalin for histopathological evaluation.

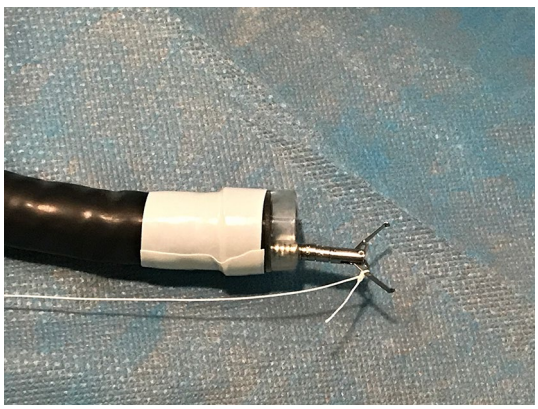

Fig. 1 Preparation of the thread-traction equipment. After insertion of a rotatable hemoclip with repeatable opening-closing function through the endoscope accessory channel, a silk thread was tied to either claw of the hemoclip

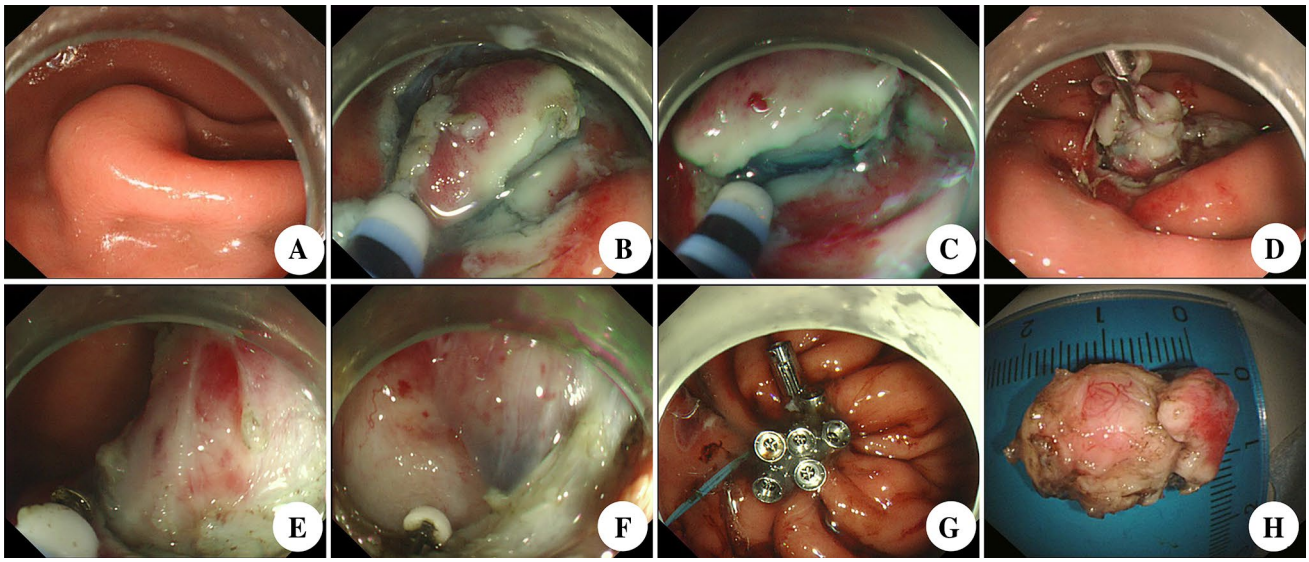

Fig. 2 Procedures of EFTR assisted by the thread-traction method. **A** Identifying the tumor; **B** circumferential incision around the tumor; **C** it is difficult to expose the dissection site; **D** a hemoclip with silk thread was anchored on the proximal edge of the resected mucosa; **E** the dissection became easy; **F** incision of the gastric wall and removal of intact tumor; **G** closure of gastric defects; **H** the resected specimens

Post-EFTR management

All patients were kept fasted and given intravenous fluids for at least 48 h after the procedure. The nasogastric tube was removed after 48 h if there were no signs of bleeding or perforation, and clear fluids and subsequent soft diets were introduced gradually. Proton pump inhibitors and preventive antibiotics were given intravenously for the first 48 h. Patients' abdominal pain was evaluated using the visual analogue system (VAS) ranged from 0 (no pain) to 10 (severe pain) after operation and daily thereafter. If the VAS score was above five and symptoms such as abdominal distension or signs of peritonitis developed, a thoracoabdominal CT would be performed to rule out perforation and the raceanisodamine hydrochloride or meperidine hydrochloride would be injected to relieve the pain afterwards. Endoscopy examination would be repeated in cases of hematemesis or melena and endoscopic hemostasis would be carried out if necessary. Oral proton pump inhibitors were prescribed routinely for 1 month after discharge.

Definitions

The total procedure time was measured as the time between injecting to submucosal and the last withdraw of the endoscope. The perforation time was defined as the time between the first observation of the perforation and complete closure of gastric wall defects. En bloc resection was defined as an intact excision of the tumor in one piece without fragmentation. Intra-operative bleeding was defined as oozing or pulsating bleeding, necessitating the use of hemostatic forceps during the procedure. Delayed bleeding was defined as one of the following: haematemesis, melena, signs of fresh blood from the nasogastric tube, and decrease in hemoglobin level > 2 g/dL after operation.

Follow-ups

Repeated surveillance endoscopy was requested for all patients in the 3rd, 6th, and 12th month postoperatively and annually thereafter, to observe wound healing or detect any residual or recurrent lesion.

Statistical analysis

The statistical analyses were performed using SPSS 17.0 software (SPSS Inc., Chicago, IL, USA). Data were expressed as mean ± standard deviation or as percentage. Statistical significance was calculated by Student's t-test. Comparison of categorical data was performed using Fisher's exact test. A two-sided $P \leq 0.05$ was considered statistically significant.

Results

Clinical characteristics and therapeutic outcomes

The study population consisted of eight males (28.6%) and 20 females (71.4%), with a mean age of 57.8 ± 7.7 years

(range 39–72 years). The average tumor size was 1.6 ± 0.4 cm (range 1.0–2.5 cm). All tumors originated from the MP layer. 19 tumors (67.9%) were located in the fundus and 9 (32.1%) in the corpus of the gastric. 16 tumors (57.1%) presented partly extra-luminal growth pattern, while 12 tumors (42.9%) showed predominantly intra-luminal growth pattern. All EFTR procedures were completed successfully with an average total procedure time of 91.0 ± 37.5 min and perforation time of 54.5 ± 27.5 min. The average postoperative hospital stay was 4.8 ± 1.2 days. All specimens achieved trans-oral retrieval and histopathological evaluation indicated that 22 tumors were gastrointestinal stromal tumors (GISTs) (78.6%) and 6 tumors were leiomyomas (21.4%). All the 22 GISTs were at low- or very low-risk according to the National Comprehensive Cancer Network Guidelines [11]. En bloc resection was achieved in 26 patients (92.9%).

There was no significant difference between patients of TT group and NA group in sex, age, tumor size, tumor location, tumor growth pattern, histopathological type and postoperative hospital stay ($P > 0.05$) (Table 1). However, both the total procedure time and the perforation time were significantly shorter in patients of TT group than those of NA group (71.9 ± 30.5 vs. 107.5 ± 35.8 min, $P = 0.010$; 38.3 ± 22.0 vs. 68.6 ± 24.2 min, $P = 0.002$) (Table 1). En bloc resection rate was 92.3% (12/13) in TT group and 93.3% (14/15) in NA group, and there was no significant difference ($P > 0.05$) (Table 1).

Complications

A total of 9 (32.1%) patients suffered complications in the study. Intra-operative bleeding happened in 5 (17.9%) patients and we conducted successful intra-operative hemostasis by coagrasper forceps or hemostatic clips immediately. Seven (25.0%) patients had fever above 38 °C after operation. The intravenous anti-biotic was upgraded to sulbactam/cefoperazone (Sulperazone®, Pfizer Pharmaceutical Co, New York, USA) at a dose of 3 g per 12 h and the temperature recovered to normal gradually. Other patients had slight elevation of the temperature (lower than 37.5 °C) in the first day after operation and recovered to normal in the second day. One patient of NA group encountered pneumoperitoneum during the procedure, which was resolved by abdominal puncture deflation on the right upper quadrant of the abdomen with a sterile injection needle. The needle was removed when the operation was completed. No abdominal bloating or subsequent leakage was noticed after operation. The VAS score was averaged 5.2 ± 1.4 after operation and decreased to 2.6 ± 0.7 after 24 h. No patient presented delayed perforation, massive bleeding or any other serious complications.

The VAS score after operation was significantly lower in patients of TT group than those of NA group (4.5 ± 1.1 vs. 5.8 ± 1.4, $P = 0.014$) (Table 1). No significant difference was observed in VAS score after 24 h between the two groups (2.4 ± 0.7 vs. 2.7 ± 0.8, $P = 0.221$) (Table 1). Although complication rate was lower in patients of TT

Table 1 Clinical characteristics of patients treated by EFTR ($n = 28$)

Variables	TT-assisted group ($n = 13$)	Non-assisted group ($n = 15$)	*P* value
Sex (M/F)	3/10	5/10	0.686
Age, mean ± SD (years)	56.2 ± 8.1	59.1 ± 7.3	0.328
Maximum tumor size, mean ± SD (cm)	1.6 ± 0.4	1.5 ± 0.4	0.621
Tumor location (corpus/fundus)	5/8	4/11	0.689
Intra-luminal growth pattern (predominantly/partly)	3/10	9/6	0.067
En bloc resection, *n* (%)	12 (92.3)	14 (93.3)	1.000
Procedure time, mean ± SD (min)	71.9 ± 30.5	107.5 ± 35.8	**0.010**
Perforation time, mean ± SD (min)	38.3 ± 22.0	68.6 ± 24.2	**0.002**
Histopathological type (leiomyoma/GIST)	2/11	4/11	0.655
Postoperative hospital stay, mean ± SD (days)	4.3 ± 1.3	5.1 ± 1.1	0.083
VAS score after operation, mean ± SD	4.5 ± 1.1	5.8 ± 1.4	**0.014**
VAS score after 24 h, mean ± SD	2.4 ± 0.7	2.7 ± 0.8	0.221
Complications, *n* (%)	2 (15.4%)	7 (46.7%)	0.114
Fever (> 38 °C), *n* (%)	2 (15.4%)	5 (33.3%)	0.396
Intra-operative bleeding, *n* (%)	1 (7.7%)	4 (26.7%)	0.333
Pneumoperitoneum, *n* (%)	0	1 (6.7%)	1.000

Bold values indicate statistically significant

EFTR endoscopic full-thickness resection; *TT* thread-traction; *M* male; *F* female; *SD* standard deviation; *cm* centimeter; *min* minute; *GIST* gastrointestinal stromal tumor; *VAS* visual analogue system; ℃ centigrade

group than those of NA group, the difference was not statistically significant (15.4% vs. 46.7%, $P = 0.114$) (Table 1).

Follow-up information

All patients completed surveillance endoscopy within the 3rd month. In all cases, the wound healing was satisfactory. No residual or recurrent tumors were observed during a mean follow-up period of 17.9 ± 4.4 months (range 8–25 months).

Discussion

Gastric SMTs refer to a series of tumor types including leiomyomas, lipomas, and GISTs [12]. Since small gastric SMTs may also present potential malignancy [13, 14], it is advisable to remove them once at diagnosis. Regular follow-ups rather than resection may involve issues related to extra medical expenses, the complication risks of repetitive endoscopic procedures and delayed diagnosis of malignancy. Many patients even developed psychological stress. Endoscopic resection of SMTs has become more and more accepted as first-line treatment because of the minimally invasiveness. Comparison studies on the efficacy and safety of EFTR and laparoscopic-assisted surgery in treating small GISTs have reported lower complication rate of EFTR with favorable en bloc resection rate and sufficient tumor tissue for histological diagnosis [15, 16]. In the present study, we achieved successful removal of all 28 gastric SMTs from the MP layer with an en bloc resection rate of 92.9%, and histopathological evaluation revealed all GISTs were at low- or very low-risk. Although the complication rate of 32.1% was relatively high, they were managed intra-operatively or by conservative medication. Our results were consistent with previous studies, and demonstrated that EFTR possessed great prospects in treating gastric SMTs from the MP layer. Nevertheless, comprehensive preoperative assessments of the SMTs including EUS, contrast-enhanced CT or MRI and serological tumor markers remain necessary to exclude SMTs with high-risk stigmata of malignancy or predominantly extra-luminal growth pattern, which were deemed not suitable for endoscopic treatment currently.

The TT method was previously reported in several studies to assist ESD in the treatment of gastrointestinal superficial neoplasm [17–21], and has demonstrated definite improvement of efficiency both in literature and our clinical practices. We perceived that the TT method could also provide viable assistance for EFTR in treating SMTs. Another potential benefit of the TT method for EFTR would be the prevention of the specimens from displacing into the peritoneal cavity. In the present study, we applied this method to assist EFTR in treating gastric SMTs originating from the MP layer and evaluated the feasibility and effectiveness of this strategy in comparison with non-assisted EFTR. Our results showed that patients of TT group had significantly shorter total procedure time and perforation time than those of NA group. They also displayed significantly reduced painful feeling after operation and suffered lower rates of complications (although not significant), which may be mainly attributed to more efficient removal of the tumor and quicker closure of the perforation. A stumbled operation process would cause more undesired injury to the surrounding tissues. The leakages of the air and/or fluids with various contaminants through the perforation may cause stimulation to the peritoneum and digestive gut and bring about inflammation reaction. A shortened procedure time, especially perforation time, would probably lead to decreased amounts of leakages with less peritoneal irritation and gastrointestinal spasm after operation. Our results demonstrated that the TT method could effectively assist EFTR to shorten operation time and perforation time and decrease the risk of complications. Although all specimens achieved trans-oral retrieval showing no difference between the two groups of patients, the underlying reason may be attributed to the study population. Patients with SMTs of predominantly extra-luminal growth pattern were excluded from endoscopic treatment in our hospital. Future efforts are warranted to investigate the feasibility of the TT method in treating such SMTs and broaden the indications of EFTR possibly.

Our study had several limitations. Firstly, it was a retrospective study with a relatively small sample size of participants. Secondly, all operations were performed by an experienced expert at a single institute. The possible subjectivity of the patient inclusion and treatment decision depending on the expertise of the operator may impact the overall generalizability of the results. Thirdly, the follow-up period was relatively short to give long-term information of therapeutical outcomes. A large-scale, randomized, control study is required for further investigation.

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Author contributions Study conception and design (FL); acquisition, analysis and interpretation of data (JL, YM, SY); drafting of the manuscript (JL, YM); critical revision of the manuscript for important intellectual content (FL); technical or material support (SY, PW, FL); study supervision (FL). The article has been approved by all authors to be published.

Compliance with ethical standards

Disclosure Drs. Jun Li, Yuting Meng, Shufang Ye, Peng Wang and Feng Liu stated that they do not have any conflict of interests or financial ties to disclose.

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