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Potential for expanded application of endoscopic hand suturing: A pilot study of 15 cases

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ABSTRACT

Endoscopic hand suturing (EHS) was first developed to firmly close a mucosal defect following endoscopic submucosal dissection and has the potential for expanded applications. This study aimed to investigate the feasibility and safety of EHS in various clinical settings. In this single-center pilot study, 15 patients who had diseases with potential indications for EHS were prospectively recruited. Technical success, clinical success after the procedure, and severe EHS-related adverse events (AEs) were evaluated. EHS was applied for defect closure after gastric subepithelial lesion removal under laparoscopic observation (n = 9), defect closure after rectal endoscopic full-thickness resection (EFTR) (n = 2), defect closure after thoracoscopy-assisted esophageal EFTR (n = 1), mucosal closure for gastric ulcer bleeding (n = 1), mucosal closure after peroral endoscopic myotomy (POEM) (n = 1), and postoperative anastomotic leak (n = 1). EHS was completed without severe AEs and the clinical courses were also favorable in 13 patients (87%). The median suturing time was 61 minutes. In patients with POEM and anastomotic leak, EHS was discontinued because of the narrow lumen. In conclusion, EHS appears feasible and safe in situations.

Introduction

Endoscopic hand suturing (EHS), which provides robust tissue approximation using a commercially available, absorbable, barbed surgical suture and a dedicated through-the-scope-type flexible needle holder, has been developed mainly for closing a postendoscopic submucosal dissection (ESD) [1, 2]. This technique is expected to prevent postoperative bleeding, particularly in patients at high risk because of continuous administration of antithrombotic agents.

EHS provides a more reliable and sustainable closure compared with other endoscopic closure methods [1]; therefore, it is expected to be effective in many clinical situations other than mucosal defect closure after ESD, where secure intraluminal closure is required. We also consider that identifying unsuitable situations of EHS is important to determine the indication for this technique thereafter.

In this pilot study, we prospectively investigated in which situation EHS was technically feasible and safe by applying the technique to various clinical situations where EHS was considered effective, with the aim of expanding the indications for EHS.

Patients and methods

Study design and ethics

This study was conducted after the approval of the Institutional Review Board of our hospital (approval no. C-2020–022; UMIN000042703), in accordance with the guidelines of the Declaration of Helsinki. Before the procedure, written informed consent was obtained from each patient. Patients were recruited based on situations in which intraluminal suturing by EHS was supposed to be clinically effective, such as intentionally created full-thickness defects, refractory intraluminal bleeding, and postoperative anastomotic leak. Patients with a postgastric/colorectal ESD defect were not recruited for this study because it was already evaluated in previous studies [1, 2].

EHS

In EHS, a double-channeled multibending scope (GIF-2TQ260 M, GIF-H290T; Olympus, Tokyo, Japan) was used. A transparent straight hood (D-201–13404, D-201–11804; Olympus) was mounted on the tip of the endoscope for the optimal endoscopic view. V-loc absorbable barbed sutures (VLOCL0604, VLOCM0804; Covidien, Mansfield, Massachusetts, United States) were manipulated with a prototype of the flexible needle holder, which was commercially launched later as the SutuArt (FG-260 L, FG-260Q; Olympus). After delivering the suture and grasping the needle at half to one-third from the tail, the first stitch was generally placed on the distal side from the endoscope, followed by suturing toward the proximal side. Suturing was provided at 5- to 10-mm intervals and at approximately 8 mm of the suture bites. A mucosal defect was closed by mucosal suturing, and a full-thickness defect was made by full-layer, double-layer, or single-layer suturing depending on the situation. After suturing, the remnant suture with the needle was cut with the scissor forceps (FS-410 L, FS-410U; Olympus) and retrieved. Details of the procedure have been described previously elsewhere [1, 2].

Outcome measures

As a primary outcome, the technical success of EHS was evaluated to investigate the feasibility of the procedure in various situations. As secondary outcomes, adverse events (AEs) regarding EHS and clinical success following EHS were assessed to evaluate the safety and efficacy of the procedure, respectively. The suturing time and number of stitches were also evaluated.

Technical success was defined as endoscopically complete closure of the suturing site. Clinical success referred was defined as achievement of the clinical purpose of EHS and favorable patient condition thereafter. Suturing time and number of stitches were defined as duration from the first grasp of the needle in the lumen to retrieval of the remnant suture and the number of tissue appositions by the suture between both sides of the tissues (the first stitch for the placement of the suture was included), respectively. AEs were assessed according to the Clavien–Dindo classification ver. 2.0.

Sample size and statistics

Owing to the nature of pilot studies, the sample size calculation was waived, and a total of 15 patients were prospectively recruited, based on consideration of the number of needle holders that were available for this study. Statistical analyses were also not conducted. Continuous variables were presented as medians and ranges.

Results

A total of 15 patients were recruited and underwent EHS for the following situations/diseases (▶ **Table 1** and ▶ **Table 2**): endoscopic full-thickness resection (EFTR) under placement of one laparoscopic port for gastric subepithelial lesions (n = 9) [3], EFTR for rectal neoplasms (n = 2) [4], thoracoscopy-assisted EFTR for esophageal gastrointestinal stromal tumor (GIST; n = 1; ▶ **Fig. 1**, ▶ **Video 1**), refractory bleeding ulcer (n = 1) [5], peroral endoscopic myotomy (POEM; n = 1), and esophago-jejunal junction (EGJ) anastomotic leak (n = 1). In the refractory bleeding case, repeated bleeding occurred twice even though tentative endoscopic hemostasis was obtained in each session; finally, we closed the ulcer by EHS at the third bleeding. In the case of type 1 POEM, we considered that the entry site of the submucosal tunnel might become too wide to close with conventional clips because of the enlarged esophageal lumen.

Technical success was achieved in 13 patients (87%). In the POEM case, EHS was discontinued because the esophageal mucosa was too elastic to pierce (▶ **Fig. 2**, ▶ **Video 1**), and we switched to using conventional clips for the closure. In EGJ anastomotic leak, EHS was not completed because of the narrow working space and the fragile tissue around the fistula. No procedure-related AEs occurred, and the clinical courses were favorable in all 13 patients. Median suturing time and number of stitches were 61 minutes and seven stitches, respectively.

In the completed 12 EFTR cases (GIST in 7; schwannoma, lipoma, rectal cancer on an anastomotic line, local recurrence of rectal adenoma, and esophageal GIST in one patient each), the median procedure time, en-bloc resection rate, and complete resection rate were 121 minutes, 100%, and 100%, respectively. Patients were discharged on median postoperative Day 9. Deflation due to the full-thickness defect occurred in four gastric and one esophageal case, whereas the intraluminal endoscopic view was well-preserved in five gastric and two rectal cases. In the two rectal cases, the defects were closed in a short-axis direction by nodule suturing with extracorporeal ligation and continuous suturing. In the esophageal case, the defect was successfully closed by endoscopic muscle suturing after thoracoscopic separation of the aorta from the esophagus, considering the difficulty of mucosal suturing in the EHS-failed POEM case, followed by mucosal clipping. For security, laparoscopic muscle suturing was also performed according to surgeon decision. No additional clipping was performed in any gastric case. In one gastric EFTR case on the anterior wall, complete mucosal closure by EHS was confirmed. However, the surgeons in charge strongly recommended laparoscopically assisting a few additional stitches of EHS for full-thickness penetration of the nee-

▶ **Table 1** Characteristics of 15 patients who underwent endoscopic hand suturing.

No	Indication	Age (years)	Sex	Disease	Location	Circumference	Lesion size (mm)	Defect size (mm)	Technical success
1	Rectal EFTR	74	Male	Rectal cancer on an anastomotic line	Rb	Ant	20	35	Yes
2	Gastric EFTR	79	Male	Gastric SEL	L	Post	14	24	Yes
3	Gastric EFTR	58	Female	Gastric SEL	U	Gre	26	26	Yes
4	Gastric EFTR	60	Female	Gastric SEL	U	Post	20	40	Yes
5	Refractory gastric ulcer bleeding	78	Male	Gastric ulcer	L	Gre	10	15	Yes
6	Gastric EFTR	78	Male	Gastric SEL	M	Ant	10	25	Yes
7	Gastric EFTR	65	Male	Gastric SEL	L	Gre	25	35	Yes
8	POEM	54	Male	Esophageal achalasia	–	–	–	15	No
9	Gastric EFTR	72	Female	Gastric SEL	M	Less	25	36	Yes
10	Gastric EFTR	47	Male	Gastric SEL	M	Less	15	15	Yes
11	Gastric EFTR	73	Male	Gastric SEL	U	Post	20	35	Yes
12	Gastric EFTR	43	Female	Gastric SEL	U	Post	14	27	Yes
13	Rectal EFTR	65	Male	Recurrent rectal tumor	Rb	Left	14	28	Yes
14	Esophageal EFTR	68	Female	Esophageal SEL	Mt	Post	10	10	Yes
15	Esophagojejunal anastomotic leak	82	Male	Esophageal cancer	–	–	–	8	No

EFTR, endoscopic full-thickness resection; Rb, lower rectum; Ant, anterior wall; SEL, subepithelial lesion; L, lower stomach; Post, posterior wall; U, upper stomach; Gre, greater curvature; M, middle stomach; Less, lesser curvature; POEM, peroral endoscopic myotomy; Mt, middle thoracic esophagus.

dle by grasping the needle with a laparoscopic needle holder through the additionally placed laparoscopic port.

In refractory bleeding ulcer, a historical diagnosis of eosinophilic gastritis was finally reached. The ulcer base was completely closed by EHS, and with peroral steroid administration, no rebleeding occurred thereafter.

Discussion

In this pilot study, EHS was applied to multiple patients, which demonstrated that this technique was feasible and safe for various endoscopic treatments, including esophageal, gastric, and rectal EFTR, and benign bleeding ulcer, as expanded indications. Moreover, fragile/elastic tissue in a narrow lumen might be difficult to approximate with EHS.

This endoscopic suturing technique was developed mainly to prevent postgastric and colorectal ESD bleeding by completely closing the mucosal defect after lesion removal [1, 2]. In these previous studies, EHS targeted mucosal defects without full-thickness perforation, in which the endoscopic visual field was well-preserved without deflation of the lumen. Although EHS requires skilled endoscopic hands and some training, it is relatively easy to perform in a wide working space with good endoscopic guidance. This study prospectively investigated use of EHS for more advanced conditions, and the obtained clinical outcomes, despite the small number, successfully indicated that EHS was clinically feasible and safe for various conditions treated with endoscopy.

In this study, the majority of the targets were postgastric EFTR defect closures. In gastric EFTR, full-thickness defects (sometimes with the serosa remaining according to location) were successfully closed in all nine cases. Practically, we first considered applying double-layer suturing and suboptimally downgrading the suturing type to full-layer and single-layer suturing, considering the technical difficulty and the estimated procedure time. A comfortable closure was enabled in the lesser curvature or posterior wall because stomach deflation did not always occur in the lesser omentum or omental bursa. Conversely, EHS becomes difficult in the anterior wall or greater curvature because of perforation of the abdominal space and subsequent deflation of the stomach. In these locations, some defects might result in mucosal closure only, although the post-procedure clinical courses were favorable.

Particularly in EFTR with lumen deflation, we need to pay close attention. In this situation, it is safe to always set the needle toward the inside of the lumen. By piercing the wall from

▶ **Table 2** Characteristics and clinical outcomes of 15 patients who underwent endoscopic hand suturing.

Adverse events	Procedure time (min)	Suturing time (min)	Number of stitches	Luminal deflation	Hospitalization (days)	Pathological diagnosis	Complete resection	Post-procedure course
No	210	67	4*	Not occurred	6	Adenocarcinoma, pTis	Yes	Uneventful
No	194	111	12	Occurred	9	Very low-risk GIST	Yes	Uneventful
No	174	78	7	Occurred	11	Low-risk GIST	Yes	Uneventful
No	120	32	6	Not occurred	9	Low-risk GIST	Yes	Uneventful
No	26	28	6	Not occurred	20	Eosinophilic gastritis	-	Uneventful
No	166	96	9†	Occurred	9	Very low-risk GIST	Yes	Uneventful
No	84	30	8	Not occurred	9	Lipoma	Yes	Uneventful
No	16	–	–	Not occurred	–	–	–	–
No	114	69	13	Not occurred	8	Low-risk GIST	Yes	Uneventful
No	111	61	13	Not occurred	10	Schwannoma	Yes	Uneventful
No	124	41	9	Not occurred	5	Very low-risk GIST	Yes	Uneventful
No	137	65	7	Occurred	8	Very low-risk GIST	Yes	Uneventful
No	81	44	7‡	Not occurred	3	Adenoma	Yes	Uneventful
No	100	42	5§	Occurred	13	Low-risk GIST	Yes	Uneventful
No	24	–	–	Not occurred	–	–	–	–

*Nodule suturing with the extracorporeal ligation method was applied in a short-axis direction.
†Two stitches of endoscopic hand suturing were laparoscopically assisted for the full-thickness penetration of the needle.
‡Continuous suturing was applied in a short-axis direction.
§Muscular suturing was performed by endoscopic hand suturing, followed by mucosal clipping.
GIST, gastrointestinal stromal tumor.

the outside to the inside with the needle, the risk of extraluminal organ injury will be decreased. Further investigations about obtaining secure full-thickness suturing are needed, along with a discussion about its importance.

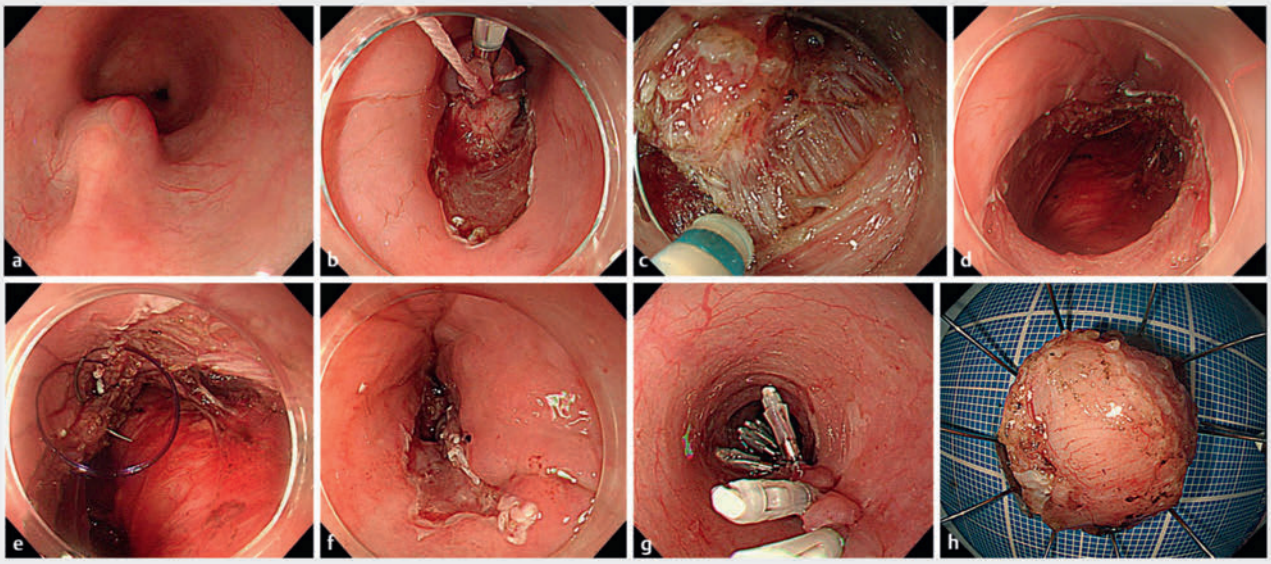
In rectal EFTR, there is no need for concern about deflation, particularly in the lower part of the rectum. However, the defect should be closed along the short axis to avoid delayed dehiscence. By contrast, defect closure after esophageal EFTR should be performed along the long axis to avoid possible anastomotic leaks.

Patients with non-iatrogenic ulcers who have refractory bleeding may be candidates for EHS. In general, tissues associated with peptic ulcers are firmer and more merged among layers than non-iatrogenic ulcers. Therefore, it is difficult to close the ulcer bed and maintain the closure using clip-based closure techniques. In contrast, the needle used in EHS is sharp and can easily pass through hard tissues/layers. If the ulcer base is small enough to close, such as in the current case, EHS is easily applied, whereas in large ulcers with a hard surrounding tissue or advanced cancer, closure may fail. Further accumulation of cases is needed to determine the optimal indication for benign ulcer closure with EHS.

Failure in two cases (esophageal mucosa closure in POEM and EGJ anastomotic leak closure) may have been caused by the narrow working space and tissue characteristics. Elastic tissue is difficult to pierce with a needle, and the needle tip cannot not be exposed, particularly in the narrow lumen. Frail tissue prevents suturing because the tissue easily tears. Accordingly, pretreatment endoscopic observation and cautious target selection would be important for successful EHS.

Various endoscopic closure techniques have been introduced, which are mainly divided into clip-based methods [6, 7] and suturing devices [8, 9]. Basically, the closure strength provided by suturing devices tends to be greater than that of the clip-based methods, in which an over-the-scope clip generates stronger force than conventional clips [10]. We suppose that EHS is comparable to surgical suturing in terms of closure strength; thus, this method may be equally or more recommended than other endoscopic suturing methods, although technically demanding. We are fully aware that long procedure time is also a disadvantage. However, that may have been expected because the cases in this study was the first exposure of an endoscopist experienced with EHS to using the technique for post-ESD mucosal defects.

This study has several limitations. First, it was a single-center, small-scale pilot study by a single endoscopist with significant clinical experience in EHS. Second, the indication criteria were not strictly determined. Third, the suturing style varied among the cases. Finally, a small laparoscopic support might have favorably affected post-procedure clinical course in one

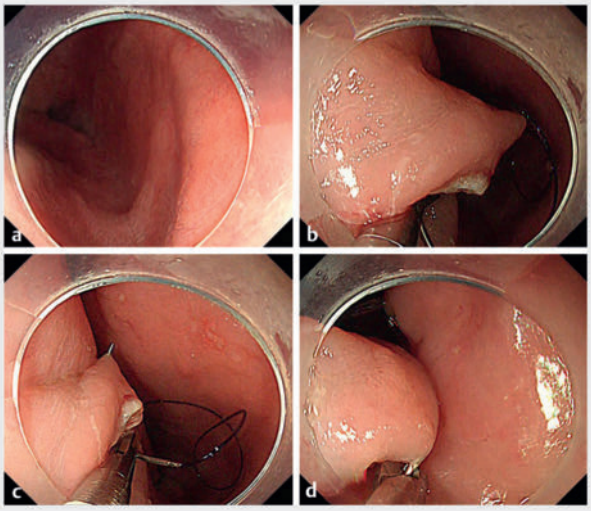


▶ **Fig. 1** Endoscopic full-thickness resection under laparoscopic assistance and endoscopic hand suturing in an esophageal gastrointestinal stromal tumor (Case 14). **a** A 10-mm intraluminally-growing type of subepithelial lesion was located at the middle esophagus. Boring biopsies revealing a gastrointestinal stromal tumor (GIST). **b** Circumferential mucosal incision was performed, followed by submucosal dissection with the lesion pulled by a clip-with-line method. **c** After thoracoscopic dissection between the middle part of the esophagus and the descending aorta, muscular incision was performed. **d** A full-thickness defect was created after lesion removal. The descending aorta was observed through the defect. **e** Continuous inner muscle suturing was started from the anal side. **f** The muscle layers were successfully apposed. **g** Mucosal clipping was applied, followed by laparoscopic outer muscle suturing for security. **h** A full-thickness resection was completed. The final diagnosis was low-risk GIST, measuring 10 mm. Neither adverse events nor postoperative stricture occurred.

VIDEO

▶ **Video 1** Representative cases of endoscopic hand suturing (EHS) for expanded application. Case No. 14: endoscopic full-thickness resection under thoracoscopic assistance in esophageal gastrointestinal stromal tumor (GIST) (a successful case). A 10-mm GIST is removed in a full-thickness fashion under thoracoscopic assistance. Case No.8: EHS for mucosal suturing in peroral endoscopic myotomy (a failure case). In the entry site closure of the submucosal tunnel after peroral endoscopic myotomy, piercing the stretchy mucosa with the needle is difficult.

gastric EFTR case, and thoracoscopic intervention might have increased the safety of EHS in one esophageal EFTR case. These limitations must be addressed in further studies.



▶ **Fig. 2** Endoscopic hand suturing for mucosal suturing in peroral endoscopic myotomy (Case 8). **a** The lumen of type 1 esophageal achalasia appeared wide enough to manipulate the needle. **b** Penetration of the elastic mucosa by the needle tip was difficult. **c** Excessive rotation of the needle holder might have injured the opposite side of the wall. **d** Picking the needle was difficult because of extension of the mucosa. Finally, EHS was discontinued and a switch was made to mucosal clipping.

Conclusions

In conclusion, this study demonstrated that EHS could be safely applied to multiple conditions, provided that the presence of a sufficient working space and nonfragile healthy tissue were guaranteed, although technical difficulty appeared to be easily influenced by lesion characteristics. Accumulation of further clinical experience is desirable to investigate the clinical usefulness of EHS in various situations.

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Conflict of Interest

The flexible needle holder and the scissors forceps which were used in this study were complimentarily provided by Olympus Co., Ltd. Dr. Osamu Goto has ties with Olympus Co. Ltd. as a consultant and a paid speaker. The remaining authors have no conflict of interest to declare.

Clinical trial

UMIN Japan (http://www.umin.ac.jp/english/)
Registration number (trial ID): UMIN000042703
Type of Study: A prospective, single-arm, single-center, pilot study

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CORRECTION

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In the above-mentioned article the affiliations were corrected as well as the footer of table 1. This was corrected in the online version on 17.04.2024.