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Randomised controlled, patient-blinded, multicentre, superiority trial to evaluate the efficacy of the line-attached sheath-type traction device for endoscopic submucosal dissection in patients with superficial gastric neoplasms

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ABSTRACT

Introduction EndoTrac is a line-attached sheath-type traction device that enables us to control the direction and the force of traction during endoscopic submucosal dissection (ESD). The efficacy of EndoTrac for gastric ESD has not been fully verified.

Methods and analysis The G-Trac study is a multicentre (nine general hospitals and two university hospitals in Japan) collaborative trial assessing the efficacy of EndoTrac for gastric ESDs. Patients with superficial gastric neoplasms will be enrolled and randomly assigned to undergo either conventional ESD or EndoTrac ESD. Allocation will be stratified according to tumour location, operator experience and tumour diameter at an allocation rate of 1:1. The type of endoknife used will be confirmed before randomisation. The primary outcome, procedure time, will be compared between the groups in both intention-to-treat and per-protocol analyses using the Wilcoxon rank sum test. The efficacy-related, safety-related and device-related outcomes will be assessed in the secondary analysis. The planned sample size of the 142 patients in the two groups will enable us to detect a difference with a power of 80% by using the Wilcoxon rank sum test, assuming an effect size of 0.54, asymptotic relative efficiency of 0.864 and a two-sided type 1 error rate of 5%.

Ethics and dissemination This trial was approved by the certified review board of Kobe University (22 December 2022). The results from this trial will be disseminated through peer-review journals, presentations at national and international conferences, and data sharing with other researchers.

Trial registration number jRCT1052220166.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The trial focuses on the efficacy of traction devices that enable control of the traction force and towing direction during endoscopic submucosal dissections.
⇒ The device's efficacy for lesions that pose controversy regarding the use of traction devices will be assessed by excluding lesions that are presumed to be difficult for en bloc resections without a traction device.
⇒ This trial will recruit participants from two university hospitals and nine general hospitals.
⇒ Operators cannot be blinded to allocation due to the nature of the intervention.
⇒ Participants and institutions are limited to a single country.

INTRODUCTION

Background and rationale

Endoscopic submucosal dissection (ESD) is a radical treatment for early gastric cancer if the likelihood of lymph node metastasis is extremely low.[1] Although it enables us to complete en bloc resections, even for lesions with a relatively large tumour diameter, the spread is limited in countries where a structured learning environment with onsite expert tutors and an abundance of easier gastric lesions are not uniformly present because complicated techniques are required.[2]

Many traction devices have been developed to overcome technical difficulties associated

with ESDs.[3–6] However, none of the traction devices showed any clinical significance. A clip with string-type traction devices was the first solution invented; however, the direction of traction was limited to the oral side. Therefore, it was effective only for lesions located in areas where traction was applied in the vertical direction, such as lesions located in the greater curvature of the upper or middle stomach, and as a result, did not result in a shorter procedure time in the overall patient population.[3] The spring-clip-type device[4] and rubber-clip-type device[5 6] were useful for overcoming the problem of the direction of traction being limited to the oral side. These devices enabled us to set the traction as desired and provide traction vertically regardless of the tumour location, resulting in a shorter procedure time in the overall population.[4 5] However, other problems were recognised: the traction force diminished as dissection progressed, and reclipping was required to adjust the towing direction during the procedure.

The EndoTrac (EndoTrac T-type, Top, Tokyo, Japan) is a traction device composed of a plastic sheath and line with a shrinkable loop at its tip.[7] The loop is tied to an endoclip, which is attached to the edge of the lesion and completes the circumferential incision. The EndoTrac enables us to maintain the traction force and adjust the optional towing direction, including the vertical direction, during the entire procedure by pulling or pushing the sheath and changing the length of the line. Hence, the EndoTrac enables us to maintain vertical traction without diminishing the traction force as the dissection progresses and adjust the towing direction as desired during the procedure. Thus, ESD using EndoTrac is likely to reduce technical difficulty compared with conventional ESD.

A single-centre, single-arm, retrospective study which was planned to clarify the safety of using EndoTrac during ESD found no device fractures and no device-related adverse events during ESD in 44 patients with lesions located in the oesophagus, stomach or duodenum.[8] However, the efficacy of the EndoTrac in reducing the technical difficulty of gastric ESDs has not yet been fully verified.

Objectives

The aim of this study is to verify the efficacy of the EndoTrac for gastric ESD.

Trial design

This study is designed as a randomised, controlled, patient-blinded, multicentre superiority trial with two parallel groups.

METHODS AND ANALYSIS

Study setting

The study participants will be recruited from two university hospitals and nine general hospitals in Japan. These hospitals are located in the same medical region.

Participating hospitals

- Kobe University Hospital.
- Kobe University Hospital International Clinical Cancer Research Center.
- Hyogo Cancer Center.
- Akashi Medical Center.
- Osaka Saiseikai Nakatsu Hospital.
- Japanese Red Cross Kobe Hospital.
- Kitaharima Medical Center.
- Yodogawa Christian Hospital.
- Sanda City Hospital.
- Konan Medical Center.
- Hyogo Prefectural Harima-Himeji General Medical Center.

Eligibility criteria

Inclusion criteria

Patients who fulfil all of the following six criteria will be included:

1. Patients who are 18 years of age or older.
2. Patients who understand and voluntarily sign an informed consent form.
3. Patients with superficial gastric neoplasms meeting the absolute or expanded indications for ESD according to the following Japanese guidelines for gastric neoplasm treatment (sixth edition)[1]:
   a. Clinically diagnosed intramucosal cancer (cT1a) representing well-differentiated adenocarcinomas of any size without ulcerative findings.
   b. cT1a, representing well-differentiated adenocarcinomas, less than 30 mm in size with ulcerative findings.
   c. cT1a, representing undifferentiated adenocarcinomas, less than 20 mm in size, without ulcerative findings.
4. Patients who have CT findings without any suspicious lesions of lymph node or distant metastases.
5. Patients who have histological findings of groups 4 and 5 according to group classification of gastric biopsy.[9]
6. Eastern Cooperative Oncology Group Performance Status: 0–2.

Exclusion criteria

Patients who fulfil any of the following ten criteria will be excluded:

1. Patients with lesions presumed to be difficult for en bloc resection without a traction device, including lesions estimated to have severe fibrosis and lesions located in the esophagogastric junction, fornix and pyloric ring.
2. Patients who have a history of either gastrectomy or reconstructive surgery of the gastric tract.
3. Patients who have either residual lesions or local recurrence after previous endoscopic treatment.
4. Patients who were registered in this trial for previous lesions.
5. Patients who were unable to comply with the cessation of anticoagulant or antiplatelet medications

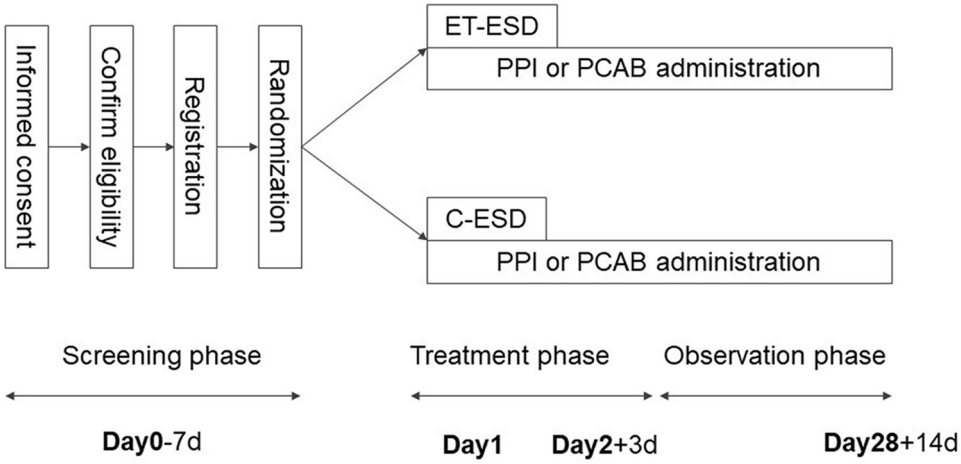

Figure 1 Overall design of the present trial. C-ESD, conventional endoscopic submucosal dissection; ET-ESD, EndoTrac endoscopic submucosal dissection; PCAB, potassium competitive acid blocker; PPI, proton pump inhibitor.

according to the Japanese guidelines for gastroenterological endoscopy in patients undergoing antithrombotic treatment[10] and its 2017 Appendix.[11]

6. Patients who have any haemostasis or coagulation abnormalities.
7. Patients who have functional failure in vital organs such as the liver, kidneys or heart.
8. Patients who were planned to undergo ESDs for more than two gastric lesions on the same day.
9. Patients who are pregnant, suspicious of being pregnant and lactating.
10. Patients who were deemed ineligible for any other specific reason.

Interventions

The overall trial design is illustrated in figure 1. ESD will be performed by senior endoscopists whose ESD experience as chief operators is more than 100 cases, or junior endoscopists, with between 10 and 99 cases of experience, within 7 days after registration. Endoknives and injection solutions will be limited to a needle-type knife or insulation-tipped diathermic knife (IT knife) and saline or hyaluronic acid. The type of operator, injection solution and endoknife used should be confirmed before randomisation. Eligible patients will be allocated equally to the EndoTrac ESD (ET-ESD) and conventional ESD (C-ESD) groups. General anaesthesia or conscious sedation was selected depending on the institution's preference. No other traction methods, underwater techniques, pocket creation methods or any other special techniques will be allowed in each group.

ET-ESD will be performed using the following steps: (1) submucosal injection, (2) whole circumferential mucosal incision, (3) attaching a traction device, (4) starting towing, (5) submucosal dissection and (6) en bloc resection. Endoscopists pull (or push) the traction device and change the length of the towing string to maintain the traction vertical (occasionally proximal to the scope) to the lesion.

C-ESD will depend on the endoknife preferred by the endoscopist. If a needle-type knife is used, ESD is performed as follows: (1) submucosal injection, (2) partial mucosal incision, (3) mucosal flap creation, (4) partial submucosal dissection, (5) whole circumferential mucosal incision, (6) completion of submucosal dissection and (7) en bloc resection. If an IT knife is used, ESD is performed as follows: (1) submucosal injection, (2) whole circumferential mucosal incision, (3) submucosal dissection and (4) en bloc resection.

Minor adjustments, such as partial submucosal dissection before the entire circumferential mucosal incision, will be allowed. Preventive haemostasis should be performed after the completion of resection, if necessary. Medical interviews about melena and stomach pain and radiography and blood tests will be performed on day 1 postoperatively. Whether to perform second-look endoscopy or when to discharge the patient depends on the decisions of the investigators and coinvestigators.

Modifications

Operators will attempt to complete the procedure themselves as far as possible. However, handover to senior endoscopists will be accepted if the following conditions are met: (1) procedure time exceeding 60 min, (2) endoscopic haemostasis which takes more than 5 min, (3) intraoperative perforation and (4) any situation in which senior endoscopists consider handover. Regarding the participants' safety, the use of an EndoTrac in the C-ESD group will be allowed if operators cannot complete the procedure without an EndoTrac, regardless of their maximum effort.

Concomitant care

Proton pump inhibitors and potassium-competitive acid blockers will be administrated from day 1 (the day of surgery) to day 28. Considering the interference between the overtube and the EndoTrac, an overtube with an inner diameter >16 mm should be used, regardless of the allocated group.

Table 1 Participant timeline

Study phase	Screening phase	Treatment phase		Observation phase	Termination
Approval range	Days 0–7	Day 1	Day 2+3 days	Day28±14 days	
Informed consent	X				
Baseline characteristics*	X				
Vital sign		X	X		
Complete blood count†	X		X		
Serum biochemistry†	X		X		
Coagulation test†	X				
Electrocardiograph†	X				
Abdominal radiography			X		
CT‡	X				
Endoscopy‡	X				
Histopathological diagnosis on biopsy sample‡	X				
Assessment of the technical difficulty§	X				
Procedure time		X			X
Efficacy-related outcomes		X		X	X
Safety-related outcomes		X	X	X	X
Device-related outcomes		X			X

*Age, performance status, pregnant or lactating, history of critical organ (liver/renal/heart) failure, history of bleeding disorders, registration history for the present trial, the possibility of discontinuing antithrombotic drugs in accordance with guidelines will be interviewed.
†All assessments must be completed within 4 weeks prior to consent.
‡All assessments must be completed within 12 weeks prior to consent.
§Based on the information regarding the operator, endoknife and injectional solution, the technical difficulty will be assessed.

Outcomes

The primary outcome is the procedure time which is defined as the duration from the submucosal injection to the completion of resection.

Secondary outcomes are classified as efficacy-related, safety-related and device-related outcomes. Efficacy-related outcomes include dissection time (procedure time without preparation time of the EndoTrac), dissection speed (procedure time per unit area), handover rate, en bloc resection rate, complete en bloc resection rate and endoscopic curability according to the Japanese guidelines for gastric treatment.[1] Safety-related outcomes included the number of intraoperative bleeding events and perioperative adverse events. Device-related outcomes included attachment time, attachment points, number of devices, number of slip-offs and damage to the specimen.

Participant timeline

The participant timeline is shown in table 1.

Sample size

In the spring-and-loop with clips study, the mean procedure time in the traction group was 43 min with a SD of 32 min, and that in the C-ESD group was 62 min with an SD of 38 min. Considering the efficacy of the EndoTrac, which is equivalent to a spring-and-loop technique with a clip, the effect size was estimated to be 0.54. When performing the Wilcoxon rank sum test with a power of 80%, a two-sided significance level of 5%, 1:1 allocation, and asymptotic relative efficiency (Pitman efficiency) of the Wilcoxon rank sum test for a t-test of 0.864, which is the theoretical minimum, the number of subjects required per group is 64. If a drop-out rate of 10% is expected, the sample size is set to 71 for each group.

Recruitment

Patient inclusion started in March 2023 in 11 participating hospitals. Enrolment is ongoing. As of 15 August 2023, 83 patients had been included.

Allocation

Investigators who register the participants will perform block randomisation with a 1:1 allocation as per a cloud software 'Mujinwari'-generated randomisation schedule stratified by tumour location, the type of operator and tumour diameter using permuted blocks of random sizes. The block sizes will not be disclosed, except to the staff responsible for the allocation, to ensure concealment.

Participants will be blinded to the treatment allocation because some secondary outcomes are related to their symptoms. Owing to the nature of the intervention, neither the operators nor the assessors could be blinded to the allocation.

Data collection methods

The primary outcome will be assessed using images or videos captured during the procedure to ensure objectivity. Lesions which are presumed to be difficult for en bloc resection without a traction device will be excluded

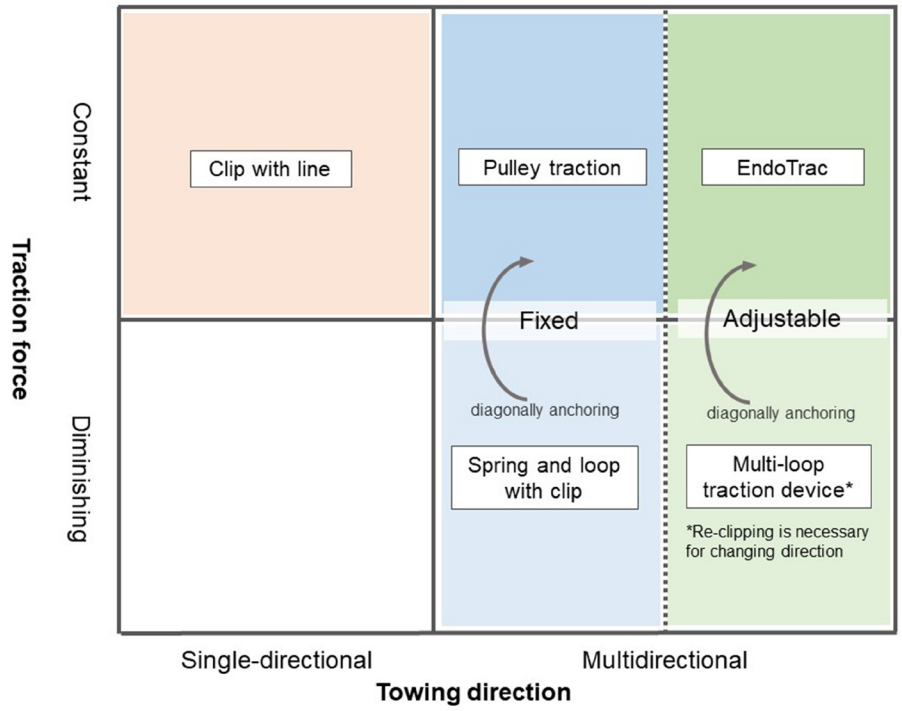

Figure 2 Classification of traction devices for ESD. ESD, endoscopic submucosal dissection.

to ensure the safety of the participant and avoid tumour recurrence due to the failure of en bloc resection.

Data management

All participant data will be coded and entered electronically. The investigators and coinvestigators will access the electric data capture (EDC) system 'REDcap' using a preissued user ID (identification) and password and complete the case report form (CRF) for each participant. After confirming that there are no errors in the created CRF, investigators at each institution will electronically sign it on the EDC system. Input errors will be detected by programmes designed to detect missing data or specific errors in the data.

Statistical methods

Of all the patients who will be enrolled in the present trial, the population excluding patients who fulfilled any of the following will be defined as the full analysis set (FAS) on which intention-to-treat analysis will be performed: (1) patients without procedure time data and (2) patients with serious violations of the protocol. Furthermore, of the FAS, the population excluding patients who fulfil any of the following will be defined as the per-protocol set on which per-protocol analysis will be performed: (1) patients with violations of inclusion criteria, (2) patients with violations of exclusion criteria, (3) patients who underwent ET-ESD in the C-ESD group, (4) patients who experienced slip-off of the EndoTrac within 20 min after attachment and (5) patients who experienced discontinuation of the protocol treatment. A per-protocol analysis will be performed only on the primary outcome. The safety analysis dataset is defined as the population who undergoes ESDs in the trial.

In the primary analysis, the procedure time will be compared between the C-ESD and ET-ESD groups using the Wilcoxon rank-sum test. In the secondary analysis, continuous variables will be compared between groups using the Student's t-test or Wilcoxon rank-sum test according to data distribution, and categorical variables will be compared using Fisher's exact test. Missing secondary outcome values will be handled using multiple imputations.

Data monitoring

The data monitoring committee is composed of three staff members. The chief staff member responsible for monitoring is independent of the study investigators and coinvestigators, but the other two staff members engage in the trial as coinvestigators. Procedural monitoring will be planned at the beginning and completion of the trial and every 6 months. Off-site monitoring will be performed for the first three and once for every five participants in each institution using the EDC data. If serious adverse events or concerns regarding the participants' safety occur, on-site monitoring, including monitoring of medical records, will be performed.

Harm

All adverse events occurring after the patient's entry into the trial and until 4 weeks after the ESD will be recorded according to the Clavien-Dindo classification.[12] An adverse event that meets the criteria for a serious adverse event will be reported to the certified review board (CRB).

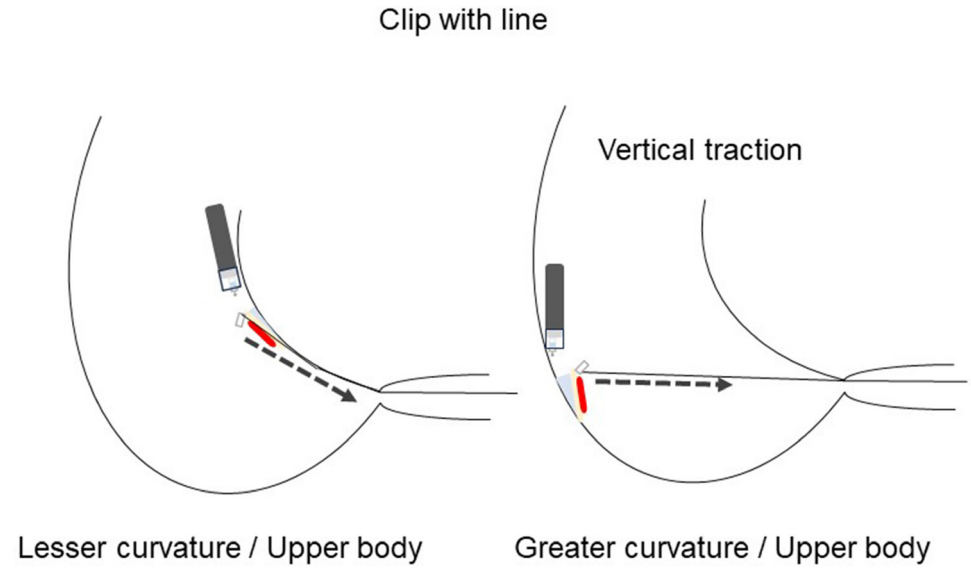

Figure 3 Clip with line.

Auditing

Auditing is not scheduled.

ETHICS AND DISSEMINATION

Research ethics approval

This protocol and the informed consent forms have been reviewed and approved by a CRB (Name of the CRB: Kobe University Clinical Research Ethical Committee; approval date: 22 December 2022; approval number: C220008). The CRB is an ethics board comprising medical experts, legal professionals and members of the general public that is certified by the Minister of Health, Labour and Welfare in Japan. Subsequently, the protocol will be implemented with the approval of the administrators of each participating medical institution. The study will be conducted in compliance with the principles of the Declaration of Helsinki the Clinical Trials Act and other current legal regulations in Japan.

Protocol version

Protocol amendment number: 02.

Authors: HA, RI and TT.

Revision chronology:

- C220008 00, 22 December 2022 Original.
- C220008 01, 10 January 2023 Amendment 01.

The primary reason for the amendment: changes in typographical errors of the investigator's name.

- C220008 02, 8 June 2023 Amendment 02:

Primary reason for amendment: changes in the member of coinvestigators.

Protocol amendments

Any modifications to the protocol which may impact the conduct of the study, potentially benefit the patient or affect patient safety, including changes in study objectives, study design, patient population, sample sizes, study procedures or significant administrative aspects, will require a formal amendment to the protocol. Such an amendment will be agreed on and approved by the CRB prior to implementation, and the jRCT and managers of each institution will be notified.

Consent or assent

Patients will be able to have an informed discussion with the investigators or coinvestigators, who will obtain written consent from patients willing to participate in the trial after the discussion. The patient consent form is cited as online supplemental file 1. Assent will not be obtained because all the participants will be adults.

Confidentiality

All electronic data will be stored in the EDC system and identified by a coded ID number to maintain participant confidentiality. All records containing names or other personal identifiers, such as informed consent forms, will be stored separately from study records identified by code numbers. The lists linking the participants' coded ID numbers to personal information will be stored in each institution.

Patient and public involvement

The development of this study protocol is without patient or public involvement. Patients will not be involved in the study design or study procedures. Our randomisation and treatment protocols will not be influenced by patient preferences. The final study results will be disseminated to participants on request.

Access to data

The principal investigator and the division of clinical studies have direct access to the EDC.

Ancillary and post-trial care

The principal investigator has insurance to cover participants' serious complications associated with the protocol, such as death and severe disability.

Dissemination

The results from this trial will be disseminated through peer-review journals, presentations at national and

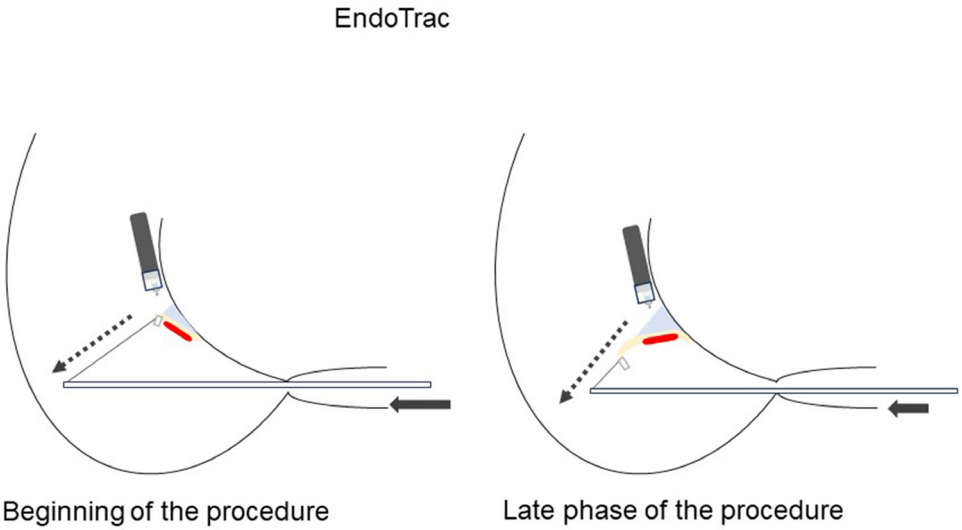

Figure 4 EndoTrac T type. Constant traction force and adjustable towing direction by pulling or pushing the sheath and changing the length of the line.

international conferences and data sharing with other researchers.

Discussion

A traction device is a solution that exposes the submucosal tissue and aids submucosal dissection by applying an external force, including a string, spring and magnetic force, to the lesion, which works similarly to the surgeon's left hand in the surgery. Many traction devices have been invented, and they are classified into subgroups in terms of two main elements: traction force and towing direction. Towing direction is classified into two groups, that are 'single-directional' or 'multidirectional' and 'multidirectional' is subclassified depending on whether the towing direction is fixed or adjustable during the procedure. Furthermore, the traction force of the device is evaluated, considering whether the force is constant or diminishing during the procedure (figure 2).

Although a clip with a line provides constant traction during the procedure, vertical traction is limited to lesions located in the greater curvature of the upper or middle stomach[3] (figure 3). A spring-and-loop with a clip provides vertical traction regardless of the tumour location[4] (online supplemental figure 1). However, the traction force diminishes as the dissection progresses, and the towing direction cannot be adjusted once the clip has been anchored. The diminishing traction force can be overcome by either changing the vertical anchoring to diagonal anchoring, in which an anchoring clip is attached proximally to the scope in the opposite lumen of the stomach[4] (online supplemental figure 1), or pulley traction, which provides multidirectional, fixed and constant traction[13] (online supplemental figure 2). The fixed towing direction can be overcome using a multiloop traction device, which provides multidirectional and adjustable traction using reclipping (online supplemental figure 3). However, EndoTrac can overcome both problems simultaneously and is presumed to provide significant efficacy for gastric ESD (figure 4).

The study population and eligibility criteria are important in this trial. 11 hospitals, including 9 general hospitals and 2 university hospitals, will be enrolled from the same medical area and participating institutions. Furthermore, the type of endoknife and operator experience are not limited. Therefore, the study population will be rich in diversity, and the results of the trial will promote generalisation. There are two reasons why patients with lesions presumed to be difficult to perform en bloc resection without a traction device will be excluded from the trial. First, allocation to the C-ESD group is likely to harm the safety of participants with challenging lesions. Second, the study's genuine interest is whether the traction device can provide significant benefit for lesions for which we can complete ESDs without a traction device because using a traction device is not controversial for such a challenging case in clinical practice.

This study has two limitations. First, operators cannot be blinded to the allocation because of the nature of the intervention. Second, participants and institutions are limited to a single country.

In conclusion, this trial will verify the efficacy of a novel and promising traction device for lesions which are controversial in terms of the use of traction devices in diverse populations and settings.

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Contributors HA conceived the study. HA and RI initiated the study design, and TT helped with the implementation. TY and HS provided statistical expertise in clinical trial design. RI, TS, YY, AI, YK, RA, YM and TI submitted the study design to the ethics committee of each participating institution. All the authors contributed to the refinement of the study protocol and approved the final version of the manuscript.

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Competing interests Takashi Toyonaga has received royalties from Top for the development of the EndoTrac. The other authors declare no conflicts of interest regarding this article.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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