


BMJ Open Effect of different oesophagojejunostomy methods on the quality of life of gastric cancer patients after totally laparoscopic total gastrectomy with self-pulling and latter transected technique: study protocol for a randomised trial

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ABSTRACT

Introduction Gastric cancer is the fifth most common cancer worldwide and the detection rate of proximal gastric cancer has been increasing. Currently, surgical resection using gastrectomy and proper perigastric lymphadenectomy is the only treatment option to enhance the survival rate of patients with gastric cancer. Laparoscopic total gastrectomy (LTG) is increasingly performed for adenocarcinoma of the oesophagogastric junction. However, totally LTG (TLTG) is only performed by a few surgeons due to difficulty associated with oesophagojejunostomy (OJ), in which there is no consensus on a standardised anastomosis technique. We propose a randomised trial to compare functional end-to-end anastomosis (FETE) and side-to-side anastomosis (Overlap) for OJ.

Methods and analysis A prospective, randomised, open-label, single-centre, interventional trial has been designed to evaluate the quality of life (QoL) outcomes and safety of FETE and Overlap, with a 1-year follow-up as the primary endpoint. The trial began in 2020 and is scheduled to enrol 96 patients according to a previous sample size calculation. Patients were randomly allocated to the FETE or Overlap groups with a follow-up of 1 year to assess QoL after the procedure. All relevant clinical data including biological markers were collected. The primary indicator is the D-value between the postoperative and preoperative QoL. Student's t-tests will be used to compare continuous variables, while χ^2 tests or Fisher's exact tests will be used to compare categorical variables. Statistical analysis will be performed with SPSS V.23.0 statistical software. A $p < 0.05$ will be considered statistically significant.

Ethics and dissemination This study has been approved by the Hospital Institutional Review Board of Huashan Hospital, Fudan University (2020-1055). The results will be submitted for publication in peer-reviewed journals.

Trial registration number ChiCTR2000035583.

INTRODUCTION

Gastric cancer is the fifth most common cancer, following breast cancer (11.7%), lung

Strengths and limitations of this study

- The current study is one of few randomised clinical trials aimed at comparing functional end-to-end anastomosis with side-to-side anastomosis for oesophagojejunostomy in totally laparoscopic total gastrectomy.
- The quality of life of patients and procedural safety of two different oesophagojejunostomy techniques will be compared, with a 1-year follow-up period.
- The study results are limited to a single centre.

cancer (11.4%), colorectal cancer (10%), and prostate cancer (7.3%).¹ In 2020, the estimated number of new cases of gastric cancer is 1 089 103 worldwide (5.6% of all incident cancer cases), with new deaths of 768 793 (7.7% of all sites). The highest incidence rates are in Japan (male population) and Mongolia (female population). Gastric cancer is the fourth leading cause of cancer death in both sexes worldwide, with an estimated gastric cancer death of 769 000 in 2020 (equivalent to one in every 13 deaths globally). In recent years, the detection rate of proximal gastric cancer has been increasing.² Currently, surgical resection using gastrectomy and proper perigastric lymphadenectomy is the only treatment option to enhance the survival rate of patients with gastric cancer. Laparoscopic total gastrectomy (LTG) has been performed since 1999.³ Evidence from several studies have demonstrated that totally LTG (TLTG) has the benefits of minimal blood loss, less postoperative pain, faster bowel function recovery, shorter duration of hospitalisation and lower postoperative morbidity, at the cost of longer

operative time compared with open total gastrectomy (OTG).⁴⁻⁶ TLTG has not been widely adapted due to difficulties associated with oesophagojejunostomy (OJ). When performing OTG, OJ with a circular stapling device is generally accepted as a substitute for hand-sutured anastomosis. However, there are two disadvantages to this technique: first, purse-string suturing is a mandatory step; second, it can be difficult to introduce the anvil of the circular stapler into the oesophagus. These disadvantages become more complicated in laparoscopic surgery than in open surgery. However, purse-string suturing and anvil introduction are not necessary when performing OJ with linear staplers. Two types of OJ have been reported using linear staplers, including the functional end-to-end (FETE) anastomosis⁷ and the side-to-side anastomosis (or the overlap method).⁸ The FETE procedure is performed by inserting the linear stapler into the oesophagus through a small hole on the left side of the oesophageal stump, while simultaneously lifting the jejunum to insert the stapler through a small hole on the opposite side of the jejunal mesentery. The entry holes are closed using the linear stapler, usually one at a time. In contrast, the overlap method is performed by creating holes on the left side of the oesophageal stump and 6–7 cm from the jejunal stump. After stapling, the entry hole is closed using hand-sewn sutures. Based on our retrospective study, the FETE group had poorer quality of life (QoL) outcomes compared with the Overlap group shortly after surgery, while the rates of postoperative complications were similar between the two groups. However, there is no agreement on the standard anastomosis technique for OJ.^{6,9-11} A retrospective study in South Korea showed that laparoscopic OJ with the Overlap method is associated with less postoperative pain and anastomotic complications compared with FETE.¹² To date, there is no prospective study to compare which method is more reasonable based on QoL outcomes and procedural safety of patients undergoing TLTG. We hypothesise that patients with gastric cancer undergoing TLTG with either FETE or Overlap intracorporeal OJ experience different QoL and surgical sequelae after the procedure.

Institutional data

Our institution is one of the leading institutions in Shanghai, China affiliated to Fudan University. Our surgeons perform over 500 gastrectomies annually, with over 200 cases performed via laparoscopy. We have

previously reported several novel reconstruction methods in performing totally laparoscopic proximal gastrectomy, distal gastrectomy, and total gastrectomy.¹³⁻¹⁵ Self-pulling and latter transected (SPLT) reconstruction is one of our novel and routine method in performing LTG. The operational procedure and difficulty of anastomosis have been simplified, which effectively resolved problems associated with traditional OJ, such as oesophageal retraction after transection, difficulty in opening the oesophagus, difficulty in closing entry holes, complex technical requirements, higher cost (cheaper than traditional linear anastomosis) and difficulty in promotion. The results of a retrospective study of 100 TLTG+SPLT cases suggest that SPLT is a safe and feasible procedure.¹⁶ Our surgeons have surpassed the learning curve for this procedure and have successfully performed over 150 SPLT surgeries.

METHODS AND ANALYSIS

Patient and public involvement

Patients and the public were not involved in the design and conduct of the trial. The results of the study will be disseminated through a peer-reviewed journal. Study participants will not be individually informed of study results.

Trial design

The current study is a prospective, randomised, open-label, single-centre, interventional trial using a parallel-arm design which would commence from 1 October 2020 to 30 September 2022. Subjects will be randomised to receive one of two interventions: FETE or Overlap. **Figure 1** shows an overview of the trial design and each aspect of the trial is introduced in detail below.

Inclusion criteria

(1) Patients between 18 and 75 years old; (2) Primary gastric adenocarcinoma confirmed pathologically by endoscopic biopsy; (3) Locally advanced tumour in the upper or middle-third of the stomach, or locally advanced adenocarcinoma of the oesophagogastric junction with Siewert type II or III (cT1-4a, N-/+, M0); (4) No distant metastasis, no direct invasion of the pancreas, spleen or other neighbouring organs found on preoperative examinations; (5) Performance status of 0 or one on the ECOG (Eastern Cooperative Oncology Group) scale; (6) ASA

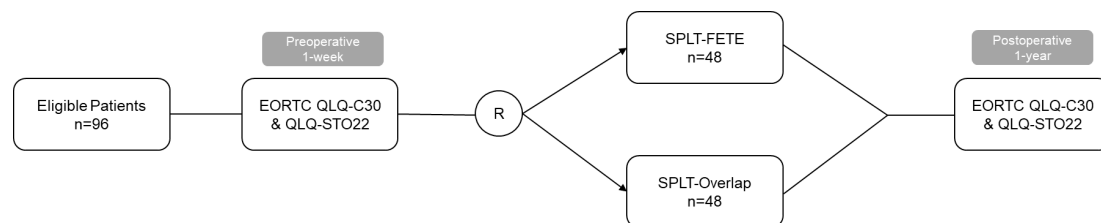


Figure 1 Study flow chart. EORTC QLQ-C30, The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; FETE, functional end-to-end; QLQ-STO22, Quality of Life Questionnaire of Stomach; SPLT, self-pulling and latter transected.

(American Society of Anesthesiology) class I–III and (7) Written informed consent.

Exclusion criteria

1. Pregnant or breastfeeding women;
2. Suffering from severe mental disorders;
3. History of previous upper abdominal surgery (except for laparoscopic cholecystectomy);
4. Enlarged or bulky regional lymph node (LN) (diameter over 3 cm) found on preoperative imaging including enlarged or bulky No.10 LN;
5. History of other malignant diseases within the past 5 years;
6. History of unstable angina or myocardial infarction within the past 6 months.
7. History of cerebrovascular accident within the past 6 months;
8. Emergency surgery (bleeding, obstruction, perforation) caused by gastric cancer.

Contrast and grouping

Patients are enrolled by the clinical research coordinator on the team.

Patients who meet the eligibility criteria are randomised to receive either laparoscopic OJ with FETE-SPLT or Overlap-SPLT on a 1:1 ratio. SPSS software is used to generate the random sequence, and the subjects are coded according to the order of entering the group. The random sequence number corresponding to the coding sequence of patients will be randomly divided into two groups (odd numbers into the SPLT-FETE group and even numbers into the SPLT Overlap Group). Blinding surgeons or participants is not feasible in this study.

Treatment

Lymphadenectomy

A D2 LNs dissection will be regularly conducted according to the Japanese gastric cancer treatment guidelines 2014 (V.4).¹⁷

Reconstruction of anastomosis

After undergoing lymphadenectomy, the abdominal oesophagus will be routinely mobilised. The subsequent conventional transection will be substituted by ligation of the cardia (or oesophagus above the upper margin of the tumour) using a sterilised hemp rope. Transection of the duodenum will be performed with a 60 mm endoscopic linear stapler per usual.

FETE group

Throughout the course of reconstruction, the ligature rope will be held to lower the oesophagus to allow easier detachment from the posterior mediastinum (figure 2). Next, a hole will be made on the posterior wall of the oesophagus, 2–3 cm above the ligature rope. Then, another hole will be made at the anti-mesenteric border of the jejunum, 25 cm distal to the ligament of Treitz, serving as an entrance for the second stapler. Then, a side-to-side OJ will be performed through two holes, creating an entry hole. The following FETE will be modified in a 'latter transected' fashion.

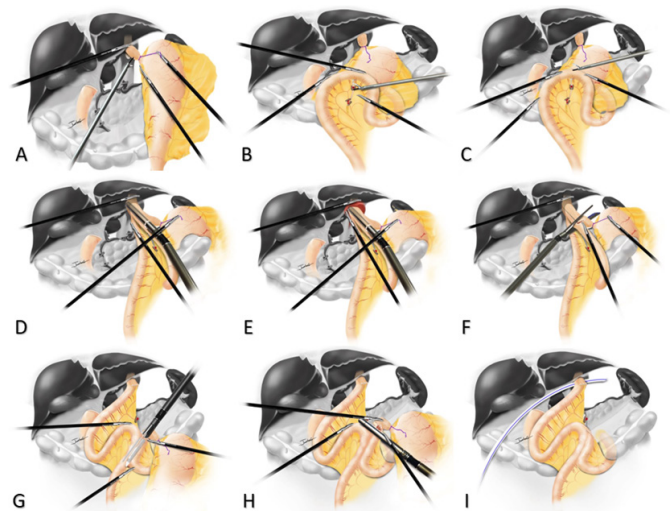


Figure 2 TLTG FETE SPLT. (A) The oesophagus is pulled to the right and a hole is made on the posterior wall of the oesophagus, 2 to 3 cm above the ligature rope. (B) The mesentery of the jejunum 25 cm distal to the ligament of Treitz is mobilised to ensure blood supply. (C) Another hole is made at the anti-mesenteric border of the jejunum. (D) The lateral posterior wall of the oesophagus is anastomosed with the jejunum. (E) The jejunum is checked for injury. (F) The entry hole is closed. (G) The jejunojejunostomy is performed at the jejunum, 40 to 45 cm distal to OJ. (H) The entry hole is closed. (I) A drainage tube is placed posteriorly to OJ. FETE, functional end-to-end; OJ, oesophagojejunostomy; SPLT, self-pulling and latter transected; TLTG, totally laparoscopic total gastrectomy.

Overlap group

The jejunum will be intracorporeally transected 20 cm distal to the ligament of Treitz using a linear stapler (figure 3). The distal side of the jejunum will be additionally removed to avoid excessive tension on the anastomosis of the OJ. A small enterotomy will be created at 7 cm distal to the stapler line on the antimesenteric side of the jejunal limb. Another small hole will be made on the left wall of the oesophagus, 2–3 cm above the ligature rope. After one fork of the stapler is inserted into the opening to form a jejunal limb towards the oral side of the lumen, the jejunal limb will be dragged up and positioned at the left side of the abdominal oesophagus. Another fork of the linear stapler will be inserted carefully into the hole of the oesophagus. After each fork has been completely inserted into each lumen, the firing of the stapler will convert the two openings into a single-entry hole to create an end-to-side OJ. The entry hole will be simultaneously closed together as the oesophagus is being transected with the stapler.

Outcomes

The primary purpose of this study is to compare the QoL outcomes between the FETE and Overlap groups (1, 3, 6, 9 and 12 months after surgery)¹⁸ using the EORTC QLQ-C30 (The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire) and QLQ-STO22 (Quality of Life Questionnaire of Stomach)

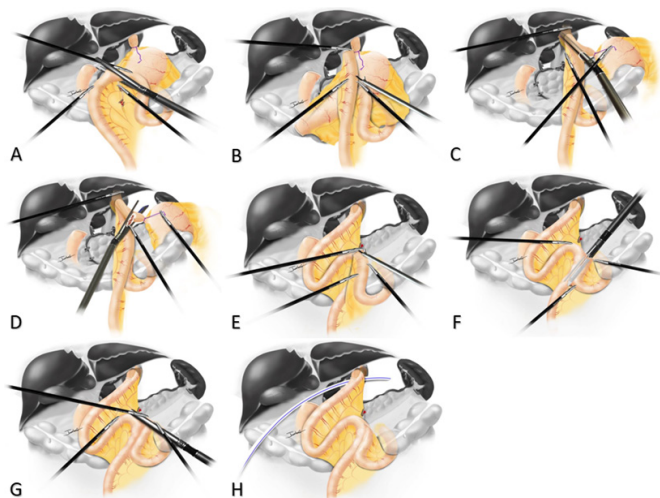


Figure 3 TLTG Overlap SPLT Step 1 and step 2 of the Overlap method are consistent with the FETE method, followed by: (A) The jejunum 20 cm distal to the ligament of Treitz is transected using a linear stapler. (B) A small enterotomy will be made 6 cm distal to the stapler line on the anti-mesenteric side of the jejunal limb. (C) The lateral posterior wall of the oesophagus is anastomosed with the distal jejunum. (D) The entry hole is closed. (E) A small hole is made in the proximal jejunum. (F) The jejunojunctionostomy is performed at the jejunum 40 to 45 cm distal to OJ. (G) The entry hole is closed. (H) A drainage tube is placed posteriorly to OJ. FETE, functional end-to-end; OJ, oesophagojejunostomy; SPLT, self-pulling and latter transected; TLTG, totally laparoscopic total gastrectomy.

questionnaires.^{19 20} The EORTC QLQ-C30 was designed as a multidimensional assessment of QoL, including five scales of functional assessment, three symptom scales, a global health status and six single items. A higher score indicates a better status in functioning domains, but a worse status in symptom domains. The EORTC STO22 was designed specifically for examining QoL in gastric cancer patients. It contains 22 questions including five symptom scales and four single items. Higher scores indicate a worse status. Early postoperative complications (anastomotic leakage, pulmonary complication, bleeding, pancreatic fistula) between FETE and Overlap groups will also be compared. Early postoperative complication is defined as an event observed within 30 days after surgery.

Adverse events

Adverse events (AEs) are any disadvantageous or uncertain events that affect the subject, regardless of its association to the treatment procedure. All AEs are recorded on the case report form in detail, including occurrence, duration, prognosis, severity and relevance to the treatment. If such events result in death, disability, dysfunction, teratogenesis, or prolonged hospitalisation, it is defined as serious AEs (SAEs). The occurrence of SAEs will be reported to the Huashan Hospital Committee within 24 hours.

Sample size

In this study, the postoperative QoL of patients is the main evaluation index, which is set as a non-inferiority study. According to the data of the retrospective study in China, the QoL scores of the OJ Overlap group and FETE group are increased by 17 points relative to the preoperative baseline,²¹ with an SD of D-value of 6.5 points and a non-inferiority margin of 4 points. According to $\alpha=0.025$, $\beta=0.20$, the sample size of 86 (43 per group) was calculated by the PASS 2020 software. The final sample size is 96 (48 per group) after considering a 10% dropout rate in each group. Our team is capable of performing 150 TLTG procedures annually, therefore the planned recruitment period is 2 years, with a 1-year follow-up period.

Data collection

Data collection will be performed by trained professionals via paper-form datasheets from inpatient and outpatient records until 1 year after the surgery. All relevant data will remain anonymous and will only be accessible to relevant researchers and statisticians.

Preoperative records

Initial staging and diagnosis include endoscopy, endoscopic pathology, endoscopic ultrasound, non-contrast enhanced CT scan of the chest and contrast-enhanced CT scan of the abdomen. The patient's age, sex, weight, ASA classification, ECOG score, haemoglobin, C reactive protein (CRP), comorbidities, history of abdominal surgery, QoL and tumour markers were recorded.

Intraoperative records

The type of OJ, operation time, blood loss (and blood transfusion), anastomosis time, intra-abdominal adhesion, specimen measurement (margin) and relevant complications were recorded.

Postoperative records

Pathological diagnosis, postoperative complications (anastomotic leakage, anastomotic bleeding, abdominal bleeding, abdominal infection and intestinal obstruction), postoperative mortality, postoperative hospital stay, postoperative time to first aerofluxus, postoperative time to liquid diet, postoperative time to soft food diet, postoperative CRP and evaluation of postoperative biological markers were recorded.

Follow-up records

The follow-up medical history and physical examination, adjuvant therapy and completion, questionnaire results, laboratory results, imaging and endoscopic examination results were recorded.

Patient follow-up in the outpatient clinic abided by postoperative standards. The follow-up period and parameters were summarised in [table 1](#).

Data analysis

Data processing of QoL scale

Table 1 Follow-up arrangements.

	Observation period					
	Preoperative 1 week	Postoperative 1 month	Postoperative 3 months	Postoperative 6 months	Postoperative 9 months	Postoperative 12 months
Patient Informed Consent	✓	✗	✗	✗	✗	✗
Previous Surgery	✓	✗	✗	✗	✗	✗
ASA Class	✓	✗	✗	✗	✗	✗
ECOG Scale	✓	✗	✗	✗	✗	✗
Weight	✓	✓	✓	✓	✓	✓
Blood routine test	✓	✓	✓	✓	✓	✓
CRP	✓	✓	✗	✗	✗	✗
Tumour markers	✓	✗	✓	✓	✓	✓
CT Scan	✓	✗	✗	✓	✗	✓
Endoscopy	✓	✗	✓	✗	✗	✓
EORTC QLQ-C30	✓	✓	✓	✓	✓	✓
QLQ-STO22	✓	✓	✓	✓	✓	✓

ASA, American Society of Anesthesiology; CRP, C reactive protein; CT, computed tomography; ECOG, Eastern Cooperative Oncology Group; EORTC QLQ-C30, The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; QLQ-STO22, Quality of Life Questionnaire of Stomach.

1. Raw Score (RS) = $(Q_1 + Q_2 + Q_3) / n$, (Q: score of each item; n: number of all items).
2. Functional field: standard score (SS) = $[1 - (RS - 1) / R(\text{Range})] \times 100$.
3. Symptom field and general health field: $SS = [(RS - 1) / R(\text{Range})] \times 100$.

Continuous data are expressed as mean \pm SD ($\bar{x} \pm S$), while categorical data are shown as percentage (%). The D-value between the standard score of postoperative and preoperative QoL is the comparative indicator. Student's t-tests will be used to compare continuous variables, while χ^2 tests or Fisher's exact tests will be used to compare categorical variables. Statistical analysis will be performed with SPSS V.23.0 statistical software. A $p < 0.05$ will be considered statistically significant.

Patient informed consent

All participants should sufficiently understand the instructions detailed in the written informed consent form (online supplemental appendix 1). All patients will be given the opportunity to ask questions and be provided with a comprehensive response. Patients may choose not to participate in the study or withdraw at any time after notifying the researchers to ensure that patient rights to treatment will not be affected. All participants are required to provide written informed consent before participating in the trial.

Data monitoring and interim analysis

Data monitoring and interim analysis will be conducted annually by a specialist committee organised by the funding organisation (Shanghai ShenKang Hospital Development Centre). An independent statistician will be invited to evaluate study outcomes after enrolment of over 60% participants. If a significant difference is

noticed between the two intervention methods, the institution Hospital Institutional Review Board will be notified to determine whether early termination is necessary.

Ethics and dissemination

This study has been approved by the Hospital Institutional Review Board (HIRB) of Huashan Hospital, Fudan University (2020-1055). On completion of the study, the results of the primary study will be published in a peer-reviewed journal.

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Contributors JW and YT performed acquisition, analysis and interpretation of data; JW, YT and JH drafted the manuscript; L-CH, H-KH and Y-PW provided critical revision of the manuscript; all authors have reviewed and approved of the final version manuscript for submission.

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Competing interests None declared.

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. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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