

Laparoscopic uncut Roux-en-Y for radical distal gastrectomy: the study protocol for a multirandomized controlled trial

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Abstract: Gastric cancer is the third most common cause of cancer-related deaths and is the fifth highest incidence of cancer worldwide, especially in Eastern Asia, Central and Eastern Europe, and South America. Currently, surgery is the only curative treatment for gastric cancer; however, digestive tract reconstruction after distal gastrectomy for gastric cancer is controversial due to the postoperative complications such as reflux gastritis. There is an increasing trend toward laparoscopic uncut Roux-en-Y (URY) for radical gastrectomy. However, evidence on the feasibility of this procedure in patients undergoing laparoscopic radical distal gastrectomy is still absent. Thus, a prospective randomized trial is warranted. This is a prospective, multicenter, two-arm randomized controlled trial in which 210 patients will be randomly assigned to two groups: laparoscopic URY (n=105) and laparoscopic Billroth II plus Braun anastomosis (n=105). Each participant must be pathologically diagnosed with gastric cancer and undergo laparoscopic radical gastrectomy at Xijing Hospital and other four hospitals. The laparoscopic URY procedure is based on the Billroth II gastrojejunostomy plus Braun anastomosis, and then blocked the jejunum input loop at the stump-jejunal anastomosis. The patients' demographic and pathological characteristics will be recorded. The total and oral nutritional intake, general data, total serum protein, serum albumin, blood glucose, and temperature will be recorded before surgery and at the time of hospitalization. Postoperative adverse events will also be recorded, as well as at follow-up appointments at three months and six months after surgery. The rate of reflux gastritis will represent the primary endpoint, and other secondary endpoints, which are all recorded.

Keywords: Billroth II gastrojejunostomy, Braun anastomosis, jejunum input loop, anastomosis, reflux gastritis

Introduction

Gastric cancer is one of the most common malignant cancers, which is fifth incidence worldwide and third most common in terms of tumor-related death.¹ The morbidity of gastric cancer is higher in Southeast Asian than in European and American regions. This includes China, which accounts for ~40% of patients with gastric cancer around the world, and this number is increasing. It has been estimated that >670,000 new cases of gastric cancer were diagnosed in China in 2015. The majority of times, the lesion is located in the lower stomach, and the distal gastric carcinoma is the major pattern in the Southeastern Asian region such as China, Japan, and South Korea. The therapy is surgery based and is an effective treatment strategy. At present, the proposal is generally changed from subtotal gastrectomy to systematic lymph node dissection. The best treatment option for lower gastric cancer is considered to be

radical distal gastrectomy. However, none of the traditional surgeries, Billroth I, Billroth II, modified Braun anastomosis, or Roux-en-Y anastomosis, could eliminate the postoperative complications, such as bile reflux. And an optimal technique has not yet been established for surgeons.² With the development and evolution of surgery technology, the effectiveness of gastrectomy for patients with gastric cancer has been remarkably improved, especially the quality of life and survival time. However, the optimum choice of a digestive tract reconstruction procedure after gastrectomy is still controversial. Generally speaking, for surgeons the Billroth I anastomosis is technically simple and widely applied, but its limitations are that anastomosis produces heavy tension and has a relatively high recurrence risk.³ While Billroth II could avoid the issue of the heavy tension, this procedure transforms the normal digestive pathway and therefore increases complications such as postoperative bile reflux, alkaline reflux gastritis, and alkaline reflux esophagitis. When it comes to Braun anastomosis, it still fails to satisfy, because it provides limited improvement of complications. Meanwhile, Roux-en-Y can prevent alkaline reflux gastritis, but patients have an incidence of Roux-en-Y stasis syndrome (RSS), which consisted of upper abdominal distension, nausea, and vomiting, because the continuity of the small intestine is destroyed and the duodenal pacing impulse conduction is altered.⁴ RSS was reported in ~30% of patients who undergo a Roux-en-Y syndrome.⁵

As an alternative method, the uncut Roux-en-Y (URY) has been developed, which performs both a Billroth II gastrojejunostomy plus a Braun anastomosis, and then blocks the jejunum input loop at the stump-jejunal anastomosis based upon the Billroth II and Braun anastomosis procedures.⁶ This prevents the bile and pancreatic juice from moving through the stomach-jejunum or anastomotic jejunum into the residual stomach. Also, the noncut jejunum could originate in the duodenum pacemaker impulse conduction in the meantime. Furthermore, this procedure could significantly reduce the alkaline reflux caused by cutting the vagus nerve and the absence of pylorus; this procedure even prevented the bile and pancreatic fluid from reaching the gastric or esophageal mucosa, reducing postoperative residual gastritis and reflux gastritis.⁷ Obviously the URY has advantages in reducing postoperative reflux gastritis theoretically.⁸

The specific operation of URY anastomosis is described as follows. First, a stomach-jejunum anastomosis is conducted from the Treitz ligament to the distal jejunum (25 cm). Then the Braun anastomosis is performed in the input

and output loop, which are 15 cm and 25–30 cm from the anastomosis of the jejunum, respectively. Finally, a nondiscrete closed jejunum at the input pouch from the gastrointestinal anastomosis (5 cm) is formed. Compared with other reconstructions, it is safe and feasible for URY to be performed laparoscopically because this surgery does not require interactions with the mesojejunum or any major vessels. Laparoscopic technologies have improved along with the optimization of the instruments, and it is a very convenient surgical method. Also, increasing understanding and use of this minimally invasive technology in specific procedures will hopefully make surgeons more willing to apply laparoscopic technology to radical gastrectomy. Nevertheless, there is no universal standard of digestive tract reconstruction after laparoscopic distal gastrectomy. In 1988, van Stiegman and Goff first presented the procedure of URY⁹ and reported that the URY reconstruction could divert bile and pancreatic juices through jejunojejunostomy. Uyama reported that laparoscopy-assisted URY reconstruction (nondiscrete closed jejunum at the input pouch from the gastrointestinal anastomosis – 10 cm) could shorten the time of reconstruction compared with other procedures such as the Billroth II plus Braun anastomosis (BB), and there were zero events of alkaline reflux gastritis (0/42).¹⁰ Ahn et al reported a study focusing on laparoscopic URY reconstruction (n=22) and concluded that the average time of reconstruction was 25 minutes without postoperative complications.¹¹ Current observational studies showed that both Roux-en-Y and URY had advantages over other methods in preventing reflux gastritis.¹² And compared with the traditional Roux-en-Y, URY could reduce the morbidity rate of RSS, but this difference was not statistically significant. Additionally, URY could also shorten the time of reconstruction and decrease bleeding during the surgery. Above all, the optimal evidence showed that URY is a procedure of the Billroth II gastrojejunostomy plus Braun anastomosis, blocking the jejunum input loop at the stump-jejunal anastomosis, preventing bile and pancreatic juice through the stomach-jejunum anastomotic jejunum into the residual stomach. Meanwhile, the noncut jejunum could still originate in the duodenum pacemaker impulse conduction. In addition, the procedure of URY is treated as a safe and reliable method, and it could play a role in the alternatives of digestive tract reconstruction.

Methods and analysis

This is a prospective, multicenter, two-arm randomized controlled trial (RCT) in which 210 patients will be randomly assigned by computer to two groups. The experimental group

will receive laparoscopic URY. The control group will receive laparoscopic BB.

The trial will assess the efficacy and safety of URY. The rate of RSS and recanalization for patients undergoing totally laparoscopic URY was also calculated. Before starting the trial, the sample size will be calculated based upon previously published studies about laparoscopic radical gastrectomy, as well as the data and safety monitoring board. A complete checklist of items according to Standardized Protocol Items: Recommendations for Intervention Trials (2013)¹³ is provided.

Participant selection

Patients diagnosed with gastric cancer and undergoing totally laparoscopic radical gastrectomy from the five hospitals listed in Table 1 will be recruited. In total, 210 eligible patients will be identified and randomized (1:1) to the URY group and BB group.

The inclusion criteria are as follows: 1) age range, 18–75 years; 2) diagnosis of gastric cancer (cT 2–4a/uT 2–4a, N±, M0), based on the 14th edition of the Japanese Classification of Gastric Carcinoma; 3) provide informed consent; 4) no history of surgical operation of stomach; and 5) no others organ malignant tumors.

The exclusion criteria are as follows: 1) transfer to the open abdomen (>10 cm); 2) primary tumor invaded surrounding organs; 3) emergency surgery; 4) gastric surgery in 30 days (endoscopic submucosal dissection [ESD]/endoscopic mucosal resection [EMR]) and a history of gastric surgery and gastrointestinal anastomosis; 5) NRS2002 score >5, and/or albumin <30 g/L; 6) have other medical diseases, such as severe systemic inflammatory disease, diabetes, or chronic lung diseases; 7) participating in other ongoing clinical trials and/or still in periods of follow-ups of other clinical trials; 8) receiving preoperative neoadjuvant chemoradiotherapy; and 9) others

reasons, such as serious mental illness, unable to communicate and unable to complete Patient Report Outcomes (PRO), etc.

Treatment protocols

This is a prospective, multicenter, two-arm RCT in which 210 patients will be randomly assigned to two groups. Patients in the experimental group will undergo laparoscopic URY, and patients in the control group will undergo laparoscopic BB. Participants in both groups will undergo similar perioperative interventions such as Enhanced Recovery After Surgery (ERAS) strategies. All study data will be recorded in an electronic database.

Follow-up

An outpatient follow-up plan will be carried out 3 and 6 months after the operation. To avoid influences from the clinicians, randomized generated process will be performed in the operation room by independent nurses who are not involved in the study before gastrointestinal anastomosis. We still consider that the participants cannot be blinded to the intervention as well as the clinicians responsible for patient care. Only data collection and analysis will be blinded. Figure 1 shows the trial flow chart.

Perioperative managements

Before surgery, gastroscopies, endoscopic biopsies, and computed tomography scans will be performed to confirm the tumor size and location, and patients with organic metastases will be excluded based on assessment by two experienced pathologists.

After surgery, the ERAS guidelines will be followed and all participants will receive preoperative education, pre-emptive and multimodal analgesia, early ambulation, and laparoscopic radical gastrectomy as part of the perioperative treatment. Briefly, during the postoperative period, fluid

Table 1 Five experienced surgical teams

Number	Center	Institute and department	Role
01	Xijing Hospital, The Fourth Military Medical University	Xijing Hospital of Digestive Disease	Management
02	Henan Cancer Hospital & Zhengzhou University Cancer Hospital, Zhengzhou University	Department of Gastrointestinal Surgery	Participant
03	The Second Hospital of Lanzhou University, Lanzhou University	Department of Minimally Invasive Surgery	Participant
04	The First Affiliated Hospital of Xinjiang Medical University, Xinjiang Medical University	Department of Gastrointestinal Surgery	Participant
05	Affiliated Hospital of Qinghai University, Qinghai University	Department of Gastrointestinal Surgery	Participant

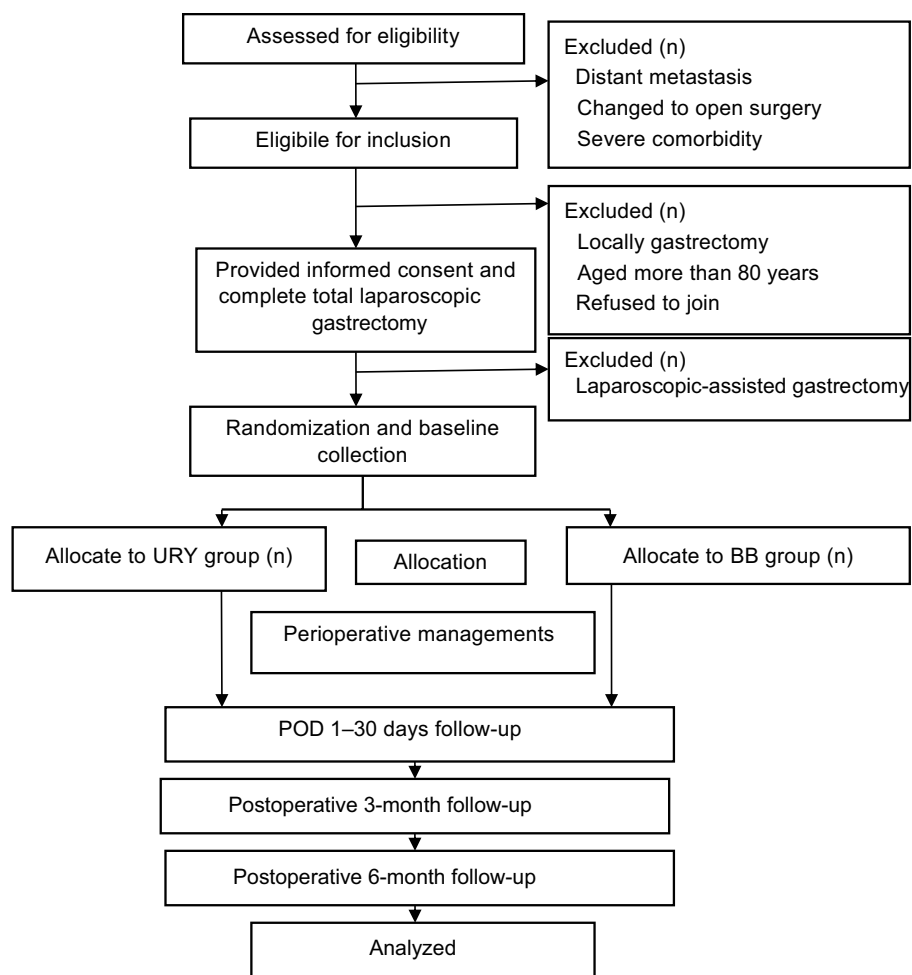


Figure 1 The trial flow chart.

Abbreviations: BB, Billroth II plus Braun anastomosis; POD, postoperative day; URY, uncut Roux-en-Y.

intake was from postoperative day (POD) 1 or 2, patients were advised to begin cautiously and increase intake according to tolerance. Furthermore, they were encouraged to take full semiliquid diet on POD 2 and normal food as soon as possible after surgery. If a patient is completely intolerant, the operators will decide whether early oral intake insist or not, and also the conventional way, including postoperative restricted oral intake, are considered to meet daily targets for mobilization. Furthermore, a nutritionist supervised the oral feeding during the trial using the diet principle of smaller and more frequent intake according to individual tolerance. Adequate caloric intake will be calculated using the Harris-Benedict formula (25–35 kcal/kg/day). An investigator will be assigned to record the clinical observation data. Urinary bladder drainage was routinely used.

Intervention protocols

Laparoscopic radical gastrectomies will be performed by experienced surgical teams from the five centers listed in

Table 1, all of which have carried out this procedure with an annual caseload of ~100 gastric patients. The lymphadenectomy and main anastomosis will be completed laparoscopically, and the abdominal incision will be defined <10 cm. In terms of Billroth II procedure with Braun anastomosis in this protocol, first, a stomach–jejunum anastomosis is conducted from the Treitz ligament to the distal jejunum (25 cm), then the Braun anastomosis is performed in the input and output loop, which are generally 15 and 25 cm from the anastomosis of the jejunum, respectively. URY gastrojejunostomy is a modification of the Billroth II procedure with Braun anastomosis, which could be defined as an additional procedure of a nondiscrete closed jejunum at the input pouch from the gastrointestinal anastomosis (5 cm). All procedures will be completed laparoscopically except Braun anastomosis, which is decided by different surgeons following their own preference (linear stapler laparoscopically or manual anastomosis through small incision), and Figure 2 illustrates URY gastrojejunostomy after distal gastrectomy.

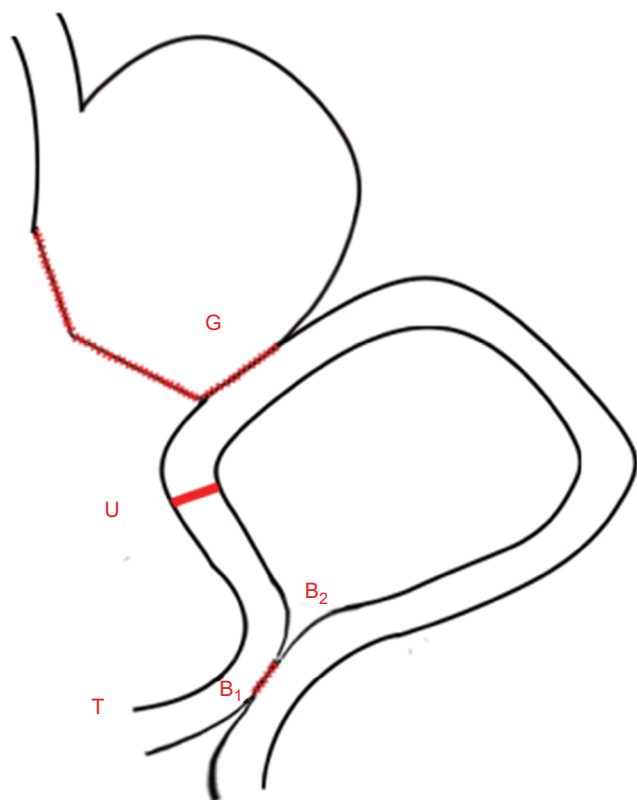


Figure 2 Uncut Roux-en-Y gastrojejunostomy after distal gastrectomy.
Notes: G means gastrojejunostomy site; B means Braun anastomosis site; T means Treitz ligament. Distance between T and G is 25 cm; distance between T and B₁ is 10 cm and between B₁ and B₂ is more than 1.5 cm; distance between U and G is 5 cm; distance between G and B (B₁ and B₂) is 25 cm.

Data collection/table schedule

Once informed consent is signed, baseline data, such as age, gender, body mass index, and complications, will be collected by a clinical research assistant. The laboratory data (pH of gastric acid after POD1–3, total serum protein, serum albumin, and blood glucose) will also be tested preoperatively and during hospitalization to monitor the patients' nutritional status. A specified operator recorded the details of surgical procedures, such as operative approach, the location of tumor, lymph node metastasis, and pathological TNM stage.

From POD1–6, clinical observation data (anastomotic leakage, the time of first flatus and defecation, postoperative hospital stay, complications, etc) will also be recorded daily by an investigator to evaluate the postoperative recovery. The clinicians will be responsible for patient care and will not be involved in data collection. The criteria for discharge are as follows: tolerance of solid diet, return of bowel habits, and ability to walk on their own. Also, the contact information and address of each patient will be confirmed before their hospital discharge. Two follow-up visits will be carried out in the outpatient clinic or via telephone 3 and 6 months after

discharge. These visits will focus on tolerance of the diet and any discomfort. The details of the time schedule are shown in Table 2.

Statistical analysis

The intention-to-treat principle will be applied in all analyses with an assumed drop-out rate. Normally distributed continuous variables will be described as the mean with corresponding SDs, and nonnormally distributed or categorical variables will be described as medians with the corresponding range or percentages and frequencies. Normally or nonnormally distributed continuous data will be compared by Student's *t*-test or the Mann–Whitney *U*-test, and the chi-squared test and Fisher's exact test will be used to compare categorical variables. With the exception of the primary outcome, secondary outcomes such as reflux gastritis, postoperative complications, time of first flatus and defecation, and postoperative length of stay will also be compared. Measurement data are expressed as mean \pm SD. The data will be analyzed using the independent Student's *t*-test, whereas categorical data will be calculated using the chi-squared test or Fisher's exact test. Data analysis will be performed using SPSS® software package version 22.0 (SPSS Inc., Chicago, IL, USA). $P < 0.05$ is considered statistically significant.

Study endpoints

The primary outcome is the rate of alkaline reflux after laparoscopic radical gastrectomy, which will include two items: subjective items and objective items. One objective item is the pH of postoperative gastric acid (>5 mL), which will be tested randomly three times after POD1–3 and will also be assessed through gastroscopies and upper gastrointestinal radiography after 3 and 6 months. Subjective items are those included on the PRO.¹⁴ Total scores of each symptom plus the frequency and the evaluated scales are shown in Table 3. And the guidelines of alkaline reflux or reflux gastritis assessed through gastroscopies are shown in Table 4.

The secondary outcomes are reconstruction time (minutes), blood loss (mL), RSS (%), blocking recanalization (%), first postoperative ventilation time (minutes), postoperative complications at 30 days per the Clavien Dindo classification, and the length of the postoperative hospital stay (days).

Sample size estimate

Previous studies reported the rate of reflux gastritis is 43.3%–67.7%,¹⁵ and basing upon this rate, we make the hypothesis of 45% in the control group (BB procedure – 45%). The parameters were designed to a noninferiority test

Table 2 The details of the time schedule

Outcomes	POD0	POD1	POD2	POD3	3 months	6 months
Reflux gastritis (%)*	Randomly select gastric acid (>5 mL) three times and test their pH after POD1–3 & Patient Report Outcomes (PRO)				Gastrosopies/ upper gastrointestinal radiography	
Reconstruction time (minutes)	※	–	–	–	–	–
Blood Loss (mL)	※	–	–	–	–	–
RSS (%)	※PRO	※PRO	※PRO	※PRO	Gastrosopies/ upper gastrointestinal radiography	
Blocking recanalization (%)	–	–	–	–	Gastrosopies/ upper gastrointestinal radiography	
First postoperative ventilation time (minutes)	※	※	※	※	–	–
Postoperative complications (n)	※	※	※	※	Till postoperative 1 month	
Postoperative hospital stay (d)	※	※	※	※	Till postoperative hospital stay	

Notes: *Primary outcomes. ※Needing to conduct at this time point. _No need to conduct at this time point.

Abbreviations: POD, postoperative day; RSS, Roux-en-Y stasis syndrome.

Table 3 The evaluated scales and frequency of Patients Report Outcomes (PRO)

	Epigastric pain	Heartburn	Biliary vomiting	Postprandial bloating	Nausea
Symptom					
No symptom (0 score)					
Very light (1 score)					
Mild symptoms ^a (2 score)					
Moderate symptoms ^b (3 score)					
Severe symptoms ^c (4 score)					
Very severe symptoms (5 score)					
Total					
Frequency					
No symptom (0 score)					
1–3 times/month (1 score)					
1 time/week (2 score)					
2–3 times/week (3 score)					
1 time/day (4 score)					
>1 time/day (5 score)					
Total					

Notes: ^aNoticed only when the doctor reminds. ^bDo not affect daily life. ^cCan affect normal life.

Table 4 The guidelines of reflux gastritis assessed through gastroscopies

<p>Bile reflux gastritis according to endoscopic findings, mucus lake, gastric mucosal hyperemia, edema degree.</p> <p>According to the grading score:</p> <p>0 points, the normal gastric mucosa</p> <p>1 point, mild</p> <p>2 points, moderate</p> <p>3 points, severe</p> <p>Mild: defined as mucus lake is pale yellow, mucous membrane surface yellow green foam, mucous membrane hyperemia.</p> <p>Medium: defined as mucous is yellow green, mucous membrane congestion, fold edema, yellow bile mucous membrane surface.</p> <p>Severe: defined as mucous yellow and mucous membranes are covered with greenish yellow bile, with bile secretion constantly flowing from the output loop. Diffuse hyperemia and edema of mucosa.</p>

with a noninferiority margin of 20% ($\alpha=0.05$, $\beta=0.20$, and a power of 80%). Considering both clinical and statistical considerations, no less than 172 participants (86 participants in each group) will be needed. Allowing for a 20% drop-out, a total of 210 participants (105 participants in each group) will be recruited.

Strengths and limitations of this study

The feasibility of URY has not been established in prospective randomized studies. This trial will be the first RCT to assess URY for patients with advanced gastric cancers suffering from totally laparoscopic radical distal gastrectomy.

The primary outcome is the rate of reflux gastritis after totally laparoscopic radical gastrectomy, which will include two items: subjective items and objective items. One objective item is the pH of postoperative gastric acid (>5 mL), which will be tested randomly three times after POD 1–3, and specifically, PRO will be recorded of subjective items.

One limitation is that a minority of patients may have no gastric fluid in their nasogastric tube and therefore could not be tested for postoperative gastric acid.

Another limitation is that this study only assessed the feasibility of URY and BB in patients undergoing laparoscopic radical distal gastrectomy; it did not compare uncut URY with traditional Roux-en-Y, which should be assessed in further studies.

Ethics and dissemination

Ethics approval has been sought from the Ethics Committee at the First Affiliated Hospital (Xijing Hospital) of Fourth Military Medical University (KY20172001-1). Before allowing participation in the study, written informed consent is obtained from each participant and their guardians, primary caregivers, and research assistants. The results of this study will be disseminated at several research conferences and as published articles in peer-reviewed journals. The present study protocol was prepared in accordance of the Standardized Protocol Items: Recommendations for Intervention Trials statement. This trial has been registered at Chinese Clinical Trial Registry: ChiCTR-INR-17010594 (registration date: 9 February, 2017).

Ethical clearance has been obtained from Ethics Committee at the First Affiliated Hospital (Xijing Hospital) of Fourth Military Medical University (KY20172001-1) and was obtained similarly at the others centers as needed. Written informed consent was obtained from the patient before screening. The results of this study will be disseminated at several research conferences and as published articles in peer-reviewed journals.

Trial status

The enrollment of this study is ongoing at the time of manuscript submission.

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Author contributions

GJ, YF, CW, WBZ, SY, and SQJ, as the main surgeon, performed each operation in each center. QW, KLY, QRN, JY, DZ, QM, and QYW were the main investigators and data recorders. KLY, QRN, and JY tested the feasibility of the study. QW, KLY and GJ wrote the manuscript. All authors approved the final version of the manuscript. All authors contributed to the research protocol design, drafting and revising the protocol, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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