Tunnel anastomosis versus double tract jejunal interposition reconstruction after proximal gastrectomy: Study protocol of a multicenter prospective randomized controlled trial

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Abstract

Background: Tunnel anastomosis is a novel anastomotic technique for digestive tract reconstruction following proximal gastrectomy. Our previous retrospective study demonstrated its favorable antireflux effect. In this study, we will prospectively compare this technique with the currently more prevalent double tract jejunal interposition reconstruction technique to further validate its safety and efficacy.

Methods and analysis: This is a multicenter, prospective, randomized controlled study that will randomly enroll 240 patients who undergo proximal gastrectomy. The study will be divided into two groups: the tunnel anastomosis (TA) group and the double tract jejunal interposition reconstruction (DTJIR) group, with 120 patients in each group. Patients will undergo clinical assessments and complete questionnaires preoperatively, as well as at the 3rd, 6th, and 12th months postoperatively. The primary outcome is the incidence of reflux esophagitis. The secondary outcomes includ perioperative safety, postoperative quality of life, and postoperative nutritional status.

Discussion: To our knowledge, this is the first prospective study on this technique, aiming to provide novel insights into the methods of digestive reconstruction following proximal gastrectomy.

Trial registration number: The trial was registered on March 11th 2022 with registration number ChiCTR2200057397.

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Original Manuscript

Tunnel anastomosis versus double tract jejunal interposition reconstruction after proximal gastrectomy: Study protocol of a multicenter prospective randomized controlled trial

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Abstract

Background: Tunnel anastomosis is a novel anastomotic technique for digestive tract reconstruction following proximal gastrectomy. Our previous retrospective study demonstrated its favorable antireflux effect.

In this study, we will prospectively compare this technique with the currently more prevalent double tract jejunal interposition reconstruction technique to further validate its safety and efficacy.

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Keywords: Gastric cancer, Proximal gastrectomy, Tunnel anastomosis, Double tract jejunal interposition reconstruction, Antireflux

Background

Gastric cancer is a type of cancer with high morbidity and mortality in China, and the incidence of proximal gastric cancer (PGC) is currently increasing.[1-3] Surgical treatment for PGC involves either total gastrectomy or proximal gastrectomy. Researches have shown that proximal gastrectomy has the same therapeutic potential and efficacy as total gastrectomy, with advantages in terms of postoperative weight loss, dumping syndrome, anemia and nutritional supplementation.[4-10] However, the issue of reflux esophagitis following proximal gastrectomy remains a significant challenge for surgeons.[11] Numerous studies have been conducted on antireflux reconstructive techniques for digestive reconstruction, including double tract jejunal interposition reconstruction (DTJIR) and the double flap technique (Kamikawa anastomosis), which have exhibited promising antireflux effects. Nevertheless, there is still no consensus on which reconstruction method should be considered the standard.[12-17]

Tunnel anastomosis (TA) is a novel technique for digestive tract reconstruction following proximal gastrectomy. Owing to its preservation of an intact muscular flap, it ensures superior blood supply to the

anastomotic site. Our previous study demonstrated that the antireflux effects of this technique are favorable. [18] DTJIR is currently the mainstream method for digestive tract reconstruction following proximal gastrectomy and is widely recognized by most experts.[19] The incidence of postoperative reflux esophagitis following this procedure is approximately 10%. Therefore, we select this group as the control group to further validate the effectiveness of TA.

The objective of this study is to further validate the surgical safety and antireflux effect of tunnel anastomosis and to assess the efficacy and advantages of this technique in improving the quality of life of patients following proximal gastrectomy. It is hoped that this research will contribute to enhancing the theoretical and clinical practice foundations for refining surgical treatment strategies for upper gastric cancer.

Materials and methods

Study Design and Participants

This multicenter, prospective study will be conducted at the Affiliated Cancer Hospital of Nanjing Medical University, the First Affiliated Hospital of Nanjing Medical University, the Nanjing University Medical School Affiliated Drum Tower Hospital, the First Affiliated Hospital of Soochow University, the Affiliated Hospital of Nanjing University of Chinese Medicine, and the Jiangsu University Affiliated Gaochun Hospital and has received ethical approval from the Affiliated Cancer Hospital of Nanjing Medical University(2021-091-01). All patients will be fully informed of the precautions by a professional physician and provided with a written informed consent form before participation. The following diagram illustrates the flow of the study (Figure 1).

The inclusion criteria for this study are as follows: (1) age range: 18--80 years, with no sex preference; (2) histopathological confirmation of adenocarcinoma via endoscopic biopsy; (3) tumor characteristics: located in the upper one-third of the stomach, without esophageal involvement; longest diameter ≤ 4 cm; preoperative clinical stage cT1--4aN0M0; (4) ECOG PS score: 0--1; (5) no surgical contraindications identified through comprehensive preoperative evaluations; and (6) voluntary and informed consent signed by the patient or their legal representative. The exclusion criteria are as follows: (1) pregnant or lactating women; (2) the presence of severe psychiatric disorders; (3) intraoperative findings indicating tumor invasion into the esophagus or unsuitability for proximal gastrectomy as determined by the primary surgeon; (4) preoperative or intraoperative discovery of distant organ metastasis or extensive peritoneal implantation metastasis; (5) the presence of concurrent or metachronous malignancies, including other organ tumors; (6) incomplete radical

surgery, including patients who underwent palliative tumor resection; (7) a history of prior gastrointestinal surgery; (8) a history of neoadjuvant radiotherapy or chemotherapy; (9) serious concomitant diseases that may make the survival period<5 years; and (10) cases considered unsuitable by the investigator.

Confidentiality

All research information will be kept strictly at the study site. This information will not be published outside the research without the consent of the patients.

Postrecruitment withdrawals and exclusions

Patients can withdraw from this study at any time. For patients who withdraw, the information collected prior to withdrawal will be used for the final analysis unless they request that their information be deleted.

Randomization

In accordance with the aforementioned criteria, eligible patients will be randomly assigned to one of the following two groups at a 1:1 ratio: the TA group or the DTJIR group. The randomization process will utilize a stratified block randomization method, with disease stage (categorized as early stage or advanced stage) serving as the stratification factor. Patient group assignment will be determined on the basis of random numbers generated by the R 4.0.2 software program.

Surgical Procedure

Both groups will undergo proximal gastrectomy with radical lymph node dissection (open/laparoscopic/robot-assisted). cT1N0 patients undergo D1+ lymph node dissection (No. 1, 2, 3a, 4 sa, 4 sb, 7, 8a, 9, 11p), whereas the remaining patients undergo D2 lymph node dissection (D1+ and 11d). All surgeries will be performed by experienced surgeons.

Anastomosis technique

Tunnel anastomosis: (1) A linear cutting stapler is used to transect the esophagus and create a gastric tube. (2) A 3 cm transverse incision is made in the anterior wall of the remnant stomach, approximately 3–4 cm from the upper edge between the greater and lesser curvatures, reaching but not incising the muscular layer. (3)

Another parallel incision of equal length 3.5 cm distal to the first incision was made. (4) Between these two incisions, dissect the connective tissue between the submucosa and muscular layers via an electrosurgical knife, creating a tunnel flap of approximately 3 cm × 3.5 cm. (5) The posterior wall of the esophagus, located 5 cm from the residual stump, is sutured with 4 stitches to the gastric wall at the upper edge of the seromuscular flap. (6) The esophageal stump is then pulled through the tunnel, and the anterior wall of the esophagus is sutured with 4 to 5 stitches to the upper edge of the gastric seromuscular flap. (7) The submucosa and mucosal layers of the stomach are incised at the lower incision of the tunnel to prepare for anastomosis with a caliber of 3cm. (8) The esophageal stump is then opened with an ultrasonic knife, and the posterior wall of the esophagus is sutured to the gastric mucosa and submucosa. (9) The anterior wall of the esophagus was sutured to the full layer of the stomach. (10) The lower edge of the seromuscular flap and the seromuscular layer of the remnant stomach were sutured. (Figure 2)[18]

DTJIR: (1) Mesenteric vessels are ligated 15–20 cm from the Treitz ligament. (2) The distal jejunum is pulled anterior to the transverse colon and anastomosed with the esophagus. (3) Approximately 10–15 cm below the esophagojejunal anastomosis, the distal jejunum is anastomosed with the residual stomach. A 6 cm linear stapler is used to create an anastomosis with a size of 4 cm. (4) Subsequently, at 30–35 cm from the gastrojejunal anastomosis, a second anastomosis is performed between the proximal and distal jejunum.

Follow-Up

All patients will undergo follow-up visits at 3 months, 6 months and 1 year postoperatively. At these visits, hematological examinations and postoperative quality of life assessments (using the QLQ-C30 scales and Short Form 36 Health Survey) will be performed. Nutritional status will be assessed on the basis of hematological test results, changes in body weight and the prognostic nutritional index (PNI). At the 1-year follow-up, gastroscopy will be performed to assess reflux esophagitis according to the LA classification. In addition, reflux symptoms will be assessed via the Visick score.

Assessment of Outcomes

Primary Endpoints

The primary endpoint is the incidence of reflux esophagitis, which is determined by gastroscopy results

one year postoperatively. To determine the severity of reflux esophagitis, the modified Los Angeles (LA) classification system for reflux esophagitis will be employed，which is considered as a reliable method for categorizing reflux esophagitis. The modified LA classification criteria are as follows: Grade N: Normal mucosa. Grade M: Minimal changes to the mucosa such as erythema and/or whitish turbidity. Grade A: Non-confluent mucosal breaks < 5mm in length. Grade B: Non-confluent mucosal breaks > 5mm in length. Grade C: Confluent mucosal breaks < 75% circumferential. Grade D: Confluent mucosal breaks > 75% circumferential. [20]

Secondary Endpoints

The secondary study endpoints include perioperative safety, postoperative nutritional status, and postoperative quality of life.

Perioperative safety primarily encompasses the duration of surgery, amount of intraoperative blood loss, and postoperative complication status. Nutritional status and quality of life following surgery will be assessed at the 3rd, 6th, and 12th postoperative months. Postoperative nutritional status will be determined on the basis of changes in patient weight, hemoglobin levels, total protein levels, albumin levels, total lymphocyte count, and the PNI. Additionally, patients' quality of life will be evaluated via the QLQ-C30 scale, daily food intake frequency. The Visick score will be used for assessing patients' symptoms and quality of life (Grade I: Patients are asymptomatic or have only mild symptoms that do not significantly affect their quality of life. Surgical outcomes are considered excellent. Grade II: Patients experience mild symptoms that have minimal impact on their daily activities. Overall, patients are satisfied with the surgical outcome. Grade III: Patients have moderate to severe symptoms that affect their daily lives. These symptoms may require medical treatment or lifestyle modifications. The surgical outcome is considered less favorable. Grade IV: Patients have severe symptoms that significantly impact their quality of life. The surgical procedure has failed to achieve the desired outcome. Further surgical intervention or other treatments may be necessary.).[21]

Power and sample size

This study is designed as a prospective, randomized controlled trial with a noninferiority objective. It comprises two groups: the experimental group (TA Group) and the control group (DTJIR Group).

On the basis of previous literature reports and retrospective data analysis results from our center, the

estimated incidence of reflux esophagitis was 10% in the DTJIR group and 5% in the TA group. With a significance level set at α = 0.025 (one-sided), a power of 1-β = 0.80, a noninferiority margin of 0.05Based on the incidence of reflux esophagitis among several commonly used digestive tract reconstruction surgeries [22-24] and clinical experience, a 1:1 ratio between the experimental and control groups, and an anticipated dropout rate of 10%, the sample size was calculated via PASS software. The resulting sample sizes for both groups were 120 patients each.

Therefore, a total of 240 patients will be included in this study, with 120 patients in the experimental group and 120 patients in the control group.

Statistical analysis

In addition to the overall comparative analysis conducted between the TA and DTJIR groups, we will further perform subgroup analyses stratified by disease stage and surgical approach.

For continuous variables, a normality test should be performed first. For those that conformed to a normal distribution, the t test will be employed for statistical analysis (all continuous values are expressed as the mean ± standard deviation). Those not conforming to a normal distribution are presented as quartiles and rank means, and the Mann–Whitney U test will be used to calculate the P value to compare differences between groups. For categorical variables, the $\chi 2$ test will be used for statistical analysis. All P values calculated in the analysis are 2-sided, and $P < 0.05$ is considered statistically significant. Statistical analyses will be performed via SPSS/Graphpad/PASS.

Discussion

Proximal gastrectomy is gaining increasing acceptance among the medical community due to its advantages in postoperative nutrition.[25] However, for patients undergoing proximal gastrectomy, postoperative gastrointestinal reflux is a significant issue. Various anastomotic techniques have been investigated in an attempt to address this problem, yet a standard approach remains elusive.[24] In pursuit of a superior method for digestive tract reconstruction, we modified the Kamikawa anastomosis to develop the tunnel anastomosis and conducted a retrospective study.[15, 18] To further validate the antireflux effect of this technique, we conduct this prospective study with the aim of providing a novel reference for digestive tract reconstruction following proximal gastrectomy. To our knowledge, this is the first prospective study on this

technique.

It is not possible to blind patients, surgeons, radiologists or clinical assessors in this trial. Both the doctors and patients have a clear understanding of the surgical procedure that will be performed. However, as a prospective study, it has the capacity to mitigate the impact of such bias on the results.

Abbreviations

TA: tunnel anastomosis; DTJIR: double tract jejunal interposition reconstruction; PGC: proximal gastric cancer; PNI: prognostic nutritional index.

Declarations

Ethics approval and consent to participate

This study has been approved by the Ethics Committee of the Affiliated Cancer Hospital of Nanjing Medical University (2021-091-01). All patients will be fully informed of the precautions by a professional physician and provided with a written informed consent form before participation.

Consent for publication

Not applicable

Availability of data and materials

The research results will be published in a peer-reviewed journal. Study protocol is available at the website of the Chinese Clinical Trail Registry (www.chictr.org.cn). Data generated or analysed during the current study will be available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Author Contributions

Gang Li, Chao Yue and Rui Peng were primarily responsible for the study design. Gang Li designed the Tunnel anastomosis technique. Qing-Yu Xie and Rui Peng drafted and revised the manuscript. Xiao-Xiao Wang and Rui Peng were responsible for the sample size calculation and randomization. Gang Li, Hao Xu, Meng Wang, Jin Zhou, Xiao-Yu Wu and Xiao-Hua Zhou were responsible for the administrative oversight of respective centers. Qing-Yu Xie, Rui Peng, Chao Yue, Wei Wei, Ling-Li Huang, Hai-Tian Wang, Liang Chen, Rong-Min Gu, Huan-Qiu Chen, Xue-Zhi Ming, Xu Wen, Wei-Guo Xu, Guang-Li Sun, Hao Fan, Zhe Wang, Long-Hao Yang, Xiao-Hua Zhou, Xiao-Yu Wu, Jin Zhou, Meng Wang, Hao Xu and Gang Li were actively involved in the execution of the research, data collection, analysis, and interpretation. All the authors critically reviewed the manuscript, provided final approval of the version to be published and reached a consensus on the journal for submission.

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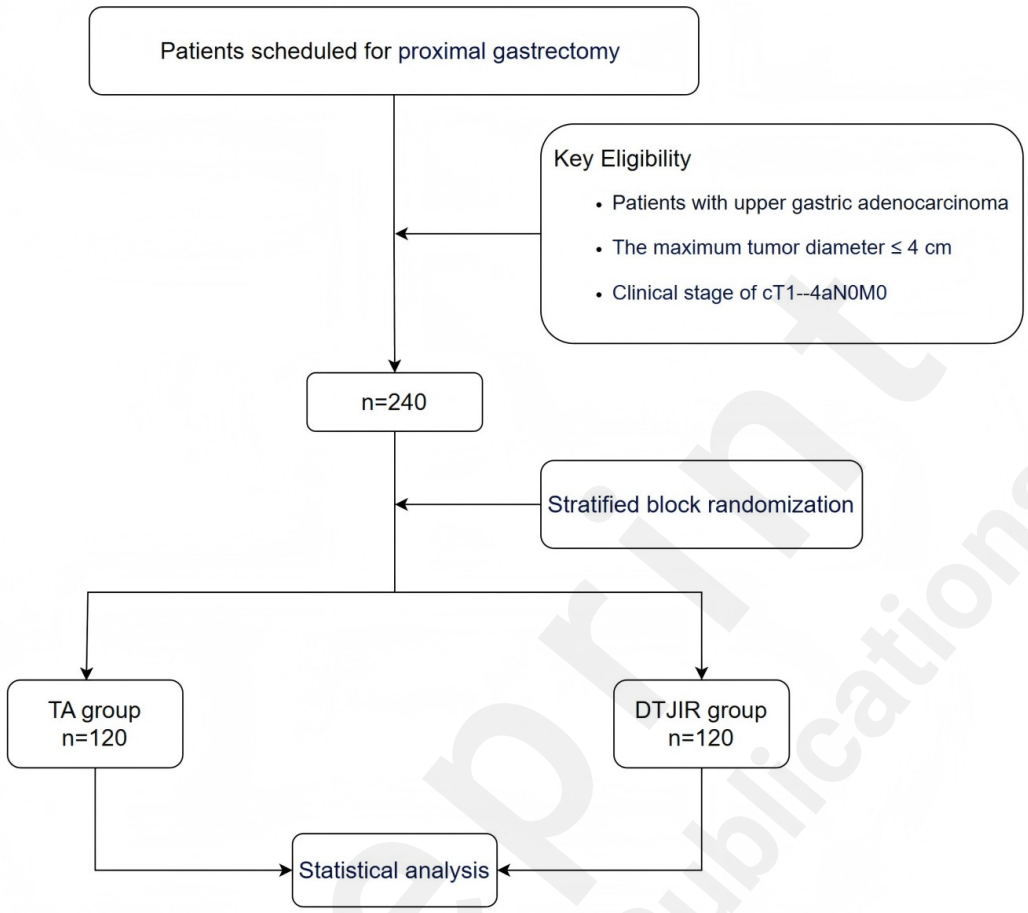


Figure 1. Study flow diagram for the study

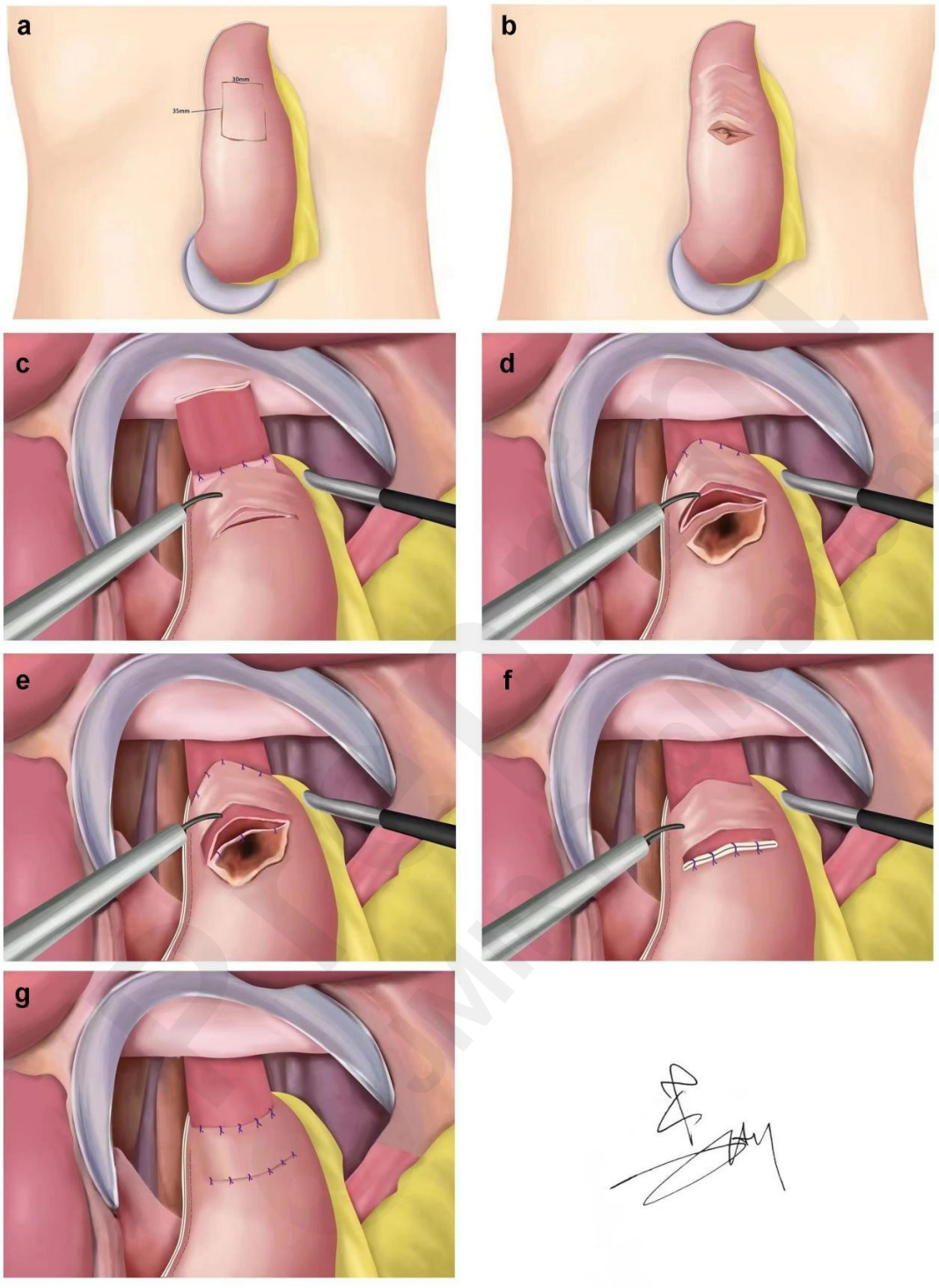
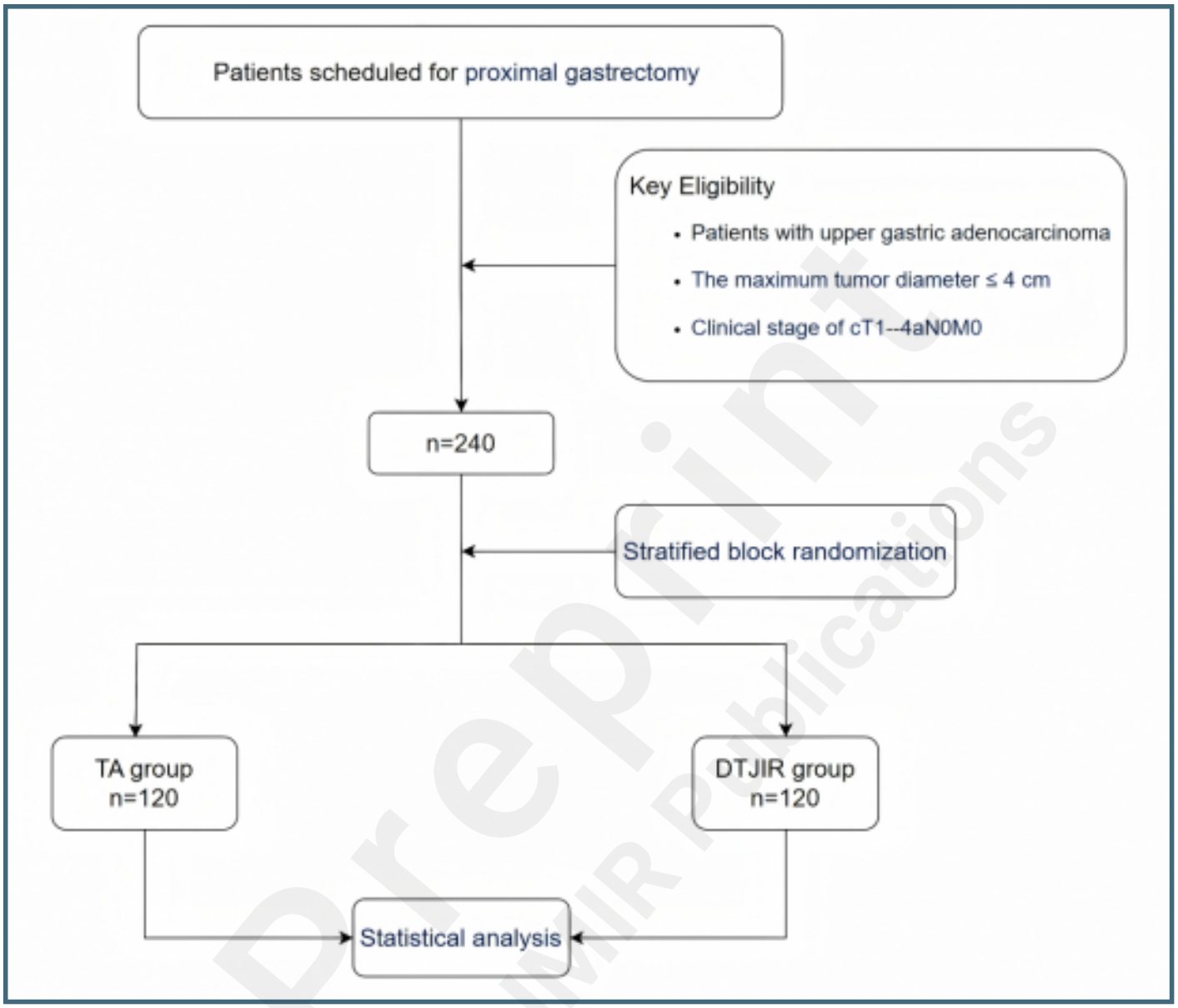


Figure 2. Surgical steps for tunnel anastomosis

Supplementary Files

Figures

Study flow diagram for the study.



Surgical steps for tunnel anastomosis.