MEDICAL SCIENCE MONITOR

CLINICAL RESEARCH

e-ISSN 1643-3750
© Med Sci Monit, 2023; 29: e938759
DOI: 10.12659/MSM.938759

Received: 2022.10.25
Accepted: 2022.11.14
Available online: 2023.01.11
Published: 2023.01.26

Comparison of Postoperative Outcomes of Hand-Sewn Versus Stapled Esophago-jejunal Anastomosis During Total Gastrectomy for Gastric Cancer in 72 Patients: A Retrospective, Single-Center Study in Poland

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABCDEF 1 Karolina Majewska
ABCDEF 1 Patryk Zemła
ACDEF 2 Beata Jabłońska
ADE 2 Sławomir Mrowiec

1 Student Scientific Society, Department of Digestive Tract Surgery, Medical University of Silesia, Katowice, Poland
2 Department of Digestive Tract Surgery, Medical University of Silesia, Katowice, Poland

Corresponding Author: Karolina Majewska, e-mail: majewskakarolina1008@gmail.com
Financial support: None declared
Conflict of interest: None declared

Background: Mechanical stapling is a commonly used alternative to hand-sewn technique for esophago-jejunal anastomosis in total gastrectomy (TG). Some studies report reduction in postoperative complications in the stapler group. This retrospective study aimed to compare short- and long-term surgical outcomes between the groups with stapled and hand-sewn esophago-jejunal anastomosis (EJA) during open TG for gastric cancer.

Material/Methods: The study included 72 adult patients with gastric cancer who underwent TG in the Department of Digestive Tract Surgery in Katowice between May 2018 and December 2021. The patients were divided into 2 groups according to the technique of EJA: stapled (44 cases) or hand-sewn (28 cases). We compared the groups in terms of the duration of the surgery, length of hospital stay, and occurrence of complications (focusing on anastomotic leakage, stricture and abdominal abscess).

Results: There were no significant differences in duration of the surgery (P=0.6), blood loss (P=0.7), or length of postoperative hospital stay (P=0.2) among the groups. Early postoperative complications rates were 9.1% (4/44) in the stapler group and 17.9% (5/28) in the hand-sewn group (P=0.27). The most frequent complication was anastomotic leakage, with 2 cases in each group (P=0.76). The mean follow-up time was 1.8±0.9 (0.3-3.6) years. During this period the anastomotic stricture occurred in 7 (15.9%) cases with stapled anastomosis and in 5 (17.9%) cases with hand-sewn anastomosis (P=0.52).

Conclusions: In this study there were no significant differences in mortality, morbidity, and surgery duration between stapled and hand-sewn esophago-jejunal anastomosis in total gastrectomy.

Keywords: Anastomosis, Surgical • Gastrectomy • Morbidity • Mortality • Retrospective Studies • Stomach Neoplasms

Full-text PDF: https://www.medscimonit.com/abstract/index/idArt/938759

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Background

The open total gastrectomy (TG) is one of the methods of curative treatment for advanced gastric cancer [1]. It is a standard procedure applied in node-positive or T2-T4a tumors, when it is essential to achieve sufficient resection margins, in case of pancreatic invasion requiring pancreaticosplenectomy, as well as in some cases of tumors located at the greater curvature of the stomach, if there is a risk of metastasis to the lymph nodes accompanying the left gastroepiploic artery [1]. Some studies reported acceptable results also for minimally invasive gastrectomy, but it is still not recommended in more advanced tumors [1-4]; therefore, open TG remains an important part of gastric cancer surgery.

Several techniques are applied for gastrointestinal tract reconstruction after TG, including jejunal interposition, double tract method, and Roux-en-Y esophago-jejunal anastomosis (EJA) [1]. Some of the most important complications after TG are those associated with EJA, including anastomotic leakage, dehiscence, bleeding, and stenosis [5]. EJA may be performed using traditional hand-sewn technique or mechanical stapling, using linear or circular devices [1]. Although stapled anastomosis is a well-described and commonly used method, there is little recent data regarding the surgical complications of open total gastrectomy with comparison of stapled and hand-sewn esophago-jejunal anastomosis [6]. Some previous studies found a reduction in duration of the surgery, along with lower incidence of anastomotic leakage and higher rate of strictures in the stapler group, while others reported no difference between these 2 techniques [7-10]. A recent meta-analysis showed that hand-sewn and stapled anastomosis have similar surgical outcomes, while staplers reduce the operative time [6], but the recent data about open TG are limited. Only 12 studies were included in the meta-analysis, with 1 recent study on open TG comprising 63 patients [11].

Therefore, this retrospective study from a single center in Poland aimed to compare postoperative outcomes from hand-sewn and stapled esophago-jejunal anastomosis during total gastrectomy in 72 patients with gastric cancer treated with total gastrectomy between May 2018 and December 2021.

Material and Methods

Ethical Statement

This was a retrospective study of patients' medical records, and all data were fully anonymized before access. Written informed consent was obtained from all participants. All procedures were in accordance with the 1964 Declaration of Helsinki on Medical Research Involving Human Subjects and its subsequent amendments or comparable ethical standards. Our retrospective analysis of patient medical records fell into the category of exempt from Institutional Review Board (IRB) approval according to local regulations [12] and according to the official response from the Ethics Committee (number: PCN/CBN/0052/KB/153/22), details of which were provided to the journal.

Background

Data from 79 consecutive patients who underwent total gastrectomy for gastric cancer at our university medical center between 2018 and 2021 were retrospectively analyzed. The following inclusion criteria were defined:

- age ≥18 years;
- preoperative computed tomography (CT) scan and gastroscopy revealed a gastric tumor and histopathological examination confirmed a gastric cancer;
- open total gastrectomy (including completion TG after previous partial resection) with esophago-jejunal anastomosis performed by a surgeon with extensive experience in gastric surgery;
- availability of medical records for the data analyzed.

The exclusion criteria were as follows:

- tumor located between 5 cm and 1 cm proximal to the anatomical cardia;
- conversion from the stapler technique to manual suturing of the esophago-jejunal anastomosis due to emergence of technical difficulties with stapler placement during surgery (remove factors that may have influenced postoperative complications);
- intraoperative complications unrelated to the anastomosis requiring a non-standardized approach (to remove factors that may have influenced postoperative complications);
- history of other neoplasms (treated with surgery, radiotherapy, chemotherapy) that were treated during the last 12 months prior to total gastrectomy (previous treatment, especially surgery, can affect the course of the procedure and the occurrence of potential postoperative complications).

After applying the above inclusion and exclusion criteria, 72 patients were eligible for the analysis.

Patients' Characteristics

Patients were treated according to the latest available European Society for Medical Oncology (ESMO) guidelines [13]. In 2022 there was a revision of ESMO guidelines with additional recommendations regarding management of gastric cancers [14]. Multidisciplinary treatment included collaboration between the surgeon, gastroenterologist, radiologist, and oncologist. Total gastrectomy was performed by experienced surgeons. Patients were divided into 2 groups according to the method of EJA:

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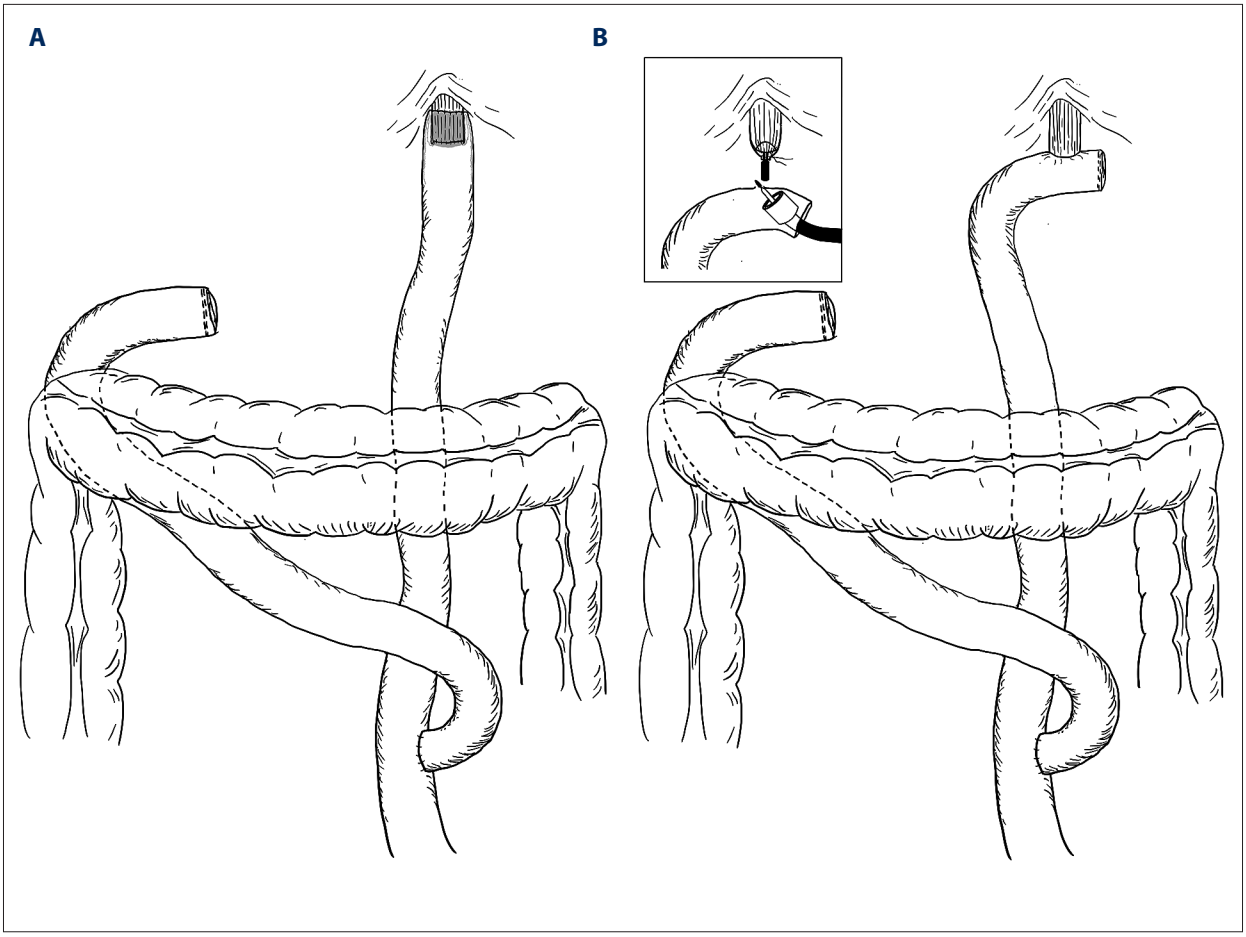

Figure 1. Schematic presentation of gastrointestinal tract reconstruction after total gastrectomy – end-to-end hand-sewn esophagojejunostomy (**A**), end-to-side circular stapled esophagojejunostomy (**B**). The figure was created by author Karolina Majewska using GoodNotes 5 application, Time Base Technology Limited, © 2011-2022 GoodNotes Limited.

(1) EJA performed using a circular stapler or (2) EJA performed with hand suturing. A significance analysis of differences in terms of preoperative, intraoperative and postoperative factors was performed between the 2 groups.

Surgical Technique

The decision about the esophago-jejunal anastomosis technique was taken intraoperatively according to surgeon preference. Esophago-jejunal anastomoses were performed by 3 different surgeons. In all patients, restoration of intestinal continuity was made without preserving duodenal passage (DP) of food performing esophagojejunostomy with Roux-Y (RY) configuration. All esophago-jejunal anastomoses were performed using a retrocolic route. The first jejunal loop was cut and the distal jejunal loop was brought up to reach the esophagus. Hand-sewn end-to-end esophago-jejunal anastomosis was performed in 2 layers of 4-0 synthetic absorbable monofilament suture (an inner layer using running suture and a second layer using single sutures) by intussusception of about 2-4 cm of the distal end of the esophagus and esophago-jejunal anastomosis into the jejunum, end-to-end (**Figure 1A**). The technique of hand-sewn EJA was designed by the surgical team of our Digestive Tract Surgery Department, and the details of the technique are available in the experimental study [15]. The first layer of sutures connected the patients' full thickness of the esophageal stump with the full thickness of the edge of the jejunal stump, and the second layer connected the esophageal tunica adventitia with the jejunal seromuscular layer. The distance between the second layer of single sutures and the ends of the esophagus and jejunum was about 4 cm, so that a jejunal cuff of 2-4 cm was created. After making the second layer of single sutures, while tying the knots, the part of the esophagus connected with the jejunal stump by the first layer of sutures was slid into the adjacent part of the jejunum, creating a jejunal cuff surrounding the esophagus edge and the EJA. For stapled end-to side esophago-jejunal anastomosis, a circular stapler-anvil method was used (**Figure 1B**) [16]. The device used for the anastomosis was the Ethicon (Johnson & Johnson) Circular Stapler – CDH25B. The anvil was introducted

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into the esophageal stump, and the purse-string suture was placed around it. The stapler was placed in the jejunal stump. The opening was made in the antimesenteric surface of the jejunum, and then the stapler was attached with the anvil. The number of staples used depended on the esophageal diameter, and number of 25 was applied. In both groups, the jejunal and duodenal stump were closed using linear stapler or hand sutures. The jejuno-jejunal end-to-side anastomosis was performed at least 50 cm distally from EJA in 1 or 2 suture layers (inner layer using running suture and second layer using additional single sutures), using hand-sewn technique (4-0 synthetic absorbable monofilament suture).

Analysis of Preoperative and Intraoperative Factors

Data collected on patients included: gender, age, body mass index (BMI), presence of comorbidities, chemotherapy before surgery, laboratory parameters – white blood cells (WBC), C-reactive protein (CRP), platelets (PLT), hemoglobin (Hb), American Society of Anesthesiologists Physical Status (ASA-PS) score, intraoperative blood loss, red blood cell concentrate supply, surgery duration, and catecholamine administration. We collected data on the prevalence of diabetes and cardiovascular diseases including hypertension, ischemic heart disease and heart failure. The frequency of respiratory diseases such as asthma or chronic obstructive pulmonary disease was also included. Given speculation that active smoking before surgery may be a cause of postoperative complications [17], regular smoking during the year preceding surgery was included in the analysis to further assess the homogeneity of the study groups.

The ASA-PS scale was used to assess the clinical status of patients before surgery [18]. The indications for blood transfusion, administration of pressor amines, and all intraoperative management were consistent with the ERAS (Enhanced Recovery After Surgery) protocol and NICE (National Institute for Health and Care Excellence) principles [19,20]. The indication for intraoperative red blood cell concentrate transfusion was hemodynamic instability. Catecholamines (norepinephrine, epinephrine, dopamine, dobutamine) were administered during surgery because of hemodynamic instability associated with a decrease in mean arterial pressure or stroke volume.

Analysis of Postoperative Complications and Follow-Up

We analyzed the length of patients' hospital stay (overall and after the surgery), the need for parenteral nutrition (along with its duration), as well as postoperative complications during hospitalization – divided as early (<30 days) and late (≥30 days). The complications were categorized using the Clavien-Dindo scale, which is a recognized scale and has been used for years to assess surgical complications [21]. The occurrence of perioperative complications was analyzed, particularly including: anastomotic leakage, abdominal bleeding, infectious complications (suppuration of the wound, abscess, sepsis), eventration, perforation, intra-abdominal fluid collection, cardiopulmonary insufficiency and the need for ICU admission (along with length of ICU stay) due to postoperative complications.

Occurrence of late postoperative complications, particularly anastomotic strictures, as well as the need for rehospitalization or reoperation, was further assessed in the collected follow-up data after the patient's discharge from the hospital.

Follow-up was conducted based on patient interviews collected between January 2022 and April 2022 (up to 4 attempted interviews at monthly intervals in case of non-response). We additionally included the information about local recurrence of the disease, metastases revealed after discharge, and overall patients' survival.

Statistical Analysis

Descriptive analysis was performed. A 95% confidence interval was used. The distribution of quantitative variables was analyzed. Variables with a normal distribution were expressed as means with their standard deviations; variables with a non-normal distribution were given as medians and their interquartile ranges (IQR). Analysis of differences between groups of patients divided according to the method of esophago-jejunal anastomosis (using stapler or manual suturing) was performed. The following factors were considered in the analysis: gender, age, BMI, comorbidities, preoperative chemotherapy, laboratory parameters, ASA-PS scale, operative time, blood loss, need for catecholamines administration and red blood cell concentrate transfusion, length of hospitalization, need for parenteral nutrition, and postoperative complications (including rehospitalizations, reoperations and death). The level of statistical significance was set at $P<0.05$. Homogeneity of variance was tested using Levene's test. Analysis of quantitative variables was performed using the *t* test (or *t* test with independent variance estimate) and Mann-Whitney U test. Analysis of nominal variables was performed using the chi-square test or Fischer's exact test when necessary. The strength of correlation was calculated using the Phi coefficient for 2x2 arrays or Cramer's V for larger arrays. Survival analysis, disease-specific survival, and disease-free survival were calculated using the Kaplan-Meier model. All calculations and statistical analysis were performed in IBM SPSS Statistics 26 (Armonk, NY, USA).

Results

Patients' Characteristics

The study group consisted of 44 males and 28 females with a mean age of 65±10 (42-85) years; 57 (79.2%) patients were

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Table 1. The general characteristics of patients.

	Hand-sewn anastomosis (n=28, 39%)	Stapled anastomosis (n=44, 61%)	P value
Age (years)	66, IQR 12 (42-85)	66, IQR 10 (43-79)	0.6
<60	6/28 (21.4%)	9/44 (20.5%)	
60-74	15/28 (53.6%)	30/44 (68.2%)	
≥75	7/28 (25%)	5/44 (11.4%)	
Male sex	14/28 (50%)	30/44 (68.2%)	0.1
BMI	27, IQR 8 (17-38)	26, IQR 5 (16-43)	0.7
Co-morbidities	20/28 (71%)	35/44 (79.5%)	0.6
Previous abdominal surgeries	11/28 (39.3%)	20/44 (45.5%)	0.6
Cigarette smoking	14/28 (50%)	19/44 (43.2%)	0.6
Preoperative chemotherapy	17/28 (61%)	31/44 (70.5%)	0.4
ASA-PS class			0.7
I	–	–	
II	9/28 (32.1%)	14/44 (31.8%)	
III	17/28 (60.7%)	26/44 (59.1%)	
IV	–	2/44 (4.5%)	
Laboratory tests results			
White blood cells (WBC)	6.4, IQR 3 (3.4-10.3)	7.3, IQR 3.1 (3.7-22.5)	0.1
Abnormal WBC (>10 000/µl)	1/28 (3.6%)	6/44 (13.7%)	
Platelets (PLT)	236, IQR 118 (114-461)	256, IQR 82 (120-432)	0.5
<150 000/µl	2/28 (7.1%)	1/44 (2.3%)	
Norm: 150 000-400 000/µl	24/28 (85.7%)	42/44 (95.5%)	
>400 000/µl	2/28 (7.1%)	1/44 (2.3%)	
Haemoglobin (Hb)	12.3, IQR 2.1 (9.8-15.9)	11.8, IQR 2.5 (9.2-15.5)	0.7
Anemia (men <13 g/dl, women <12 g/dl)	12/28 (42.9%)	23/44 (52.3%)	
C-reactive protein (CRP) ≥5 mg/dl	0	9/44 (20.5%)	0.1

n – number of patients; IQR – interquartile range; BMI – Body Mass Index; ASA-PS – American Society of Anesthesiologists Physical Status.

older than 59 years and 12 (16.7%) were over 74 years of age. Hand-sewn anastomosis was performed in 28 (39%) cases, while stapled anastomosis was performed in 44 (61%). All procedures were elective. According to the types and definitions of the gastric surgery provided by the Japanese Gastric Cancer Association, there were 54 (75%) standard TG, 11 (15.3%) extended TG, 5 (6.9%) palliative TG, and 2 (2.8%) completion TG [1]. The characteristics of the patients and their laboratory results are presented in **Table 1**.

Perioperative Parameters and Postoperative Complications

Perioperative parameters are shown in **Table 2**. Most patients were in ASA-PS class III (43 patients – 59.7%). Early postoperative complications occurred in 14 patients (19.4%). The most frequent complication was an esophago-jejunal anastomosis leakage – 4 patients (5.6%). The most common surgical complications were Clavien-Dindo grade IV (6 patients – 8.3%). There was 1 case of in-hospital mortality (1.4%) due

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Table 2. Perioperative parameters.

	Hand-sewn anastomosis (n=28, 39%)	Stapled anastomosis (n=44, 61%)	P value
Type of the surgery			0.7
Standard TG	23/28 (82.1%)	31/44 (70.5%)	
Extended TG	4/28 (14.3%)	7/44 (15.9%)	
Palliative TG	1/28 (3.6%)	4/44 (9.1%)	
Completion TG	–	2/44 (4.5%)	
Surgery duration	300, IQR 120 (190-421)	293, IQR 83 (195-465)	0.6
Intraoperative blood loss	200, IQR 300 (0-1400)	200, IQR 200 (0-700)	0.7
Catecholamine administration during the surgery	24/28 (85.7%)	33/44 (75%)	0.5
Red blood cell concentrate transfusion	–	2/44 (4.5%)	0.5
Parenteral nutrition	5/28 (17.9%)	5/44 (11.4%)	0.5
Duration of parenteral nutrition	10, IQR 5 (6-14)	15, IQR 13 (2-44)	0.5
Hospitalization time	11, IQR 3 (9-45)	11, IQR 5 (7-58)	0.5
Postoperative hospitalization time	9, IQR 2 (8-44)	9, IQR 3 (6-57)	0.2

n – number of patients; TG – total gastrectomy; IQR – interquartile range; Standard TG – resection of at least two-thirds of the stomach with a D2 lymph node dissection performed with curative intent; Extended TG – (1) Gastrectomy with combined resection of adjacent involved organs. (2) Gastrectomy with extended lymphadenectomy exceeding D2; Paliative TG – surgery to relieve symptoms, palliative gastrectomy or gastrojejunostomy is selected depending on the resectability of the primary tumor and/or surgical risks; Completion TG – total resection of the remnant stomach including the cardia or pylorus depending on the type of previous gastrectomy.

to the perforation of the duodenum, abscess, and subsequent sepsis. Postoperative complications are presented in **Table 3**.

Histopathological Examination

According to American Joint Committee on Cancer (AJCC) classification [22], most of the patients had cancer stage IA (12 patients – 17%), followed by IIB and IIIB (11 and 11 patients respectively – 16%, **Table 4, Figure 2**). The most uncommon was stage IV – 2 patients (3%). There were 32 patients with nodal metastases (44%) and 2 (3%) with distal metastases (**Table 4**).

Follow-Up

Mean follow-up time was 1.7±0.9 (0.4-3.7) years. During this period, anastomotic stricture occurred in 13 cases (18.1%). Median time after surgery when the stricture appeared was 3.5 months (IQR 8; range 1.5-15 months). The number of patients alive at the end of observation period (01.2022, including interviews and medical records) was 53/72 (73.6%). Twelve patients (17%) died (1 in-hospital) while 7 patients (9.7%) were lost to follow-up. The most common cause of death was cancer progression or its recurrence – 7 patients (58.3% of all deaths). Follow-up of the patients is presented in **Table 5**. Overall disease-specific survival (DSS) after 12 and 24 months was 93.8% and 86.5%, respectively. Overall disease-free survival (DFS) after 12 and 24 months was 81.9% and 73.9%, respectively. DSS and DFS for particular groups are presented in **Figures 3 and 4**, respectively.

Comparison Between Hand-Sewn and Stapled Groups

The groups were very similar to each other. There were no statistically significant differences among the patients' age, gender, BMI, comorbidities (including hypertension, non-ischemic heart disease, diabetes, asthma, and others), chemotherapy before surgery or laboratory parameters, or ASA-PS scores ($P>0.05$ for all mentioned variables, **Table 1**). Perioperative parameters such as duration of surgery, blood loss, catecholamines administration, need for red blood cell concentrate transfusion, and length of hospital stay were also not significantly different between the analyzed groups ($P>0.05$ in each case, **Table 2**). This ensured homogeneity of the studied groups and tested as many potential confounding factors as possible.

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Table 3. Early surgical complications.

Complications	Hand-sewn group	Stapler group	p
Overall number of patients with complications	6/28 (21.4%)	8/44 (18.2%)	0.48
Anastomotic leakage	2/28 (7.1%)	2/44 (4.5%)	0.8
Abdominal abscess	2/28 (3.6%)	3/44 (6.8%)	0.7
Eventeration	2/28 (7.1%)	–	0.1
Cardiopulmonary insufficiency	2/28 (7.1%)	3/44 (6.8%)	0.7
Pulmonary embolism	1/28 (3.6%)	–	0.4
Clostridium difficile infection	1/28 (3.6%)	–	0.4
Sepsis	–	1/44 (2.6%)	0.8
Intraperitoneal haemorrhage	1/28 (3.6%)	–	0.4
Intraabdominal fluid collection	1/28 (3.6%)	2/44 (4.5%)	0.7
Suppuration of a wound	–	1/44 (2.6%)	0.8
Perforation of the duodenum	1/28 (3.6%)	–	0.4
In-hospital death	1/28 (3.6%)	–	0.4
ICU admissions	3/28 (10.7%)	4/44 (9.1%)	1.0
ICU LOS	8, IQR 0	2, IQR 2.5 (1-4)	0.2
Rehospitalization	2/28 (7.1%)	1/44 (2.3%)	0.5
Reoperation	–	2/44 (4.5%)	0.1
Clavien Dindo Grade			0.9
I	–	1/44 (2.3%)	
II	1/28 (3.6%)	1/44 (2.3%)	
III	2/28 (7.1%)	2/44 (4.5%)	
IV	2/28 (7.1%)	4/44 (9.1%)	
V	1/28 (3.6%)	–	

ICU – Intensive Care Unit; LOS – length of stay; IQR – interquartile range.

Early postoperative complications rates were 18.2% (8/44) in the stapled group and 21.4% (6/28) in the hand-sewn group (p=0.48, **Table 3**). The most frequent complication was anastomotic leakage – 2 cases in the stapled group and 2 in the hand-sewn group (4.5% and 7.1%, respectively, *P*=0.76). There were 3 (11%) admissions to the ICU in the hand-sewn group and 4 (9%) in the stapled group (*P*=1.0). There were no significant differences regarding response to follow-up (88.6% response in stapled group, 77.8% in hand-sewn group; *P*=0.21) (**Table 5**). During the follow-up period, anastomotic stricture occurred in 7 (15.9%) of 44 cases with stapled anastomosis, and in 6 (21.4%) of 28 cases with hand-sewn anastomosis (*P*=0.52). There were 12 deaths (17%), 6 in each group, with no between-group differences (*P*=0.32). Disease-specific survival was similar in both groups (88.9% for hand-sewn anastomosis and 70.2% for stapled anastomosis, with no significant difference in follow-up duration; *P*=0.59) (**Figure 3**). There were no differences in disease-free survival (68.4% for hand-sewn group and 61.5% for stapled group; *P*=0.89) (**Figure 4**).

Discussion

We compared surgical outcomes of hand-sewn and circular stapled esophago-jejunal anastomosis in open total gastrectomy. The groups of patients were fairly homogenous with respect to age, laboratory parameters, cancer staging, and other potentially confounding variables. The main finding of this study is that there were no between-group differences in terms of surgery duration, LOS, and postoperative complications, with particular emphasis on anastomotic leakage, abdominal abscess, and anastomotic strictures in long-term follow-up. Additionally, during the follow-up we assessed the recurrence rate and long-term survival of patients with gastric cancer after TG, and there

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Table 4. Histopathological classification.

	Hand-sewn group	Stapler group	p
Tumor location			0.6
Between 1 cm proximal and 2 cm distal to the anatomical cardia	9/28 (32.1%)	11/44 (25%)	
More than 2 cm distal to the anatomical cardia	19/28 (67.9%)	31/44 (70.5%)	
Site of anastomosis after previous surgery	–	2/44 (4.5%)	
AJCC stage			0.3
0 (complete response)	1/28 (3.6%)	6/44 (13.6%)	
I	8/28 (28.6%)	13/44 (29.5%)	
II	7/28 (25%)	13/44 (29.5%)	
III	11/28 (39.3%)	9/44 (20.5%)	
IV	–	2/44 (4.5%)	
T stage			0.1
0	1/28 (3.6%)	5/44 (11.4%)	
Tis	–	1/44 (2.3%)	
1	9/28 (32.1%)	7/44 (15.9%)	
2	2/28 (7.1%)	10/44 (22.7%)	
3	7/28 (25%)	12/44 (27.3%)	
4	9/28 (32.1%)	8/44 (18.2%)	
N stage			1.0
0	15/28 (53.6%)	24/44 (54.5%)	
1	4/28 (14.3%)	7/44 (15.9%)	
2	4/28 (14.3%)	5/44 (11.4%)	
3	5/28 (17.9%)	7/44 (15.9%)	
M stage			0.5
0	28/28 (100%)	40/44 (90.9%)	
1	–	2/44 (4.5%)	
Tumor grade			0.1
1	–	4/44 (9.1%)	
2	16/28 (57.1%)	14/44 (31.8%)	
3	11/28 (39.3%)	17/44 (38.6%)	
Unknown	1/28 (3.6%)	9/44 (20.5%)	
Number of collected lymph nodes			0.3
<15	3/28 (10.7%)	10/44 (22.7%)	
≥15	22/28 (78.6%)	30/44 (68.2%)	

AJCC – American Joint Committee on Cancer; T stage – extent of the main (primary) tumor and any spread of cancer into nearby tissue; N stage – spread to local lymph nodes; M stage – distant metastasis.

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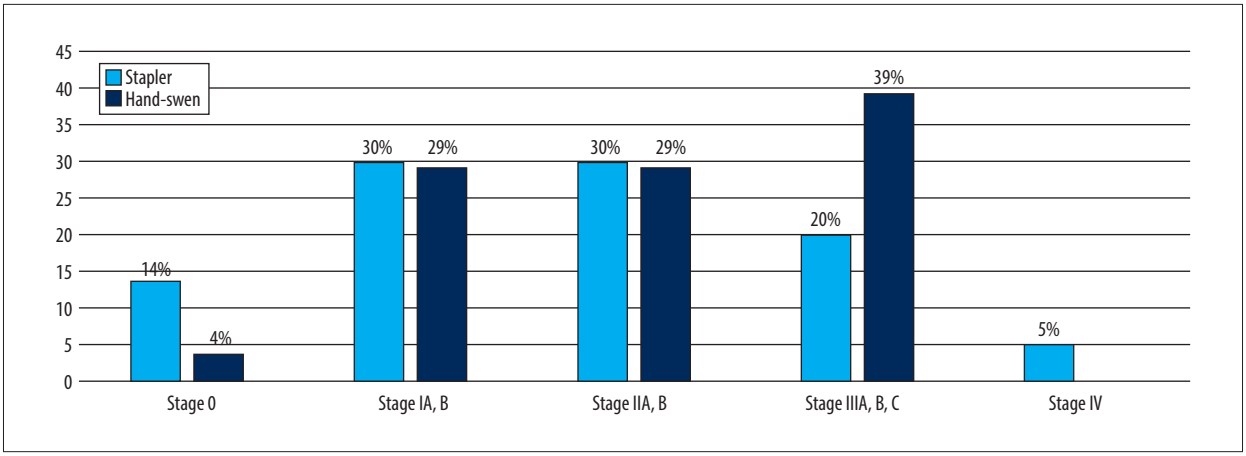

Figure 2. American Joint Committee on Cancer (AJCC) staging – comparison between stapler and hand-sewn esophago-jejunal anastomosis.

Table 5. Follow-up of the patients.

	Hand-sewn group	Stapler group	p
Follow up response rate	21/27 (77.8%)	39/44 (88.6%)	0.2
Median follow up time (months)	24.5, IQR 17.1 (4-43.9)	13.2, IQR 14.4 (1.9-41.5)	**0.01**
Occurrence of the anastomotic stricture	6/28 (21.4%)	7/44 (15.9%)	0.5
Median time of the stricture occurrence	6, IQR 11 (1.5-15)	3.5, IQR 3.7 (3.3-7)	1.0
Cancer recurrence			
Local recurrence	3/28 (10.7%)	1/44 (2.3%)	0.1
Distant metastases	4/28 (14.3%)	10/44 (22.7%)	0.5
General outcome at the end of follow up			
Alive	17/28 (60.7%)	36/44 (81.8%)	0.2
Deceased (overall mortality)	6/28 (21.4%)	6/44 (13.6%)	0.3
Lost to follow-up	5/28 (17.9%)	2/44 (4.5%)	0.1
30-day mortality	1/28 (3.6%)	–	0.4
90-day mortality	1/28 (3.6%)	–	0.4
Cause of death			
Cancer progression/recurrence	2/28 (7.1%)	5/44 (11.4%)	0.7
Other	4/28 (14.3%)	1/44 (2.3%)	0.1
Disease specific survival (DSS)			0.59
1-year	88.9%	97.0%	
2-year	88.9%	70.2%	
Disease free survival (DFS)			0.89
1-year	78.3%	85.1%	
2-years	68.4%	61.5%	

IQR – interquartile range.

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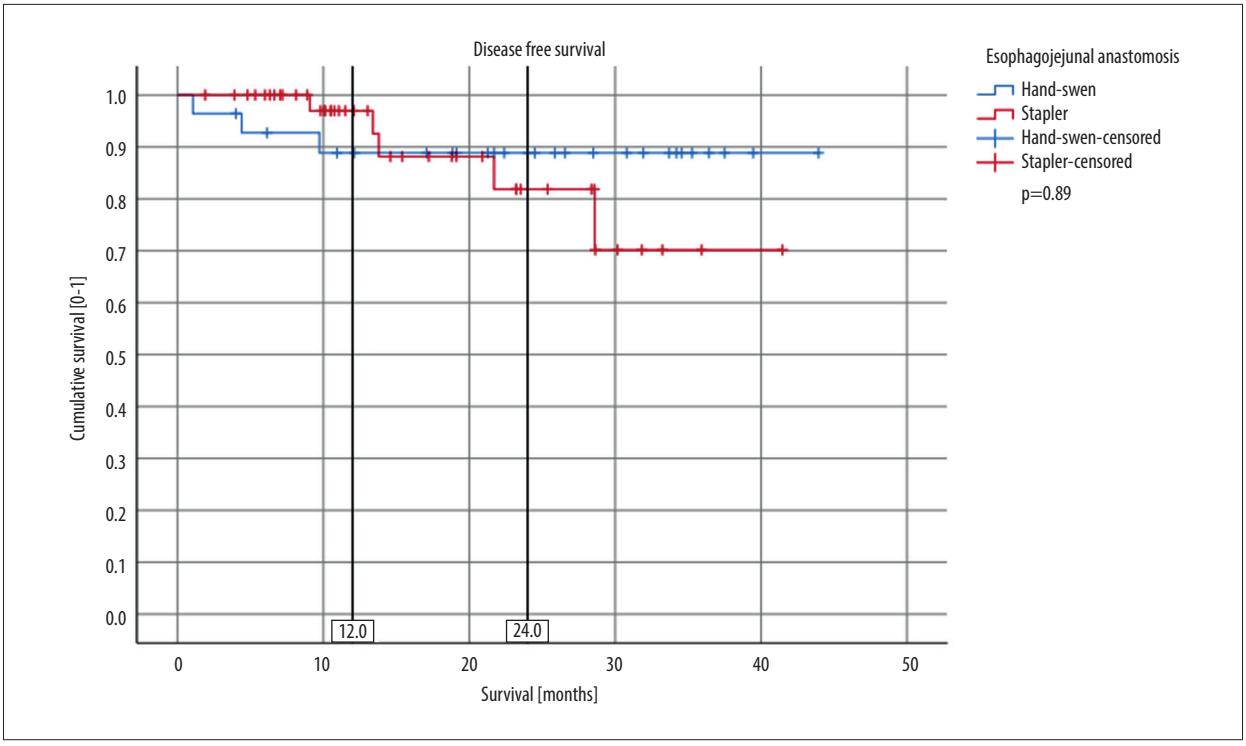

Figure 3. Disease-Specific Survival (DSS) – comparison between stapler and hand-sewn esophago-jejunal anastomosis.

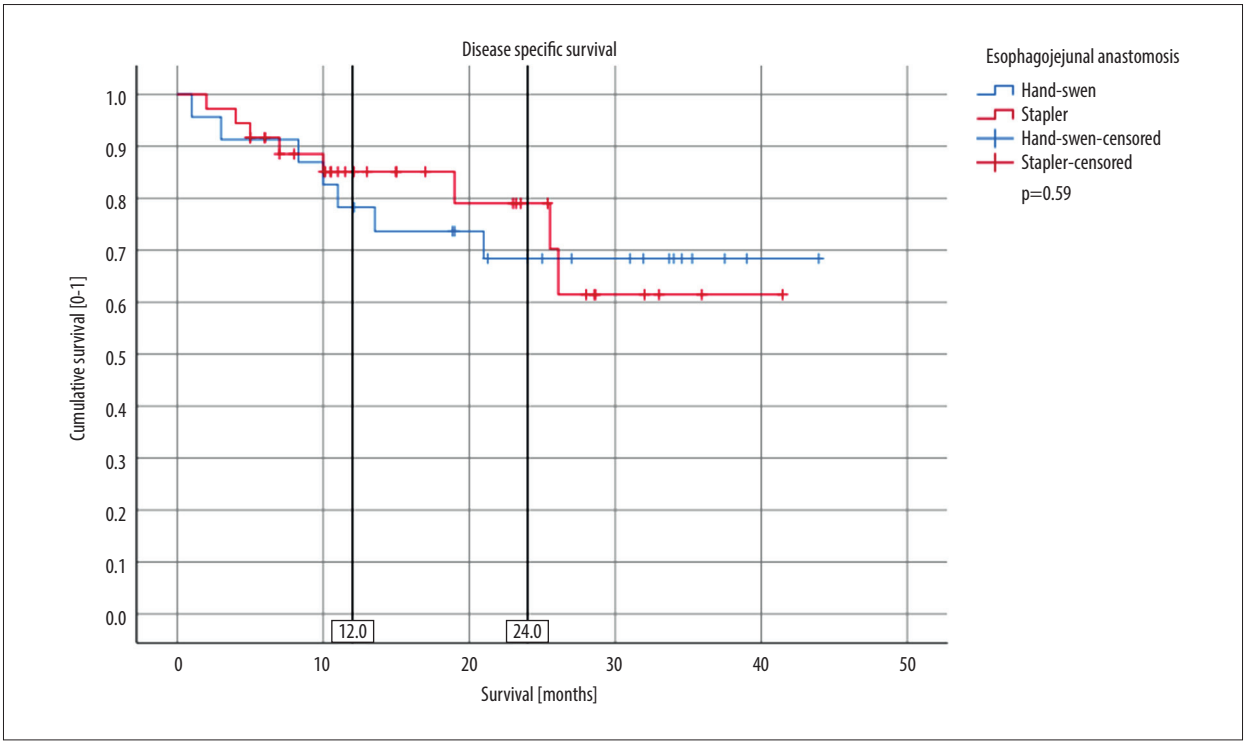

Figure 4. Disease-Free Survival (DFS) – comparison between stapler and hand-sewn esophago-jejunal anastomosis.

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were no significant differences, which is another factor proving the similarity of these 2 groups.

The length of the procedure, which is associated with anastomosis time, is one of the most important factors influencing the patient's condition after surgery. Longer surgery and anesthesia puts additional strain on the patient and increases the incidence of postoperative complications [23]. In our study, there was no significant difference between hand-sewn anastomosis and circular stapling anastomosis (P=0.61). However, there are conflicting reports on this issue. A recent meta-analysis [6] revealed that duration of the surgery was 22 minutes shorter for stapling anastomosis than for hand-sewn EJA, but without further impact on the morbidity and mortality after surgery. However, the analysis included data from studies comparing different surgical techniques – linear and circular stapling and laparoscopic and open gastrectomy. In the subgroup analysis according to stapler type, the duration of the surgery did not differ significantly between the hand-sewn and circular stapler groups, similar to our present study. Moreover, most of analyzed studies were observational. Among 2 included randomized controlled trials (RCT), 1 compared hand-sewn technique to circular stapler [24], and showed no difference in operating time. There are other papers that also reported no significant difference in surgery duration between the 2 methods of performing anastomoses [25,26]. In contrast, an RCT by Liu et al reported a significant difference in the duration of surgery between the use the stapler group and hand-sewn group (193 and 226 minutes respectively, P<0.001) in the creation of esophagogastric anastomosis [27]. A meta-analyses of randomized trials came to similar conclusions [28,25], as did several studies on laparoscopic gastrojejunostomy [29,30]. However, a meta-analysis of patients undergoing laparoscopic bariatric surgery found no difference in surgery time between the 2 approaches [31]. Regarding laparoscopic total gastrectomy, hand-sewn anastomosis takes significantly more time than stapling [32], due to the technical difficulty of performing hand-sewn anastomosis laparoscopically. While stapled anastomosis seems to be favorable during fully laparoscopic gastrectomy and esophagectomy, the difference in anastomotic time is less remarkable in open gastrectomy, as in this case hand-sewn suturing seems to be an acceptable alternative, especially when performed by an experienced surgeon.

Regardless of the continuous development of anastomotic techniques, esophago-jejunal anastomotic leakage (EJAL) remains one of the most serious complications in total gastrectomy, affecting 4-15% of patients [33]. Several potential risk factors of EJAL were proposed, including advanced age, male sex, anemia, malnourishment, cardiovascular diseases, pulmonary insufficiency, diabetes, smoking, obesity, stage and localization of the tumor, and surgical technique [33]. Considering the EJA method, some comparative studies reported lower leakage rates for stapled anastomosis [7,8,34], with differences also for particular types of staplers, while in other large cohorts the methods were equivalent [25], or even a higher leakage incidence after circular stapled anastomosis was observed [35]. Muneoka et al [36] compared the efficacy of linear and circular stapling in open total gastrectomy, showing that the occurrence of surgical complications was similar in both groups, but the use of a linear stapler improved patients' nutritional status after the surgery and reduced blood loss. In a review by Umemura et al [35],a linear stapler was superior to a circular stapler in terms of both leakage and stenosis. In our cohort, 4 patients (5.6%) were diagnosed with EJAL, which is an acceptable rate, similar to that reported in the Japanese National Clinical Database (4.4%) [37]. EJAL was associated with longer hospitalization time (over 30 days for each patient) and half of the patients required ICU admission. All patients were above 65 years old with cardiovascular diseases, and 3 of them were overweight. Both stapler and hand-sewn technique in our study seem to provide safe anastomosis in open total gastrectomy. The occurrence of EJAL was not associated with anastomosis technique, tumor staging, preoperative chemotherapy, surgery duration, or combined organ resection, but the sample size was too small for extended analysis of EJAL risk factors. The results are also limited by the fact that we investigated only 1 method of stapled anastomosis, while the linear stapled technique seems to be beneficial in most studies. Therefore, further research should take into account more potential confounding factors not included in this study, but some of them (like surgical technique details, experience of the surgeon, or tension on the anastomosis site) are difficult to assess and may be potential sources of bias.

Overall complications rate in our study was 18.1%, with no significant difference between the analyzed groups (21% for hand-sewn; 16% for stapler group; P=0.50), same as reported in a recent meta-analysis [6]. The work of Watanabe, et al from Japan on over 20 000 patients reported overall morbidity at 26.2%, which is similar to our study [37]. We have not observed statistically significant difference in hospitalization time between the hand-sewn and stapler approaches (P=0.229). This overlaps with a paper published last year by Wang et al [32]. Hospitalization duration is a variable affected by many factors, including general patients' condition and occurrence of complications, which influence this variable more importantly than the anastomotic technique.

Among the long-term complications associated with EJA, anastomotic stricture is one of the most important, as it affects patient's quality of life and often requires invasive treatment by endoscopic dilation. The frequency of anastomotic strictures in the literature varies from 4.1 to 38% [38-45], with various factors indicated as possibly affecting the stenosis rates. In a study on the efficacy of esophagogastric anastomosis with a

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circular stapler [38], the overall stricture rate was 38%, with differences reported for the various stapler sizes. A higher stricture risk was observed when a 25-mm stapler was used compared with a 28- or 29-mm device (53% vs 23%, respectively). Moreover, the occurrence of anastomotic leakage was an independent risk factor for stenosis. In a recent analysis, Tyler et al [39] excluded patients with anastomotic leakage as a known risk factor for stenosis, and they observed a 10% stenosis rate (most occurring during the first 100 days after surgery). In our study, symptomatic anastomotic strictures mostly occurred 3.5 months after surgery, in a total of 13 cases (18.1%). In 1 case of stenosis, the postoperative course was complicated by anastomotic leakage. The slightly higher incidence of stenosis might be the result of stapler size used for gastrointestinal tract reconstruction. The most commonly used size of circular stapler in our clinic was 25 mm, followed by 21 mm. The decision about stapler size was made intraoperatively, based on the inner diameter of the patient's esophagus. In some studies there was no difference in strictures rates, comparing 21-mm and 25-mm [40] or 23-25-mm and 28-33-mm circular staplers [39,41,42]. However, a large Japanese cohort [43], as well as a randomized trial by Fisher et al [44], reported the use of smaller stapler as a risk factor for stenosis. The impact of stapler size on formation of anastomotic strictures was confirmed in a recent meta-analysis [45] in which the mean stricture rate was 31% and it was significantly higher for smaller staplers, comparing 21-mm and 25-mm, as well as 25-mm and 28-mm circular devices. A review on laparoscopic total gastrectomy indicated that the linear stapler technique is superior to circular in terms of anastomotic stenosis [35], which was confirmed in a recent study by Park et al [46]. Moreover, similar results were found for linear staplers in comparison with hand-sewn anastomosis [47]. A meta-analysis by Honda et al [48] revealed a higher incidence of strictures in stapled anastomosis than in hand-sewn anastomosis, but only when the circular stapler diameter was below 30 mm, but in some studies there was no difference [7]. Another study reported superior results of the linear stapler technique, with diameter of anastomosis measured in endoscopy 1.6 cm in the linear group, 1.2 cm in the hand-sewn group, and 1.0 cm in the circular group, without significant difference between the last 2 groups [49]. In that paper, despite the relatively small sizes of staplers used, no difference was found regarding anastomotic stricture, with stenosis rates of 15.9% in the stapler group and 21.4% in the hand-sewn group (P=0.52). The surprisingly higher rate of stenosis in the hand-sewn group may be due to the fact that follow-up time was significantly longer in the hand-sewn group (median 2.1 years vs 1.1 years, respectively), as the stapled anastomosis was used more frequently over time. However, most strictures tend to occur during the first 3 months after surgery, which was observed both in the present study and in previous studies [39,43], and most of our patients had follow-up time longer than 4 months (there was only 1 case with 2-month follow-up), suggesting that this between-group difference did not affect the analysis. Nevertheless, follow-up duration should always be taken into account, as it may be one of factors responsible for disparity in stenosis rates across studies. A follow-up lasting at least 6 months from the surgery appears to be reasonable to describe most strictures, but studies with longer observation also are needed, as in our study stenosis in some cases occurred up to 15 months after gastrectomy. Taking the above into consideration, as the size of circular stapler is determined by esophagus diameter and in many cases must remain unchanged, the use of a linear stapler or hand-sewn anastomosis (particularly in cases when a linear stapler is not available or the surgical team has no experience with this type of device) may be considered, especially for a small esophagus.

There was no significant difference in hospital mortality between the hand-sewn and stapled anastomosis groups in our study (P=0.837). A meta-analysis on esophagogastric anastomosis by Markar et al, as well as recent meta-analysis on esophago-jejunal anastomosis, confirmed these results [6,50]. Two large-cohort studies performed using the National Cancer Databases reported in-hospital mortality (2.2%), 30-day mortality (0.9-4.7%), and 90-day mortality (9.1%) [37,51]. In our study, there was only 1 death during the first 90 days after surgery, due to the surgical complications and subsequent sepsis during hospitalization (90-day mortality was 1.39%), which is acceptable percentage, similar to other high-volume centers [52]. Some recent studies reported differences in mortality rates, with lower mortality observed after centralization of gastric cancer surgery. Analysis by Iwatsuki et al [53], comprising over 71 000 patients, showed favorable results regarding postoperative mortality, both for high-volume surgeons and high-volume centers. Hospitals were divided into 3 categories depending on the number of TGs performed annually (H1=0-11, H2=12-26, H3=26-79), and the study revealed mortality rates of 3.1%, 1.7%, and 1.2%, respectively. Similar findings were observed for 30-day and 90-day mortality, as well as for 2-year survival, in a study which defined high-volume centers as performing at least 20 gastrectomies per year [54]. Our analysis included 3 full years, with 26 TGs performed in 2019 and 21 in both 2020 and 2021. During the observation period, 12 patients (17%) died, 6 in each group, with no difference between hand-sewn and stapler anastomosis. Several meta-analyses showed no difference in mortality regardless of the esophagogastric anastomosis technique [48,50,55]. Considering gastroduodenostomy, a randomized clinical trial reported similar outcomes for both methods in terms of 5- and 10-year survival [56]. In our study, regarding gastrojejunostomy in open total gastrectomy, as well as in studies concerning laparoscopic gastrectomy, no difference in mortality was found in comparison of hand-sewn vs stapled gastrojejunostomy techniques [5]. This was observed both for short- and

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long-term outcomes, with overall 2-year survival of 82.2% for the hand-sewn group and 77.2% for the stapler group. DSS for the overall cohort after 12 and 24 months was 93.8% and 86.5%, respectively, also without between-group differences. Disease-free survival was equivalent as well (68.4% for hand-sewn group and 61.5% for stapled group). The recurrence rate was 23.6%, which was similar to the literature data showing rates between 16.1% and 29.2% [35]. The literature reports 5-year overall survival of 57.4% and DFS of 54.4% after TG [57]. In a large-cohort study based on the Netherlands Cancer Registry, 2-year overall survival was 58.5% [54], while in our study it was 81.2%, but with 9.7% lost to follow-up, so the mortality rate may actually be higher. Another possible cause of this disparity may be the difference between tumor stage in that cohort study vs our study (complete response in 4.8% vs 10%, stage I in 24.1% vs 30%, and stage IV in 6.9% vs 3%, respectively), and the fact that they analyzed a wide range of hospitals, including 54.3% of centers performing 20 or more gastrectomies each year. The observation period varies among reports, but long-term survival including 5- and 10-year observation is one of the most important outcome variables in oncology, so we are going to continue the follow-up, as the oncological outcome interpretation is now limited.

It is also worth noting that there is a significant difference in cost between methods of performing anastomosis, which in many clinical centers may be crucial when choosing a particular method. Depending on various factors, the cost of using a stapler compared to the hand-sewn approach may be several hundred euros more expensive [30,32,58]. Taking into account similar clinical outcomes of patients after stapled and traditional EJA, the hand-sewn technique may be a good alternative when a cost-effective approach is needed.

There are some limitations to our research. This was a single-center retrospective study restricted to 72 patients; however, the groups were comparable, with good homogeneity. The relatively short time of observation (3.5 years) limited the number of patients included, but guaranteed similar cancer treatment protocol and surgical technique. The study is also limited to the comparison of only 2 types of anastomoses, as we included those with higher surgeon experience in our center to avoid the factors associated with a learning curve. Anastomosis was also performed by 3 different surgeons, which may have influenced results, although all surgeons had extensive experience in gastric surgery, which should have limited any potential impact. Another limitation is that some possible confounding factors were not taken into account, as these were difficult to assess retrospectively and could create potential risk of bias. Variables such as anastomosis site tension or duration of the anastomosis creation should be taken into account in further prospective comparative studies on gastrointestinal tract anastomoses. The main limitation associated with the retrospective design of our study is the risk of selection bias, as the choice of anastomosis technique was based only on the surgeon's preference; therefore, randomized controlled trials are needed to confirm these findings. The low incidence of postoperative anastomotic leakage did not allow us to perform analysis of risk factors for this complication, so comparison of leakage incidence between the 2 anastomotic techniques needs to be further performed in larger cohorts, and the incidence of this complication is itself an important outcome. In our study, the anastomosis diameter was not assessed prospectively during endoscopic follow-up for the whole cohort; we assessed only the occurrence of symptomatic strictures (with or without the need for endoscopic dilation), as we believe these are the most important ones, taking into account the impact on patients' quality of life, nutritional status, and further management, as well as possible subsequent complications.

Conclusions

There were no significant differences in postoperative complications and surgery duration between the hand-sewn and stapler esophago-jejunal anastomosis groups. The results indicate that stapled and hand-sewn anastomoses in open total gastrectomy are equivalent. The postoperative mortality after open total gastrectomy is low, despite the patients' burden.

Declaration of Figures' Authenticity

All figures submitted have been created by the authors, who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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