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Article type: Original paper

Received: March 27, 2026.

Revision accepted: May 8, 2026.

Published online: May 27, 2026.

Online ISSN: 2299-0054

Wideochir Inne Tech Maloinwazyjne

doi:10.20452/wiitm.2026.18033

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ORIGINAL PAPER

A novel clipping method for duodenal stump reinforcement in laparoscopic gastric cancer surgery: does it prevent leaks? Results from a multicenter study

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Abstract

Introduction Duodenal stump leakage is a serious complication after laparoscopic gastrectomy for gastric cancer. This condition is associated with increased morbidity, mortality, prolonged hospital stay, and complex management.

Aim The aim of this study was to evaluate whether a novel, technically simple clipping technique is associated with a reduced rate of duodenal stump leakage.

Materials and Methods This retrospective multicenter study included patients who underwent laparoscopic radical gastrectomy with D2 lymphadenectomy for gastric adenocarcinoma at two tertiary centers. Patients were categorized according to the use of duodenal stump clipping. Demographic, clinical, intraoperative, and postoperative variables were compared. Risk factors for duodenal stump leakage were evaluated using univariate and multivariable analyses.

Results A total of 381 patients were analyzed (median age: 63 years; 65.1% male), of whom 175 (45.9%) underwent duodenal stump clipping. The incidence of duodenal stump leakage was lower in the clipping group compared with the non-clipping group (1.7% vs. 5.8%, $p = 0.04$).

The clipping group also demonstrated a shorter median hospital stay (7 vs. 10 days, $p < 0.001$) and a lower 30-day major complication rate (9.1% vs. 16.0%, $p = 0.046$). In multivariable analysis, duodenal clipping was not significantly associated with duodenal stump leakage.

Conclusions Duodenal clipping is described as a simple and technically feasible method for reinforcing the duodenal stump during laparoscopic gastric cancer surgery.

Key words Duodenal stump leakage; Gastrectomy; Postoperative complications; Surgical stapling; Laparoscopy

Introduction

Gastric cancer, the fifth most common cancer worldwide, accounts for the fourth leading cause of cancer-related deaths [1]. In the curative treatment of gastric cancer, laparoscopic radical gastrectomy with Roux-en-Y reconstruction is one of the most commonly preferred surgical approaches today [2]. Advances in laparoscopic surgical techniques and surgical expertise have led to a substantial decrease in postoperative complication rates following minimally invasive gastrectomy compared to open surgery [3]. However, despite the significant advancements in surgical techniques, complications such as duodenal stump leakage and anastomotic leakage persist as life-threatening complications, capable of inducing severe morbidity, sepsis, and even mortality in the postoperative period.

Duodenal stump leakage is an uncommon but serious complication associated with significant morbidity and mortality. This condition is particularly associated with elevated morbidity and mortality rates in cases developing after gastrectomy, prolonged hospital stays, and treatment complications. The incidence of duodenal stump leakage reported in the existing literature ranges from 1.6% to 6.3%, and a multidisciplinary approach is necessary for effective management of diagnosis, treatment, and follow-up [4-6]. In the development of duodenal stump leakage, systemic risk factors such as advanced age, malnutrition, and obesity, as well as local surgical factors such as excessive vascular and pancreatic dissection around the duodenal stump and thermal injury, play an important role [7-10]. During open surgery, reinforcement sutures can be applied to the duodenal stump to prevent duodenal stump leakage. However, the anatomical posterior location of the duodenum complicates the process of intracorporeal suture placement during laparoscopic surgery. Consequently, some surgeons

contend that routine reinforcement of the duodenal pouch is not necessary during laparoscopic surgery. However, the current literature documents the development of various laparoscopic reinforcement suture techniques targeting the duodenal stump, with the objective of reducing this risk [11,20]. However, inconsistent findings across studies and the low incidence of duodenal stump leakage continue to limit the evidence supporting routine reinforcement. Conversely, despite the plethora of methodologies proposed in the existing literature to enhance the safety of the duodenal stump during laparoscopic gastric cancer surgery, a universally accepted and standardized surgical technique remains to be delineated in this domain.

Aim

The objective of this study was to present a novel method, designated "duodenal clipping," which is technically uncomplicated and feasible. This method was developed for the purpose of fortifying the duodenal stapler line in patients who have undergone laparoscopic gastrectomy due to gastric cancer. The secondary objective was to assess the impact of this technique on postoperative surgical outcomes.

Materials and methods

Patient selection and study design From January 2020 to April 2025, patients diagnosed with gastric adenocarcinoma by endoscopic biopsy and treated with curative surgery at two tertiary referral centers were retrospectively assessed.

The inclusion criteria were as follows:

(i) histologically confirmed gastric adenocarcinoma,

(ii) patients who underwent laparoscopic gastrectomy,

(iii) D2 lymph node dissection, and

(iv) curative-intent surgery.

The exclusion criteria were as follows:

(i) open gastrectomy,

(ii) duodenal invasion,

(iii) conversion to open surgery due to tumor invasion of surrounding organs,

(iv) multiorgan resection,

(v) stage IV disease,

(vi) history of malignancy other than gastric adenocarcinoma,

(vii) prior abdominal surgery, and

(viii) absence of D2 lymph node dissection (Figure 1).

In this retrospective cohort study, patients were divided into two groups according to the surgical procedure performed to evaluate the effectiveness of the duodenal clipping technique: the duodenal clipping group (DC group) and the non-duodenal clipping group (non-DC group). The study included data from two high-volume tertiary centers with comparable surgical volume and experience. At one of these centers, duodenal clipping was routinely applied during laparoscopic gastrectomy for the past three years, whereas the other center did not adopt this practice during the study period. This natural variation in institutional practice allowed for a comparative analysis without altering standard surgical protocols. No explicit patient selection or allocation method was used. To minimize selection bias, all consecutive patients meeting the inclusion criteria during the study period were included. The inclusion and exclusion criteria were applied uniformly at both centers. No patients meeting the inclusion criteria were excluded for non-clinical reasons (e.g., administrative issues or personal preferences). Data collection was performed prospectively in institutional databases and retrospectively reviewed for the purposes of this analysis. To minimize variations in

surgical protocols between centers, the same brand of endoscopic linear stapler was used in both centers, and D2 lymph node dissection was performed in accordance with the Japanese Gastric Cancer Treatment Guidelines [2]. Additionally, postoperative care protocols were standardized and identical across both centers. Patient selection and data collection processes were conducted consistently to reduce potential bias.

Preoperative data, including age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) physical status classification, and tumor localization, were meticulously documented. Postoperative data such as duodenal fistula, intra-abdominal infection, length of hospital stay, and number of dissected lymph nodes were evaluated in all patients. Patients in whom no other anastomotic leak or gastrointestinal perforation was detected by imaging methods but whose drainage fluid contained bile were considered to have duodenal stump leakage. Tumor stages were classified according to the 8th edition of the AJCC [12]. Postoperative mortality was defined as any death occurring within 30 days after surgery or during the same hospital stay. Follow-up was limited to the in-hospital period and the first 30 days after surgery. Reoperation was defined as any unplanned surgical intervention performed within 30 days after the initial surgery. Intra-abdominal infection was defined as the presence of clinically or radiologically confirmed infection within the abdominal cavity requiring antibiotic therapy or intervention. Postoperative bleeding was defined as clinically significant hemorrhage requiring blood transfusion, interventional radiology, endoscopic intervention, or reoperation. Length of hospital stay was defined as the number of days from surgery to discharge. ICU admission was defined as the need for postoperative intensive care unit monitoring for any clinical indication.

Short-term postoperative complications were defined as complications occurring within 30 days after surgery. The Clavien-Dindo (CD) complication grading system was utilized to categorize the severity of surgery-related postoperative complications [13]. The classification

system employed in this study divided cases into two categories, with grade 1,2 designated as mild complications and grade 3a-5 classified as severe complications.

The analysis of duodenal stump leakage rates and surgical complications was conducted in relation to the surgical techniques employed. The study was approved by the Institutional Ethics Committee of Ankara University School of Medicine (approval number: I06-555-25). Written informed consent for the use of clinical data for research purposes had been obtained from patients at the time of hospital admission.

Surgical technique The study's participants underwent surgical intervention by two distinct surgical teams, each with extensive experience, at two separate medical centers. All patients underwent laparoscopic radical subtotal or total gastrectomy, depending on the location and stage of the tumor. The surgical procedure and the extent of lymph node dissection were performed in accordance with the recommendations of the Japanese Gastric Cancer Treatment Guidelines [2]. All patients underwent Roux-en-Y reconstruction.

In all atients, the duodenum was transected using the same brand of endoscopic linear stapler (60–3.5 mm blue cartridge). In the duodenal clipping group, titanium clips (10 mm) were applied along the entire length of the stapler line to reinforce the duodenal stump (Figure 2). Clips were placed sequentially starting from one edge of the stapler line to the other, ensuring full coverage of the transection line. Typically, 6–10 clips were used depending on the length of the duodenal stump, with an approximate distance of 5 mm between adjacent clips to achieve uniform reinforcement without excessive tissue compression.

Care was taken to avoid deep penetration of the clips into the duodenal wall and to prevent injury to adjacent structures. No additional reinforcement (e.g., sutures) was used in the clipping group.

In the non-duodenal clipping group, no reinforcement procedure was performed on the stapler line. In all cases, a Jackson-Pratt type drain with a 10 Fr caliber was placed around the duodenal stump as part of the standard surgical protocol.

Statistical analysis All statistical analyses were conducted using IBM SPSS Statistics for Windows, version 30.0 (IBM Corp., Armonk, NY, USA). Categorical variables were summarized as frequencies and percentages, while continuous variables were presented as medians with interquartile ranges (IQR) (Q1–Q3) due to non-normal distributions. Comparisons between groups were performed using the Chi-square test or Fisher's exact test for categorical variables, and the Mann–Whitney U test for continuous variables. To identify independent predictors of duodenal stump leakage, univariate logistic regression analyses were first performed. Variables with a p-value less than 0.20 in univariate analysis were considered for inclusion in the multivariable logistic regression model. Additionally, clinically relevant parameters were included regardless of their univariate significance to account for potential confounding factors. A backward stepwise logistic regression approach based on the likelihood ratio method was used for multivariable modeling. Odds ratios (OR) and 95% confidence intervals (CI) were reported. Model fit was assessed using the Hosmer–Lemeshow goodness-of-fit test. In addition, the discriminatory performance of the final logistic regression model was assessed using receiver operating characteristic curve analysis based on model-derived predicted probabilities, and the area under the curve with 95% CI was reported. A p-value <0.05 was considered statistically significant. All statistical analyses were performed with the assistance of a biostatistics expert.

Results

Patient characteristics Among the 573 patients who underwent surgical treatment for gastric cancer, 67 underwent open gastrectomy, while the remaining 506 underwent laparoscopic gastrectomy. After excluding patients who met the predetermined exclusion

criteria, a total of 381 patients who underwent laparoscopic gastrectomy were included in the final analysis. The median age was 63 years (IQR, 55–71), and 248 patients (65.1%) were male. Most patients were classified as ASA II (62.2%), and tumors were most frequently located in the lower third of the stomach (49.1%). The 30-day major complication, reoperation, and mortality rates were 12.9%, 3.7%, and 2.9%, respectively.

Comparison according to duodenal clipping status Duodenal stump clipping was performed in 175 patients (45.9%), while it was not used in 206 patients (54.1%). The demographic and clinical characteristics at the baseline were found to be largely similar between the groups. However, a significant difference was observed in preoperative albumin levels between the clipping and control groups (4.1 mg/dL vs. 3.9 mg/dL, $p = 0.002$). Additionally, the tumors exhibited larger dimensions in the clipping group (median 4 cm vs. 3 cm, $p = 0.003$). Furthermore, the distribution of pathological stages differed significantly between the groups ($P < 0.001$), with a higher proportion of stage II disease and a lower proportion of stage III disease in the clipping group and a marginally shorter operation time (190 vs. 200 minutes, $p = 0.02$). The retrieved lymph node count was found to be higher in the clipping group (24 vs. 22, $p = 0.007$). A lack of statistically significant disparities was identified in the following demographic variables: age, sex distribution, BMI, ASA score, and neoadjuvant treatment status (Table 1).

Postoperative outcomes The incidence of duodenal stump leakage was found to be significantly lower in patients who underwent duodenal clipping (1.7% vs. 5.8%, $p = 0.04$). Subsequent postoperative outcomes, encompassing bleeding, intraabdominal infections, and overall complications, were found to be equivalent between the two groups. However, patients without clipping exhibited a prolonged hospital stay (10 vs. 7 days, $p < 0.001$) and a higher rate of 30-day major complications (16.0% vs. 9.1%, $p = 0.046$). No significant

differences were observed in ICU admission, reoperation, and mortality rates (Table 2). No cases of pancreatic fistula were observed in either group.

Risk factors for duodenal stump leakage In the univariate logistic regression analysis, female sex was significantly associated with duodenal stump leakage. Duodenal clipping showed lower odds of duodenal stump leakage; however, this association did not reach statistical significance. No statistically significant associations were observed for other variables, including age, BMI, ASA class (II–III vs. I), preoperative hemoglobin, preoperative albumin, neoadjuvant treatment, and the numbers of retrieved lypmph nodes. However, these variables were included in the multivariable model due to their clinical relevance or a univariate p-value of <0.20. In the final multivariable logistic regression model, female sex demonstrated a persistent independent association with an elevated risk of duodenal stump leakage (OR=5.33; 95% CI: 1.65–17.17; p = 0.005). Duodenal clipping was associated with lower odds of duodenal stump leakage, but this association did not reach statistical significance in the final multivariable model (OR, 0.29; 95% CI, 0.08–1.08; P = 0.07). The final model demonstrated adequate calibration according to the Hosmer–Lemeshow goodness-of-fit test (p = 0.46), whereas the Nagelkerke R^2 value of 0.125 indicated limited explanatory power. The discriminatory performance of the model was evaluated using ROC curve analysis based on the predicted probabilities, yielding an AUC of 0.764 (95% CI: 0.665–0.863; p < 0.001), suggesting fair discrimination (Table 3).

Discussion This multicenter study aimed to evaluate the impact of a novel duodenal reinforcement technique on duodenal stump leakage rates. The findings demonstrated that the use of duodenal clipping was associated with a lower incidence of duodenal stump leakage (p = 0.04) and a reduction in major postoperative complications within 30 days (p = 0.046). While the multivariable analysis identified female sex as an independent risk factor, duodenal

clipping demonstrated a borderline association ($p = 0.07$). Therefore, these findings should be interpreted as hypothesis-generating rather than confirmatory evidence of an independent protective effect.

Methodologies intended to prevent duodenal stump leakage play a pivotal role in laparoscopic gastrectomy. In this context, the application of intracorporeal suture techniques to the duodenal stump has been proposed as a method to reduce the incidence of this serious complication by strengthening the stapler line [14]. In the literature, various intracorporeal suturing techniques have been described for this purpose, including Lembert, purse-string, and barbed sutures [15-20]. Despite the demonstrated efficacy of these techniques in preventing duodenal stump leakage, their implementation is often technically challenging, may prolong the operative time, and requires advanced laparoscopic skills as well as close coordination between the surgeon and assistant. Conversely, the duodenal clipping method introduced in the present study offers a simpler and more practical alternative, with a gentle learning curve and the ability to be performed independently without additional assistance.

This study describes the “duodenal clipping” technique, applying metal clips to the duodenal stapler line during laparoscopic gastrectomy. While not previously detailed in gastric cancer surgery, similar approaches in obesity surgery have shown improved staple-line safety and reduced complications. In a retrospective analysis conducted by Yigit et al., it was reported that metallic clips applied to the stapler line during laparoscopic sleeve gastrectomy (LSG) provided advantages in terms of both stapler line bleeding and leak rates [21]. Although no statistically significant difference was found between the groups in terms of postoperative bleeding in the present study, it was observed that bleeding rates were relatively lower in the clipping group. In a prospective randomized controlled trial, omentopexy applied along the stapler line during LSG was compared with clip reinforcement methods. The clipping group

demonstrated a significantly shorter operating time [22]. In the present study, surgical time was found to be significantly shorter in the clipping group, a finding that aligns with the results reported in the existing literature.

While the literature suggests that extensive dissection around the duodenum and pancreas may increase the risk of duodenal stump leakage [23], the present study found no such increase, even with the greater lymph node removal in the clipping group. This finding suggests that the duodenal clipping method may be feasible even in cases involving extensive dissection; however, an independent protective effect could not be confirmed in the present analysis. Although the point estimate favored clipping, the confidence interval crossed unity and the association did not reach statistical significance. These results suggest a possible reduction in crude leakage with duodenal clipping, particularly in high-risk patients. However, one case of duodenal stump leakage due to clip penetration required reoperation. This exceptional circumstance underscores the necessity for meticulous examination of specific technical aspects in the implementation of the procedure. It is imperative to acknowledge that, akin to any surgical procedure, this method is not without its inherent risks and potential complications. Surgeons must remain vigilant and cognizant of the possibility of adverse effects.

This study has limitations, including its relatively small sample size and retrospective design, which may introduce selection bias. Additionally, all duodenal clipping procedures were performed in one institution, while the control group consisted of patients from another high-volume center. Therefore, institutional and surgeon-related differences, including variations in surgical experience and operative techniques, may have influenced the outcomes and cannot be completely excluded. This center-related bias may also have contributed to differences in operative time between groups. Future prospective, multicenter studies with balanced group

allocation are needed to better control for these potential confounding factors. However, our study is unique and significant in that it is the first to describe the duodenal clipping method in gastric cancer surgery and to evaluate its association with early postoperative outcomes.

Conclusions In this study, the duodenal clipping technique is described as a simple and technically feasible method for reinforcing the duodenal stump during laparoscopic gastric cancer surgery. Although patients who underwent clipping had a lower crude rate of duodenal stump leakage, duodenal clipping was not independently associated with leakage in multivariable analysis. Therefore, the present findings should be interpreted cautiously and considered hypothesis-generating. Further prospective studies with larger sample sizes are needed to determine whether this technique provides a true protective effect against duodenal stump leakage.

Article information

Acknowledgments We express our deepest appreciation to all authors of this research.

Funding No funding was received for this study.

Contribution statement ST: Conception and design of study, Data analysis and/or interpretation, Drafting of manuscript and/or critical revision, Approval of final version of manuscript. SÇ: Conception and design of study, Acquisition of data, Drafting of manuscript and/or critical revision, Approval of final version of manuscript. İCT: Acquisition of data, Data analysis and/or interpretation. FT: Acquisition of data, Data analysis and/or interpretation. SUÇ: Data analysis and/or interpretation, Drafting of manuscript and/or critical revision. EA: Drafting of manuscript and/or critical revision. GGA: Acquisition of data. MAG: Acquisition of data. AEÜ: Approval of final version of manuscript. SD: Conception and design of study, Approval of final version of manuscript.

Conflicts of interest The authors declare no conflicts of interest.

AI statement Artificial intelligence was not used in the preparation of this manuscript.

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How to cite Tamam S, Culcu S, Tercan IC, et al. A novel clipping method for duodenal stump reinforcement in laparoscopic gastric cancer surgery: does it prevent leaks? Results from a multicenter study. Wideochir Inne Tech Maloinwazyjne. 2026; Epub ahead of print. doi:10.20452/wiitm.2026.18033

Journal information

Videosurgery and Other Miniinvasive Techniques is an official journal of the Videosurgery Foundation.

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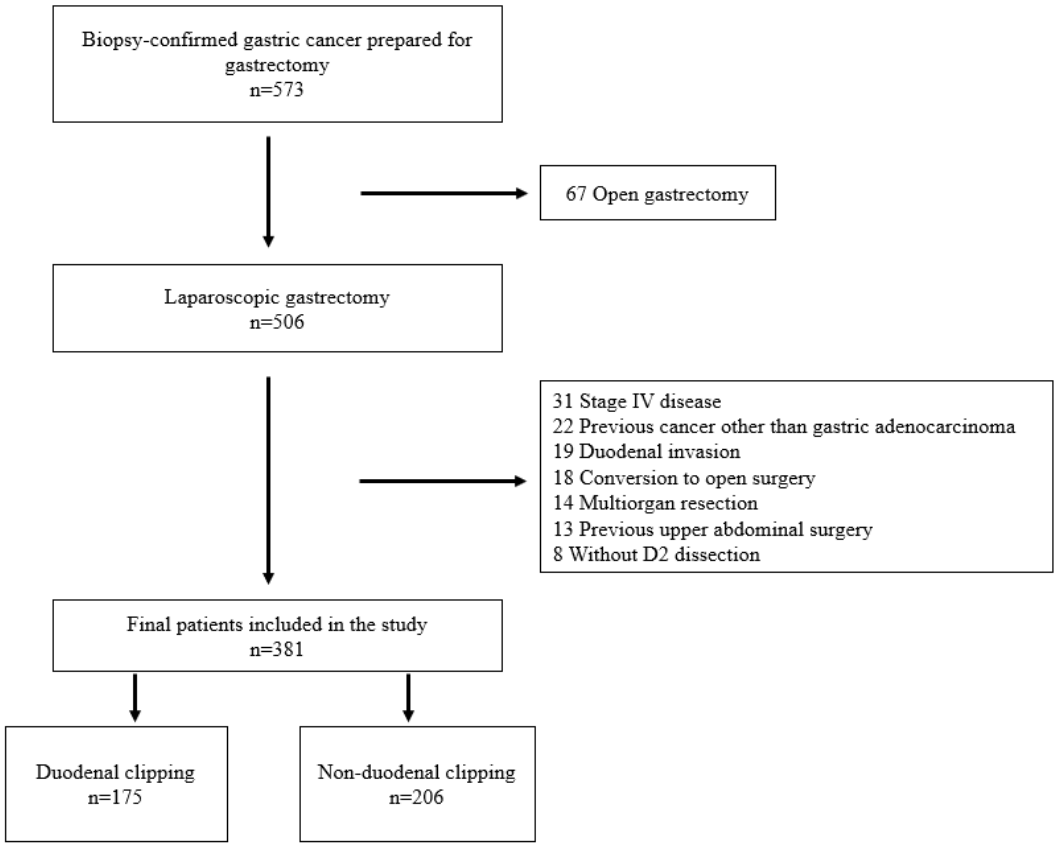


Figure 1 Patient selection diagram

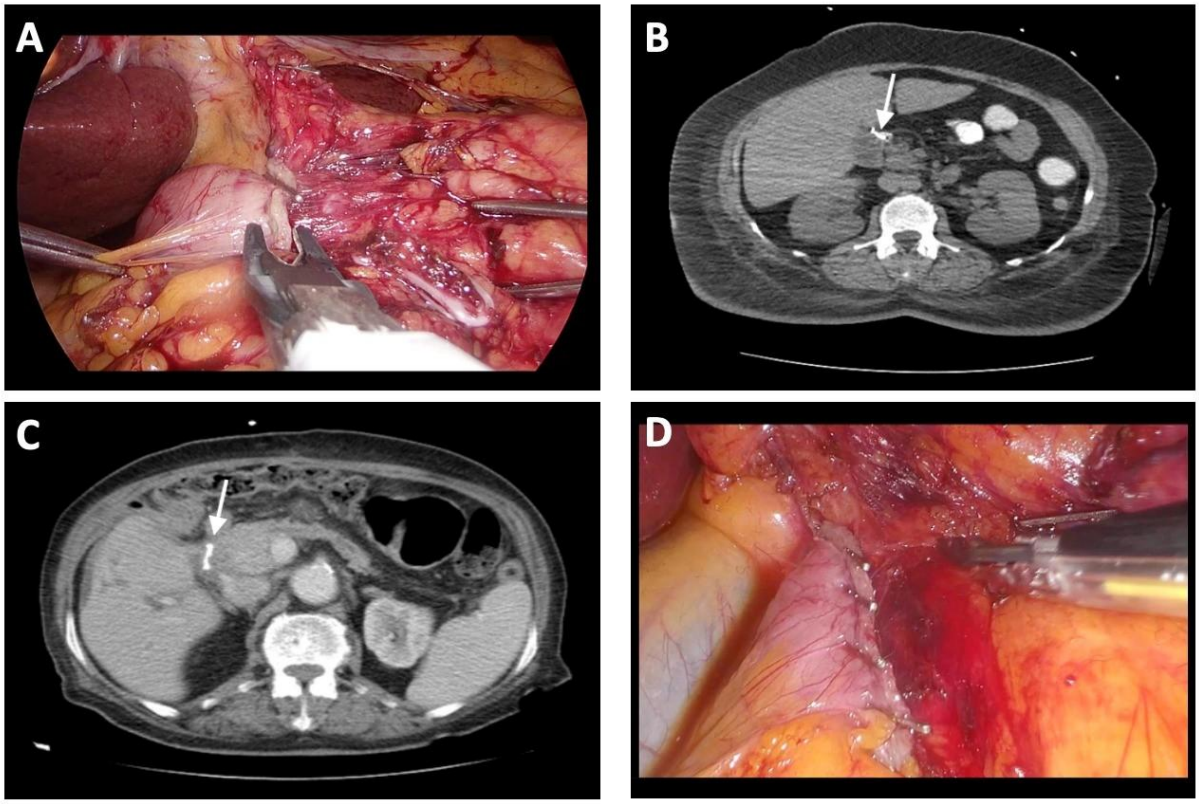


Figure 2 Intraoperative views of the duodenal clipping technique (A, D). Postoperative CT images showing the duodenal stapler line (B, C)

Table 1 Patient characteristics stratified by the presence of duodenal clipping			
	No clipping (n = 206)	Duodenal clipping (n = 175)	*P* value
Age, years	62 (54−70)	65 (56−71)	0.07
Male sex, n (%)	130 (63.1%)	118 (67.7%)	0.38
BMI, kg/m^2	25.6 (23.1−27.4)	25.0 (22.6−27.7)	0.82
ASA score, n (%)			0.47
I	36 (17.5%)	35 (20.0%)	
II	126 (61.2%)	111 (63.4%)	
III	44 (21.4%)	29 (16.6%)	
Preoperative hemoglobin, g/dL	12.5 (10.9−13.7)	12.0 (10.7−13.9)	0.18
Preoperative albumin, mg/dL	3.9 (3.5−4.2)	4.1 (3.7−4.3)	**0.002**
Tumor location, n (%)			0.55
Upper third	50 (24.3%)	51 (29.1%)	
Middle third	51 (24.8%)	42 (24.0%)	
Lower third	105 (51.0%)	82 (46.9%)	
Tumor size, cm	3 (2−4.5)	4 (2.5−5.2)	**0.003**
Neoadjuvant treatment, n (%)	59 (28.6%)	49 (28.0%)	0.89
Extent of resection, n (%)			0.84
Subtotal	121 (58.7%)	101 (57.7%)	
Total	85 (41.3%)	74 (42.3%)	
Perioperative blood transfusion, n (%)	5 (2.4%)	9 (5.1%)	0.16
Operation duration, minutes	200 (180−260)	190 (180−240)	**0.02**
pTNM stage, n (%)			**<0.001**
Stage I	66 (32.0%)	44 (25.1%)	

Stage II	46 (22.3%)	72 (41.1%)	
Stage III	94 (45.6%)	59 (33.7%)	
Retrieved lymph nodes	22 (17−29)	24 (19−32)	**0.007**
Metastatic lymph nodes	0 (0−4)	1 (0−4)	0.60

Abbreviations: **ASA, American Society of Anesthesiologists; BMI, body mass index**

Continuous variables are presented as median with interquartile range (Q1–Q3), and categorical variables are presented as n (%)

Table 2 Short-term outcomes stratified by the presence of duodenal clipping

	No clipping (n = 206)	Duodenal clipping (n = 175)	*P* value
Length of intensive care unit stay, days	1 (1−2)	1 (1−2)	0.98
Length of hospital stay, days	10 (8−13)	7 (6−10)	**<0.001**
Duodenal stump leakage, n (%)	12 (5.8%)	3 (1.7%)	**0.04**
Bleeding, n (%)	10 (4.9%)	3 (1.7%)	0.09
Intraabdominal infection, n (%)	14 (6.8%)	1 (0.6%)	0.84
Other complications, n (%)*	33 (16.0%)	24 (13.7%)	0.53
Overall complication, n (%)	54 (26.2%)	42 (24.0%)	0.62
30-day major complications, n (%)	33 (16.0%)	16 (9.1%)	**0.046**
30-day reoperation, n (%)	7 (3.4%)	7 (4.0%)	0.76
30-day mortality, n (%)	8 (3.9%)	3 (1.7%)	0.21

* Other complications included wound-related, pulmonary, cardiac, and urinary events

Continuous variables are presented as median with interquartile range (Q1–Q3), and categorical variables are presented as n (%)

Table 3 Multivariable analysis for predictors of duodenal leakage after surgical procedure for gastric adenocarcinoma

	Univariate analysis		Multivariable analysis	
	OR (95% CI)	***P* value**	**OR (95% CI)**	***P* value**
Age	1.01 (0.97−1.06)	0.70	−	−
Sex (female vs male)	5.50 (1.72−17.60)	0.004	5.33 (1.65−17.17)	**0.005**
BMI	0.98 (0.84−1.16)	0.86	−	−
ASA score (II-III vs I)	3.31 (0.43−25.60)	0.25	−	−
Preoperative hemoglobin	0.85 (0.66−1.09)	0.19	−	−
Preoperative albumin	0.93 (0.84−1.03)	0.14	−	−
Neoadjuvant treatment (yes vs no)	0.38 (0.08−1.70)	0.21	−	−
Duodenal clipping (yes vs no)	0.28 (0.08−1.02)	0.053	0.29 (0.08−1.08)	0.07
Retrieved lymph nodes	0.97 (0.90−1.03)	0.34	−	−

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index, OR: odds ratio; CI: confidence interval.

Short title: Duodenal Clipping in Gastric Cancer Surgery