ORIGINAL PAPER General surgery

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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KEY WORDS

duodenal stump leakage, gastrectomy, laparoscopy, postoperative complications, surgical stapling

ABSTRACT

INTRODUCTION Duodenal stump leakage (DSL) is a serious complication after laparoscopic gastrectomy due to gastric cancer (GC). It is associated with increased morbidity and mortality rates, prolonged hospital stay, and complex management.

AIM The aim of this study was to evaluate whether a novel, technically simple clipping technique could help reduce the rate of DSL.

MATERIALS AND METHODS This retrospective multicenter study included patients who underwent laparoscopic radical gastrectomy with D2 lymphadenectomy for gastric adenocarcinoma at 2 tertiary centers. The patients were categorized according to the use of duodenal stump clipping during the procedure. Demographic, clinical, intraoperative, and postoperative variables were compared. The risk factors for DSL were evaluated using univariate and multivariable analyses.

RESULTS A total of 381 patients at a median (interquartile range [IQR]) age of 63 (55–71) years were analyzed; 175 (45.9%) underwent duodenal stump clipping, and 248 (65.1%) were men. The incidence of DSL was lower in the clipping group than the nonclipping group (1.7% vs 5.8%; $P = 0.04$). The clipping cohort also demonstrated reduced median (IQR) hospital stay (7 [6−10] vs 10 [8−13] d; $P < 0.001$) and a lower 30-day major complication rate (9.1% vs 16%; $P = 0.046$). In the multivariable analysis, duodenal clipping was not significantly associated with DSL.

CONCLUSIONS Duodenal clipping is a simple and technically feasible method for reinforcing the duodenal stump during laparoscopic GC surgery.

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Received: March 27, 2026.
Revision accepted: May 8, 2026.
Published online: May 27, 2026.
Wideochir Inne Tech Maloinwazyjne. 2026; 21 (2): 154-160
doi:10.20452/wiitm.2026.18033

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

DSL is an uncommon but serious complication associated with considerable morbidity and mortality, especially after gastrectomy, prolonged

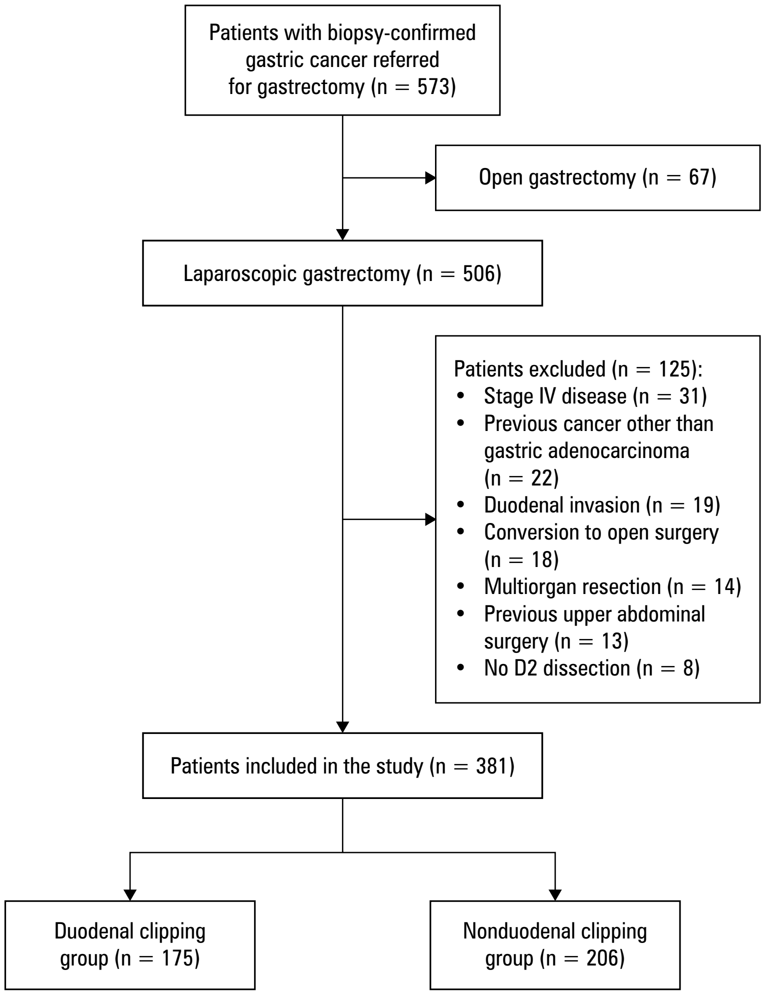

FIGURE 1 Patient selection diagram

hospital stays, and treatment complications. The incidence of DSL 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 DSL, systemic risk factors, such as advanced age, malnutrition, and obesity, as well as local surgical factors (eg, 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 DSL. However, the anatomical posterior location of the duodenum complicates the process of intracorporeal suture placement during laparoscopic surgery. Consequently, some surgeons regard routine reinforcement of the duodenal pouch as not necessary during laparoscopic procedures. However, the current literature documents the development of various laparoscopic reinforcement suture techniques targeting the duodenal stump, with the objective of reducing DSL risk.[11,20] Yet, inconsistent findings across studies and low incidence of DSL continue to limit the evidence supporting routine reinforcement. Despite the plethora of methodologies proposed in the existing literature to enhance the safety of the duodenal stump during laparoscopic GC surgery, a universally accepted and standardized surgical technique remains to be established.

AIM The objective of this study was to present a novel, technically uncomplicated and feasible method of duodenal clipping. This method was developed for the purpose of fortifying the duodenal stapler line in patients who undergo laparoscopic gastrectomy due to GC. 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 based on endoscopic biopsy results, treated with curative surgery at 2 tertiary referral centers (Ankara University School of Medicine and Gulhane Faculty of Medicine, University of Health Sciences, Ankara, Türkiye) were retrospectively assessed.

The inclusion criteria were as follows: 1) histologically confirmed gastric adenocarcinoma, 2) a history of laparoscopic gastrectomy, 3) a history of D2 lymph node dissection, and 4) planned curative-intent surgery. The exclusion criteria comprised: 1) open gastrectomy, 2) duodenal invasion, 3) conversion to open surgery due to tumor invasion of surrounding organs, 4) multiorgan resection, 5) stage IV disease, 6) a history of malignancy other than gastric adenocarcinoma, 7) prior abdominal surgery, and 8) no history of D2 lymph node dissection (**FIGURE 1**).

In this retrospective cohort study, the patients were divided into 2 groups according to the surgical procedure used to evaluate the effectiveness of the duodenal clipping technique: the duodenal clipping (DC) group and the nonduodenal clipping (NDC) group. The study included data from 2 high-volume tertiary centers with comparable surgical volume and experience. At 1 of these centers, duodenal clipping has been routinely applied during laparoscopic gastrectomy for the past 3 years, whereas the other one 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 were enrolled. No individuals meeting the inclusion criteria were excluded for nonclinical reasons (eg, 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 the centers, the Endo GIA (Medtronic, Minneapolis, Minnesota, United States) endoscopic linear stapler was used in both, 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 in both centers. Patient selection and data collection processes were conducted consistently to reduce potential bias.

Preoperative data, including age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) class, and tumor localization, were meticulously documented. Postoperative information, such as the presence of duodenal fistula or intra-abdominal infection, length of hospital stay, and the number of dissected lymph nodes were evaluated in all patients. The individuals in whom no other anastomotic leak or gastrointestinal perforation was detected on imaging, but whose drainage fluid contained bile, were considered to have DSL. Tumor stages were classified according to the eighth edition of the American Joint Committee on Cancer.[12] Postoperative mortality was defined as any death occurring within 30 days after surgery or during 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 procedure. Intra-abdominal infection was understood as the presence of clinically or radiologically confirmed infection within the abdominal cavity, requiring antibiotic therapy or intervention. Postoperative bleeding referred to clinically significant hemorrhage requiring blood transfusion, interventional radiology, endoscopic intervention, or reoperation. Length of hospital stay was the number of days from surgery to discharge. Intensive care unit (ICU) admission was defined as the need for postoperative ICU monitoring for any clinical indication. Short-term postoperative complications referred to complications occurring within 30 days after surgery. The Clavien–Dindo grading system was used to categorize the severity of surgery-related postoperative complications.[13] The classification system employed in this study divided the cases into 2 categories, with grades 1 and 2 corresponding to mild complications, and grades 3a–5 classified as severe complications. The analysis of DSL and complication rates was conducted in relation to the surgical techniques employed.

Ethics The study was approved by the Institutional Ethics Committee of Ankara University School of Medicine (I06-555-25). Written informed consent for the use of clinical data for research purposes was obtained from all patients on hospital admission.

Surgical technique The study participants underwent surgical intervention performed by 2 distinct surgical teams, each with extensive experience, at 2 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 participants underwent Roux-en-Y reconstruction.

In all patients, the duodenum was transected using the Endo GIA (Medtronic) endoscopic linear stapler (60–3.5 mm blue cartridge). In the DC group, titanium clips (10 mm) were applied along the entire length of the stapler line to reinforce the duodenal stump (**FIGURE 2**). The 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 the adjacent clips to achieve uniform reinforcement without excessive tissue compression.

Deep penetration of the clips into the duodenal wall and injuries to adjacent structures were avoided. No additional reinforcement (eg, sutures) was used in the DC group.

In the NDC group, no reinforcement procedure was performed on the stapler line. In all cases, a Jackson–Pratt type 10 French drain was placed around the duodenal stump as part of the standard surgical protocol.

Statistical analysis All statistical analyses were conducted using SPSS Statistics software for Windows, version 30.0 (IBM Corp., Armonk, New York, United States). Categorical variables were summarized as frequencies and percentages, while continuous variables were presented as medians with interquartile ranges (IQRs) when non-normally distributed. Comparisons between the groups were performed using the χ^2 test or the Fisher exact test for categorical variables, and the Mann–Whitney test for continuous variables. To identify independent predictors of DSL, univariate logistic regression analyses were first performed. Variables with a *P* value below 0.2 in the 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 (ORs) and 95% CIs 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 below 0.05 was considered significant. All statistical analyses were performed with the assistance of a biostatistics expert.

RESULTS **Patient characteristics** Among the 573 patients who were operated on due to GC, 67 underwent open gastrectomy, while the remaining 506 were subjected to laparoscopic gastrectomy. After excluding the patients who met

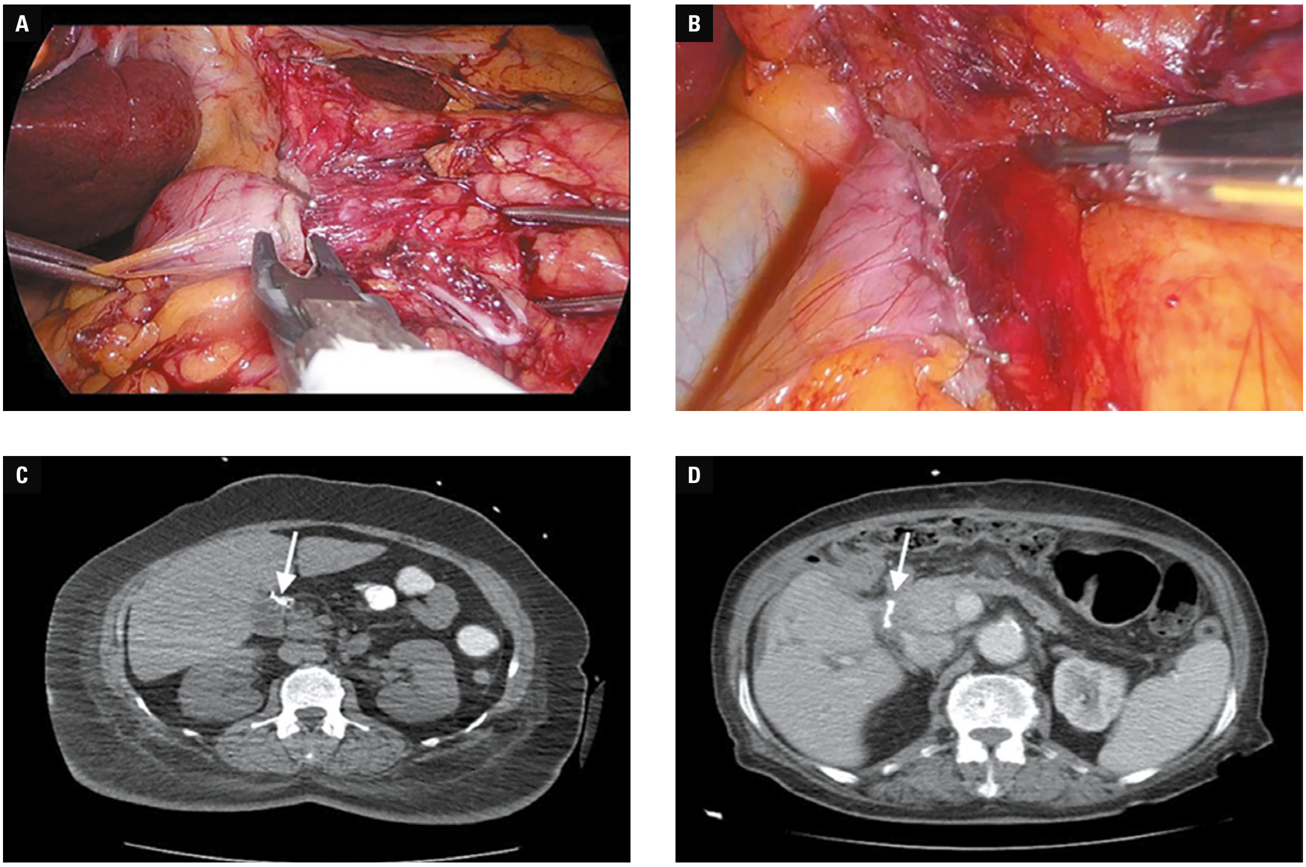

FIGURE 2 **A**, **B** – intraoperative views of the duodenal clipping technique; **C**, **D** – postoperative computed tomography images showing the duodenal stapler line (arrows)

the predetermined exclusion criteria, a total of 381 individuals who underwent laparoscopic gastrectomy were included in the final analysis. Median (IQR) patient age was 63 (55–71) years, and 248 patients (65.1%) were men. Most participants were classified as ASA class II (62.2%), and the 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%), and it was not used in 206 individuals (54.1%). The demographic and clinical characteristics at baseline were largely similar between the groups. However, a difference was observed in preoperative albumin levels between the DC and NDC groups (4.1 vs 3.9 g/dl; $P = 0.002$). Additionally, the tumors exhibited larger dimensions in the DC group (median [IQR], 4 [2.5–5.2] vs 3 [2–4.5] cm; $P = 0.003$). Furthermore, the distribution of pathological stages differed between the cohorts ($P < 0.001$), with a higher proportion of stage II disease, a lower proportion of stage III disease, and a marginally shorter operation time in the DC group (190 vs 200 min; $P = 0.02$). The retrieved lymph node count was found to be higher in the DC than the NDC cohort (24 vs 22; $P = 0.007$). No significant disparities were identified for age, sex distribution, BMI, ASA class, and neoadjuvant treatment status (**TABLE 1**).

Postoperative outcomes The incidence of DSL was lower in the patients who underwent duodenal clipping, as compared with those who did not (1.7% vs 5.8%; $P = 0.04$). Subsequent postoperative outcomes, encompassing bleeding, intra-abdominal infections, and overall complications, were similar in both groups. However, the patients without clipping exhibited a prolonged hospital stay (10 vs 7 d; $P < 0.001$) and a higher rate of 30-day major complications (16% vs 9.1%; $P = 0.046$) than those in the DC group. 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 DSL. Duodenal clipping showed lower odds of DSL; however, this association did not reach significance. No significant associations were observed for other variables, including age, BMI, ASA class (II–III vs I), preoperative hemoglobin and albumin levels, neoadjuvant treatment, and the number of retrieved lypmph nodes. Still, these variables were included in the multivariable model due to

TABLE 1 Patient characteristics stratified by the performance of duodenal clipping

Parameter		No clipping group (n = 206)	Duodenal clipping group (n = 175)	*P* value
Age, y		62 (54–70)	65 (56–71)	0.07
Men		130 (63.1)	118 (67.7)	0.38
BMI, kg/m^2		25.6 (23.1–27.4)	25 (22.6–27.7)	0.82
ASA class	I	36 (17.5)	35 (20)	0.47
	II	126 (61.2)	111 (63.4)	
	III	44 (21.4)	29 (16.6)	
Preoperative hemoglobin level, g/dl		12.5 (10.9–13.7)	12 (10.7–13.9)	0.18
Preoperative albumin level, g/dl		3.9 (3.5–4.2)	4.1 (3.7–4.3)	0.002
Tumor location	Upper third part of the stomach	50 (24.3)	51 (29.1)	0.55
	Middle third part of the stomach	51 (24.8)	42 (24)	
	Lower third part of the stomach	105 (51)	82 (46.9)	
Tumor size, cm		3 (2–4.5)	4 (2.5–5.2)	0.003
Neoadjuvant treatment		59 (28.6)	49 (28)	0.89
Extent of resection	Subtotal	121 (58.7)	101 (57.7)	0.84
	Total	85 (41.3)	74 (42.3)	
Perioperative blood transfusion		5 (2.4)	9 (5.1)	0.16
Operative time, min		200 (180–260)	190 (180–240)	0.02
pTNM stage	I	66 (32)	44 (25.1)	<0.001
	II	46 (22.3)	72 (41.1)	
	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)	0.6

Data are presented as number (percentage) or median (interquartile range).

SI conversion factors: to convert hemoglobin and albumin to g/l, multiply by 10.

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; pTNM, pathological tumor-node-metastasis

TABLE 2 Short-term outcomes stratified by the performance of duodenal clipping

Outcome		No clipping group (n = 206)	Duodenal clipping group (n = 175)	*P* value
Length of intensive care unit stay, d		1 (1–2)	1 (1–2)	0.98
Length of hospital stay, d		10 (8–13)	7 (6–10)	<0.001
Complications	Duodenal stump leakage	12 (5.8)	3 (1.7)	0.04
	Bleeding	10 (4.9)	3 (1.7)	0.09
	Intra-abdominal infection	14 (6.8)	1 (0.6)	0.84
	Other complications[a]	33 (16)	24 (13.7)	0.53
	Overall complications	54 (26.2)	42 (24)	0.62
	30-day major complications	33 (16)	16 (9.1)	0.046
	30-day reoperation	7 (3.4)	7 (4)	0.76
	30-day mortality	8 (3.9)	3 (1.7)	0.21

Data are presented as number (percentage) or median (interquartile range).

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

their clinical relevance or a univariate *P* value below 0.2. In the final multivariable logistic regression model, female sex demonstrated a persistent independent association with an elevated risk of DSL (OR, 5.33; 95% CI, 1.65–17.17; *P* = 0.005). Duodenal clipping was associated with lower odds of DSL, but this association did not reach significance in the final multivariable model (OR, 0.29; 95% CI, 0.08–1.08). 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

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

Variable	Univariate analysis		Multivariable analysis	
	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Age	1.01 (0.97–1.06)	0.7	–	–
Sex	5.5 (1.72–17.6)	0.004	5.33 (1.65–17.17)	0.005
BMI	0.98 (0.84–1.16)	0.86	–	–
ASA class (II–III vs I)	3.31 (0.43–25.6)	0.25	–	–
Preoperative hemoglobin level	0.85 (0.66–1.09)	0.19	–	–
Preoperative albumin level	0.93 (0.84–1.03)	0.14	–	–
Neoadjuvant treatment (yes/no)	0.38 (0.08–1.7)	0.21	–	–
Duodenal clipping (yes/no)	0.28 (0.08–1.02)	0.053	0.29 (0.08–1.08)	0.07
Retrieved lymph nodes	0.97 (0.9–1.03)	0.34	–	–

Abbreviation: OR, odds ratio; others, see **TABLE 1**

was evaluated using the receiver operating characteristic curve analysis based on the predicted probabilities, yielding an area under the curve of 0.764 (95% CI, 0.665–0.863; $P < 0.001$), which indicates fair discrimination (**TABLE 3**).

DISCUSSION This multicenter study aimed to evaluate the impact of a novel duodenal reinforcement technique on DSL rates. The use of duodenal clipping was associated with a lower incidence of DSL ($P = 0.04$) and a reduction in the 30-day postoperative major complication rate ($P = 0.046$). 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 DSL 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, including Lembert, purse-string, and barbed sutures.[15-20] Despite the demonstrated efficacy of these techniques in preventing DSL, their implementation is often technically challenging, may prolong operative time, and requires advanced laparoscopic skills as well as close coordination between surgeons and assistants. Conversely, the duodenal clipping method introduced in our study offers a simpler and more practical alternative, gentle learning curve, and can be performed independently without additional assistance.

This study describes the duodenal clipping technique that consists in the application of metal clips to the duodenal stapler line during laparoscopic gastrectomy. While not previously detailed in GC surgery, similar approaches in bariatric surgery have shown improved stapler-line safety and reduced complications. In a retrospective analysis, Yigit et al[21] reported that metallic clips applied to the stapler line during laparoscopic sleeve gastrectomy provided advantages in terms of both stapler line bleeding and leak rates. Although no significant difference was found between the groups in terms of postoperative bleeding in this study, we observed that bleeding rates were relatively lower in the DC group. In a prospective randomized controlled trial, omentopexy applied along the stapler line during laparoscopic sleeve gastrectomy was compared with clip reinforcement methods. The clipping group demonstrated a significantly shorter operative time.[22] We observed that operative time was markedly shorter in the DC 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 DSL,[23] this study found no such increase, even with the more extensive lymph node removal in the DC group. This finding suggests that the duodenal clipping method may be feasible even in the cases involving extensive dissection; however, an independent protective effect could not be confirmed in the present analysis. Although the point estimate favored clipping, the CI crossed unity and the association did not reach significance. These results suggest a possible reduction in crude leakage with duodenal clipping, particularly in high-risk patients. However, 1 case of DSL 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, as 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.

Limitations This study has limitations, including its relatively small sample size and retrospective design, which may have introduced selection bias. Additionally, all duodenal clipping procedures were performed in 1 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 the differences in operative time between the groups. Future prospective, multicenter studies with balanced group allocation are needed to better control for these potential confounding factors. However, our study is the first to describe the duodenal clipping method in GC surgery and evaluate its association with early postoperative outcomes.

CONCLUSIONS Duodenal clipping is a simple and technically feasible method for reinforcing the duodenal stump during laparoscopic GC surgery. Although the patients who underwent clipping had a lower crude rate of DSL, it was not independently associated with leakage in the multivariable analysis. Therefore, our 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 DSL.

ARTICLE INFORMATION

ACKNOWLEDGMENTS None.

FUNDING None.

CONTRIBUTION STATEMENT ST: conception and design of the study, data analysis and/or interpretation, drafting of the manuscript, and/or critical revision. SC: conception and design of the study, data acquisition, drafting of the manuscript, and/or critical revision. ICT and FT: data acquisition data analysis, and/or data interpretation. SUC: data analysis and/or interpretation, drafting of the manuscript, and/or critical revision. EA: drafting of the manuscript and/or critical revision. GGA and MAG: data acquisition. AEU: critical revision. SD: conception and design of the study. All authors read and apporved the final version of the manuscript.

CONFLICT OF INTEREST None declared.

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

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; 21: 154-160. 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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