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Totally intracorporeal delta-shaped B-I anastomosis following laparoscopic distal gastrectomy using the Tri-Staple™ reloads on the manual Ultra handle: a prospective cohort study with historical controls

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Abstract

Background A delta-shaped anastomosis in totally laparoscopic Billroth I gastrectomy could be performed easily and sufficiently using only laparoscopic linear staplers. However, the restricted maneuverability and severe blurring of these staplers along with their limited hemostability induced strain. In this study, we determined the feasibility and safety of performing delta-shaped anastomosis using the Endo GIA™ Reloads with Tri-Staple™ Technology combined with Endo GIA™ Ultra Universal stapler (Tri-Staple) with a particular focus on short-term surgical outcomes.

Methods We performed a single-institutional prospective interventional study (UMIN 000008014). The Tri-Staple was prospectively used on 23 consecutive patients who underwent a curative totally laparoscopic Billroth I gastrectomy with delta-shaped anastomosis. These patients were matched with the 19 patients previously treated using the ENDOPATH® ETS Articulating Linear Cutters (ETS) on clinical and demographic characteristics.

Results There were no differences between the groups in anastomosis-related local complications, morbidity, non-anastomosis-related local complications, total systemic complications, and short-term outcomes with the exception of significantly reduced blood loss in the Tri-Staple group (ETS vs. Tri-Staple: 37 [10–306] vs. 15 [5–210] mL, $p = 0.02$). Intraoperative bleeding from the staple line was significantly reduced in the Tri-Staple group. The postoperative drain indwelling period (ETS vs. Tri-Staple, 6 [4–10] vs. 4 [2–43] days, $p = 0.032$), fasting period (5 [3–7] vs. 3 [3–24] days, $p = 0.022$), and hospital stay (14 [10–47] vs. 11 [6–58] days, $p = 0.025$) were significantly shorter in the Tri-Staple group. There was no mortality in this series. Acceleration assessed as indices of blurring of stapler tip might have a significant adverse influence on staple-line bleeding at stapling sites.

Conclusion Totally laparoscopic Billroth I distal gastrectomy using Tri-Staple was feasible and safe with favorable short-term surgical outcomes. Reduced blurring while stapling may be a novel endpoint which newly developed stapling devices should target.

Keywords Stomach neoplasms · Laparoscopic distal gastrectomy · Delta-shaped anastomosis · Complication · Staple-line bleeding · Endo GIA Tri-Staple

Abbreviations

LADG	Laparoscopically assisted distal gastrectomy
TLDG	Totally laparoscopic distal gastrectomy
ETS	ENDOPATH® ETS Articulating Linear Cutters

Clinical Trial Registration We registered the trial procedure described in this manuscript in the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) under the following authors: Ichiro Uyama and Koichi Suda. UMIN-CTR ID: UMIN 000008014.

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Tri-Staple	Endo GIA™ Reload with Tri-Staple™ Technology combined with Endo GIA™ Ultra Universal stapler
Ccr	Creatinine clearance
ECOG	Eastern Cooperative Oncology Group
ASA	American Society of Anesthesiologists
PaO_2	Arterial oxygen pressure
UMIN-CTR	University Hospital Medical Information Network Clinical Trials Registry
JGCA	Japanese Gastric Cancer Association
AUC	Area under the curve

Gastric cancer is the second most common cause of death among patients with malignant diseases in Japan. Surgical resection remains the only curative treatment option, and a regional lymphadenectomy is recommended as part of radical gastrectomy. Compared with open distal gastrectomy, a laparoscopically assisted distal gastrectomy (LADG) reportedly offers significant advantages such as reduced intraoperative blood loss, reduced postoperative pain, and a shortened postoperative hospital stay [1, 2]. Recently, totally laparoscopic distal gastrectomy (TLDG), a more advanced approach, has been used in the treatment of patients with gastric cancer [3–6]. TLDG has several advantages over LADG including smaller wounds, reduced invasiveness, and greater feasibility of secure ablation [3].

In our institution, we have been using the delta-shaped anastomosis in totally laparoscopic Billroth I gastrectomy as reported by Kanaya [7] since 2007. This technique can be performed with ease using only laparoscopic linear staplers (ENDOPATH® ETS Articulating Linear Cutters, ETS, Ethicon Endo-Surgery, Cincinnati, OH). To date, our accumulated experience with this technique comprises over 150 cases with sufficient outcomes (anastomotic leakage, 2 %; anastomotic stenosis, 0 %; anastomotic bleeding, 1.3 %; and remnant gastric stasis, 0.7 %). However, we at times felt strained during this procedure due to the stapler's restricted maneuverability and the severe blurring caused by the hard grip as well as its limited hemostability.

The Endo GIA™ Reload with Tri-Staple™ Technology combined with Endo GIA™ Ultra Universal stapler (Tri-Staple; Covidien, Mansfield, MA) [8, 9] is a novel endoscopic linear stapler with outstanding performance across a broader range of tissues and applications. The Tri-Staple technology has provided improved burst pressure strength, reduced tissue compression stress, consistent hemostatic performance, and improved tissue retention during manipulation and transection. These outstanding features might reduce surgeons' frustration during the anastomosis, increasing their familiarity with TLDG and improving patient safety. The present study was therefore designed to determine the feasibility and safety of performing delta-shaped anastomosis using the Tri-Staple in patients with gastric cancer who undergo totally laparoscopic Billroth I distal gastrectomy, with a special focus on short-term surgical outcomes related to anastomosis.

Materials and methods

Patients

This study was conducted in a single-institutional prospective interventional manner. Twenty-three consecutive patients with primary distal gastric cancer who were curatively treated with laparoscopic distal gastrectomy followed by intracorporeal Billroth I reconstruction using the Tri-Staple between Oct 2010 and Feb 2011 were prospectively assigned to the Tri-Staple group. These patients were matched to the baseline clinical and demographic characteristics of 19 gastric cancer patients previously treated with laparoscopic distal gastrectomy followed by intracorporeal Billroth I reconstruction using the ETS-Flex 45-3.5 [10] (ETS group).

Cancer staging was done based on contrast-enhanced computed tomography, gastrography, endoscopic study, and endoscopic ultrasonography findings. The cancer stage was described according to the 14th edition of the Japanese Classification of Gastric Carcinoma [11]. A clinical stage ≤III was considered indicative for gastrectomy. Pathological staging was also performed based on analysis of the resected stomach and lymph nodes.

The routine preoperative evaluation to decide operability included blood count, serum chemistry, arterial blood gas analysis, electrocardiography, spirometry, creatinine clearance (Ccr), activated partial thromboplastin time, and prothrombin time. Patients who met the following criteria were considered eligible for radical gastrectomy under general anesthesia: an Eastern Cooperative Oncology Group (ECOG) performance status ≤2 [12], American Society of Anesthesiologists (ASA) Physical Status Classification ≤2 [13, 14], white blood cell count $\geq$3,000/mm^3, hemoglobin concentration ≥10 g/dL, platelet count $\geq$100,000/mm^3, total bilirubin ≤1.2 mg/dL, aspartate aminotransferase ≤70 IU/L, alanine aminotransferase ≤80 IU/L, serum creatinine ≤1.2 mg/dL, blood urea nitrogen ≤25 mg/dL, Ccr ≥60 mL/min, arterial oxygen pressure (PaO_2) ≥70 torr, forced expiratory volume in one second >1.5 L, % vital capacity >40 %, and fasting blood sugar count <140 mg/dL.

The procedures were performed by several fully trained endoscopic surgeons with experience of more than 30 TLDGs under the guidance of experts who performed more than 200 TLDGs (I.U, S.K, and S.S). The study protocol was approved by the Ethics Committee of the Fujita Health University Hospital. This study was registered in the University Hospital Medical Information Network Clinical

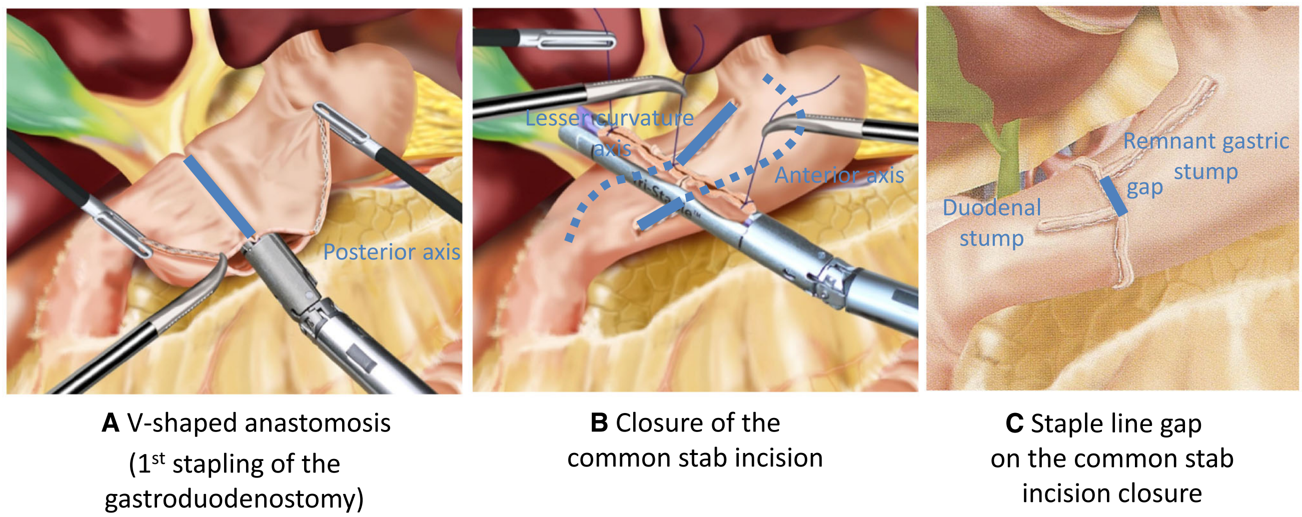


Fig. 1 Schematic outline of the delta-shaped anastomosis. It is a torsion-free anastomosis that maintains the physiological axes of the intestinal tract. **A** V-shaped anastomosis was made on the posterior walls of the remnant stomach and the duodenum putting their posterior axes together. A 45-mm linear stapler is used to create the anastomosis. **B** Closure of the common stab incision: The common stab incision was permanently closed to connect the stump and the anterior axis of the remnant stomach to the lesser curvature axis and the stump of the duodenum, respectively. **C** Staple-line gap on the common stab incision closure

Trials Registry (UMIN-CTR ID: UMIN 000008014). Written informed consent was obtained from all patients.

Extent of gastric resection and lymph node dissection

The Japanese Gastric Cancer Association (JGCA) has recommended that non-early, potentially curable gastric cancers should be treated with D2 lymphadenectomy and defined standard gastrectomy, which is the principal surgical procedure performed with curative intent, as a resection of not less than two-thirds of the stomach along with a D2 lymph node dissection [15]. The extent of lymph node dissection involved in D1+ or D2 lymphadenectomy was clearly defined in the third edition of the JGCA guidelines according to the extent of gastric resection [15]. Thus, distal gastrectomy was used for tumors localized to the M and/or L area. A D1+ lymphadenectomy was performed for preoperative Stage IA disease, and a D2 lymphadenectomy was performed for preoperative Stage IB, II, or III disease.

Surgical procedures for totally intracorporeal delta-shaped anastomosis

Most of the details pertaining to the technical aspects and perioperative management of laparoscopic gastrectomy were reported previously [16–18]

1. Under general anesthesia, a longitudinal 12-mm incision was created on the umbilicus and a camera trocar was put in place. Pneumoperitoneum was then established, and four additional trocars (5 or 12 mm in diameter) were placed in the upper abdominal area.
2. After mobilization of the gastroduodenum, the duodenal bulb was transected using an endoscopic linear stapler. The stapler was introduced through the left lower port, positioned across the duodenum in the dorsoventral direction, and fired.
3. Sufficient lymphadenectomy was performed, and the stomach was transected between the final ascending branch of the left gastric artery and the prefinal branch of the left gastroepiploic artery. The resected specimen was removed through the extended umbilical incision using a large plastic bag.
4. Small incisions (approximately 1 cm in size) were created on the greater curvature side of the remnant gastric stump and the posterior side of the duodenal stump.
5. The 45-mm endoscopic linear stapler was inserted into the gastric and duodenal stumps through the left lower port, with one jaw in each incision.
6. The posterior wall of the remnant stomach and that of the duodenum were put together, and the stapler was closed and fired. A V-shaped anastomosis was made on the posterior wall (the first stapling of the gastroduodenostomy).
7. The common stab incision was temporarily closed using Endo Universal (Covidien) and then permanently closed with two applications of the 45-mm staplers.

These processes enabled a torsion-free anastomosis while maintaining the physiological axes of the intestinal tract, resulting in an appropriate gap on the staple line of the common stab incision closure between the staple lines of the remnant gastric and the duodenal stumps (Fig. 1).

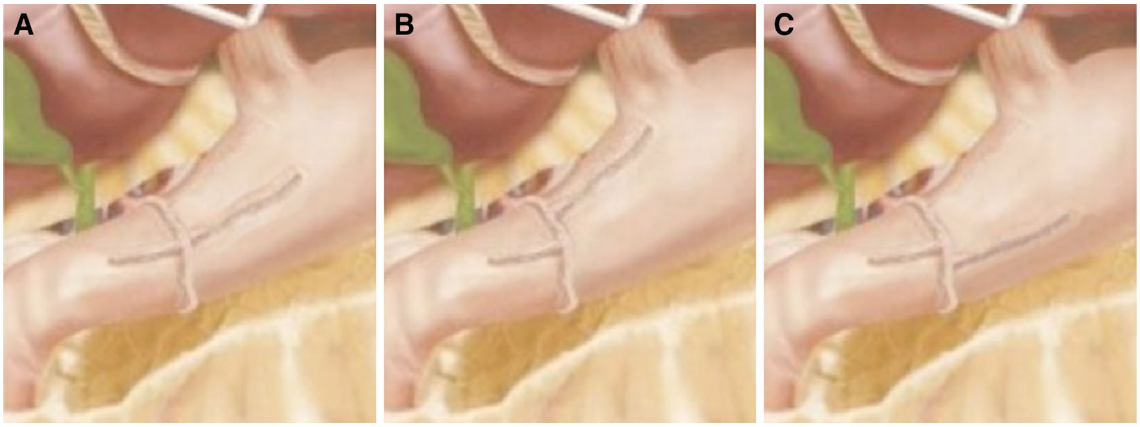
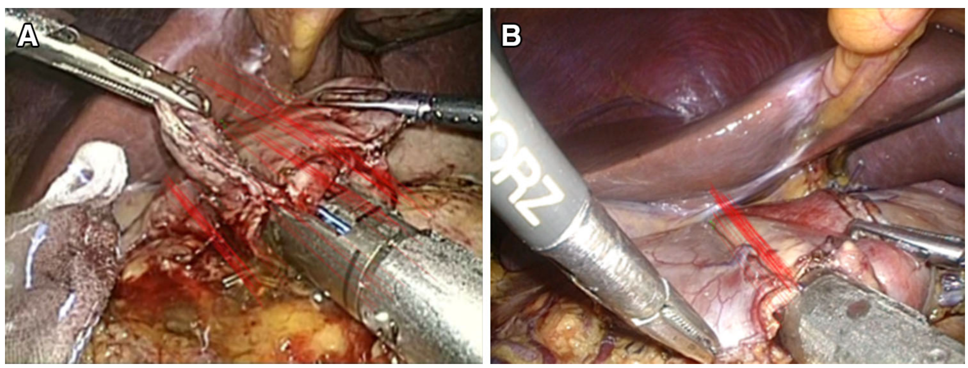


Fig. 2 Staple-line gap on the common stab incision closure. **A** Zero: no gap. **B** Plus: The gastric stump was cranial to the duodenal stump. **C** Minus: The gastric stump was caudal to the duodenal stump

Fig. 3 Blurring of the stapler tip on the staple line was quantitatively assessed by motion analysis software. A stick diagram from the tip and base of the stapler was assessed using motion analysis software (Move-Tr/2D 7.0, Library CO., Ltd) every 0.1 s in the process of firing at the transection. **A** ETS. **B** Tri-Staple



Endpoints and evaluated parameters

Endpoints

The primary endpoints were short-term surgical outcomes related to anastomosis including anastomotic leakage, stenosis, bleeding, and stasis. All other measurements were considered secondary. Postoperative complications were classified using the Japan Clinical Oncology Group Postoperative Complication Criteria according to the Clavien–Dindo classification system [19], and those with a grade higher than II were recognized as postoperative complications.

Assessment of stapler maneuverability and hemostability

To determine stapler maneuverability and hemostability, whole surgical procedures were recorded on DVD and the following factors were evaluated postoperatively: time for anastomosis, and the gap between the gastric and duodenal stumps after closure of the common stab incision (0: no gap, +: the gastric stump was cranial to the duodenal stump, and −: the gastric stump was caudal to the duodenal stump) (Fig. 2). The extent of staple-line bleeding was classified as no bleeding (−) or positive bleeding (+). Blurring of the stapler tip in the process of firing was also assessed using motion analysis software (Move-Tr/2D 7.0, Library CO., Ltd) (Supplementary Video) by measuring the coordinates of the tip and base of the stapler every 0.1 s during the process of firing at the stomach transection and V-shaped anastomosis (the first stapling of the gastroduodenostomy) (Fig. 3). Thereafter, the movement distance, velocity, and acceleration were calculated (Fig. 4). Since the force loaded onto the staple line through the blurring must be physically determined by the acceleration and weight of the stapler, the absolute value of the acceleration ([tip + base]/2) at each time point was graphically displayed in chronological order, and the areas under the curve (AUCs) were assessed as indices of blurring (Fig. 5).

Statistical analyses

Data were presented as median [range]. Independent continuous variables were compared by the Mann–Whitney *U* test or Kruskal–Wallis test, and categorical variables were compared by the χ^2 (Chi-squared) test or Fisher's exact test using Statview version 5.0. A two-sided p value <0.05 was considered significant. No correction was made for multiple testing of the data due to the limited sample size.

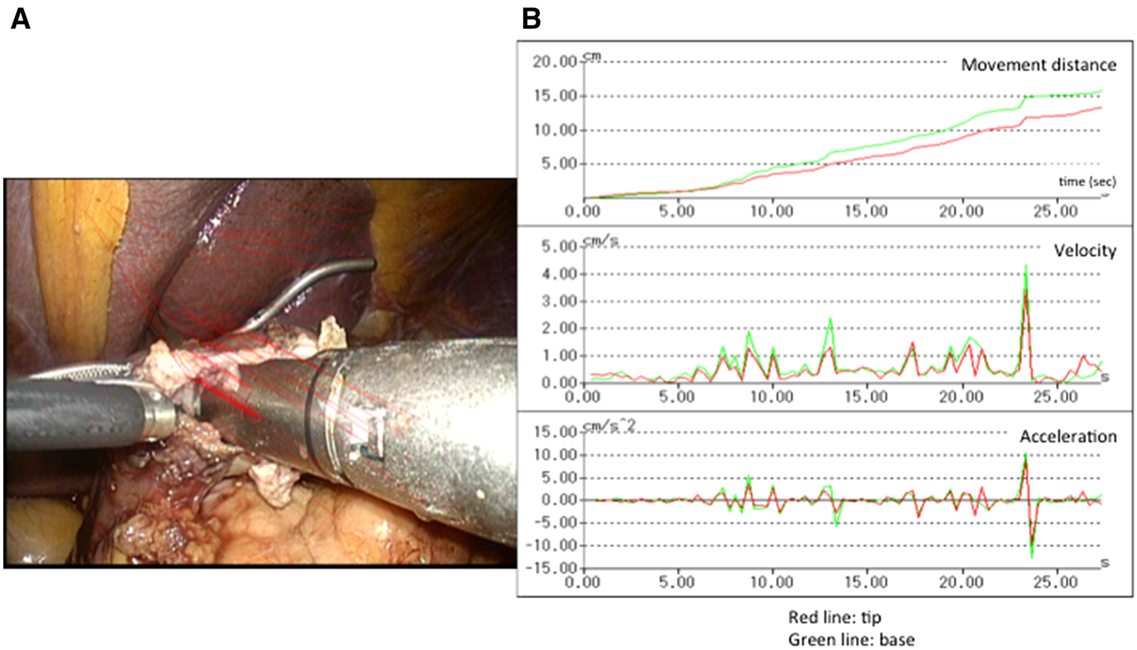
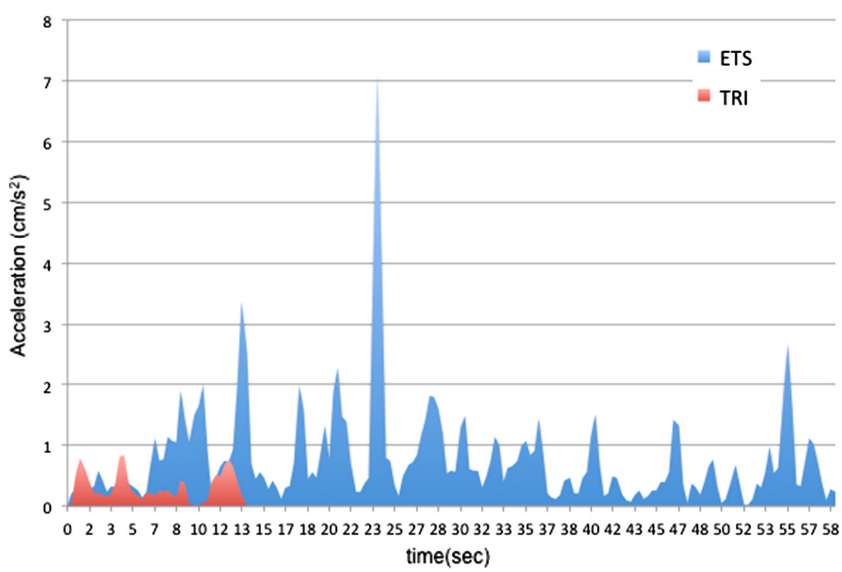


Fig. 4 Movement distance, velocity, and acceleration of the tip and base of the stapler on the staple line calculated by the motion analysis software. **A** Stick diagram from the tip and base of the stapler during the transection. **B** The data in a chronological order; *red line*: stapler tip, *green line*: stapler base

Fig. 5 The chronologically integrated value of the acceleration loaded onto the staple line (the area under the curve, AUC) was used as the index of stapler-tip blurring



Results

Patient and demographic data

Background characteristics including age, sex, body mass index, ASA physical status, operation history, tumor location, median tumor size, and final stage were not significantly different between the two groups (Table 1).

Short-term surgical outcomes

There was no significant difference in morbidity (ETS vs. Tri-Staple, 36.8 vs. 26.1 %, $p = 0.45$), anastomosis-related local complications (15.8 vs. 4.3 %, $p = 0.47$), non-anastomosis-related local complications (15.8 vs. 13.0 %, $p > 0.99$), and total systemic complications (15.8 vs. 8.7 %, $p = 0.82$) between the ETS and Tri-Staple

Table 1 Patient and demographic data

	ETS	Tri-Staple	p Value
No. of cases	19	23	
Age [range]	69 [36–86]	65 [42–83]	0.24
Sex (M:F)	14:5	16:7	>0.99
Body mass index (kg/m^2)	22.0 [14.5–30.8]	22.0 [16.2–29.8]	0.54
ASA physical status (1:2:3)	4:15:0	6:15:2	0.36
Operation history % (n)	15.7 (3/19)	0 (0/23)	0.84
Tumor location (middle:lower)	9:10	18:5	0.079
Median tumor size (cm) [range]	22.5 [12.0–30.0]	20.0 [2.0–60.0]	0.22
final Stage (IA:IB:IIA:IIB)	12:4:2:1	18:3:2:0	0.22

Table 2 Postoperative complications (Clavien–Dindo classification grade≥ II)

	ETS ($n = 19$)	Tri-Staple ($n = 23$)	p Value
Morbidity: % (n)	36.8 (7)	26.1 (6)	0.45
Local complications: % (n)	26.3 (5)	17.4 (4)	0.75
Anastomosis related: % (n)	15.8 (3)	4.3 (1)	0.47
Stasis	15.8 (3)	4.3 (1)	0.47
Anastomotic leakage	0	0	
Anastomotic stenosis	0	0	
Anastomotic bleeding	0	0	
Non-anastomosis related: % (n)	15.8 (3)	13.0 (3)	>0.99
Pancreatic fistula	15.8 (3)	8.7 (2[a])	0.82
False aneurysm	0	4.3 (1[b])	>0.99
Liver infarction	5.3 (1)	4.3 (1)	>0.99
Systematic complications: % (n)	15.8 (3)	8.7 (2)	0.82
Pneumonia	15.8 (3)	0	0.17
Coagulation disorder	0	4.3 (1)	>0.99
Ascites	0	4.3 (1)	>0.99

All except 2 cases were Clavien–Dindo classification grade II: [a]1/2 cases of pancreatic fistula and [b]1 false aneurysm were classified as Clavien–Dindo classification grade IIIa

Table 3 Short-term surgical outcomes

	ETS ($n = 19$)	Tri-Staple ($n = 23$)	p Value
Extent of lymph node dissection (D1:D1+:D2)	0:10:9	2:13:8	0.35
Number of dissected lymph nodes (n) [range]	26 [12–76]	30.5 [15–70]	0.46
Number of metastatic lymph nodes (n) [range]	0 [0–3]	0 [0–2]	0.72
Operative time (min.) [range]	319 [230–463]	278 [201–437]	0.056
Time for anastomosis (min.) [range]	9.2 [5.8–14.3]	9.0 [3.6–20.4]	0.93
Staple-line gap on common stab incision closure (0, +: −)	10:9	23:0	<0.001
Blood loss (mL)	37 [10–306]	15 [5–210]	0.020
Indwelling drain rate: % (n)	68.4 (13)	78.3 (18)	0.71

groups. No anastomotic leakage or stenosis occurred in this patient series (Table 2). Pancreatic fistula and gastric stasis were the most frequent non-anastomosis-related and anastomosis-related local complications, respectively. The amount of blood loss (37 [10–306] vs. 15 [5–210] mL, $p = 0.020$) was significantly smaller in the Tri-Staple group. There was no difference in operative time, time for anastomosis, extent of lymph node dissection, the number of dissected lymph nodes, the number of metastatic lymph nodes, and indwelling drain rate between the groups (Table 3). In the Tri-Staple group, the gastric stump was never positioned caudally to the duodenal stump (ETS vs. Tri-Staple, zero or plus:minus, 10:9 vs. 23:0, $p < 0.001$), suggesting that the physiological axes of the gastroduodenum could be better preserved with the Tri-Staple.

Postoperative courses

The drain indwelling period (ETS vs. Tri-Staple, 6 [4–10] vs. 4 [2–43] days, $p = 0.032$), fasting period (5 [3–7] vs. 3 [3–24] days, $p = 0.022$), and hospital stay (14 [10–47] vs. 11 [6–58] days, $p = 0.025$) were significantly shorter in the Tri-Staple group. Dietary intake was similar between the two groups, and there was no re-operation or mortality in this series (Table 4).

Blurring and bleeding on the gastric stump and V-shaped anastomosis: ETS versus Tri-Staple

Regarding blurring, AUCs at the gastric stump (ETS vs. Tri-Staple, 67.3 [17.9–140.4] vs. 26.7 [9.5–82.4] cm/s, $p < 0.001$) and at the V-shaped anastomosis (137.0 [30.6–291.3] vs. 65.9 [13.2–221.3] cm/s, $p = 0.025$) were smaller in the Tri-Staple group. The staple-line bleeding rate in the Tri-Staple group was smaller than that in the ETS group at the gastric stump (ETS vs. Tri-Staple, 89.5 vs. 8.7 %, $p < 0.001$) (Fig. 6).

Relationship between blurring of the stapler tip and staple-line bleeding

For each of the two individual staple lines (the V-shaped anastomosis and the gastric stump), cases were divided into staple-line bleeding-positive and staple-line bleeding-negative groups and the influence of blurring on staple-line bleeding was examined. At the V-shaped anastomosis, the AUC of the staple-line bleeding-positive group ($n = 31$) was larger than that of the staple-line bleeding-negative group ($n = 11$) (positive vs. negative, 47.2 [16.4–140.4] vs. 27.4 [9.5–97.6] cm/s, $p = 0.042$). At the gastric stump, the AUC of the staple-line bleeding-positive group ($n = 19$) was larger than that of the staple-line bleeding-negative group ($n = 23$) (positive vs. negative, 150.2 [31.7–291.3] vs. 66.0 [13.2–210.6] cm/s, $p = 0.003$). These results suggest that acceleration might have a significant adverse influence on staple-line bleeding at both stapling sites (Fig. 7).

Discussion

The present study demonstrated the feasibility and safety as well as the potential advantages of performing delta-shaped anastomosis [7] using Tri-Staple [8, 9]. The study yielded three major findings.

First, there was no difference in anastomosis-related local complications between the ETS and Tri-Staple groups. Most complications were graded lower than grade II, suggesting the equivalent and sufficient feasibility and safety of performing delta-shaped anastomosis using an

Table 4 Postoperative courses

	ETS ($n = 19$)	Tri-Staple ($n = 23$)	p Value
Drain indwelling period (days) [range]	6 [4–10]	4 [2–43]	0.032
Fasting period (days) [range]	5 [3–7]	3 [3–24]	0.022
Dietary intake: n (0 %: 50 %: >80 %)	1:0:18	0:1:22	0.36
Hospital stay (days) [range]	14 [10–47]	11 [6–58]	0.025
Reoperation: % (n)	0	0	1.00
Mortality: % (n)	0	0	1.00

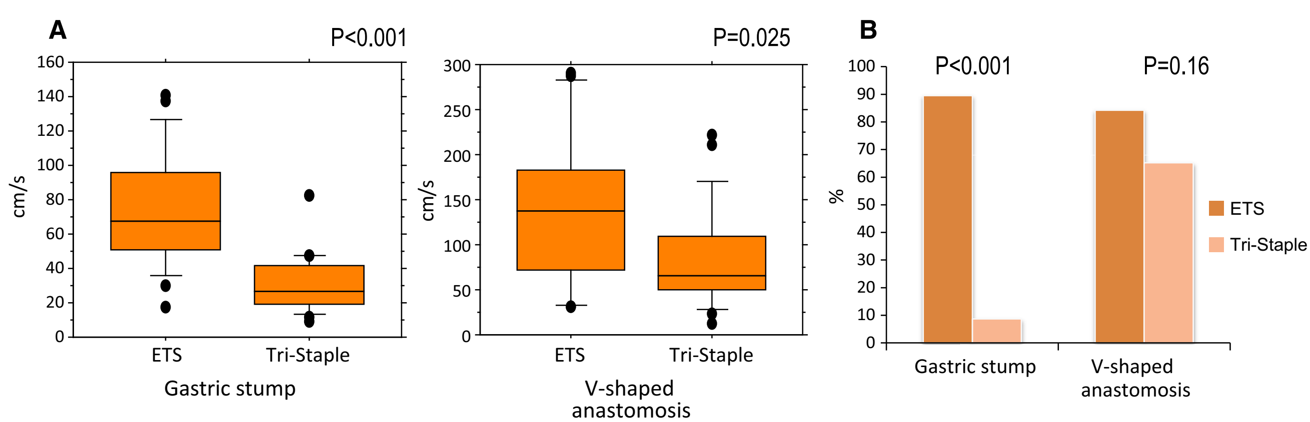


Fig. 6 Blurring and bleeding at the gastric stump and V-shaped anastomosis: ETS versus Tri-Staple. **A** Blurring of the stapler at the gastric stump and V-shaped anastomosis. **B** The staple-line bleeding rate of the ETS and Tri-Staple groups at the gastric stump and V-shaped anastomosis

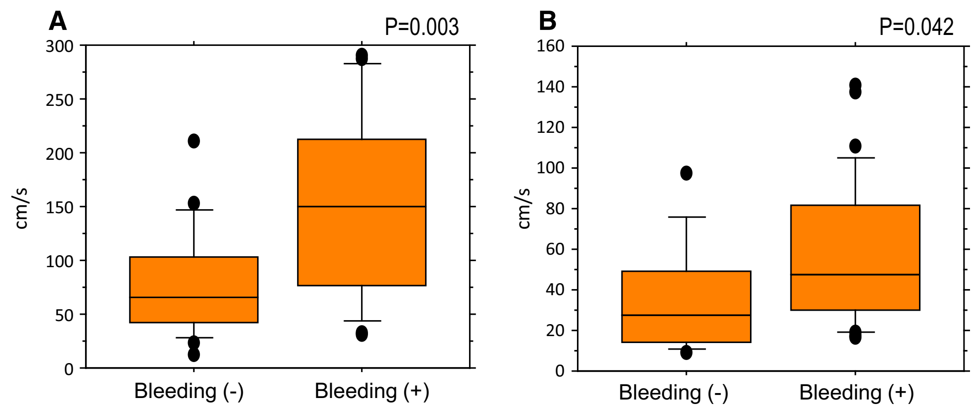


Fig. 7 The relationship between blurring of the stapler tip and staple-line bleeding. **A** Gastric stump. **B** V-shaped anastomosis

ETS or Tri-Staple [20–23]. In addition, morbidity, non-anastomosis-related local complications, total systemic complications, and short-term outcomes except for blood loss did not differ between the groups, suggesting a similar quality of operation in the prospective and historical control arms. The significant blood loss reduction of approximately 20 mL observed in the Tri-Staple group may reflect the attenuated intraoperative bleeding from the staple line.

Second, intraoperative bleeding from the staple line was significantly reduced in the Tri-Staple group. This can certainly be attributed to the advantages of the Tri-Staple such as the Tri-Staple technology and use of a fresh knife at each stapling. However, the present study revealed that the attenuation of blurring while stapling might also contribute to the reduction, at least to some extent.

Third, regarding the postoperative courses, the drain indwelling period, fasting period, and length of hospital stay were improved in the Tri-Staple group, with no difference in morbidity between the groups. Although the clear mechanism was unclear, these results may at least in part be ascribed to the highly reproducible excellent completion of the delta-shaped anastomosis without torsion made possible by the Tri-Staple, which must have allowed the operating surgeons to feel sufficiently confident with regard to patient feeding. Actually, the Tri-Staple technology made it easier to perform secure circumferential full-thickness closure of the common stab incision with preservation of the physiological axes of the gastroduodenum, which may allow for smoother food passage.

The present study had some limitations. First, this study was conducted in a non-randomized manner; therefore, the data may be biased, and the overall results should be interpreted cautiously. Second, there may be a considerable degree of difference in the maturity of the delta-shaped anastomosis technique, which must have varied according to experience, between the historical controls and the prospective cohort. Finally, our results may be affected by a lack of power due to the relatively small sample size. A randomized trial comparing the manual Endo GIA™ Ultra Universal stapler and the newly developed motor-driven iDrive™ Ultra Powered stapling system [24–26] has been prepared. The study will aim to confirm the possibility that attenuation of stapler blurring can lead to a reduction in bleeding on the staple line.

Conclusion

A delta-shaped anastomosis using the Tri-Staple in patients with gastric cancer who underwent totally laparoscopic Billroth I distal gastrectomy was feasible and safe with favorable short-term surgical outcomes. A reduction in blurring while stapling may be a novel endpoint which newly developed stapling devices should target.

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