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ORIGINAL ARTICLE

Feasibility of Endo GIA™ Reinforced Reload with Tri-Staple™ Technology for delta-shaped anastomosis

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KEYWORDS
Laparoscopic distal gastrectomy;
Reinforced;
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Summary *Background:* We report the short-term clinical outcomes of a delta-shaped (DS) anastomosis in laparoscopic distal gastrectomy (LDG), comparing Endo GIA™ Reinforced Reload (Reinforced GIA) with Endo GIA™ (GIA) staplers.
Methods: This was a retrospective analysis of 40 patients who underwent totally LDG with DS anastomosis with Reinforced GIA (group A) and 90 patients who underwent the same procedure with GIA (group B) for clinical T1–T3 gastric cancer from May 2013 to December 2016. Operation time, intraoperative blood loss, hospital length of stay, reconstruction time, and complications were compared.
Results: No patients required conversion to open surgery, and no patients died. There was no significant difference between the groups regarding patient background, postoperative hospital stay, and operation time. Bleeding from the V-shaped anastomosis was significantly less frequent in group A compared with group B (0% vs 11.2%, $p = 0.021$). Anastomosis-related complications were less frequent in group A, but there was no statistically significant difference between the groups. The fasting period in group A was significantly shorter than that of group B (2.81 vs 3.39 days, $p = 0.034$).
Conclusion: DS anastomosis using Reinforced GIA can prevent minor postoperative anastomosis leakage. Based on our findings and experience, we recommend DS anastomosis with Reinforced GIA after LDG for gastric cancer as an effective procedure with good short-term outcomes.

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1. Introduction

Compared with open surgery, laparoscopic surgery is associated with benefits that include decreased perioperative blood loss, faster patient recovery, and shorter hospital stay with similar overall survival rate. Delta-shaped gastroduodenostomy (DS anastomosis), an intracorporeal Billroth I anastomosis after laparoscopic distal gastrectomy (LDG) using only endoscopic linear staplers, has been increasingly adopted since being introduced by Kanaya et al in 2002.[1] DS anastomosis is relatively straightforward and has good long-term outcomes,[2] but the learning curve for surgeons is steep.[3] A modified DS anastomosis has been described that reduces the incidence of complications and decreases reconstruction time; however, DS anastomosis fails to completely eliminate postoperative complications.[3,4] Small incision closures using endoscopic linear staplers can have pitfalls. According to Noshiro et al, unsuccessful common channel closure of the greater curvature may result in abscess, pancreatitis, or anastomosis leakage, and additional suturing is necessary.[5] Fortunately, endoscopic linear staplers continue to improve. The Endo GIA™ Reinforced Reload (Reinforced GIA) with Tri-Staple™ Technology (Covidien, Mansfield, MA, USA) is a new endoscopic linear stapler with its forks covered with Neoveil (Gunze, Tokyo, Japan), a polyglycolic acid sheet. We evaluated the short-term outcomes of DS anastomosis using Reinforced GIA compared with standard Endo GIA™ (GIA).

2. Methods

2.1. Patients

This retrospective comparative cohort study was reviewed and approved by our institutional ethics committee. We included patients with uncomplicated gastric cancer who underwent LDG and DS anastomosis with lymph node dissection in our hospital. All emergency surgeries were excluded. A total of 132 American Society of Anesthesiologists physical status I, II, and III adult patients underwent LDG and DS anastomosis from May 2013 to December 2016. We divided the patients into two groups: Group A included patients who underwent DS anastomosis with Reinforced GIA, and Group B included patients who underwent DS anastomosis with standard GIA. Intracorporeal DS anastomosis was performed using methods described by Kanaya et al[1,6]

2.2. Operation

In all cases, after mobilizing the gastroduodenum, the duodenal bulb was transected using Endo GIA with the camel cartridge. Next, the transection line was rotated approximately 90° from the usual position. Sufficient lymphadenectomy was performed, and the stomach was transected using the purple cartridge Endo GIA. The surgeon stapled each incision in the gastric remnant and duodenum, then stapled together the posterior walls. The surgeon then selected either GIA or Reinforced GIA as the endoscopic stapler. The groups were compared in terms of patient history, surgery, and outcome. Patients' sex, age, body mass index (BMI), and lymph node dissection data are shown in Table 1. Standard lymphadenectomy was defined according to the Japanese Gastric Cancer Association guidelines.[7] All operations were performed by 12 surgical residents who were learning LDG and DS anastomosis and who were overseen by a single surgeon who acted as the surgical teaching assistant. We recorded the duration of surgery, length of postoperative stay, and complications during follow-up. Postoperative complications were evaluated using the extended Clavien-Dindo classification system.[8]

3. Statistical analysis

All statistical analyses were performed on a compatible personal computer using Statistical Package for Social Scientists software for Windows 15 (IBM, Armonk, NY, USA). Duration of surgery was analyzed with one-way analysis of variance, and paired comparisons of the data were made using the paired t-test, with $p < 0.05$ considered statistically significant.

4. Research involving human participants and/or animals

All procedures performed in this study involving human participants were in accordance with the ethical standards of our institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

5. Informed consent

Informed consent was obtained from all individual participants included in the study.

6. Surgical procedure

All surgeries were performed through five trocars using a flexible endoscope with patients under general anesthesia

Table 1 Patients' background characteristics.

	Group A (Reinforce[a])	Group B (Tri-Staple[b])	*p* Value
No. of cases	40	90	
Age (years)[c] [range]	63 [39—95]	68.5 [36—90]	0.186
Sex, M/F	22/18	56/34	0.438
BMI (kg/m^2)[c] [range][d]	21.0 [17.8—35.5]	22.8 [15.0—36.8]	0.201
Combined surgery % (n)	5.0% (2)	12.2% (11)	0.205
Final stage (I/II/III)	31/6/3	76/11/3	0.419

[a] Reinforced Reload Endo GIA™ with Tri-Staple™ Technology.
[b] *Tri-Staple* Endo GIA™ with Tri-Staple™ Technology.
[c] Median.
[d] *BMI* body mass index.

without epidural anesthesia. Abdominal CO_2 pressure was maintained at 10 mmHg during the procedure. Once the stomach and duodenum were transected at predetermined locations, small incisions were made with electrical scissors on the greater curvature of the stomach remnant and the posterior side of the duodenum. The 45-mm Reinforced GIA purple cartridge was used to make a common channel for anastomosis gastroduodenostomy in group A, and the 45-mm GIA purple cartridge was used in group B (Fig. 1). In group A, the V-shaped anastomosis was covered with a Neoveil sheet (Fig. 2a and b). Before the common channel was closed, temporary sutures were placed in the middle of the common channel. The operator held up the common channel, and the assistant stapled, approximating the gastric and duodenal walls using the 60-mm GIA purple cartridge in both groups. After common channel closure with endoscopic linear staplers, the greater curvature was examined to confirm that no additional sutures were required. Resected specimens were analyzed to confirm the presence of all gastric and duodenal layers. We performed no additional suturing (Fig. 3 and Video).

Supplementary video related to this article can be found at http://dx.doi.org/10.1016/j.asjsur.2017.04.002.

7. Results

7.1. Patients' background

From May 2013 to December 2016, 132 patients underwent LDG and DS anastomosis for gastric cancer at Kurashiki Central Hospital in Japan. Two cases were excluded by criteria. Patient characteristics including age, sex, BMI, and the incidence of concurrent surgery were not significantly different between the groups (Table 1).

Concurrent resection of other organs was performed in 13 (9.2%) patients and consisted of cholecystectomy for gallstones, n = 7 (5.4%); colectomy for synchronous colon cancer, n = 3 (2.3%); transabdominal preperitoneal hernia repair, n = 2 (1.5%); and mastectomy for synchronous breast cancer, n = 1 (0.8%). All patients successfully underwent LDG, with no operation-related deaths during the perioperative period. There were no cases of conversion to open surgery.

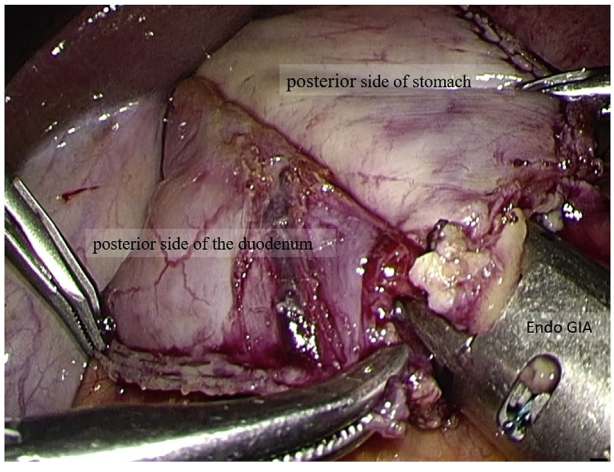

Figure 1 Intraoperative photograph showing the delta-shaped anastomosis. The 45-mm Reinforced GIA or GIA purple cartridge was used to make a common channel for anastomosis gastroduodenostomy.

Grade II or higher postoperative complications occurred in 12 patients (9.2%); abscess formation and pancreas-related complications were the most common (2.3%). Using the Reinforced GIA trended toward a reduction in postoperative morbidity from anastomosis-related local complications, but there was no significant difference between groups (0% vs 3.3%, p = 0.209). There were no cases of anastomotic stricture, anastomotic bleeding, or stasis, and we found no significant difference in other complications unrelated to the anastomosis (7.5% vs 6.7%, p = 0.863) (Table 2). All patients but three were classified as Clavien-Dindo grade II. One patient with bleeding on postoperative day 4 and one other patient with port site hernia on postoperative day 5 required surgical revision (grade III b); one patient with pancreas-related complications was classified as grade III a.

7.2. Operation

Bleeding from the V-shaped anastomosis line requiring treatment occurred in 11 patients in group B (12.2%), but did not occur in group A (p = 0.021); one patient required banding for hemostasis. Specimen analysis confirmed excision of all gastric and duodenal layers in all cases but one, and this patient required additional suturing. The mean operating time and anastomosis time in group B were longer than in group A (248.4 ± 64.9 vs 264.4 ± 54.5, respectively, p = 0.251; 11.4 ± 3.8 vs 12.1 ± 4.5, respectively, p = 0.615), but there was no statistically significant difference between the groups (Table 3).

7.3. Postoperative hospital course

There were no significant differences in the length of hospital stay between the two groups (average 9 days, with discharge on postoperative day 7), but the fasting period was significantly shorter in group A than group B (2.71 ± 0.87 vs 3.39 ± 1.16, respectively, p = 0.034) (Table 3). No patients developed postoperative fever as a symptom of Reinforced GIA infection.

8. Discussion

Complications related to stapled resection or anastomosis usually consist of bleeding and leakage. Previous studies report that totally laparoscopic Billroth I distal gastrectomy using GIA is feasible and safe with favorable short-term surgical outcomes.[9–11] Previous reports also state that intraoperative bleeding from the staple line is significantly reduced using GIA because it makes a fresh cut with each staple.[9] We hypothesized that a secure anastomosis was related to staple line bleeding; therefore, we used GIA as the standard stapler for DS anastomosis. In our study, anastomosis-related complications were observed in only 2.3% of patients, and the median time for anastomosis was 11 min (range, 6–22 min). These results suggest the feasibility and safety of performing DS anastomosis using GIA.

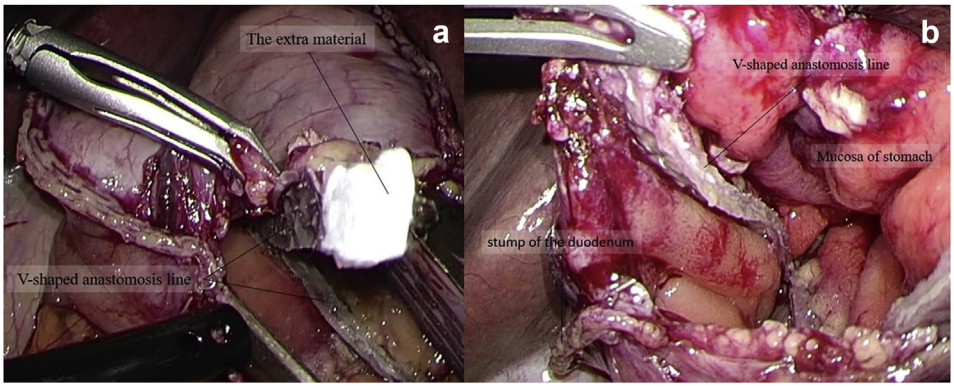

Figure 2 The Staple lines of V-shaped anastomosis were covered with Neoveil sheets in group A. These lines were a very dry and straight without any bleeding or blurring.

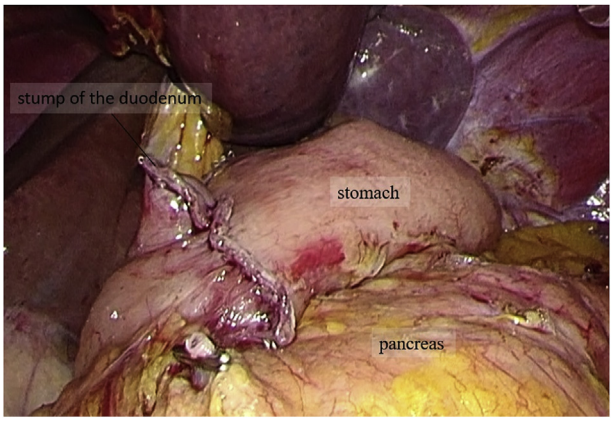

Figure 3 Delta-shaped anastomosis without an additional suture.

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

	Group A (Reinforce) n = 40	Group B (Tri-Staple) n = 90	*p* Value
Morbidity: % (n)	7.5% (3)	10.0% (9)	0.649
Anastomosis related: % (n)	0	3.3% (3)	0.209
Abscess formation around the anastomosis	0	2.2% (2)	0.342
Anastomotic leakage	0	1.1% (1)	0.503
Anastomotic bleeding	0	0	NA
Stenosis	0	0	NA
Stasis	0	0	NA
Non-anastomosis related: % (n)	7.5% (3)	6.7% (6)	0.863
Pancreas-related complication	3.3% (1)	2.2% (2)	0.922
Abscess formation	0	1.1% (1)	0.503
Postoperative bleeding	0	1.1% (1)	0.503
Pneumonia	3.3% (1)	1.1% (1)	0.553
Port site hernia	3.3% (1)	0	0.132
Cerebral infarction	0	1.1% (1)	0.503

NA not applicable.

Table 3 Short-term surgical outcomes and postoperative course.

	Group A (Reinforce) n = 40	Group B (Tri-Staple) n = 90	*p* Value
Short-term surgical outcomes			
Extent of lymph node dissection (D1:D1+:D2)	0:23:17	2:67:21	0.060
Number of dissected lymph nodes (n)[a]	38.3 ± 15.0	34.3 ± 13.8	0.620
Operative time (min)[a]	248.4 ± 64.9	264.4 ± 54.5	0.251
Time for anastomosis (min)[a]	11.4 ± 3.8	12.1 ± 4.5	0.615
Blood loss (g)[b] [range]	5 [0—75]	7 [0—325]	0.105
Bleeding of V-shaped anastomosis: n (%)	0	11 (12.2%)	0.021
Additional suture for anastomosis	0	1	0.503
Postoperative course			
Fasting period (days)[b] [range]	3 [1—5]	3 [2—7]	0.034
Postoperative hospital stay (days)[b] [range]	7 [3—28]	8 [5—51]	0.253
Reoperation: % (n)	3.3% (1)	1.1% (1)	0.553
Mortality: %	0	0	NA

NA not applicable.
[a] Average.
[b] Median.

A recent strategy for reducing and eliminating leaks and hemorrhage after gastrointestinal surgery involves reinforcing the staples with various materials. Applying reinforcing material in the staple line is thought to moderate tension on the staple line because it acts as a neutralizing plate. The buttressing material seals off the staple holes and narrows the spaces between the staples.[12] As a result, staple line reinforcement had some reported efficacy for gastrointestinal surgery.[13,14] Several types of materials have been used to reinforce the staple line, including non-absorbable, semi-absorbable, and absorbable materials. Our procedure includes buttressing materials in the inner

cavity to create the common channel at the anastomosis; therefore, we selected absorbable material with the Reinforced GIA to prevent infection. Neoveil sheeting is made of a synthetic fiber web that is composed of polyglycolic acid. Generally, this material is broken down by hydrolytic reactions after 6 months without an antigenic response.[12] However, in our study, two patients in group A who underwent gastroendoscopy at postoperative week 3 no longer had visible material at the anastomosis staple line. This material may undergo faster hydrolysis in the inner cavity because of gastric acid or duodenal fluid.

We covered the staples with Neoveil sheets because we expected this procedure to form a more secure pressure bonding. In our study, the V-shaped anastomosis made by Reinforced GIA was a very dry and straight line without bleeding or blurring in all cases. This method also increased the amount of tissue available adjacent to the common channel, which helped with manipulation. If the operator held up the extra tissue, the common channel was elevated enough that the endoscopic forceps were less likely to obstruct the GIA (Fig. 4).

Intracorporeal anastomotic procedures are complex and involve a high degree of technical difficulty. Given this consideration, there are certain key technical points in DS anastomosis using Reinforced GIA. First, we felt some friction when placing the anvil forks in small incisions on the posterior side of the duodenum because of the Neoveil sheets. Therefore, we coated the anvil forks of the Reinforced GIA with medical lubricant. Second, before the common channel was closed, the operator held up the extra tissue of the common channel. The posterior side of the duodenal wall near the extra tissue was always the lower position; therefore, we could easily check the duodenal wall serosa when we closed the common channel using Endo GIA.

We used laparoscopy to assess the anastomosis site and confirm no bleeding from the common channel, which reduced concern for the surgeon. In our study, the fasting period was significantly shorter in group A because of not only fewer postoperative complications, but also because of this reduced concern.

Endoscopic linear staplers are expensive and are associated with increased medical costs compared with extra-abdominal anastomotic procedures.[15] However, some surgeons have reported several advantages with totally laparoscopic surgery compared with laparoscopy-assisted surgery.[16,17] Reinforced GIA could make intracorporeal anastomosis easier and less expensive with the possibility of a shorter length of hospital stay. Our study is the first to our knowledge to show that the use of Reinforced GIA can lead to fewer postoperative complications in the early postoperative phase. This method is also very useful for creating the common channel at the anastomosis in gastrointestinal surgery.

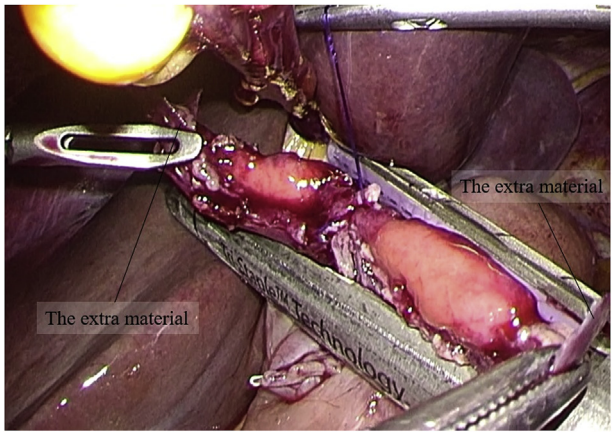

Figure 4 To held up the extra material elevates the common channel which were less likely to obstruct the GIA.

The present study has certain limitations. First, this study was retrospective and non-randomized. Second, selection bias is possible. Third, the anastomosis technique may have varied according to each surgeon's experience when comparing historical controls and the retrospective cohort.

In conclusion, DS anastomosis using Reinforced GIA without additional suturing could reduce the incidence of postoperative minor anastomosis leakage, as shown in our study where symptoms related to Reinforced GIA infection were not observed. Based on our findings and experience, we recommend DS anastomosis with Reinforced GIA after LDG for gastric cancer as an effective procedure with good short-term outcomes.

Conflict of interest

None of the authors have financial or personal conflicts of interest to disclose.

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