Langenbeck's Archives of Surgery (2022) 407:3147–3152
https://doi.org/10.1007/s00423-022-02669-4

HOW-I-DO-IT ARTICLES

The DOLFIN method: a novel laparoscopic Billroth-I gastroduodenostomy for gastric cancer with duodenal invasion

Naoki Shinno[1] · Takeshi Omori[1] · Hisashi Hara[1] · Masaaki Yamamoto[1] · Kohei Fujita[1] · Takashi Kanemura[1] · Tomohira Takeoka[1] · Takahito Sugase[1] · Masayoshi Yasui[1] · Chu Matsuda[1] · Hiroshi Wada[1] · Junichi Nishimura[1] · Naotsugu Haraguchi[1] · Hirofumi Akita[1] · Shinichiro Hasegawa[1] · Nozomu Nakai[1] · Kei Asukai[1] · Yousuke Mukai[1] · Hiroshi Miyata[1] · Masayuki Ohue[1] · Masato Sakon[1]

Received: 20 March 2022 / Accepted: 26 August 2022 / Published online: 14 September 2022
© The Author(s), under exclusive licence to Springer-Verlag GmbH Germany, part of Springer Nature 2022

Abstract

Background Laparoscopic Billroth-I gastroduodenostomy using a delta-shaped anastomosis is safe and feasible. However, it is often difficult to perform in patients who have a short posterior wall of the duodenum. Thus, we have developed a new method named duodenal overlap functional anastomosis with linear stapler (DOLFIN). We hereby report the technical details of the new method and our preliminary experience performing it.

Methods After the completion of lymphadenectomy, the duodenum was transected craniocaudally with an endoscopic linear stapler. The hepatoduodenal mesentery was dissected approximately 4 cm along the duodenal bulb, and the anastomosis between the posterior wall of the stomach and the lesser curvature of the duodenum was created. The common entry hole was then transected using an endoscopic linear stapler, and the anastomosis was finally completed.

Results There were 36 patients with gastric cancer who underwent laparoscopic distal gastrectomy (LDG) or robotic distal gastrectomy (RDG) with B-I reconstruction using DOLFIN. There were no postoperative complications classified as C-D grade 3 or more and complications related to anastomosis, such as anastomotic leak or stenosis.

Conclusions Our DOLFIN gastroduodenostomy can be performed safely. In addition, it results in good postoperative outcomes. A long-term comparative study is required to further evaluate the clinical usefulness of this method.

Keywords DOLFIN · LDG · RDG · B-I reconstruction · Duodenal invasion

Introduction

Gastric cancer is the fourth leading cause of cancer-related deaths worldwide [1]. The only radical treatment for gastric cancer is gastrectomy with adequate lymphadenectomy. Fortunately, the 5-year survival rate of early gastric cancer has improved to 90% with the development of advanced surgical techniques [2]. Although the incidence of gastric cancer in the upper third of the stomach has gradually increased due to the emergence of diagnostic endoscopic techniques, the majority is at the distal part of the stomach, specifically the antrum and pylorus, which requires distal gastrectomy, especially in East Asian patients [3, 4].

Various anastomotic methods are used based on the surgeon's preference and the tumor location after distal gastrectomy. Among them, the Billroth-I (B-I) gastroduodenostomy is most commonly performed method in Asia because of its technical simplicity and physiological advantages [5, 6]. With the development of instruments and advances in techniques, gastroduodenostomy can also be performed laparoscopically. In laparoscopic distal gastrectomy, delta-shaped anastomosis (DSA) using an endoscopic linear stapler is the most popular, safe, and feasible [7–10]. However, in advanced cases of duodenal invasion, the length of the posterior wall cannot be secured; hence, anastomosis of the posterior wall is often difficult.

In cases not suitable for B-I gastroduodenostomy, the Billroth-II (B-II) or Roux-en-Y (R-Y) reconstruction is often

✉ Takeshi Omori
oomori-ta@mc.pref.osaka.jp

[1] Department of Gastroenterological Surgery, Osaka International Cancer Institute, 3-1-69 Otemae, Chuo-ku, Osaka 541-8567, Japan

performed [11]. However, B-II has complications such as reflux esophagitis and remnant gastritis, which are closely related to the high risk of Barrett's esophagus or esophageal cancer and remnant gastric cancer [5, 11, 12]. Contrastingly, R-Y is more complicated to perform with more anastomoses. In addition, several patients may develop Roux stasis syndrome with functional obstruction of the Roux limb, which manifests as delayed gastric emptying [12, 13]. Therefore, there is a need to develop a method that makes B-I gastroduodenostomy possible even in cases where anastomosis of the posterior wall is difficult. Therefore, we have developed a new B-I gastroduodenostomy called duodenal overlap functional anastomosis with linear stapler (DOLFIN) to circumvent this problem. This technique is safe and easy to perform. Moreover, it is similar to that of DSA. In addition, we have applied this method to robotic-assisted distal gastrectomy (RDG). Herein, we report the technical details of this method and our preliminary experience performing it.

Patients and methods

Patients

We retrospectively reviewed the medical records of all 36 patients (22 men, 14 women) who underwent LDG or RDG with B-I reconstruction using DOLFIN between January 2018 and April 2020 at the Osaka International Cancer Institute. Preoperative staging was classified according to the third edition of the Japanese classification of gastric carcinoma, which was based on the results of gastroendoscopy, computed tomography, abdominal ultrasonography, or positron emission tomography [14]. All cases were histologically diagnosed as adenocarcinomas.

This study was approved by the Institutional Review Board of Osaka International Cancer Institute [18033–4]. All Surgery was then performed by five surgeons (N.S, T.O, H.H, M.Y, and K F) after the provision of informed consent.

Surgical technique

Under general anesthesia, the patient was placed in the lithotomy position. The operator stood on the right side of the patient, while the first assistant stood on the left. The video laparoscope operator was positioned between the patient's legs. The first trocar was inserted at the umbilicus, and a CO_2 pneumoperitoneum of 10–12 cmH_2O was then established. A video laparoscope was introduced via the umbilical port, while another four operating ports were placed in the upper abdomen. To keep the surgical field open, the ligamentum teres hepatis was fixed to the anterior abdominal wall, while the left lateral segment of the liver was retracted to a craniomedial position using the clipping and suturing method (FLICS) as previously reported [15].

After the completion of lymphadenectomy, the duodenum and stomach body were transected using an endoscopic linear stapler, which was inserted through the left lower port. The transection line of the duodenum was in the craniocaudal direction. The trocar wound on the umbilicus was extended to 5 cm, and the resected specimen was extracted.

Prior to the reconstruction, the hepatoduodenal mesentery was dissected approximately 4 cm along the duodenal bulb for the linear stapler to be introduced. A small incision was made on the greater curvature edge of the remnant stomach and on the lesser curvature edge of the duodenum but not on the greater curvature. An endoscopic linear stapler (cartridge size; 60 mm) was introduced through the left lower port with one jaw in each incision. First, the cartridge side was inserted into the stomach of the upper left abdomen. Thereafter, the linear stapler on the stomach was moved to the patient's right side, while another jaw was inserted into the duodenum. It was very important to rotate the stapler to the left to align it with the duodenal axis. After the introduction of a linear stapler approximately 4 cm into the stomach and duodenum, the posterior wall of the stomach and the lesser curvature of the duodenum were combined. The stapler was fired, and a V-shaped anastomosis was performed. The common entry hole was then transected and closed using an endoscopic linear stapler (cartridge size; 60 mm). A silicon drainage tube was inserted from the upper right port. The operation was completed by closing the skin of the trocar wound.

Robotic gastrectomies were performed using the da Vinci Xi robotic system (Intuitive Surgical Inc., Sunnyvale, CA, USA). The placement of the trocar is similar to laparoscopic surgery. After the completion of lymphadenectomy, an endoscopic linear stapler was introduced through the left lower port by the first assistant, then the duodenum and stomach body were transected. The anastomosis was performed using an endoscopic linear stapler inserted by the first assistant from left lower port, which was almost the same as the laparoscopic surgery.

Results

A total of 36 patients underwent LDG or RDG, which was followed by B-I anastomosis, as described in the "Methods" section. The characteristics of the patients are shown in Table 1. The patients' median age and median body mass index were 72 years (range, 45–84 years) and 22.1 kg/m^2 (range, 14.7–30.0 kg/m^2), respectively. The patients' perioperative findings are summarized in Table 2. The median operative time was 182 min (range, 96–422 min), and the median estimated blood loss was 0 g (range, 0–125 g). The median

Table 1 The clinicopathological characteristics of the patients

	N = 36
Age (year)	72 (45–84)[a]
Sex, male/female	22/14
Body mass index (kg/m^2)	22.1 (14.7–30.0)[a]
ASA-PS, 1/2/3	3/28/5
Clinical depth of invasion T1/T2/T3/T4	8/2/9/17
Clinical nodal involvement N0/N1/N2/N3	11/11/13/1
Clinical stage[b] IA/IB/IIA/IIB/IIIA/IIIB/IIIC/IV	8/1/4/1/13/7/1/1
Neoadjuvant chemotherapy, yes/no	2/34
Length of duodenal invasion (mm)	5 (0–30)[a]

[a]The data are shown as median (range)

[b]The clinical stages were determined and based on the third English edition of the Japanese classification of gastric carcinoma

Table 2 Perioperative findings

	N = 36
Operative time (minutes)	182 (96–422)[a]
Blood loss (g)	0 (0–125)[a]
Length of duodenal resection (mm)	30 (0–60) [a]
Combined resection Transverse colon	1 (2.8%)
Any complications > grade III[b]	0[c]
Postoperative hospital stay (day)	7 (5–23)[a]

[a]Data are shown as median (range)

[b]Grading of complications was based on the Clavien-Dindo classification

length of duodenal resection was 30 mm (range, 0–60 mm). No patient required blood transfusion. There were no severe intraoperative complications nor conversion to open surgery.

There were no postoperative complications classified as C-D grade 3 or more and complications related to anastomosis, such as anastomotic leak or stenosis. All patients tolerated a clear liquid diet on postoperative day 2 and a solid diet on day 3. The median postoperative hospital stay was 7 days (range, 5–23 days). Upper gastrointestinal endoscopy performed one year after surgery showed no cases of grade B or higher reflux esophagitis, as defined by the Los Angeles classification (Figs. 1, 2, 3, 4, 5, 6, 7).

Discussion

For patients with gastric cancer in the distal part of the stomach, distal gastrectomy with D2 lymphadenectomy is the standard treatment [16]. Randomized controlled trials

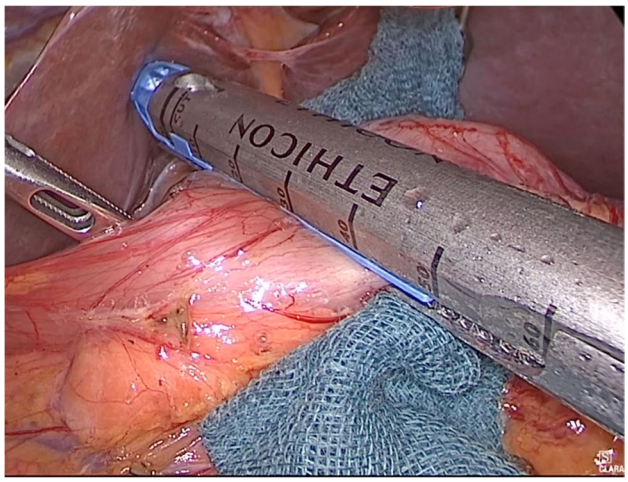

Fig. 1 The duodenum was transected craniocaudally using an endoscopic linear stapler

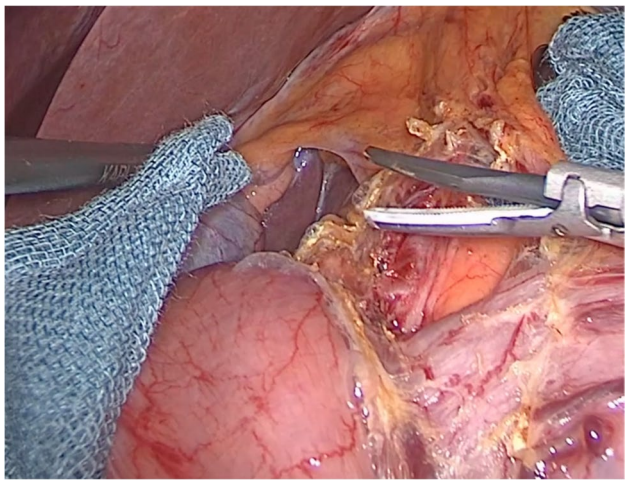

Fig. 2 The hepatoduodenal mesentery was dissected about 4 cm along the duodenal bulb

(RCTs) have shown that in the early stage, laparoscopic surgery is considered as an alternative to open surgery [17, 18]. In the advanced stage, however, some RCTs have shown that short-term outcomes, such as postoperative morbidity and mortality rate, are equivalent in open and laparoscopic surgery [19–21]. In addition, laparoscopic surgery has been shown to have some benefits, such as faster recovery and less pain compared with open surgery [22]. Therefore, laparoscopic distal gastrectomy is widely performed, especially in East Asian countries.

Duodenal invasion occurs in 11.9–23.8% of all patients with gastric cancer in the distal part of the stomach [23–26]. Tumor spread into the duodenum is often limited to within 2 cm in 76% of the patients and within 3 cm in 81% of the patients. Therefore, gastrectomy with resection of 3–4 cm of

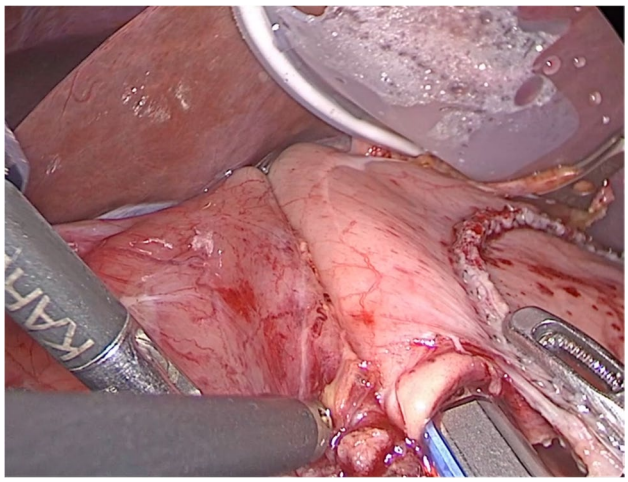

Fig. 3 The posterior wall of the stomach and the lesser curvature of the duodenum were combined. The *V*-shaped anastomosis was made

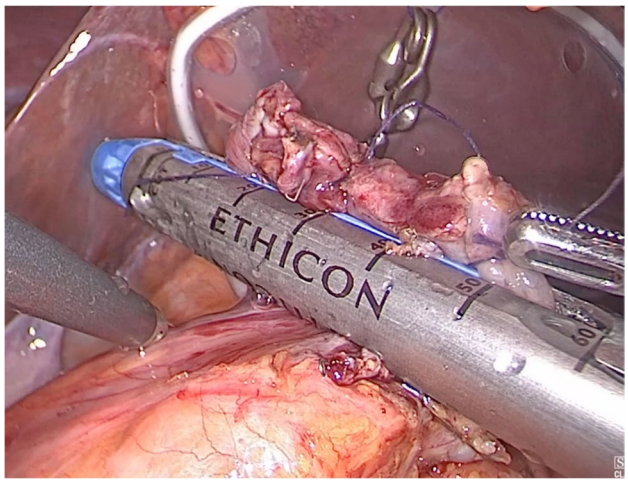

Fig. 4 The common entry hole was transected and closed using the endoscopic linear stapler

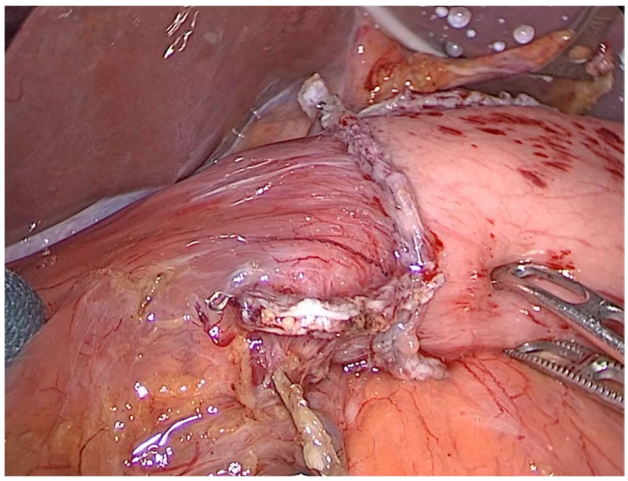

Fig. 5 The completed DOLFIN B-I gastroduodenostomy

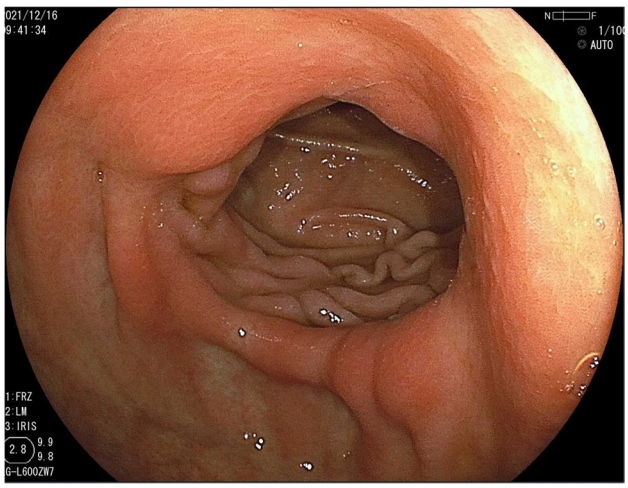

Fig. 6 Representative endoscopic photographs 1 year after surgery of DOLFIN method

the duodenum is recommended for patients with advanced gastric cancer with duodenal invasion [27]. B-I gastroduodenostomy using DSA is the most widely accepted reconstruction method after laparoscopic distal gastrectomy because of its technical simplicity. Previous studies have proven the safety of DSA with an acceptable morbidity rate of 5.5–3.5% and an anastomosis-related complication rate of 1.5–1.3% [7, 10, 28–30]. In this original technique, a small incision was created on the posterior side of the duodenum, and a *V*-shaped anastomosis was made on the posterior wall. However, the risks of intraoperative duodenal injury and postoperative anastomotic stenosis were reportedly high when the length of the posterior wall of the duodenal bulb was short [31]. We therefore developed DOLFIN B-I method to overcome this disadvantage.

The key technique of this procedure is to make a small incision on the lesser curvature side of the duodenal stump. In addition, a *V*-shaped side-to-side anastomosis should be made between the lesser curvature of the duodenum and the remnant stomach. The common entry hole can be closed using a linear stapler, which is similar to that of DSA. This procedure has several advantages. First, creating a space around the posterior wall of the duodenum is not required; therefore, this procedure reduces the possibility of damage to the surrounding structures, such as the pancreas. Second, since the *V*-shaped anastomosis is formed almost perpendicular to the duodenal stump, the triangular area of ischemia between the duodenal stump and the *V*-shaped anastomosis does not occur. In addition, since there is no attachment to the pancreas, the anastomotic length is easier to maintain at the lesser curvature of the duodenum than at the greater

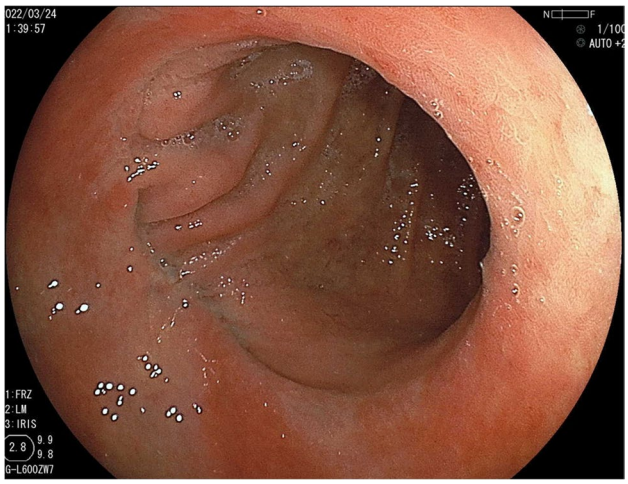

Fig. 7 Representative endoscopic photographs 1 year after surgery of DSA

curvature or posterior wall even when the tumor invades the duodenal bulb. Furthermore, the insertion of the stapler is easier because the linear stapler is introduced along the long axis of the duodenum. This is contrast with that of the original DSA method, in which the stapler is introduced diagonally from the posterior to the lesser curvature. In this case, the tip of the stapler may hit the lesser curvature side, which makes the stapler difficult to introduce. The disadvantage of this method is that it requires a slightly larger remnant stomach compared to DSA. It is extremely difficult to repair or re-anastomosis when troubles such as perforation by the linear stapler occur. And since the anastomosis is closer to the papilla Vater than the DSA, the frequency of bile reflux may increase.

This study has several limitations. First, the study was a retrospective design with a small sample size in a single center and there was a patient selection bias (low BMI, ASA < 3). Second, we reported the short-term results of this method, but the long-term outcomes are not available to show the advantages of our new technique compared with DSA, B-II or R-Y. Long-term results are important for postoperative reconstruction because nutritional status, symptoms such as reflux or dumping, and the development of residual gastric cancer are also issues. A long-term comparative study is required to further evaluate the clinical usefulness of this method.

Conclusion

We reported the technical details of and our preliminary experience with the new laparoscopic DOLFIN gastroduodenostomy. This method can be performed safely and it may be an alternative for B-II and R-Y for gastric cancer with duodenal invasion. A long-term comparative study is required to further evaluate the clinical usefulness of this method.

Acknowledgements We would like to thank Editage (https://www.editage.com/) for English language editing.

Authors' contributions N. Shinno and T. Omori drafted the first manuscript. All the authors individually made substantial contributions to conception and design, and acquisition of data, and analysis and interpretation of data, and gave final approval of the version to be published.

Declarations

Conflict of interest The authors declare no competing interests.

References

1. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, Bray F (2021) Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin 71:209–249
2. Ferlay J, Soerjomataram I, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray F (2015) Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. Int J Cancer 136:E359-386
3. Ahn HS, Lee HJ, Yoo MW, Jeong SH, Park DJ, Kim HH, Kim WH, Lee KU, Yang HK (2011) Changes in clinicopathological features and survival after gastrectomy for gastric cancer over a 20-year period. Br J Surg 98:255–260
4. Li S, Gu L, Shen Z, Mao D, Khadaroo PA, Su H (2019) A meta-analysis of comparison of proximal gastrectomy with double-tract reconstruction and total gastrectomy for proximal early gastric cancer. BMC Surg 19:117
5. Lombardo F, Aiolfi A, Cavalli M, Mini E, Lastraioli C, Panizzo V, Lanzaro A, Bonitta G, Danelli P, Campanelli G, Bona D (2022) Techniques for reconstruction after distal gastrectomy for cancer: updated network meta-analysis of randomized controlled trials. Langenbecks Arch Surg 407:75–86
6. Takiguchi S, Yamamoto K, Hirao M, Imamura H, Fujita J, Yano M, Kobayashi K, Kimura Y, Kurokawa Y, Mori M, Doki Y; Osaka University Clinical Research Group for Gastroenterological Study (2012) A comparison of postoperative quality of life and dysfunction after Billroth I and Roux-en-Y reconstruction following distal gastrectomy for gastric cancer: results from a multi-institutional RCT. Gastric Cancer 15:198–205
7. Kanaya S, Gomi T, Momoi H, Tamaki N, Isobe H, Katayama T, Wada Y, Ohtoshi M (2002) Delta-shaped anastomosis in totally laparoscopic Billroth I gastrectomy: new technique of intraabdominal gastroduodenostomy. J Am Coll Surg 195:284–287
8. Kim MG, Kawada H, Kim BS, Kim TH, Kim KC, Yook JH, Kim BS (2011) A totally laparoscopic distal gastrectomy with gastroduodenostomy (TLDG) for improvement of the early surgical outcomes in high BMI patients. Surg Endosc 25:1076–1082
9. Kinoshita T, Shibasaki H, Oshiro T, Ooshiro M, Okazumi S, Katoh R (2011) Comparison of laparoscopy-assisted and total laparoscopic Billroth-I gastrectomy for gastric cancer: a report of short-term outcomes. Surg Endosc 25:1395–1401
10. Noshiro H, Iwasaki H, Miyasaka Y, Kobayashi K, Masatsugu T, Akashi M, Ikeda O (2011) An additional suture secures against pitfalls in delta-shaped gastroduodenostomy after laparoscopic distal gastrectomy. Gastric Cancer 14:385–389

11. Lirong He, Yajie Zhao (2019) Is Roux-en-Y or Billroth-II reconstruction the preferred choice for gastric cancer patients undergoing distal gastrectomy when Billroth I reconstruction is not applicable? A meta-analysis. Medicine (Baltimore), https://doi.org/10.1097/MD.0000000000017093
12. G Piessen , JP Triboulet, C Mariette (2010) Reconstruction after gastrectomy: which technique is best? J Visc Surg, https://doi.org/10.1016/j.jviscsurg.2010.09.004
13. Zong L, Chen P (2011) Billroth I vs. Billroth II vs. Roux-en-Y following distal gastrectomy: a meta-analysis based on 15 studies. Hepatogastroenterology 58:1413–1424
14. Japanese Gastric Cancer Association (2011) Japanese classification of gastric carcinoma 3rd English edition. Gastric Cancer. 14:101–112
15. Ushimaru Y, Omori T, Fujiwara Y, Shishido Y, Yanagimoto Y, Sugimura K, Yamamoto K, Moon JH, Miyata H, Ohue M, Yano M (2019) A novel liver retraction method in laparoscopic gastrectomy for gastric cancer. Surg Endosc 33:1828–1836
16. Songun I, Putter H, Kranenbarg EM, Sasako M, van de Velde CJ (2010) Surgical treatment of gastric cancer: 15-year follow-up results of the randomised nationwide Dutch D1D2 trial. Lancet Oncol 11:439–449
17. Katai H, Mizusawa J, Katayama H, Morita S, Yamada T, Bando E, Ito S, Takagi M, Takagane A, Teshima S, Koeda K, Nunobe S, Yoshikawa T, Terashima M, Sasako M (2020) Survival outcomes after laparoscopy-assisted distal gastrectomy versus open distal gastrectomy with nodal dissection for clinical stage IA or IB gastric cancer (JCOG0912): a multicentre, non-inferiority, phase 3 randomised controlled trial. Lancet Gastroenterol Hepatol 5:142–151
18. Kim HH, Han SU, Kim MC, Kim W, Lee HJ, Ryu SW, Cho GS, Kim CY, Yang HK, Park DJ, Song KY, Lee SI, Ryu SY, Lee JH, Hyung WJ; Korean Laparoendoscopic Gastrointestinal Surgery Study (KLASS) Group (2019) Effect of laparoscopic distal gastrectomy vs open distal gastrectomy on long-term survival among patients with stage I gastric cancer: the KLASS-01 randomized clinical trial. JAMA Oncol 5:506–513
19. Lee HJ, Hyung WJ, Yang HK, Han SU, Park YK, An JY, Kim W, Kim HI, Kim HH, Ryu SW, Hur H, Kong SH, Cho GS, Kim JJ, Park DJ, Ryu KW, Kim YW, Kim JW, Lee JH, Kim MC; Korean Laparo-endoscopic Gastrointestinal Surgery Study (KLASS) group (2019) Short-term outcomes of a multicenter randomized controlled trial comparing laparoscopic distal gastrectomy with D2 lymphadenectomy to open distal gastrectomy for locally advanced gastric cancer (KLASS-02-RCT). Ann Surg 270:983–991
20. Inaki N, Etoh T, Ohyama T, Uchiyama K, Katada N, Koeda K, Yoshida K, Takagane A, Kojima K, Sakuramoto S, Shiraishi N, Kitano S (2015) A multi-institutional, prospective, phase II feasibility study of laparoscopy-assisted distal gastrectomy with D2 lymph node dissection for locally advanced gastric cancer (JLSSG0901). World J Surg 39:2734–2741
21. Yu J, Huang C, Sun Y, Su X, Cao H, Hu J, Wang K, Suo J, Tao K, He X, Wei H, Ying M, Hu W, Du X, Hu Y, Liu H, Zheng C, Li P, Xie J, Liu F, Li Z, Zhao G, Yang K, Liu C, Li H, Chen P, Ji J, Li G; Chinese Laparoscopic Gastrointestinal Surgery Study (CLASS) Group (2019) Effect of laparoscopic versus open distal gastrectomy on 3-year disease-free survival in patients with locally advanced gastric cancer: the CLASS-01 randomized clinical trial. JAMA 321:1983–1992
22. Kim HH, Hyung WJ, Cho GS, Kim MC, Han SU, Kim W, Ryu SW, Lee HJ, Song KY (2010) Morbidity and mortality of laparoscopic gastrectomy versus open gastrectomy for gastric cancer: an interim report–a phase III multicenter, prospective, randomized trial. Ann Surg 251:417–420
23. Namikawa T, Hanazaki K (2009) Clinicopathological features of early gastric cancer with duodenal invasion. World J Gastroenterol 15:2309–2313
24. Kakeji Y, Tsujitani S, Baba H, Moriguchi S, Mori M, Maehara Y, Kamegawa T, Sugimachi K (1991) Clinicopathologic features and prognostic significance of duodenal invasion in patients with distal gastric carcinoma. Cancer 68:380–384
25. Perng DS, Jan CM, Wang WM, Chen LT, Liu CS, Huang TJ, Chen CY (1996) Clinicopathological study of gastric carcinoma with duodenal invasion. Kaohsiung J Med Sci 12:461–465
26. Castleman B (1936) Extension of gastric carcinoma into the duodenum. Ann Surg 103:348–352
27. Kakeji Y, Korenaga D, Baba H, Watanabe A, Tsujitani S, Maehara Y, Sugimachi K (1995) Surgical treatment of patients with gastric carcinoma and duodenal invasion. J Surg Oncol 59:215–219
28. Matsuhashi N, Yamaguchi K, Okumura N, Tanahashi T, Matsui S, Imai H, Tanaka Y, Takahashi T, Osada S, Yoshida K (2017) The technical outcomes of delta-shaped anastomosis in laparoscopic distal gastrectomy: a single-center safety and feasibility study. Surg Endosc 31:1257–1263
29. Hong J, Wang YP, Wang J, Bei YB, Hua LC, Hao HK (2017) A novel method of self-pulling and latter transected delta-shaped Billroth-I anastomosis in totally laparoscopic distal gastrectomy. Surg Endosc 31:4831
30. Tokuhara T, Nakata E, Tenjo T, Kawai I, Kondo K, Ueda H, Tomioka A (2018) An option for delta-shaped gastroduodenostomy in totally laparoscopic distal gastrectomy for gastric cancer: a single-layer suturing technique for stapler entry hole using knotless barbed sutures combined with the application of additional knotted sutures. Oncol Lett 15:229–234
31. Watanabe Y, Watanabe M, Suehara N, Saimura M, Mizuuchi Y, Nishihara K, Iwashita T, Nakano T (2019) Billroth-I reconstruction using an overlap method in totally laparoscopic distal gastrectomy: propensity score matched cohort study of short- and long-term outcomes compared with Roux-en-Y reconstruction. Surg Endosc 33:3990–4002

Publisher's note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Springer Nature or its licensor holds exclusive rights to this article under a publishing agreement with the author(s) or other rightsholder(s); author self-archiving of the accepted manuscript version of this article is solely governed by the terms of such publishing agreement and applicable law.