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ORIGINAL ARTICLE

The Learning Curve of Linear-Shaped Gastroduodenostomy Associated with Totally Laparoscopic Distal Gastrectomy

Bo Wang[1] · Sang-Yong Son[1] · Ho-Jung Shin[1] · Hoon Hur[1] · Sang-UK Han[1]

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Abstract

Background Linear-shaped gastroduodenostomy (LSGD) is a new method of intracorporeal reconstruction that is simpler to perform and associated with a lower rate of bile reflux than delta-shaped anastomosis. Here, we analyzed the learning curve of LSGD in totally laparoscopic distal gastrectomy.

Methods The cumulative sum method was used to retrospectively analyze consecutive gastric cancer patients undergoing intracorporeal gastroduodenostomy after distal gastrectomy between January 2009 and May 2016. The duration of surgery, postoperative complications, hospital stay, and endoscopic findings in the postoperative period and the first, third, and fifth year were evaluated according to the two phases of the learning curve (learning period versus mastery period).

Results Data from 222 patients were included in the analysis. The LSGD learning period was 29 cases. The surgical time in mastery period was significantly shorter than the learning period (124.9 ± 34.5 versus 168.2 ± 42.0 min, $p < 0.001$). The incidence of minor complications was significantly reduced after the learning period ($p = 0.041$), although there was no statistically significant difference in the rate of major complications. The long-term endoscopic findings showed that the presence of residual food decreased over the time ($p = 0.022$).

Conclusions LSGD can be mastered easily after a reasonable number of cases and was associated with safe and satisfactory short- and long-term outcomes before and after learning curve.

Keywords Gastric cancer · Minimally invasive surgery · Reconstruction · Learning curve · Gastroduodenostomy

Introduction

Laparoscopic-assisted gastrectomy with perigastric lymphadenectomy for the treatment of gastric cancer was first introduced by Kitano et al. in 1994.[1] As surgical techniques and devices have improved, the gastrectomy procedure has progressed from laparoscopic-assisted to a totally laparoscopic approach, and reconstruction of the digestive tract is performed intracorporeally, maximizing the benefits of minimally invasive surgery.[2, 3] After distal gastrectomy, the gastrointestinal tract can be restored by a gastroduodenal anastomosis (Billroth I), gastrojejunal anastomosis (Billroth II), or a Roux-en-Y gastrojejunostomy. Among these, Billroth I reconstruction is the only anastomosis that maintains physiological food passage and prevents internal hernia, whilst retaining the ability to easily perform endoscopic retrograde cholangio-pancreatography (ERCP) examination, especially in young patients who underwent early gastric cancer surgery. However, Billroth I is not the most commonly used method of intracorporeal reconstruction due to the demanding technical requirements. After the delta-shaped gastroduodenostomy (DSGD) was first reported by Kanaya et al. in 2002,[4] it became the most popular intracorporeal method of gastroduodenostomy after distal gastrectomy. However, a nationwide survey conducted by the Korean Gastric Cancer Association has shown that use of the Billroth I has decreased, possibly due to the demanding technical requirements.[5] DSGD also has some limitations, being a complicated technique that is associated with a relatively high rate of anastomotic complications.[6–8]

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✉ Sang-Yong Son
sonsy@aumc.ac.kr

1 Department of Surgery, Ajou University School of Medicine, 164 Worldcup-ro, Yeongtong-gu, Suwon 16499, South Korea

The linear-shaped gastroduodenostomy (LSGD) was developed by our institute and published in 2010.[9] Our original study showed that this new approach was simple to perform and was associated with a lower rate of bile reflux than that with delta-shaped anastomosis in 2016.[10]

Several previous papers have described the learning curve for delta-shaped anastomosis, showing that a plateau is reached after approximately 20 laparoscopic surgery procedures.[11, 12] However, as the learning curve for LSGD has not previously been investigated, we have conducted a study to analyze the learning curve for LSGD and to investigate the long-term endoscopic findings associated with this new procedure.

Materials and Methods

Patients

This was a retrospective study of data obtained between June 2009 and May 2016 at the Ajou University Hospital, South Korea, and all the cases were conducted by a single surgeon (Han SU), who had performed laparoscopic gastrectomy more than 800 cases before performing totally laparoscopic distal gastrectomy. During this period, 923 cases of laparoscopic radical distal gastrectomy with Billroth I reconstruction were conducted. Patients undergoing extracorporeal reconstruction, delta-shaped anastomosis, hand-sewn gastroduodenostomy, and other anastomosis methods were excluded from the analysis.

LSGD Surgical Technique

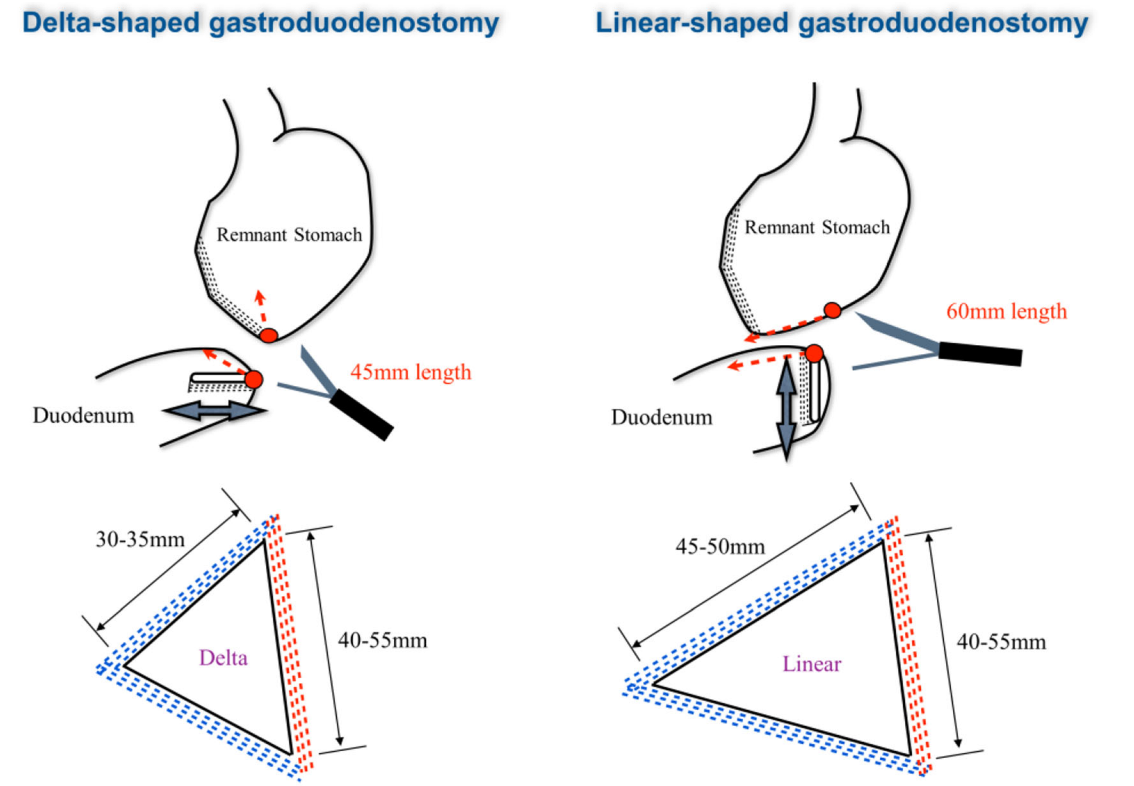
All patients included in the study underwent totally laparoscopic distal radical gastrectomy with intracorporeal reconstruction using the LSGD approach, which was firstly described in 2010,[9] and the short-term and intermediate outcomes regarding safety and feasibility of this technique were reported in 2016.[10] The great differences of this technique from DSGD are that a 60-mm endo-stapler is used for the anastomosis and that the anastomosis is made parallel between duodenal stump and gastric stump (Fig. 1). Thus, the diameter or intraluminal space of anastomosis in LSGD is greater than those in DSGD, which might reduce bile reflux and gastric stasis compared with DSGD. The major procedure was conducted as follows: (1) after V-shaped liver retraction[13] and perigastric lymphadenectomy, a linear endo-stapler was introduced through the left lower assistant port, transecting the duodenum in a craniocaudal direction without 90° duodenal rotation; (2) a small entry hole was made on the superior edge of the duodenal transection line; (3) a small incision was made on the greater curvature of the remnant stomach 60 mm from the resection line; (4) the cartridge jaw of the 60-mm endoscopic linear stapler was inserted into the remnant stomach; (5) the greater curvature of the remnant stomach and anterosuperior side of the duodenum were aligned and the stapler fired; (6) using another 60-mm endo-stapler to close the common entry hole.[10] The perigastric lymph node stations were numbered according to the Japanese classification of gastric carcinoma.[14] The extent of the lymphadenectomy was determined using the 2010 Japanese gastric cancer treatment guidelines (Version 3).[15]

Endoscopic Surveillance and Classification of Endoscopic Findings

Endoscopic surveillance was performed in the first, third, and fifth years, and was performed by one of three endoscopists who were highly specialized in gastric cancer and were belonged to the Gastric Cancer Center. The entire procedure has been standardized by our institution and has been described in detail previously.[10] Endoscopic findings of the remnant stomach were evaluated using the RGB (Residual food, Gastritis, Bile reflux) classification.[16]

CUSUM and Statistical Analysis

The cumulative sum (CUSUM) method is a graphic approach to detecting small shifts in an overall process that can also indirectly detect data trends. The CUSUM chart plots the cumulative sum of the deviation of the raw value of each sample from the target or mean value.[17] As the CUSUM chart is cumulative, even minor drifting in the process mean will cause steadily increased or decreased cumulative deviation values. In the present study, the cases were numbered chronologically from the first to the last and the formula of CUSUM operation time (CUSUMOT) was represented as follows: $\mathrm{CUSUMOT}\cdot\max = \sum_{i=1}^{n} [\mathrm{Xi}-(\mu+K)+\mathrm{FIR}]$ and $\mathrm{CUSUMOT}\cdot\min = \sum_{i=1}^{n} [\mathrm{Xi}-(\mu-K)+\mathrm{FIR}]$, where Xi is an individual operation time, μ is the overall mean values of operation time, K is a constant representing the allowable “slack” in the process and specifying the magnitude of the shift you want to detect (usually defined as half of standard deviations), and FIR is also a constant, usually equal to 0. The learning curve of LSGD regarding the operation time was represented intuitively and determined by plotting the outcomes in the CUSUM chart. There were two fluctuating lines, the upper indicates that the individual operation time was greater than the population mean and the lower indicates that it was lower and, therefore, not necessary to include in the analysis. Therefore, the upper line was defined as the learning curve of LSGD. The CUSUM charts were plotted using the Excel plugin, named QI Macros, version 2018 student for Windows (KnowWare International Inc., CO, USA).



	DSGD	Ratio	LSGD
* Triangle area	447 ~ 595 mm²	1 : 1.80~1.92	806 ~ 1148 mm²
** Diameter of the anastomosis	31.8 ~ 39.8 mm	1 : 1.23~1.30	41.4 ~ 49.3 mm

*Triangle area $=\sqrt{s(s-a)(s-b)(s-c)}$ cf) $s = (a+b+c)/2$

**Diameter of the anastomosis $= 2s/\pi$

DSGD: Delta-shaped gastroduodenostomy; ***LSGD***: Linear-shaped gastroduodenostomy

Fig. 1 The schematic illustration for LSGD and DSGD, and the comparison of intraluminal space between them

All the statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS), version 24.0 for Windows (SPSS Inc., Chicago, USA). For quantitative data, the results are expressed as the mean ± standard deviations; for categorical data, the results are expressed as number (%). Categorical variables were analyzed by the chi-square test or Fisher's exact test; continuous variables were analyzed by Student's *t* test. Furthermore, repeated values were analyzed by the repeated measured ANOVA method. The level for rejection of the null hypothesis was set at a p value of < 0.05.

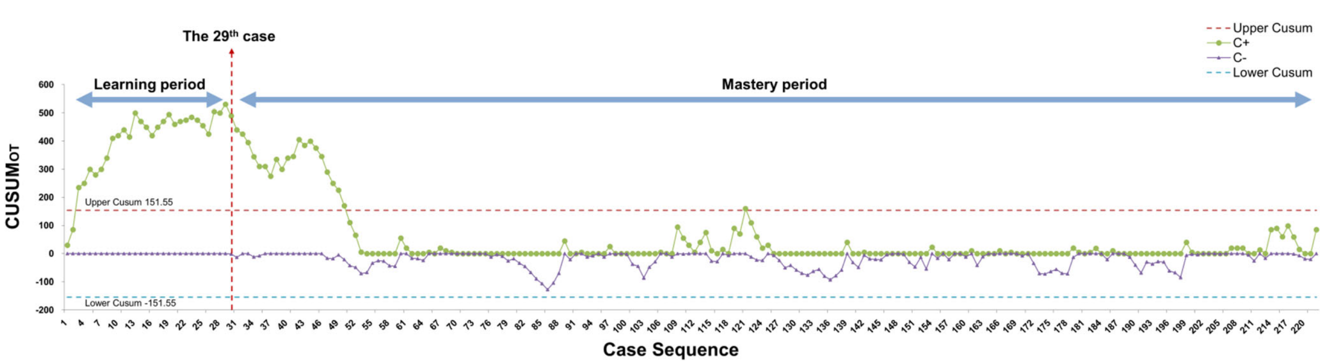


Fig. 2 Learning curve for linear-shaped gastroduodenostomy after laparoscopic distal gastrectomy

Table 1 Interphase comparisons of characteristics after LSGD

Variables	Learning period $n = 29$ (case 1 to case 29)	Mastery period $n = 193$ (case 30 to case 222)	*p*
Age (years)	58.9 ± 11.1	60.4 ± 13.4	0.578
Gender			0.614
Male	16 (55.2%)	116 (60.1%)	
Female	13 (44.8%)	77 (39.9%)	
BMI (kg/m^2)	23.8 ± 3.7	23.5 ± 3.0	0.728
ASA score			0.229
1	12 (41.4%)	100 (51.8%)	
2–3	17 (58.6%)	93 (48.2%)	
Previous abdominal surgery			0.232
Absent	24 (82.8%)	174 (90.2%)	
Present	5 (17.2%)	19 (9.8%)	
Tumor location (vertical)			0.016
Middle third	3 (10.3%)	62 (32.1%)	
Lower third	26 (89.7%)	131 (67.9%)	
Tumor location (horizontal)			0.554
Lesser curvature	10 (34.5%)	74 (38.3%)	
Greater curvature	8 (27.6%)	32 (16.6%)	
Anterior wall	3 (10.3%)	34 (17.6%)	
Posterior wall	5 (17.2%)	39 (20.2%)	
Circumferential	3 (10.3%)	14 (7.3%)	
pT classification			0.417
T1	25 (86.2%)	165 (85.5%)	
T2	2 (6.9%)	14 (7.3%)	
T3	1 (3.4%)	13 (6.7%)	
T4a	1 (3.4%)	1 (0.5%)	
pN classification			0.257
N0	22 (75.9%)	168 (87.0%)	
N1	4 (13.8%)	16 (8.3%)	
N2	3 (10.3%)	7 (3.6%)	
N3	0	2 (1.0%)	
pStage*			0.376
IA	21 (72.4%)	154 (79.8%)	
IB	5 (17.2%)	17 (8.8%)	
IIA	1 (3.4%)	13 (6.7%)	
IIB	1 (3.4%)	5 (2.6%)	
IIIA	0	3 (1.6%)	
IIIB	1 (3.4%)	1 (0.5%)	
IIIC	0	0	

The data were expressed as mean ± standard deviation or number (%)

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

*The stages were classified by the 7th UICC/AJCC staging system

Ethics Statement

All patients provided informed consent for their information to be stored in the hospital database and used for research. The study protocol was approved by the Institutional Review Board of the Ajou University Hospital.

Results

CUSUM Analysis of the LSGD Learning Curve

The CUSUM analysis was performed to analyze the total operation times according to the experienced cases, and it

Table 2 Interphase comparisons of operative and postoperative outcomes after LSGD

Variables	Learning period $n = 29$ (case 1 to case 29)	Mastery period $n = 193$ (case 30 to case 222)	p
Lymph node dissection[a] (no. %)			0.194
< D2	15 (51.7%)	124 (64.2%)	
≥ D2	14 (48.3%)	69 (35.8%)	
Combined resection			0.791
No	28 (96.6%)	188 (97.4%)	
Yes	1 (3.4%)	5 (2.6%)	
Operation time (min)	168.2 ± 42.0	124.9 ± 34.5	< 0.001
Estimated blood loss (ml)	137.9 ± 141.4	94.6 ± 93.9	0.120
Retrieved lymph nodes	35.2 ± 12.9	37.1 ± 14.4	0.479
Metastatic lymph nodes	0.6 ± 1.2	0.3 ± 1.2	0.267
Tumor size (cm)	2.8 ± 1.5	2.2 ± 1.1	0.027
Resection margin (cm)			
Proximal	5.7 ± 2.8	4.6 ± 2.1	0.040
Distal	4.3 ± 1.8	4.6 ± 2.3	0.476
Start sips of water (days)	2.2 ± 0.7	1.6 ± 0.7	< 0.001
Start soft diet (days)	5.9 ± 1.2	4.9 ± 2.1	0.017
Postoperative hospital stays (days)	8.0 ± 3.6	7.7 ± 5.4	0.756
Overall complications	5 (17.2%)	18 (9.3%)	0.192
Minor complications	4 (13.8%)	7 (3.6%)	0.041
Wound infection	2 (7.0%)	1 (0.5%)	
Fluid collection		1 (0.5%)	
Intraabdominal bleeding		1 (0.5%)	
Pancreatitis	1 (3.4%)	2 (1.0%)	
Pulmonary	1 (3.4%)	2 (1.0%)	
Major complications*	1 (3.4%)	11 (5.6%)	0.617
Fluid collection		1 (0.5%)	
Anastomotic leakage	1 (3.4%)	3 (1.5%)	
Anastomotic stenosis[†]		3 (1.5%)	
Pancreatic fistula		2 (1.0%)	
Intestinal obstruction		2 (1.0%)	
Operative mortality (within 30 days)	0	0	NA

The data were expressed as mean ± standard deviation or number (%)

[a] According to the Japanese gastric cancer treatment guideline 2010

*The major complication was defined according to the *Clavian-Dindo* classification ≧ IIIa

[†] A half-covered stent was applied and removed after about 2–4 weeks endoscopically

showed a gradual increase until the 29th case; thereafter, it declined sharply until the 54th case (Fig. 2). Therefore, the learning curve was considered as 29 cases in the present study and the cases were divided into two groups; the initial learning period (1st–29th cases) and the mastery period (30th–222nd cases).

Comparison of Patients' Characteristics and Short-term Outcomes

Patient characteristics according to the learning curve phase are described in Table 1. It showed that the proportion of middle located tumor were significantly higher in the mastery period ($p = 0.016$, respectively), but no statistically significant differences in other variables between the two phases.

Operative and postoperative outcomes are shown in Table 2. The surgical time was significantly longer in the learning phase than the mastery phase (168.2 ± 42.0 versus 124.9 ± 34.5 min, $p < 0.001$). During the learning period, the tumor size was bigger and gained more wider proximal resection margin compared with mastery period ($p = 0.027$ and $p = 0.040$, respectively). There were statistically significant differences regarding time to restoration of diet between the two phases (sips of water, 2.2 ± 0.7 versus 1.6 ± 0.7 days;

Table 3 Interphase comparisons results of long-term endoscopic findings after LSGD

Characteristic	Year 1		p	Year 3		p	Year 5		p
	Learning period	Mastery period		Learning period	Mastery period		Learning period	Mastery period	
Follow-up ratio	29/29 (100%)	180/193 (93.3%)		26/29 (89.6%)	116/140 (82.8%)		24/29 (82.7%)	34/47 (72.3%)	
Residual food			0.032			0.045			1.000
Grade 0	22 (75.9%)	164 (91.1%)		22 (84.6%)	110 (94.8%)		23 (95.8%)	33 (97.1%)	
Grade 1	6 (20.7%)	15 (8.3%)		3 (11.5%)	6 (5.2%)		1 (4.2%)	1 (2.9%)	
Grade 2	1 (3.4%)	1 (0.5%)		1 (3.8%)	0		0	0	
Gastritis			0.406			0.310			0.066
Grade 0	2 (6.9%)	4 (2.2%)		2 (7.7%)	2 (1.7%)		3 (12.5%)	0	
Grade 1	27(93.1%)	174 (96.7%)		24 (92.3%)	113 (97.4%)		21 (87.5%)	33 (97.1%)	
Grade 2	0	2 (1.1%)		0	1 (0.9%)		0	1 (2.9%)	
Bile reflux			0.675			0.633			0.552
Grade 0	18 (62.1%)	120 (66.7%)		20 (76.9%)	81 (69.8%)		19 (79.2%)	24 (70.6%)	
Grade 1	11 (37.9%)	60 (33.3%)		6 (23.1%)	35 (30.2%)		5(20.8%)	10 (29.4%)	

The data were expressed as mean ± standard deviation or number (%)

$p < 0.001$; soft diet, 5.9 ± 1.2 vs. 4.9 ± 2.1 days; $p = 0.017$). The rate of minor complications also differed significantly between the two phases ($p = 0.041$).

Comparison of Long-term Endoscopic Findings

An interphase comparison of the long-term endoscopic findings in the first, third, and fifth postoperative year is shown in Table 3; There were significant difference in residual food between learning and mastery period in the first and third year, but the difference disappeared at the fifth year postoperatively. There were no significant differences in degree of gastritis, and bile reflex in the follow-up period. However, in 57 cases for whom follow-up data were available for the entire period, the residual food classification improved significantly over the 5-year period ($p = 0.022$; Fig. 3).

Discussion

Currently, the DSGD is still a popular reconstruction approach for intracorporeal Billroth I after totally laparoscopic distal gastrectomy. However, it has been reported with relatively high rate of anastomosis-related complications.[6–8] As like we previously reported, we developed LSGD to overcome the technical difficulty of DSGD in 2009 and reported promising outcomes to reduce bile reflux and gastric stasis compared with DSGD in 2006. However, this technique has not been popular because only a few papers with modified method or different name have been reported.[18, 19] In addition, there was no report on learning curve of this technique, which make the surgeons hesitating to perform this novel technique for intracorporeal Billroth I anastomosis. Thus, we analyzed the learning curve of LSGD.

This is the first study to describe the LSGD learning curve, demonstrating this method to be a safe approach that can be

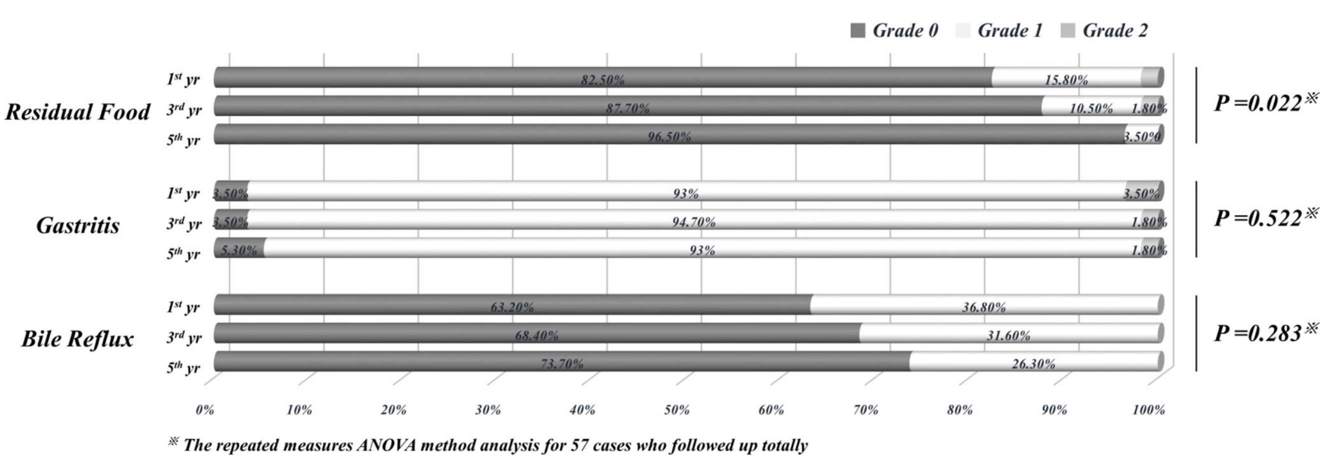


Fig. 3 Results of the residue, gastritis, bile (RGB) classification in the first, third, and fifth postoperative year for 57 patients who followed up totally

mastered rapidly; short-term surgical outcomes and long-term endoscopic findings after totally laparoscopic distal gastrectomy were acceptable, even during the learning period.

CUSUM analysis of the learning curve showed that, the number of cases required to master the LSGD was considered as 29, it was shorter than in other previous studies. Huang et al.[20] reported the learning period for DSGD was 41 cases. Once into the mastery period, the surgical time stabilized at around 124.9 ± 34.5 min, it was also shorter than that in previous studies (393.9 ± 70.8 min reported by Huang et al.,[20] and 142 ± 19 min reported by Jeong et al.[11]).

The major complication rate showed no significant difference between the phases. The anastomosis-related complication rate associated with LSGD was relatively low even during the learning period (3.4%). These data are comparable with DSGD reconstruction method. Kanaya et al.[12] reported the rate of anastomosis-related complication in the initial 100 consecutive procedures was 4.1%, even with an additional suture, the anastomotic leakage remained higher than that with LSGD (7.1% versus 1.5%).[7] Compared with other overlap reconstruction methods, Watanabe Y et al.[19] reported the rate of anastomotic complication was 3.6%; the rate of anastomotic complication of LSGD was also acceptable. In light of inherent safety of LSGD method, overall anastomotic complication rate was comparable as 17.2% and it was possible to lower it by mastering this technique in only 29 cases (9.3% in the mastery period).

The long-term endoscopic findings showed there were no significant differences between the two phases except the residue in the first and third postoperative year; the rate of food residue was higher in learning period than that in master period. We speculated that the reason for gastric stasis was due to the closing direction of the common entry hole. The "parallel direction to duodenum" approach to close the common entry hole which had been performed in the initial period, later we changed the closing direction from parallel to tangential to maintain the intraluminal space effectively. However, this difference of residual food could ameliorate over the time apparently. Compared with DSGD used in the study of Kanaya et al.,[12] the incidence of endoscopic findings in the first postoperative year was lower in our study (residual food ≥ grade 1, 28% versus 11%, respectively; gastritis ≥ grade 2, 18% versus 1%, respectively; presence of bile reflux, 73.5% versus 34%). In the present study, the follow-up ratio in the first year postoperatively was 94.1%, which was higher than that of the Kanaya et al. study (83.0%) (Supplement figure 1). We suggest that larger anastomosis lumen and these downward-straightforward structural alignments between the remnant stomach and the duodenum may facilitate the gastric food passage into the duodenum and reduce the incidence of gastritis and bile reflux in the stomach remnant, as we have described previously.[10]

The present study had some limitations. Firstly, all procedures in this study were undertaken by a single surgeon and we did not analyze the pure anastomotic time but total operation time for the learning curve. Therefore, our results should be interpreted carefully and applied in a clinical practice. Secondly, although the major complication rate between the two phases showed no statistically significant differences, there were some differences in patient morbidity, and these may have had a minimal effect on the results. Thirdly, we did not introduce the risk-adjusted CUSUM method, due to the focus being on functional and surgical outcomes. Finally, the whole procedure was performed by a single experienced surgeon, so surgical failure (defined as intraoperative mortality or conversion to open gastrectomy due to the technical problems) did not occur, meaning that risk-adjusted CUSUM was not necessary.[21–23]

Conclusions

The LSGD method was a safe, simple, and feasible approach to intracorporeal anastomosis. Furthermore, it could be mastered easily after a reasonable number of cases and was associated with satisfactory short-term surgical outcomes and long-term endoscopic findings.

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Author Contributions Bo Wang and Sang-Yong Son: Designed research, conducted clinical study, acquired data, analyzed data, wrote the manuscript. Ho-Jung Shin: Acquired data and analyzed data. Hoon Hur and Sang-UK Han: Revised the manuscript critically for important intellectual content. All authors revised and approved the manuscript for publication.

Compliance with Ethical Standards

All patients provided informed consent for their information to be stored in the hospital database and used for research. The study protocol was approved by the Institutional Review Board of the Ajou University Hospital.

Conflict of Interest The authors declare that they have no conflicts of interest.

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