ABSTRACT

Background: Billroth I anastomosis is one of the most common reconstruction methods after distal gastrectomy for gastric cancer. Intracorporeal Billroth I (ICBI) anastomosis and extracorporeal Billroth I (ECBI) anastomosis are widely used in laparoscopic surgery. Here we compared ICBI and ECBI outcomes at a major gastric cancer center.

Methods: We retrospectively analyzed data from 2,284 gastric cancer patients who underwent laparoscopic distal gastrectomy between 2009 and 2017. We divided the subjects into ECBI (n=1,681) and ICBI (n=603) groups, compared the patients' clinical characteristics and surgical and short-term outcomes, and performed risk factor analyses of postoperative complication development.

Results: The ICBI group experienced shorter operation times, less blood loss, and shorter hospital stays than the ECBI group. There were no clinically significant intergroup differences in diet initiation. Changes in white blood cell counts and C-reactive protein levels were similar between groups. Grade II–IV surgical complication rates were 2.7% and 4.0% in the ECBI and ICBI groups, respectively, with no significant intergroup differences. Male sex and a body mass index (BMI) ≥30 were independent risk factors for surgical complication development. In the ECBI group, patients with a BMI ≥30 experienced a significantly higher surgical complication rate than those with a lower BMI, while no such difference was observed in the ICBI group.

Conclusion: The surgical safety of ICBI was similar to that of ECBI. Although the chosen anastomotic technique was not a risk factor for surgical complications, ECBI was more vulnerable to surgical complications than ICBI in patients with a high BMI (≥30).

Keywords: Intracorporeal gastroduodenostomy; Extracorporeal gastroduodenostomy; Laparoscopic distal gastrectomy; Gastric cancer; Body mass index; Surgical injuries
INTRODUCTION

With the increasing incidence of early gastric cancer and the development of surgical techniques and endoscopic devices, laparoscopic gastrectomy has become very popular and for treating early gastric cancer in East Asian countries, particularly Japan, Korea, and China [1]. Various anastomotic methods after distal gastrectomy are used based on the surgeon’s preference and tumor conditions. However, Billroth I anastomosis (gastroduodenostomy) is recognized as the standard reconstruction method after distal gastrectomy because of its simplicity with only one anastomosis, allowance for physiologic food passage, and ease of access to the papilla of Vater via follow-up endoscopy for common bile duct stone and mass removal [2,3]. The advantages of Billroth I anastomosis include better preservation of the iron metabolism and prevention of post-gastrectomy anemia compared to Billroth II or Roux-en Y anastomosis [4]. With various instrument developments and techniques, gastroduodenostomy can be performed totally laparoscopically via intracorporeal anastomosis. Many studies have accumulated data comparing laparoscopically assisted distal gastrectomy (LADG), which has been performed with extracorporeal anastomosis since the first laparoscopic surgery, and total laparoscopic distal gastrectomy (TLDG), which has been performed with intracorporeal anastomosis regarding the safety of both procedures [5-10]. Although previous studies showed the advantages and disadvantages of laparoscopic distal gastrectomy with intracorporeal or extracorporeal anastomosis, some surgeons remain concerned that the previously reported data are insufficient to determine the safety of intracorporeal anastomosis.

Extracorporeal Billroth I (ECBI) anastomosis is usually performed through a small incision in the upper abdomen. Performing an anastomosis securely in obese patients and those with a long anteroposterior diameter may be difficult due to poor vision and the need to extend the incision frequently to secure a better view. During extracorporeal anastomosis, tissue traction and injury may occur, and the anastomosis procedure may be difficult to perform in narrow spaces [5,11]. After the introduction of intracorporeal gastroduodenostomy, also known as delta-shaped anastomosis, in laparoscopic surgery [12], some surgeons attempted total intracorporeal Billroth I (ICBI) anastomosis after laparoscopic distal gastrectomy. Some advantages of this technique, such as smaller incision, less pain, faster recovery, and better visualization during the surgery, have been reported [5,7,8].

Therefore, here we compared the short-term outcomes of patients undergoing ECBI versus ICBI after laparoscopic distal gastrectomy performed at a major gastric cancer surgery center. In particular, we aimed to determine which technique was safer for application in obese patients.

METHODS

Patients

A total of 2,284 patients who underwent laparoscopic distal gastrectomy with ECBI and total ICBI for gastric cancer between March 2009 and December 2017 in 2 tertiary hospitals were enrolled. ECBI was performed in 1,681 patients by three primary surgeons using similar techniques, while ICBI was performed in 603 patients by a single surgeon. Enrolled institutes were major gastric cancer surgery centers where more than 1,000 cases of gastric cancer surgery are performed annually, and each surgeon in this study encountered more than 500 cases of laparoscopic gastrectomy. The enrolled patients in this study underwent
partial omentectomy and radical gastrectomy with D2 lymph node dissection. Those patients
with concomitant malignancy or combined resection of other organs were excluded. The
participants’ medical records were prospectively collected from databases of two hospitals
and retrospectively reviewed. Information was obtained with the appropriate Institutional
Review Board waivers, and data were collected without revealing any personal information
(Samsung Medical Center IRB No. 2018-06-101 and Yonsei University College of Medicine
IRB No. 4-2018-0494).

Operative procedure
The operative techniques were described in a previous report [13]. The patients were placed
in the supine or lithotomy position. The surgeon stood on the patient’s right side, while the
camera assistant stood on the right side or the space between the patient’s legs. We inserted 4
or 5 trocars. The surgeon used 2 trocars on the right side, while the first assistant used one or 2
trocars on the left side according to surgeon’s preference. In both groups, sufficient duodenal
length for gastroduodenostomy was ensured and the duodenum was resected intracorporeally.

After the lymph node dissection, the surgeon was able to detect the lesion by palpating the
stomach extracted through the small incision located at the upper midline and determine
the resection extent of the stomach for ECBI, in which the gastroduodenostomy anastomosis
was performed using a 28-mm circular stapler.

When gastroduodenostomy using ICBI, the delta-shaped anastomosis introduced by Kanaya
et al. [12] was performed using 6 or more linear staples. After all procedures including
anastomosis and drainage tube insertion were performed, the surgeon extended a 2.5- to
3-cm infraumbilical port site and extracted the specimen into the endobag.

Evaluations
Clinical characteristics including age, sex, American Society of Anesthesiologists (ASA) score,
body mass index (BMI), and tumor classification including 7th American Joint Committee
on Cancer Staging System pathologic stage [14] were analyzed. Factors associated with
the surgical techniques such as operative time, amount of blood loss, extent of resection,
extent of lymph node dissection, length of hospital stay after surgery, time to the first flatus
passage, diet initiation, and postoperative complications were measured during and recorded
immediately after surgery. Postoperative complications were classified according to the criteria
proposed by Clavien et al. [15]. Hospital mortality was defined as death during hospitalization
or postoperative death from any cause within 30 days. To assess the inflammatory response
after surgery, the white blood cell (WBC) count and serum C-reactive protein (CRP) level were
examined on operative days as well as postoperative days 1, 3, and 5.

Perioperative management
Each patient received standardized pre- and postoperative care. Patients wore anti-embolic
stockings as a prophylaxis for deep vein thrombosis from before surgery until active
ambulation after surgery. Patients received intravenous patient-controlled analgesia (PCA)
including fentanyl beginning in the immediate postoperative period, and the duration
of use was approximately 48 hours in both groups. Additional analgesic drugs were
administered depending on the requirements of the individual patient for the management
of postoperative pain. Oral feeding was initiated after the passage of flatus and the diet was
resumed slowly, starting with water and progressing to a liquid and then soft diet as tolerated
by the patient. Patients were discharged once they were free of complications.
Statistical methods

The statistical analysis was performed using SPSS version 23.0 (IBM Corp., Armonk, NY, USA). The data were statistically compared using an independent t-test for continuous variables and the $\chi^2$ test or Fisher’s exact test for categorical data analysis as appropriate. Risk factors for postoperative complication development were analyzed with odds ratios and their 95% confidence intervals using a binary logistic regression model, and the chosen multivariate model used the forward likelihood ratio method. P values less than 0.05 were considered significant.

RESULTS

Patient characteristics

Patient characteristics are shown in Table 1. Patients in the ICBI group were older and had a higher male to female ratio, higher BMI, ASA score of 1 more frequently, and higher proportion of advanced gastric cancer than those in the ECBI group.

Operative and postoperative outcomes

The outcomes associated with surgery are shown in Table 2. There was no difference in the number of retrieved lymph nodes or proximal resection margin length. The operative time was significantly shorter in the ICBI group than in the ECBI group (161.1±42.8 vs. 147.4±39.8 minutes, P<0.001). The intraoperative blood loss was significantly lower in the ICBI group than in the ECBI group (89.3±63.5 vs. 75.3±71.0 mL, P<0.001). In patients with

| Table 1. Patients' clinical characteristics |
|--------------------------------------------|
| Characteristics | ECBI (n=1,681) | ICBI (n=603) | P-value |
| Age (years) | 53.6±11.5 | 57.4±11.9 | <0.001 |
| Sex | | | 0.001 |
| Male | 851 (50.6) | 352 (58.4) | |
| Female | 830 (49.4) | 251 (41.6) | |
| BMI (kg/m$^2$) | 22.9±2.7 | 23.7±3.1 | <0.001 |
| BMI WHO classification | | | <0.001 |
| <23 | 866 (51.5) | 257 (42.6) | |
| ≥23 and <25 | 487 (29.0) | 174 (28.9) | |
| ≥25 and <30 | 311 (18.5) | 148 (24.5) | |
| ≥30 | 17 (1.0) | 24 (4.0) | |
| ASA score | | | <0.001 |
| I | 907 (54.0) | 390 (64.7) | |
| II | 766 (45.6) | 202 (33.5) | |
| III | 8 (0.5) | 11 (1.8) | |
| pT stage | | | <0.001 |
| T1 | 1,599 (95.1) | 521 (86.4) | |
| T2 | 54 (3.2) | 43 (7.1) | |
| T3 | 20 (1.2) | 22 (3.6) | |
| T4 | 8 (0.5) | 17 (2.8) | |
| pN stage | | | 0.005 |
| N0 | 1,521 (90.5) | 516 (85.6) | |
| N1 | 103 (6.1) | 51 (8.5) | |
| N2 | 41 (2.4) | 23 (3.8) | |
| N3 | 16 (1.0) | 13 (2.2) | |
| Tumor size | 2.5±1.5 | 2.5±1.6 | 0.582 |

Data are shown as number of patients (percentage) or mean ± standard deviation.
ECBI = extracorporeal Billroth I; ICBI = intracorporeal Billroth I; BMI = body mass index; WHO = World Health Organization; ASA = American Society of Anesthesiologists.
no postoperative complications, the duration of hospital stay after surgery was shorter in the ICBI group than in the ECBI group (7.2±0.7 vs. 6.2±1.0 days, P<0.001). Although the mean time to first flatus was shorter in the ECBI group than in the ICBI group (3.2±0.6 vs. 3.5±0.7 days, P<0.001), the time of starting a liquid diet was similar in both groups. As shown in Fig. 1, the WBC count (Fig. 1A) and serum CRP levels (Fig. 1B), which were checked sequentially after surgery, showed similar changing patterns with several significantly different points between groups.

**Surgical complications**

Surgical complications were graded by the Clavien-Dindo classification [15] (Table 3), and grade II or more complications requiring postoperative management were analyzed. Grades II–V surgical complications developed in 3.0% of all patients, with 2.7% in the ECBI group and 4.0% in the ICBI group. The distribution of surgical complication grades was similar between the 2 groups. Delayed gastric emptying, a postoperative status in which the distended stomach was filled with matter, was identified through abdominal X-ray in 8 patients (0.5%) of the ECBI group and 4 patients (0.7%) of the ICBI group; all cases resolved with supportive care. Anastomosis leakage, which was diagnosed by the presence of bilious fluid in the abdominal drain and abdominal computed tomography scan, developed in 5 patients (0.3%) in the ECBI group and in 1 (0.2%) in the ICBI group. There were no cases of open conversion or in-hospital mortality.

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**Table 2. Operative and postoperative outcomes of the open versus laparoscopic gastrectomy groups**

| Operative and postoperative outcomes | ECBI (n=1,681) | ICBI (n=603) | P-value |
|-------------------------------------|---------------|--------------|---------|
| Retrieved lymph nodes               | 36.3±11.6     | 36.7±13.3    | 0.668   |
| Proximal resection margin (cm)      | 4.4±2.9       | 4.2±2.5      | 0.083   |
| Operation time (min)                | 161.1±42.8    | 147.4±39.8   | <0.001  |
| Intraoperative blood loss (mL)      | 89.3±63.5     | 75.3±71.0    | <0.001  |
| Hospital stay after surgery (days)  | 7.2±0.7       | 6.2±1.0      | <0.001  |
| First flatus (days)                 | 3.2±0.6       | 3.5±0.7      | <0.001  |
| Liquid diet (days)                  | 4.3±0.8       | 4.3±0.8      | 0.125   |
| Soft diet (days)                    | 5.1±0.6       | 4.6±0.8      | <0.001  |

Data are shown as mean ± standard deviation.

ECBI = extracorporeal Billroth I; ICBI = intracorporeal Billroth I.

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**Fig. 1.** Postoperative inflammatory response in the ECBI and ICBI groups. (A) WBC counts of each reconstruction method after laparoscopic gastrectomy. (B) CRP levels by reconstruction method after laparoscopic gastrectomy.

ECBI = extracorporeal Billroth I; ICBI = intracorporeal Billroth I; WBC = white blood cell; CRP = C-reactive protein.
Risk factor analysis of postoperative complications

Table 4 shows the risk factors for postoperative complications that were analyzed with multivariate methods using a binary logistic regression model. Only sex and BMI were identified as independent risk factors for surgical complications; male rather than female sex and a BMI >30 were risk factors for surgical complications. Anastomotic technique, i.e. ECBI vs. ICBI, did not differ in the development of surgical complications.

As shown in Fig. 2, in the ECBI group, the surgical complication rate was significantly higher in patients with a BMI ≥30 (P<0.001). In patients with a BMI ≥30, the complication rate was 23.5% versus 2.3%–2.6% in those with a lower BMI. The most common postoperative complication of patients with a BMI ≥30 in ECBI group was wound complication (36.4%), second only to postoperative complicated fluid collection (54.5%). Although there was no significant difference in anastomosis leakage rate in patients with a BMI ≥30 in either group, the anastomosis leakage rate (6.7%) of ECBI group was higher than that of the ICBI group (4.2%). In the ICBI group, the complication rate tended to increase as BMI increased, but there was no significant correlation between BMI increase and complication rate (P=0.288).
Table 4. Risk factors associated with postoperative complications

| Characteristics | Odds ratio | 95% confidence interval | P-value |
|-----------------|------------|-------------------------|---------|
| Age             | 1.007      | 0.980–1.035             | 0.622   |
| Sex             |            |                         |         |
| Male            |            |                         |         |
| Female          | 0.511      | 0.275–0.950             | 0.034   |
| BMI             |            |                         |         |
| <23             |            |                         |         |
| ≥23 and <25     | 1.264      | 0.683–2.505             | 0.502   |
| ≥25 and <30     | 1.272      | 0.593–2.732             | 0.537   |
| ≥30             | 11.412     | 3.563–36.553            | <0.001  |
| ASA score       |            |                         |         |
| I               |            |                         |         |
| II              | 0.723      | 0.387–1.350             | 0.308   |
| III             | 3.948      | 0.456–34.158            | 0.212   |
| Operation time (min) | 1.005     | 0.999–1.012             | 0.121   |
| Blood loss (mL) | 0.998      | 0.992–1.003             | 0.339   |
| Operation type  |            |                         |         |
| ECBI            |            |                         |         |
| ICBI            | 1.730      | 0.851–3.518             | 0.130   |
| pT stage        |            |                         |         |
| T1              |            |                         |         |
| T2              | 0.321      | 0.077–1.453             | 0.140   |
| T3              | 0.265      | 0.030–2.364             | 0.234   |
| T4              | 1.870      | 0.422–8.275             | 0.410   |
| pN stage        |            |                         |         |
| N0              |            |                         |         |
| N1              | 1.613      | 0.683–3.811             | 0.275   |
| N2              | 2.477      | 0.798–7.687             | 0.117   |
| N3              | 2.744      | 0.529–14.240            | 0.230   |

BMI = body mass index; ASA = American Society of Anesthesiologists; ECBI = extracorporeal Billroth I; ICBI = intracorporeal Billroth I.

Fig. 2. Complication rate according to BMI changes in the ECBI and ICBI groups.

BMI = body mass index; ECBI = extracorporeal Billroth I; ICBI = intracorporeal Billroth I.
DISCUSSION

With the improvement in laparoscopic instruments and techniques used by surgeons, the number of surgeons who have tried to perform an ECBI or ICBI anastomosis with totally laparoscopic distal gastrectomy has increased [5,11,12,16]. Many reports have evaluated the surgical outcomes and safety of ICBI versus ECBI [6-8,13,16-22]. A recent meta-analysis [9,10] of more than 10 articles revealed that ICBI was feasible and safe. Although many reports [5-10,13,16-22] have shown that total laparoscopic ECBI anastomosis is feasible and safe, some surgeons still avoid the procedure and hesitate to perform ICBI anastomosis using linear staplers due to concerns about anastomosis problems. Considering that surgeons currently perform laparoscopic gastrectomy after adaptation for open gastrectomy, it is anticipated that surgeons would be comfortable performing ECBI anastomosis under direct vision using the circular stapler, similar to open surgery.

Although several reports have compared ECBI and ICBI, the number of ICBI cases is relatively small (<300) [5-7,11,13,16-22]. Both institutions in this study have a specialized gastric cancer center and all surgeons were experts for both open and laparoscopic gastric cancer surgery. Three surgeons were experienced in ECBI and one surgeon was experienced in both ECBI and ICBI. Therefore, the large number was sufficient for surgical quality assessment, while the technical quality of ECBI and ICBI appeared to be similarly high. Consequently, the comparison of well-adapted ECBI and ICBI was possible and our data revealed no clinically significant differences in the surgical outcome or postoperative complications between the 2 anastomotic techniques.

Several previous reports [3,5-10,18] showed that obese patients have more complications with the mini-laparotomy wound in ECBI, where there is a narrow and restricted space for safe anastomosis. However, in this study, high BMI (≥30), but not the anastomotic method, was the risk factor for surgical complications. Because ECBI was performed using a mini-laparotomy in the upper abdomen, patient characteristics including sex, long anterior-to-posterior abdominal diameter, and BMI affected the surgeon's decision. As shown in Table 1, the ECBI group had higher female ratio and lower mean BMI, which means that surgeons may consider the patients' physical conditions to ensure a safe and easy extracorporeal anastomosis compared to intracorporeal anastomosis.

Because ECBI requires a longer incision than ICBI, we expected that ECBI would be associated with greater inflammatory response and delayed recovery after surgery compared to ICBI. However, in our study, we found no superiority of ICBI over ECBI in terms of the WBC counts, CRP level, time to the first flatus, or diet progress. Although the serum CRP levels were decreased with similar changing patterns in both groups, the mean serum CRP level at 3 days postoperative in the ICBI group (16.5±7.5) was higher than that in the ECBI group (10.4±7.3 mg/dL, P=0.009). The small incision used for ECBI may not appear to be associated with a greater inflammatory response or delayed recovery. Although ICBI was associated with shorter hospital stay and less intraoperative blood loss than ECBI, the difference was not large and the clinical meaning was not significant.

For ECBI, we typically create a 3.5- to 4-cm mini-laparotomy in the right upper quadrant or epigastric area, which looks sufficient for safe anastomosis in ordinary patients. However, in obese patients, especially those with a BMI ≥30 in this study, ECBI is expected to be more difficult due to poor vision. As shown in Fig. 2, the surgical complication rate was dramatically increased in high BMI patients treated with ECBI, while this was not the case in those treated

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with ICBI. Although the anastomotic method was not an independent risk factor for surgical complications, in high BMI patients, ICBI appeared to be more beneficial than ECBI.

Some surgeons who favor ECBI are concerned about the safety of the anastomotic site in delta-shaped ICBI because anastomotic tension cannot be confirmed manually during intracorporeal anastomosis and double stapling around the anastomosis site can result in an area of weak blood supply. In this study, 5 patients (0.3%) in the ECBI group and 1 (0.2%) in the ICBI group experienced anastomotic leakage. The 4 patients in the ECBI group recovered without additional intervention because they already had an intra-abdominal drainage catheter (grade II); one recovered after endoscopic clipping on leakage area with ICU care (grade IVa). The patient in the ICBI group recovered after percutaneous drainage (grade IIIa). There were no cases of mortality in either group. Because the anastomotic leakage rate was low in both groups, it is evident that ICBI can be performed as safely as ECBI.

There were some limitations to our study. Because 3 surgeons performing ECBI did not perform ICBI, the comparison of the outcomes of ECBI and ICBI in the same surgeons was impossible. In addition, we perform more than 1,000 gastrectomy procedures annually and each surgeon in this study has performed more than 500 cases of laparoscopic gastrectomy. Therefore, it seems to be difficult to generalize our results. Because most patients had a BMI <25 and fewer had a BMI ≥30, we could not evaluate the detailed benefit or superiority of ICBI over ECBI in very obese patients.

In conclusion, both extracorporeal and intracorporeal anastomosis could be safely performed in laparoscopic distal gastrectomy. Although the anastomotic method was not an independent risk factor for surgical complications, ECBI appeared more vulnerable to surgical complications than ICBI in high BMI (≥30) patients. Also, ICBI featured an earlier recovery and fewer negative postoperative short-term outcomes in obese patients.

Therefore, the anastomosis method may be selected according to patient conditions and the surgeon’s preference, and ICBI might be more beneficial in high BMI patients.

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