

# Morbidity and Mortality Results From a Prospective Randomized Controlled Trial Comparing Billroth I and Roux-en-Y Reconstructive Procedures After Distal Gastrectomy for Gastric Cancer

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## Abstract

**Background** Billroth I (B-I) and Roux-en-Y (R-Y) reconstructions are commonly performed after distal gastrectomy. Which reconstruction procedure is superior remains controversial. We conducted a randomized controlled trial to compare the clinical efficacy of B-I and R-Y. **Methods** Between August 2005 and December 2008, a total of 332 patients with potentially curable gastric cancer enrolled from 18 institutions were intraoperatively randomized to either the B-I group or the R-Y group. Postoperative morbidity and hospital mortality were recorded prospectively in a fixed format and were compared between these two groups.

**Results** The operating time was significantly longer in the R-Y group than in the B-I group (214 vs. 180 minutes,  $P < 0.0001$ ). Regarding clinical symptoms during the

postoperative hospital stay, the incidence of nausea, vomiting, and discontinuance of food intake was significantly higher in the R-Y group than in the B-I group (12.4% vs. 3.7%,  $P = 0.0027$ ; 8.9% vs. 3.1%,  $P = 0.022$ ; and 12.4% vs. 4.3%,  $P = 0.0064$ , respectively). There was no significant difference in the overall operative morbidity rate between the R-Y and B-I groups (13.6% vs. 8.6%, respectively,  $P = 0.14$ ). Anastomotic leakage occurred in two patients (1.2%) in the B-I group and in none in the R-Y group; the difference did not reach statistical significance ( $P = 0.09$ ). Postoperative hospital stay was significantly longer in the R-Y group than in the B-I group (16.4 vs. 14.1 days,  $P = 0.019$ ).

**Conclusions** We concluded that B-I reconstruction was superior to R-Y reconstruction in terms of perioperative complications.

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## Introduction

In Japan, Billroth I (B-I) reconstruction has commonly been performed after distal gastrectomy because of its technical simplicity and the physiological intestinal continuity [1, 2]. Although B-I reconstruction is a more simple procedure than Roux-en-Y (R-Y) reconstruction, B-I has been shown to be more frequently associated with complications induced by gastroesophageal and duodenogastric reflux [3, 4], including severe gastritis, esophagitis, and gastric ulcer [5–8]. These problems often induce clinical symptoms that include epigastralgia and dyspepsia [9]. Nunobe et al., after retrospective analysis of high volume cases, reported that R-Y was superior to B-I symptomatically and functionally at 5 years. Epigastralgia and dyspepsia sometimes cause loss of appetite and body weight loss [10]. Bile reflux has also been reported to have the

potential to cause malignancy in the remnant stomach and esophagus [11–13].

For about four decades, R-Y reconstruction has been performed with the aim of preventing gastroesophageal and duodenogastric reflux after distal gastrectomy [14]. Despite its advantages, patients undergoing R-Y reconstruction often experience so-called R-Y stasis, which makes surgeons reluctant to perform this procedure [15, 16]. Moreover, after R-Y reconstruction there is the possibility of an internal hernia, and it is difficult to observe the duodenum with endoscopy. Accordingly, the clinical benefits and advantages of R-Y reconstruction should be evaluated scientifically against those of conventional B-I reconstruction.

In the present study, we conducted a multiinstitutional randomized controlled trial comparing the efficacy of B-I and R-Y reconstructions after distal gastrectomy. The primary endpoint was body weight loss at 1 year after operation compared to preoperative body weight because it is a reliable factor reflecting the postoperative course of patients after distal gastrectomy. We here present our operative morbidity and mortality data, the secondary endpoints of this trial. The final analysis of the primary endpoint, body weight loss, is scheduled to take place in the near future.

## Patients and methods

### Study design

We conducted a multicenter randomized Phase II study that was approved by the institutional review boards of all participating hospitals and conducted in accordance with the Declaration of Helsinki. The primary endpoint of this study was body weight loss 1 year after surgery compared to preoperative body weight. Secondary endpoints included surgical outcomes, postoperative morbidity and hospital mortality, and nutritional evaluation.

In our surgical study group, the Osaka University Clinical Research Group for Gastroenterological Study, the standard reconstructive method following distal gastrectomy has been the B-I reconstruction because of its surgical simplicity compared to that of the R-Y method. It has been reported that the rate of body weight loss at postoperative year 1 was 10% to 15% following B-I operations [17, 18]. Tanaka et al. reported that R-Y reconstruction had been superior to B-I regarding body weight loss rate but with no significance difference [19]. In this study, we hypothesized that relative to the B-I operation, the R-Y operation may decrease body weight loss at 1 year after surgery by 5%.

### Patients

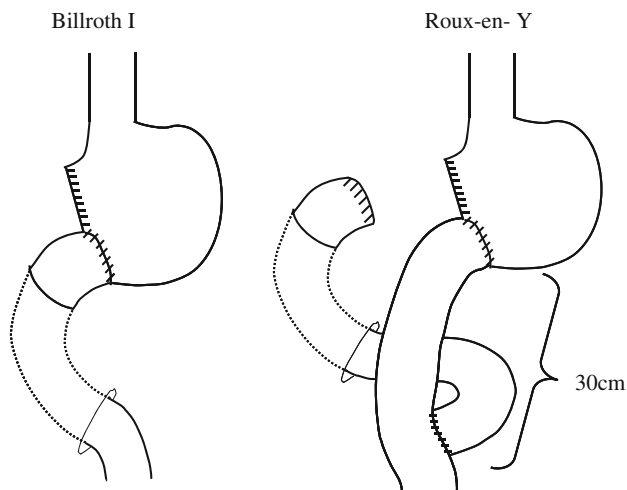
After completion of the informed consent process prior to randomization, patients were included in the study if they met the following eligibility criteria: histologically proven gastric cancer, a lack of noncurative surgical factors except for positive lavage cytology, age between 20 and 90 years, Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1, no prior chemotherapy or radiation therapy, and no history of gastrectomy or other malignancy (except carcinoma in situ of uterine cervical cancer and focal cancer in an adenoma of colorectal cancer) during the past 5 years. Exclusion criteria included a history of laparotomy (except appendectomy and laparoscopic cholecystectomy), interstitial pneumonia or pulmonary fibrosis, severe heart disease, liver cirrhosis or active hepatitis, chronic renal failure, severe diabetes [hemoglobin A1c (HbA1c)  $\geq 9.0\%$ ], and severe reflux esophagitis. After initial laparotomy, tumor was confirmed to be located at a middle or lower third of the stomach, and a proportion of residual stomach was regulated as one-third. The operator also checked the length of residual stomach to confirm that either reconstruction procedure could be performed after distal gastrectomy. The surgeon confirmed the above eligibility and exclusion criteria immediately following the initial laparotomy, and patients were then randomized intraoperatively to either the B-I group or the R-Y group. Randomization was performed by the minimization method according to the patient's body mass index (BMI) ( $<25$  or  $\geq 25$  kg/m<sup>2</sup>) and institution.

### Surgery

Endotracheal general anesthesia and standard laparotomy or laparoscopic operations were used for all patients in each institution. In both the B-I and R-Y groups, the surgeon performed a distal gastrectomy and D1–3 lymphadenectomy as defined by the Japanese Classification of Gastric Carcinoma [20]. D1 involves dissecting paragastric nodes, and D2 adds dissection of the nodes along the left gastric artery, common hepatic artery, and celiac artery. D3 incorporates the D2 procedure plus dissection of hepatoduodenal nodes, retropancreatic nodes, nodes along the superior mesenteric vein, and the paraaortic nodes between the level of the celiac axis and the inferior mesenteric artery.

The protocol specified that prophylactic cholecystectomy should not be performed. Reconstructive procedures, such as by hand or automatic sutures, were not specified other than those 30 cm between the gastrojejunostomy and jejunojejunostomy in the R-Y group (Fig. 1).

Patients were enrolled from 18 hospitals belonging to the Osaka University Clinical Research Group for



**Fig. 1** Reconstructive procedure

Gastroenterological Surgery. Overall, more than 50 gastrectomies were performed each year in these 18 hospitals. All operations were performed or supervised by senior surgeons who were members of the Japanese Gastric Cancer Association. During the planning of the study, all participating surgeons reached a consensus concerning the technical details of the reconstructive procedures. This study was registered with clinical trial identification number UMIN000000878.

#### Postoperative evaluation

The following parameters were recorded: operative methods and pathology results according to the 13th edition of the Japanese Classification of Gastric Carcinoma [20], BMI, serum albumin, lymphocyte count, and existence of delayed gastric emptying. We defined delayed gastric emptying in patients who fulfilled all of the following conditions after resumed oral intake: (1) symptoms of nausea or vomiting, (2) discontinuance of food intake for  $\geq 3$  days, (3) confirmation by imaging tests, and (4) absence of bowel obstruction.

Morbidity data on six representative conditions, including a pancreatic fistula, anastomotic leakage, abdominal abscess, bowel obstruction, hemorrhage, and pneumonia, were prospectively collected. A pancreatic fistula was defined as drainage output on or after postoperative day (POD) 5 with an amylase content greater than three times the upper normal serum value. Pneumonia, anastomotic leakage, abdominal abscess, and bowel obstruction were diagnosed radiologically or clinically. A postoperative hemorrhage requiring a transfusion was recorded as a morbidity factor. The effects of surgical morbidity over a 3 month interval were also analyzed in this study. Operating time, blood loss, duration of hospital stay after surgery, and

reoperation details were recorded. Hospital mortality was defined as postoperative death of any cause within 30 days, or death during the same hospital stay. Patients were followed up every 3 or 6 months until 5 years postoperatively. Adjuvant therapy was not specified in the protocol.

#### Statistical analysis

The sample size was determined to provide 80% power to detect an effect size of 5% using a one-sided alpha error of 5% under the normal distribution with a standard deviation of 0.1 in both groups. The primary endpoint was evaluated by *t* test. The planned sample size was 320 patients (160 for each arm), allowing for a 10% dropout rate. The Mann-Whitney *U* test and  $\chi^2$  test were used for the analysis where appropriate to assess differences between groups. All statistical analyses were performed with SPSS software version 15.0 J. Two-sided *P* values were calculated and presented. A *P* value of  $<0.05$  was considered to indicate statistical significance.

## Results

#### Clinicopathologic findings

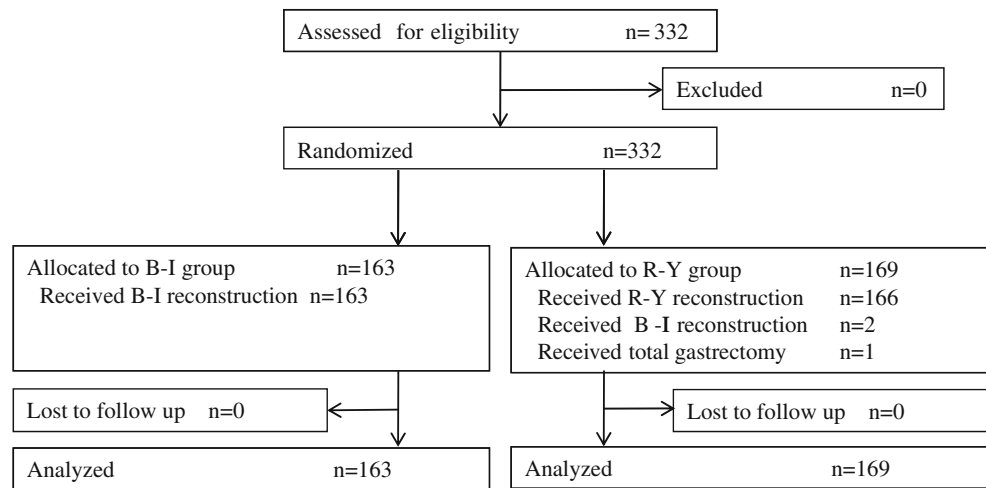
CONSORT flow chart was shown in Fig. 2. Between August 2005 and December 2008, a total of 332 patients were randomly assigned into either the B-I group (163 patients) or the R-Y group (169 patients). One patient underwent total gastrectomy due to microscopic residual cancer at the proximal margin, and two patients in the R-Y group mistakenly underwent B-I reconstruction. Patients' clinical and pathologic characteristics are summarized in Table 1. No significant differences between the two groups were observed for age, sex, BMI, location, size, and histology, depth of invasion, lymph node metastases, stage, or curability. Surgical outcomes are shown in Table 2. There was no significant difference in approach (open/laparoscopic) (B-I 134/29, R-Y 136/33, *P* = 0.68).

The operating time was significantly longer in the R-Y group than in the B-I group (median 214 min vs. 180 min, *P* < 0.0001). There was no significant difference in intraoperative bleeding (median 210 ml vs. 220 ml, *P* = 0.64) or extent of lymph node dissection (*P* = 0.50).

#### Postoperative course

The postoperative course after resumed oral intake during the hospital stay is shown in Table 3. There was no significant difference in time to resumed oral intake between the two groups (median 4.3 days vs. 3.8 days, *P* = 0.16). Frequency of nausea, vomiting, and discontinuance of food

**Fig. 2** CONSORT flow chart



**Table 1** Clinicopathologic characteristics

Characteristic	B-I group (n = 163)	R-Y group (n = 169)	P
Age (years)	64.4 ± 9.3	63.9 ± 10.5	0.68
Sex(male/female)	105/58	115/54	0.48
Height (cm)	161.3 ± 8.3	161.1 ± 9.6	0.87
Body weight (kg)	58.3 ± 9.7	59.5 ± 11.3	0.29
Body mass index (kg/m <sup>2</sup> )	22.4 ± 3.0	22.8 ± 3.1	0.20
Approach (open/ laparoscopic)	134/29	136/33	0.68
Macro type (0/1/2/3/5)	118/6/19/17/3	120/9/19/20/1	0.77
Tumor location (L/M)	108/55	112/57	0.99
Tumor size (cm)	2.9 ± 1.6	3.0 ± 1.6	0.57
Histology (intestinal/diffuse)	87/76	90/79	0.98
Depth of invasion (m/sm/mp/ss/se)	52/62/25/16/8	53/67/21/19/9	0.94
Lymph node metastasis (-/+)	126/37	120/49	0.19
Stage (IA/IB/II/IIIA/IIIB/IV)	103/30/23/5/2/0	104/26/24/8/2/5	0.48
Curability (A + B/C)	162/1	164/4	0.17

Results are the mean ± SD or the number, unless otherwise specified  
L/M low/middle, m mucosal, sm submucosal, mp muscularis propria, ss subserosal, se serosa exposed

**Table 2** Surgical outcomes

Outcome	B-I group (n = 163)	R-Y group (n = 169)	P
Operating time (min)	180 ± 48	214 ± 44	<0.0001
Intraoperative bleeding (ml)	210 ± 217	220 ± 180	0.64
Lymph node dissection: D1(+α,β)/D2/D3)	58/105/0	61/107/1	0.50

Results are the mean ± SD or the number

**Table 3** Postoperative course after resumed of intake during hospital stay

Postoperative parameter	B-I group (n = 163)	R-Y group (n = 169)	P
Time to resumed oral intake (days)	4.3 ± 4.6	3.8 ± 1.8	0.16
Nausea	6 (3.7%)	21 (12.4%)	0.0027
Vomiting	5 (3.1%)	15 (8.9%)	0.022
Discontinuance of food intake	7 (4.3%)	21 (12.4%)	0.0064
Delayed gastric emptying	7 (4.3%)	16 (9.5%)	0.06
Postoperative hospital stay (days)	14.1 ± 6.5	16.4 ± 10.4	0.019

Results are the mean ± SD or the number

intake were significantly lower in the B-I group than in the R-Y group (3.7% vs. 12.4%,  $P = 0.0027$ ; 3.1% vs. 8.9%,  $P = 0.022$ ; 4.3% vs. 12.4%,  $P = 0.0064$ , respectively). Frequency of delayed gastric emptying was lower in the B-I group than in the R-Y group (4.3% vs. 9.5%), but the difference did not reach statistical significance ( $P = 0.057$ ). Postoperative hospital stay was significantly shorter in the B-I group than in the R-Y group (14.1 days vs. 16.4 days,  $P = 0.019$ ).

**Operative morbidity and mortality**

Operative morbidity and mortality are shown in Table 4. The overall operative morbidity rate was lower in the B-I group than in the R-Y group (8.6% vs. 13.6%), but this difference was not significant ( $P = 0.14$ ). Of the prespecified six morbidity factors, the frequencies of pancreatic fistula, anastomotic leakage, abdominal abscess, and bowel obstruction were not significantly different between groups; and hemorrhage and pneumonia did not occur in either group. Regarding other complications, postoperative

**Table 4** Morbidity and mortality

Parameter	B-I group ( <i>n</i> = 163)	R-Y group ( <i>n</i> = 169)	<i>P</i>
<b>Morbidity</b>			
Overall operative morbidity	14 (8.6%)	23 (13.6%)	0.14
Pancreatic fistula	2 (1.2%)	3 (1.8%)	0.68
Anastomotic leakage	2 (1.2%)	0	0.09
Abdominal abscess	3 (1.8%)	3 (1.8%)	0.96
Bowel obstruction	1 (0.6%)	2 (1.2%)	0.57
Hemorrhage	0	0	1.00
Pneumonia	0	0	1.00
Postoperative pancreatitis	2 (1.2%)	2 (1.2%)	0.97
Surgical site infection	3 (1.8%)	2 (1.2%)	0.62
Anastomotic stricture	3 (1.8%)	2 (1.2%)	0.62
Reoperation	0	1 (0.6%)	0.24
Mortality	0	0	1.00

pancreatitis, surgical site infection, and anastomotic stricture occurred in both groups, but the difference was not significant. Reoperation was required in one patient in the R-Y group and in none in the B-I group ( $P = 0.24$ ). No postoperative hospital deaths occurred in either group.

## Discussion

The choice of reconstructive procedure after distal gastrectomy remains controversial. Fukuhara et al. [21] reported the superiority of R-Y reconstruction over B-I and Billroth-II (B-II) reconstruction for preventing bile reflux into the gastric remnant and esophagus, but their study had the disadvantage of being retrospective. Montesani et al. [22] reported the results of a prospective randomized controlled study demonstrating that the R-Y procedure was more effective at preventing postoperative reflux disease than B-I or B-II, although the number of subjects in each group was insufficient. In contrast, Ishikawa et al. [17] reported that R-Y reconstruction had limited advantages compared with B-I reconstruction because R-Y reconstruction induced the frequent complication of Roux-en-Y stasis, causing longer postoperative hospital stays, although the frequency of bile reflux and degree of inflammation of the remnant stomach were much lower in the R-Y group than in the B-I group. In this study as well, however, the number of subjects in each group was insufficient. Thus, we performed a prospective multiinstitutional randomized controlled trial directly comparing B-I and R-Y reconstruction after distal gastrectomy using a sufficient number of patients with gastric cancer.

The operating time for B-I reconstruction has been reported as relatively shorter than that for R-Y

reconstruction—not only with open gastrectomy [17] but also with laparoscopy-assisted gastrectomy [18], although these differences were not significant. In our study, the operating time was significantly shorter for B-I reconstruction than for R-Y reconstruction. The reason was thought to be the technical simplicity of B-I compared to R-Y reconstruction and the statistically sufficient number of patients in this study.

R-Y reconstruction has been reported to cause R-Y stasis syndrome occasionally [17, 23]. Gustavsson et al. reported that the mean length of the Roux-limb in patients with stasis was 41 cm, compared with 36 cm in patients without stasis ( $P < 0.001$ ) [24]. Based on this report, which suggested that an excessively long Roux-limb could cause R-Y stasis syndrome, we selected the length of the Roux-limb to be approximately 30 cm. Nevertheless, in terms of the postoperative course, the R-Y group showed a significantly higher frequency of nausea, vomiting, and discontinuance of food intake, as well as a longer postoperative hospital stay, compared to the B-I group.

The rate of anastomotic leakage was 1.2% in the B-I group, whereas no anastomotic leakage was encountered in 169 patients in the R-Y group. Kojima et al. [18] and Ishikawa et al. [17] had reported respective rates of anastomotic leakage of 5% and 4% in the B-I groups in their respective studies, whereas no anastomotic leakage was encountered in 68 and 24 patients in the R-Y groups, respectively. They considered that excessive duodenal stump devascularization and tension on the anastomosis could be a causative factor of leakage.

## Conclusions

This study showed that B-I reconstruction was superior to R-Y reconstruction in terms of the perioperative course—taking into consideration the operating time, incidence of various complications, and postoperative hospital stay. However, anastomotic leakage was rarely encountered with the R-Y reconstruction.

This study evaluated only the immediate postoperative period. Regarding morbidity over a longer postoperative period and the primary endpoint of this study—body weight loss at 1 year after operation—we await the results of our final analysis once our data collection is complete.

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**Conflict of interest** The authors declare that there are no conflicts of interest.

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