

# Billroth-I vs Roux-en-Y after distal gastrectomy: A comparison of long-term nutritional status and survival rates from a large-scale multicenter cohort study

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## Abstract

**Background:** The optimal standard reconstruction procedure after distal gastrectomy is controversial. No large-scale persuasive clinical studies from long-term perspectives on this topic have yet been conducted.

**Study design:** This retrospective multicenter study analyzed a database of 2510 consecutive patients with clinical stage I gastric cancer who underwent distal gastrectomy followed by Billroth-I (B-I) or Roux-en-Y (R-Y) anastomosis from 2006 to 2012. After adjusting for 30 potential confounding factors using propensity score matching, we compared the body weight loss and other nutritional status for 5 years as primary outcomes between the two groups. We also investigated surgical outcomes, endoscopic findings, and long-term survival rates as secondary outcomes.

**Results:** After matching the inclusion criteria, 940 patients (470 in each group) were enrolled. There was no marked difference in the body weight loss and other nutritional indicators. The incidence of grade  $\geq 3$  postoperative complications (Clavien-Dindo classification) or the incidence of gallstone formation was not markedly different between the two groups. The postoperative hospital stay after surgery was significantly longer, and the readmission rate was significantly higher in the R-Y group than in the B-I group. An endoscopic examination revealed no trends regarding the incidence and severity of gastritis or residual food in the remnant stomach. The 5-year overall survival rate was 92.6% in the B-I group and 91.8% in the R-Y group, with no significant difference ( $P = .379$ , log-rank test).

**Conclusions:** Roux-en-Y reconstruction may be nearly equal to Billroth-I with regard to the long-term nutritional perspectives.

## KEYWORDS

Billroth-I, gastric cancer, nutrition, Roux-en-Y, survival

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## 1 | INTRODUCTION

According to surveillance data from the World Health Organization,<sup>1</sup> approximately 1 million new cases of gastric cancer occurred worldwide in 2018, half of which were in East Asia. However, this disease is extremely important not only in East Asia but also globally; it has the sixth highest incidence and is the fourth leading cause of cancer deaths worldwide.<sup>2</sup> Early detection by screening, radical surgery with D2 lymph node dissection, and appropriate perioperative chemotherapy have improved its prognosis;<sup>2</sup> however, surgical resection still plays the most pivotal role in treatment.

Maintenance of patients' quality of life as well as safety in the perioperative period should be carefully considered during reconstruction after stomach resection. The optimal reconstruction procedure after distal gastrectomy (DG) has been long debated, but a sufficient consensus has not yet been established; thus, decisions are likely to be made according to surgeons' preferences. Billroth-I (B-I) and Roux-en-Y (R-Y) are commonly performed after DG in the clinical setting.<sup>3</sup> Some surgeons consider B-I the first choice because of its technical simplicity and the physiological passage of food through the duodenum. Many of these surgeons switch to R-Y only when the remnant stomach has shrunk due to extended resection. In contrast, other surgeons insist on the superiority of R-Y,<sup>4</sup> especially in terms of its lower risk of bile reflux into the remnant stomach,<sup>5</sup> and try to perform it in almost all cases. Billroth-II is not generally preferred in Japan<sup>3</sup> because of concerns regarding the high incidence of postoperative bile reflux to the remnant stomach and its presumed carcinogenic effect; therefore, Billroth-II tends to be performed only in elderly patients.

Several retrospective studies<sup>6-9</sup> and prospective studies with small to medium sample sizes have compared B-I and R-Y.<sup>10-14</sup> However, fundamentally, most such studies have limitations due to the influence of selection bias. In addition, there are no relevant data from the perspective of long-term nutritional conditions. To overcome these problems, we conducted a large-scale cohort study using rigorous propensity score matching<sup>15</sup> to evaluate the hypothesis that similar long-term nutritional conditions would be observed following B-I and R-Y reconstruction after DG.

## 2 | METHODS

### 2.1 | Cohort development

This retrospective multicenter study analyzed the data of 2510 consecutive patients who underwent DG for clinical stage I (T1N0, T2N0, or T1N1) gastric cancer, either by laparotomy or laparoscopy, from 2006 to 2012 at three major cancer centers in Japan. During this period, the reconstruction method after DG was determined based on the surgeon's preference or decision.

The exclusion criteria in this study were the presence of another primary malignant disease and a history of chemotherapy or chemoradiotherapy before surgery. Surgeons from each hospital provided

the specified preoperative, operative, and postoperative data using a common database. The study protocol was approved by the institutional review board at each participating institution, and the study was conducted in accordance with the Declaration of Helsinki and the National Guidelines.

### 2.2 | Study design and propensity score matching

In a consensus meeting involving surgeons and biostatisticians, preoperative information that might possibly influence surgeons' decision making concerning procedures or be potentially associated with the outcomes were identified in order to enable the rigorous estimation of propensity scores. Ultimately, 30 factors that should be adjusted for during comparisons were identified as follows: age, gender, American Society of Anesthesiologists physical status, body mass index, year of operation, operating history, history of endoscopic resection, history of other malignant diseases, tumor location (upper, middle or lower/anterior, posterior, greater or lesser curvature), number of lesions, tumor size, macroscopic type, histological type of biopsy specimens, clinical T and N stage, duodenal invasion, surgical approach, symptoms, comorbidities, and other surgical risk factors. Symptoms included stenosis and body weight loss. Comorbidities and other surgical risk factors included cardiovascular disease, diabetes mellitus, anemia, chronic obstructive pulmonary disease, renal dysfunction, liver function disorder, history of cerebrovascular disease, emergency operation, use of steroids, anticoagulants, or antihypertensive agents. The propensity score estimation and matching were performed by a biostatistician who was blinded to the outcomes. The score was estimated using a logistic regression model, and greedy matching was performed (ratio = 1:1 and without replacement) with a caliper width of 0.2 standard deviations.

### 2.3 | Follow-up and outcomes

The postoperative follow-up protocol was almost identical in each participating institution. Physical and laboratory examinations were performed every 6 months for 5 years. Computed tomography or ultrasonography was performed every 6 or 12 months for 5 years to check for recurrence or cholelithiasis. An endoscopic examination was performed approximately 1 year after surgery.

The primary outcome was body weight loss, and the secondary outcomes were the nutrition status, endoscopic findings, postoperative complications, and overall survival. As nutrition parameters, the serum levels of total protein and albumin, lymphocyte count and body weight were evaluated before gastrectomy and at 6, 12, 36, and 60 months after surgery. The endoscopic findings of the remnant stomach were graded according to a classification proposed by Kubo et al.,<sup>16</sup> in which residual food and remnant gastritis are graded from 0 (normal) to 4 (great amount or apparent), and bile reflux is graded from 0 (absence) to 1 (presence). Postoperative complications were graded according to the Clavien-Dindo classification.<sup>17</sup>

**TABLE 1** Patients' characteristics and propensity score matching

	All patients (n = 2510)				Propensity-matched patients (n = 940)			
	B-I (n = 1720)	%	R-Y (n = 790)	%	B-I (n = 470)	%	R-Y (n = 470)	%
<b>Age</b>								
Mean	73.2		64.7		64.7		64.2	
<b>Sex</b>								
Male	1073	62.4	559	70.8	311	66.2	325	69.1
Female	647	37.6	231	29.2	159	33.8	145	30.9
<b>Year</b>								
2006	294	17.1	55	7.0	43	9.1	45	9.6
2007	278	16.2	62	7.8	39	8.3	34	7.2
2008	274	15.9	62	7.8	55	11.7	46	9.8
2009	274	15.9	111	14.1	66	14.0	71	15.1
2010	254	14.8	128	16.2	74	15.7	81	17.2
2011	180	10.5	205	25.9	103	21.9	106	22.6
2012	166	9.7	167	21.1	90	19.1	87	18.5
<b>ASA-PS</b>								
1	671	39.0	350	44.3	205	43.6	203	43.2
2	947	55.1	400	50.6	242	51.5	242	51.5
3	102	5.9	40	5.1	23	4.9	25	5.3
<b>BMI</b>								
Mean	23.3		22.5		23.0		22.9	
<b>History of abdominal surgery</b>								
Combined surgery	19	1.1	7	0.9	7	1.5	5	1.1
<b>Lesion site</b>								
Upper	19	1.1	103	13.1	11	2.3	11	2.3
Middle	732	42.6	405	51.3	264	56.2	264	56.2
Middle to upper	11	0.6	12	1.5	2	0.4	2	0.4
Middle to lower	68	4.0	15	1.9	8	1.7	8	1.7
Lower	887	52.6	241	30.5	185	39.4	185	39.4
Entire	1	0.1	0	0.0	0	0.0	0	0.0
Duodenal invasion	13	0.8	2	0.3	0	0.0	0	0.0
Preoperative ER	196	11.4	74	9.4	38	8.1	43	9.1
<b>Clinical T</b>								
1a	339	19.7	122	15.4	66	14.0	66	14.0
1b	1081	62.8	441	55.8	275	58.5	275	58.5
2	300	17.4	227	28.7	129	27.4	129	27.4
<b>Clinical N</b>								
0	1660	96.5	745	94.3	459	97.7	459	97.7
1	60	3.5	40	5.1	11	2.3	11	2.3

(Continues)

**TABLE 1** (Continued)

	All patients (n = 2510)				Propensity-matched patients (n = 940)			
	B-I (n = 1720)	%	R-Y (n = 790)	%	B-I (n = 470)	%	R-Y (n = 470)	%
Maximum size of tumor (mm)								
Mean	30.2		29.7		31.6		31.1	
Approach								
	1031	59.9	330	41.8	216	46.0	219	46.6
Laparoscopic	689	40.1	460	58.2	254	54.0	251	53.4
Multiple lesions	178	10.3	82	10.4	35	7.4	35	7.4

Abbreviations: ASA-PS, American Society of Anesthesiologists physical status; B-I, Billroth-I; ER, Endoscopic resection R-Y, Roux-en-Y.

The Union for International Cancer Control 7th TNM classification of gastric cancer<sup>18</sup> was used to describe the tumor stage. The extent of lymph node dissection was determined according to the guideline of the Japanese Gastric Cancer Association.<sup>19</sup>

## 2.4 | Statistical analyses

The categorical variables were compared by the  $\chi^2$  test. Chronological changes in the nutrition parameters were examined using the Wilcoxon test. The cumulative overall survival rates were estimated by the Kaplan–Meier method, and differences were determined using the log-rank test. All statistical analyses were performed using the JMP software program, version 12 (SAS Institute) and were two-sided. A P-value of <0.05 was considered to indicate statistical significance.

## 3 | RESULTS

### 3.1 | Patients

After propensity score matching, 940 patients (470 each for B-I and R-Y) were included in the final analysis. The patient and tumor characteristics both before (n = 2510) and after (n = 940) matching are shown in Table 1. The background characteristics in both patient groups were rigorously adjusted in matched patients. Five hundred and five patients (53.7%) underwent laparoscopic gastrectomy.

### 3.2 | Operative and pathological outcomes

The operative and pathological findings are shown in Table 2. On comparing the B-I and R-Y groups, the operation time was significantly longer in the R-Y group than in the B-I group (188.9 vs 238.3 minutes, respectively;  $P < .0001$ ), and the intraoperative estimated blood loss was larger in the R-Y group than in the B-I group (103.1 vs 129.5 g, respectively;  $P = .0005$ ). In the R-Y group, the jejunal limb was brought up in an antecolic fashion in 265 patients (56.4%), in a retrocolic fashion in 103 patients (21.9%), and in an unknown fashion in 102 patients

(21.7%). There were no marked differences in the pathological findings. The postoperative hospital stay was longer in the R-Y group than in the B-I group (10 vs 11 days, respectively;  $P < .0001$ ), although the difference was only 1 day. There was no mortality in either group.

### 3.3 | Long-term trends in body weight and other nutritional status items

Changes in the four nutritional parameters are shown in Figure 1. Statistically significant differences were recognized between the B-I and R-Y groups only in the serum level of total protein at 1 year (100.12% vs 102.12%, respectively;  $P = .0001$ ) and 3 years (100.32% vs 101.73%, respectively;  $P = .01$ ) after surgery.

### 3.4 | Endoscopic findings

Postoperative endoscopic findings of the remnant stomach were available in 58% of patients who underwent B-I and 50% of those who underwent R-Y. The grades of endoscopic findings in each group are shown in Table 3. Bile juice reflux was more common in the B-I group than in the R-Y group ( $P < .001$ ). The incidence and severity of gastritis and food residue in the remnant stomach were inconsistent. The incidence in the B-I group was greater than that in the R-Y group; however, patients with grade 3/4 food residue or grade 2 gastritis were remarkably common in the R-Y group.

### 3.5 | Long-term survival outcomes

The 5-year overall survival rate was 92.6% in the B-I group and 91.8% in the R-Y group, with no significant difference ( $P = .379$ , log-rank test).

### 3.6 | Postoperative complications and readmission

Postoperative complications (within 60 days after surgery) are shown in Table 4. Wound infection and acalculous cholecystitis/

TABLE 2 Operative and pathological findings

	Billroth-I (n = 470)	Roux-en-Y (n = 470)	P-value
Operation time (min)			
Mean (SD)	188.9 (54.8)	238.3 (65.4)	<.0001
Blood loss (g)			
Mean (SD)	103.1 (152.6)	129.5 (162.8)	.0005
Extent of lymph node dissection			
D1+	215	230	.36
D2	255	240	
Retrieved number of lymph nodes			
Median	33	33	1.00
Pathological T			
1	357	344	.36
2	68	78	
3	28	31	
4a	17	16	
4b	0	1	
Pathological N			
0	383	365	.34
1	55	66	
2	21	21	
3a	10	13	
3b	1	5	
Pathological M			
0	468	465	0.45
1	2	5	
Histological type			
Well	202	200	.002
Poor	212	241	
Mixed	55	25	
Others	1	4	
Route of Roux limb			
Antecolic	N.A.	265	
Retrocolic	N.A.	103	
Unknown	N.A.	102	
Simultaneous cholecystectomy	338	325	.391
Reoperation	4	1	.18
Hospital stay after surgery (d)			
Median	10	11	<.0001
Death within 30 d after operation	0	0	N.A.
In-hospital death	0	0	N.A.

cholangitis were more common in the R-Y group than in the B-I group when counted as grade  $\geq 2$  ( $P = .0051$  and  $P = .0024$ , respectively). With respect to the total number of complications, the incidence of grade  $\geq 2$  complications was larger in the R-Y group than in the

B-I group ( $P = .0004$ ), but the incidence of grade  $\geq 3$  complications was not markedly different. In terms of anastomosis-related complications, such as leakage, stricture, and intraluminal hemorrhaging, there was no marked difference between the two groups. The incidence of reoperation was four (0.85%) in the B-I group and one (0.21%) in the R-Y group ( $P = .18$ ). These included drainage for abdominal abscess (two cases), hemostasis after preserving the omentum (one case), and drainage for bile leakage from the stump of the cystic duct after cholecystectomy (one case) in the B-I group; and external drainage for leakage from the duodenal stump (one case) in the R-Y group. The incidence and reasons for readmission after discharge are shown in Table 5. The readmission rate was higher in the R-Y group than in the B-I group (2.55% vs 5.53%, respectively;  $P = .0204$ ). Three internal hernias (0.64%) were recorded in the R-Y group.

### 3.7 | Gallstone formation after surgery

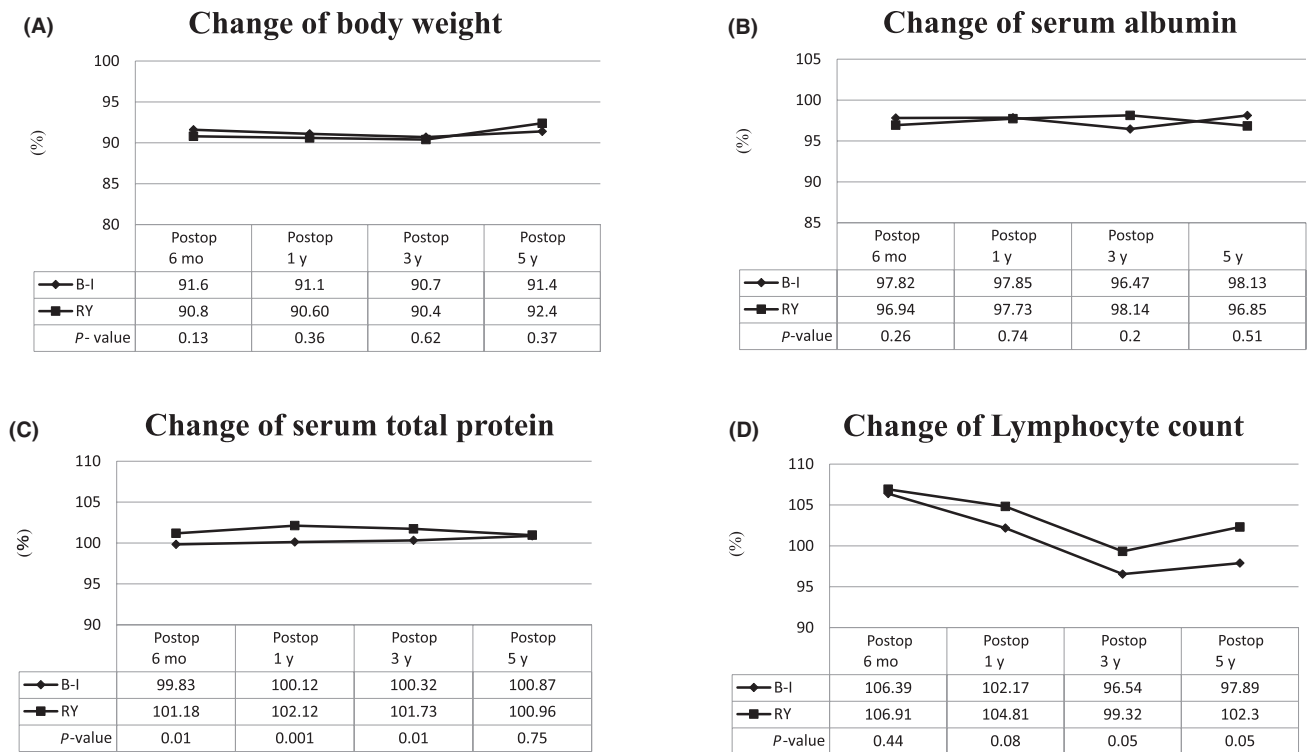
Postoperative gallstone formation was observed in five (3.8%) cases in the B-I group and five (3.4%) cases in the R-Y group; the difference was not statistically significant ( $P = 1.00$ ).

## 4 | DISCUSSION

When suitably employed, propensity score matching can adjust for biases that arise from confounding variables.<sup>15</sup> In the current study, the tumor and patient characteristics, as well as the surgeons' preferences, were strictly balanced between the two groups with large numbers of patients; thus, we may expect the scientific reliability of our approach to be comparable to that of large-scale randomized trials. In addition, the current study included the largest number of patients ever reported regarding this issue.

The current study verified the technical complexity of R-Y compared with B-I, showing a longer operation time and greater blood loss, as has been reported in previous articles.<sup>7,9,10,12</sup> However, there was no obvious difference in the severe morbidity rate. A higher rate of grade  $\geq 2$  wound infection was found in patients who underwent R-Y, which seems natural because R-Y requires two intestinal anastomoses and a longer operation time. The wound infection rate was also higher in patients in the R-Y group who underwent laparoscopic surgery than patients in the B-I group, probably because most jejunojunostomies are performed through a mini-laparotomy under direct vision to reduce the operation time.

Delayed gastric emptying, known as Roux stasis, is a specific complication of R-Y.<sup>4</sup> It is thought to be caused by the destruction of the natural pacemaker of the small intestine or a bent limb in the early postoperative period. In the current study, the incidence of postoperative stasis was not markedly different between the groups, either as a postoperative complication or as a reason for



**FIGURE 1** Nutritional status. Rate of change in (A) body weight, (B) serum albumin, (C) serum total protein, and (D) lymphocyte count. B-I, Billroth-I; RY, Roux-en-Y; postop, postoperative

readmission. Surgeons working in high-volume centers presumably took measures to prevent this complication according to their experience, such as by creating a Roux limb of relatively short length (<30 cm). Internal hernia is another specific complication after R-Y, and the tendency for hernia formation is thought to be enhanced in laparoscopic surgery because of the fewer adhesions than open surgery.<sup>20,21</sup> Three readmissions (0.64%) occurred due to this complication in the R-Y group of the current study. Closure of defects that may lead to internal hernia formation using nonabsorbable sutures is recommended by many researchers,<sup>20</sup> so we have begun routinely following this recommendation. It has been established that R-Y is associated with specific potential postoperative complications,<sup>21</sup> and surgeons should take maximum care to avoid them. Overall, B-I has several advantages with respect to short-term outcomes, but both procedures seem equally safe.

Nutritional parameters are likely to be affected by the progression of cancer or a patient's performance status, but in the current study, these factors were adjusted for in order to achieve an accurate comparison. There was no clear difference in the nutritional parameters between the two groups, even at the five-year follow-up. Bias of the tumor location was excluded; therefore, the size of the remnant stomach might have been similar between the two groups. This indicates that the presence of food passage to the duodenum is not a crucial determinant of the nutritional condition. Interestingly, however, the incidence of acalculous cholecystitis in the early postoperative period was significantly higher in the R-Y group than in the B-I group, although the incidence of postoperative gallstone formation was almost identical

**TABLE 3** Postoperative endoscopic findings of the remnant stomach

Grade	Billroth-I (n = 271)		Roux-en-Y (n = 229)		P-value
	n	(%)	n	(%)	
<b>Residual food<sup>a</sup></b>					
0	243	89.7	214	93.4	<.001
1,2	23	8.5	8	3.5	
3,4	5	1.8	10	4.4	
<b>Gastritis<sup>b</sup></b>					
0	126	46.5	119	52.0	<.001
1	119	43.9	61	26.6	
2	16	5.9	41	17.9	
3,4	10	3.7	8	3.5	
<b>Bile reflux<sup>c</sup></b>					
0	245	90.4	227	99.1	<.001
1	26	9.6	2	0.9	

<sup>a</sup>Grade 0, no residual food; grade 1, small amount; grade 2, moderate amount, but possible to observe the entire surface of the remnant stomach with body rolling; grade 3, moderate amount that hinders observation of the entire surface even with body rolling; grade 4, large amount making endoscopic observation impossible.

<sup>b</sup>Grade 0, normal mucosa; grade 1, mild redness; grade 2, intermediate grade between grades 1 and 3; grade 3, severe redness; grade 4, apparent erosion.

<sup>c</sup>Grade 0, absence; 1, presence.

TABLE 4 Postoperative complications

	Billroth-I (n = 470)			Roux-en-Y (n = 470)			P-value		
	All grades	≥2	≥3	All grades	≥2	≥3	All grades	≥2	≥3
Anastomotic leakage	9	9	4	8	8	4	.81	.81	1.00
Intra-abdominal hemorrhage	1	0	0	1	1	1	1.00	.24	.24
Anastomotic hemorrhage	4	3	1	1	1	1	.16	.31	1.00
Pancreatic fistula	10	10	5	11	11	7	.83	.83	.56
Intra-abdominal abscess	16	15	6	13	12	2	.57	.56	.15
Wound infection	8	3	1	22	14	1	.0081	.0051	1.00
Anastomotic stricture	3	3	3	8	7	3	.12	.20	1.00
Paralytic ileus	7	6	2	8	5	2	.79	.76	1.00
Chylorrhea	2	2	0	5	5	1	.25	.25	.24
Anesthetic complications	0	0	0	1	1	0	.24	.24	N.A.
Respiratory complications	5	5	1	14	13	0	.033	.053	.24
Cardiovascular complications	1	1	0	2	2	0	.56	.56	
Intracranial complications	0	0	0	0	0	0			
Acalculous cholecystitis/ cholangitis	17	17	2	35	35	0	.011	.011	.16
Other	8	8	2	7	7	1	.79	.79	.56
All	82	73	25	128	114	22	.0003	.0008	.65
All (%)	17.45	15.53	5.32	27.23	24.68	4.68			

	Billroth-I (n = 470)		Roux-en-Y (n = 470)		P-value
	n	%	n	%	
Readmission	12	2.55	26	5.53	.0204
Internal hernia	0	0.00	3	0.64	.0828
Loss of appetite, malnutrition	2	0.43	1	0.21	.5631
Ileus, stasis	7	1.49	10	2.13	.4628
Anastomotic stricture	1	0.21	1	0.21	1.00
Abdominal pain	1	0.21	1	0.85	.1786
Incisional infection, hernia	0	0.00	2	0.43	.1569
Intra-abdominal abscess	0	0.00	1	0.21	.3171
Cholecystitis/cholangitis	0	0.00	4	0.85	.045
Splenic infarction	1	0.21	0	0.00	.3171

TABLE 5 Readmission incidence and reasons

between the two groups. This finding may imply a transient influence of the loss of food passage to the duodenum. The incidence of gallstone formation reportedly ranged from 1.8% to 29.0% in previous reports<sup>6</sup> and seems to be strongly affected by the extent of lymph node dissection. In the current study, this incidence was less than 4% in both procedures. This may be explained by the fact that this study enrolled only patients with stage I cancer with limited lymph node dissection and with preservation of the vagus nerve; in such situations, there will be no marked difference between the two procedures.

Food residue and remnant gastritis at the time of endoscopic examination have been suggested as objective parameters that can be used to assess the effectiveness of reconstruction procedures after DG. As expected, in the current study, we found a

lower incidence of remnant gastritis and bile reflux in the R-Y group than in the B-I group at the time of the endoscopic examination. Some researchers have hypothesized that bile acid and pancreatic proteolytic enzymes will damage the gastric mucosa, resulting in inflammation or, hypothetically, cancer promotion<sup>5</sup>; thus, these findings may represent drawbacks of B-I. Experimental studies have also proposed this hypothesis, but an article from Italy reported no marked difference in bile reflux between reconstruction methods.<sup>22</sup> In the current study, the incidence of bile reflux in B-I was within 10%, and, at present, it is difficult to say whether B-I is associated with an increased possibility of remnant gastric cancer. An observation period of at least 10 years may be necessary to compare the incidence of gastric stump cancer.

Food residue was also less commonly observed in the R-Y group than in the B-I group. Notably, however, these endoscopic findings are not always linked to a patient's symptoms or quality of life. Takiguchi et al.<sup>13</sup> demonstrated equivalent results in their quality of life assessment at 1 year after surgery between B-I and R-Y in their multicenter prospective randomized study of 332 patients; Lee et al.<sup>11</sup> reported similar results in their small randomized trial. Another problem associated with food residue is difficulty conducting surveillance of the remnant stomach, as these patients may be at high risk for the redevelopment of gastric cancer. Further long-term observation will be necessary in order to assess the incidence of gastric stump cancer.

The present study was associated with some important limitations. First, there is no guarantee that all confounding factors were included in our database. It is possible that unmeasurable or unknown but important factors were overlooked due to a selection bias. Second, although the issue of evaluating surgical procedures is common to all research, the operative methods are heterogeneous among institutions or surgeons. For example, the anastomotic techniques, which might influence the outcome, included hand sewing or mechanical anastomosis. In addition, we need to consider recent advances in surgical skill and devices. In order to estimate long-term outcomes in this study, the patients included underwent gastrectomy from 2006 to 2014; however, the stapling devices, surgeons' performance, improvement of optic system, and the introduction of robot-assisted surgery has rapidly progressed in this decade. Thus, our results cannot be exactly applied to the present practice.

In conclusion, similar long-term nutritional and survival outcomes were observed in B-I and R-Y reconstruction. R-Y may be just as suitable as a standard procedure as B-I, although surgeons should be aware of the defining features of each approach.

## DISCLOSURE

Funding: There is no financial support for this article.

Conflict of Interest: Authors declare no conflict of interests for this article.

Author Contribution: Takahiro Kinoshita, Michitaka Honda, Atsushi Matsuki, Naoki Enomoto, Masaki Aizawa, Souya Nunobe, Hiroshi Yabusaki, and Naoki Hiki have substantial contributions to the conception and analysis of data for work. Takahiro Kinoshita and Michitaka Honda drafted the manuscript. Takayuki Abe and Michitaka Honda have substantial contributions to the statistical analyses.

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**How to cite this article:** Kinoshita T, Honda M, Matsuki A, et al. Billroth-I vs Roux-en-Y after distal gastrectomy: A comparison of long-term nutritional status and survival rates from a large-scale multicenter cohort study. *Ann Gastroenterol Surg*. 2020;4:142–150. <https://doi.org/10.1002/ags3.12309>