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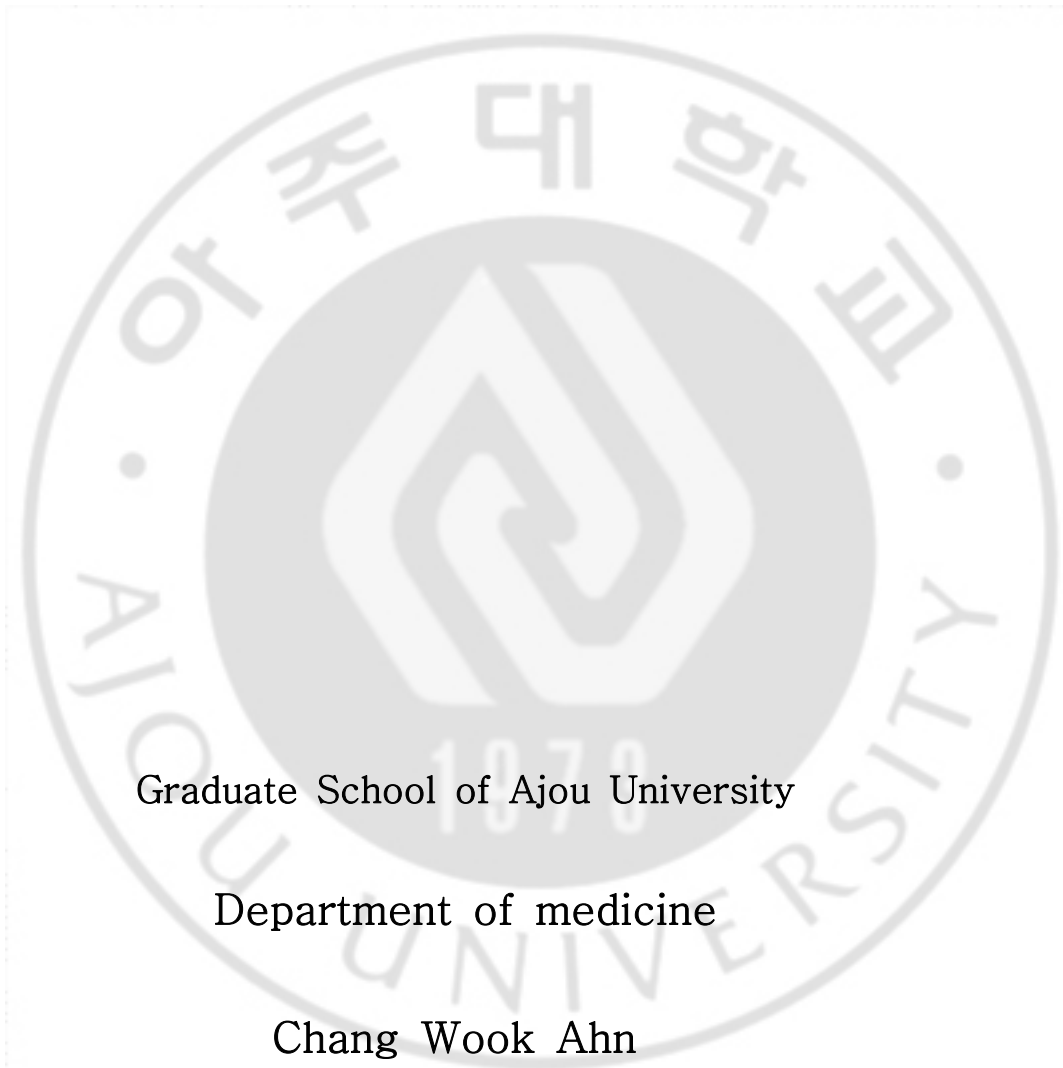
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A Novel Roux-en-Y
reconstruction involving the use of two
circular staplers after distal subtotal
gastrectomy for gastric cancer



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gastrectomy for gastric cancer

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I submit this thesis as the
Doctoral thesis in medicine.

August 2019

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ABSTRACT

Background: Although Roux-en-Y (R-Y) reconstruction after distal gastrectomy has several merits such as prevention of bile reflux into the remnant stomach, it is rarely used because of the technical difficulty. This study aimed to show the efficacy of a novel method of R-Y reconstruction involving the use of 2 circular staplers through a prospective randomized clinical trial comparing the novel method with Billroth-I (B-I) reconstruction.

Materials and Methods: 118 patients were randomly allocated into the RY (59 patients) and B-I reconstruction (59 patients) groups. R-Y anastomosis was performed using 2 circular staplers and no hand sewing. The primary end-point of this clinical trial was the reflux of bile into the remnant stomach, and it was evaluated through endoscopic and histological findings at 6 months after surgery.

Results: No significant differences were observed in the clinicopathologic findings between the 2 groups. Although anastomosis time ($P < 0.001$) was significantly longer for the patients of the R-Y group than them for the B-I group, there was no difference between the 2 groups in terms of the total surgery duration ($P = 0.112$). Endoscopic findings showed a significant reduction of bile reflux in the remnant stomach in the R-Y group ($P < 0.001$), and the histological findings showed that reflux gastritis was more significant in the B-I group than in the R-Y group ($P = 0.026$).

Conclusions: The results of our randomized controlled clinical trial showed that compared with B-I reconstruction, R-Y reconstruction using circular staplers is a safe and feasible procedure.

Keywords: Gastric cancer; Distal gastrectomy; Roux en Y reconstruction; Circular stapler

Registration number: NCT01142271 (<http://www.clinicaltrials.gov>)



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1. Introduction

Distal subtotal gastrectomy and proper lymphadenectomy are common surgical strategies used for treating gastric cancer in the middle or distal stomach, where gastric cancers commonly occur [1]. The selection of an appropriate reconstruction method after distal subtotal gastrectomy has been emphasized, because reconstruction tends to affect on the remnant stomach and quality of life of patients [2]. The standard methods for reconstruction are gastroduodenostomy also termed as Billroth-I (B-I) reconstruction and gastrojejunostomy also termed as Billroth-II (B-II) reconstruction, both of which involve a single anastomosis. Most surgeons prefer B-I reconstruction because it retains the physiologic passage for ingested food, as long as it is anatomically possible [3]. However, the major disadvantage of B-I reconstruction is the reflux gastritis caused by the loss of the pylorus, which is the anatomical barrier preventing the reflux of the bile into the stomach, and the reflux of bile eventually increase the risk of cancer in the remnant stomach [4]. In addition, the reflux of bile into the remnant stomach can affect on the quality of life of the patients who have undergone gastric cancer surgery [5]. Therefore, many surgeons have found Roux en Y (R-Y) reconstruction more favorable than B-I reconstruction in eliminating the likelihood of bile reflux [6-8]. In spite of these benefits, surgeons are reluctant to use the R-Y reconstruction method widely in clinical practice because of some drawback of this method.

The R-Y reconstruction after distal gastrectomy requires 2 anastomoses, i.e. for the gastrojejunostomy and the jejunojejunostomy involving the resection of the small intestine and its mesentery. The need for these complicated procedures has emerged as a major demerit of R-Y reconstruction method. Several clinical studies have shown that R-Y reconstruction takes more time and has a higher complication rate than other methods [9, 10]. To overcome these demerits, we performed a pilot study for developing a novel and simple method using 2 circular staplers for R-Y reconstruction; our results showed that compared with B-I method, this method was safe, and it reduced the incidence of postoperative bile reflux [11]. However, for recommending the this procedure as a novel method for replacing conventional reconstruction method, a prospective randomized controlled clinical trial (RCT) is required to show the superiority of this method to the B-I method, with respect to prevention of bile reflux into the remnant stomach, as well as safety of this procedure. To examine the effect of R-Y reconstruction on bile reflux of bile, we used 3 kinds of measurements, namely histologic, gastroscopic, and quality of life for enrolled patients, to be as objective as possible. Here, we present the results of the RCT conducted to evaluate the efficacy of the simple R-Y reconstruction method involving the use of 2 circular staplers.

2. Methods

The institutional review board of the Ajou University Hospital, Suwon, Korea approved this RCT (AJIRB-MED-DEO-09-297); this study followed the ethical standards of the Helsinki Declaration of 1975. This study was registered in www.clinicaltrials.gov as NCT01142271 before enrollment of the first patient, and we obtained written informed consents from each patient.

The patients were randomly assigned into 2 groups before the surgery: the B-I or R-Y reconstruction group. The patients and operations were not blinded to the randomized allocation, whereas the investigators and data collectors were blinded during the trial.

Patients were assessed for this RCT if they met with following inclusion criteria: gastric adenocarcinoma diagnosis, age between 25 and 74 years, primary tumor located in the middle or distal portion of the stomach that could be curatively resected by distal gastrectomy, and American Society of Anesthesiology (ASA) score of ≤ 3 . Patients who were pregnant or those with uncontrolled systemic disease or synchronous malignancy were excluded from this trial. For 18 months from July 2010 to November 2011, 120 patients were assessed for determining their eligibility for this trial.

Two surgeons (Han and Hur), who had a experience of over 100 gastric cancer surgeries respectively when this trial began, performed surgery for all participants.

The surgeries were performed according to the third edition of Japanese Gastric Cancer Treatment Guideline [12]. Laparoscopic surgery including limited lymph node dissection (less than D1+) were performed according to the formal protocol of our institution the patients who were clinically diagnosed with early gastric cancer. For the laparoscopic surgery, a small incision (4-6cm) was made for reconstruction in the epigastric area after laparoscopic lymph node dissection. For the patients in B-I group, gastroduodenostomy was performed according to Tonado method using a 29-mm circular stapler (Ethicon Endosurgery Inc., Blue Ash, OH, USA), which has shown favorable results in a previous study reported by Yang and colleagues [13]. The methods for R-Y reconstruction are described in detail in our pilot study [11]. In brief, we resected the jejunum and its mesentery 30 cm distal portion from the Treiz ligament (Figure 1A), and then the anvil of a 21-mm circular stapler (Ethicon Endosurgery Inc.) was inserted into the proximal end of the resected jejunum (Figure 1B). For the jejunojejunostomy, the body of 21 mm circular stapler, the body of this stapler was inserted into the distal end of the resected jejunum and passed through the Roux limb into the site of the jejunojejunostomy (Figure 1C). With the Roux limb measuring > 30 cm, the jejunojejunostomy was performed (Figure 1D). Thereafter, the larger anvil of the 29-mm circular stapler (Ethicon Endosurgery Inc.) was placed at the distal end of the resected jejunum (Figure 1E), and the gastrojejunostomy was performed in a manner similar to the Tonado method (Figure 1F).

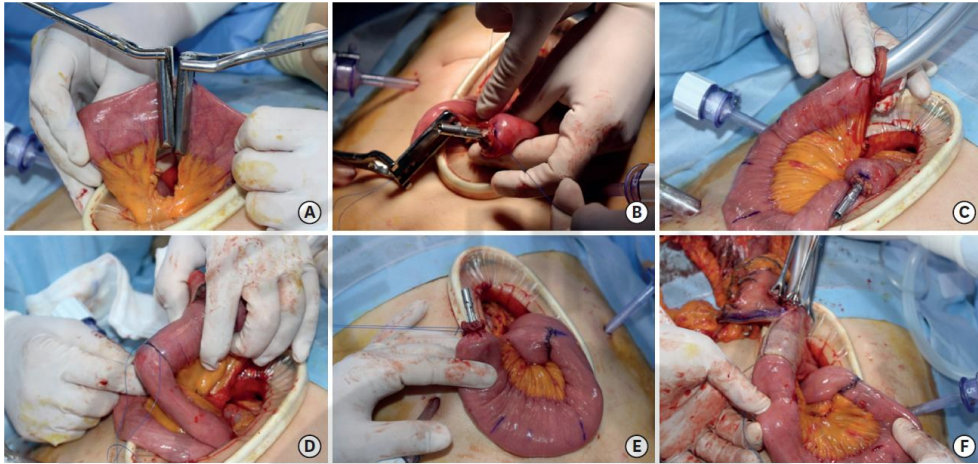


Fig. 1 Surgical procedure for Roux-en-Y reconstruction included (A) division of the proximal jejunum and mesentery, (B) insertion of a 21-mm anvil into the resected distal jejunum, (C) insertion of the stapler body into the resected proximal jejunum, (D) anastomosis of jejunojejunostomy using a 21-mm circular stapler, (E) insertion of a 29-mm anvil into the proximal jejunum, and (F) anastomosis of the gastrojejunostomy by the Tonado method with a 29-mm circular stapler.

The primary end-point of this RCT was the reflux of bile into the remnant stomach at 6 months after surgery. Therefore, the patients underwent gastroscopy for the patients, and the degree of bile reflux was evaluated as per the classification suggested by Japanese surgeons [7]. With regard to residual food, Grade 0 denoted no residual food; Grade 1 is small amount; Grade 2 is moderate amount with the entire surface of the remnant stomach visible; Grade 3 is high amount, with some part of the remnant stomach visible; and Grade 4, non-visualization of the remnant

stomach. Further, Grade 0 of gastritis denoted normal mucosa; Grade 1, mild redness; Grade 2, intermediate state; Grade 3, severe redness; and Grade 4, apparent erosion. Bile reflux was graded as Grade 0 (Absence) or 1 (Present) (Table 4).

Additionally, we determined the histological degree of reflux using specimens of the remnant stomach that were obtained through endoscopic biopsy. Histological grading of the specimen was carried out according to previous reports by Dixon and colleagues [14], considering the elongation and tortuosity of the glands, interstitial oedema or congestion, paucity of chronic inflammatory cells, and the prominence of the smooth muscle cells in the lamina propria (Figure 2). Two pathologists determined the score from point 0 to 3 in terms of hyperplasia or congestion of the lamina propria, and acute or chronic inflammation.

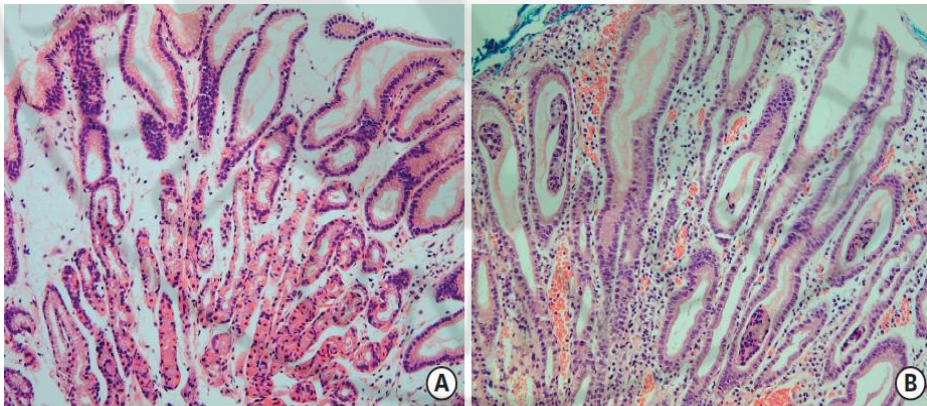


Fig. 2 Histological findings of biopsied tissues in the remnant stomach. (A) The tissue was given a score of 0 on evaluation, as per the grading system suggested by Dixon et al. (B) The tissue was given a score of 12.

The secondary outcomes were morbidity and mortality related to the surgery, the operation and reconstruction time, and quality of life scores determined using the European Organization Research and Treatment for Cancer Life Core-30 (EORTC QLQ-C30) and a specific questionnaire for gastric surgery (QLQ-STO22) at 6 months after surgery (Figure 4).

The aim of this study was to show the superiority of the novel R-Y reconstruction method over the B-I method with respect to bile reflux into the remnant stomach after distal gastrectomy as the primary end point. We used a standard superiority design, and the sample size was estimated considering the following points: A 2-sided significance level of 0.05, 80% power, χ^2 test results, and alternative hypothesis based on the reflux rate of primary end points of 10% in the R-Y group vs, 30% in the B-I group: the reflux rates were based on the results of a previous study by Ishikawa and colleagues [15]. Considering a 10% drop rate, 120 patients were needed to detect any significant difference between the 2 groups.

Sample size was calculated using Excel 2011 (Microsoft Corp., Redmond, WA, USA), and statistical analysis was conducted using the SPSS version 18.0 (IBM Inc, Armonk, NY, USA). To compare the outcomes between the 2 groups, the Student t-test and χ^2 test were conducted for continuous variables and absolute variables, respectively. The continuous variables were expressed as mean \pm standard deviation. Statistical significance was set at $P < 0.05$.

3.Results

The recruitment and progression of this clinical trial are summarized in [Figure 3](#). Of the 120 patients who were selected, 118 patients who agreed to participate in this trial and then were randomized. 59 patients were allocated into each group. Of the 59 patients allocated to the B-I group, 3 patients underwent other methods for reconstruction using other methods such as R-Y and B-II because the length of the remnant stomach was too short for performing reconstruction via gastroduodenostomy. We performed total gastrectomy in 1 patient in the R-Y group to secure a tumor-free proximal margin. Finally, 56 patients in the B-I group and 58 in the R-Y underwent the allocated procedures. The clinicopathologic and surgical characteristics of these patients are listed in [Table 1](#): no major differences were observed between the 2 groups. We then compared the surgical outcomes between the 2 groups.

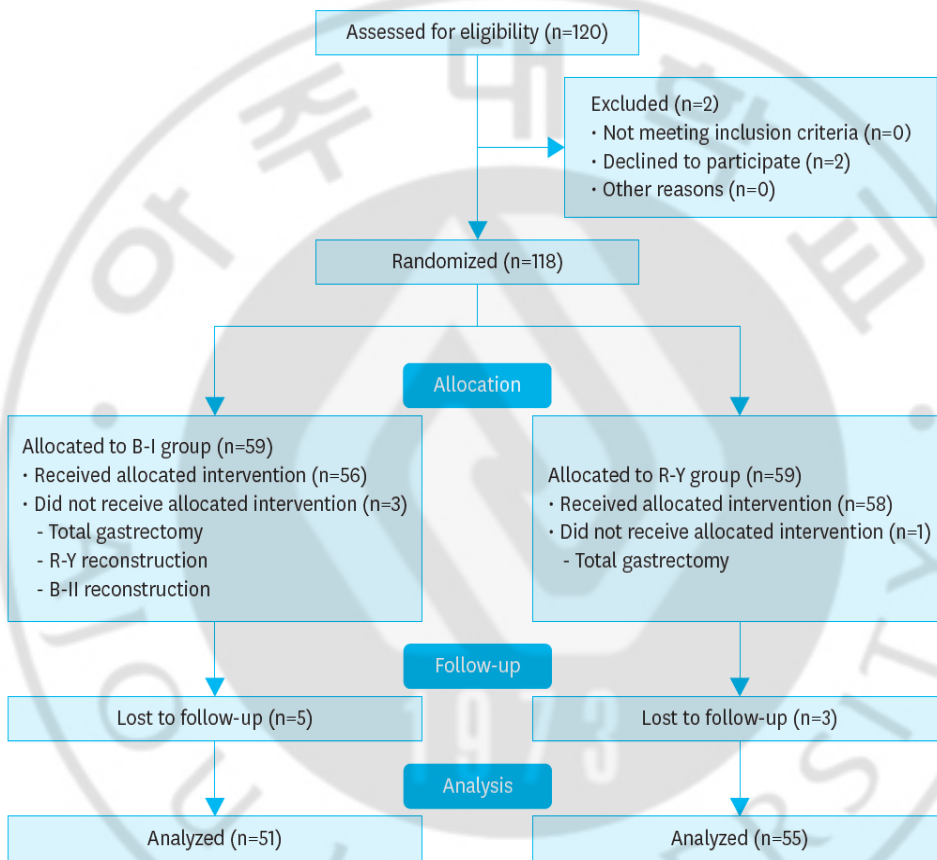


Fig. 3 Study design according to the CONSORT diagram

CONSORT = Consolidated Standards of Reporting Trials; B-I = Billroth-I;

B-II = Billroth-II; R-Y = Roux-en-Y.

Table 1 Demographic and clinical characteristics of patients who received the allocated intervention

Characteristics	B-I (n=56)	R-Y (n=58)	P value
Age (years old)			
<65	37 (66.1%)	41 (70.7%)	0.593
≥65	19 (33.9%)	17 (29.3%)	
Gender			
Male	36 (64.3%)	32 (55.2%)	0.321
Female	20 (35.7%)	26 (44.8%)	
BMI (kg/m ²)			
<25	39 (67.2%)	41 (70.7%)	0.688
≥25	19 (32.8%)	17 (29.3%)	
Comorbidity			
Yes	20 (35.7%)	26 (44.8%)	0.321
None	36 (64.3%)	32 (55.2%)	
Approach			
Open	7 (12.5%)	5 (8.6%)	0.500
Laparoscopy-assisted	49 (87.5%)	53 (91.4%)	
LN dissection			
D1 or D1+	34 (60.7%)	24 (41.4%)	0.039
D2 or D2+	22 (39.3%)	34 (58.6%)	
Stage (AJCC, 7 th Edition)			
I	48 (85.7%)	51 (87.9%)	0.920
II	5 (8.9%)	4 (6.9%)	
III	3 (5.4%)	3 (5.2%)	

B-I = Billroth-I, R-Y = Roux en Y, BMI = Body mass index, LN = lymph node, AJCC = American Joint Committee on Cancer.

At the 6-month follow-up, 8 (6.7%) patients were lost to follow-up, 5 from the B-I group and 3 from the R-Y. Finally, the primary end points for 106 (88.3%) patients, 51 in the B-I and 55 in the R-Y group, of the 120 patients assessed for this trial were analyzed to compare the primary end-points between the 2 groups.

There was no significant difference in the surgical outcomes such as intraoperative bleeding, the length of hospital stay, postoperative recovery time, and postoperative complication rate between the 2 groups (Table 2). Although most of the complications were resolved by medical or conservative treatment, 1 patient with anastomosis leakage in the R-Y group was required reoperation. However, the patient fully recovered, and there was no mortality in both the groups.

The time taken to perform the reconstruction was significantly longer in the R-Y groups than in the B-I group (34.3 vs. 29.0 minutes, $P < 0.001$). However, there was no statistical difference in total surgery time between the 2 groups ($P = 0.112$).

The quality of life score at 6-month follow-up, determined using EORTC questionnaires questionnaire, were not significantly different between the two groups (Table 3).

Table 2 Surgical outcomes for patients who received the allocated intervention

Characteristics	B-I (n=56)	R-Y (n=58)	P Value
Bleeding (cc)	189.1±141.6	185.1±123.9	0.874
Operation time (min)	159.4±40.7	172.0±43.2	0.112
Anastomosis time (min)	29.0±6.7	34.3±8.4	<0.001
Length to PRM (cm)	5.8±3.3	5.9±3.2	0.904
Time to Soft diet (days)	5.5±0.9	5.6±1.4	0.577
Length of HD (days)	7.4±1.6	7.8±2.4	0.295
Complication	7 cases (12.5%)	8 cases (13.8%)	0.838
Description for complication (No of cases)	Postoperative ileus Pneumonia Intraabdominal fluid Cholecystitis Voiding difficulty Unknown fever (2)	Postoperative ileus (3) Pneumonia Leakage Wound seroma Voiding difficulty Wound pain (2)	

B-I = Billroth-I, R-Y = Roux-en-Y, PRM = proximal resection margin, HD = hospital days.
Continuous variables were presented as mean ± standard deviation.

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week: Not at A Quite Very All Little a Bit Much

31. Have you had problems eating solid foods? 1 2 3 4
 32. Have you had problems eating liquidised or soft foods? 1 2 3 4
 33. Have you had problems drinking liquids? 1 2 3 4
 34. Have you had discomfort when eating? 1 2 3 4
 35. Have you had pain in your stomach area? 1 2 3 4
 36. Have you had discomfort in your stomach area? 1 2 3 4
 37. Did you have a bloated feeling in your abdomen? 1 2 3 4
 38. Have you had trouble with acid or bile coming into your mouth? 1 2 3 4
 39. Have you had acid indigestion or heartburn? 1 2 3 4
 40. Have you had trouble with belching? 1 2 3 4
 41. Have you felt full up too quickly after beginning to eat? 1 2 3 4
 42. Have you had trouble enjoying your meals? 1 2 3 4
 43. Has it taken you a long time to complete your meals? 1 2 3 4
 44. Have you had a dry mouth? 1 2 3 4
 45. Did food and drink taste different from usual? 1 2 3 4
 46. Have you had trouble with eating in front of other people? 1 2 3 4
 47. Have you been thinking about your illness? 1 2 3 4
 48. Have you worried about your weight being too low? 1 2 3 4
 49. Have you felt physically less attractive as a result of your disease or treatment?
1 2 3 4
 50. Have you worried about your health in the future? 1 2 3 4
 51. Have you lost any hair? 1 2 3 4
 52. Answer this question only if you lost any hair:
If so, were you upset by the loss of your hair?
-

Fig.4 EORTC QLQ – STO22 questionnaire

Table 3 Change in quality of life of the patients who were followed up 6 months postoperatively using EORTC questionnaires

Questionnaires	B-I (n=51)	R-Y (n=55)	P Value
C30			
Physical	0.97±0.24	1.02±0.26	0.354
Role	1.00±0.37	1.09±0.45	0.287
Pain	1.01±0.43	0.94±0.33	0.358
Fatigue	0.97±0.43	1.07±0.40	0.220
Nausea and vomiting	0.98±0.36	1.03±0.47	0.559
Emotional	0.98±0.48	0.92±0.37	0.429
Cognitive	1.06±0.37	0.97±0.30	0.168
Social	1.04±0.56	0.94±0.41	0.298
Financial	1.19±0.79	0.98±0.55	0.103
Global	1.15±0.38	1.17±0.32	0.702
Single symptoms	0.96±0.39	0.99±0.41	0.748
STO22			
Dysphasia	1.13±0.39	1.08±0.27	0.400
Pain	0.97±0.46	0.91±0.31	0.391
Restriction	1.00±0.30	0.94±0.29	0.280
Upper GI symptoms	1.05±0.42	1.08±0.38	0.742
GI emotional	1.06±0.35	1.15±0.41	0.242
GI single symptoms	1.05±0.43	1.05±0.43	0.995

B-I = Billroth-I, RY = Roux en Y, GI = gastrointestinal.

Continuous variables were calculated as the ratio of score of the postoperative 6-month score to the preoperative score, and presented as mean ± standard deviation. The gastroscopic finding showed that reflux of bile in the remnant stomach was significantly reduced in the R-Y group compared with that in the B-I group (23.6%

vs. 62.7%, $P < 0.001$). Gastritis in the remnant stomach was shown more severe in the B-I group than in the R-Y group ($P = 0.016$) (Table 5). However, findings regarding residual food in the remnant stomach were similar between the R-Y and B-I group ($P = 0.117$).

Table 4 the RGB score classification

Residual food	
0	no residual food
1	a small amount of residual food
2	a moderate amount of residual food, but possible to observe entire surface of the remnant stomach with body rolling
3	a moderate amount of residual food, which hinders observation of the entire surface even with body rolling
4	a great amount of residual food, for which endoscopic observation is impossible
Gastritis	
0	normal mucosa
1	mild redness
2	intermediate grade between grade 1 and grade 3
3	severe redness
4	apparent erosion
Reflux	
0	absence of bile reflux
1	presence of bile reflux

Table 5 Gastroscopic findings for patients who were followed up 6 months postoperatively using the RGB score

Findings	B-I (n = 51)	R-Y (n =55)	P Value
Residual food			
0	13 (25.5%)	23 (41.8%)	0.117
1	21 (41.2%)	12 (21.8%)	
2	8 (15.7%)	5 (9.1%)	
3	3 (5.9%)	6 (10.9%)	
4	6 (11.8%)	9 (16.4%)	
Gastritis			
0	0 (0.0%)	2 (3.6%)	0.016
1	10 (19.6%)	16 (29.1%)	
2	13 (25.5%)	22 (40.0%)	
3	23 (45.1%)	15 (27.3%)	
4	5 (9.8%)	0 (0.0%)	
Reflux			
0	19 (37.3%)	42 (76.4%)	<0.001
1	32 (62.7%)	13 (23.6%)	
Total score^a	4.45 ± 2.18	3.53 ± 2.39	0.041

B-I = Billroth-I, R-Y = Roux en Y.

^aTotal score was calculated as the sum of scores from each group, and was presented as mean ± standard deviation

Histological evaluation was performed using biopsied specimens from 79 patients who agreed to undergo biopsy of the remnant stomach. Although there was no difference between the groups when the scores were itemized as hyperplasia, congestion, and inflammation, the total score was higher for the B-I group than for the R-Y group (5.05 vs. 3.93, $P = 0.026$) (Table 6), thereby showing the superiority

of R-Y over B-I in preventing histological gastritis.

Table 6 Histological findings for the remnant stomach in patients in patients who were followed up 6 months postoperatively using the scoring system suggested by Dixon et al

Findings	B-I (n = 38)	R-Y (n =41)	P Value
Laminar hyperplasia			
0	8 (21.1%)	9 (22.0%)	0.166
1	19 (50.0%)	28 (68.3%)	
2	7 (18.4%)	3 (7.3%)	
3	4 (10.5%)	1 (2.4%)	
Laminar congestion			
0	5 (13.2%)	8 (19.5%)	0.113
1	23 (60.5%)	30 (73.2%)	
2	9 (23.7%)	2 (4.9%)	
3	1 (2.6%)	1 (2.4%)	
Acute inflammation			
0	5 (13.2%)	9 (22.0%)	0.061
1	20 (52.6%)	28 (68.3%)	
2	12 (31.6%)	4 (9.8%)	
3	1 (2.6%)	0 (0.0%)	
Chronic inflammation			
0	10 (26.3%)	14 (34.1%)	0.783
1	8 (21.1%)	10 (24.4%)	
2	11 (28.9%)	10 (24.4%)	
3	9 (23.7%)	7 (17.1%)	
Total score^a	5.05 ± 2.35	3.93 ± 2.05	0.026

B-I = Billroth-I, R-Y = Roux en Y.

^a Total score was calculated as the sum for each group, and was presented as mean ± standard deviation.

4. Discussion

This RCT showed the efficacy of the novel R-Y reconstruction method involving the use of 2 circular staplers and no hand sewing after distal gastrectomy in gastric cancer surgery. Compared with the conventional B-I method, the novel R-Y reconstruction method did not yield poor surgical outcomes. Moreover, our postoperative endoscopic and histologic findings showed the superiority of the R-Y reconstruction method in preventing the bile reflux into the remnant stomach.

In our RCT, we introduced the novel method of using only staplers to make the relatively complicated R-Y procedure after distal gastrectomy as easy as the conventional B-I or B-II method. Currently, many surgeons are using staplers for performing anastomoses because they are safe and time saving; these advanced instruments facilitated the novel procedure in this study as well. To date, several studies have shown that using advanced stapling devices reduces the incidence of complications such as leakage and bleeding; in addition, stapling makes anastomosis of the intestine easier and more secure than hand sewing [16-18]. The advantage of using a stapling device is heightened in complicated procedures such as the conventional R-Y reconstruction method that requires many anastomoses. Because we used circular staplers for performing 2 anastomoses, we found it difficult to combine the anvils and the body of the staplers without an additional enterotomy. To overcome this problem, first, the body of a 21-mm stapler for the jejunojejunostomy was inserted through the distal opening of the resected jejunum,

and it was passed through 30–40 cm of the jejunum to combine with the anvil fixed to the proximal end of the resected jejunum. Second, the body of a 29-mm stapler for the gastrojejunostomy was inserted through the resected part of the stomach to combine with the anvil inserted into the distal end of the resected jejunum; this procedure was not difficult because it was similar to the Tonado method for B-I reconstruction. Since additional hand sewn sutures for anastomosis were not required, the total operation time including all the procedures was not significantly long compared with that for the B-I method that requires only 1 anastomosis. In addition, the operation time for patients in the R-Y group in this study was less than that observed in R-Y reconstruction in previous reports [7, 15]. The acceptable operation time for R-Y reconstruction could have led to favourable surgical outcomes, with no major differences in the complication rate, length of hospital staying, and diet schedule between the R-Y and B-I groups.

In this RCT designed to prove the efficacy of the novel yet simple procedure, we also determined whether this novel procedure could retain an important benefit of conventional R-Y reconstruction, i.e. prevention of bile reflux. Bile reflux into the remnant stomach after distal gastrectomy is usually detected by 24-h bilirubin monitoring or biliary scintigraphy [8, 19]. However, we used endoscopic and histological findings because these findings would directly reflect the damage to the mucosal layer of the remnant stomach from the refluxed bile. Although different anastomotic procedures from our novel method have been used in other studies, compared with B-I or B-II reconstruction, R-Y reconstruction has shown

improved gastroscopic and histological findings in the remnant stomach after distal gastrectomy [20, 21]. To maintain objectivity in the evaluation of bile reflux into the remnant stomach in our RCT, the gastroscopic findings were examined by both a gastroenterologist and a surgeon. We classified the endoscopic findings into food stasis, mucosal gastritis, and bile existence according to a previous report [7], to determine whether the patients experienced stasis of food in the remnant stomach along with bile reflux. In addition, the degree of histological changes in the remnant stomach is an important measurable outcome for bile reflux. Dixon and colleagues classified the severity of reflux gastritis according to histological findings and found that the severity of reflux gastritis was correlated to the degree of alkalinity in the stomach [14]. Two pathologists scored the biopsied specimens from the remnant stomach 6 months after surgery; their findings also presented the superiority of R-Y reconstruction in the prevention reflux gastritis.

Besides the distinct drawback of the conventional R-Y reconstruction method being a complicated procedure, the Roux stasis syndrome can also pose a serious postoperative problem [7, 22]. This syndrome is characterized by epigastric discomfort and even pain after consuming food. This drawback cannot be addressed by our procedure using staplers because the problem is caused by the poor motility of the Roux limb after division of the jejunal mesentery. Therefore, we advised the patients of both groups to consume a small amount of food at a time during the immediate postoperative 3 months. Ultimately, the gastroscopic findings for food stasis did not show significant differences between the B-I and R-

Y group, and none of the patients in the R-Y group complained of symptoms related to Roux stasis syndrome. On the other hand, 3 patients in the R-Y group were treated for postoperative ileus as opposed to only 1 patient in the B-I group. Some physiological studies on intestinal motility have reported that the separation of the jejunum from the natural small intestinal pacemaker located in the duodenum could be the cause of decreased motility [23, 24]. However, there was no significant difference in the incidence of postoperative ileus between both the groups, and the 3 patients of the R-Y group with ileus were managed by conservative treatment only.

Postoperative quality of life is an important outcome to be considered when deciding on the reconstruction method after distal gastrectomy. Therefore, we evaluated the quality of life using the EORTC QLQ-C30 questionnaire, which is already well validated [25, 26]. This questionnaire helps researchers analyze the physical, psychological, and social views of cancer patients. However, more specialized questionnaires are required to examine the quality of life of patients after they have undergone gastrectomy, so we also used the EORTC QLQ-STO22 questionnaire (Figure 4) that has several questions about gastrointestinal symptoms. Because gastrectomy has a temporary effect on the quality of life of the patients [27], we expected the R-Y reconstruction method to prevent any decline in the quality of life at 6 months after surgery. Previous retrospective studies using the EORTC QLQ-C30 and STO22 also reported that the patients who underwent R-Y reconstruction showed better scores than those who underwent B-I or B-II

reconstruction [28]. In contrast, we did not find any difference in any of the fields of the questionnaires between the groups, probably because our patients were well educated about food intake restrictions and adhered to the physician's instructions. Because the previous retrospective study looked into the quality of life at a mean duration of 88 months after gastrectomy [28], the quality of life scores may have been different according to the reconstruction methods and follow-up duration. We are planning to examine this aspect in the future for the same patients enrolled in this RCT.

5. Conclusions

The results of the present RCT showed that the R-Y reconstruction method using only staplers was favourable with regard to surgical outcomes. Therefore, this method can be considered an appropriate option for patients requiring distal subtotal gastrectomy for gastric cancer.

Conflict of interest

The authors declare that they have no conflict of interests.

6. References

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두개의 원형 문합기를 이용하는 방법을 포함한 위 아전 절제술 후 새로운 Roux-en-Y 문합법에 의한 위암 수술법에 대한 고찰

안 창 욱

배경: 위암환자의 수술에서 위 아전 절제술후 Roux-en-Y (R-Y) 술식은 담즙 역류를 방지 할 수 있는 등 몇가지 장점을 가지고 있지만 술식에 어려움이 있어 그 동안 위 아전 절제술후 드물게 사용 되었다. 그래서 이연구의 목적은 이 새로운 두개의 원형 문합기를 이용한 Roux-en-Y (R-Y) 술식의 효용성을 증명하기 위함 이며 이연구는 전향적 무작위 임상 실험 방법으로 Billroth-I (B-I) 술식과 비교분석 하였다.

대상 및 방법: 무작위로 할당된 118 명의 위암 환자를 대상으로 연구 분석하였고 그중 RY 술식 59 명, B-I 술식 59 명이였다. R-Y 술식은 두개의 원형문합기 만 사용되었고 수기 문합법은 사용되지 않았다.

이연구의 첫번째 목표는 수술 후 6 개월후 내시경을 통해 남은 위의 담즙 역류를 확인하고 내시경적 소견과 조직학적 소견을 평가하는 것이다.

결과: 두개의 그룹간에는 임상 병리학적 소견상 큰 차이를 보이지 않았고 R-Y 술식이 문합 시간이 유의 할만 하게 길었으나 ($P < 0.001$) 전체 수술 시간은 두그룹간에 큰 차이를 보이지 않았다 ($P = 0.112$). 6 개월후 내시경적 소견은 R-Y 그룹에서 담즙 역류가 유의할 만하게 줄었음을 확인하였고 ($P < 0.001$) 조직학적 소견에서도 남은 위에서 역류성 위염이 B-I 그룹보다 R-Y 그룹에서 발생률이 현저히 줄어들음을 확인할 수 있었다. ($P = 0.026$).

결론: 이번 연구결과 새로운 두개의 원형 문합기를 이용한 R-Y 술식이 실험결과를 통하여 안전하고 유용한 방법임이 확인되었고 이방법은 충분히 위암환자에서 위 아전 절제술후 재건 술식으로 적절하게 이용될 수 있을 것이다.

핵심어: 위암 , 위아전 절제술 ,R-Y 술식 , 원형문합기