

Randomized Controlled Trial

Randomized controlled trial of uncut Roux-en-Y vs Billroth II reconstruction after distal gastrectomy for gastric cancer: Which technique is better for avoiding biliary reflux and gastritis?

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Abstract**AIM**

To identify which technique is better for avoiding biliary reflux and gastritis between uncut Roux-en-Y and Billroth II reconstruction.

METHODS

A total of 158 patients who underwent laparoscopy-assisted distal gastrectomy for gastric cancer at the First Hospital of Jilin University (Changchun, China) between February 2015 and February 2016 were randomized into two groups: uncut Roux-en-Y (group U) and Billroth

II group (group B). Postoperative complications and relevant clinical data were compared between the two groups.

RESULTS

According to the randomization table, each group included 79 patients. There was no significant difference in postoperative complications between groups U and B (7.6% vs 10.1%, $P = 0.576$). During the postoperative period, group U stomach pH values were lower than 7 and group B pH values were higher than 7. After 1 year of follow-up, group B presented a higher incidence of biliary reflux and alkaline gastritis. However, histopathology did not show a significant difference in gastritis diagnosis ($P = 0.278$), and the amount of residual food and gain of weight between the groups were also not significantly different. At 3 mo there was no evidence of partial recanalization of uncut staple line, but at 1 year the incidence was 13%.

CONCLUSION

Compared with Billroth II reconstruction, uncut Roux-en-Y reconstruction is secure and feasible, and can effectively reduce the incidence of alkaline reflux, residual gastritis, and heartburn. Despite the incidence of recanalization, uncut Roux-en-Y should be widely applied.

Key words: Gastric cancer; Uncut Roux-en-Y; Billroth II; Bile reflux; Alkaline gastritis

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Core tip: Because of the challenge of recanalization, the uncut Roux-en-Y reconstruction is still controversial and needs further study. This study is the first randomized controlled trial concentrating on uncut Roux-en-Y vs Billroth II reconstruction after distal gastrectomy for gastric cancer. This study aimed to compare uncut Roux-en-Y and Billroth II reconstruction in terms of postoperative complications, including biliary reflux and gastritis. Despite the incidence of recanalization, uncut Roux-en-Y reconstruction is secure and feasible, and can effectively reduce the incidence of alkaline reflux, residual gastritis, and heartburn.

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INTRODUCTION

There remains no clear consensus regarding the preferred reconstructive surgical procedure after

laparoscopy-assisted distal gastrectomy (LADG) for gastric cancer^[1,2]. Compared with Japan^[3] and Korea^[4], early gastric cancer only accounts for a small percentage in China, and most gastric cancer cases are found in advanced stages at the initial diagnosis. It is inappropriate for surgeons to perform Billroth I anastomosis after subtotal gastrectomy. In 2005, Uyama first combined LADG with uncut Roux-en-Y reconstruction; however, its use remains controversial^[5,6]. In our department, we usually prefer Billroth II and uncut Roux-en-Y reconstruction.

The current study aimed to compare these two reconstruction techniques in terms of postoperative complications, including biliary reflux and gastritis.

MATERIALS AND METHODS

This is a randomized controlled trial which was evaluated and approved by the ethics committee at our institution, and registered in clinicaltrials.gov with the number NCT02694081. Between February 2015 and February 2016, a total of 158 patients with gastric cancer treated at the First Hospital of Jilin University (Changchun, China), who met the inclusion criteria and provided informed consent, were randomized into one of two groups: uncut Roux-en-Y group (group U) or Billroth II group (group B). Randomization was done after laparoscopic exploration with the randomization table, which was produced using SPSS v18.0 for Windows software by the Division of Clinical Research at our hospital. Patients as well as investigators (assessing outcomes and analyzing data) were masked. The inclusion criteria were: (1) distal gastric cancer diagnosed by endoscopy, CT scan, and pathology study; (2) patients who underwent LADG; and (3) age between 18 and 75 years. The exclusion criteria were: (1) late-stage gastric carcinoma or pyloric obstruction; (2) preoperative esophageal reflux symptoms, esophagitis, or hiatal hernia; and (3) systemic disease including diabetes, severe chronic lung disease, cirrhosis, or esophageal varices.

All included patients underwent LADG with D2 lymphadenectomy, which was performed by the same surgical team. For reconstruction, a 5-cm mini-laparotomy was made to complete a delta-shaped Billroth II anastomosis using a 80 mm linear stapler^[7]. In the uncut Roux-en-Y group, gastrojejunostomy was performed at 25 cm distal to the Treitz ligament, and jejunum-jejunum anastomosis at 40 cm from the afferent limb. The blade of the linear stapler (Covidien GIA8038S, Medtronic, Minneapolis, MN, the United States of America) was removed to perform the uncut procedure of the afferent jejunal limb, 5 cm proximal to the gastrojejunostomy in the jejunum (Figure 1A and B).

During the postoperative period, omeprazole 40 mg was given to all patients twice a day. Ambulation was encouraged from the first day after operation, and the nasogastric tube was kept in place for 5 d. All patients

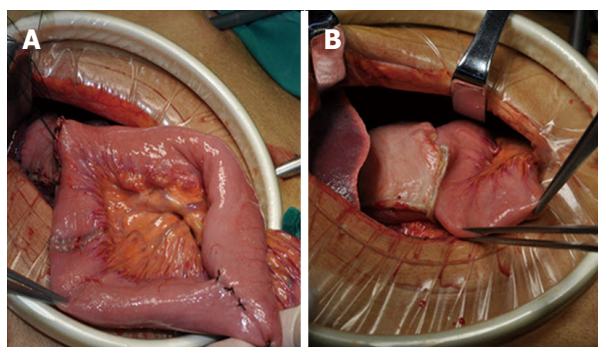


Figure 1 Two kinds of reconstruction after laparoscopy-assisted distal gastrectomy. A: Uncut Roux-en-Y reconstruction; B: Billroth II reconstruction. All included patients underwent LADG with D2 lymphadenectomy, which was performed by the same surgical team. Then, two groups underwent different reconstructions as shown.

Table 1 Clinical and pathological data of the patients			
Variable	Group U	Group B	P value
Age (yr)	58.0 ± 11.4	61.8 ± 11.4	0.030
Gender			0.287
Male	60 (75.9)	54 (68.4)	
Female	19 (24.1)	25 (31.6)	
Pathological tumor stage			0.822
I B	3 (3.8)	2 (2.5)	
II A	31 (39.2)	27 (34.2)	
III B	28 (35.4)	29 (36.7)	
III A	17 (21.5)	21 (26.6)	
Operative time (min)	154.8 ± 17.8	145.5 ± 15.1	0.001
Blood loss (mL)	74.1 ± 26.7	74.0 ± 36.6	0.980

Values are presented as number (%) or mean ± SD.

received uniform diet guidance after discharge.

Demographic data, clinical outcomes, and follow-up data were collected. Change of potential of hydrogen (pH) in the remnant stomach was recorded at 8:00 am on the day before surgery as well as 1-5 d after surgery.

Three months later, an upper esophagogastro-duodenal series was performed in each patient with 100 mL of meglumine diatrizoate. The full emptying rate at 30 min and the ratio of partial recanalization were collected.

Twelve months later, items were monitored as follows: (1) number of patients with heartburn symptoms; (2) changes in body weight within 1 year; and (3) gastric residue, residual gastritis, and biliary reflux (RGB; monitored by endoscopy). Combined with standard RGB^[8], a modified biliary reflux classification in three grades was applied-grade 0: absence of bile (Figure 2A); grade 1: small amount of bile located in the bottom of residual stomach without overflow (Figure 2B); and grade 2: bile spilled into the jejunum with tidal rhythm (Figure 2C).

Gastric tissue biopsies were taken to compare the degree of gastritis at 2 cm from anastomosis and then evaluated by two pathologists. Classification included three grades: grade 0, normal mucosa with

a small amount of lymphocytes and transparent microscopic field (Figure 3A); grade 1, intermediate between grades 0 and 2 (Figure 3B); and grade 2, acute inflammation with fully infiltrated tissue by lymphocytes or inflammatory cells (Figure 3C).

Statistical analysis

All statistical analyses were performed using SPSS v18.0 for Windows software. Continuous variables are expressed as mean and SD and compared by Student's *t*-test. Categorical variables were analyzed by Pearson χ^2 test. The pH variables were compared by repeated measures analysis of variance. A two-tailed *P* value < 0.05 was considered statistically significant.

RESULTS

According to the randomization table, each group included 79 patients. Baseline data are shown in Table 1. There were no significant difference in gender or pathological data (*P* > 0.05), but the average age of group U patients was older than group B patients (58.0 ± 11.4 vs 61.8 ± 11.4 years, *P* = 0.030). The surgical time was slightly longer in group U (154.8 ± 17.8 vs 145.5 ± 15.1 mins, *P* = 0.001), but there was no difference in blood loss (74.1 ± 26.7 vs 74.0 ± 36.6 mL, *P* > 0.05).

There was no significant difference in postoperative complications between the two groups (7.6% vs 10.1%, *P* = 0.576). One patient in each group underwent reoperation because of intra-abdominal bleeding. In group U, a patient with ileus required reoperation after 1 mo of conservative treatment. In group B, a patient received emergency endoscopy to insert a stomach tube into the afferent loop to release pressure due to A-loop syndrome. For both groups, no gastroparesis syndrome was found during the postoperative period (Table 2). According to the Clavien-Dindo classification for surgical complications^[9], in group U grade I complications were recorded in 3.8%, grade II in 1.3%, and grade III b in 2.5% of the cases. In group B grade I complications were recorded in 3.8%, grade II in 2.5%, grade III a in 1.3%, and grade III b in 2.5% of the cases. There was still no significant difference between the two groups (*P* = 0.954).

The stomach pH was lower in group U patients, with a significant statistical difference (*P* < 0.05) (Table 3).

During the postoperative period, all stomach pH values in group U patients were below 7.00. Conversely, all stomach pH values in group B patients were higher than 7.00 (Figure 4).

Three months later, regarding the postoperative esophagogastroduodenal series after 30 min, a higher ratio of full emptying was seen in group B patients (88.2% vs 76.6%, *P* = 0.061), but with no statistical significance.

At the end of the 1-year follow-up period, three patients in group U and one patient in group B were

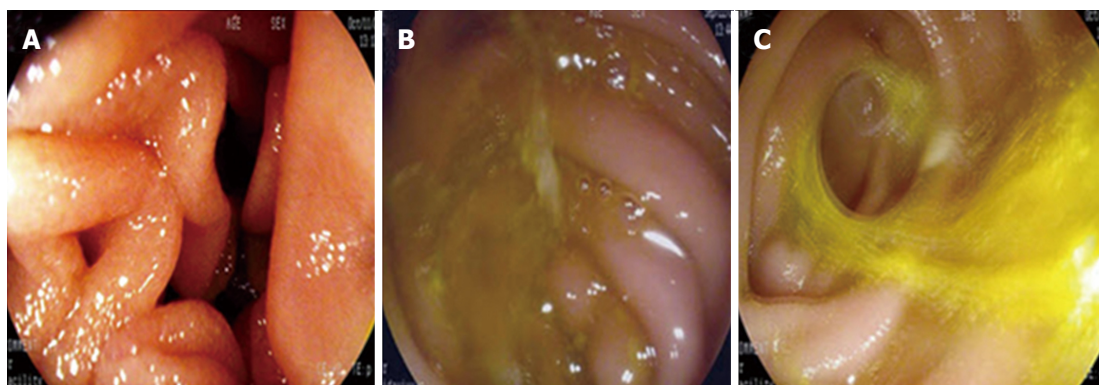


Figure 2 Bile reflux grades. During the endoscopic examination, a modified biliary reflux classification in three grades was applied. A: grade 0, absence of bile (Figure 2A); B: grade 1, small amount of bile located in the bottom of residual stomach without overflow (Figure 2B); C: grade 2, bile spilled into the jejunum with tidal rhythm (Figure 2C).

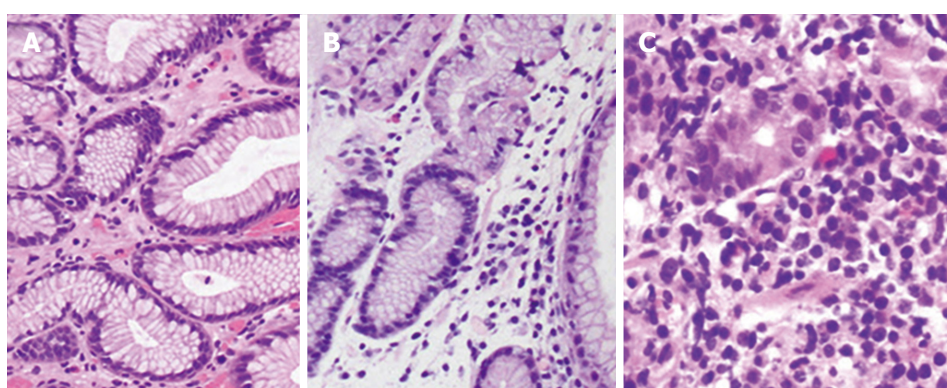


Figure 3 Biopsy for gastritis. Gastric tissue biopsies were taken to compare the degree of gastritis: A: grade 0 [hematoxylin and eosin (HE) staining, × 200], normal mucosa with small amount of lymphocytes and transparent microscopic field; B: grade 1 (HE, × 200), intermediate between grades 0 and 2 with a moderate amount of lymphocytes or other kinds of inflammatory cells; C: grade 2 (HE, × 400), acute inflammation with fully infiltrated tissue by lymphocytes or other kinds of inflammatory cells.

Table 2 Postoperative complications in the two groups *n* (%)

Item	Group U	Group B	<i>P</i> value
Duodenal stump leakage	1 (1.3)	3 (3.8)	0.620
Chylous fistula	1 (1.3)	0	1.000
Ileus	1 (1.3)	1 (1.3)	1.000
Anastomotic bleeding	0	1 (1.3)	1.000
Intra-abdominal bleeding	2 (2.5)	2 (2.5)	1.000
Incision infection	1 (1.3)	0	1.000
Gastroparesis syndrome	0	0	-
A-loop syndrome	0	1 (1.3)	1.000
Total	6 (7.6)	8 (10.1)	0.576

Values are presented as number only, or number (%). A-loop syndrome: Afferent loop syndrome.

lost to follow-up. Besides, seven patients in group U and six patients in group B had died. Therefore, the survival rates at 1 year for group U and B patients were 90.79% and 92.31%, respectively, and showed no significant difference ($P = 0.735$). The biliary reflux incidence in group B was higher than that in group U patients with a significant difference (60.9% vs 90.3%, $P = 0.000$). The ratio of gastritis in group B (72.2%) was significantly higher than that in group

Table 3 Perioperative stomach pH values

Time	Group U	Group B	<i>P</i> value
Preoperative	1.97 ± 0.19	1.99 ± 0.21	
Day 1	6.38 ± 0.18	7.21 ± 0.36	
Day 2	6.28 ± 0.29	7.35 ± 0.32	
Day 3	6.48 ± 0.38	7.27 ± 0.38	
Day 4	6.64 ± 0.22	7.27 ± 0.35	
Day 5	6.56 ± 0.29	7.24 ± 0.42	0.000

Values are presented as mean ± SD. Change of potential of hydrogen (pH) in the remnant stomach was recorded at 8:00 am on the day before surgery as well as 1-5 d after surgery.

U (55.1%). However, the result of biopsy showed no significant difference (63.8% vs 70.8%, $P = 0.278$), but the linear-by-linear association was significant ($P_{\text{trend}} = 0.015$). Besides, there was no significant difference for the incidence of diarrhea, residual food, or gain of weight between the two groups (Table 4).

DISCUSSION

In 1988, uncut Roux-en-Y reconstruction was first

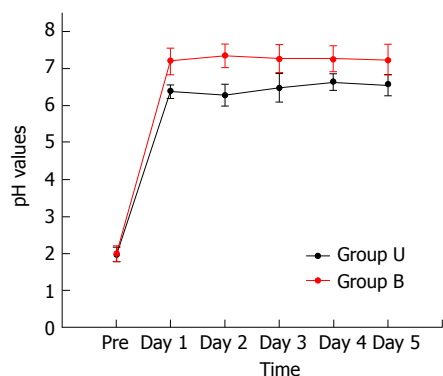


Figure 4 Perioperative potential of hydrogen (pH) in the stomach of the patients. Change of potential of hydrogen (pH) in the remnant stomach was recorded at 8:00 am on the day before surgery as well as 1-5 d after surgery. During the postoperative period, all stomach pH values of group U patients were below 7.00. Conversely, all stomach pH values of group B patients were higher than 7.00.

Table 4 The follow-up data			
Item	Group U	Group B	P value
3 mo later	n = 77	n = 76	
Esophagogastroduodenal series			
Full emptying at 30 min	59 (76.6)	67 (88.2)	0.061
Partial recanalization	0	-	-
1 yr later	n = 69	n = 72	
Heartburn	7 (10.1)	17 (23.6)	0.033
Weight gain (kg)	-0.04 ± 3.6	-0.18 ± 3.8	0.723
Endoscopic finding			
Residual food	8 (11.6)	3 (4.2)	0.178
Grade 0	61	69	
Grade 1	7	3	
Grade 2	1	0	
Grade 3-4	0	0	
Gastritis	38 (55.1)	52 (72.2)	0.044
Grade 0	31	20	
Grade 1	30	35	
Grade 2	8	17	
Grade 3-4	0	0	
Bile reflux	42 (60.9)	65 (90.3)	0.000
Grade 0	27	7	
Grade 1	34	23	
Grade 2	8	42	
Partial recanalization	9 (13.0)	-	-
Biopsy of gastritis	44 (63.8)	51 (70.8)	0.278
Grade 0	25	21	
Grade 1	39	45	
Grade 2	5	6	

Values are presented as number only, or number (%).

reported by Stiegman and Goff¹⁰. Some studies over the years have confirmed that this reconstruction can preserve myoneural continuity to eliminate Roux stasis syndrome¹¹⁻¹³. Because uncut Roux-en-Y is a modification of Billroth II reconstruction, it makes sense to compare Billroth II and uncut Roux-en-Y to determine the better procedure after LADG.

Our study showed there was no significant difference for the incidence of postoperative complications between the two groups (7.6% vs 10.1%, *P* > 0.05). Moreover, for the severity of postoperative complications,

according to the Clavien-Dindo classification of surgical complications, there was no significant difference (*P* = 0.954). A-loop syndrome does not occurred in the uncut Roux-en-Y group, and the incidence of duodenal stump leakage was lower than that of the Billroth II group. The reason for this may be that the Braun anastomosis effectively relieves the pressure of the afferent loop¹⁴, but more cases should be included to confirm this difference.

For biliary reflux, during the postoperative period, all group U pH values were lower than 7.00, thus representing an acidic stomach environment. In group B patients, all pH values were higher than 7.00, representing an alkaline stomach environment with alkaline reflux, which can be considered an important risk factor for gastric stump cancer¹⁵ (Figure 2). In addition, according to patient outcomes at the 1-year follow-up, the bile reflux incidence in group B patients was significantly higher than that in group U (*P* = 0.000). However, the incidence of bile reflux in group U patients was 60.9%, which is higher than the equivalent statistic in Park and Kim's report (less than 30%)⁴. There are two main reasons that can explain these data. On one hand, the incidence of partial recanalization reached 13.0%. In this study, for partial recanalization, all those cases were first observed by endoscopy, and the result would be confirmed by esophagogastroduodenal series if there was doubt. Recanalization eventually allowed bile access to the gastric remnant. On the other hand, for some other cases, the bile reflux happened through the efferent loop, and a small amount of bile was usually found in the bottom of residual stomach with no overflow (grade 1).

Regarding gastritis, the incidence in group B patients (72.2%) was significantly higher than that in group U patients (55.1%), with a higher incidence of heartburn in group B patients as well (23.6%). These results allow us to conclude that uncut Roux-en-Y can reduce the occurrence of residual gastritis and heartburn proportion in Billroth II reconstruction. However, the biopsy results showed no significant difference between the two groups (*P* = 0.278).

We draw two conclusions from these results. First, the pattern of bile reflux is different. The majority of group U patients were classified into grade 1 (49.3%), characterized by a small bile amount usually located in the bottom of the stomach as gastric residue, whereas most group B patients belonged to grade 2 (58.3%), characterized by considerable tidal rhythm. Hence, the stomach bile was fresh and temporary, which may be less corrosive to the gastric mucous membranes. Park showed a correlation between bile reflux and the degree of gastritis⁴, but perhaps it depends not only on the amount but also on the pattern of biliary reflux. Second, the follow-up time was too short to show differences in the percentage of residual gastritis on biopsy, so the linear-by-linear association *P* value was also calculated. The result showed a significant

difference ($P_{\text{trend}} = 0.015$), meaning that the severity of residual gastritis for group B was worse than that for group U on biopsy.

For residual food, there was no significant difference between the two groups (11.6% vs 4.2%, $P > 0.05$). For gastrointestinal anastomosis of both procedures, the stoma was extensive along the greater curvature. No gastroparesis syndrome was found during follow-up, which is perhaps related to myoneural continuity. At 3-mo follow-up, the incidence of full emptying at 30 min reached 76.6% and 88.2% in group U and B patients, respectively (Table 4). As a result, no retention of afferent loop stump was found during the follow-up, and the incidence of residual food was lower than that in other studies^[4,16].

This study adopted body weight change to evaluate postoperative nutritional status of patients, and 1 year later, the weight change values of group U and group B patients were -0.04 ± 3.6 kg and -0.18 ± 3.8 kg, respectively, with no significant difference. Moreover, there was no significant difference in survival rates of group U and group B patients after 1 year (90.79% vs 92.31%, respectively; $P > 0.05$).

In conclusion, the uncut Roux-en-Y digestive reconstruction procedure is secure and feasible. Moreover, it can effectively reduce the incidence of alkaline reflux, residual gastritis, and heartburn seen in classical Billroth II procedure. Besides, the uncut technique still needs improvement so that the risk of staple line dehiscence is minimized, with a longer follow-up period to reevaluate the exact risk. Despite the incidence of recanalization^[17-21], uncut Roux-en-Y should be widely applied.

COMMENTS

Background

In 1988, uncut Roux-en-Y reconstruction was first reported by Stiegman and Goff. Some studies over the years have confirmed that this reconstruction can preserve myoneural continuity to eliminate Roux stasis syndrome. However, because of the challenge of recanalization, the uncut Roux-en-Y is still controversial and really needs further study. Since uncut Roux-en-Y is a modification of Billroth II reconstruction, it makes sense to compare Billroth II and uncut Roux-en-Y to determine the better procedure after laparoscopy-assisted distal gastrectomy (LADG).

Research frontiers

Compared with Japan and Korea, early gastric cancer only accounts for a small percentage in China, and most gastric cancer cases are found in advanced stages at the initial diagnosis. It is inappropriate for surgeons to perform Billroth I anastomosis after subtotal gastrectomy. In 2005, Uyama first combined LADG with uncut Roux-en-Y reconstruction, and since then it has been the hotspot for many years. However, its use remains controversial. Some surgeons believe that it is better than Billroth II and Roux-en-Y reconstructions, while others do not.

Innovations and breakthroughs

This study is the first randomized controlled trial concentrating on uncut Roux-en-Y vs Billroth II reconstruction after distal gastrectomy for gastric cancer. It aimed to compare uncut Roux-en-Y and Billroth II reconstruction in terms of postoperative complications, including biliary reflux and gastritis. Despite the incidence of recanalization, uncut Roux-en-Y reconstruction is secure and

feasible, and can effectively reduce the incidence of alkaline reflux, residual gastritis, and heartburn.

Applications

There remains no clear consensus regarding the preferred reconstructive surgical procedure after LADG for gastric cancer. In this study, uncut Roux-en-Y reconstruction is secure and feasible, and can effectively reduce the incidence of alkaline reflux, residual gastritis, and heartburn. Therefore, uncut Roux-en-Y should be widely applied in the future. Besides, the uncut technique still needs improvement so that the risk of staple line dehiscence is minimized, with a longer follow-up period to reevaluate the exact risk.

Peer-review

Interesting comparison of two techniques of postgastrectomy reconstruction.

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