

Research

Application of accommodated jejunal interposition double tract reconstruction after total gastrectomy for gastric cancer: a retrospective study

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Abstract

Background The aim of this study was to compare the effects of accommodated jejunal interposition double tract reconstruction (aji-DTR) and Roux-en-Y reconstruction after laparoscopic-assisted total gastrectomy on intraoperative and postoperative indicators in advanced gastric cancer (AGC) patients.

Methods A retrospective analysis was performed on 80 AGC patients, including 43 with aji-ATR and 37 with Roux-en-Y reconstruction. Propensity score matching was performed between the two groups.

The primary outcome measures included operative time, intraoperative blood loss, postoperative complications, postoperative hospital stay, total hospitalization costs, and survival rate. The secondary outcome measures were postoperative nutritional status, recovery of digestive function, and postoperative gastrointestinal symptoms.

Results There were 24 pairs of patients after matching. There were no significant differences in the operative time, intraoperative blood loss, time of first flatus, time of first defecation, time of liquid diet, time of semi-liquid diet, postoperative complications, postoperative hospital stays, and total hospitalization costs (all $P > 0.05$). Interestingly, Roux stasis syndrome was significantly more frequent in Roux-en-Y group than aji-DTR group [6 (25.0%) vs 1 (4.2%), $P = 0.045$]. While no significant difference was observed in survival rates, reflux esophagitis, dumping syndrome and nutritional parameter including hemoglobin, albumin, and prognostic nutritional index (all $P > 0.05$).

Conclusions Compared with Roux-en-Y reconstruction, aji-DTR had similar surgical parameters, postoperative digestive function recovery, nutritional parameters, and survival rate, but showed an advantage in reducing Roux stasis syndrome. Therefore, aji-DTR after laparoscopic assisted total gastrectomy may be a safe and feasible alternative for AGC patients.

Keywords Gastric cancer · Gastrectomy · Prognosis

1 Introduction

Gastric cancer (GC) is a common malignant tumor of the digestive tract, ranking fifth in incidence and fourth in mortality among all cancers worldwide in 2020 [1]. In Japan and South Korea, GC is the most common cancer in men, while in China it is the leading cause of cancer-related mortality [2]. For early gastric cancer, the main treatment is endoscopic resection, with a 5-year survival rate of more than 90% [3]. Nonetheless, due to the absence of typical clinical manifestations, the majority of patients present at an advanced stage when they first seek hospital treatment. Despite a 5-year survival rate

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below 30%, comprehensive treatment, which involves surgical resection as its primary approach, is currently the mainstay of treatment for advanced gastric cancer (AGC) [3].

The complete surgical strategy for AGC includes radical tumor resection, D2 lymphadenectomy (including lymph node stations in the perigastric mesentery and along the celiac arterial branches), and gastrointestinal reconstruction. There is consensus on tumor resection and D2 lymphadenectomy, but the choice of gastrointestinal reconstruction is still controversial. Globally, Roux-en-Y reconstruction is the most common reconstruction procedure after total gastrectomy due to its simplicity, satisfactory nutritional results and ability to prevent bile and pancreatic reflux [4]. Nonetheless, due to the transection of the jejunum, the integrity of the function of the intestinal nerves is compromised, leading to gastric emptying disorders, including gastric paresis and digestive arrest, known as Roux-en-Y stasis syndrome [5]. In addition, Roux-en-Y reconstruction may affect the postoperative patient's digestion and absorption of food because the duodenum is left open, leading to asynchronous secretion of pancreatic enzymes [5].

Without any division of the jejunum, double tract reconstruction (DTR) after proximal gastrectomy can restore the stimulatory effect of food on the duodenal mucosa, promote the secretion of gastrointestinal hormones, and effectively reduce the incidence of Roux-en-Y stasis syndrome [6]. Previous studies have shown that the accommodated jejunal interposition DTR (aji-DTR) can be used as a method for the reconstruction of the gastrointestinal tract after laparoscopic-assisted total gastrectomy [7]. However, there are relatively few relevant reports on aji-DTR, and the effect of aji-DTR on postoperative nutritional indicators in patients with AGC is still unclear.

Based on the above findings, we performed a retrospective review of a prospectively collected database to compare the effects of aji-DTR and Roux-en-Y reconstruction on intraoperative and postoperative indicators, with the aim of investigating the safety and efficacy of aji-DTR for laparoscopic-assisted total gastrectomy. We expected that our findings would provide a reference for the selection of digestive tract reconstruction after laparoscopic-assisted total gastrectomy.

2 Methods

2.1 Study design and population

A prospective electronic database identified 87 patients with AGC who underwent total gastrectomy at a single center between January 2020 and May 2024. All surgeries were performed by the same team of experienced surgeons, who were in charge of the gastrointestinal reconstruction technique. Written informed consent was obtained from all subjects, and the study was approved by the Ethics Committee of Hui'an County Hospital.

The inclusion criteria were as follows: (1) Patients with preoperative pathological diagnosis of gastric cancer and undergoing total gastrectomy; (2) Age 18–85 years; (3) No preoperative radiotherapy or chemotherapy; (4) Patient willing to participate in this study. The exclusion criteria were as follows: (1) History of abdominal surgery, including history of gastrointestinal surgery; (2) Combined with other cancers; (3) Non-radical resection or combined resection; (4) Incomplete clinical data.

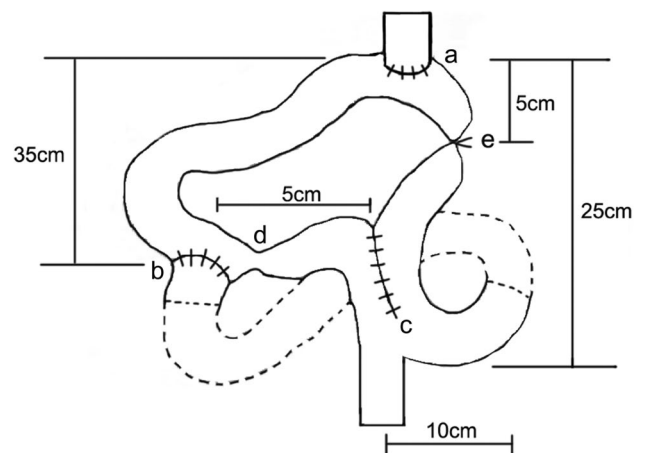
2.2 Surgical methods

All patients in the enrolled group underwent D2 radical laparoscopic-assisted total gastrectomy in strict accordance with the Japanese gastric cancer guideline [8].

The surgical procedure for aji-DTR was based on the previous study [7, 9–11]. After laparoscopic-assisted total gastrectomy, the jejunum located 25 cm distal to the Treitz ligament was lifted anteriorly from the colon to create an end-to-side anastomosis with the esophagus, and then the jejunum located 35 cm distal to this anastomosis was end-to-side anastomosed to the duodenum. A Braun anastomosis was performed between the jejunum 10 cm distal to the Treitz ligament and 5 cm distal to the duodenal anastomosis. The bowel between the Braun and duodenal anastomoses is incised longitudinally, then the linear cutter stapler is placed from the incision to complete the anastomosis, and the incision is sutured to maintain a natural bowel stenosis. Finally, the afferent limb, located 5 cm between the esophageal anastomosis and the Braun anastomosis, will be moderately ligated with silk thread to prevent food transit without inducing regional jejunal tissue necrosis (Fig. 1).

For the Roux-en-Y reconstruction, after the standard laparoscopic-assisted total gastrectomy, the procedure was performed by cutting the jejunum located 15–20 cm distal to the Treitz ligament. The distal jejunum was lifted anteriorly

Fig. 1 Schematic models of accommodated jejunal interposition double tract reconstruction after total gastrectomy



from the colon to create an end-to-side anastomosis with the esophagus, while the distal jejunum at a distance of 40 cm from the anastomosis was end-to-side anastomosed to the proximal jejunum. Finally, manual reinforcement of the duodenal stump was conducted using a 3–0, 15-cm barbed suture, as previously reported [12].

2.3 Data collection

All patients were followed up routinely at 3, 6, 9, 12, 18, 24, and 36 months after surgery. Clinical pathological data included gender, age, body mass index (BMI), preoperative nutrition risk screening (NRS) 2002 score [13], American Society of Anesthesiologists physical status classification system (ASA), and tumor Tumor-Node-Metastasis (TNM) classification [14] were collected for propensity score matching (PSM). The primary outcome measure was the safety of surgery, including operative time, intraoperative blood loss, postoperative complications, postoperative hospital stay, total hospitalization costs, and survival rate. The diagnosis of postoperative complications was conducted in accordance with the criteria established by the Japan Clinical Oncology Group [15]. The secondary outcome measure was the efficacy of surgery, including postoperative nutritional status, recovery of gastrointestinal function, and postoperative gastrointestinal symptoms. Body weight, blood hemoglobin (HB) and albumin (ALB) levels, and prognostic nutritional index (PNI, the score of $PNI = 10 \times \text{serum albumin (g/100 ml)} + 0.005 \times \text{total lymphocytes count/mm}^3$ in peripheral blood) [16] were used to evaluate postoperative nutritional status; time of first flatus, defecation, liquid and semi-liquid diet were used to assess the recovery of digestive function; the incidence of reflux esophagitis, dumping syndrome, and Roux stasis syndrome was used to evaluate postoperative gastrointestinal symptoms. The diagnostic criteria for Roux stasis syndrome are as follows: (1) the presence of nausea, vomiting, and abdominal pain postoperatively; (2) the need for fasting following the recurrence of symptoms upon resuming a semifluid or normal diet; and (3) hospital readmission due to these symptoms after surgery. Patients were excluded if they had intestinal obstruction, anastomotic stenosis, or tumor recurrence [17].

2.4 Statistical analysis

According to a previous study involving 704 patients who underwent total gastrectomy, the incidence rates of postoperative complications of reconstruction, including reflux esophagitis, dumping syndrome, and Roux stasis syndrome, ranged from 6.0 to 48.3% [18]. In this study, an incidence rate of 40% was assumed for patients in the Roux-en-Y group and 6% for those in the aji-DTR group, with $\alpha = 0.05$ and $\beta = 0.2$, ultimately requiring at least 21 participants in each group. The continuous variables were presented as mean \pm standard deviation and analyzed using Student's t-test for normally distributed continuous variables and Wilcoxon-Mann-Whitney test for non-normally distributed continuous variables. The categorical variables were presented as the frequency (%) and analyzed using the χ^2 test or Fisher's exact test. PSM was used to accomplish the removal of confounding bias from observational cohorts. Kaplan-Meier curves was used to estimate survival rates, the incidence of reflux esophagitis, dumping syndrome, and Roux stasis syndrome. In these analyses, all statistical tests were 2-sided, and $P < 0.05$ was considered to be statistically significant. The analyses were performed using SPSS version 22.0 (Inc., Armonk, NY, USA).

3 Results

3.1 Study population and baseline characteristics

During the study period, a total of 87 patients underwent laparoscopic-assisted total gastrectomy at our institution, of which 80 were included in this study and 7 were excluded (Fig. 2). The reasons for exclusion were as follows: 3 cases with non-radical resection; 2 cases combined with other cancers; 1 case with history of gastrointestinal surgery; and 1 case with incomplete clinical data.

The clinical and demographic characteristics of the included patients were shown in Table 1. Before PSM, patients who received aji-DTR had a higher proportion of males (74.4% vs. 25.6%, $P = 0.034$) and a higher proportion of ASA grade ≥ 3 (81.4% vs. 59.5%, $P = 0.047$) compared to those who received Roux-en-Y reconstruction. After PSM, we derived paired cohorts for Roux-en-Y versus aji-DTR (24 and 24 patients, respectively). These cohorts were well matched for sex, age, BMI, NRS 2002 score, ASA grade, and TNM stage and were all comparable (all $P > 0.05$).

3.2 Intraoperative and postoperative indicators

As shown in Table 2, there were no significant differences in the operative time, intraoperative blood loss, time of first flatus, time of first defecation, time of liquid diet, time of semi-liquid diet, postoperative hospital stays, and total hospitalization costs (all $P > 0.05$).

3.3 Postoperative complications

As shown in Table 3, there were 7 cases (29.2%) of Roux-en-Y complications including 3 cases of pneumonia (12.5%), 1 case of abdominal infection (4.2%), 1 case of anastomotic fistula (4.2%), 1 case of abdominal bleeding (4.2%), and 4 cases (16.7%) of aji-DTR complications including 2 cases of pneumonia (8.3%), 1 case of abdominal infection (4.2%), 1 case of anastomotic fistula (4.2%), with no statistically significant difference ($P = 0.494$).

3.4 Survival analyses

The median (interquartile range) follow-up time was 17.50 (14.0, 29.75) months for patients with Roux-en-Y group and 19.0 (11.25, 28.75) months for patients with aji-DTR. As shown in Fig. 3, there was no significant difference in survival rates between the two groups ($P = 0.77$).

Fig. 2 The flow diagram of patients enrolled in this study

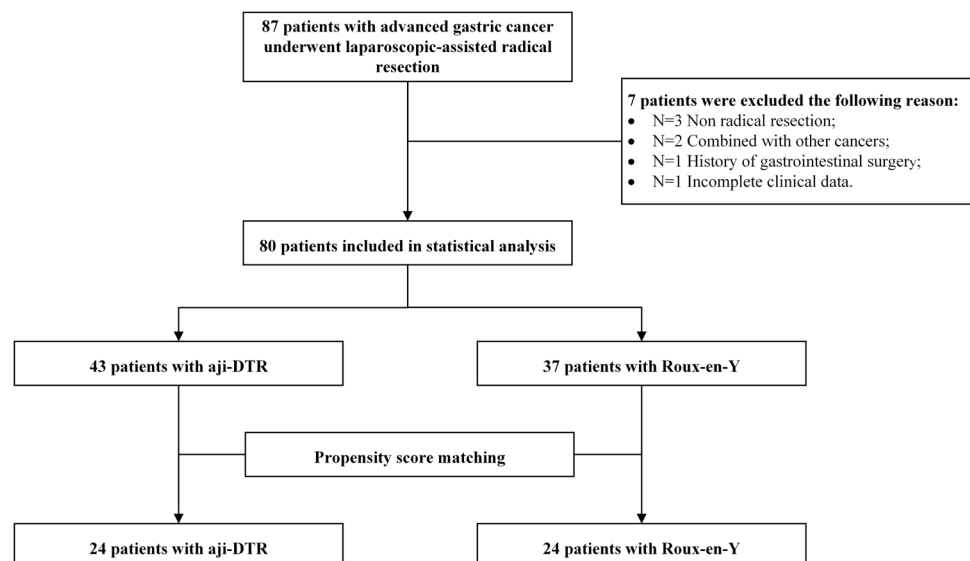


Table 1 Patient clinical and demographic characteristics (before and after PSM, n = 80)

Variables	Before PSM			After PSM		
	Roux-en-Y	aji-DTR	<i>P</i>	Roux-en-Y	aji-DTR	<i>P</i>
Number of patients	37	43		24	24	
Gender (%)			0.038			1.000
Male	19 (51.4%)	32 (74.4%)		16 (66.7%)	15 (62.5%)	
Female	18 (48.6%)	11 (25.6%)		8 (33.3%)	9 (37.5%)	
Mean age (years)	70.05 ± 10.81	71.23 ± 9.68	0.608	69.25 ± 11.09	69.42 ± 6.73	0.950
BMI (kg/m ²)	22.20 ± 5.62	21.00 ± 4.17	0.277	22.22 ± 6.40	21.86 ± 4.51	0.821
NRS 2002 score			0.248			0.359
< 3	15 (40.5%)	12 (27.9%)		10 (41.7%)	6 (25.0%)	
≥ 3	22 (59.5%)	31 (72.1%)		14 (58.3%)	18 (75.0%)	
ASA grade (%)			0.047			1.000
< 3	15 (40.5%)	8 (18.6%)		7 (29.2%)	8 (33.3%)	
≥ 3	22 (59.5%)	35 (81.4%)		17 (70.8%)	16 (66.7%)	
TNM stage, n (%)			0.622			0.760
< III	12 (32.4%)	11 (25.6%)		9 (37.5%)	7 (29.2%)	
III	25 (67.6%)	32 (74.4%)		15 (62.5%)	17 (70.8%)	

PSM, propensity score matching; aji-DTR, accommodated jejunal interposition double tract reconstruction; BMI, body mass index; NRS, nutrition risk screening; ASA, American Society of Anesthesiologists; TNM, Tumor-Node-Metastasis

Table 2 Intraoperative and postoperative indicators after PSM

Variables	Roux-en-Y (n = 24)	aji-DTR (n = 24)	<i>P</i>
Operative time (min)	296.25 ± 63.23	321.67 ± 62.53	0.168
Intraoperative blood loss (ml)	175.00 ± 93.25	197.92 ± 110.81	0.442
Time of first flatus (days)	3.25 ± 0.85	2.79 ± 0.78	0.057
Time of first defecation (days)	5.46 ± 0.66	5.08 ± 0.83	0.089
Time of liquid (days)	4.71 ± 1.12	4.58 ± 1.14	0.703
Time of semi-liquid (days)	8.38 ± 1.14	8.71 ± 1.08	0.363
Postoperative hospital stay (days)	15.79 ± 5.23	13.96 ± 3.25	0.152
Total hospitalization costs (¥)	54,265.96 ± 11,889.03	51,340.33 ± 11,811.59	0.397

PSM, propensity score matching; aji-DTR, accommodated jejunal interposition double tract reconstruction

Table 3 Postoperative complications between two groups

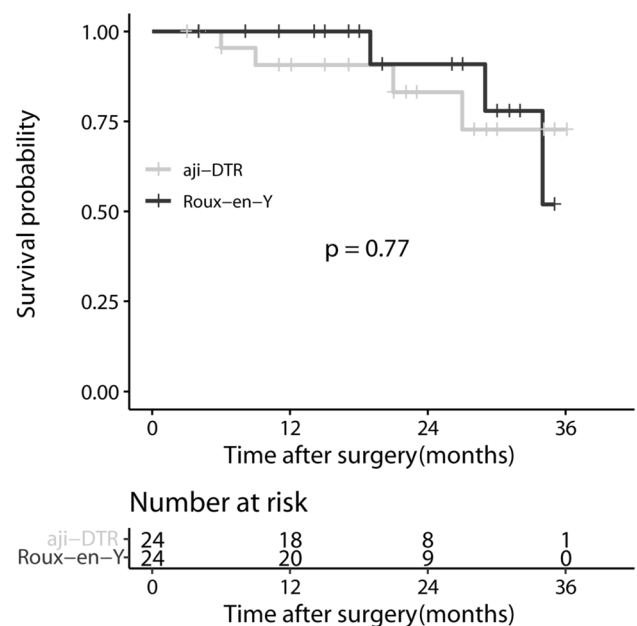
Complications	Roux-en-Y (n = 24)	aji-DTR (n = 24)	<i>P</i>
Total complications	7 (29.2%)	4 (16.7%)	0.494
Pneumonia	3 (12.5%)	2 (12.5%)	
Abdominal infection	1 (4.2%)	1 (4.2%)	
Anastomotic fistula	1 (4.2%)	1 (4.2%)	
Abdominal bleeding	1 (4.2%)	0	

aji-DTR, accommodated jejunal interposition double tract reconstruction

3.5 Postoperative gastrointestinal symptoms

During the follow-up period, 4 cases of reflux esophagitis (16.7%) and 6 cases of dumping syndrome (25.0%) in Roux-en-Y group, while 2 cases of reflux esophagitis (8.3%) and 3 cases of dumping syndrome (12.5%) in aji-DTR group (Fig. 4a, b), and there was no significant difference in two symptoms between the two groups (both $P > 0.05$).

Fig. 3 Kaplan–Meier survival curves for patients underwent accommodated jejunal interposition double tract reconstruction (aji-DTR) and Roux-en-Y reconstruction



Interestingly, Roux stasis syndrome was significantly more in Roux-en-Y group than aji-DTR group [6 (25.0%) vs 1 (4.2%), $P = 0.045$] (Fig. 4c).

3.6 Postoperative nutritional status

Since the 75 th percentiles of follow-up were 29.75 months in the Roux-en-Y group and 28.75 months in the DTR group, the nutritional indicators of the two groups were statistically analyzed only at postoperative 3, 6, 9, 12, 18, and 24 months. Not surprisingly, all of the nutritional parameters decreased dramatically immediately after total gastrectomy (Fig. 5). There was no statistically significant difference in BMI of the two groups, which decreased to its lowest point at 9 months after surgery and then gradually increased (Fig. 5a). Although HB, ALB and PNI of these two groups decreased to its lowest point at 3 months after surgery and then gradually increased, and no significant difference was found at each follow-up month, these three indexes were maintained approximately at the preoperative levels in the Roux-en-Y group and showed a slight downward trend in the aji-DTR group (Fig. 5b–d).

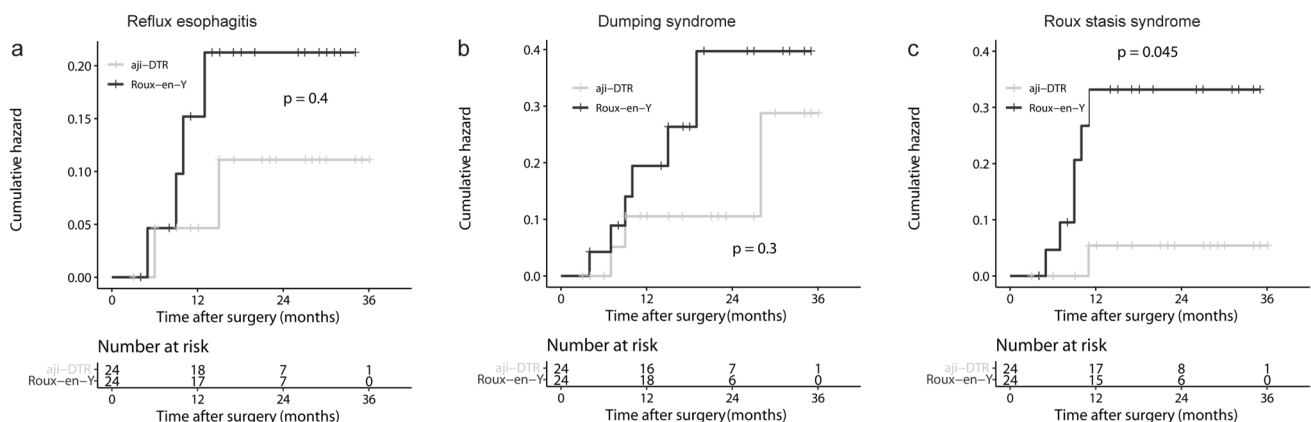


Fig. 4 Kaplan–Meier curves for postoperative gastrointestinal-symptoms (**a** reflux esophagitis; **b** dumping syndrome; **c** Roux stasis syndrome)

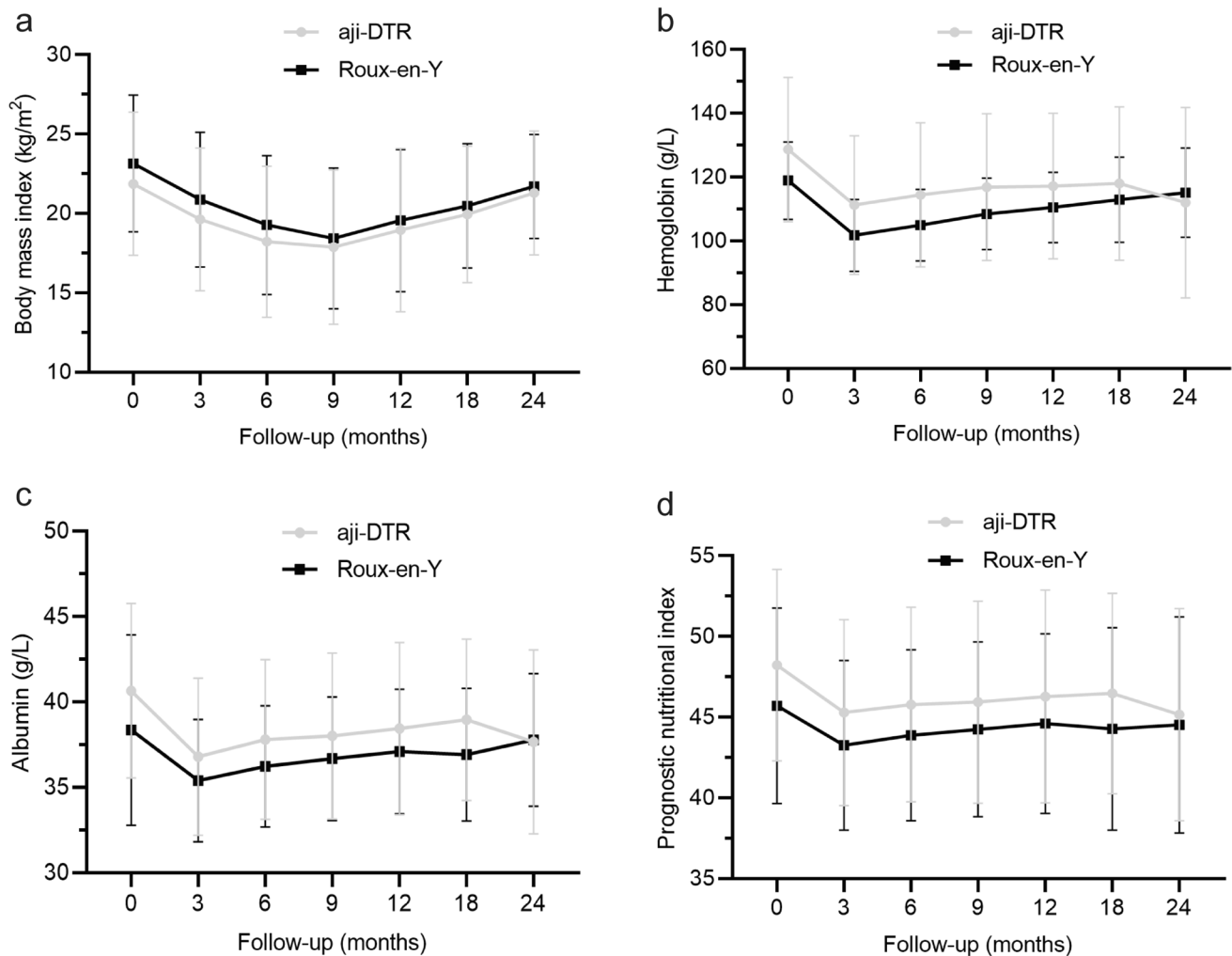


Fig. 5 Changes of nutritional status (**a**, body mass index; **b** hemoglobin; **c** albumin; **d** prognostic nutritional index)

4 Discussion

Although many reconstruction methods had been developed after total gastrectomy for AGC, none of them was universally applicable. Roux-en-Y reconstruction was the most common form because it was considered simple and safe [4], but it was associated with more dumping syndrome and Roux stasis syndrome [5]. Since aji-DTR was a proven method for gastrointestinal reconstruction after total gastrectomy [7], we conducted this study and found that aji-DTR had less Roux stasis syndrome compared to Roux-en-Y reconstruction. Nonetheless, there are relatively few reports comparing Roux-en-Y reconstruction and aji-DTR after total gastrectomy.

There were relatively few reports on aji-DTR, and the surgical steps for DTR after proximal gastrectomy and functional jejunal interposition (FJI) reconstruction after gastrectomy differed from aji-DTR. After removal of the cardia and preservation of the pylorus, DTR consisted of three anastomoses: an esophagojejunostomy, a gastrojejunostomy, and a jejunostomy-jejunostomy [19]. Compared with total gastrectomy, proximal gastrectomy with DTR was safe and showed shorter operative time, less blood loss and lower incidence of postoperative reflux [19–21]. Different from aji-DTR, for functional jejunal interposition, a moderate ligation with thread was performed at the input segment 2–3 cm away from the esophageal-jejunal anastomosis and at the output segment 2–3 cm away from the jejunal-duodenal anastomosis [22]. While for aji-DTR, there was only one moderate ligation with thread on the input segment 5 cm away from the esophageal-jejunal anastomosis. A prospective randomized clinical trial had found that the intake in a single meal, PNI, weight loss and the Gastrointestinal Symptom Rating Scale core at 12 months after surgery, FJI had a worse performance

than Roux-en-Y anastomosis [22]. Nevertheless, due to the complexity of three anastomoses, we consider this technique as an option in gastric cancer centers with technically proficient surgical teams, while in centers with limited experience, it can be explored experimentally under controlled conditions and with appropriate supervision.

In terms of operative time, Aji DTR surgery, which involves three anastomoses, is generally considered to take longer than Roux-en-Y surgery, which involves two anastomoses. In our study, although the operative time for Aji-DTR was longer than for Roux-en-Y (321.67 ± 62.53 min vs 296.25 ± 63.23 min), the difference was not statistically significant, which is consistent with a previous study reporting a mean operative time of nearly 300 min. Two studies reported significantly longer operative times for Aji DTR, with an average operative time of 150 min for one and 200 min for the other. Additionally, several studies did not report surgical times, which may indicate the presence of study design flaws or publication bias. The variability in reported surgical times across studies highlights the complexity of this issue and underscores the need for more comprehensive data to draw definitive conclusions. Therefore, a meta-analysis or a prospective, multicenter, large-sample trial is needed to further explore this metric.

Specifically, there was no statistically significant difference in the intraoperative blood loss, time of first flatus, time of first defecation, time of liquid diet, time of semi-liquid diet, and postoperative complications. It can be assumed that the safety of the two procedures is equivalent and the postoperative recovery of the patients is similar. There was no statistically significant difference in the incidence of anastomotic leakage between the two groups, which may be related to our choice to use 3-0 type absorbable suture to reinforce the anastomotic site with intermittent suturing of the muscular layer after gastrointestinal reconstruction. Outcomes from two experienced centers revealed that for patients underwent total gastrectomy, extracorporeal esophagojejunostomy had higher incidence of wound infection and pneumonia than intracorporeal esophagojejunostomy [23]. In addition, the linear stapler was inferior to the circular stapler in reflux and diarrhea at 1 year [23]. These may be our future research directions.

Not surprisingly, survival was not significantly different between the two groups. There had been many long-term prognostic studies comparing total gastrectomy and proximal gastrectomy. A review that included 8 studies with a total of 753 patients found that there was no statistically significant difference in 5-year survival in proximal gastrectomy with DTR compared with total gastrectomy [24]. A similar finding was reported in a study comparing long-term outcomes of patients who underwent proximal gastrectomy with jejunal interposition to those who underwent total gastrectomy (94% vs 84%, $P > 0.05$) [25]. The reason why there was no statistically significant difference in survival rates between aji-DTR and Roux-en-Y reconstruction in our study was that both groups underwent the same D2 radical laparoscopic-assisted total gastrectomy in strict accordance with the Japanese gastric cancer guideline.

Compared to Roux-en-Y reconstruction, aji-DTR had several theoretical advantages. First, it maintained the physiological duodenal pathway and preserved the continuity of the enteric neuromuscular system [26, 27]. Second, food mainly passed through the duodenal pathway, promoting the secretion of bile and pancreatic juice, which was beneficial for maintaining the alkaline environment of the intestine, inhibiting the excessive growth of intestinal bacteria, and was of great significance for the growth and repair of intestinal mucosa. Then, the fluid and alkaline reflux fluid could reduce the tension of the duodenal anastomosis by narrowing the channel, thereby reducing the occurrence of reflux esophagitis and Roux stasis syndrome [7]. Although postoperative recovery of gastrointestinal function, reflux esophagitis and dumping syndrome were similar between two groups, Roux stasis syndrome was significantly more in Roux-en-Y group than aji-DTR group. We believed that by increasing the population included and extending the follow-up time, we may be able to obtain different results.

Both groups of patients showed some decrease in BMI, HB, ALB and PNI after surgery, which is related to the loss of gastric storage and initial digestive capacity for food in patients undergoing total gastrectomy, resulting in further impaired digestion and absorption of food in the intestine. These nutritional parameters did not improve as we expected, suggesting that aji-DTR does not have advantages over Roux-en-Y anastomosis regarding postoperative nutritional recovery. Kim and colleagues indicated that although malabsorption and malnutrition are prevalent among patients who have undergone gastrectomy, most nutritional indicators tend to remain stable or experience a slight decline over the long term [28]. Therefore, they recommend the implementation of more comprehensive monitoring approaches to accurately assess the nutritional status of patients after gastrectomy [28].

This study had several limitations. First, this study was a single-center, retrospective study with a relatively small number of patients enrolled. The reduced sample size may limit the generalizability of our findings and affect the precision of the survival estimates. Consequently, studies with multicenter involvement, larger sample sizes, and randomized controlled trial designs are needed to confirm the conclusions of this study. Second, we focused only on the clinical impact of aji-DTR, not basic research such as human gut microbiota, intestinal transmission rate animal experiments, and pathological tissue observation. Third, quality of life (QOL) assessment tools including the European Organization for Research and

Treatment of Cancer Quality of Life Questionnaire—Stomach (EORTC QLQ-STO-22) [29] and the Functional Assessment of Cancer Therapy—Gastrointestinal (FACT-Ga) [30] were not used in this study, which may be useful in investigating the quality of life of AGC patients.

5 Conclusions

In summary, there was no significant difference in surgical parameters, postoperative digestive function recovery, and survival rate between the two groups, indicating that aji-DTR after laparoscopic assisted total gastrectomy was safe and feasible. Moreover, aji-DTR showed an advantage in reducing Roux stasis syndrome. However, the optimal reconstruction after total gastrectomy for gastric cancer still required further study.

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Author contributions Study conception and design: C.k., H.M., G.B., and H.Z.. Administrative support: C.k., W.X., and H.Z.. Provision of materials and samples: C.k., H.M. and G.B.. Acquisition of data: C.k. and W.X.. Analysis and interpretation of data: C.k., H.M., W.X. and H.Z.. Drafting of manuscript: C.k., H.M., G.B. and H.Z.. Critical revision of manuscript: H.Z.. All authors reviewed the manuscript.

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Data availability The datasets analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Competing interests The authors declare no competing interests.

Ethical approval Written informed consent was obtained from all subjects, and the study was approved by the Ethics Committee of Hui'an County Hospital. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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