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ORIGINAL ARTICLE

Feasibility of robotic radical gastrectomy using a monopolar device for gastric cancer

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Abstract

Purposes Laparoscopic gastrectomy using ultrasonic devices occasionally causes postoperative pancreatic fistula. Robotic gastrectomy using monopolar scissors may reduce intraoperative injury to the pancreas. We evaluated the safety and feasibility of robotic gastrectomy.

Methods A multicenter prospective study was conducted to evaluate the surgical outcomes of robotic gastrectomy. The primary endpoints were the incidence of intraoperative and postoperative complications and operative mortality.

Results A total of 115 patients were enrolled. The clinical T stages were T1 in 68 patients and T2 or higher in 47 patients. The types of surgery included distal gastrectomy ($n=72$), total gastrectomy ($n=39$), and proximal gastrectomy ($n=4$). Two patients developed intraoperative complications (1.7%), but no cases required conversion to open surgery. The amylase concentration in drainage fluid was higher in cases with pancreatic compression, especially in those with compression for longer than 20 min. Postoperative complications of Clavien–Dindo grade ≥ II occurred in 11 patients (9.6%). There was no mortality. A multivariate analysis indicated that a high body mass index and pancreatic compression by an assistant for longer than 20 min were independent risk factors for postoperative complications ($P=0.029$ and $P=0.010$).

Conclusions Robotic gastrectomy using monopolar scissors is safe and feasible. Robotic dissection without compression of the pancreas may reduce postoperative complications.

Keywords Gastric cancer · Robotic surgery · Laparoscopic surgery · Gastrectomy · Pancreatic fistula

Introduction

Laparoscopic gastrectomy (LG) for gastric cancer began in the early 1990s as a minimally invasive approach [1, 2]. Several benefits of LG, such as less pain, earlier recovery, and lower rates of complications, have been confirmed in well-designed randomized controlled trials and meta-analyses [3, 4], and LG is now considered a standard option for stage I gastric cancer in the current Japanese gastric cancer treatment guidelines [5]. While the number of LG cases has continuously increased in Japan and East Asian countries, technical difficulties and limitations are also well recognized. Gastric cancer surgery requires dissection of the regional lymph nodes, including the peripancreatic lymph nodes. However, complete resection of these lymph nodes without damage to the pancreas is difficult in LG because of fixed working ports and the straight shape of the dissection device. Intraoperative damage to the pancreas may result in the formation of a postoperative pancreatic fistula or an

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intraabdominal abscess. A recent study using the Japanese National Clinical Database showed that LG is associated with a higher incidence of pancreatic fistula in comparison to open gastrectomy, although it is also associated with a shorter hospital stay [6]. The frequency of pancreatic fistula after LG exceeds 5% in many case series [2, 7–9]. Subclinical pancreatic damage may also occur more frequently because the amylase levels in drainage fluid after LG have been found to be higher than those found after open gastrectomy [2].

Robotic gastrectomy (RG) was introduced in the mid-2000s as a new minimally invasive approach that allows surgeons to perform more precise dissection with increased dexterity under better 3D visualization. Theoretically, dissection by a robot with a wrist function could reduce the risk of heat injury to the pancreas and decrease the need for pancreatic compression during dissection. Together with other mechanical advantages of robotic systems, RG may overcome the limitations of laparoscopic surgery and could lead to better outcomes for patients with gastric cancer.

We conducted a multicenter prospective study to evaluate the safety and feasibility of RG using monopolar scissors with a wrist function. We herein report the primary endpoints of the study, which were the rates of intraoperative and postoperative complications and operative mortality.

Patients and methods

Endpoints and inclusion criteria

This prospective cohort study was designed to evaluate the safety and feasibility of RG for gastric cancer, and was conducted at Kyoto University Hospital, Kyoto City Hospital, and Otsu City Hospital (UMIN Clinical Trials Registry: UMINUMIN000004020 and UMIN000020886). Operations were performed by one of two surgeons (HO and KO), who are qualified in the endoscopic surgical skill qualification system of the Japan Society for Endoscopic Surgery. Two surgeons moved among three institutions during the study period. The study protocol was approved by the internal review boards of Kyoto University, and then at each institution.

The primary endpoints were rates of intraoperative and postoperative complications, and operative mortality. The eligibility criteria included histologically proven adenocarcinoma of the stomach amenable to curative resection, age ≥ 20 years, written informed consent, and an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Patients who received preoperative chemotherapy were included if they met the eligibility criteria after chemotherapy. Patients were excluded if they were pregnant, had a severe psychiatric disorder, or were judged to be inappropriate for inclusion in this study.

Patient evaluation

Before registration, patients were fully evaluated by upper endoscopy, an upper gastrointestinal series, and multi-detector-row CT scans of the chest and abdomen to determine the clinical TNM classification and clinical stage of gastric cancer according to the 14th version of the Japanese Classification of Gastric Carcinoma (3rd English edition) [10]. Other evaluations included basic laboratory tests, electrocardiography, and spirometry to determine the functional capacity. Anesthesiologists assessed the preoperative physical status according to the American Society of Anesthesiologists classification (ASA-PS).

Surgery

Gastrectomy with D1 + or D2 lymphadenectomy (based on the Japanese gastric cancer treatment guidelines 2010 [English version 3]) was performed according to the clinical stage [5]. For advanced upper gastric cancer, D2 with splenic hilar dissection or splenectomy was the standard procedure. However, lymphadenectomy of the splenic hilum was omitted in some cases with tumors that did not invade the greater curvature. The extent of lymphadenectomy in such cases was recorded as D1 + . When a primary tumor or metastatic lymph node had invaded the adjacent organs, combined resection was permitted if R0 resection was possible.

Patients were placed in the reverse Trendelenburg position at 15 degrees. After the insertion of the initial port through the umbilicus and the establishment of pneumoperitoneum, four ports were placed, as shown in Fig. 1. A robotic system (da Vinci S™ or Si™) was then rolled in and the camera arm was docked to the umbilical port; the 1st, 2nd, and 3rd arms were docked to the lower left, upper left, and upper right ports, respectively. The lower right port was used by an assistant for suction and for the insertion and removal of gauze.

The main concepts of dissection were as follows (Fig. 2). A Cadiere forceps (held with the 3rd arm) provided the main traction. Countertraction was added using a fenestrated bipolar forceps (held with the 2nd arm) to reveal the dissection plane. Dissection along the targeted layer was performed sharply using monopolar scissors (held with the 1st arm) by cutting loose connective tissue. Using this approach, most exposure and dissection were performed using only robotic arms. In some cases, the pancreas was temporarily retracted by an assistant to help dissection along the splenic artery. Ultrasonic or sealing devices were only used for dissection along the greater curvature and infrapyloric area in certain cases. Reconstruction was performed using a laparoscopic

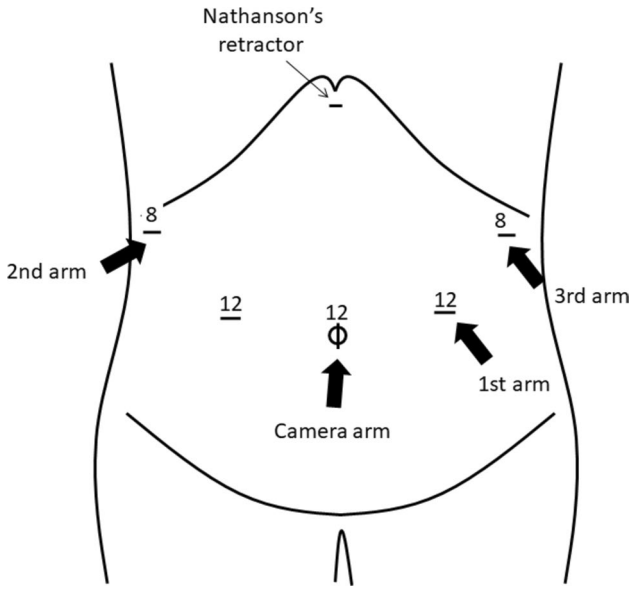

Fig. 1 Port placement. The camera arm was docked to the umbilical port. The 2nd and 3rd arms were connected to 8-mm da Vinci ports inserted at the indicated locations. The 1st arm connected to a da Vinci port was inserted into the left lower port (diameter: 12-mm). The right lower port was used by an assistant. A Nathanson liver retractor was inserted through the epigastrium

or robotic procedure, as reported in detail elsewhere [11]. A Blake drain was inserted through the right upper trocar to the vicinity of the site of anastomosis and the suprapancreatic area.

The type of gastrectomy, extent of lymphadenectomy, reconstruction method, operation time, console time for dissection, time of pancreas retraction by the assistant, and estimated blood loss were recorded in each case. The console time for dissection was defined as the time between the docking of the robot and the completion of dissection. The compression time of the pancreas was defined as the time between the start and end of retraction by the assistant during suprapancreatic lymphadenectomy. Each time point was determined by video reviews. When retraction was performed more than twice, it was defined as the time between the start of the first retraction and the end of the last retraction. Unplanned conversion was defined as any conversion to laparoscopic or open procedures other than planned laparoscopic reconstruction.

Complications

Intraoperative and postoperative complications were defined using the Clavien–Dindo classification; grade ≥ II complications were recorded [12]. Intraabdominal abscess was defined as fever and evidence of localized fluid collection on a CT scan. Pancreatic fistula was defined as a clinically obvious pancreatic leakage that required continuous drainage or exchange of a drain.

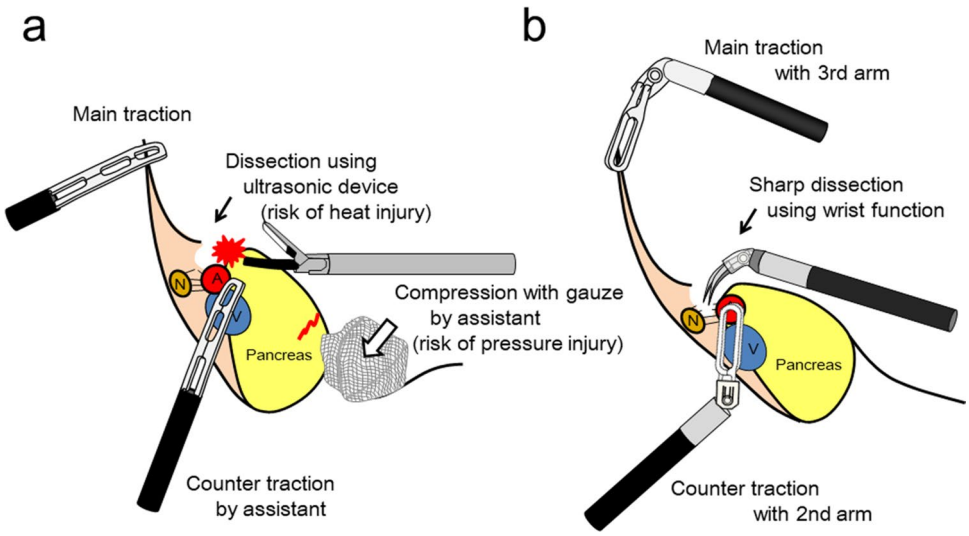

Fig. 2 Differences in laparoscopic and robotic procedures for suprapancreatic dissection along splenic vessels. **a** Laparoscopic dissection. The gastrosplenic fold is retracted by an assistant. Exposure is obtained by compression of the pancreas by the assistant. Additional countertraction by the assistant's forceps holding the perivascular nerve fibers is often used. Lymph node dissection is performed by activating an ultrasonic device near the pancreas. **b** Robotic dissection. The gastrosplenic fold is retracted by the 3rd arm. Exposure is obtained by countertraction with the operator's 2nd arm without compression of the pancreas. Sharp fine dissection using the wrist function is performed to cut small fibers and remove the splenic lymph nodes. *A* splenic artery, *V* splenic vein, *N* lymph node

Amylase concentration in drainage fluid

To evaluate the intraoperative damage to the pancreas, the amylase concentration in drainage fluid (d-AMY) was measured [2]. On the night of the operation day or early on postoperative day 1, 2 mL of drainage fluid was collected to evaluate the d-AMY concentration. The highest value was recorded as the representative d-AMY concentration.

Pathological findings

Resected specimens were prepared by surgeons for pathological evaluation. Pathological T, N, M factors, and proximal and distal margins were evaluated by pathologists. The number of retrieved lymph nodes and the residual tumor classification (R factor) were recorded.

Statistical analysis

Continuous variables are shown as medians and ranges, and were compared by the Mann–Whitney *U* test or Kruskal–Wallis test. Dunn's rank sum method was used for multiple comparisons. A binominal confidence interval (CI) was estimated by the normal approximation method. In the univariate analyses, categorical data were compared by Fisher's exact test. A multivariate analysis was performed to compare groups with and without postoperative complications using a logistic regression model to estimate the odds ratio for clinical valuables. *P* values of < 0.05 were considered to indicate statistical significance. All statistical analyses were performed using SPSS Statistics 19 (IBM, Armonk, NY, USA).

Results

Patient characteristics

Between January 2012 and December 2017, 115 eligible patients (male, $n = 75$; female, $n = 40$) were enrolled. The background characteristics of these patients are shown in Table 1. The median age of the patients was 68 years (range 34–86 years). All patients were diagnosed with gastric adenocarcinoma, with the exception of one patient with a large gastrointestinal stromal tumor in the prepyloric area requiring distal gastrectomy (DG). In most cases, the performance status was 0 (94%) and the physical status was class 1 or 2 (96%). Tumors were diagnosed clinically as T1 in 68 patients (59%) and T2 or higher in 47 patients (40%).

Table 1 Patient characteristics

Characteristics	Value
Age, median (range)	68 (34–86)
Body mass index, median (range)	22.4 (15.7–30.1)
Sex, *n* (%)	
Male	75 (65%)
Female	40 (35%)
ECOG-PS, *n* (%)	
0	108 (94%)
1	7 (6%)
ASA-PS, *n* (%)	
1	26 (23%)
2	84 (73%)
3	5 (4%)
Preoperative chemotherapy, *n* (%)	
No	102 (89%)
Yes	13 (11%)
Clinical T classification, *n* (%)	
cT1a/b	10/58 (59%)
cT2	14 (12%)
cT3	19 (17%)
cT4a/b	13/1 (12%)
Clinical stage, *n* (%)	
IA/IB	59/20 (69%)
IIA/IIB	8/13 (18%)
IIIA/IIIB/IIIC	7/6/2 (12%)

ECOG-PS Eastern Cooperative Oncology Group Performance Status, *ASA-PS* American Society of Anesthesiologists Physical Status

Surgical procedures

The surgical procedures and outcomes are summarized in Table 2. The median operation time was 372 min; the console time for dissection was 234 min. Robotic dissection was completed without compression of the pancreas by an assistant in 50 patients (43%). Among 65 cases requiring pancreatic retraction, the compression time was < 20 min in 30 cases and ≥ 20 min in 35 cases. The median blood loss was 15 g. The types of gastrectomy included DG ($n = 72$), total gastrectomy (TG) ($n = 39$), and proximal gastrectomy (PG) ($n = 4$). D2 dissection was performed in 63 patients (55%). In advanced cancer, D2 lymphadenectomy was performed in 91% of the patients who underwent DG, whereas the proportion of D2 dissection was 67% among patients with advanced cancer who underwent TG because dissection of #10 lymph node station was omitted in 7 patients. The reasons for this omission included tumor not invading the greater curvature ($n = 5$) and superficial extension of tumors to the upper third stomach ($n = 2$). Lymph node station #14v was dissected in 11 patients. Combined resection of the adjacent organs and structures was performed in four patients: mesentery ($n = 2$),

Table 2 Surgical procedures and outcomes

Variables	Value
Operation time, median (range, min)	372 (206–763)
Console time for dissection	234 (124–470)
Blood loss, median (range, g)	15 (0–1135)
Type of gastrectomy, *n* (%)	
Distal gastrectomy	72 (63%)
Total gastrectomy	39 (34%)
Proximal gastrectomy	4 (3%)
Reconstruction, *n* (%)	
Robotic	38 (33%)
Laparoscopic	77 (67%)
Extent of lymphadenectomy, *n* (%)	
D1+	52 (45%)
D2	63 (55%)
Type of omentectomy, *n* (%)	
Partial omentectomy	91 (79%)
Total omentectomy	24 (21%)
Combined/concomitant resection, *n* (%)	
No	107 (93%)
Yes	8 (7%)
Intraoperative complications, *n* (%)	2 (2%)
Unplanned conversion, *n* (%)	
To laparoscopic procedure	2 (2%)
To open procedure	0 (0%)
Retrieved lymph nodes, median (range)	46 (14–92)
Postoperative hospital stay, median (range, days)	12 (7–70)

Table 3 Postoperative complications in the Clavien–Dindo classification

Local complications	*n* (%)
Grade II[a]	8 (7.0%)
Intraabdominal abscess	5
Anastomotic leakage	1
Delayed gastric emptying	1
Ascites	1
Portal thrombus	1
Grade IIIa	3 (2.6%)
Pancreatic fistula	1
Ileus	1
Intraabdominal abscess	1
Any grade[a]	11 (9.6%)
Systemic complications	*n* (%)
Grade II	2 (1.7%)
Atelectasis	1
Cellulitis in the arm	1
Any Grade	2 (1.7%)
Total number of cases with complications[a]	11 (9.6%)

[a]Totals are not equal to the sum of complications because some cases involved multiple complications

pancreas ($n=1$), and spleen ($n=1$). Concomitant resection of the gallbladder was performed in another four patients. Total omentectomy was performed in 24 of 33 patients with a tumor classified as T3 or higher.

Intraoperative complications

Intraoperative complications were observed in 2 cases (1.7%): hemorrhage due to injury of the upper splenic polar artery and tearing of the esophagus during hand-sewn esophagogastric anastomosis. Bleeding from the upper polar artery was successfully controlled after gauze packing during robotic procedures. Laceration of the esophagus was repaired after conversion to a laparoscopic procedure. In addition, there were two mechanical problems: a sudden blackout that required the system to be restarted, and a shutdown of right-eye vision that was caused by cable damage. In the latter case, we were able to continue the robotic procedure under 2D vision. No cases required conversion to an open procedure.

Postoperative complications

Postoperative complications (Clavien–Dindo grade ≥ II) occurred in 11 patients (Table 3). The incidence of complications was 9.6% (95% CI 4.2–14.9%). These included three grade IIIa events in three patients (2.6%): pancreatic fistula requiring an exchange of a drainage tube, ileus requiring decompression with a long tube, and intraabdominal abscess requiring percutaneous drainage. No patients developed grade ≥ IIIb complications. There was no mortality. No patients required reoperation. The median postoperative hospital stay was 12 days (range 7–70 days).

Amylase concentration in drainage fluid (d-AMY)

The d-AMY concentration was measured in 113 of 115 cases. The median value was 611 IU/L (range 103–17,154 IU/L). There was a weak correlation between the d-AMY concentration and the compression time of the pancreas (Supplemental Fig. 1). The median d-AMY was significantly higher in cases with pancreatic compression (506 vs. 769 IU/L, $P=0.003$), especially in cases with a compression time of > 20 min ($P<0.001$, Fig. 3), and in patients with postoperative complications (582 vs. 1867 IU/L, $P=0.001$).

Pathological findings

The median number of retrieved lymph nodes was 46 (range 14–92): 43 in DG cases and 58 in TG cases. Based on the pathological examination of the resected specimen, the resection status was classified as R0 in 112 patients (97%). The resection margin was positive in two patients due to tumor infiltration beyond the gross margin. Multiple

peritoneal seeding was observed in a limited area in one patient, despite negative peritoneal cytology. The residual tumor status was considered to be R1, although all macroscopic tumors were removed with D2 TG. The pathological stage was IA or IB in 80 patients (69%), II in 11 (10%), III in 23 patients (20%), and IV in one patient (1%).

Risk factors for postoperative complications

The relationships of patient factors, the tumor status, and surgical factors with postoperative complications in RG are shown in Table 4. In the univariate analysis, a high body mass index (BMI) and pancreatic compression for ≥ 20 min were associated with morbidity ($P = 0.003$, $P = 0.0003$). A multivariate analysis using variables with an odds ratio of ≥ 2 revealed that high BMI and longer pancreatic compression were independent risk factors for postoperative complications ($P = 0.029$, $P = 0.010$).

Discussion

The primary aim of this study was to evaluate the safety of RG using monopolar scissors based on the incidence of intraoperative and postoperative complications. We found that the rate of grade ≥ II complications after LG was 15–20% in our previous studies [2, 14]. Because the overall complication rate in this study was 9.6% (95% CI 4.2–14.9%), with major complications occurring in only 2.6% of patients, we concluded that the study demonstrated the safety of RG. Recent studies of laparoscopic DG in high-volume centers in Japan have reported grade ≥ II complication rates of 17–24% [15, 16]. Given that our patients also included TG cases, for which higher complication rates have been reported, RG may have a lower complication rate.

It is controversial as to whether RG reduces postoperative complications in comparison to LG. A prospective multicenter study in Korea did not find any advantages of RG, but two retrospective studies from Japanese expert centers showed fewer complications after RG [13, 16, 20]. We noted a technical difference in that both Japanese centers used a device with a wrist function (e.g., monopolar scissors) as the main dissection device, while ultrasonic shears were mainly used in the Korean study. Heat injury caused by an ultrasonic device is a major cause of pancreatic damage in LG [8, 19]. Theoretically, devices with a wrist function can dissect lymph nodes without direct contact with the pancreas and thereby reduce the risk of heat injury.

Pancreatic fistula (grade III) occurred in one patient (0.9%) in the early period in this study. Among cases recorded in the National Clinical Database, the rates of pancreatic fistula after laparoscopic DG and TG are 2.2% and 5.3%, respectively; thus, RG may contribute to reducing the incidence of pancreatic fistula [6, 17]. Pancreatic fistula after gastrectomy is thought to be caused by intraoperative pancreatic injury. Because a higher d-AMY concentration is a predictive factor for pancreatic fistula [2, 18], we routinely monitor the d-AMY concentration after each operation as an indicator of pancreatic damage. The median d-AMY value after RG was significantly lower in comparison to that after LG in our previous study (611 vs. 934 IU/L, $P = 0.022$) [2]. This suggests that RG using monopolar scissors is a less traumatic procedure for the pancreas and may contribute to a lower rate of associated complications (e.g., pancreatic fistula).

A recent study indicated that pressure injury caused by direct compression of the pancreas during LG also leads to the increased occurrence of pancreatic fistula [15]. In LG, to access the suprapancreatic area with a straight-shaped device, the pancreas often needs to be compressed. In contrast, peripancreatic lymph node dissection without direct compression of the pancreas is easier in RG when the wrist function is used (Fig. 2). We found higher d-AMY values and a higher incidence of postoperative complications in cases requiring pancreatic compression, especially when the compression time was longer than 20 min. Moreover, a risk analysis showed that longer pancreatic compression was the only surgical factor significantly associated with postoperative complications. Although there was only one

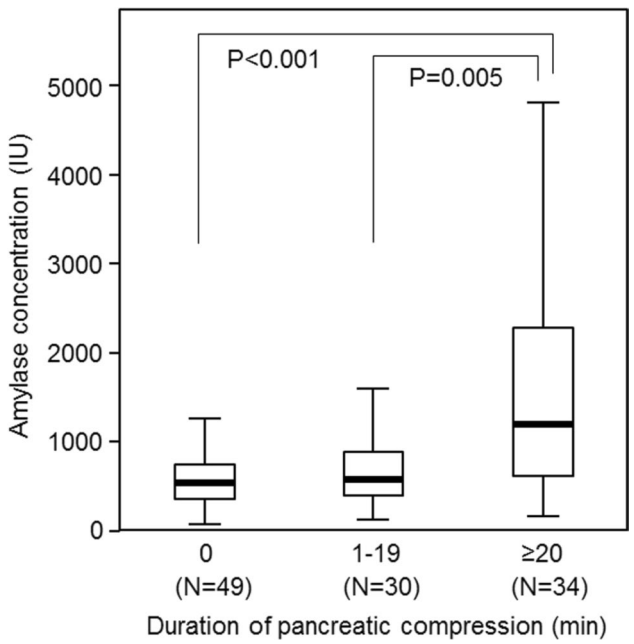

Fig. 3 Box plot showing the amylase concentrations in drainage fluid in three groups with different periods of pancreatic compression: 0 min, 1–19 min, and ≥ 20 min. Thick lines show median values. Lower bars show the minimum values and upper bars show the 1.5 × interquartile range. The *P* value was calculated using Dunn's rank sum method

Table 4 Risk factors for postoperative complications

Variables	Univariate analysis[a]		Multivariate analysis[b]	
	OR (95% CI)[b]	*P* value	OR (95% CI)[b]	*P* value
Age (≥ 70 years vs. < 70 years)	1.46 (0.42–5.07)	0.752	–	–
Sex (male vs. female)	2.59 (0.53–12.6)	0.325	5.72 (0.49–66.6)	0.164
ASA-PS (2–3 vs. 1)	3.17 (0.39–25.9)	0.452	3.35 (0.32–34.8)	0.311
ECOG-PS (1 vs. 0)	0.00 (0.00–5.22)	1.000		
Body mass index (≥ 25 vs. < 25)	7.35 (1.96–27.6)	0.003	6.29 (1.21–32.7)	0.029
Preoperative therapy (yes vs. no)	0.77 (0.09–6.53)	1.000		
cStage (2–4 vs. 1)	0.81 (0.20–3.24)	1.000	–	–
Type of surgery (TG/PG vs. DG)	0.95 (0.27–3.46)	1.000		–
Extent of lymphadenectomy (D1 + vs. D2)	0.66 (0.19–2.30)	0.541	–	–
Blood loss (≥ 100 vs. < 100 mL)	4.58 (1.25–16.8)	0.014	0.56 (0.12–2.70)	0.471
Operation time (≥ 360 vs. < 360 min)	2.67 (0.67–10.6)	0.209	–	–
Pancreatic compression (≥ 20 vs. < 20 min)	13.5 (2.74–66.5)	0.0003	17.2 (1.98–149.4)	0.010

OR odds ratio, *CI* Confidence interval, *ASA-PS* American Society of Anesthesiologists Physical Status, *ECOG-PS* Eastern Cooperative Oncology Group Performance Status, *TG* total gastrectomy, *PG* proximal gastrectomy, *DG* distal gastrectomy

[a]Fisher's exact test

[b]Logistic regression model

case of pancreatic fistula, intraabdominal abscess occurred in six patients and all six cases had a compression time of > 20 min. Longer pancreatic compression would also be closely associated with these infectious complications (Supplemental Table 1). Thus, avoiding compression of the pancreas is expected to be a pivotal technical tip for the safe performance of RG.

Although the manipulation of the robot is intuitive, the mastery of robotic surgery skills is necessary to perform RG efficiently, and this involves a learning curve. Because patients with different types of gastrectomy procedures were included in this study, it was difficult to determine the learning curve based on the operation time. However, we found that the proportion of patients requiring > 20 min of compression time was reduced from 43 to 16% after the experience of 30 cases. With this improvement, the complication rate was also reduced from 13 to 5%. These data suggest that 30 cases were a sufficient number to reach the first learning curve plateau from the viewpoint of operative morbidity.

We believe that our results indicate the safety and potential advantages of RG. However, the present study was associated with several limitations and caution is required in the interpretation of the results. First, the study did not directly compare RG with LG, and a randomized controlled study or large-scale registration study is required to establish evidence for the superiority of RG. However, before conducting a prospective study, it is important to establish a standard method to perform RG safely. Our finding that the compression of the pancreas is closely associated with higher d-AMY values and the occurrence of postoperative pancreas-related complications in patients undergoing RG will help to establish a safe procedure. Second, we did not discuss the cost-effectiveness of RG. Currently, the total cost of RG is higher than that of LG. However, the depreciation of the surgical robot accounts for a substantial portion of the cost. Thus, this cost will be decreased with increased use of robots, once the benefit of RG is recognized. Third, retraction of the pancreas was still required in some patients with high BMI values. Thus, obese patients have an increased risk of postoperative complications, even in RG. Finally, it should be noted that all operations in this study were performed by two surgeons qualified to perform LG. Optimal training and experience to perform RG safely should be widely discussed prior to its broader application.

Conclusion

This study showed the safety of RG using monopolar scissors and indicated the importance of surgical techniques that avoid direct compression of the pancreas for reducing the incidence of postoperative complications. The surgical and oncological safety of RG for gastric cancer requires further evaluation in a multicenter prospective study or a large-scale registration study.

Author contributions OH contributed to the conception, data acquisition, analysis, and writing the manuscript. OK contributed to the conception, data acquisition, analysis, interpretation of data, and revision.

MK contributed to the data acquisition. TS, TE, HS, and SY contributed to the interpretation of data and revision.

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Compliance with ethical standards

Conflict of interest The authors declare no conflicts of interest in association with the present study.

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