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Late phase II study of robot-assisted gastrectomy with nodal dissection for clinical stage I gastric cancer

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Abstract
Background The feasibility of robot-assisted gastrectomy (RG) in terms of safety is unclear due to a lack of prospective studies. We showed feasible surgical outcomes in our previous study. In this phase II study, we assessed feasibility of the procedure by recruiting a larger number of patients.
Method This single-center, prospective phase II study included patients with clinical stage I gastric cancer undergoing RG. The primary end point was the incidence of postoperative intra-abdominal infectious complications, including anastomotic leakage, pancreas-related infection, and intra-abdominal abscess. The secondary end points were overall survival, relapse-free survival, RG completion rate, and incidence of all surgical morbidities.
Results A total of 120 patients were recruited between December 2012 and April 2015. The incidence of intra-abdominal infectious complications was 3.3 % (95 % CI 0.9–8.3 %), and all complications were successfully treated conservatively without re-operation. The incidence of overall adverse events was 14.2 % (95 % CI 8.5–21.7 %). Three patients required conversion to open gastrectomy according to the protocol due to advancement of disease.
Conclusion Our data show that RG is safe in terms of the incidence and severity of postoperative complications.

Keywords da Vinci · Gastric cancer · Gastrectomy · Clinical trial · Robot

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Laparoscopy-assisted gastrectomy (LG) is being used increasingly. The safety of this procedure for stage I gastric cancer has been demonstrated in large randomized controlled trials in Japan and Korea [1–3], and long-term outcomes have been investigated in these trials [4–6]. In addition, it has been reported that complicated procedures—such as total and proximal gastrectomy, and gastrectomy with D2 lymphadenectomy—can be performed safely using a laparoscopic approach [7, 8]. However, currently used laparoscopic procedures have several drawbacks, including limitations in the range of forceps movement and physiological tremor.

Robot-assisted gastrectomy (RG) was developed to overcome these drawbacks and is also being used increasingly in Asia. Using the da Vinci® Surgical System (Intuitive Surgical, Sunnyvale, Calif, USA), surgeons can attain a three-dimensional surgical view, increased instrument flexibility, tremor suppression, and improved ergonomics, although RG has disadvantages such as high cost and lack of tactile sensation. No prospective clinical trials evaluating the safety of RG were undertaken before we commenced the study described in this article, although retrospective and prospective cohort studies of RG have been undertaken [9–14]. Therefore, we planned an early phase II study to investigate the short-term outcomes of using RG for distal gastrectomy with D1+ lymph node dissection in patients with early gastric cancer [15]. We set the incidence of intra-abdominal infectious complications as the primary end point, and the incidence of intra-abdominal infectious complications was 0 (90 % confidence interval [CI], 0–12 %). Therefore, we subsequently conducted a late phase II study.

In the late phase II study, we evaluated the safety of using RG by recruiting a larger number of patients with stage IA and IB gastric cancer who were undergoing total or proximal gastrectomy as well as distal gastrectomy.

Methods

The present study was a single-center, prospective phase II trial. The institutional review board of the Shizuoka Cancer Center approved the study protocol in November 2012, and patients were recruited from December 2012 to April 2015. The inclusion criteria were histologically confirmed adenocarcinoma of the stomach, clinical stage IA or IB early gastric cancer according to the International Union Against Cancer classification system [16], no indication for endoscopic submucosal dissection, a tumor located in the lower two-thirds of the stomach, no involvement of the duodenum, patient age of 20–80 years, an Eastern Cooperative Oncology Group performance status of 0 or 1, a body mass index (BMI) of less than 30 kg/m^2, no prior upper abdominal surgery or intestinal resection other than appendectomy, no prior chemotherapy or radiotherapy for any malignancy, adequate organ function, and written informed consent. The study was registered with the UMIN Clinical Trials Registry (UMIN identifier: UMIN 000009737).

During the study period, the medical costs of admission for the first 20 patients who were enrolled in the study (including the fee for the surgery) were covered by the Shizuoka Cancer Center because the national insurance system in Japan did not reimburse patients for RG. Subsequently enrolled patients paid 500,000 JPY, and the remaining costs were covered by the Shizuoka Cancer Center.

Protocol amendment

In September 2013, we amended the protocol because the incidence of intra-abdominal infectious complications was zero. We thought that a more complicated procedure—total gastrectomy or proximal gastrectomy—could be performed safely using the robotic technique, and we felt that testing the feasibility of using robotic technique for these procedures was important. Therefore, the inclusion criteria were changed: Patients who had stage IA gastric cancer with a tumor located in the upper third of the stomach and who underwent total or proximal gastrectomy were included. Patients who had stage IB gastric cancer and who underwent total gastrectomy were not included because splenectomy, a procedure that has a higher postoperative complication rate than the other procedures, was recommended for these patients by the third version of the Japanese gastric cancer treatment guidelines [17, 18].

In October 2014, we amended the protocol again, to include patients who had stage IB gastric cancer and who underwent total gastrectomy because the final result of the JCOG 0110 trial, which compared splenectomy with spleen preservation in patients with upper third advanced gastric cancer, was opened among investigators of the trial and splenectomy became a non-mandatory procedure unless the tumor had infiltrated the greater curvature line, even if it was located in the upper third of the stomach [19].

Surgical procedure

All RG procedures were performed using the da Vinci® Surgical System. Details of the surgical procedure have been described elsewhere [15]. All but one of the RG procedures were performed by one of three experienced laparoscopic surgeons who were board certified by the Japanese Society For Endoscopic Surgery (JSES); details of the JSES board certification are described elsewhere [15]. The other RG procedure was the first case of total gastrectomy and was performed by an invited surgeon who was experienced in robot-assisted total gastrectomy.

In our early phase II study, one of the surgeons had performed 13 RG procedures and one had performed five. The other had no experience of RG in our early phase II study but, as recommended by the JSES, had completed a training program (e-learning, training sessions at an animal laboratory, and site visits to a specified high-volume center to observe RG) before performing RG for this study.

End points

The primary end point in this study was the incidence of postoperative intra-abdominal infectious complications, including anastomotic leakage, pancreas-related infection, and intra-abdominal abscess. Patients who developed Clavien-Dindo classification grade II or more complications within 2 weeks of discharge were regarded as having complications [20, 21]. The secondary end points were overall survival, relapse-free survival, RG completion rate, and incidence of all surgical morbidities.

Anastomotic leakage was diagnosed by radiological examination using orally administered contrast media. Pancreas-related infection was defined as amylase-rich purulent discharge. Intra-abdominal abscess was defined as abscess not associated with anastomotic leakage or pancreas-related infection. The completion of RG was defined as the proportion of patients who were not converted from RG to laparoscopic gastrectomy or open gastrectomy.

Statistical methods

We calculated that a sample size of 97 cases would provide 90 % power for testing the hypothesis of a primary end point with an expected value of 4 % and a threshold value of 12 %, using one-sided testing at a 5 % significance

level. Statistical analyses were conducted using R Statistics version 3.2.1.

Results

We recruited 120 patients, whose characteristics are summarized in Table 1. Median body mass index was 22.4 kg/m^2, and more than half of the patients had a tumor located in the middle third of the stomach. Clinical stage was IA in 83 % of patients (99/120). Differentiated histological type was observed more frequently than undifferentiated histological type.

Table 2 shows details of the surgical procedures. The median duration of the surgery was 348.5 min (range, 187–591 min). Total and proximal gastrectomy was performed in 12 and 3 patients, respectively. In the cases of proximal gastrectomy, double-tract reconstruction was selected, while Roux-en-Y was selected following total gastrectomy. The surgery was converted to open surgery in three cases according to the protocol because the tumor was diagnosed as stage II or III during the surgery. No patients required conversion to laparoscopic or open surgery due to intra-operative troubles such as bleeding or severe adhesion.

Table 1 Patient characteristics

Number of patients	120
Sex (cases)	
Male	73
Female	47
Age (years)	
Median	64
Range	24–80
Body mass index (kg/m^2)	
Median	22.4
Range	15.2–29.6
Tumor location (cases)	
Upper third of stomach	21
Middle third of stomach	70
Lower third of stomach	29
Histological type (cases)	
Differentiated	66
Undifferentiated	54
Tumor size (mm)	
Median	30
Range	8–150
Clinical stage (cases)	
IA	99
IB	20
IIA	1

Postoperative clinical course data for all cases in this study are shown in Table 3. The median duration of postoperative hospital stay was 9 days. Six intra-abdominal infectious complications were observed in four patients; thus, the incidence of intra-abdominal infectious complications was 3.3 % (4/120; 95 % CI 0.9–8.3 %). Overall, 20 complications were observed in 17 patients (14.2 %; 95 % CI 8.5–21.7 %). Other adverse events not listed in the Table 3 included cerebral infarction, herpes zoster infection, cholecystitis, urinary tract infection, catheter-related infection, and early dumping syndrome.

Discussion

This late phase II study showed that RG is feasible in terms of safety; the incidence of intra-abdominal infectious complications was 3.3 % (95 % CI 0.9–8.3 %). The null hypothesis—a 12 % threshold value of intra-abdominal infectious complications—was rejected, so we conclude that RG is safe for patients with stage IA and IB gastric

Table 2 Details of surgical procedures

Operation time (min)	
Median	348.5
Range	187–591
Blood loss (mL)	
Median	19
Range	0–264
Perioperative blood transfusion (cases)	
Yes	0
No	120
Type of gastrectomy (cases)	
Total gastrectomy	12
Proximal gastrectomy	3
Pylorus-preserving gastrectomy	40
Distal gastrectomy	65
Reconstruction method	
Roux-en-Y	37
Billroth I	40
Gastrogastrostomy	40
Double-tract	3
Extent of lymph node dissection (cases)	
D1+	92
D2	28
Number of retrieved lymph nodes (cases)	
Median	44
Range	16–95
Completion of RADG (cases)	
Yes	117
No	3

Table 3 Postoperative clinical course

Postoperative hospital stay (days)						
Median						9
Range						6–129
	Total number	Grade II	Grade IIIa	Grade IIIb	Grade IV	Grade V
Postoperative morbidities (cases)						
Intra-abdominal infectious complications						
Anastomotic leakage	1	0	1	0	0	0
Stump leakage	1	0	1	0	0	0
Pancreas-related infection	1	0	1	0	0	0
Intra-abdominal abscess	3	1	2	0	0	0
Other complications						
Wound infection	1	0	1	0	0	0
Delayed gastric emptying	3	3	0	0	0	0
Chylous ascites	1	0	1	0	0	0
Paralytic ileus	2	2	0	0	0	0
Pneumonia	1	1	0	0	0	0
Other complications	6	6	0	0	0	0

cancer who undergo total or proximal gastrectomy as well as distal gastrectomy. In addition, no patients had severe complications that required additional surgery or resulted in postoperative mortality. RG is, therefore, a feasible procedure in terms of the severity and incidence of complications.

There are many reports on the value of RG. However, most are case series or case–control comparative studies with laparoscopic gastrectomy [9–14, 22–32]. Although satisfactory outcomes have been shown in these studies, few prospective clinical trials of RG have been done. To our knowledge, our previously reported study [15] and one non-randomized comparative study conducted in Korea [33] are the only prospective clinical trials that have been conducted so far. In addition, the question of whether the surgical outcomes of RG are superior compared with those of LG is a subject of controversy. Some retrospective studies have failed to show superiority of RG over LG in terms of early surgical outcomes [13, 14, 27, 33]. Evidence from prospective studies is, therefore, essential for RG to be accepted as standard treatment.

The non-randomized comparative study conducted in Korea, which compared RG and LG, involved 17 surgeons in 11 hospitals, 223 RG procedures and 211 LG procedures [33]. The incidence of postoperative morbidity following RG and LG was 11.9 and 10.3 %, respectively. The authors concluded that although RG is assumed to provide a technically superior operative environment, RG is not superior to LG.

In our early phase II study, although the incidence of intra-abdominal infectious complications was zero, it could be argued that only patients expected to have a low chance of complications were recruited because it included more female patients with low BMI compared with our other studies [34, 35]. In the present late phase II study, however, the male-to-female ratio and BMI were similar to those in our previous retrospective study, in which we compared morbidity rates for laparoscopic and open gastrectomy [35]. Nevertheless, the incidence of intra-abdominal infectious complications was low, indicating that RG is safe for use in the general population of Japan.

In the present study, two patients had Clavien-Dindo grade IIIa complications other than intra-abdominal infectious complications. One of them was discharged from the hospital 8 days after surgery and had an uneventful postoperative clinical course, but presented to the outpatient clinic with fever and redness around the naval. Superficial surgical site infection was diagnosed, and the patient was treated by drainage under local anesthesia and antibiotic therapy. The patient recovered uneventfully. The other patient was discharged 9 days after surgery and had an uneventful postoperative clinical course, but presented to the outpatient clinic with abdominal distention. Drainage under general anesthesia was performed, and chylous ascites was found. The patient was treated with diuretics and a fat-restricted diet, the abdominal distention resolved, and further treatment was not necessary.

In Japan, the use of ultrasonic shears for RG was not approved by the government during our study period. For this reason, lymphatic vessel seals might have been weaker than those in laparoscopic surgery in which ultrasonic shears are used. Lymphorrhea can be avoided by using ultrasonic shears, but only if surgeons give up the articulation of the device because ultrasonic shears are not

articulated. Other authors have also reported the benefit of devices with articulation over ultrasonic shears [36, 37].

There are drawbacks in RG that are yet to be solved. As previously reported, RG is time-consuming compared to LG [14, 22–31]. In the present study, the median duration of surgery was even longer than in the previous early phase II study (348.5 min vs. 311.5 min). Possible explanations include expanding the inclusion criteria (e.g., including patients requiring total gastrectomy or D2 lymphadenectomy) and introducing intracorporeal anastomosis including hand-sewn gastrogastrostomy following pylorus-preserving gastrectomy. The use of ultrasonic shears might reduce the duration of surgery as reported in the Korean series [9, 33]. However, we believe that a lower complication rate is much more beneficial to patients than shorter duration of surgery because worse oncological outcomes are reported after surgery with postoperative complications [38]. Therefore, a lower complication rate following RG may result in improved long-term survival.

The present study was conducted in a single center, with some costs covered by the hospital because the government insurance system did not cover RG. Under current insurance systems in Eastern countries, conducting randomized control trials is difficult. Therefore, the evidence level of the present study is the highest that is available to date for RG. In October 2014, the Japanese government approved RG under advanced medical system B, which means medical expenses other than RG itself are now covered by national insurance system. A nationwide multicenter phase II trial (UMIN identifier: UMIN000015388) under advanced medical system B had started, and we participated in the study from April 2015; the trial is expected to run for 3 years.

In conclusion, the present late phase II study showed that RG is feasible in terms of the incidence and severity of postoperative complications.

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Compliance with ethical standards

Disclosures Tokunaga, Makuuchi, Miki, Tanizawa, Bando, Kawamura, Terashima have no conflict of interest or financial ties to disclose.

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