

## Early phase II study of robot-assisted distal gastrectomy with nodal dissection for clinical stage IA gastric cancer

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### Abstract

**Background** Robot-assisted distal gastrectomy (RADG) is increasingly performed in Japan and Korea and is thought to have many advantages over laparoscopic gastrectomy. However, a prospective study investigating the safety of RADG has never been reported. The present study evaluated the safety of RADG with nodal dissection for clinical stage IA gastric cancer.

**Methods** This single-center, prospective phase II study included patients with clinical stage IA gastric cancer located within the lower two-thirds of the stomach. The primary endpoint was the incidence of postoperative intraabdominal infectious complications including anastomotic leakage, pancreas-related infection, and intraabdominal abscess. The secondary endpoints included all in-hospital adverse events, RADG completion rate, and survival outcome.

**Results** From May 2012 to November 2012, 18 eligible patients were enrolled for this study. The incidence of intraabdominal infectious complication was 0 % (90 % CI, 0–12.0 %). The overall incidence of in-hospital adverse events was 22.2 % (90 % CI, 8.0–43.9 %). No patient required conversion to laparoscopic or open gastrectomy; thus, the RADG completion rate was 100 %.

**Conclusions** This early phase II study suggested that RADG might be a safe and feasible procedure for stage IA gastric cancer, providing experienced surgeons perform the

surgery. This conclusion should be clarified in subsequent late phase II studies with a larger sample size.

**Keywords** da Vinci · Gastric cancer · Gastrectomy · Clinical trial · Safety

### Introduction

Laparoscopy-assisted distal gastrectomy (LADG) is performed increasingly often, particularly in East Asian countries where the incidence of early gastric cancer is higher than in Western countries. The safety of LADG was clarified by prospective studies [1, 2], and survival outcome of LADG compared with open gastrectomy was under investigation in two large, nationwide, randomized controlled trials in Japan and Korea [1, 3]. However, current laparoscopic procedures have several drawbacks, including a limitation in range of forceps movement and the two-dimensional surgical view available to the operating surgeons.

Robot-assisted distal gastrectomy (RADG) may enable us to overcome these drawbacks. Using the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA), surgeons were able to attain a three-dimensional surgical view, instrument flexibility, tremor suppression, and improved ergonomics, although RADG still has disadvantages such as high cost and lack of tactile sensation [4–8]. In addition, a shorter learning curve has been reported for robotic surgery compared to laparoscopic surgery [9–11].

Reported studies rate RADG as a feasible procedure, although most such studies involved a retrospective or prospective study cohort [4, 5, 8–10, 12–22]. So far, no prospective clinical trials have focused on the feasibility of RADG, a step that is necessary before RADG could be

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explored further with greater number of patients. To this end, the current prospective study evaluated the safety of RADG with nodal dissection for clinical stage IA gastric cancer.

## Methods

The present study was designed as a single-center, prospective phase II trial. The institutional review board of Shizuoka Cancer Center approved the study protocol, which had the following inclusion criteria: histologically confirmed adenocarcinoma of the stomach, clinical stage IA early gastric cancer according to the International Union Against Cancer classification system (UICC) [23], no indication for endoscopic submucosal dissection (ESD), 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 (ECOG) performance status (PS) of 0 or 1, a body mass index (BMI) less than 30 kg/m<sup>2</sup>, 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 clinical trials.gov (clinical trials.gov identifier: NCT 1504997).

In this study period, medical cost for hospital admission, including surgical fee, was funded by the Shizuoka Cancer Center because the national insurance system in Japan did not reimburse patients for RADG.

### Surgical procedure

All RADG operations were performed using the da Vinci Surgical System with four robotic arms; a central arm for a dual-channel endoscope, and the other three for a Cadiere forceps, fenestrated bipolar forceps, and bipolar Maryland forceps or monopolar electrocautery, respectively. One assistant port was placed in the right umbilical level. The surgical procedures were similar to that used in LADG, with a standardized surgical field to achieve omentum preservation, D1+ lymph node dissection according to the Japanese gastric cancer treatment guidelines [24–27], and vagal nerve preservation [28, 29]. Removal of resected specimens and reconstruction were performed by a 4- to 5-cm upper midline incision. In the case of distal gastrectomy, a Billroth I reconstruction with circular stapler was selected in general. In the case of pylorus-preserving gastrectomy, reconstruction was performed by hand-sewn sutures.

In this study, the operations were separated into three parts. The docking time was defined as the time from skin incision to completion of docking. The console time was

the time that the da Vinci system was used by the surgeon at the console. The anastomosis time was the time spent from the creation of the mini-laparotomy to the completion of the surgery.

### Training for RADG

A team of two gastric surgeons who were board certified by the Japanese Society of Endoscopic Surgery (JSES) as experts in laparoscopic surgery performed RADG in all cases. To be board certified by the JSES as an expert laparoscopic surgeon, an applicant is required to perform more than 20 laparoscopic gastrectomies or alternative advanced laparoscopic surgeries within 3 years and to submit a non-edited video of one of the surgeries for a review by at least two board-qualified referees. The strict review process, which takes place once a year, allows only one-third of the applicants to be certified. Before introducing RADG at Shizuoka Cancer Center, the two surgeons completed a fixed training program for RADG as recommended by the JSES. The program consisted of e-learning, training sessions at an animal laboratory, and site visits to a specified high-volume center to observe actual RADG. In addition, surgeons with sufficient experience in RADG were invited as instructors in the initial two cases of RADG at our institution.

### Endpoints

The primary endpoint in this study was the incidence of postoperative intraabdominal infectious complications, which included anastomotic leakage, pancreas-related infection, and intraabdominal abscess. Patients who developed Clavien–Dindo classification grade II or more complications by discharge were regarded as having complications [30, 31]. The secondary endpoints were overall survival (OS), relapse-free survival (RFS), RADG completion rate, and the incidence of all surgical morbidities.

Anastomotic leakage was diagnosed by radiologic examination using orally administered contrast media. Pancreas-related infection was defined as amylase-rich purulent discharge. Intraabdominal abscess was defined as an abscess not associated with anastomotic leakage or pancreas-related infection. The completion of RADG was defined as the proportion of patients without conversion from RADG to LADG or open distal gastrectomy (ODG).

### Study design and statistical methods

In this phase II trial, the sample size was 18 cases, providing 70 % power under the hypothesis of a primary endpoint with an expected value of 4 % and a threshold

value of 15 %, using one-sided testing at a 10 % significance level. The expected value was decided according to the postoperative outcome of 265 patients who had undergone an ODG or LADG for early gastric cancer in the lower two-thirds of the stomach at the Shizuoka Cancer Center; the incidence of intraabdominal infectious complication among these patients was 4.5 % [32]. All statistical analyses were conducted using R Statistics version 2.13.1.

## Results

A total of 18 patients were recruited in this phase II study from May 2012 to November 2012. Table 1 summarizes the patient characteristics. The male-to-female ratio was 1.57, median body mass index was 21.1 kg/m<sup>2</sup>, and all patients had stage IA gastric cancer located within the lower two-thirds of the stomach. Undifferentiated histology was more frequently observed than differentiated histology.

Table 2 shows details of the surgical procedure. The median duration of the surgery was 311.5 min; median docking, console, and anastomosis times were 22, 212.5, and 63 min, respectively. Distal gastrectomy and pylorus-preserving gastrectomy were performed in nine patients

each, and all patients underwent D1 + lymph node dissection. No patient required conversion to laparoscopic or open surgery; thus, the RADG completion rate was 100 %. Median blood loss was 32.5 ml; blood transfusion was not required in any of the patients.

Postoperative clinical course is shown in Table 3. The median duration of postoperative hospital stay was 8 days. Incidence of intraabdominal infectious complication was 0 % [0/18; 90 % confidence interval (CI), 0–12.0 %]. The overall proportion of in-hospital adverse events was 22.2 % (90 % CI, 8.0–43.9 %), with all rated as grade II, from which all patients recovered well with medical treatment only and no surgical interventions.

**Table 1** Patient characteristics

Number of patients	18
Sex (cases)	
Male	11
Female	7
Age (years)	
Median	65.5
Range	53–80
Body mass index (kg/m <sup>2</sup> )	
Median	21.1
Range	16.2–25.8
Tumor location (cases)	
Upper third	0
Middle third	11
Lower third	7
Histological type (cases)	
Differentiated	6
Undifferentiated	12
Tumor size (cm)	
Median	
Range	
Clinical stage (cases)	
IA	18
IB	0

**Table 2** Details of surgical procedures

Operation time (min)	
Median	311.5
Range	225–375
Docking time (min)	
Median	22
Range	11–41
Console time (min)	
Median	212.5
Range	161–291
Anastomosis time (min)	
Median	63
Range	41–111
Blood loss (ml)	
Median	32.5
Range	0–160
Perioperative blood transfusion (cases)	
Yes	0
No	18
Type of gastrectomy (cases)	
PPG	9
DG	9
Reconstruction method	
Roux-en-Y	1
Billroth I	8
Gastro-gastrostomy	9
Extent of lymph node dissection (cases)	
D1+	18
D2	0
Number of retrieved lymph nodes (cases)	
Median	40
Range	26–89
Completion of RADG (cases)	
Yes	0
No	18

PPG pylorus-preserving gastrectomy

DG distal gastrectomy

**Table 3** Postoperative clinical course

Postoperative hospital stay (days)	
Median	8
Range	7–10
Postoperative morbidities (cases)	
Intraabdominal infectious complications	0
Anastomotic leakage	0
Pancreas-related infection	0
Intraabdominal abscess	0
Other complications	
Wound infection	2
Delayed gastric emptying	1
Liver dysfunction	1

## Discussion

The present study showed RADG is feasible in terms of safety if experienced laparoscopic surgeons perform the surgery, with a zero incidence of intraabdominal infectious complications recorded (90 % CI, 0–12.0 %).

Before May 2012, we had performed five RADGs at our institute, and based on this experience, we assessed RADG as technically feasible. In addition, none of these five patients developed any postoperative complications. We therefore decided to more thoroughly assess the safety of RADG in the present prospective study.

Previous retrospective studies demonstrated that RADG was a feasible treatment for gastric cancer [4, 5, 10, 12, 14, 18, 19]. Surgeons generally believed that much more meticulous surgery could be performed with the da Vinci Surgical System because of the three-dimensional surgical view provided and the flexibility of instrumentation. However, RADG required longer operation times [5, 14, 17–19, 21] and was more expensive than laparoscopic or open gastrectomy [14, 16, 21, 33]. In addition, the advantages of RADG compared to conventional procedures were not clear from these previous studies, and no prospective study investigating the safety of RADG was reported.

The incidence of postoperative intraabdominal infectious complication in the present study was 0 % (90 % CI, 0–12.2 %) with a 22.2 % overall proportion of in-hospital adverse events (90 % CI, 8.0–43.9 %) in this study. A similar complication rate (0–47.3 %) has been reported in previous retrospective studies, although none had focused on the incidence of intraabdominal infectious complication [4, 5, 8–10, 12, 17, 18, 22, 33]. With the three-dimensional magnified view available with RADG, surgeons were able to recognize anatomical structures much more precisely than with the standard two-dimensional view. In addition, the flexibility of instruments used helped surgeons perform meticulous surgery. We propose that these advantages of RADG resulted in the low complication rate.

Other possible reasons for the low complication rate recorded in this study were involving only experienced laparoscopic surgeons to perform the procedures and the relatively lower BMI of the patients compared with that reported in Western series. High BMI is a possible risk factor for postoperative complications after open and laparoscopic gastrectomy, although this association remains controversial [34–38]. The present study included only one overweight patient (BMI, 25.8). The feasibility of RADG in overweight or obese patients is still unclear and must be clarified in a future trial.

RADG procedures required longer surgical times than LADG. Indeed, there was a difference of 86.5 min in our institute between RADG and LADG [31]. We considered that the meticulousness of the procedure was inversely proportional to operation time to some degree. With the magnified and three-dimensional magnified view and instrument flexibility, surgeons were able to perform much more meticulous surgery at the expense of increased operation time.

There were other possible reasons for the longer operation times. First, RADG was performed during our learning curve period whereas LADG was not. Second, we did not use ultrasonic shears provided for RADG because such usage is not allowed in Japan with the da Vinci Surgical System. Thus, if we achieve our learning curve with RADG and the usage of ultrasonic devices is permitted in the future, we will be able to reduce the operation time.

We believe that the advantages of the da Vinci Surgical System would be enhanced when we use it for more complicated surgery such as gastrectomy with extended (D2) lymph node dissection or mediastinal lymph node dissection. During extended lymph node dissection, we were able to recognize layers precisely as well as small vessels because of the three-dimensional magnified view. In addition, the flexibility of instruments and tremor suppression enabled us to do each procedure meticulously, resulting in high-quality lymph node dissection. Similar advantages would be obtained when we perform lower mediastinal lymph node dissection for adenocarcinoma of esophagogastric junction in which the surgical field is narrow and linear instruments used in laparoscopic surgery frequently interfere. Thus, our next step is to indicate the da Vinci Surgical System for these complicated surgeries.

In the present study, early surgical outcomes of RADG were not compared with conventional open or laparoscopic surgery; thus, it is still unclear if RADG is superior to conventional surgeries in this regard. Although previous retrospective studies compared surgical outcomes of RADG with LADG or ODG, there is no prospective randomized trial comparing RADG and other procedures [5, 17, 18, 20, 22]. In addition, survival outcomes of RADG

remain unclear. Future trials are needed to clarify the superiority of RADG over other procedures, including both short- and long-term outcomes, before it can be accepted as a standard treatment for gastric cancer.

The present study had limitations including the relatively small sample size. The Japanese national insurance system does not reimburse patients for RADG; thus, either the patient or the hospital has to pay the entire admission fee in addition to the surgical fee (around USD \$20,000). It was therefore challenging to recruit sufficient patient numbers even for a small phase II trial, and so long as this situation persists, the cost of such surgeries will be an issue and the forthcoming surgeries will be paid by the hospital or the patient in our hospital. We consider that the future practical use of RADG in Japan as an advanced medical technology will require a well-planned prospective trial involving sufficient patient numbers to provide important information about issues such as reimbursement. However, we also believe that accumulated evidence from smaller prospective studies such as ours will help future, larger-scale trials for RADG.

In conclusion, this early phase II study suggested that RADG might be a safe and feasible procedure for stage IA gastric cancer, providing experienced surgeons perform the surgery. This conclusion should be clarified in subsequent late phase II studies with a larger sample size.

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