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ORIGINAL ARTICLE

Equivalent feasibility and safety of perioperative care by ERAS in open and laparoscopy-assisted distal gastrectomy for gastric cancer: a single-institution ancillary study using the patient cohort enrolled in the JCOG0912 phase III trial

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Abstract

Background Laparoscopy-assisted distal gastrectomy (LADG) has an advantage of earlier recovery after surgery due to having lower invasiveness and wound pain than open distal gastrectomy (ODG). However, whether the same enhanced recovery after surgery (ERAS) program for LADG is equally feasible and safe for ODG remains unclear.

Methods We retrospectively extracted the clinical data of the patients enrolled in JCOG0912 from the medical record system of our hospital and compared the treatment process and short-term surgical outcomes between LADG and ODG. Our ERAS program consisted of 13 elements (4 preoperative, 4 intraoperative, and 5 postoperative elements). The morbidity was defined as complications of grade 2 or more.

Results One hundred and sixty-three patients were entered from our hospital and randomized to undergo ODG (82 patients) or LADG (81 patients). The patient's backgrounds, surgical outcomes, and pathological outcomes were similar between the ODG and LADG groups. The rate of completing the clinical pathway was 95.1% in both groups, and the rates of completing each ERAS element were similar. However, the additional use of acetaminophen was significantly more frequent in the ODG group than in the LADG group (18.3% vs. 6.2%, $p = 0.03$). The median hospital stay after surgery was 9 days in both groups. Morbidity, defined as Clavien–Dindo classification > grade 2, was observed in 6.1% of the ODG group and 11.1% of the LADG group. No mortality occurred in either group.

Conclusion This study showed that the regimen of perioperative care performed by the ERAS program for LADG was equally feasible and safe for ODG with additional pain control. Less pain observed in LADG was not so apparent advantage for completion and safety of ERAS care.

Keywords ERAS · Laparoscopy-assisted distal gastrectomy · Open distal gastrectomy · Randomized

Introduction

Gastric cancer (GC) is the fourth most common malignant disease and the second most frequent cause of cancer-related deaths worldwide [1]. Complete resection is essential for the cure of localized gastric cancer [2, 3].

The use of laparoscopy-assisted distal gastrectomy (LADG) to treat gastric cancer was first described by Kitano in 1994 [4]. Since then, the number of cases of gastric cancer treated with LADG has gradually increased. The advantages of this procedure in comparison to open distal gastrectomy (ODG) include a reduced amount of operative blood loss, reduced pain, an earlier recovery of bowel activity, and

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an earlier resumption of oral intake [5, 6]. With regard to the survival, the Japan Clinical Oncology Group (JCOG) conducted a multi-center phase III trial to confirm the non-inferiority of LADG to ODG for stage I gastric cancer in terms of the relapse-free survival (JCOG0912) [7, 8]. Although JCOG0912 trial showed similar short-term outcomes between LADG arm and ODG arm, it remains unclear whether same perioperative care program is equally feasible and safe for LADG and ODG.

The enhanced recovery after surgery (ERAS) program has been proposed to maintain physiological function and facilitate postoperative recovery [9]. We previously demonstrated that an ERAS program for gastric cancer surgery had advantages not only with regard to an early recovery but also for preventing body weight loss after surgery [10, 11]. As LADG is associated with the clinical advantage of an earlier recovery after surgery than ODG, laparoscopic surgery is recommended in perioperative care under the ERAS program. We therefore hypothesized that the compliance and safety of the ERAS with LADG was superior to the same ERAS with ODG.

The present retrospectively study aimed to confirm our hypothesis in a randomized cohort of patients who received LADG or ODG for gastric cancer as a single-institutional exploratory analysis of the JCOG0912 phase III trial.

Patients and methods

Patients

This study was performed as a single-institution exploratory analysis of the Japan Clinical Oncology Group (JCOG)-0912 trial. The JCOG-0912 trial was a multi-center phase III trial to confirm the non-inferiority of LADG to ODG in terms of the relapse-free survival in patients with clinical stage I gastric cancer diseases that were diagnosed according to the 14th edition of the general rules for gastric cancer published by the Japanese Gastric Cancer Association (UMIN-ID 000003319). The details of the JCOG-0912 trial have been previously reported [8, 12]. The accrual of patients for the JCOG-0912 trial was initiated in March 2010 and terminated in November 2013. Institutions were selected as a stratification factor for randomization in the JCOG-0912 trial. This study is a retrospective comparison of data from patients who were registered for a randomized trial.

The surgical procedures

All of the patients received distal gastrectomy with nodal dissection. D1+or D2 nodal dissection was applied depending on clinical stage IA or IB disease, regardless of the surgical approach.

In accordance with the protocol of the JCOG-0912 trial, one of two certified laparoscopic staff surgeons was responsible for the surgical quality of laparoscopic surgery. Five or six ports were used. Lymph node dissection was performed in the laparoscopic field. The omentum was preserved except where resection was necessary for lymph node dissection along the right gastroepiploic artery. For laparoscopic surgery, a small abdominal incision (<6 cm) was made in the middle or left upper abdomen to remove the specimen and perform reconstruction. For open surgery, an upper abdominal median incision extending from the xiphoid to the navel was created. The nodal dissection and reconstruction procedure was the same in both the laparoscopic and open surgery approaches. Reconstruction was done with Billroth-I gastroduodenostomy, in principle, but Roux-en Y gastrojejunostomy was applied for small remnant stomachs. All of the reconstruction procedures were performed extracorporeally with circular staplers. In addition, in principle, a drain was not placed for laparoscopy or open distal gastrectomy. The nasogastric tube was removed immediately after surgery.

ERAS program

Spanjersberg et al. reported that the perioperative care was regarded as having been carried out per the ERAS protocol if the program included ≥7 of the 17 items constituting ERAS [13]. Our ERAS program included 13 elements (four preoperative, four intraoperative, and five postoperative elements). Previously, we compared the clinical characteristics, oncological factors, surgical factors, and outcomes in patients who underwent elective radical gastrectomy for gastric cancer before and after the introduction of an ERAS protocol. We demonstrated that ERAS protocol was safe and feasible for the patients who underwent elective radical gastrectomy, almost half of which was conducted by the laparoscopic approach. Moreover, the ERAS protocol evaluated in the present study was developed by a team of surgeons and anesthesiologists working in close cooperation with a data safety monitoring committee (DSMC). Audit by the DSMC evaluated feasibility and safety of ERAS care for both ODG and LADG in September 2009, when 50 patients had been treated according to the ERAS protocol.

Preoperative care

Preoperative counseling was held in the outpatient clinic before hospitalization and in the ward after admission. Patients were able to eat a normal diet until the evening meal of the day before surgery. Magnesium oxide and a New Lecicarbon® suppository (Zeria Pharmaceutical Co., Ltd., Tokyo, Japan) were administered on the day before surgery. Patients were asked to drink two 500-ml plastic bottles of OS-1® (2.5% carbohydrate, Otsuka Pharmaceutical,

Tokushima, Japan) 3 h before surgery. Premedication was not administered.

Intraoperative care

Anesthesia consisted of a combination of epidural analgesia and general anesthesia. To prevent hypothermia, a blanket warming system and warming set for intravenous infusions was used.

Postoperative pain management

To prevent postoperative pain, a continuous thoracic epidural infusion of analgesics (Th 7–11) was given until two days after surgery. A non-steroidal anti-inflammatory drug was regularly used to prevent wound pain. Flurbiprofen axetil (50 mg) was intravenously administered twice daily at postoperative days (PODs) 0 and 1, and then 300 mg of acetaminophen was orally given three times daily at PODs 2–6. When the patients complained of wound pain, additional medication of 300 mg of acetaminophen was administered with at least 4-h intervals.

Other postoperative care

On POD 1, patients were encouraged to get out of bed for more than 6 h. On POD 2, the oral intake was started with water and a can of oral nutrition supplement (250 ml Ensure Liquid®, Abbott Japan Co., Ltd., Tokyo, Japan). The patients were encouraged to walk the length of the ward from POD 2. An antithrombotic agent (enoxaparin sodium 2000 IU twice daily or fondaparinux 2.5 mg daily) was injected for 2 days at 6 h after the removal of the epidural catheter. On POD 3, the patients started to eat soft food and graduated stepwise to regular food every 2 days (over three steps). The patients were discharged when they had achieved adequate pain relief and soft food intake, had returned to their preoperative mobility level, and exhibited normal laboratory data on POD 7.

The evaluation of operative morbidity and mortality

The morbidity was defined as complications of grade 2 or more [14]. Operative mortality was defined as postoperative death from any cause within 30 days after surgery or during the same hospital stay.

Completion of the clinical pathway and ERAS element

Completion of the clinical pathway was defined to as the patient being discharged without any delay in the planned surgical care, including oral intake. This definition included two categories. In the first category, the patient was discharged 7–8 days after surgery as planned. In the second category, the patient decided to stay longer for personal reasons and was discharged 9–10 days after surgery. A patient was considered to have dropped out of the clinical pathway if the surgeon decided to change the schedule because of a patient's postoperative condition or complication. Completion of ERAS was assessed based on the outcomes, such as preoperative counseling, the use of oral bowel preparation, preoperative fasting or treatment with carbohydrates, no preanaesthetic medication, the use of epidural analgesia, the use of a short-acting anesthetic agent, the use of warm air body heating in the surgery theater, the avoidance of sodium/fluid overload, the prevention of nausea and vomiting, the stimulation of gut motility, the early removal of catheters, perioperative oral nutrition, and the adoption of the mobilization care pathway.

Statistical analyses and ethical considerations

The length of hospital stay (LOS) was defined as the number of nights spent in the hospital after surgery. Adherence to each ERAS protocol element was specifically reviewed. The values were expressed as the median and range. The data were compared using the chi-squared test and Wilcoxon's signed-rank test. p values of < 0.05 were considered to indicate statistical significance. The SPSS software program (version 12.0 J Win; SPSS, Chicago, IL, USA) was used for all of the statistical analyses. The R category and extent of dissection were determined according to the Japanese Classification of Gastric Carcinoma, third English edition and the Japanese Gastric Cancer Association guidelines [15, 16]. The institutional review board of our hospital approved the JCOG-0912 phase III study and this exploratory analysis. The primary investigators of the JCOG-0912 trial, the representative director of the JCOG Gastric Cancer Study Group, and the chairperson of the JCOG approved this exploratory study of the JCOG-0912 trial. All of the data were prospectively collected. This study was in compliance with the Declaration of Helsinki.

Results

Background

This retrospective study examined 163 patients who were registered to JCOG-0912 from Kanagawa Cancer Center and were randomized to undergo ODG (82 patients) or LADG (81 patients). A flow diagram of the study is shown in Fig. 1. Three patients who were assigned to LADG needed conversion to ODG (two due to bleeding and one due to serosal invasion). Although the background characteristics and

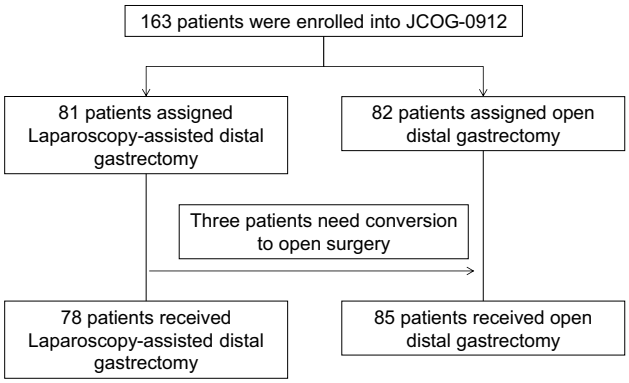

Fig. 1 Consort diagram of the present study

baseline data were well-balanced between the both groups, age was marginally higher in the ODG group as compared with LADG group ($p = 0.116$) (Table 1).

The surgical and pathological outcomes

The duration of surgery in the LADG group was significantly longer than that in the ODG group ($p < 0.001$). In contrast, the amount of bleeding in the LADG group tended to be lower than that in the ODG group ($p = 0.082$). In addition, the length of the skin incision in the LADG group was significantly shorter than that in the ODG group ($p < 0.001$) (Table 2). No marked differences in the pathological outcomes between the two groups were observed.

No mortalities occurred in either group. The surgical morbidities are shown in Table 3. The incidences of surgical complications were similar between the two groups.

Clinical course after surgery

Completing the clinical pathway was achieved in 95.1% of cases in both groups. The reason for dropping out from the clinical pathway was postoperative complications in all cases. The rate of adherence to each element of the ERAS program was also similar in both groups (Table 4). However, the additional use of acetaminophen was significantly more frequent in the ODG group than in LADG group (18.3% vs. 6.2%, $p = 0.03$).

The median hospital stay after surgery was 9 days (range 6–76 days) in the ODG group and 9 days (range 7–18 days) in the LADG group, with no significant difference between the two groups.

Discussion

The aim of the present study was to confirm our hypothesis that compliance and safety of ERAS with LADG is superior to that with ODG. Because of age was slightly higher in

Table 1 A comparison of the patients' backgrounds

	LADG ($n = 81$, [%])	ODG ($n = 82$, [%])	p value
Age, years (median) (range)	63 (33–79)	67 (36–80)	0.116
Gender			0.952
Male	51 (63.0%)	52 (63.4%)	
Female	30 (37.0%)	30 (36.6%)	
ASA-PS			0.600
1	24 (29.6%)	25 (30.5%)	
2	56 (69.1%)	57 (69.5%)	
3	1 (1.3%)	0 (0%)	
Total body weight, kg (median) (range)	60 (37–82)	56 (41–81)	0.216
Body mass index (median) (range)	22.4 (16.4–27.6)	21.9 (16.4–27.7)	0.185
Clinical T factor			0.570
T1	56 (69.1%)	60 (73.1%)	
T2-	25 (30.9%)	22 (26.9%)	
Clinical N factor			0.572
Negative	80 (98.7%)	80 (97.6%)	
Positive	1 (1.3%)	2 (2.4%)	
Comorbidity			
Hypertension	35 (43.2%)	27 (32.9%)	0.176
Diabetes mellitus	6 (7.4%)	4 (4.9%)	0.501
COPD	7 (8.6%)	8 (9.8%)	0.806

ASA-PS ASA physical status, *COPD* chronic obstructive pulmonary disease, *LADG* laparoscopy-assisted distal gastrectomy, *ODG* open distal gastrectomy

Table 2 Surgical and pathological outcomes

	LADG ($n=81$, [%])	ODG ($n=82$, [%])	p value
Lymph node dissection			0.817
D1+dissection	63 (77.8%)	65 (79.3%)	
D2 dissection	18 (22.2%)	17 (20.7%)	
Reconstruction			0.151
Billroth-1	62 (76.5%)	70 (85.4%)	
Roux-en-Y	19 (23.5%)	12 (14.6%)	
Bleeding, g (median) (range)	50 (5–1400)	130 (20–690)	0.082
Operation time, min (median) (range)	288 (97–587)	175 (85–418)	<0.001
Length of skin incision (cm), median (range)	5.8 (5–23)	16 (12.5–22)	<0.001
Number of harvested lymph nodes (median, range)	41 (15–92)	39 (11–114)	0.916
Pathological T factor			0.802
-T1	68 (84.0%)	70 (85.4%)	
T2-	13 (16.0%)	12 (14.6%)	
Pathological N factor			0.482
Negative	73 (90.1%)	71 (86.6%)	
Positive	8 (9.9%)	11 (13.4%)	

LADG laparoscopy-assisted distal gastrectomy, *ODG* open distal gastrectomy

Table 3 A comparison of the morbidity and mortality between the ODG and LADG groups

	LADG ($n=81$, [%])	ODG ($n=82$, [%])	p value
Total cases	9 (11.1%)	5 (6.1%)	0.253
Pancreatic fistula	Grade 2: 4	Grade 3a: 1	
Anastomotic leakage	–	Grade 2: 1 Grade 3a: 2	
Abdominal abscess	Grade 3a: 1	–	
Pneumonia	Grade 2: 2	–	
Ileus	Grade 2: 1	–	
Anastomotic stenosis	–	Grade 3b: 1	
Delayed gastric emptying	–	Grade 3a: 1	
Postoperative bleeding	Grade 2: 1	–	
Surgical site infection	–	Grade 2: 1	

LADG laparoscopy-assisted distal gastrectomy, *ODG* open distal gastrectomy

ODG group than LADG group, LADG group has a potential advantage for completion and safety of ERAS as compared with ODG. However, the present study showed that accomplishment of clinical pathway and the adherence of each element of ERAS program were almost similar in both LADG group and ODG group. In addition, the incidence of accomplishment of clinical pathway was similar to our previous reports. These results suggested that the ERAS program is equally feasible and safe both for LADG and ODG. However, the additional use of acetaminophen was significantly more frequent in the ODG group than in LADG group in the present study, indicating that postoperative pain was more frequent and severe in ODG than in LADG. Similar to the present study, the JCOG-0912 trial also showed that the use of analgesics after POD 5 was more frequent in the open surgery arm than in the laparoscopic surgery arm (270 [59.3%] with open surgery vs. 230 [50.3%] with laparoscopic surgery, $p=0.006$) [12]. Postoperative pain might be stronger and/or more frequent with ODG than LADG. Takiguchi et al. evaluated the postoperative physical activity and visual analog scale (VAS) for pain after LADG and ODG in a randomized study using the same perioperative care [17]. They found that the VAS score at rest and walking results were significantly lower in the LADG arm than in the ODG arm. Although the same ERAS program can be used for ODG, additional pain control seems to be necessary.

In the present study, the incidence and details of postoperative surgical complications were also similar between the two groups, which were concordant with the results of the JCOG-0912 trial [12]. Grade ≥ 3 surgical complications were observed in 4.9% (5/103) of the patients in the current study and 3.5% (32/912) of the patients in the JCOG-0912 trial. In

Table 4 A comparison of the postoperative course and completion of ERAS elements between the ODG and LADG groups

	LADG ($n=81$, [%])	ODG ($n=82$, [%])	p value
Accomplishment of clinical pathway			0.986
Yes	77 (95.1%)	78 (95.1%)	
No	4 (4.9%)	4 (4.9%)	
Hospital stay (median, range)	9 (7–18)	9 (6–76)	0.667
Re-admission rate	0%	0%	–
Additional use of analgesics after planned use	5 (6.2%)	15 (18.3)	0.030
Compliance of each ERAS elements			
Preoperative counseling	100%	100%	–
Use of oral bowel preparation	100%	100%	–
Preoperative fasting and preoperative treatment with carbohydrates	100%	100%	–
No preanaesthetic medication	100%	100%	–
Use of epidural analgesia	93.8% (76/81)	96.3% (79/82)	0.458
Use of a short-acting anesthetic agent	100%	100%	–
Use of warm air body heating in the surgery theater	100%	100%	–
Avoidance of sodium/fluid overload	100%	100%	–
Prevention of nausea and vomiting	100%	100%	–
Stimulation of gut motility	100%	100%	–
Early removal of catheters	100%	100%	–
Gastric tube after surgery	100%	100%	
Urinary catheter at POD3	100%	100%	
Epidural catheter at POD3			
Perioperative oral nutrition	100%	100%	–
Mobilization care pathway	100%	100%	–

ERAS enhanced recovery after surgery, *POD* postoperative day, *LADG* laparoscopy-assisted distal gastrectomy, *ODG* open distal gastrectomy

addition, the rates of grade ≥ 3 pancreatic fistula (1.0% vs. 0.4%), anatomic leakage (1.0% vs. 0.2%), and abdominal abscess (1.0% vs. 1.6%) were similar in the present study and JCOG-0912 trial. Thus, our randomized cohort had a similar safety profile to the cohort of the JCOG-0912 trial, which suggested that the present results were not specific to our randomized cohort and could be generalized to the cohort of the JCOG-0912 trial. The same ERAS program would be safe for both LADG and ODG without increasing the risk of postoperative complications and mortality.

The length of hospital stay after surgery was similar between the two groups. Recent randomized trials of ODG vs. LADG for gastric cancer have shown that the hospital stay was shorter and the recovery of function and clinical course faster with LADG than with ODG [18, 19]. However, the details of the perioperative management and the discharge criteria in the previous studies were unclear. Therefore, the faster recovery and shorter hospital stay observed in LADG might be due to differences in the perioperative management rather than differences in the surgical approach. Some investigators have reported that discharge at POD 6 or 7 was possible in patients who received LADG, which conflicts with the protocol of our ERAS program, where discharge is set at POD 8 or 9, since the recovery of the oral intake typically takes at least one week after gastrectomy [20, 21]. Whether a 6- or 7-day program is suitable for patients who have undergone ODG remains unclear.

Several limitations associated with the present study warrant mention. First, the recovery of physical activity was not evaluated in this study. A low physical activity may cause rare but serious complications, such as vein thrombosis or pulmonary embolism. The sample size of the present study was too small to show the differences in such morbidities. Second, the quality of life (QOL) was not shown in the present study. As such, whether the QOL is equally maintained after ODG and LADG remains unclear. The suitable duration for perioperative care must be determined by considering the risk and QOL. The present study cannot guarantee that the duration of the hospital stay was equally suitable for LADG and ODG.

In conclusion, the present study showed that perioperative care performed according to the ERAS program for LADG was equally feasible and safe for ODG with additional pain control. Less pain observed in LADG was not so apparent advantage for completion and safety of ERAS care.

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Compliance with ethical standards

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

Human rights The study data and informed consent were obtained in accordance with the Declaration of Helsinki and were approved by the Ethics Review Board of Kanagawa Cancer Center.

Informed consent Informed consent or substitute for it was obtained from all patients for being included in the study.

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