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Comparison of Laparoscopic Distal Gastrectomy With Open Distal Gastrectomy for Patients With Advanced Gastric Cancer: A Single-Center Analysis From a Community Hospital

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Objective: This study is aimed to investigate the safety and efficacy of laparoscopic distal gastrectomy (LDG) at the community hospital.

Summary of Background Data: Although various clinical trials have shown that laparoscopic distal gastrectomy was feasible in patients with early gastric cancer, its safety and efficacy for patients with advanced gastric cancer need to be elucidated.

Methods: Patients with pathological Stage IB-III gastric cancer who underwent open distal gastrectomy (ODG) or LDG with D1+ or more extended lymph node (LN) dissection between 2007 and 2014 were eligible for this retrospective study. Patient characteristics, clinicopathologic factors, and post-treatment recurrence were recorded. To evaluate the safety of the surgery, surgical outcomes and postoperative complication were investigated.

Results: 638 patients underwent gastrectomy for gastric cancer, with 67 patients included in ODG group and 61 included in LDG group. Patients in the ODG group showed significantly more progressive disease than those in the LDG group. Postoperative

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infectious complications, [≥Clavien-Dindo (C-D) classification grade III] occurred 6% in all patients, and there was no significant difference between groups. Hospital stay (median, range) was (9, 6–45) in ODG and (7, 5–58) in LDG, with significantly shorter stays in the LDG group (<0.001).

Conclusions: LDG could be safely performed for advanced gastric cancer in a community hospital. However, long-term outcomes, including types of postoperative recurrence, need further evaluation.

Key words: Advanced gastric cancer – Distal gastrectomy – Laparoscopic gastrectomy – Peritoneal recurrence – Postoperative complication

From the view point of a minimally invasive approach, laparoscopic gastrectomy (LG) has been widely accepted worldwide. In patients who underwent LG, postoperative analgesics could be reduced, and the amount of intraoperative hemorrhage was less than that during open gastrectomy (OG).[1] In contrast, operative time was shown to be significantly longer in LG group, and surgical trainees take longer to learn the required skills for LG. Katai *et al* reported the short-term outcome of a randomized controlled trial, which compared open distal gastrectomy (ODG) with laparoscopic distal gastrectomy (LDG) in patients with gastric cancer [cT1N0-1, T2N0].[1] Consequently, there was no significant difference in the incidence of postoperative surgical complications. The time to first flatulence was shorter and the amount of analgesics used was less in the LDG group. In the KLASS 01 trial, postoperative morbidity rate was significantly less in the LDG group.[2] In terms of long-term outcome for LG, there was a large-scale historical cohort trial for cStage I gastric cancer patients, showing that LG was comparable to OG.[3]

In contrast, concrete evidence about the safety and efficacy of LG for patients with advanced gastric cancer is not available. The safety of LDG for patients with advanced gastric cancer was reported in a prospective phase II trial in Japan.[4] The incidence rate of postoperative complications and the mortality rate was acceptable in the study, and long-term outcome has been investigated in the subsequent phase III trial. In CLASS01 trial, the safety of LDG for patients with advanced gastric cancer (cT2-4aN0-3M0) was compared to ODG,[5] with no significant difference in morbidity rate between the groups.

As shown in previous reports, the clinical outcome of gastrointestinal cancer surgery could be impacted by hospital volume.[6,7] Furthermore, LDG for advanced gastric cancer is technically challenging. Therefore, to standardize the surgical procedure, the clinical outcome needs to be elucidated in community hospitals. In the present study, short- and long-term outcomes were reviewed and compared for LDG and ODG in patients with advanced gastric cancer in one community hospital in Japan.

Materials and Methods

Patient selection and study design

LG was introduced in 2007 at our institution. In the present study, patients who were histologically diagnosed with gastric adenocarcinoma and underwent gastrectomy in Saiseikai Yokohamashi Tobu Hospital in 2007–2014 were retrospectively reviewed. All patients were informed that the standard treatment for advanced gastric cancer in Japan was OG. When a patient requested a laparoscopic procedure, LG was performed. To evaluate surgical outcomes and survival between groups, patients with pStage IB-III gastric cancer who underwent ODG or LDG with D1+ or more extended LN dissection were included. To determine clinical stages, all patients were assessed by esophagogastroduodenoscopy (EGD) and computed tomography (CT) before treatment. Endoscopic ultrasonography (EUS) is not routinely included as a part of pretreatment examinations at our institution. However, for patients in whom precise pretreatment evaluation could not be determined using EGD and CT, EUS was additionally performed. The present study was conducted with the approval of the Ethics Committee of Saiseikai Yokohamashi Tobu Hospital. The extent of tumor spread was evaluated according to the 14th edition of the *Japanese Classification of Gastric Carcinoma*, which was established by the Japanese Gastric Cancer Association.[8]

Open and laparoscopic distal gastrectomy

As a curative surgery, distal gastrectomy with D1+ or D2 was performed. The range of LN dissection was determined on the basis of the 4th version of the *Gastric Cancer Treatment Guidelines* in Japan.[9] D1+ dissection was applied in patients with cStage IA gastric cancer, and D2 dissection was applied in patients with cStage IB-III gastric cancer. However, if a patient was more than 75 years old or had comorbidities, the range of LN dissection was reduced to D1+. Billroth-I reconstruction (B-I) after gastrectomy has been most frequently performed at our institution. When the B-I was not applicable, Roux-en Y reconstruction was performed. Billroth-II reconstruction was selected for elderly patients because the anastomosis was more straightforward and surgical duration could be reduced. All ODG were supervised by the board certified surgeons of the Japanese Surgical Society, all LDG supervised by TE or KM, who are the Japanese endoscopic surgical skill qualification-system qualified surgeons.

Surgical outcome, postoperative complications, and number of dissected lymph nodes

Patient characteristics, clinicopathologic factors, post-treatment recurrence, and survival were recorded. We investigated American Society of Anesthesiologists (ASA) physical status classification and body mass index (BMI) to evaluate the status of patients. To evaluate the safety of the surgery, operative time and total blood count were reviewed. The Clavien-Dindo (C-D) classification was used to evaluate postoperative complications. In the present study, postoperative infectious complications, including anastomotic leakage (C-D $\geq$ grade IIIa), pancreatic fistula (C-D $\geq$ grade IIIa), and deep organ surgical site infection (C-D $\geq$ grade IIIa), were investigated. As one of the indicators of surgical efficacy, the number of dissected LNs was reviewed. To evaluate the intensity of postoperative inflammatory response, serum C-reactive protein (CRP) levels on postoperative days 1 and 3 were investigated in patients who underwent surgery since March 2012 when we started to measure CRP routinely in postoperative management in our department.

Follow-up

Post-treatment follow-up included EGD and CT every 6 months for 5 years after initial treatment. Recurrence-free survival (RFS) for all patients was calculated from the date of surgery to the date of recurrence, and death without any sign of recurrence was considered a censored case. Patients were followed up until death or until the completion of the study (December 31, 2016). Those who were lost to follow-up before death or the completion of the study were censored as of their last visit. The pattern of recurrence was reviewed to compare the incidence of peritoneal recurrence between groups.

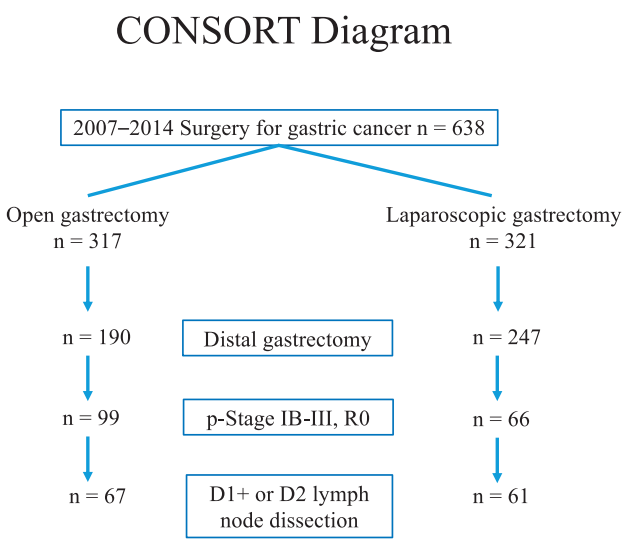

Fig. 1 Patient selection flow diagram.

Statistical analysis

Means and standard deviations were calculated, and differences were identified using Student's *t* test. In nonparametric analysis, Mann–Whitney U test was used. Chi-square test or Fisher's exact test was used to identify imbalanced factors between categories. In multivariate analysis for postoperative complications, logistic regression analysis was used. Kaplan–Meier method was used to produce survival curves, and RFS was determined. In the analyses of RFS, two-sided log-rank test was used to compare Kaplan–Meier curves. SPSS Statistics Version 24 for Windows (IBM, Chicago, IL, USA) was used to perform all statistical analyses, and differences were considered significant for $P < 0.05$.

Results

Patient selection

In 2007–2014, 638 patients underwent gastrectomy for gastric cancer. Of these, 317 patients underwent OG and 321 patients underwent LG. As shown in the CONSORT diagram in Fig. 1, of 437 patients who

Table 1 Patient characteristics and clinicopathologic factors

	All patients, n = 128	ODG, n = 67	LDG, n = 61	*P*
Age (mean ± SD)	69.9 ± 11.3	70.2 ± 11.1	69.5 ± 11.6	0.741
Sex				0.003
Male	84 (66%)	36 (54%)	48 (79%)	
Female	44 (34%)	31 (46%)	13 (21%)	
NAC				0.462
Done	16 (12%)	7 (10%)	9 (15%)	
Not done	112 (88%)	60 (90%)	52 (85%)	
ASA score				<0.001
1	61 (48%)	45 (67%)	16 (26%)	
2	55 (43%)	19 (28%)	36 (59%)	
3	12 (9%)	3 (5%)	9 (15%)	
BMI (median, range)	21.9, 13.9–35.1	20.9, 13.9–29.9	23.8, 15.4–35.1	<0.001
Location of primary tumor				0.463
U	1 (1%)	1 (1%)	0 (0%)	
M	62 (48%)	30 (45%)	32 (52%)	
L	65 (51%)	36 (54%)	29 (48%)	
Histology				0.873
Differentiated	66 (52%)	35 (52%)	31 (51%)	
Undifferentiated	62 (48%)	32 (48%)	30 (49%)	
cStage				<0.001
cStage I	35 (28%)	8 (12%)	27 (44%)	
cStage II	53 (41%)	33 (49%)	20 (33%)	
cStage III	40 (31%)	26 (39%)	14 (23%)	
pT				0.417
pT1	11 (8%)	4 (7%)	7 (11%)	
pT2	24 (19%)	13 (19%)	11 (18%)	
pT3	70 (55%)	35 (52%)	35 (57%)	
pT4	23 (18%)	15 (22%)	8 (13%)	
pN				0.039
pN0	48 (38%)	19 (28%)	29 (48%)	
pN1	35 (27%)	17 (25%)	18 (30%)	
pN2	24 (19%)	16 (24%)	8 (13%)	
pN3	21 (16%)	15 (23%)	6 (9%)	
pStage				0.082
pStage IB	21 (17%)	9 (14%)	12 (20%)	
pStage II	63 (49%)	29 (43%)	34 (56%)	
pStage III	44 (34%)	29 (43%)	15 (24%)	

LDG, laparoscopic distal gastrectomy; ODG, open gastrectomy.

underwent distal gastrectomy, 165 underwent curative (R0) surgical resection and were diagnosed with pStage IB-III gastric cancer. In addition, 128 patients who underwent distal gastrectomy with D1+ or D2 LN dissection were included in the analysis. In addition, 67 patients in the ODG group and 61 patients in the LDG group did not have surgical conversion from LDG to ODG. Four patients who underwent robotic distal gastrectomy were included in the LDG group. The median follow-up, which was defined as the follow-up period of patients who did not show postoperative tumor recurrence, was 41 months. There was no significant difference between the ODG and LDG group (ODG: 45 months, LDG: 36 months, $P = 0.322$).

Patient characteristics and clinicopathologic factors: comparison between ODG and LDG

The patient characteristics are shown in Table 1. Of 128 patients, 66% were male. Both ASA score and BMI were significantly higher in the LDG group. Of all patients, 12% received neoadjuvant chemotherapy and 48% were diagnosed with undifferentiated tumors, without any significant difference between groups. Regarding clinicopathologic factors, 28% of all patients were diagnosed with cStage I, including 9 patients with cStage IA before surgery. The patients in the ODG group showed significantly more advanced disease ($P < 0.001$). There was no significant difference in the depth of the primary tumor; however, pathologic nodal status was sig-

Table 2 Surgical outcomes, postoperative complications, and number of dissected lymph nodes

	All patients, n = 128	ODG, n = 67	LDG, n = 61	*P*
Time (min; median, range)	294, 150–510	245, 150–353	321, 200–510	<0.001
Blood (g; median, range)	135, 0–1964	333, 50–1964	50, 0–570	<0.001
Reconstruction				0.054
B-I	63 (49%)	29 (43%)	34 (56%)	
B-II	10 (8%)	3 (4%)	7 (11%)	
R-Y	55 (43%)	35 (52%)	20 (33%)	
Range of LN dissection				0.106
D1+	24 (19%)	9 (13%)	15 (25%)	
D2	104 (81%)	58 (87%)	46 (75%)	
Postoperative complication (≥C-D grade III)				
Infectious complication	8 (6%)	5 (7%)	3 (4%)	0.720
Leakage	2 (2%)	1 (1%)	1 (2%)	
Pancreatic fistula	4 (3%)	3 (4%)	1 (2%)	
Deep organ SSI	2 (2%)	1 (1%)	1 (2%)	
Hospital stay (days; median, range)	8, 5–45	9, 6–45	7, 5–58	<0.001
Number of LN dissected (median, range)	33, 12–66	33, 15–66	29, 9–59	0.591

B-I, Billroth-I reconstruction; B-II, Billroth-II reconstruction; C-D, Clavien-Dindo classification; LDG, laparoscopic distal gastrectomy; LN, lymph node; ODG, open gastrectomy; R-Y, Roux-en Y reconstruction.

nificantly worse in the ODG group ($P = 0.031$). Pathological stage tended to be progressed in the ODG group without significance.

Surgical outcomes, postoperative complications, and number of dissected lymph nodes

Surgical outcomes are shown in Table 2. The operative time was significantly longer in the LDG group (ODG, 245 minutes; LDG, 321 minutes, $P < 0.001$), and the amount of hemorrhage was significantly larger in the ODG group (ODG, 333g; LDG, 50g, $P < 0.001$). When patients who underwent robotic-assisted distal gastrectomy were excluded from analysis, the significant difference in operative time and hemorrhage were maintained. Regarding range of LN dissection, 81% of patients underwent gastrectomy with D2 LN dissection. Postoperative infectious complications (≥C-D grade III) occurred in 6% of all patients, including an incidence rate of 2% for leakage, 3% for pancreatic fistula, and 2% for deep organ surgical site infection (SSI). There was no significant difference between the ODG and LDG groups. To investigate the difference in cStage between the ODG and LDG groups, we conducted logistic multiregression analysis using age, sex, neoadjuvant chemotherapy, cStage, and ODG/LDG as covariates. The surgical approach was not shown to be an independent factor in predicting postoperative infectious complications. Median hospital stay was 9 days in the ODG group and 7 days in the LDG group, which was significantly shorter in the LDG group (<0.001). In terms of efficacy of surgery, there was no difference in the number of dissected LN between groups. When the inflammatory response induced by surgery was investigated, serum CRP was examined on postoperative days 1 and 3 in 69 patients (54%) with no significant difference in CRP levels (Table 3).

Survival analysis and incidence of peritoneal recurrence

In survival analysis, no significant difference was observed between the ODG and LDG groups for patient with cStage I/II/III gastric cancer in RFS (Fig. 2). In patients with cStage III gastric cancer, those in the ODG group tended to show worse prognosis (ODG, 58.0% with 3 years RFS; LDG, 78.6% with 3 years RFS, $P = 0.185$). Regarding the type of postoperative recurrence, in 18 ODG patients who had recurrence, 9 patients (50%) showed peritoneal metastasis. In the LDG group, 7 out of 9

Table 3 Postoperative serum C-reactive protein level

	All patients, n = 69	ODG, n = 33	LDG, n = 36	*P*
CRP POD 1 (mg/dL; median, range)	6.49, 0.50–13.07	6.63, 2.70–13.07	5.83, 0.50–12.59	0.239
CRP POD 3 (mg/dL; median, range)	9.46, 1.24–29.20	9.07, 2.20–21.96	10.42, 1.24–29.20	0.337

CRP, C-reactive protein; LDG, laparoscopic distal gastrectomy; ODG, open distal gastrectomy; POD, postoperative day.

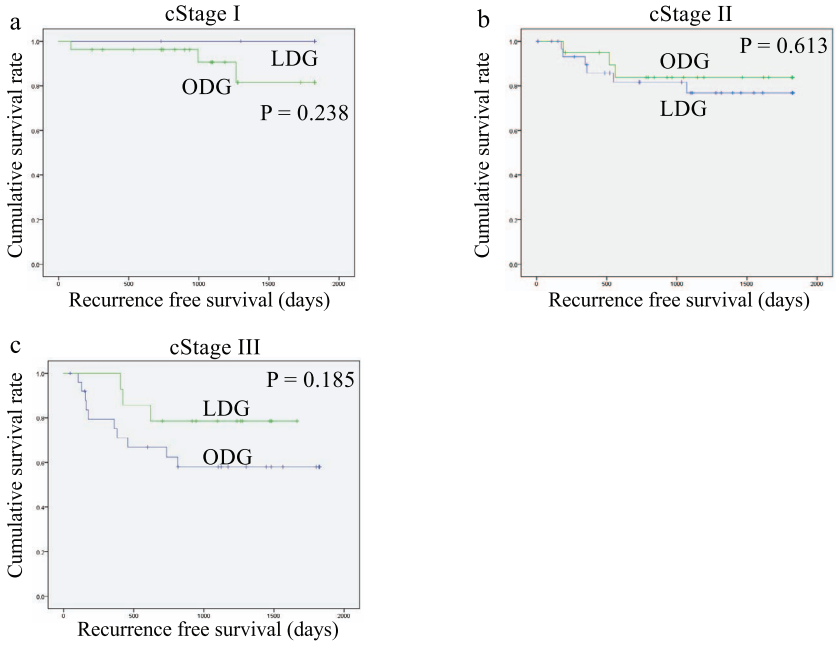

Fig. 2 Postoperative recurrence-free survival. Under the stratification by cStage, there was no significant difference in recurrence-free survival (RFS) between LDG and ODG in cStage I, cStage II, and cStage III. LDG; laparoscopic distal gastrectomy, ODG; open distal gastrectomy.

patients (78%) showed peritoneal metastasis. Although not significant, peritoneal recurrence was observed frequently in the LDG group.

Discussion

On the basis of the retrospective study of a single institution, LDG was shown to be comparable to ODG in advanced gastric cancer patients. In short-term outcome, no difference was observed in postoperative infectious complications between the ODG and LDG groups, and the total blood count during surgery was smaller in the LDG group, indicating that LDG can be safely performed in advanced gastric cancer. Although the background of patients may differ between groups, hospital stay was shown to be shorter in the LDG group. Based on these results, LDG for advanced gastric cancer under supervision by certified surgeon is feasible to be performed in a community hospital.

To date, the various previous studies have shown that LDG has been safely conducted in early gastric cancer.[10,11] Conversely, in advanced gastric cancer, extended LN dissection is recommended, and bulky tumor may make mobilization during surgery more challenging. In the present study, surgical time was longer in the LDG group, which was consistent with previous reports. Previously, several groups showed that longer operative time was independently associated with postoperative outcome, including infectious complications.[12,13] However, in the current analysis, there was no significant difference in short- and long-term outcomes, even with significantly longer operative time in the LDG group. Even though longer operative time might not be feasible in terms of cost, the safety of LDG was not be affected by longer operative time. In terms of LN dissection, there was no significant difference in the number of dissected LNs, which demonstrates that the quality of LN dissection is comparable for ODG and LDG. In addition, there was no significant difference in postoperative complications. In general, the magnified view in LDG enables the surgeon to visualize the adequate dissection line between LN and organs such as pancreas, thereby possibly reducing the risk of postoperative complications. In fact, the total blood count was smaller in the LDG group, illustrating that a more precise surgical procedure could be achieved with LDG.

Although several retrospective trials from high volume centers have been coming out showing long-term survival after LDG in patients with advanced gastric cancer,[14,15] it has not been fully clarified yet. In LDG, the surgeon needs to grasp the gastric wall or tissue around LNs with forceps, which produces more focal manipulation than open surgery. In the present study, there was no significant difference in RFS in cStage IB and II patients, showing that LDG can be safely performed. Although patients with cStage III gastric cancer tended to have worse RFS, patients with progressed nodal status were observed in the ODG group. Because of

a limited number of cases, the background of patients could not be matched. Therefore, long-term outcome needs further evaluation in the current ongoing prospective trials.

In terms of the type of recurrence, peritoneal recurrence rate tended to be higher in the LDG group. In advanced gastric cancer, the choice of surgical procedure may influence the oncological outcome. When the laparoscopic forceps touch the primary tumor or metastatic LNs, tumor cell may spill into the abdomen. Furthermore, in highly advanced gastric cancer, peritoneal lavage after surgery was shown to reduce peritoneal metastasis.[16] Although peritoneal lavage has been routinely performed in LDG, its efficacy may not be comparable to ODG. In the present study, because of the difference in pathological stage between groups, the tendency of increased peritoneal recurrence could not be directly linked to surgical approach. However, the present study showed that LDG could potentiate to increase the peritoneal recurrence in patients with advanced gastric cancer.

The present study was limited to retrospective assessments. The patients who underwent OG or LG in our institution were reviewed on the basis of an established flow diagram, which led to reduced selection bias. Another limitation was that the patients in the LDG group were selected on the basis of the patients' preference for a laparoscopic procedure. As a result, the background of patients could influence the long-term outcome, which is consistent with a poor prognosis in patients in the ODG group with cStage III gastric cancer. In terms of the patients' status before surgery, both ASA score and BMI were significantly higher in the LDG group. In general, higher ASA could be disadvantageous for surgery, and higher BMI may increase the difficulty of surgery. Regardless of these challenges, surgical outcomes in LDG did not differ from ODG, indicating that LDG could be safely performed.

In conclusion, LDG could be safely performed for advanced gastric cancer in a community hospital. However, long-term outcomes, including types of postoperative recurrence, need further evaluation.

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