



Laparoscopic Versus Open Distal Gastrectomy With D2 Lymph Node Dissection for cT2 Gastric Cancer: A Retrospective Cohort Study of Short- and Long-Term Outcomes

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The purpose of this study was to determine whether laparoscopy-assisted distal gastrectomy (LDG) with D2 lymphadenectomy could be a standard treatment for cT2N0-1 gastric cancer. There have been few reports regarding the long-term outcomes of patients with advanced gastric cancer who underwent LDG with D2 lymphadenectomy. The study included 32 patients who underwent LDG with D2 lymphadenectomy and 44 patients who underwent open distal gastrectomy (ODG) with D2 lymphadenectomy. There was no clinicopathologic difference in patient background between the groups. Operative duration was significantly longer in the LDG group than in the ODG group (297 ± 12 minutes versus 226 ± 10 minutes; $P < 0.001$). However, blood loss was significantly less (90 ± 27 mL versus 314 ± 23 mL; $P < 0.001$) and the number of days to assisted ambulation significantly shorter (1.1 ± 0.1 days versus 1.5 ± 0.1 days; $P = 0.010$) in the LDG group than in the ODG group. Median follow-up period was 60 months. The 5-year overall survival rates for the LDG group and the ODG group were 89.5% and 97.1%, respectively. The 5-year relapse-free survival rates for the LDG group and the ODG group were 88.0% and 97.7%, respectively. There were no significant differences in overall and relapse-free survival rates between the groups. LDG with D2 lymphadenectomy for cT2N0-1 gastric cancer is oncologically and technically safe and feasible, and is

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an option in the surgeon's arsenal. Randomized controlled study including the investigation of cost-effectiveness should be conducted.

Key words: Retrospective cohort study – Laparoscopy – Gastrectomy – Lymph node excision
– Treatment outcome – Prognosis

Laparoscopy-assisted distal gastrectomy (LDG) was first reported in 1994.¹ Since then, it has been widely performed for early gastric cancer, although it is currently considered an investigational treatment in Japan. Short-term outcomes of LDG versus open distal gastrectomy (ODG) for early gastric cancer, including estimated blood loss, post-operative pain, and recovery of bowel function, have been reported to be better for LDG than for ODG in several randomized controlled trials.^{2–4} Short-term outcomes of LDG with D2 lymph node dissection versus ODG with D2 lymph node dissection for resectable advanced gastric cancer have also been reported for a few retrospective case-control studies. Results of these studies also favored LDG. However, long-term outcomes, including overall survival (OS) and relapse-free survival (RFS), have not yet been reported for early or advanced gastric cancer in randomized, controlled settings.

D2 lymph node dissection has been widely accepted as standard treatment for resectable advanced gastric cancer in Eastern countries, including Japan, but is not performed in Western countries because no survival benefit has been demonstrated, and increased morbidity and mortality have been reported.^{5,6} However, since publication of the 15-year follow-up results of a Dutch trial,⁷ D2 lymph node dissection has gradually become more accepted in the West. Laparoscopic D2 lymph node dissection is an essential part of laparoscopic surgery for resectable advanced gastric cancer. However, it is not known whether laparoscopic D2 lymph node dissection is comparable to open D2 lymph node dissection in terms of survival outcomes.

If survival rates prove to be the same for both approaches, then LDG with D2 lymph node dissection for resectable advanced gastric cancer could become one of the standard treatment modalities.

The purpose of this study was to clarify whether LDG with D2 lymph node dissection can be considered a standard treatment for cT2N0 and cT2N1 gastric cancer.

Patients and Methods

This study was conducted in accordance with the 1995 Declaration of Helsinki (as revised in Edin-

burgh 2000) and was approved by the of Kitasato University School of Medicine Research Ethics Committee. The requirement for informed consent was waived because of the study's retrospective design.

Patients

We retrospectively reviewed the medical records of 34 consecutive patients who underwent LDG with D2 dissection for cT2N0 or cT2N1 gastric cancer from April 2005 to December 2011, and 50 consecutive patients who underwent ODG with D2 dissection for cT2N0 or cT2N1 gastric cancer from January 2006 to December 2011. Median length of follow-up was 60 months [interquartile range (IQR), 44–71 months]. Clinical and pathologic tumor depth (cT and pT), and lymph node metastasis (cN and pN) were classified according to the International Union Against Cancer TNM staging system, seventh edition.⁸ Clinical diagnosis of tumor depth was made using either endoscopic ultrasonography or a combination of barium examination and gastro-fibroscopy. Clinical diagnosis of lymph node metastasis was made using computed tomography. A clinically metastatic lymph node was one with a longest diameter (long axis) of ≥ 10 mm or a longest diameter perpendicular to that (short axis) of ≥ 8 mm. D2 dissection was defined according to the Japanese gastric cancer treatment guidelines 2010 (version 3).⁹ The choice of surgical procedure (open or laparoscopic) was based on the patient's choice after the risks and benefits of each procedure had been explained and informed consent obtained. Patients with tumors other than adenocarcinoma and those who had a previous history of upper abdominal surgery were excluded. Patients who underwent simultaneous resection of organs other than the gallbladder were also excluded. The remaining 32 patients who had undergone LDG with D2 dissection and 44 patients who had undergone ODG with D2 dissection were enrolled. The same clinical pathway was used for both groups. Short- and long-term outcomes were compared between groups.

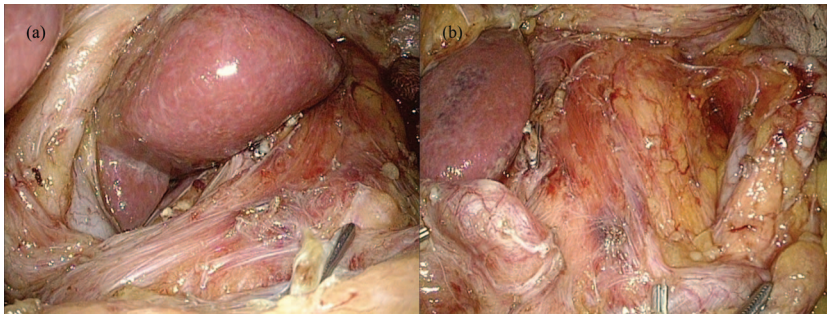


Fig. 1 Laparoscopic view of D2 lymph node dissection. (a) The lymph nodes along the hepatic artery (no. 12a) have been dissected, and the portal vein is exposed. (b) The lymph nodes along the proximal splenic artery (no. 11p) have been dissected, and the splenic vein is exposed.

Surgical procedures

Laparoscopic-assisted distal gastrectomy

A 12-mm subumbilical camera port was inserted. The abdominal cavity was insufflated with carbon dioxide to maintain an intra-abdominal pressure of 8 to 10 mmHg. A flexible fiberoptic laparoscope with a 10-mm tip (Olympus LTF Type VH, Olympus Optical Co Ltd, Tokyo, Japan) was inserted through this port. A suture placed around the falciform ligament was pulled out of the abdomen to elevate the liver. There were 5-mm trocars placed in the lower left side and upper right side of the abdomen, whereas 12-mm trocars were placed in the lower right side and upper left side of the abdomen.

The greater omentum was dissected under laparoscopic vision using ultrasonically activated coagulating shears (Harmonic Ace, Ethicon Endo-Surgery, Cincinnati, Ohio), and the lymph nodes along the right gastroepiploic vessels (no. 4d) were removed. The left gastroepiploic vessels were exposed and divided near the spleen, and the lymph nodes along the left gastroepiploic vessels (no. 4sb) were dissected. The nodes around the superior mesenteric vein (14v) were dissected if lesions were located in the antrum. The right gastroepiploic vessels were then exposed and divided, and the infrapyloric lymph nodes (no. 6) were dissected, completing the procedure at the greater curvature of the stomach. Before starting the procedure at the lesser curvature, another trocar was inserted just below the xiphoid process. A liver retractor was inserted through the port to retract the left lobe of the liver, thereby providing a good view of the lesser curvature. The retractor was fixed to a surgical arm to secure a stable field of view. The lesser omentum was dissected, the right gastric artery was exposed and divided, and the suprapyloric lymph nodes (no. 5) were dissected. Before starting the suprapancreatic lymph node dissection, the peritoneum along the superior pancreatic margin was divided. The outermost layer of nerves was preserved, and the

common hepatic artery, proper hepatic artery, and portal vein were exposed. The lymph nodes along the hepatic artery (no. 12a) were dissected (Fig. 1a). Next, the left gastric vein and the left gastric artery were exposed and divided at their root, and the lymph nodes along the left gastric artery (no. 7) were removed. This allowed the lymph nodes along the common hepatic artery (no. 8a) to be pulled up easily for dissection at their deepest point. At the same time, the lymph nodes around the celiac artery (no. 9) were dissected. The lymph nodes along the proximal splenic artery (no. 11p) and the pancreas were mobilized together from the cranial side, and the no. 11p lymph nodes were then safely dissected (Fig. 1b). Finally, the right pericardial lymph nodes (no. 1) and the lymph nodes along the lesser curvature (no. 3) were dissected.

A 4- to 5-cm minilaparotomy was made by extending the incision for the liver retractor port caudally. A wound protector was placed into the minilaparotomy, through which the stomach was exteriorized. Reconstruction was performed extracorporeally under direct vision with a Billroth I anastomosis. A purse string suture device was placed on the duodenum, and the duodenum was transected. Next, the anvil of a 25-mm-diameter EEA stapler (Covidien, Dublin, Ireland) was inserted into the cut end of the duodenum. The distal two thirds of the stomach were resected using a linear stapler, and mechanical anastomosis of the posterior wall of the remnant stomach and duodenal stump was then performed. If the gastric remnant was small or if, in obese patients, tension was noted at the anastomosis, Roux-en-Y reconstruction was performed. After hemostasis and irrigation of the abdominal cavity, the abdomen was closed to complete the operation.

Open distal gastrectomy

An incision approximately 20 cm in length was made from just below the xiphoid process to the subumbilical region. The extent of lymph node

Table 1 Patient characteristics^a

	LDG (n = 32)	ODG (n = 44)	P value
Age, y	60.6 ± 11.1 (30–73)	64.6 ± 9.3 (45–81)	0.086
Sex			0.37
Male	21 (66)	33 (75)	
Female	11 (34)	11 (25)	
BMI (kg/m ²)	23.2 ± 3.4 (16.7–30.5)	23.0 ± 3.0 (13.2–29.5)	0.98
Past history of laparotomy	7 (22)	9 (20)	0.88
Appendectomy	7 (22)	9 (20)	
Gynecologic	1 (3)	0	
Performance of EUS			0.23
Yes	16 (50)	28 (64)	
No	16 (50)	16 (36)	
cN			0.22
0	27 (84)	41 (93)	
1	5 (16)	3 (7)	
Pathologic size, cm	3.9 ± 2.7 (1–13)	4.7 ± 2.1 (1.8–11)	0.18
pT			0.25
1a	4 (13)	4 (9)	
1b	19 (59)	22 (50)	
2	4 (13)	15 (34)	
3	2 (6)	1 (2)	
4a	3 (9)	2 (5)	
pN			0.96
0	22 (68)	30 (68)	
1	4 (13)	6 (14)	
2	3 (9)	6 (14)	
3	3 (9)	2 (5)	
pStage			0.96
IA	18 (56)	23 (52)	
IB	4 (13)	8 (18)	
IIA	4 (13)	6 (14)	
IIB	1 (3)	1 (2)	
IIIA	2 (6)	3 (7)	
IIIB	1 (3)	1 (2)	
IIIC	1 (3)	0	
IV	1 (3)	2 (5)	
Histology			0.86
Differentiated	14 (44)	24 (55)	
Undifferentiated	18 (56)	20 (45)	
Reconstruction			0.05
Billroth I	25 (78)	25 (57)	
Roux-en-Y	7 (22)	19 (43)	

BMI, body mass index; EUS, endoscopic ultrasound.

^aData are expressed as mean ± SD (range) or n (%).

dissection was the same as that in LDG. The reconstruction method was performed in a similar fashion, using similar devices, as for LDG.

Adjuvant therapy

In 2007, the Adjuvant Chemotherapy Trial of S-1 for Gastric Cancer (ACTS-GC) demonstrated S-1 (Taiho

Pharmaceutical Co Ltd, Tokyo, Japan), which combines tegafur, 5-chloro-2,4-dihydropyridine, and potassium oxonate in a molar ratio of 1:0.4:1,¹⁰ to be an effective adjuvant chemotherapeutic agent.¹¹ Subsequently, nearly all patients with advanced gastric cancer of pathologic stages IIA, IIB, IIIA, IIIB, and IIIC, except for pT1 and pT3N0, were recommended for adjuvant chemotherapy with S-1.

Table 2 Surgical outcomes

	LDG (n = 32)	ODG (n = 44)	P value
Operative duration, min	297 ± 12	226 ± 10	<0.001 ^a
Estimated blood loss, mL	90 ± 27	314 ± 23	<0.001 ^a
No. of dissected lymph nodes	44 ± 2	39 ± 2	0.12
Days to oral intake	2.6 ± 0.2	2.5 ± 0.2	0.74
Days to first flatus	2.0 ± 0.1	2.3 ± 0.1	0.16
Days to first assisted ambulation	1.1 ± 0.1	1.5 ± 0.1	0.010 ^a
Removal of epidural catheter within 3 days, n (%)	25 (78)	22 (50)	0.013 ^a
Postoperative maximum body temperature, °C	37.9 ± 0.1	38.0 ± 0.1	0.085
No. of times analgesics were administered after POD4	2.8 ± 0.8	3.3 ± 0.7	0.64
Days of postoperative hospital stay	9.7 ± 0.5	10.3 ± 0.4	0.38

^aDescriptive data for discrete and continuous variables are expressed as mean ± SE.

Statistical analysis

Continuous variables were evaluated using Student *t*-test; categorical variables were evaluated using the χ^2 test. Survival was calculated using the Kaplan-Meier method. Univariate analyses of prognostic factors for OS and RFS were performed using the log-rank method. All calculations were performed using JMP version 10 (SAS Institute Inc, Cary, North Carolina). A 2-sided *P* value of less than 0.05 was considered statistically significant.

Results

Patient demographics

Although patients in the LDG group tended to be younger than those in the ODG group (60.6 ± 11.1 years versus 64.6 ± 9.3 years; *P* = 0.086) and the proportion of patients who underwent Roux-en-Y reconstruction tended to be smaller in the LDG group than in the ODG group (22% versus 43%; *P* = 0.053), there were no significant differences in terms of clinicopathologic features between the LDG group and the ODG group (Table 1). More than half of patient staging was overestimated preoperatively (*i.e.*, actually had pT1a or pT1b tumors) in both groups. Adjuvant chemotherapy using S-1 was administered to 7 patients in the LDG group and 11 patients in the ODG group.

Short-term outcomes

Short-term outcomes for both groups are presented in Table 2. The laparoscopic procedure was not converted to an open procedure for any patient in the LDG group. Operative time was significantly longer (*P* < 0.001) and estimated blood loss significantly less (*P* < 0.001) in the LDG group. First ambulation took significantly fewer days (*P* = 0.010) in the LDG group,

with 88% of LDG patients able to walk on postoperative day 1 (POD1), compared with only 61% of ODG patients. Significantly more LDG patients (78%) than ODG patients (50%) had the epidural catheter removed within 3 days (*P* = 0.013). Although the difference was not significant, the number of dissected lymph nodes tended to be larger in the LDG group than in the ODG group (*P* = 0.12).

There was no postoperative mortality. Postoperative complications of Clavien-Dindo grade II or above were observed in 1 patient (3.1%) in the LDG group and 4 patients (9.1%) in the ODG group (*P* = 0.39; Table 3).

Long-term outcomes

Median length of follow-up was sufficiently long, being 60 months (IQR, 44–71 months) for all patients; it was 49 months (IQR, 36–67 months) in the LDG group and 60 months (IQR, 48–72 months) in the ODG group. The OS rates in the LDG group were 100% at 1 year, 96.4% at 3 years, and 89.5% at 5 years (Fig. 2a), whereas those in the ODG group were 100% at 1 year, 100% at 3 years, and 97.1% at 5 years (Fig. 2b). The 5-year RFS rate was 88.0% for the LDG group and 97.7% for the ODG group. No significant differences were seen between the LDG and ODG groups in OS (*P* = 0.27; Fig. 2a) or in RFS (*P* = 0.29; Fig. 2b).

The details for patients who had recurrence are given in Table 4. One patient in the LDG group had recurrence at the site of lymph nodes along the hepatoduodenal ligament. He was treated with chemoradiotherapy and was alive 36 months after chemoradiotherapy, without further recurrence.

Discussion

In the current study, we found that short-term outcomes of LDG with D2 lymph node dissection

Table 3 Postoperative complications

Morbidity	LDG (n = 32)		ODG (n = 44)		P value
	CD II	CD IIIa	CD II	CD IIIa	
Intra-abdominal abscess, n	0	1	0	0	0.39
Pancreatic fistula, n	0	0	1	1	
Chyle leakage, n	0	0	1	0	
Bile leakage, n	0	0	0	1	
Total, n (%)	1 (3.1)		4 (9.1)		

CD, Clavien-Dindo grade.

for cT2N0 or cT2N1 gastric cancer were better than—and long-term outcomes similar to—those of ODG.

Several authors have reported short-term outcomes of LDG for cT2 or more advanced gastric cancer,^{12–15} including longer operative durations but less blood loss, shorter time to first flatus and first oral intake, and shorter postoperative of hospital stay, compared with ODG.

In the current study, operative duration was significantly longer and estimated blood loss significantly less in the LDG group than in the ODG group, consistent with previous studies. However, time to first oral intake and length of postoperative hospital stay were not significantly different between groups. We used the same clinical pathway for both groups. In this pathway, oral intake was stipulated to be initiated on POD2 and patients were to be discharged on POD 7 or later if they had no complications or had any complications that could be managed on an outpatient basis. Because of this, the current analysis was unable to show the superiority of LDG with respect to time to first oral intake and length of postoperative hospital stay. On the other hand, time to first ambulation was significantly shorter in the LDG group than in the ODG group. The clinical pathway stipulated that patients were to walk on POD1 with the assistance

of nurses. The less invasive nature of LDG enabled a significantly higher percentage of patients in the LDG group (88% versus 61%) to walk on POD1, whereas extensive destruction of the abdominal wall in the ODG group would have made walking difficult for patients on POD1.

The number of dissected lymph nodes was greater, albeit not significantly so, in the LDG group than in the ODG group. Lymph node dissection is an important aspect of treatment for gastric cancer. The number of dissected lymph nodes has been reported to be significantly lower in LDG than in ODG.^{16–18} More recently, Kanaya *et al*¹⁹ reported the successful performance of a new technique for suprapancreatic lymph node dissection in LDG with D2 lymph node dissection—a medial approach in which dissection is started by identifying the left gastric artery and then performed toward bilateral sides. They reported that a mean of 45.1 regional lymph nodes were retrieved, which was not fewer than has been reported previously. In addition, there have been several reports that the number of dissected lymph nodes was not significantly different between LDG and ODG.^{3,20,21} We speculate that improved skill at performing D2 lymph node dissection and a magnified view with a high-definition camera enabled us to perform meticulous

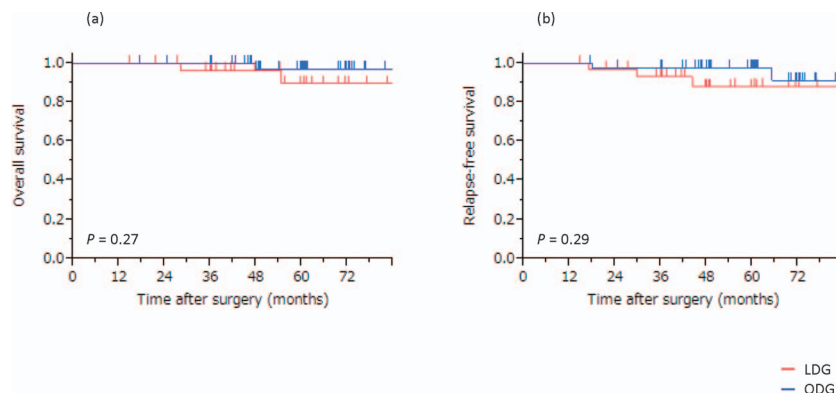


Fig. 2 Kaplan-Meier curves for OS and RFS between the LDG group and the ODG group, showing no significant between-group differences in OS (a) and RFS (b).

Table 4 Postoperative recurrence

Laparoscopic or open	Age, y	Sex	cN	Histopathology	pT	pN	pStage	Site of recurrence	RFS, mo	Survived
Laparoscopic	30	Male	0	por	3	3a	IIIB	Bone	44	No
Laparoscopic	66	Male	1	tub2	2	3a	IIIA	LN (no. 12) ^a	30	Yes
Laparoscopic	60	Male	0	tub2	2	1	IV	Peritoneum	17	No
Open	69	Male	0	sig	4a	2	IV	LN (no. 13) ^b	18	No
Open	59	Male	1	tub2	2	0	IB	LN (no. 16) ^c	65	Yes

LN, lymph node; por, poorly differentiated adenocarcinoma; sig, signet ring cell carcinoma; tub, tubular adenocarcinoma.

^aNo. 12, lymph nodes along the hepatoduodenal ligament.

^bNo. 13, lymph nodes on the posterior surface of the pancreatic head.

^cNo. 16, para-aortic lymph nodes.

lymph node dissection, which resulted in an increased number of dissected lymph nodes.

With respect to long-term outcomes, there was no difference in OS and RFS between the LDG and ODG groups in the present study. Few studies have reported the long-term outcomes of clinically resectable advanced gastric cancer.^{22–24} They have reported that there was no difference in terms of survival outcomes between LDG and ODG groups. However, the median lengths of follow-up of these reports were not sufficiently long (29–60 months). The median length of follow-up for our current study was one of the longest follow-up periods (60 months). Our results for long-term survival were consistent with those of previous reports. Therefore, we are fully convinced that LDG with D2 lymph node dissection for at least cT2N0-1 gastric cancer is not inferior to ODG in terms of long-term survival outcome.

However, these studies including ours were conducted using patients with up to pT3 gastric cancer. If patients with pT4 gastric cancer were included, more patients would potentially have port site recurrence or peritoneal dissemination. Indications for LDG should be expanded carefully, and a phase 3 study is necessary.

The current study has some important limitations. First, the analysis was based on retrospective data collection at a single institution. Second, clinical diagnosis of tumor depth was overestimated in more than half of all analyzed patients. In other words, it was overestimated in all patients with pT1 tumors. Third, cost-effectiveness, which was one of the major concerns for laparoscopic surgery, was not one of the parameters studied. A randomized controlled study is needed to assess definitively whether LDG with D2 lymph node dissection is superior to ODG with D2 lymph node dissection for patients with advanced gastric cancer.

In conclusion, LDG with D2 lymph node dissection for cT2N0 or cT2N1 gastric cancer is oncologically and technically safe and feasible, and is an option in the surgeon's arsenal. However, prospective randomized controlled study including the investigation of cost-effectiveness should be conducted for LDG to become a standard treatment for advanced gastric cancer.

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