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Benefits of laparoscopic surgery compared to open standard surgery for gastric carcinoma in elderly patients: propensity score-matching analysis

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Abstract

Background Laparoscopic surgery is frequently performed, and laparoscopic gastrectomy (LG) is also widely performed for gastric cancer. Elderly population with gastric cancer has increased in East Asia, including in Japan.

Methods We examined 1131 patients with gastric cancer who underwent laparoscopic and open standard surgeries (OG). A total of 921 patients of age < 75 years (non-E group) and 210 patients of age ≥ 75 years (E group) underwent surgery for gastric cancer. The mortality, morbidity, and prognosis of LG and OG were compared by propensity score-matched analysis.

Results Mortality and morbidity in the E group were significantly higher than those in the non-E group ($p < 0.05$). Propensity score-matching revealed that the incidence of postoperative complications of grade ≥ 2 in the OG subgroup was significantly higher than that in the LG subgroup in the E group ($p < 0.05$). The overall survival rate of the LG subgroup was significantly higher than that of the OG subgroup in both the non-E and E groups ($p < 0.05$). The depth of tumor invasion, lymph node metastasis, and the number of dissected lymph nodes were dependent factors for survival in the non-E group, whereas the depth of tumor invasion was the only dependent factor for survival in the E group in the multivariate analysis.

Conclusion The survival rate of patients who underwent LG showed significantly good prognosis in both the non-E and E groups, although the E group patients who underwent OG subgroup showed higher severe complication incidences than those who underwent LG subgroup.

Keywords Gastric cancer · Laparoscopic gastrectomy · Elderly · Propensity score-matching · Multivariate analysis

Although the incidence of gastric cancer has decreased in recent years, it remains one of the leading causes of cancer-related deaths in the East Asia and Eastern Europe [1]. Gastric cancer is the fourth most common cancer worldwide and the second most frequent cause of cancer-related deaths [2]. Surgery is the most effective treatment for resectable gastric cancer [3–5].

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The average age of the population and the number of elderly people have been increasing worldwide, particularly in Japan, wherein 23.3% of the current population is aged ≥ 65 years; this percent is predicted to reach 33% by 2035 and to approximately 40% by 2060 [6]. In the future, surgeons can expect to operate more frequently on elderly patients with both malignancies and comorbid medical conditions, such as pre-existing diseases such as cardiovascular disease, diabetes mellitus, and impair physical function, which make their treatment difficult [7, 8]. Age ≥ 70 years is an independent predictor of increased postoperative complications, in-hospital mortality, and longer hospital stay [7, 9, 10].

Since the first report by Kitano in 1994 [11], laparoscopy-assisted distal gastrectomy has been rapidly adopted for the treatment of both early and advanced gastric cancers requiring lymph node dissection [12–14]. Prospective randomized trials have revealed that laparoscopic surgery for

gastric cancer is feasible and oncologically safe and is associated with superior perioperative outcomes as compared to the conventional open surgery [15]. Several studies have reported decreased morbidity rate, decreased pain, faster recovery, and shorter postoperative hospital stay [16–19]. However, in the future, determining whether elderly patients with gastric cancer can benefit from laparoscopic surgery will be important. Elderly patients with less functional reserve and more comorbid disease may be affected by carbon dioxide pneumoperitoneum, which is almost harmless in young patients [20, 21]. Considering that the interactions among age, comorbidity, and short-term surgical outcomes were unclear, perioperative outcomes in laparoscopic surgery for elderly patients with gastric cancer remained non-conclusive.

Recently, a meta-analysis of laparoscopic gastrectomy (LG) versus open standard gastrectomy (OG) for elderly patients with gastric cancer was performed [22] to find that the former results in less blood loss, faster postoperative recovery, and reduced postoperative morbidity than the latter.

In the present study, we aimed to determine whether LG benefits short and long-term outcomes of elderly patients as compared with OG.

Patients and methods

Study design

A total of 1131 patients with gastric cancer who underwent surgery at the Department of Gastroenterological Surgery, National Kyushu Cancer Center, Fukuoka, Japan, between January 2003 and December 2014 were included in the present study. Moreover, 921 patients who underwent surgery for gastric cancer were aged < 75 years (non-elderly patients; non-E group) and 210 were aged ≥ 75 years (elderly patients; E group). At this institute, laparoscopic distal gastrectomy (LDG) using Delta and Roux-en-Y anastomosis, laparoscopic total gastrectomy using functional end-to-end anastomosis (FEEA) [23], and laparoscopic-assisted total gastrectomy using a transorally inserted anvil (OrVil; DST Series™ EEA™ OrVil™, 21, 25 mm; Covidien, USA) were performed [24]. Clinicopathological factors, such as the mean age at the time of surgery, gender, histological features of the tumor, depth of tumor invasion, lymph node metastasis, pathological stage (pStage), number of dissected lymph nodes, surgical procedures, operation time, and blood loss volume were studied as potential prognostic factors. Surgical and clinicopathological evaluations were conducted in accordance with the Japanese Classification of Gastric Cancer [25].

Evaluation of complications

In the postoperative period, all patients were kept under observation to detect any possible complications, and only those patients who developed complications within 1 month postoperatively were considered in the present study. Anastomotic leakage was clinically diagnosed by the presence of saliva or gastrointestinal contents in the drain or during repeat laparotomy and radiologically by a contrast swallow test. A drain output of any measurable volume of fluid on or after postoperative day 3 with amylase content 3 times higher than the serum level was considered to be indicative of a pancreatic fistula. Prolonged fever and/or inflammation with positive findings on computed tomography and those requiring antibiotic therapy were defined as having "prolonged fever-up/inflammation." Wound infection was diagnosed when positive results were obtained for bacterial culture of purulent discharge. We objectively evaluated the presence and severity of these postoperative complications using the Clavien–Dindo classification system [26, 27].

Follow-up

After discharge from the hospital, all patients were followed up with both physical and blood examinations (e.g., tumor markers) every 3 months and a combination of chest radiography, computed tomography, and abdominal ultrasonography every 3–6 months up to 2 years and subsequently at 6–12 months iof ntervals up to 5 years after the initial surgery. The sites of recurrence and causes of death were carefully investigated. In some cases, the mode of recurrence was determined by cytology, biopsy, or surgery. The type of recurrence was classified as hepatic metastasis, peritoneal recurrence, lymph node recurrence or others. The median lengths of follow-up for the non-E and E groups were 50.9 and 36.6 months, respectively (range 2–100 months).

Statistical analysis

The patient characteristics were summarized using descriptive statistics or contingency tables. Student *t* test or Chi-square test was used to compare variables between the two groups. Survival was estimated using the Kaplan–Meier method, and compared using the log-rank test. The Cox proportional hazards models were used to identify the prognostic factors for overall survival (OS).

The propensity score approach was attempted to construct a randomized experiment-like situation wherein the treatment groups were compared and contrasted for the observed prognostic factors [28]. We performed a one-to-one matching analysis using a caliper width of 0.1 between the LG

and OG subgroups in each of the non-E or E groups. The propensity scores were calculated using a logistic regression model, and the model included the following factors: age, gender, histology, T and N factors, and pStage.

A probability of <0.05 was considered statistically significant. Statistical analyses were performed using the JMP software and SAS 9.4 (SAS Institute, Inc., USA).

Results

Patient characteristics

In total, 1131 patients were enrolled in this study, including 921 patients of age <75 years, and 210 patients of age ≥ 75 years. The patient characteristics are summarized in Table 1. The clinicopathological findings were compared in terms of age, gender, histology, T and N factors, pStage, surgical procedures, and laparoscopic/open surgery. The rate of well-moderately differentiated adenocarcinoma in the E group was significantly higher than that in the non-E group ($p<0.001$).

Table 1 Clinicopathological characteristics of gastric cancer in patients with performed in the non-E and E groups

	Non-E group ($n=921$)	E group ($n=210$)	p
Age	60.7 ± 9.5	79.6 ± 3.7	<0.001
Gender			
Male	583	131	NS
Female	338	79	
Histology			
Poorly	567	79	<0.001
Well and moderately	354	131	
Depth of tumor invasion			
T1	524	110	
T2	85	25	NS
T3	117	28	
T4	195	47	
Lymph node metastasis			
N0	613	134	
N1	105	27	NS
N2	97	26	
N3	106	23	
pStage			
I	545	124	
II	157	29	NS
III	169	44	
IV	50	13	
Surgical procedures			
Distal	555	138	
Total	359	71	NS
Pancreaticoduodemostomy	4	1	
Others	3	0	
Open	480	113	NS
Laparoscopic	441	97	

NS not significant

Comparison of complications between non-E and E groups

The rates of morbidity (26.2%) and mortality (0.9%) in the E group were significantly higher than those in the non-E group ($p<0.05$, in both the groups). The relationship among wound infections, intra-abdominal infections, pancreatic fistula, anastomotic leakage, ileus, postoperative bleeding, postoperative cholecystitis, lung complications, and other complications in both non-E and E groups are summarized in Table 2. Postoperative cholecystitis, lung complications, and other complications were significantly different between the non-E and E groups ($p<0.05$, $p<0.01$, $p<0.05$, respectively), although wound infections, intra-abdominal infections, pancreatic fistula, anastomotic leakage, ileus and postoperative bleeding showed no difference between the non-E and E groups.

Propensity score-matched analysis

A total of 1131 patients with gastric cancer who underwent LG or OG were considered in our analysis. Propensity score-matched analysis was performed for age, gender, histology, T and N factors, and pStage. Using one-to-one propensity score-matching, 276 pairs of LG and OG non-elderly patients and 69 pairs of LG and OG elderly patients were selected for the final analysis (Fig. 1).

Table 2 Postoperative complications in the non-E and E groups

	Non-E group ($n=921$)	E group ($n=210$)	p value
Morbidity	179 (19.4)	55 (26.2)	<0.05
Postoperative complications (Grade 2 ≧)	150 (16.3)	47 (22.4)	<0.001
Wound infections	29 (3.1)	12 (5.7)	NS
Intra-abdominal infection	15 (1.6)	2 (1.0)	NS
Pancreatic fistula	51 (5.5)	5 (2.4)	NS
Anastomotic leakage	26 (2.8)	9 (4.3)	NS
Ileus	5 (0.5)	1 (0.5)	NS
Postoperative bleeding	8 (0.9)	1 (0.5)	NS
Postoperative cholecystitis	3 (0.3)	3 (1.4)	<0.05
Lung complications	7 (0.8)	8 (3.8)	<0.01
Others	35 (3.8)	14 (8.1)	<0.05
Mortality	1 (0.1)	2 (0.9)	<0.05

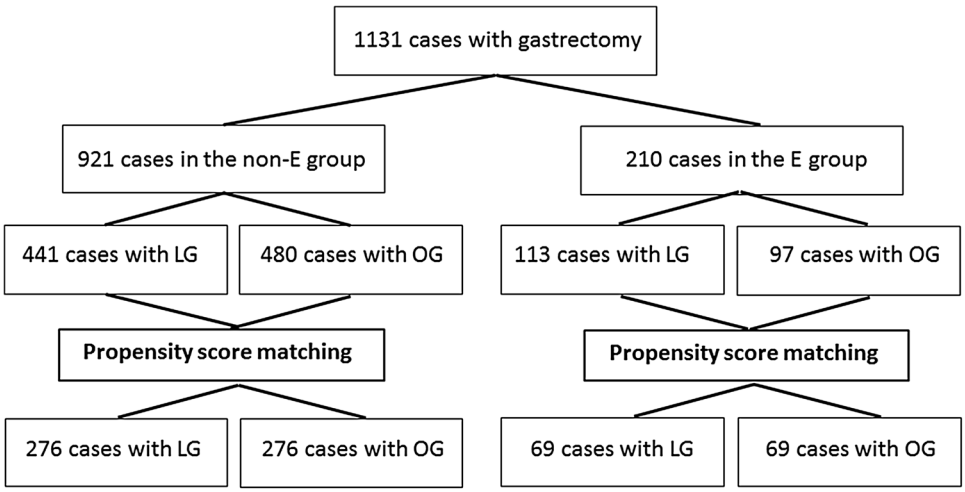

Fig. 1 Study flow diagram

Short-term surgical outcomes

Tables 3 and 4 provide the details of operative outcomes, hospital courses, and postoperative complications for the LG and OG subgroups in the non-E groups. The blood loss volume in the LG subgroup was significantly lower than that in the OG subgroup (153.0 vs. 423.4 mL, $p < 0.001$), although there were no significant differences in the operation time between the LG and OG subgroups (370.5 vs. 322.3 min). In the clinicopathological findings, gender, T factor and surgical procedures were significantly different between the LG and OG subgroups, as shown in Table 3. However, in the non-E group, we ascertained no imbalance between the LG and OG subgroups because their pStage was equal. Table 4 summarizes the postoperative complications of both the LG and OG subgroups in the non-E group. No significant differences were noted in postoperative complications between the LG and OG subgroups in the non-E group.

Similarly, Tables 5 and 6 provide the details of operative outcomes, hospital courses, and postoperative complications between the LG and OG subgroups in the E groups. The blood loss volume in the LG subgroup was significantly lower than that in the OG subgroup (137.0 vs. 477.8 mL, $p < 0.001$), although there was no difference in the operation time between the LG and OG subgroups (337.6 vs. 312.4 min). Table 6 summarizes the postoperative complications in both the LG and OG subgroups in the E group. The incidence of postoperative complications of grade ≥ 2 in the OG subgroup was significantly higher than that in the LG subgroup in the E group ($p < 0.05$).

Long-term survival

The survival data of both non-E and E groups were obtained until March 2016, with a median follow-up of 50.9 and 36.6 months, respectively. The 5-year OS rates of the LG and OG subgroups in the non-E group were 92 and 87%, respectively (Fig. 2A). Similarly, the 5-year OS rates in the LG or OG subgroup in the E group were 79 and 54%, respectively (Fig. 2B). The 5-year OS of the LG subgroup was significantly longer than that of the OG subgroup for both the non-E ($p < 0.05$) and E groups ($p < 0.05$). In addition, the rate of cancer-specific survival in the LG subgroup in the E group was significantly higher than that in the OG subgroup ($p < 0.05$); however, the rate of cancer-specific survival in the non-E group was not different in both the LG and OG subgroups (Fig. 3A, B).

Multivariate analysis

Multivariate analysis using Cox proportional hazards model (Tables 7, 8) imply shows that the T and N factors and the number of dissected lymph nodes in the non-E group were significant predictors of survival, whereas the T factor was the only dependent factor for OS in the E group.

Discussion

Presently, gastric cancer is the second most common cause of cancer-related deaths worldwide [2]. With the increase in life expectancy, the numbers of elderly patients with both malignancies and comorbid medical conditions have significantly increased.

The proportion of elderly patients with gastric cancer is expected to increase gradually over the next few decades in Eastern Asia, Eastern Europe, and South America [29, 30]. Surgical resection has remained the mainstay treatment for patients with gastric cancer. Because aging is associated with a gradual loss of functional reserve capacity [31], even in individuals without obvious underlying comorbidities, aged ≥ 70 years is an independent risk

Table 3 Clinicopathological characteristics of gastric cancer in patients with performed in the non-E group

	OG group ($n=276$)	LG group ($n=276$)	p
Age	60.4 ± 9.8	60.7 ± 8.9	NS
Gender			
Male	186	163	< 0.05
Female	90	113	
Histology			
Poorly	163	158	NS
Well and moderately	113	118	
Depth of tumor invasion (T)			
T1	164	186	
T2	38	20	< 0.05
T3	26	44	
T4	48	26	
Lymph node metastasis (*N*)			
N0	210	204	
N1	28	32	NS
N2	20	22	
N3	18	18	
pStage			
I	187	187	
II	53	53	NS
III	35	35	
IV	1	1	
Surgical procedures			
Distal	167	138	
Total	105	71	< 0.05
Pancreaticoduodemostomy	2	1	
Others	2	0	
Operation time (min)	322.3 ± 102.5	336.7 ± 85.6	NS
Blood loss volume	423.4 ± 329.8	153.0 ± 187.0	< 0.001
The number of dissected lymph nodes	34.92 ± 18.24	40.65 ± 19.89	< 0.001

NS not significant

Table 4 Postoperative complications in the non-E groups

	OG group ($n=276$)	LG group ($n=276$)	p value
Morbidity	47 (17.0)	41 (15.0)	NS
Postoperative complications (Grade 2 ≧)	42 (15.2)	30 (10.9)	NS
Wound infections	10 (3.7)	10 (3.7)	NS
Intra-abdominal infection	3 (1.1)	4 (1.4)	NS
Pancreatic fistula	14 (5.1)	13 (4.7)	NS
Anastomotic leakage	7 (2.5)	4 (1.4)	NS
Ileus	3 (1.1)	0	NS
Postoperative bleeding	1 (0.4)	3 (1.1)	NS
Postoperative cholecystitis	0	0	
Lung complications	1 (0.4)	1 (0.4)	NS
Others	8 (2.9)	6 (2.2)	NS
Mortality	0	0	

factor for gastric cancer with potentially increasing occurrence of postoperative mortality, complications, and longer hospital stay [7, 9]. Several investigators have discussed that elderly patients in Japan are defined as individuals aged ≥ 75 ~ 85 years [32–36]. In the present study, patients aged ≥ 75, 80, and 85 years accounted for 18.6, 8.1, and 1.9% of all patients, respectively. In the present study, elderly patients were defined as patients who were aged ≥ 75 years. Because, most investigators have defined elderly patients as those aged ≥ 75 years [32–34], and statistical significance decreases if elderly patients are defined as those aged ≥ 80 or 85 years.

In the present study, the non-E group had significantly lower overall mortality and morbidity than the E group. In particular, the incidences of lung complication, postoperative cholecystitis, and other complications in the E group were significantly higher than those in the non-E group

Table 5 Clinicopathological characteristics of gastric cancer in patients with performed E group

	OG group ($n=69$)	LG group ($n=69$)	p
Age	79.3 ± 3.3	79.9 ± 3.8	NS
Gender			
Male	47	42	NS
Female	22	27	
Histology			
Poorly	21	26	NS
Well and moderately	48	43	
Depth of tumor invasion (*T*)			
T1	37	44	
T2	15	7	NS
T3	7	11	
T4	10	7	
Lymph node metastasis (*N*)			
N0	46	50	
N1	11	8	NS
N2	8	7	
N3	4	4	
pStage			
I	47	47	
II	10	10	NS
III	12	12	
Surgical procedures			
Distal	45	48	
Total	23	21	NS
Pancreaticoduodemostomy	0	0	
Others	1	0	
Operation time (min)	312.4 ± 114.0	337.6 ± 67.0	NS
Blood loss volume	477.8 ± 489.8	137.0 ± 134.9	< 0.001
The number of dissected lymph nodes	30.09 ± 16.06	37.42 ± 19.42	< 0.05

NS not significant

Table 6 Postoperative complications in the E groups

	OG group ($n=69$)	LG group ($n=69$)	p value
Morbidity	20 (29.0)	15 (21.7)	NS
Postoperative complications (Grade 2 ≧)	19 (27.5)	9 (13.0)	< 0.05
Wound infections	6 (8.7)	4 (5.8)	NS
Intra-abdominal infection	2 (2.9)	0	NS
Pancreatic fistula	0	0	
Anastomotic leakage	3 (4.3)	3 (4.3)	NS
Ileus	1 (1.4)	0	NS
Postoperative bleeding	0	2 (2.9)	NS
Postoperative cholecystitis	1 (1.4)	1 (1.4)	NS
Lung complications	2 (2.9)	3 (4.3)	NS
Others	5 (7.2)	2 (2.9)	NS
Mortality	2 (2.9)	0	NS

(Table 2). The results of randomized clinical trials have shown that LG for gastric cancer has several postoperative benefits, such as improved cosmetic effect, reduced pain, earlier recovery, short hospital stay, less morbidity, less mortality, and better quality of life as compared with OG for gastric cancer [16–19, 37]. In the present study, we observed that the blood loss volume in the LG subgroup was lower than that in the OG subgroup. The incidence of postoperative complications in the LG subgroup was similar to that in the OG subgroup in both the non-E and E groups; however, the incidence of postoperative complications of grade ≥ 2 in the E group was significantly lower for the LG subgroup than for the OG subgroup (Tables 4, 6).

Laparoscopic surgery is widely performed for patients with gastric cancer, especially in those with early-stage disease [38]. Several studies have indicated that LG is safe and feasible, although this remains to be established. On a larger scale, in the phase III trial (KLASS-01) for stage I

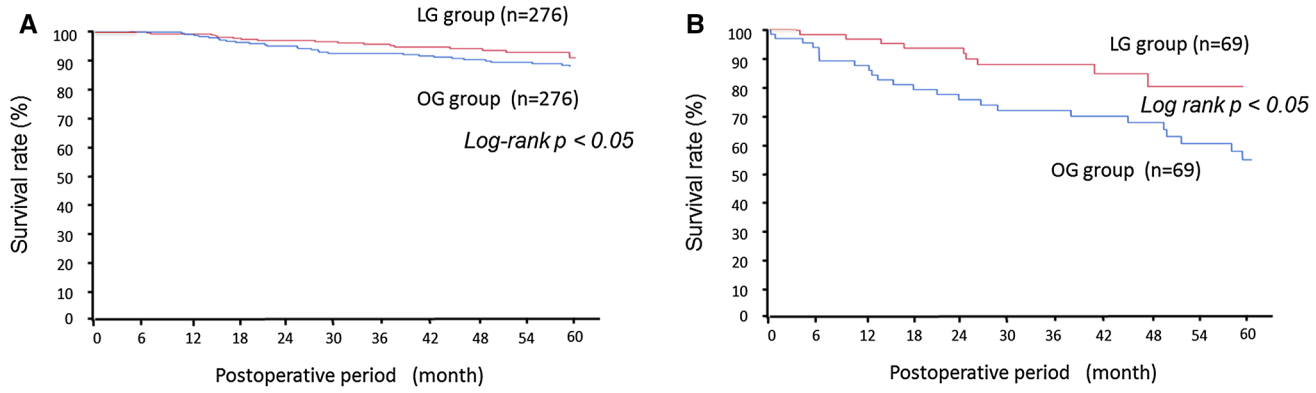

Fig. 2 Survival curves of patients who underwent laparoscopic gastrectomy (LG) (red curve) and open standard gastrectomy (OG) (blue curve) (**A** non-E group, **B** E group)

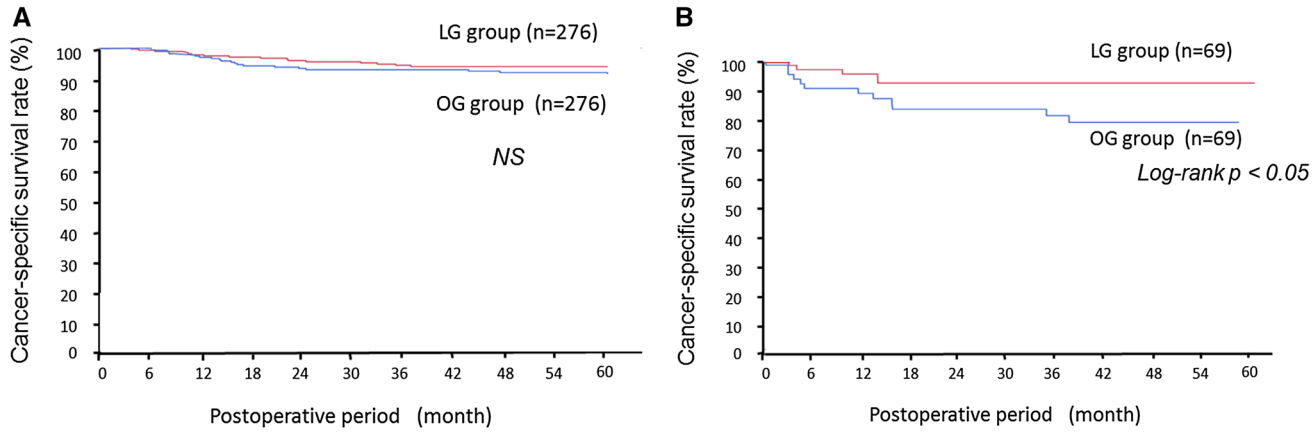

Fig. 3 The cancer-specific survival curves of patients who underwent laparoscopic gastrectomy (LG) (red curve) and open standard gastrectomy (OG) (blue curve) (**A** non-E group, **B** E group)

Table 7 Univariate and multivariate analysis for survival in non-E group

Factors	Object	Control	Univariate analysis	Multivariate analysis		
			p	Hazard ratio	95% CI	*p*
Gender	Male	Female	0.1166	1.5223	0.8332–2.8747	0.1808
Histology	Poorly	Well–mode[a]	0.7612	0.7350	0.4059–1.3486	0.3128
T factor	More than T2	T1	< 0.0001	2.6281	1.3780–5.1050	0.0032
N factor	N1–3	N0	< 0.0001	3.5937	1.9684–6.6674	0.0001
Complications	Grade 2–3	Grade 0–1	0.0385	1.0187	0.4883–1.9860	0.9584
Surgical procedures	Opened	Laparo	0.0388	1.7467	0.9085–3.3930	0.0953
Surgical methods	Total	Distal	0.0005	1.1617	0.9148–2.8592	0.0971
Dissected lymph nodes	≧40	< 40	0.0011	2.2939	1.2910–4.0932	0.0048
Intraoperative blood loss	≧400	< 400	0.0577	1.2715	0.6262–2.6625	0.3350
Operation time	≧420	< 420	0.0653	1.4510	0.6558–3.0153	0.5132

Sample size is 552 patients

[a]Well and moderate differentiated adenocarcinoma

Table 8 Univariate and multivariate analysis for survival in E group

Factors	Object	Control	Univariate analysis	Multivariate analysis		
			p	Hazard ratio	95% CI	*p*
Gender	Male	Female	0.2233	1.9212	0.8461–4.6659	0.8572
Histology	Poorly	Well–mode[a]	0.7024	0.7949	0.3321–1.7833	0.5831
T factor	More than T2	T1	< 0.0001	4.3906	1.8685–10.867	0.0006
N factor	N1–3	N0	0.0066	1.1221	0.4509–2.7449	0.8019
Complications	Grade 2–3	Grade 0–1	0.5233	0.8225	0.3012–2.0081	0.6793
Surgical procedures	Opened	Laparo	0.0161	1.9212	0.8461–4.6660	0.1207
Surgical methods	Total	Distal	0.1979	1.1967	0.5329–2.5758	0.6547
Dissected lymph nodes	≧40	< 40	0.3615	0.9142	0.4064–2.1591	0.8822
Intraoperative blood loss	≧400	< 400	0.1482	1.9455	0.6794–4.8869	0.8409
Operation time	≧420	< 420	0.1680	0.9123	0.3653–2.2240	0.2005

Sample size is 138 patients

[a]Well and moderate differentiated adenocarcinoma

gastric cancer in Korea, the overall complications in patients who underwent LDG were significantly lower than those in patients who underwent open distal gastrectomy [39]. These finding suggest that LG is a safe method for the treatment of elderly patients with early-stage gastric cancer. In the present study, the overall complications in patients who underwent LG were also lower than those who underwent OG for advanced gastric cancer (LG: OG = 24.0%:37.5%, not significant).

Several investigators have discussed that the number of dissected lymph nodes in both the LG and OG subgroups was similar [40, 41]. A recent meta-analysis revealed that the number of dissected lymph nodes in the LG subgroup was similar to that in the OG subgroup [22]. However, in the present study, the LG subgroup showed increased numbers of dissected lymph nodes than the OG subgroup in both the non-E and E groups. The reason for this predominance in the LG subgroup is unknown. The extent of visual effect by a laparoscopy may influence the increase in the numbers of dissected lymph nodes. The major concern in performing LG in combination with lymphadenectomy is the long-term survival of patients [42, 43].

Several investigators have reported that OS of patients with LG was similar to that of patients with OG [44]. A recent meta-analysis revealed that OS for LG is similar to that for OG [45]. However, OS of the LG subgroup was significantly better than that of the OG subgroup in both the non-E and E groups in the present study. In particular, the difference in prognosis between the non-E and E-groups in the OG subgroup was larger than that in the LG subgroup (Fig. 2A, B). The cancer-specific survival of the LG subgroup was significantly longer than that of the OG subgroup ($p < 0.05$) in the E group; however, the cancer-specific survival in the non-E group was not different in both the LG and OG subgroups. The cancer-specific survival of the LG subgroup in both the groups predominated that of the OG subgroup (Fig. 3A, B). The reason for better prognosis of the LG subgroup in both the non-E and E-groups is unknown. We believe that there are different reasons for the better prognosis of the LG subgroup in the non-E and E groups. In the LG subgroup, a higher number of dissected lymph nodes are one of the reasons for better prognosis in the non-E group because in multivariate analysis, the T and N factors, as well as the number of dissected lymph nodes are independent factors for survival. However, other factors including after-effects of surgery may be one of the reasons for better prognosis in both the groups.

The present study has certain limitations. First, this study is limited by its retrospective nature, and selection bias may have influenced the survival data. Second, generation bias may have influenced the survival data because some of the registered patients underwent gastrectomy over decade years. In fact, the complication rates between the earlier and later periods were 18.6 and 23.3%, respectively. Third, individual surgeon bias may have influenced the resultant surgical complications. We compared the surgical complication rates by the surgical operators, had without or with surgical skills based on the endoscopic surgical skill qualification system (so-called minimally invasive surgeon). The complication rate by the qualified surgeons was found to be higher than that by the non-qualified surgeons (19.2 and 16.9%, respectively). The reason for this high complication rate of qualified surgeons is unknown. Our surgical terms consisted of three surgeons, including one qualified surgeon. The position of the qualified surgeon (operator or supervisor) may be considered as one of the reasons of influence on the surgical complications. However, LG is the most important factor for the prognosis of curative gastric cancer in both the non-E and E groups.

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Compliance with ethical standards

Disclosures Manabu Yamamoto, Mototsugu Shimokawa, Hiroyuki Kawano, Mitsuhiko Ohta, Daisuke Yoshida, Kazuhito Minami, Masahiko Ikebe, Masaru Morita, and Yasushi Toh have no conflict of interest to disclose.

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