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Long-term outcomes of laparoscopic versus open gastrectomy for advanced gastric cancer: A large cohort study

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ABSTRACT

Background: The adequacy of laparoscopy-assisted gastrectomy (LAG) for advanced gastric cancer (AGC) treatment remains uncertain. There are few reports on the long-term outcomes of laparoscopic versus open gastrectomy (OG) in AGC using subgroups with adequate patient numbers; which may provide further evidence to validate the long-term efficacy of LAG in AGC.
Methods: A retrospective cohort study included 1198 consecutive AGC patients underwent LAG or OG between September 2005 and October 2012 was conducted to compare the long-term outcomes.
Results: Of the 1198 patients, 430 (35.9%) underwent LAG, and 768 (64.1%) underwent OG. Recurrences occurred in 203 patients (47.2%) in LAG group and in 387 patients (50.4%) in the OG group ($P = 0.091$). Five-year overall survival and disease-free survival rates of the two groups were similar, which is 51.2% vs. 46.7%, ($P = 0.081$) and 52.8% vs. 49.6%, ($P = 0.091$). The surgical approach (LAG or OG) did not influence the disease-free survival (HR 0.975, 95% CI 0.712 to 1.336; $P = 0.875$).
Conclusions: This study suggests that LAG with D2 lymphadenectomy may be a feasible and safe procedure for AGC treatment.

Introduction

Since Kitano et al.[1] first reported the use of LAG for early gastric cancer (EGC), LAG has become a well-established surgical approach for EGC that offers significant advantages.[2–4] With the improvement in laparoscopic techniques and instrumentation, one of the most pressing issues is to determine whether the indication of laparoscopic gastrectomy can be safely extended to patients with AGC.[5,6]

At present, there is only one report of a 5-year randomized clinical trial (RCT) concerning laparoscopic-assisted subtotal gastrectomy for distal gastric cancer; this trial indicated that laparoscopic-assisted subtotal gastrectomy had long-term oncologic results similar to those of the open, standard procedure.[7] However, the series of 59 total patients in this RCT was relatively small and consisted of 46 AGC and 13 EGC patients. A number of reported single- or multicenter retrospective studies[8–12] have also demonstrated acceptable long-term oncologic outcomes for LAG with D2 lymphadenectomy in AGC, but these retrospective studies have some limitations, such as lacking control studies, being small matched studies or lacking subgroups with adequate numbers of AGC patients; thus, these studies do not adequately represent the reality of AGC.

Therefore, to provide further evidence validating the long-term efficacy of radical LAG for AGC, in addition to the ongoing multicenter RCTs evaluating laparoscopy-assisted distal gastrectomy (LADG) for AGC,[13–15] a well-designed retrospective cohort study with subgroups that all include adequate numbers of AGC patients and encompass a sufficient follow-up period can be quite valuable.

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Materials and methods

Patient selection

From September 2005 to October 2012, a total of 2262 patients with gastric cancer underwent surgery at our institute; 1544 of these patients underwent OG, and 718 underwent LAG. Among these patients, 1198 patients with AGC (430 LAG patients and 768 OG patients) were finally enrolled in the present study, which compared and analyzed the surgical outcomes and the 5-year survival of patients with AGC treated with each procedure. The inclusion criteria were identified through a comprehensive consideration of the scientific statistical procedure. Eventually, we had to exclude 1064 patients who did not meet the inclusion criteria or were lost to follow-up; 288 LAG patients and 776 OG patients were excluded (Fig. 1). Both the LAG and OG approaches were indicated for each patient and the performed surgical approach was selected by the patients themselves after they received sufficient explanation of the advantages and limitations of each surgical approach. A written informed consent for surgery was obtained from every patient. Routine preoperative examinations were carried out in our study as previously described.[12] This study was approved by the Institutional Review Board of Xijing Hospital, The Fourth Military Medical University. All patients were required to provide informed consent for enrollment in this study.

Surgical technique and complications

The details of our surgical technique for LAG have been described in previous reports.[12] Briefly, a routine exploration of the abdominal cavity was performed to exclude invasion of adjacent organs and peritoneal seeding. Distal subtotal or total gastrectomy was performed depending on the location of the primary tumor. Laparoscopic D2 lymph node dissection was performed as described in the Japanese Gastric Cancer Treatment Guidelines.[16] All operations were performed by the same surgical group at our institution; this group was experienced in both laparoscopic and open gastrectomy. From our experience, surgeon's learning curve was complete after 30–50 laparoscopic operations in the training phase. To control the quality of LAG as an oncologic surgery, videos of the laparoscopic approach with D2 lymph node dissection were reviewed by a monitoring committee composed of oncologic surgeons.

Postoperative complications were defined as any unintended events occurring within 30 days after surgery (early) or more than 31 days after surgery (late). The Clavien-Dindo (C-D) classification was adopted to grade the severity of the postoperative complications.[17] The complications classified as C-D $\geq$ grade III, which were serious concerns for many surgeons, were defined as major complications.

Follow-up

Adjuvant chemotherapy was given to all patients after surgery in both groups. All patients were followed up for more than 5 years or until death. An abdominopelvic CT scan or an abdominal ultrasound examination was performed on all patients every 6 months after surgery during their follow-up appointment. Endoscopy was recommended for patients with serous invasion or significant positive lymph node metastasis every 6 months after the surgery to

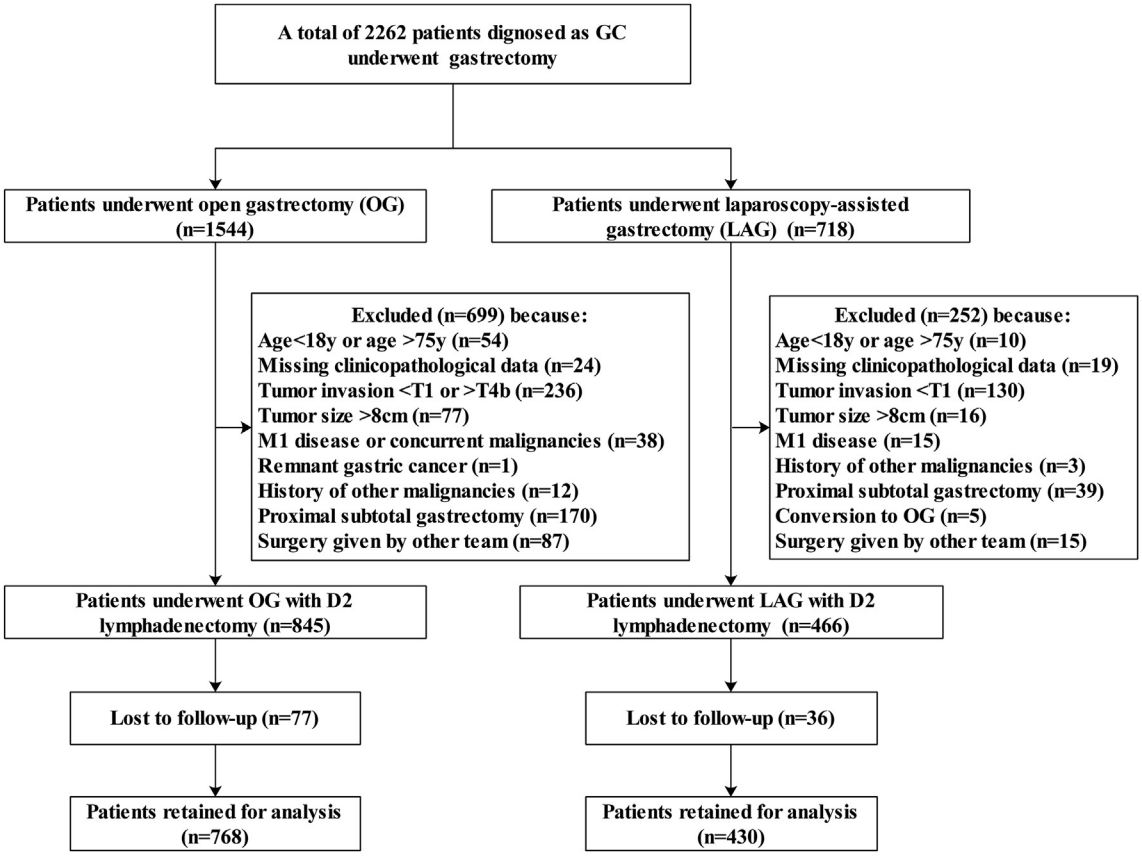

Fig. 1. Flowchart showing patient treatment and inclusion in the analysis.

closely monitor recurrence and was recommended for other AGC patients once a year. All patients were subjected to follow-up.

Statistical analysis

SPSS software was used to conduct the statistical comparisons (version 22.0; IBM, Armonk, New York, USA). Comparisons between groups were tested, as appropriate, with Student's t-test, the chi-squared test, and Fisher's exact test. The overall survival and disease-free survival rates were assessed by Kaplan-Meier analysis. Potentially important factors associated with the presence of recurrence were obtained using multivariate analysis performed by Cox's proportional hazards model. Comparisons between curves were performed by the log-rank test for model. Statistical significance was defined as $P < 0.05$.

Results

Patient demographics and clinicopathological characteristics

The patient demographics and clinicopathologic characteristics are shown in Table 1. The patients in the laparoscopic group underwent a similar number of combined organ resections as the patients in the open group (8.4% vs. 11.8%, $P = 0.061$). There were no significant differences in age, BMI, sex ratio, or ASA score between the LAG and OG groups. The proportions of patients with cancers classified as each TNM stage were distributed as follows in the LAG and OG groups: 46 (10.7%) vs. 61 (7.9%), stage Ib; 159 (37.0%) vs. 266 (34.6%), stage II; and 225 (52.3%) vs. 441 (57.4%), stage III. No significant differences were observed between the two groups in terms of tumor invasion and nodal status ($P > 0.05$). Moreover, the proportion of patients with more advanced stages of disease (≥IIIa) was similar in the LAG and OG groups (52.3% vs. 57.4%, $P = 0.132$).

Table 1
Patient demographics and clinicopathological characteristics.

Variables	OG (n = 768)	LAG (n = 430)	P value
Age (y)	56.8 ± 10.6	55.6 ± 10.4	0.059
Sex			0.407
Male	595 (77.5%)	342 (79.5%)	
Female	173 (22.5%)	88 (20.5%)	
BMI (kg/m2)	22.2 ± 3.2	22.4 ± 3.0	0.321
ASA score, n (%)			0.349
I	103 (13.4%)	65 (15.1%)	
II	557 (72.5%)	316 (73.5%)	
III	108 (14.1%)	49 (11.4%)	
Prior abdominal surgery, n (%)	110 (14.3%)	46 (10.7%)	0.074
No. of comorbidity			0.409
0	557 (72.5%)	325 (75.6%)	
1	158 (20.6%)	82 (19.1%)	
2	45 (5.9%)	17 (4.0%)	
3	8 (1.0%)	6 (1.4%)	
Tumor size (cm)	4.9 ± 1.8	4.7 ± 1.8	0.087
Tumor location			0.299
Upper third	185 (24.1%)	120 (27.9%)	
Middle third	190 (24.7%)	114 (26.5%)	
Lower third	391 (50.9%)	195 (45.3%)	
Multiple	2 (0.3%)	1 (0.2%)	
Tumor invasion[a], n (%)			0.372
T2	148 (19.3%)	97 (22.6%)	
T3	371 (48.3%)	195 (45.3%)	
T4a	249 (32.4%)	138 (32.1%)	
Nodal status[a], n (%)			0.243
N0	178 (23.2%)	117 (27.2%)	
N1	159 (20.7%)	99 (23.0%)	
N2	176 (22.9%)	92 (21.4%)	
N3a	191 (24.9%)	96 (22.3%)	
N3b	64 (8.3%)	26 (6.0%)	
TNM stage[a], n (%)			0.470
Ib	61 (7.9%)	46 (10.7%)	
IIa	110 (14.3%)	69 (16.0%)	
IIb	156 (20.3%)	90 (20.9%)	
IIIa	145 (18.9%)	78 (18.1%)	
IIIb	192 (25.0%)	98 (22.8%)	
IIIc	104 (13.5%)	49 (11.4%)	

[a] According to the 7th edition of the Union for International Cancer Control (UICC) staging manual.

Comparison of surgical results

The surgical outcomes are described in Table 2. The number of retrieved lymph nodes did not differ significantly between the LAG group (21.6 ± 8.6) and the OG group (22.4 ± 10.3). The average distant of proximal and distal resection margin did not differ significantly between LAG and OG group (5.0 ± 2.8 cm vs. 5.4 ± 2.9 cm, $P = 0.066$; 7.2 ± 4.3 cm vs. 6.9 ± 4.6 cm, $P = 0.292$). The proximal and distal resection margin was determined without tumor invasion diagnosed by both frozen section analysis during the operation and postoperative pathological examination in either group. The distribution of complications in both groups is presented in Table 3. The incidence of major complications (≥grade III) in the LAG group and the OG group was 2.6% and 3.0%, respectively ($P > 0.05$). The total frequency of complications during both the early and late postoperative periods did not differ significantly between the LAG group and the OG group (early: 6.3% vs. 7.2%, late: 0.9% vs. 0.4%, $P > 0.05$). In the LAG group, one patient died from a cerebrovascular accident, whereas in the OG group, two patients died from respiratory failure as a result of severe pneumonia.

Oncologic outcomes

The median follow-up period was 58 months (range, 0–129 months) among all patients in the LAG group and 49.5 months (range, 0–104.5 months) among all patients in the OG group. Recurrences occurred in 203 patients in the LAG group and in 387 patients in the OG group (Table 4). Two cases of port-site recurrence were observed. The 5-year cumulative overall survival rate (OS) was 51.2% in the laparoscopic group and 46.7% in the open group ($P = 0.081$) (Fig. 2). The disease-free survival rate (DFS) in the LAG group and the OG group was 52.8% and 49.6%, respectively ($P = 0.091$) (Fig. 3). The subgroup analysis showed significant differences in both OS and DFS for the different TNM stages within each group (Fig. 4).

Prognostic factors related to disease-free survival

The results of multivariate analysis for predictive factors of disease-free survival in the AGC patients were described in Table 5.

Table 2
Surgical outcomes of patients for laparoscopic versus open gastrectomy.

Variable	OG (n = 768)	LAG (n = 430)	P value
Type of surgery, n (%)			0.070
Distal	347 (45.2%)	171 (39.8%)	
Total	421 (54.8%)	259 (60.2%)	
Operating time (min)	191.5 ± 50.6	283.8 ± 70.0	<0.01
Estimated blood loss (ml)	233.6 ± 183.4	273.7 ± 233.7	0.002
Retrieved lymph nodes (n)	22.4 ± 10.3	21.6 ± 8.6	0.136
Resection margin (cm)			
Proximal	5.4 ± 2.9	5.0 ± 2.8	0.066
Distal	6.9 ± 4.6	7.2 ± 4.3	0.292
Positive resection margins	0	0	
Combined organ resection	91 (11.8%)	36 (8.4%)	0.061
First flatus time (d)	4.4 ± 1.1	4.0 ± 1.0	<0.01
Duration of hospitalization (d)	8.7 ± 4.0	8.2 ± 4.3	0.025

Table 3
Complications of patients for laparoscopic versus open gastrectomy.

Variable	OG (n = 768)		LAG (n = 430)		P value
	Early[c]	Late[d]	Early[c]	Late[d]	0.828
Total, n (%)	55 (7.2%)	3 (0.4%)	27 (6.3%)	4 (0.9%)	
Grade I[a], n (%)	12 (1.6%)		8 (1.9%)		
Incision infection	6		4		
liquefaction of incision	4		2		
Incomplete intestinal obstruction	2		2		
Grade II[a], n (%)	23 (3.0%)		12 (2.8%)		
Pneumonia	19		10		
Pleural effusion	2		1		
Intra-abdominal abscess	1		1		
Duodenal stump leakage	2		0		
Grade IIIa[a], n (%)	10 (1.3%)	1 (0.1%)	4 (0.9%)	2 (0.5%)	
rupture of incision	3		1		
Anastomotic stenosis	0	1	0	2	
Anastomotic leakage	7		3		
Grade IIIb[a], n (%)	8 (1.0%)	2 (0.3%)	2 (0.5%)	2 (0.5%)	
Anastomotic bleeding	1		0		
Intra-abdominal bleeding	2		2		
Intestinal obstruction	3	2	0	2	
Deep venous thrombosis	2		0		
GradeV[a], n (%)	2 (0.3%)		1 (0.2%)		
Mortality	2		1		
Major complication[b], n (%)	23 (3.0%)		11 (2.6%)		

[a] According to the Clavie-Dindo classification of surgical complications.
[b] Clavien-Dindo classification of more than III was defined as major complication.
[c] Early defined as complications occurring within 30 days of surgery.
[d] Late defined as complications occurring more than 31 days after surgery.

In multivariate analysis, tumor size, pT4a stages, number of retrieved lymph nodes and presence of lymphatic invasion were identified as predictors related to disease-free survival. The surgical approach (laparoscopy or open) did not influence the disease-free survival (HR 0.975, 95% CI 0.712 to 1.336; P = 0.875).

Discussion

To the best of our knowledge, the present study might be the largest retrospective study focused exclusively on the long-term outcomes of LAG for the curative treatment of AGC with radical D2 lymph node resection. In the present study, a total of 1198 consecutive AGC patients were enrolled, and the longest follow-up period was nearly 11 years. In the LAG group, the distribution of stage Ib, II, and III disease was 46 (10.7%), 159 (37.0%; IIa/IIb, 69/90) and 225 (52.3%; IIIa/IIIb/IIIc, 78/98/49), respectively; thus, this study offered subgroups that all contained adequate numbers of AGC patients.

Currently, two of the three reported ongoing RCT[13–15] studies evaluating LADG for AGC, from China[13] (CLASS-01) and Japan[14] (JLSSG0901), have demonstrated the technical safety of LADG for AGC only in terms of short-term surgical morbidity and mortality. The remaining study (COACT 1001), involving 204 AGC patients in 2017[15], reported no difference in 3-year DFS between LADG and open distal gastrectomy (ODG) (80.1% vs. 81.9%; P = 0.448). Moreover, the subgroup analysis in the COACT 1001 study suggested that further studies are needed for stage III gastric cancer. Except for these three studies, the present long-term outcomes for laparoscopic and open gastrectomy for AGC come almost entirely from single- or multicenter retrospective studies.[8–12] These retrospective studies may be commonly burdened with some limitations, such as lacking control studies, being small matched studies or lacking subgroups with adequate numbers of AGC patients.

Table 4
Sites of first recurrence between laparoscopic and open gastrectomy.

Recurrence pattern	OG (n = 768)	LAG (n = 430)	P value
Total	387(50.4%)	203(47.2%)	0.091
Locoregional or distant lymph nodes	175(22.8%)	97(22.6%)	
Lung	26(3.4%)	16(3.7%)	
Liver	77(10.0%)	42(9.8%)	
Bone	24(3.1%)	12(2.8%)	
Peritoneum	12(1.6%)	6(1.4%)	
Port-site	0	2(0.5%)	
Anastomotic stoma	33(4.3%)	10(2.3%)	
Gut	16(20.8%)	9(2.1%)	
Pancreas	5(0.7%)	1(0.2%)	
Brain	7(0.9%)	2(0.5%)	
Kidney	0	1(0.2%)	
Other	12(1.6%)	5(1.2%)	

In the present study, we observed more intraoperative blood loss in the LAG group than in the OG group (273.7 ± 233.7 ml vs. 233.6 ± 183.4 ml, P = 0.002), which was not in accordance with the results of past studies.[11,18] Remarkably, over 50% of the patients in this cohort who underwent LAG had stage III disease, and D2 lymphadenectomy dealing with locally metastatic lymph nodes was a higher-level skill in the LAG group than in the OG group. The metastatic lymph nodes may blend with each other or closely adhere to the blood vessels or the surrounding tissues in some patients. Bleeding or blood oozing of wound sometimes can occur in this cohort over 50% LAG patients with stage III disease.

Based on the Clavien-Dindo classification, the severity of postoperative complications in the laparoscopic group was similar to that in the open group. When we conducted a limited analysis of the late complications (occurring more than 30 days after surgery) in both groups, 2 cases of anastomotic stricture and 2 cases of intestinal obstruction were found in the LAG group; the incidence of late complications in the LAG group tended to be greater, although not significantly so, than that in the OG group (0.9% vs. 0.4%, P > 0.05). In this study, all cases of anastomotic stricture occurred in patients of either group who underwent total gastrectomy. The hazards associated with esophagojejunostomy in patients treated with the laparoscopic approach were primarily anastomosis-related complications, such as leakage and stricture.[19]

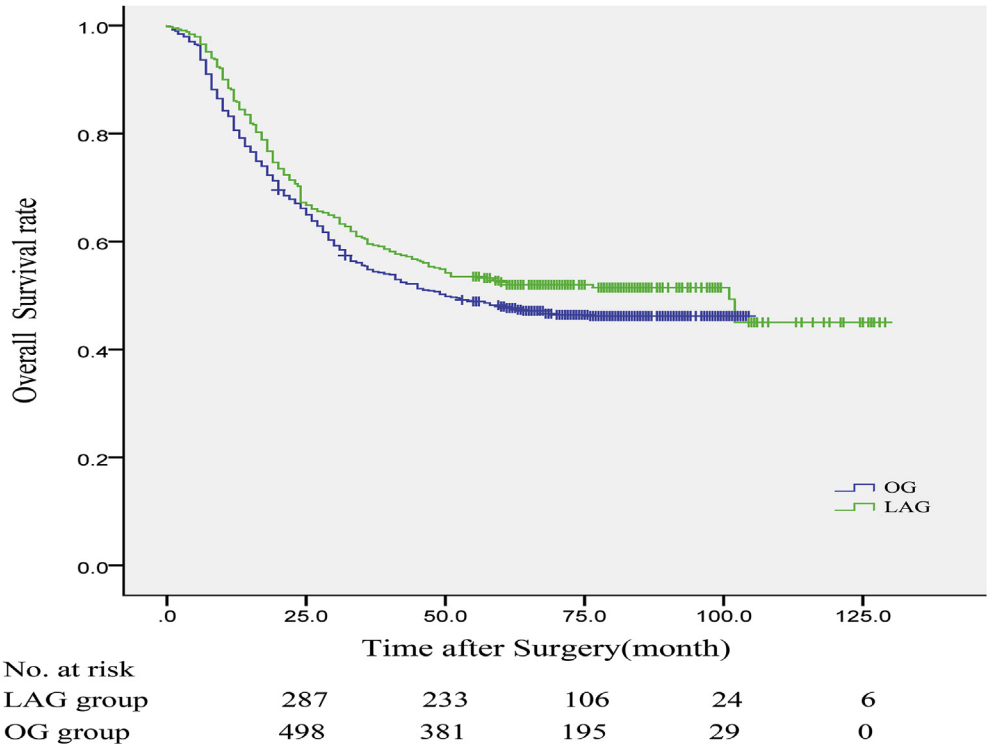

Fig. 2. Kaplan–Meier overall survival curves for patients undergoing LAG or OG.

In the present study, not only the 5-year OS but also DFS were comparable in the LAG and OG groups. Moreover, the subgroup analysis showed significant differences in both OS and DFS according to TNM stage within each group. In this study, we found that tumor size, number of retrieved lymph nodes and presence of lymphatic invasion were significantly associated with disease-free survival, which was similar with the previous studies.[20,21] Although overall pT-stage was not a factor notably associated

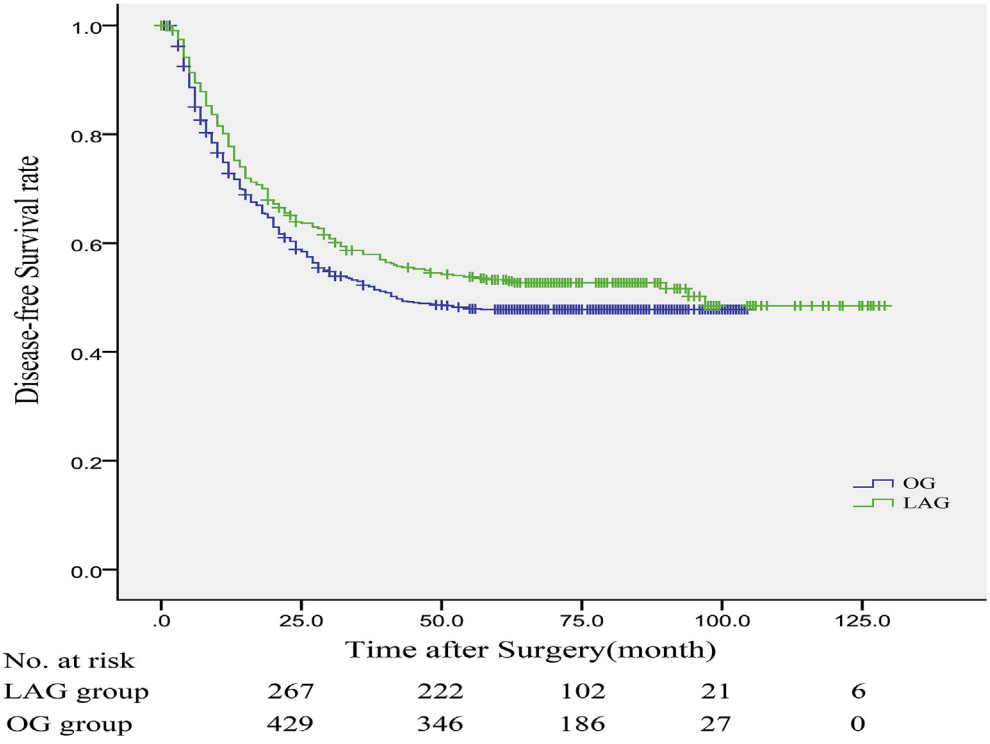

Fig. 3. Kaplan–Meier disease-free survival curves for patients undergoing LAG or OG.

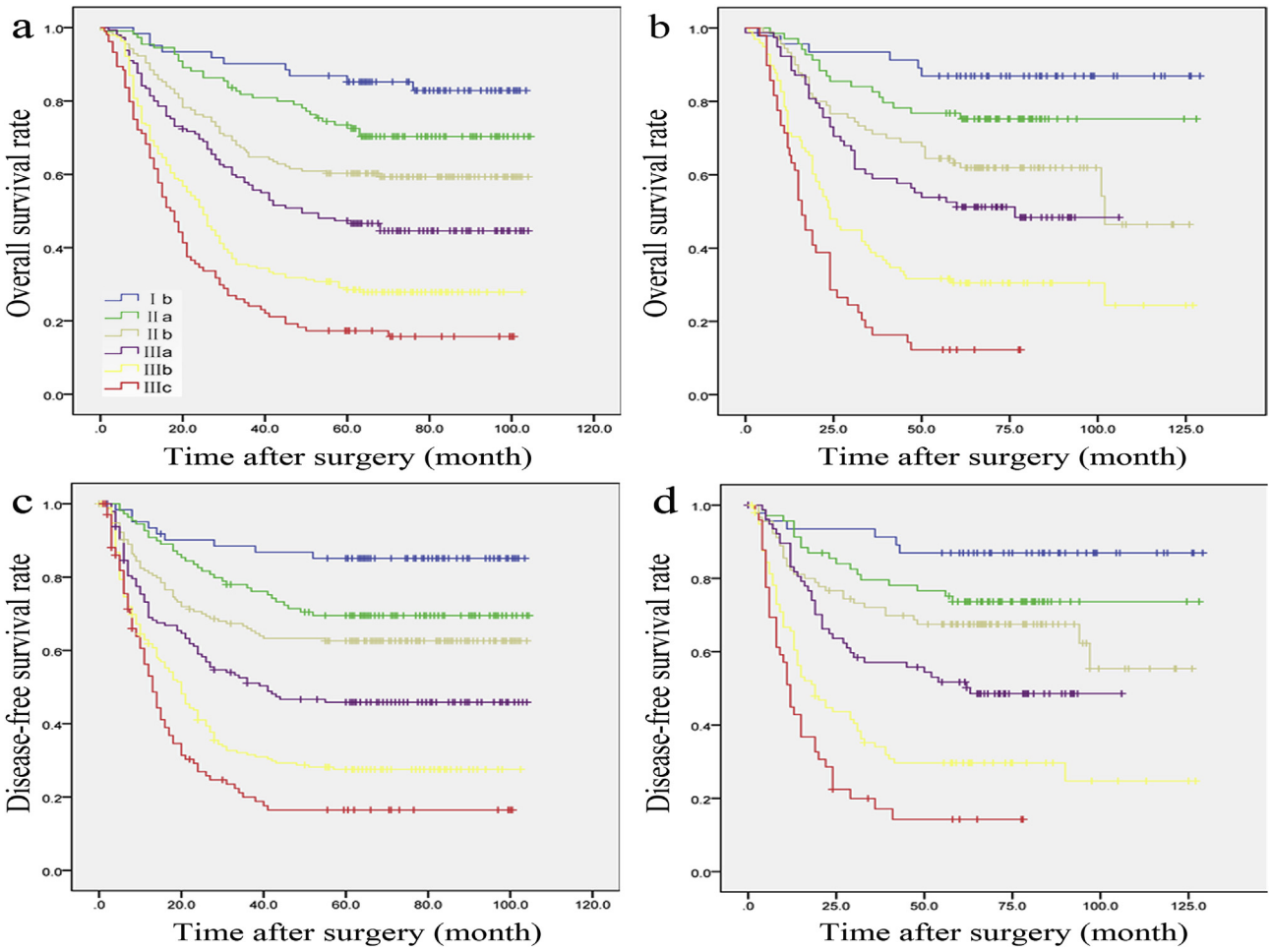

Fig. 4. Subgroup analysis according to UICC pathology; a, OS for patients undergoing OG; b, OS for patients undergoing LAG; c, DFS for patients undergoing OG; d, DFS for patients undergoing LAG.

with disease-free survival (P = 0.113), whereas, pT4a-stage was significantly associated with disease-free survival (HR 0.773, 95% CI 0.603 to 0.991; P = 0.042). Particularly, the surgical approach (laparoscopy or open) did not influence the disease-free survival in our analysis.

Table 5
Multivariate analysis of clinicopathologic factors potentially associated with the presence of recurrence.

Factors	Hazard ratio (95% CI)	p value
Age (y)	1.004 (0.995–1.002)	0.397
Gender	1.143 (0.933–1.399)	0.198
BMI (kg/m^2)	0.962 (0.936–0.988)	0.005
ASA score, n (%)		0.710
II/I	0.938 (0.679–1.298)	0.703
III/I	1.040 (0.808–1.339)	0.759
Type of operation	0.975 (0.712–1.336)	0.875
Tumor size	1.088 (1.033–1.145)	0.001
Tumor location		0.796
Upper/multiple	0.518 (0.124–2.172)	0.369
Middle/multiple	0.523 (0.125–2.191)	0.375
Lower/multiple	0.568 (0.132–2.436)	0.446
T status		0.113
T3/T2	0.567 (0.304–1.059)	0.075
T4a/T2	0.773 (0.603–0.991)	0.042
No. of examined LN	0.974 (0.964–0.984)	<0.001
Lymphatic invasion	1.049 (1.012–1.087)	0.009
Complications	1.375 (0.976–1.937)	0.069

CI, confidence interval.
LN, lymph node.

With reference to recurrence patterns, two patients who experienced port-site recurrence were observed to have widespread metastasis. Although the cause of port-site recurrence was not clear,[22] the specific relevance of potential port-site metastasis associated with pneumoperitoneum should be evaluated properly in future studies. Unlike previous studies,[23,24] we observed lower peritoneum implanting. It might associate with less sensitive imaging examination for peritoneum implanting, including abdominal ultrasonography (AUS) and enhanced MRI/CT, even ^{18}F-FDG PET/CT.[25] The actual incidence of peritoneum implanting would be higher.

In fact, this study has several inherent limitations, including its retrospective nature, single-center design, and potential for undetected selection bias. However, we believe that our unique analysis is valuable because the length of the follow-up period in this study is sufficient to assess the technical feasibility and oncologic adequacy of LAG for the treatment of AGC. In addition, this study involves subgroups that all contain adequate numbers of AGC patients. In particular, over 50% of the patients included in this study had stage III disease, a rate which might facilitate the detection of the potential negative effects of LAG on oncologic efficiency compared with those of OG.

Conclusion

Our results suggest that LAG not only may be technically feasible in the setting of AGC but also may result in long-term oncologic adequacy comparable to that achieved with OG.

Conflicts of interest

The authors declare that there is no conflict of interests regarding the publication of this article.

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Author contributions

Study conception and design: Jianjun Du, Yonggang Xu, Jin Hua, Jipeng Li, Liubin Shi, Hongyuan Xue, Jianbo Shuang.

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Drafting of manuscript: Yonggang Xu, Jin Hua, Hongyuan Xue.

All authors were responsible for the writing, review, critical revision, and final approval of the manuscript, and all authors have agreed to be accountable for its content.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.amjsurg.2018.07.012.

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