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Feasibility and safety of laparoscopy-assisted distal gastrectomy performed by trainees supervised by an experienced qualified surgeon

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Abstract

Background Laparoscopic gastrectomy is becoming more commonly performed, but acquisition of its technique remains challenging. We investigated whether laparoscopy-assisted distal gastrectomy (LDG) performed by trainees (TR) supervised by a technically qualified experienced surgeon (QS) is feasible and safe.

Methods The short-term outcomes of LDG were assessed in patients with gastric cancer between 2008 and 2018. We compared patients who underwent LDG performed by qualified experienced surgeons (QS group) with patients who underwent LDG performed by the trainees (TR group).

Results The operation time was longer in the TR group than in the QS group (median time: 270 min vs. 239 min, $p<0.001$). The median duration of the postoperative hospital stay was 9 days in the QS group and 8 days in the TR group ($p=0.003$). The incidence of postoperative complications did not differ significantly between the two groups. Grade 2 or higher postoperative complications occurred in 18 patients (12.9%) in the QS group and 47 patients (11.7%) in the TR group ($p=0.763$). Grade 3 or higher postoperative complications occurred in 9 patients (6.4%) in the QS group and 17 patients (4.2%) in the TR group ($p=0.357$). Multivariate analysis showed that the American Society of Anesthesiologist Physical Status was an independent predictor of grade 2 or higher postoperative complications and that gender was an independent predictor of grade 3 or higher postoperative complications. The main operator (TR/QS) was not an independent predictor of complications.

Conclusions Laparoscopy-assisted distal gastrectomy performed by trainees supervised by an experienced surgeon is a feasible and safe procedure similar to that performed by experienced surgeons.

Keywords Laparoscopy-assisted distal gastrectomy · Trainee · Feasibility · Safety · Education

Gastric cancer is the third leading cause of cancer-related deaths annually worldwide [1]. Surgical resection plays the most important role in the treatment of early gastric cancer. Laparoscopy-assisted distal gastrectomy (LDG) has been widely used to treat patients with early gastric cancer since it was first reported by Kitano et al. in 1991 [2].

Recently, several clinical studies have demonstrated that LDG is safe, feasible, and effective [3–5]. However, acquisition of the technique of LDG remains challenging. The Japan Society for endoscopic surgery developed its endoscopic surgical skill qualification system (ESSQS) in 2001 [6]. The rate of passing the examination has been about 30% in recent years. Education and training are very important with respect to LDG because of the difficulty in acquiring the skills required to perform LDG.

Our institute always has 4 to 5 trainees who want to master such a technique. We have an original education system to provide training about LDG. LDG performed by trainees in our institute must be supervised by a qualified experienced surgeon certificated by the ESSQS. However, the feasibility and safety of such surgical procedures remain

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unclear. The aim of this study was to evaluate the feasibility and safety of LDG performed by trainees applying our original educational system.

Materials and methods

Patients

We retrospectively studied consecutive patients with a clinical diagnosis of stage IA or IB gastric adenocarcinoma according to the Japanese Classification of Gastric Carcinoma [7] who underwent LDG in the Department of Gastrointestinal Surgery, Kanagawa Cancer Center, from April 2008 through March 2018. Patients with other types of cancer were excluded.

Surgical procedures

A qualified experienced surgeon certified by the ESSQS (QS) always attended the operations as the main operator or a teaching assistant. Laparoscopic procedures were performed using six ports. We always used a snake retractor to lift up the left lobe of the liver. The extent of lymph-node dissection was performed according to the Japanese Gastric Cancer Treatment guidelines [8]. We usually performed Billroth-I reconstruction using an automatic anastomotic device via a mini-laparotomy in the epigastric area. If the tumor invaded the pylorus or was located in upper gastric body, Roux-en Y reconstruction was performed using an automatic anastomotic device via a mini-laparotomy in left upper abdominal region.

Perioperative care

Patients received conventional perioperative care program before June 2009, whereas they received perioperative care according to our original enhanced recovery surgery (ERAS) program after June 2009 [9]. The patients could be discharged after they had achieved adequate pain relief, soft food intake, and normal laboratory data on postoperative day 7 in both perioperative care programs.

Education system

Trainees must satisfy the following regulations before they start LDG training: Trainees must i) be Board Certified Surgeons approved by the Japan Surgical Society, ii) have received lectures about LDG by an experienced surgeon, iii) always learn by directly viewing videos of standard LDG, iv) practice laparoscopic procedures with the use of a dry box, v) receive animal laboratory training, vi) have experience performing open gastrectomy in least five patients in our institute, vii) understand the standard techniques and strategies of gastric cancer surgery in Japan, viii) have experience as a scopist and main assistant performing LDG in least each of the five patients in our institute, and ix) have passed an original paper quiz about LDG. Basically, only one or two trainees trained during same period. We consider that it is better for trainees to learn by intensively performing the procedure within a short period. One trainee would be given 20 to 25 chances to perform LDG.

Data collection

The clinical, surgical, and pathological data were retrieved from the patients' clinical records retrospectively. Postoperative complications that occurred within 30 days after surgery were defined according to the Clavien–Dindo classification [10].

Statistical analysis

We compared patients who underwent LDG performed by QS (QS group) with patients who underwent LDG performed by the trainees (TR group). The groups were compared with the use of $\chi 2$ tests and Mann–Whitney U tests. We assessed predictors of postoperative complications by multivariate logistic-regression analysis. Data analyses were performed using SPSS software, version 24 for Windows (SPSS Inc., Chicago, IL). Two-sided p values were calculated, and a difference was considered statistically significant at $p < 0.05$.

Results

Patients' clinicopathological characteristics (Table 1)

The clinicopathological characteristics of the patients, including gender, age, American Society of Anesthesiologists Physical Status (ASA-PS), body mass index, and history of abdominal surgery, did not differ between the QS group and TR group. Pathological findings of gastric cancer also did not differ significantly.

Surgical outcomes (Table 2)

The rate of D2 lymphadenectomy was higher in the QS group (32% in QS group, 16% in TR group, $p < 0.001$). Reconstruction methods and blood loss did not differ between the two groups. The operation time was significantly longer in the TR group than in the QS group (median time: 270 min vs. 239 min, $p < 0.001$). One patient (0.7%) in the QS group and 9 patients (2.2%) in the TR group underwent combined organ resection. All

Table 1 Patients' clinicopathological characteristics

	QS n(%)	TR n(%)	*p* value
Gender			
Male	93 (66)	249 (62)	0.416
Female	47 (34)	152 (38)	
Age (years old)			
Median (IQR)	65 (59–71)	67 (59–73)	0.189
< 75	119 (85)	317 (79)	0.137
≥ 75	21 (15)	84 (21)	
ASA-PS			
1	42 (30)	106 (26)	0.373
2	98 (70)	291 (73)	
3	0 (0)	4 (1)	
BMI			
Median (IQR)	22.6 (20.3–24.7)	22.5 (20.3–24.5)	0.601
< 25	109 (78)	321 (80)	0.627
≥ 25	31 (22)	80 (20)	
History of abdominal surgery			
(+)	34 (24)	90 (22)	0.642
(-)	106 (76)	311 (78)	
pT			
T1	112 (80)	334 (83)	0.600
T2	20 (14)	41 (10)	
T3	5 (4)	18 (4)	
T4	3 (2)	8 (2)	
pN			
N0	114 (91)	354 (88)	0.131
N1	10 (7)	27 (7)	
N2	12 (9)	15 (4)	
N3a	3 (2)	4 (1)	
N3b	1 (1)	1 (0)	
pM			
M0	140 (100)	400 (100)	1.000
M1	0 (0)	1 (0)	
pStage			
I	118 (84)	353 (88)	0.377
II	20 (14)	38 (9)	
III	2 (1)	9 (2)	
IV	0 (0)	1 (0)	

IQR interquartile range, *ASA-PS* American Society of Anesthesiologist Physical Status, *BMI* body mass index

of these patients underwent cholecystectomy. One patient (0.7%) in the QS group and 4 patients (0.9%) in the TR group required conversion to open surgery ($p = 1.000$). Although the number of harvested lymph nodes was significantly lower in the TR group than in the QS group, more than 15 lymph nodes were harvested in most patients in both groups (100% in QS group, 96.5% in TR group).

Table 2 Surgical outcomes

	QS n(%)	TR n(%)	*p* value
Lymph-node dissection			
D1+	95 (68)	335 (84)	< 0.001
D2	45 (32)	66 (16)	
Reconstruction			
B-I	103 (74)	289 (72)	0.826
R-Y	37 (26)	112 (28)	
Combined organ resection			
(+)	1 (1)	9 (2)	0.466
(-)	139 (99)	392 (98)	
Operation time			
Median (IQR)	239 (205–310)	270 (230–311)	< 0.001
Blood loss			
Median (IQR)	30 (15–90)	40 (10–80)	0.762
Conversion to open procedure			
Yes	1 (1)	4 (1)	1.000
No	140 (99)	397 (99)	
Harvested LN (number)			
Median (IQR)	44 (35–59)	39.5 (30–49)	< 0.001
Harvested LN number ≥ 15	140 (100)	387 (97)	< 0.026
Postoperative hospital stay (days)			
Median (IQR)	9 (8–10)	8 (8–9)	0.003

B-I Billroth-I method, *R-Y* Roux-en Y method, *IQR* interquartile range, *LN* lymph node

The median postoperative stay was 9 days in the QS group and 8 days in the TR group ($p = 0.003$).

Postoperative complications (Table 3)

The incidence of postoperative complications did not differ significantly between the groups. Grade 2 or higher postoperative complications occurred in 18 patients (12.9%) in the QS group and 47 patients (11.7%) in the TR group ($p = 0.763$). Grade 3 or higher postoperative complications occurred in 9 patients (6.4%) in the QS group and 18 patients (4.2%) in the TR group ($p = 0.357$). Major postoperative complications after gastrectomy, such as anastomotic leakage, pancreatic fistula, and intra-abdominal abscess, also did not differ between the groups. No patient had a grade 3 or higher pancreatic fistula in the QS group, whereas two patients had this complication in the TR group ($p = 1.000$).

Independent predictors of postoperative complications (Table 4)

Multivariate analysis showed that ASA-PS was an independent predictor of grade 2 or higher postoperative complications and gender was an independent predictor of grade 3

Table 3 Morbidity and Mortality

Grade 2 or more	QS n(%)	TR n(%)	*p* value
Any complication	18 (12.9)	47 (11.7)	0.763
Anastomotic leakage	3 (2.1)	8 (2.0)	1.000
Pancreatic fistula	3 (2.1)	8 (2.0)	1.000
Intra-abdominal abscess	4 (2.9)	5 (1.2)	0.249
Pneumonia	2 (1.4)	8 (2.0)	1.000
Stenosis	1.(0.7)	1 (0.2)	0.451
Ileus	1 (0.7)	3 (0.7)	1.000
Bleeding	1 (0.7)	1 (0.2)	0.451
Transaminase elevation	1 (0.7)	2 (0.5)	1.000
Delirium	1 (0.7)	2 (0.5)	1.000
Others	1 (0.7)	9 (2.2)	0.466
Grade 3 or more			
Any complication	9 (6.4)	17 (4.2)	0.357
Anastomotic leakage	3 (2.1)	6 (1.5)	0.702
Pancreatic fistula	0 (0)	2 (0.5)	1.000
Intra-abdominal abscess	2 (1.4)	2 (0.5)	0.276
Pneumonia	1 (0.7)	1 (0.2)	0.451
Stenosis	1 (0.7)	1 (0.2)	0.451
Ileus	0 (0)	1 (0.2)	1.000
Bleeding	1 (0.7)	0 (0)	0.259
Transaminase elevation	1 (0.7)	0 (0)	0.259
Delirium	0 (0)	0 (0)	N.S.
Others	0 (0)	4 (1.0)	0.577
Mortality	0 (0)	2 (0.5)	1.000

or higher postoperative complications. The main operator was not an independent predictor of either grade or of more severe complications.

Discussion

This study investigated whether LDG performed by trainees educated with the use of our original training system is as safe and feasible as LDG performed by experienced surgeons. The incidence of postoperative complications in the TR group was similar to that in the QS group, although the operation time was longer in the TR group than in the QS group.

We mainly attribute the good results of our study to several educational factors. The first was preoperative study. In our education system, trainees thoroughly learned our surgical procedure by attending sessions of LDG performed by experienced surgeons, self-learning by viewing a video library, and experience performing open gastrectomy. When an experienced surgeon acknowledged that a trainee understood our procedure and the trainee passed a paper quiz, they could perform LDG in our education system. Kuroda et al. reported that standardization of procedures and establishment of a training system enable good-quality operations (operation time < 240 min., blood loss < 50 ml, and retrieved lymph nodes ≥ 15) [11].

The second educational factor was sharing of experience. Trainees studied various techniques under the supervision of multiple teaching staff. Trainees also always attended LDG sessions performed by other trainees and thereby acquired experience. Furthermore, we had the opportunity to periodically review the surgical videos. Because of these factors, we could mature as a surgical team. Nunobe et al. reported that sufficient experience as an assistant and scopist effectively ensured the clinical safety of LDG performed by a trainee [12]. We believe that sharing of experience might complement such experience.

The third educational factor was basic laparoscopic skill. Two previous prospective feasibility studies required that the main operator had sufficient basic skill acquired through experience by performing laparoscopic cholecystectomy [13, 14]. Recently, however, laparoscopic cholecystectomy, laparoscopic inguinal hernia repair, and laparoscopic colectomy are already general procedures and are more popular than laparoscopic gastrectomy in Japan [15]. Because of this factor, now nearly all trainees in our hospital already had sufficient basic laparoscopic skills.

Kaito and Kinoshita also mentioned that the three factors of "learning (study)," "practice (skill)," and "experience" are important for mastering laparoscopic gastrectomy [16]. Previous studies have demonstrated that LDG performed by trainees under the guidance of an experienced surgeon is safe and feasible [12, 17]. These studies compared the short-term outcomes of LDG between trainers and trainees. However, only univariate analysis was performed. There were different distributions of gender, body mass index, lymph-node dissection, and surgical procedures in the results. These differences might have lead to great bias resulting in the good results in the trainee group. In present study, we carried out multivariate analysis to adjust for differences in background factors. As a result, we found that TR was not an independent predictor of postoperative complications, whereas ASA-PS and gender were independent predictors of such complications. In both the present study and previous studies, the incidences of postoperative complications did not differ significantly between the trainees and trainers [12, 17]. However, the incidence of pancreatic fistula was slightly higher in trainee-performed surgery [12, 17]. Our results also showed that severe pancreatic fistula (Clavien–Dindo classification grade 3) occurred only in the TR group. Dissection of the infrapyloric lymph nodes and suprapancreatic lymph nodes is one of the most complicated procedures of LDG and might cause pancreatic fistula. We

Table 4 Multivariate analysis

For ≥ grade 2 postoperative complication			
Factors	Odds ratio	95% C.I.	p value
Gender			
Female	1.000		
Male	1.513	0.842–2.719	0.167
ASA-PS			
1	1.000		0.131
2	1.144	0.611–2.140	0.674
3	8.327	1.062–65.294	0.044
Body mass index			
< 25	1.000		
≥ 25	1.027	0.539–1.955	0.936
Extent of lymph-node dissection			
D1	1.000		
D2	1.336	0.714–2.499	0.364
Main operator			
QS	1.000		
TR	0.900	0.494–1.638	0.730
For ≥ grade 3 postoperative complication			
Factors	Odds ratio	95% C.I.	p value
Gender			
Female	1.000		
Male	3.573	1.186–10.758	0.024
ASA-PS			
1	1.000		0.105
2	0.556	0.233–1.326	0.185
3	5.192	0.438–61.586	0.192
Body mass index			
< 25	1.000		
≥ 25	0.478	0.138–1.657	0.244
Extent of lymph-node dissection			
D1	1.000		
D2	1.431	0.559–3.664	0.455
Main operator			
QS	1.000		
TR	0.645	0.267–1.558	0.330

ASA-PS American Society of Anesthesiologist Physical Status

believe that we must pay special attention to the potential risk of pancreatic fistula in patients who undergo LDG performed by trainees and that it might be better that we do not allow trainees to unconditionally perform LDG in patients with a high ASA-PS score or male patients.

The operation time in the TR group was longer than that in the QS group in present study, as reported repeatedly [11, 17, 18]. Kuwabara et al. reported that a longer operation time was associated with delayed postoperative feeding in an analysis of 14,465 patients who underwent gastrectomy [19]. However, the postoperative hospital stay was conversely shorter in the TR group than in the QS group in our study. We consider that there were several reasons for this outcome. The first is perioperative care. In 2009, an ERAS program was induced to our hospital for patients undergoing gastrectomy [9]. Kuwabara et al. reported that postoperative epidural analgesia and the early initiation of rehabilitation are significant determinants of the postoperative fasting period and are thus important factors of the ERAS program [19]. The second factor is the extent of lymph-node dissection. The proportion of patients who underwent D2 dissection was higher in the QS group than in the TR group. Previous randomized controlled studies of lymph-node dissection repeatedly reported that the postoperative hospital stay of patients who underwent D2 dissection was longer than that of patients who underwent D1 dissection [20–22].

Our study had several limitations. First, some bias must be present because this study was retrospective. Although we carried out multivariate analysis, there might be potential risk factors that were not included in analysis. For instance, trainees were not allowed to perform LDG in high-risk patients in our hospital, such as those with a high BMI, at least within the first 10 patients they treated. Second, the event number of postoperative complications might not have been sufficient. Consequently, some factors might not have been included in the multivariate analysis. Third, this study was conducted at a single Japanese hospital that is located in a region with a high risk of gastric cancer. We believe that intensive experience is necessary to acquire the LDG technique or providing education on such skills. In low-risk regions, centralization of patients undergoing surgery or educational systems to educate young surgeons at foreign high-volume centers might be necessary. Fourth, the studied patients were accumulated over a 10-year interval. Surgical techniques, skills, and perioperative care were changing during the decade. Because new innovative techniques may initially be performed by experienced surgeons, this factor may have also affected the results.

Although our study demonstrated that LDG performed by trainees is feasible and safe, the oncologic safety and long-term outcomes of this procedure remain unclear. In the present study, more than 15 lymph nodes were retrieved in most of the patients, as recommended by National Comprehensive Cancer Network/European Society for Medical Oncology guidelines [23, 24]. However, harvested number of lymph nodes did not reach 15 in some patients in the TR group. This could be a potential risk for long-term outcomes. An ongoing multicenter phase III clinical trial (JCOG0912) is evaluating whether laparoscopy-assisted distal gastrectomy is non-inferior to open distal gastrectomy [25]. That trial requires that well-experienced surgeons serve as the main operators or teaching assistants, similar to our strategy. The results of the JCOG0912 study might provide the answer to this issue in the future.

Conclusions

Laparoscopy-assisted distal gastrectomy performed by trainees supervised by experienced surgeons is a feasible and safe procedure, similar to that performed by experienced surgeons. We should recognize the potential risks, importance of perioperative care, and appropriate patient selection for laparoscopy-assisted gastrectomy performed by trainees.

Compliance with ethical standards

Disclosures T. Yamada, Y. Kumazu, M. Nakazono, K. Hara, S. Nagasawa, Y. Shimoda, T. Hayashi, Y. Rino, M. Masuda, M. Shiozawa, S. Morinaga, T. Ogata, and T. Oshima have no conflicts of interest or financial ties to disclose.

Ethical approval This study, a retrospective analysis, was approved by the institutional review board of Kanagawa Cancer Center.

Informed consent Informed consent for using the clinical data without disclosing any personal information was obtained from all patients before surgery.

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