

The learning curve associated with laparoscopic total gastrectomy

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Received: 19 June 2014 / Accepted: 17 November 2014 / Published online: 7 December 2014
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Abstract

Background Although the frequency of laparoscopic total gastrectomy (LTG) has been increasing, the procedure requires considerable experience because of its technical difficulty and the concern for oncological safety. This study intended to define the learning curve associated with the procedure.

Methods All 256 cases of LTG performed from June 2003 to December 2012 were enrolled. The cases were divided into ten groups of 25 cases based on when they occurred. The learning curve was defined using the moving average method. LTG, performed in the absence of other procedures (pure-LTG, 132 cases), was extracted from the ten groups, and the mean operative time and estimated blood loss (EBL) were compared to define the learning curve. Retrieved lymph nodes, hospital stay, and complications were compared across the phases of the learning curve. LTG with spleen resection, performed in the absence of other procedures (pure-srLTG, 53 cases), was also analyzed by the same method.

Results A three-phase learning curve of LTG was defined: the first two groups, the following two groups, and

the final six groups (mean operative time: 223.0, 244.8, and 207.8 min, respectively, $p = 0.003$; mean EBL: 94.6, 237.0, and 116.5 ml, respectively, $p < 0.001$). The rates of complications and open conversions were similar across the three phases. There were no significant differences in mean operative time, EBL, retrieved LNs, hospital stay, or complication rates between pure-LTG and pure-srLTG, after completing the respective learning curves.

Conclusions Experience with approximately 100 LTG cases was required to complete learning of the procedure.

Keywords Learning curve · Laparoscopic total gastrectomy · Stomach neoplasms

Introduction

The use of laparoscopy-assisted distal gastrectomy (LADG) for early gastric cancer has increased since it was first reported by Kitano et al. in 1994 [1]. Currently, because LADG is considered technically feasible and oncologically safe for the treatment of early gastric cancer, its indications have been extended from early gastric cancer to advanced disease [2]. Because the indication for LADG has expanded, surgeons who have experience with LADG cautiously attempt laparoscopic total gastrectomy (LTG) in selected patients [3]. Recently, several reports have compared the outcomes of LTG to that of open total gastrectomy (OTG) [4, 5]. However, concerns about the technical difficulty and oncological safety of LTG remain [6]. In addition, there is no standard or superior method for esophagojejunostomy in LTG; therefore, many different types of esophagojejunostomy are performed [7, 8].

Several previous reports have described the learning curves for LADG [9, 10]. However, reports on the learning

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curve for LTG are rare. Therefore, the present study was conducted to analyze the learning curve of LTG.

Materials and methods

Patients

All 256 gastric cancer patients who underwent LTG completely between January 2003 and December 2012 were enrolled in the present study. Of these 256 patients, 82 who underwent LTG with spleen resection (srLTG) were also included. All operations were performed by a surgeon who had introduced and standardized laparoscopic gastrectomy at our institution. Patients undergoing laparoscopic explorations and laparoscopic biopsies were excluded.

Patients who were converted to open surgery and those with a history of prior gastrectomy were included in the present study. Patients enrolled in other studies, including those who underwent sentinel node navigation surgeries, D3 lymph node (LN) dissection after chemotherapy, etc., were also included in the present study. Patients who underwent combined resection for invasive organ or coexistent disease were also included. These cases, which were combined with other procedures, were included because they provided LTG experience to the surgeon. However, the learning curve analysis was performed by including only LTG performed in the absence of other procedures (pure-LTG) or srLTG in the absence of other procedures (pure-srLTG), extracted from the 256 cases, to avoid operative procedure heterogeneity.

Variables

General data

Patient demographics, surgical factors, pathological factors, and postoperative outcomes were collected from electronic medical reports and reviewed retrospectively.

Surgical quality

The following variables were analyzed for evaluating the quality of the operations: operative time, estimated blood loss (EBL), number of retrieved LNs, hospital stay, and complications. Postoperative complications included 30-day morbidity and mortality. Complications were graded by the Clavien–Dindo classification [11]. A simple hospital course deviation (grade I) was not regarded as an event, whereas those requiring medical or surgical interventions (grade II or higher) were regarded as an event.

Techniques

The LN groups were numbered according to the Japanese classification of gastric cancer in the present study [12]. Our LTG technique has been previously described [4, 8]. Briefly, the distal pancreas was mobilized by incising the peritoneum along the inferior margin of the distal pancreas, during left-side omentectomy. If indicated, full mobilization of the spleen was performed for splenectomy. After dissecting LNs 7, 8, 9, and 12a, the lower esophagus was transected using a linear stapler for intracorporeal side-to-side esophagojejunostomy. Extracorporeal end-to-side esophagojejunostomy was sometimes performed in non-obese patients under direct vision through a mini-laparotomy in the epigastrium. Since October 2008, intracorporeal end-to-side esophagojejunostomy has been performed using an endoscopic purse-string instrument [Endo-PSI (II); Chiba, Japan or Lap-Jack; Eterne, Gyeong-gi, Korea]. After transecting the lower esophagus, LNs 11p, 11d, and 10 were completely dissected. For splenectomy, the caudal splenic artery was clipped and divided, and the splenic vein was clipped and divided at the point of entry into the distal pancreas. In cases of intracorporeal side-to-side esophagojejunostomy, the specimen was extracted through an extended transumbilical incision and the negative resection margin was confirmed by frozen biopsy. The esophagojejunostomy was performed using a 45-mm-long linear stapler, and the common entry hole was subsequently closed with an intracorporeal continuous suture. In cases in which the intracorporeal end-to-side esophagojejunostomy was performed using the endoscopic purse-string instrument, the left lower port was extended to a length of about 3 cm for removing the specimen and inserting a circular stapler. Before any type of esophagojejunostomy was performed, an extracorporeal jejunojunal anastomosis was performed at the site of specimen extraction.

Defining the learning curve of LTG for gastric cancer

Two sequential variables, operative time and EBL, were used to define the learning curve by using a moving average method with split groups [9, 10]. The 256 patients were divided into ten sequential groups of 25 cases each; the last group comprised 31 patients. The pure-LTG cases in each group were extracted to avoid operative heterogeneity. Thereafter, cases with combined resection and those enrolled in other studies that may have extended the operative time were not used in the learning curve analysis. The mean values of the operative time and EBL of pure-LTG in each group were calculated and compared to define the learning curve. Other variables, such as the occurrence of complications, hospital stay, and the number of retrieved

LN, were compared across the different phases of the calculated learning curve.

D2 + LN dissection might be more time consuming and difficult to achieve than D1 + LN dissection. Therefore, we analyzed additionally the learning curve of pure-LTG with D2 LN dissection. The pure-LTG with D2 LN dissection cases in each group were extracted to avoid the heterogeneity of LN dissection. The mean values of the operative time and EBL of pure-LTG in each group were calculated and compared to define the learning curve.

Defining the learning curve of srLTG for gastric cancer

The 82 patients who underwent srLTG were divided into seven sequential groups of 12 cases each; the last group comprised 10 patients. Cases of pure-srLTG in each group were extracted to avoid operative heterogeneity. The moving average method with two sequential variables was used for pure-srLTG cases extracted from each split group in the learning curve analysis similar to that for pure-LTG.

Statistics

Statistical analyses were performed using Student's *t* test and the Mann–Whitney *U* test for continuous variables; the χ^2 test was used for analysis of categorical variables. One-way analysis of variance (ANOVA) and the Kruskal–Wallis test were used for comparing continuous variables among more than three groups; $p < 0.05$ (two-sided) was considered statistically significant. All statistical analyses were performed with SPSS 18.0 software (SPSS, Chicago, IL, USA).

Results

Types of other procedures among the LTG cases

The 256 LTG cases included many groups: pure-LTG, pure-srLTG, LTG with laparoscopic cholecystectomy, LTG with laparoscopic distal pancreatectomy, LTG in cooperation with other departments, LTG enrolled in other studies, conversion to open surgery, and completion LTG for remnant gastric cancer (Table 1). Conversion to open surgery occurred in 17 cases (6.6 %) among the 256 cases in which LTG was attempted. There were 8 cases of open conversion among the 17 cases in which completion LTG was attempted for remnant gastric cancer. The reasons for the conversion to open surgery included adhesion (9 cases), bleeding (6 cases), and faulty anastomosis devices (2 cases).

Table 1 Types of laparoscopic total gastrectomy cases enrolled in the present study

Combined procedures or studies	Cases (%)
Pure-LTG	132 (51.6)
Pure-srLTG	53 (20.7)
LTG with laparoscopic cholecystectomy	12 (4.7)
LTG with laparoscopic distal pancreatectomy	9 (3.5)
LTG in cooperation with other departments	13 (5.1)
LTG enrolled in other studies	11 (4.3)
Completion LTG for remnant gastric cancer	9 (3.5)
Open conversion	17 (6.6)
Total	256 (100)

LTG laparoscopic total gastrectomy, *Pure-LTG* LTG in the absence of other procedures, *Pure-srLTG* LTG with spleen resection in the absence of other procedures

General data

General data for the 256 patients are shown in Table 2. There were 178 male and 78 female patients, with a median age of 61 (range, 22–88) years; body mass index (BMI) ranged from 15.8 to 37.2 kg/m². Fifty-nine patients had a past history of abdominal operations. However, past histories did not affect operative time (past abdominal operation history: presence, 217.9 min vs. absence, 214.9 min, $p = 0.802$ in pure-LTG) or EBL (131.9 vs. 128.3 ml, respectively, $p = 0.912$ in pure-LTG). The patients with prior abdominal surgery were distributed equally across all phases. The rate of total complications was 27.3 %, with local and systemic complications being 15.6 % and 11.7 %, respectively. Minor local complications (grade II in the Clavien–Dindo classification) accounted for 5.8 %; major local complications (grade III or higher) accounted for 9.8 %. There were five cases of esophagojejunostomy leakage (2.0 %) and six cases of esophagojejunostomy stenosis (2.3 %). There was one surgical mortality (0.4 %) in a patient undergoing LTG with concurrent endovascular aneurysm repair (EVAR) as a consequence of aorta aneurysmal bleeding.

Learning curve for LTG

Among the 256 patients, 132 cases of pure-LTG were extracted from the ten sequential groups. For cases of pure-LTG in each sequential group, the mean operative time and mean EBL are shown in Fig. 1. Viewing these two variables together, three phases could be defined, with the first two groups constituting the training phase, the following two groups belonging to the intermediate phase, and the last six groups comprising the well-developed phase. The operative time decreased significantly after the intermediate

Table 2 Patient characteristics, surgical factors, pathological factors, and postoperative outcomes of 256 cases undergoing laparoscopic total gastrectomy

Variable	Cases (%) / mean \pm SD (range)
Sex	
Male	178 (69.5)
Female	78 (30.5)
Age (years)	59.4 \pm 12.8 (22–88)
BMI (kg/m ²)	23.3 \pm 3.3 (15.8–37.2)
Past history of abdominal operation (<i>n</i>)	59 (23.0)
Comorbidity	
None	143 (55.9)
One	62 (24.2)
More than two	51 (19.9)
ASA	
Score I	123 (48.1)
Score II	115 (44.9)
Score III	18 (7.0)
Time of operation (min)	232.8 \pm 60.9 (120–495)
Estimated blood loss (ml)	164.7 \pm 159.8 (10–1,000)
Tumor size (cm)	5.3 \pm 3.4 (0.4–17.5)
Range of LN dissection	
D1+	53 (20.7)
D2	198 (77.3)
D3	5 (2.0)
Retrieved LN	56.4 \pm 24.0 (19–157)
Positive LN	5.4 \pm 10.0 (0–46)
T stage	
T1	108 (42.1)
T2	30 (11.7)
T3	58 (22.7)
T4	60 (23.5)
N stage	
N0	143 (55.8)
N1	25 (9.8)
N2	24 (9.4)
N3a	30 (11.7)
N3b	34 (13.3)
Hospital stay (days)	9.3 \pm 5.7 (4–43)
Complications	
Grade II	43 (16.8)
Grade IIIa	20 (7.8)
Grade IIIb	6 (2.3)
Grade IV	0 (0)
Grade V	1 (0.4)
Total	70 (27.3)

SD standard deviation, BMI body mass index, ASA American society of Anesthesiologists, LN lymph node

phase and remained at a relatively low level during the well-developed phase. After the intermediate phase, in which EBL increased to some degree, a well-developed phase emerged with small EBL.

When the five variables evaluating operation quality were compared among the three phases, operative time and EBL during pure-LTG were significantly different between the second and third phases. Retrieved LNs and hospital stay during pure-LTG were significantly different between the first two phases. However, these two variables were not significantly different between the second and third phases. The complication rates during pure-LTG were similar across all phases (Table 3).

The pure-LTG patients in each phase were statistically homogeneous in terms of their general data, including sex composition ($p = 0.143$ between the first and second phases, $p = 0.417$ between the second and third phases), age ($p = 0.689$, $p = 0.554$), past history of abdominal operations ($p = 0.723$, $p = 0.275$), comorbidities ($p = 0.637$, $p = 0.988$), American Society of Anesthesiologists (ASA) score ($p = 0.246$, $p = 0.988$), tumor size ($p = 0.783$, $p = 0.742$), T stage ($p = 0.634$, $p = 0.293$), and N stage ($p = 0.537$, $p = 0.846$). The average BMI of patients in the first, second, and third phases was 23.2 ± 3.3 , 25.2 ± 3.3 , and 23.3 ± 3.1 kg/m², respectively ($p = 0.036$ between the first and second phases, $p = 0.014$ between the second and third phases).

Among 132 cases of pure-LTG, 73 cases of pure-LTG with D2 LN dissection were extracted from the ten sequential groups. Viewing two variables (mean operative time and mean EBL) together, the learning curve of pure-LTG with D2 LN dissection was not different from the learning curve of pure-LTG. The operative time decreased significantly after the intermediate phase and remained at a relatively low level during the well-developed phase (intermediate phase, 276.7 min, vs. well-developed phase, 211.4 min, $p = 0.003$). After the intermediate phase, in which EBL increased to some degree, a well-developed phase emerged with small EBL (intermediate phase, 208.3 ml, vs. well-developed phase, 111.1 ml, $p = 0.042$).

The rate of conversion to open surgery was not different significantly among the three phases: first phase, 8.0 %; second phase, 6.0 %; and third phase, 6.4 %.

Learning curve for srLTG

Among the 82 patients, 53 cases of pure-srLTG were extracted from the seven sequential groups. For cases of pure-srLTG in each sequential group, the mean operative time and mean EBL are shown in Fig. 2. Viewing these two variables together, two phases could be defined, with the first three groups constituting the training phase and the last four groups comprising the well-developed phase. Both mean operative time and mean EBL decreased significantly after the training phase and remained at relatively low levels during the well-developed phase.

Fig. 1 Learning curve: operative time and estimated blood loss (EBL) in the ten sequential groups of laparoscopic total gastrectomy in the absence of other procedures (pure-LTG) (mean and range). **a** Operative time. **b** EBL

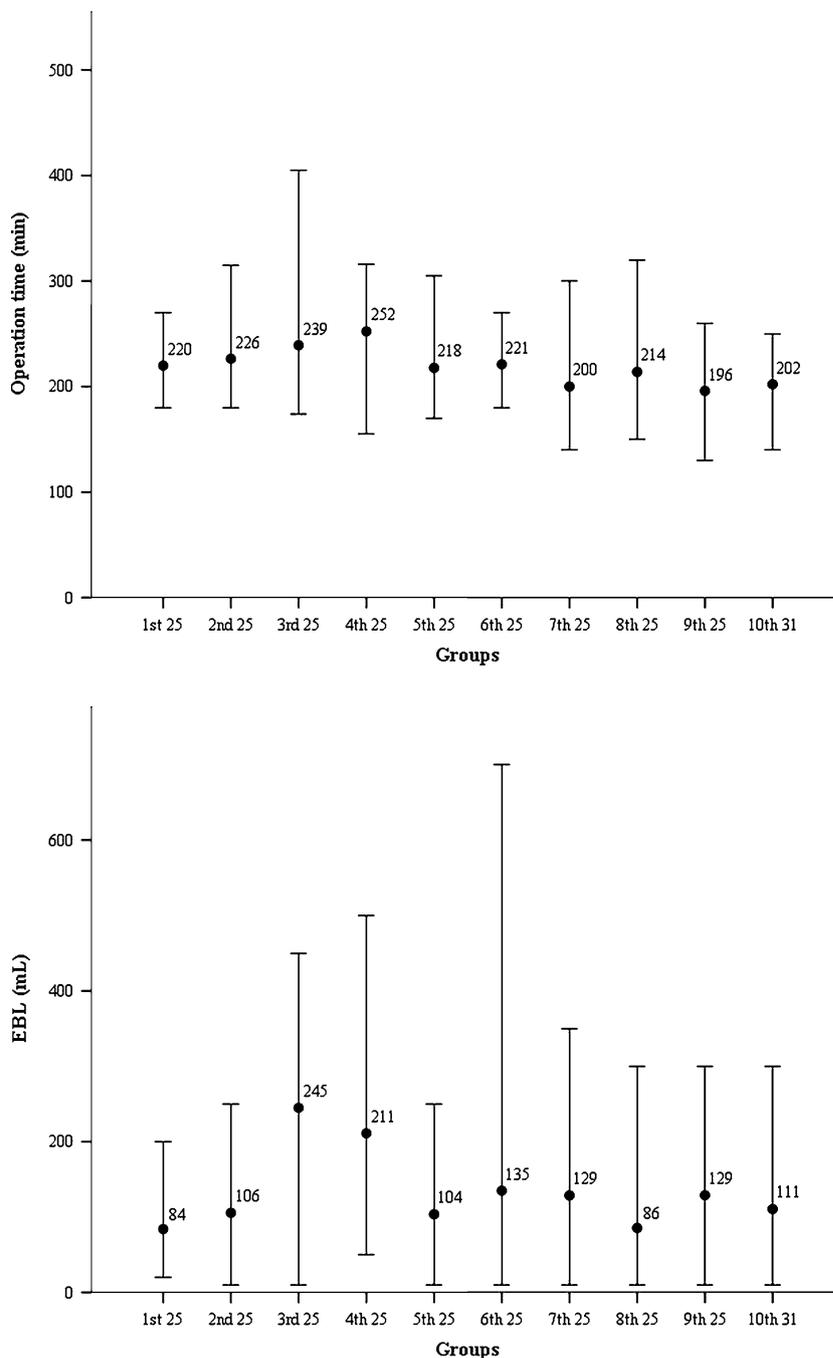
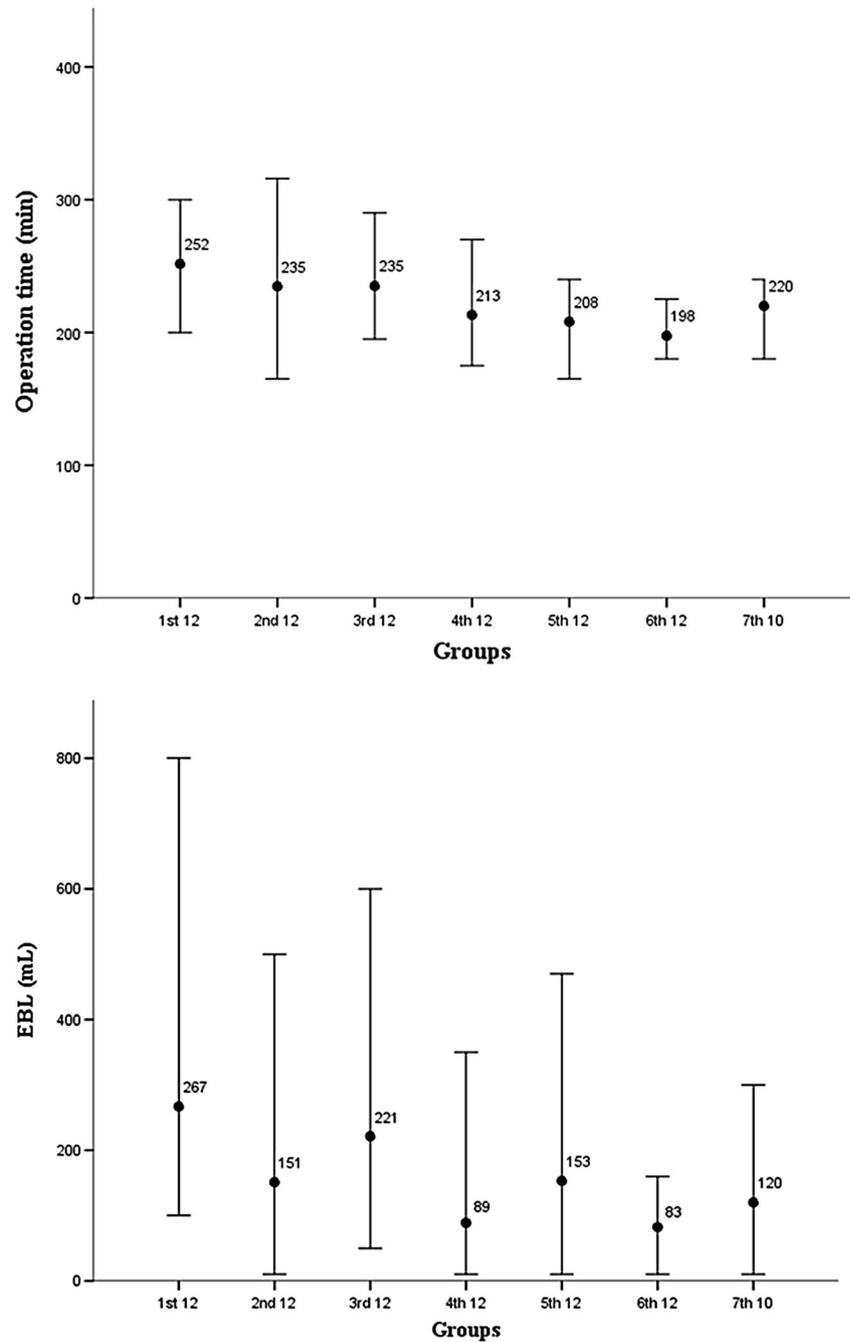


Table 3 Comparison of the five variables used to evaluate operative quality in the three phases of the pure laparoscopic total gastrectomy (in the absence of other procedures; pure-LTG) learning curve

Variables	First phase <i>n</i> = 33 (median)	Second phase <i>n</i> = 21 (median)	Third phase <i>n</i> = 78 (median)	<i>P</i> value (1st vs. 2nd phase, 2nd vs. 3rd phase)
Operative time (min)	223.0 ± 36.4 (215.0)	244.8 ± 58.9 (237.0)	207.8 ± 42.2 (205.0)	0.139, 0.002
EBL (ml)	94.6 ± 62.1 (100.0)	237.0 ± 141.9 (225.0)	116.5 ± 123.7 (90.0)	<0.001, <0.001
Retrieved LNs	41.9 ± 14.3 (40.0)	53.1 ± 18.1 (53.0)	61.9 ± 22.6 (58.0)	0.015, 0.100
Hospital stay (days)	11.9 ± 8.6 (8.0)	6.9 ± 1.4 (6.0)	8.5 ± 5.4 (6.5)	0.002, 0.164
Complications	9 (27.3 %)	4 (19.0 %)	19 (24.4 %)	0.536, 0.774

EBL estimated blood loss, LNs lymph nodes

Fig. 2 Learning curve: operative time and estimated blood loss (EBL) in the seven sequential groups of the pure laparoscopic total gastrectomy with spleen resection (in the absence of other procedures; pure-srLTG). **a** Operative time. **b** EBL



When the five variables evaluating operation quality were compared between the training and well-developed phases, the operative time and EBL during pure-srLTG were significantly different. Retrieved LNs, hospital stay, and complication rates during pure-srLTG were similar between the two phases (Table 4).

The pure-srLTG patients in each phase were statistically homogeneous in terms of their general data, including sex

composition ($p = 0.125$ between the first and second phases), age ($p = 383$), BMI ($p = 0.657$), past history of abdominal operation ($p = 0.293$), comorbidities ($p = 0.196$), ASA score ($p = 0.893$), tumor size ($p = 0.374$), and T stage ($p = 0.610$). The N stage was significantly different between the training and well-developed phases (N0 stage: training phase, 34.6 %; well-developed phase, 11.1 %; $p = 0.041$).

Table 4 Comparison of the five variables used to evaluate operative quality in the two phases of the pure laparoscopic total gastrectomy with spleen resection (in the absence of other procedures; pure-LTG) learning curve

Variables	First phase, <i>n</i> = 26 (median)	Last phase, <i>n</i> = 27 (median)	<i>P</i> value
Operative time (min)	241.4 ± 44.6 (232.5)	209.6 ± 28.2 (205.0)	0.004
EBL (ml)	214.6 ± 187.5 (160.0)	117.6 ± 130.7 (60.0)	0.033
Retrieved LNs	65.0 ± 21.7 (61.5)	71.3 ± 17.2 (69.0)	0.244
Hospital stay (days)	10.9 ± 8.1 (7.5)	8.4 ± 2.4 (8.0)	0.156
Complications	8 (30.8 %)	6 (22.2 %)	0.480

EBL estimated blood loss, LNs lymph nodes

Discussion

LADG for early gastric cancer has gradually been accepted because its short-term benefits and oncological safety have also been established [13]. Some authors have reported that LADG also has short-term benefits and oncological safety for advanced gastric cancer [2]. The technical feasibility and oncological safety of LTG have also been recently reported. However, many surgeons have undertaken LTG only after many years of experience with OTG and LADG for gastric cancer because LTG requires dissection of LNs at the splenic hilum or along distal splenic vessels, as well as anastomosis of the esophagus to the jejunum [3]. Therefore, a significant learning curve for LTG is associated with the mastering these operative techniques.

Theoretically, ideal approaches for conducting statistical assessments of learning curves such as multivariate logistic regression or the cumulative sum (CUSUM) method have been used recently [13–15]. Commonly used outcome-related variables, such as conversion to open surgery and the occurrence of severe complications, were also evaluated in the present study and were considered very useful for monitoring operative performance. However, in the present study, the open conversion rate was only 6.6 %. Additionally, the rate of surgical complications requiring endoscopic, radiologic, and surgical therapy (grade III or higher in Clavien–Dindo classification) was 9.8 %. Further, the rates of open conversion and severe surgical complications were not significantly different across the defined learning phases in the present study. Thus, the moving average method of split groups was used to define the learning curve associated with LTG in the present study because the outcome-related variables were too infrequent to perform reliable statistical analyses using other approaches [9, 10].

Operative time, EBL, retrieved LNs, hospital stay, and complication rates were used to evaluate the quality of the operations. Retrieved LNs and hospital stay stabilized earlier than the operative time and EBL during pure-LTG. The complication rates were not significantly different across the phases of the learning curves associated with LTG. The early stabilization of retrieved LNs and hospital stay and the similar complication rates were believed to be mainly the result of the length of surgical experience with other types of laparoscopic gastrectomy, including LADG [9]. The present experience with 100 cases of LTG, which included 54 pure-LTG cases, was accompanied by experience with approximately 880 cases of LADG. However, the operative time and EBL were not stabilized until after gaining experience associated with 100 LTG cases, suggesting that there are intrinsic LTG techniques that are different from those involved in LADG.

In 2004, LTG was not a standard treatment choice for gastric cancer, and only 5 patients underwent LTG during that year; fewer than 10 LTG procedures were performed annually before 2007. These small numbers of cases during the early phase were not ideal for learning LTG; many procedures are believed to be best for learning an operative skill within a short period [16, 17]. Thus, the small number of LTG cases during the early phase might have prolonged the learning period. The number of LTG cases increased as the feasibility and safety of LTG was gradually demonstrated at our institution, with the number of LTG patients increasing from 16 in 2007 to 49 in 2012. Recently, several surgeons have reported short- and long-term outcomes of LTG. In addition, a randomized clinical trial for LTG (KLASS-03) will be conducted (ClinicalTrials.gov ID: NCT01584336). If the feasibility and safety of LTG are confirmed during the KLASS-03 trial, surgeons may be more likely to perform many LTG cases within a short period, possibly shortening the learning curve.

All operations were performed by a surgeon who is a first-generation laparoscopic surgeon of our country. When he started laparoscopic gastrectomy including LTG, there was neither standardization of LTG nor a training system. A standardized surgical technique and an established educational system may help in shortening the LTG learning curve. It was reported that experience of about 50–60 cases of LADG was required for completion of learning at the beginning [9, 10]. However, it has been reported recently that the learning curve could be shortened by a standardized surgical technique and effective educational system [17, 18]. Therefore, LTG learning curves of second-generation laparoscopic surgeons will be also shortened.

The mean EBL was 94.6 ml (median, 100.0 ml) during the first phase of the pure-LTG learning curve. However, the mean EBL was 237.0 ml (median, 225.0 ml) during the

second phase of the learning curve, a significant increase. The cause of increased EBL was believed to be related to the selected patients, assistants, and scopists during the first phase. During the very early phase of the learning curve, the indication for LTG was restricted to patients with a BMI within the normal range, no previous history of operations, and a diagnosis of early gastric cancer. Additionally, only experienced assistants and scopists were asked to participate in LTG during the early phase. As the feasibility and safety of LTG was gradually demonstrated at our institution, the indications for LTG were expanded, which was associated with a temporary increase in EBL. Similar complications rates and open conversion rates across all phases were also believed to be associated with the same reason as the temporary increase in EBL.

Several authors have reported on the technical feasibility and oncological safety of LTG [5]. We have also reported that LTG for gastric cancer has an advantage over OTG in terms of improved short-term outcomes and similar long-term outcomes [4]. Some authors have reported worse outcomes associated with LTG combined with D2 LN dissection [6]. However, these reports involved only small numbers of cases. When the outcomes of LTG and OTG are compared, the learning curve should also be considered [19, 20]. Thus, the experience of the surgeons should be checked before a prospective study, including randomized clinical trials, to minimize bias resulting from operator-associated factors [21].

Learning of srLTG was completed after 26 cases of pure-srLTG. Experience with 36 srLTG cases, which included the 26 pure-srLTG cases, was accompanied by experience from approximately 60 cases of pure-LTG. Thus, learning of srLTG was completed within a similar period as required for the learning curve of LTG; this would be expected because the LTG experience would help speed the learning of srLTG. The similar completion time was thought to be mainly the result of the close relationship between learning LTG and srLTG.

The present study has the limitations of a retrospective study. Therefore, future prospective studies that record the reconstruction time will aid in understanding the learning curve of LTG. Based on our analysis of the 256 cases of LTG at our institution, we conclude that there is a significant learning curve associated with this procedure. Experience with about 100 cases of LTG was required to complete the learning of the LTG technique.

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