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Learning curve and short-term outcomes of modularized LADG for advanced gastric cancer

A retrospective study

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Abstract

Laparoscopy-assisted distal gastrectomy (LADG) is a complicated procedure. To reduce the difficulty of the operation and standardize the surgical procedure, we explored a new operation mode, which we termed modularized LADG (MLADG). To further extend the new operation mode, we conducted this study to evaluate the short-term outcomes of MLADG for advanced gastric cancer, and determine the learning curve.

Data from 100 consecutive patients who received LADG between October 2016 and October 2017 were retrospectively analyzed. Short-term outcomes, such as operation time and intraoperative blood loss, were evaluated, and the learning curve was calculated.

For MLADG, the mean operation time was 168.2 ± 13.0 minutes, the mean intraoperative blood loss was 93.6 ± 29.1 ml, the mean number of harvested lymph nodes was 28.6 ± 4.2, and conversion to open surgery occurred in only 1 case. In addition, MLADG had an acceptable postoperative complication incidence and fast postoperative recovery. After the first 20 cases, the operation skill reached a mature and stable level.

Our results indicate that MLADG is an oncologically feasible and technically safe surgical procedure. For the trainees with rich experience in open distal gastrectomy, the learning curve is considered to be completed after 20 MLADG cases.

Abbreviations: ASA = American Society of Anesthesiologists, BMI = body mass index, CA = celiac artery, CHA = common hepatic artery, COPD = chronic obstructive pulmonary disease, LADG = laparoscopy-assisted distal gastrectomy, LGA = left gastric artery, LGEA = left gastroepiploic artery, LGEV = left gastroepiploic vein, LGV = left gastric vein, MLADG = modularized laparoscopy-assisted distal gastrectomy, ODG = open distal gastrectomy, PHA = proper hepatic artery, RGA = right gastric artery, RGEA = right gastroepiploic artery, RGEV = right gastroepiploic vein, RGV = right gastric vein.

Keywords: gastric cancer, learning curve, modularized laparoscopy-assisted distal gastrectomy

1. Introduction

Gastric cancer is the fifth most common cancer and the third leading cause of death worldwide (723,000 deaths annually).[1] In general, the incidence rates are highest in Eastern Asia (particularly in Korea, Mongolia, Japan, and China), Central and Eastern Europe, and South America.[2] Despite the continuing advancement in chemotherapy, radiotherapy, biotherapy, and so on, radical gastrectomy still remains the primary treatment strategy for gastric cancer.[3,4]

Since being first reported by Kitano in 1994, laparoscopy-assisted gastrectomy has revolutionized the treatment approach to gastric cancer.[5] In Eastern countries, laparoscopy-assisted distal gastrectomy (LADG) has become a common treatment option for early gastric cancer located at the lower third part of stomach.[6–8] With the development of laparoscopic instruments, and the accumulation of laparoscopic surgery experience, LADG is currently being used to treat locally advanced gastric cancer.[9–13] LADG has many advantages over open distal gastrectomy (ODG), such as less blood-loss, less postoperative pain, faster flatus, earlier feeding, shorter hospitalization stays, and smaller incision scars.[8,14–16] However, LADG is technically a more complicated and advanced procedure that is challenging for surgeons.

At our institution, LADG was first performed in 2007, and LADG surgical experience was accumulated over time. To reduce the difficulty of the operation and standardize the surgical procedure, we divided the complex surgical procedure of LADG into 4 simple different modularized parts, and then we performed the standardized and streamlined operative procedures in order. The new operation mode was named as modularized LADG (MLADG). To provide a foundation to further extend the new operation mode, we conducted the present study to evaluate the short-term outcomes of the initial consecutive MLADG cases, which were performed by a single surgeon with abundant experience in ODG, and then determine the learning curve for MLADG.

Editor: Lei Huang.

This work was supported by the National Key Clinical Specialties Construction Program of China ([2012]649).

The authors report no conflicts of interest.

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Medicine (2019) 98:10(e14670)

Received: 20 October 2018 / Received in final form: 10 January 2019 / Accepted: 3 February 2019

http://dx.doi.org/10.1097/MD.0000000000014670

2. Patients and methods

2.1. Patients

The Ethics Committee at the First Affiliated Hospital of Chongqing Medical University approved the retrospective analysis for this study. Written informed consent was obtained from the patients who agreed to undergo LADG. From October 2016 to October 2017, a total of 100 consecutive patients with advanced gastric cancer located at the lower third part of stomach and who underwent MLADG with D2 lymph node dissection at our institution, were retrospectively analyzed in this study. The clinical classification was cT2-T4aM0, based on the results of upper gastrointestinal endoscopy and biopsy, as well as abdominal contrast computed tomography.[17] Patients with a history of abdominal operations, or severe comorbidities were not included. The 100 patients who received this treatment were placed into 5 sequential groups, with 20 cases in each group (group A: 1–20 cases; group B: 21–40 cases; group C: 41–60 cases; group D: 61–80 cases; and group E: 81–100 cases).

2.2. Trainer and trainee

The trainer was highly experienced with MLADG. The trainee's experience with ODG prior to starting MLADG training was more than 50 cases. First, the trainee participated in an educational seminar organized by our institution, and then repeatedly reviewed video recordings of the trainer performing the operation. Then, he practiced using a laparoscopic simulation system. Finally, the trainee participated in a MLADG procedure as a first assistant. The trainers decided if the trainee was capable of performing the MLADG procedure as an operator based on the trainee' s laparoscopic surgical skills. Three surgeons performed 1 procedure simultaneously. The trainee acted as an operator, the trainer and another surgeon acted as a first assistant and a second assistant, respectively.

2.3. Surgical procedure

Under general anesthesia, the patient was placed in a supine position, with legs apart. The operator stood on the right side of the patient, the assistant stood on the left side, and the endoscopist stood between the patient's legs. Five abdominal trocar ports were used: 2 right operator ports (5-mm upper and 12 mm lower ports), 2 left 5 mm assistant ports, and 1 12 mm umbilical port for laparoscope insertion (Fig. 1). CO_2 pneumoperitoneum pressure was kept at approximately 12 mmHg.

Based on the operating sequence, operative route and lymph node dissection region, we divided the LADG laparoscopic operative procedure into 4 simple different modularized parts, including part A, B, C and D. The 4 parts are described below (Fig. 2).

2.4. Part A

The greater omentum and gastrocolic ligament were included in the operation area.

The greater omentum was pulled cephalad, and the transverse colon was pulled footward. The greater omentum and the gastrocolic ligament were divided along the border of the transverse colon with a Harmonic scalpel (Ethicon Endo-Surgery, OH), beginning at the middle portion of transverse colon rightward to the hepatic flexure, and then leftward to the lower pole of the spleen. The left gastroepiploic artery (LGEA) and vein

Figure 1. Port locations. For A and B, 12 mm ports are used. Three 5 mm ports are used for C, D, and E.

(LGEV) were exposed and then divided individually at their roots with double clips (Teleflex Medical, NC) (Fig. 3A and B), and then the left greater curvature lymph nodes along the LGEA (no.4sb) were dissected. The stomach was pulled cephalad, while the transverse colon was pulled footward, and then the capsule of pancreas was removed.

2.5. Part B

The surgical area was from the right gastroepiploic artery (RGEA) and vein (RGEV) to the superior part of the duodenum.

The RGEA and RGEV were exposed and divided individually at their roots with double clips (Fig. 3C and D), and the no. 4d lymph nodes were dissected. After the lymphatic fatty tissue and small vessels between the pylorus and the pancreas were removed, the duodenum was separated 3 cm distal to the pylorus, and the infrapyloric lymph nodes (no. 6) were dissected.

2.6. Part C

The operation areas were hepatoduodenal ligament and suprapyloric area.

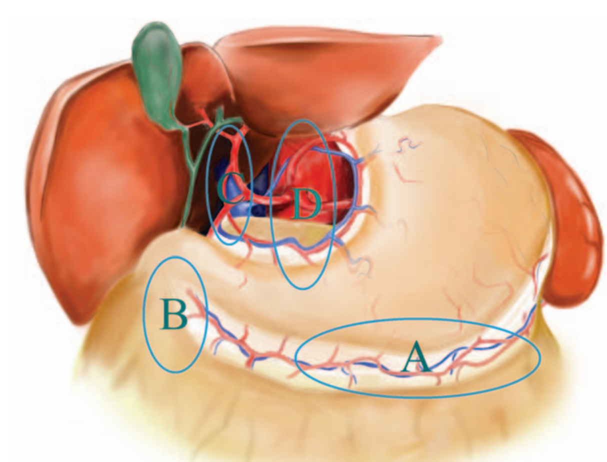

Figure 2. Four modularized parts.

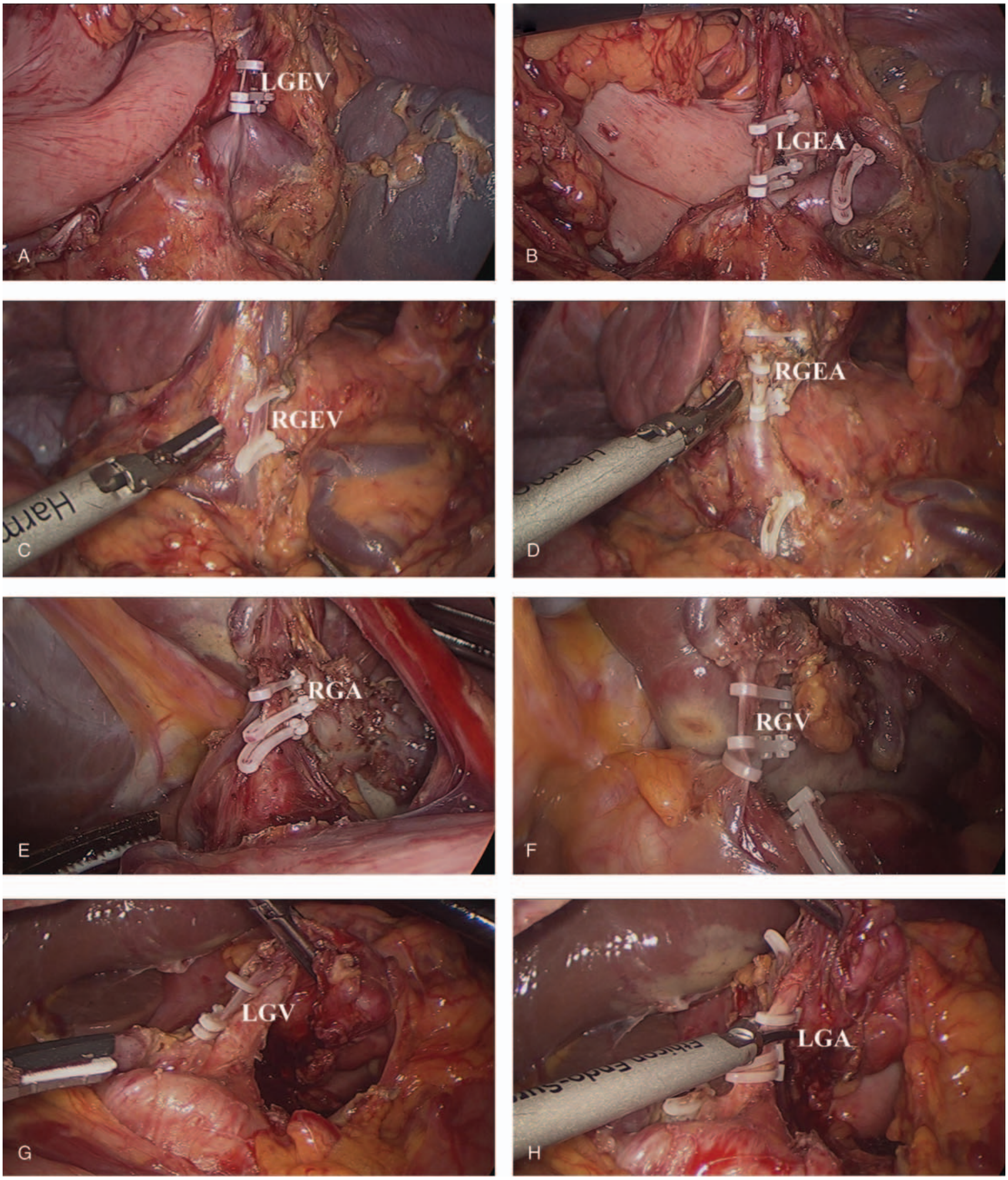

Figure 3. Management of major blood vessels. (A) Left gastroepiploic vein (LGEV). (B) Left gastroepiploic artery (LGEA). (C) Right gastroepiploic vein (RGEV). (D) Right gastroepiploic artery (RGEA). (E) Right gastric artery (RGA). (F) Right gastric vein (RGV). (G) Left gastric vein (LGV). (H) Left gastric artery (LGA).

After exposing the hepatoduodenal ligament and the suprapyloric area, the hepatogastric ligament was resected from the hepatoduodenal ligament to the cardia along the liver edge. The duodenal bulb was continually pulled cephalad to maintain the tension of the hepatoduodenal ligament. The lymphatic fatty tissue of hepatoduodenal ligament was removed to expose the proper hepatic artery (PHA), the right gastric artery (RGA) and vein (RGV). The RGA and the RGV were then divided at the root with double clips (Fig. 3E and F). The suprapyloric lymph nodes (no. 5) and the hepatoduodenal ligament lymph nodes along the PHA (no. 12a) were dissected.

2.7. Part D

The surgical area stretched from the common hepatic artery (CHA), celiac artery (CA), the left gastric artery (LGA) and vein (LGV), to the cardia.

The lesser curvature was pulled cephalad to expose the area above the pancreas, and the CHA and CA were skeletonized to allow en bloc dissection of the no. 8a and no. 9 lymph nodes. The gastropancreatic fold was pulled cephalad, and the peritoneum was removed to expose the LGA and LGV. The lymph nodes along the LGA trunk (no. 7) were dissected, and the LGA and LGV were divided individually at their roots with double clips

Table 1

Clinicopathological characteristics of the patients.

Characteristics	Group A	Group B	Group C	Group D	Group E	P value
Age (years)	57.2±13.7	57.8±13.7	56.6±14.4	58.4±11.1	56.8±14.3	.993
Gender						.932
Male	16	17	15	16	15	
Female	4	3	5	4	5	
BMI (kg/m^2)	22.6±6.1	23.8±3.2	22.9±2.7	23.6±1.9	23.7±2.0	.723
ASA score						.834
1	4	2	5	2	5	
2	14	15	11	14	12	
3 or more	2	3	4	4	3	
Adjuvant chemotherapy	6	5	4	5	6	.328
Main comorbidity	6	6	5	4	5	.948
Hypertension	2	3	2	2	1	
Diabetes	1	2	2	2	2	
COPD	3	2	0	0	2	
Method of reconstruction						.832
B-I	15	14	17	16	15	
B-II	5	6	3	4	5	
T stage						.662
T2	8	14	11	12	10	
T3	9	4	6	5	5	
T4a	3	2	3	3	5	
Histological type						.675
Well and moderately	13	14	17	15	14	
Poorly and undifferentiated	7	6	3	5	6	

COPD=chronic obstructive pulmonary disease; BMI=body mass index; ASA=American Society of Anesthesiologists.

(Fig. 3G and H). Then the proximal splenic artery (SA) lymph nodes (no.11p) were dissected leftward along the SA. The lesser omentum was resected footward, beginning at the cardia (along the lesser curvature), with dissection of the right paracardial lymph nodes (no.1) and the lesser curvature lymph nodes (no. 3).

After sequential implementation of parts A, B, C and D, gastric dissection and lymph node dissection were completed. Then a median superior abdominal incision measuring approximately 5 cm was made. Gastrectomy and anastomosis were performed through the incision under direct vision. After the distal two-thirds of the stomach were resected, Billroth-I reconstruction was performed using a circular stapler, or Billroth-II reconstruction was performed using a linear stapler.

2.8. Clinical data

The analyzed patient clinicopathologic characteristics included age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) score, adjuvant chemotherapy, main comorbidity, method of reconstruction method, T stage, and histological type. The short-term outcomes included the operation time, intraoperative blood loss, harvested lymph nodes, time to ambulation, time to first flatus, postoperative complication, and postoperative hospital stay.

2.9. Statistical analysis

Data were presented as the mean±standard deviation for continuous variables and numbers for categorical variables. The continuous variables were assessed by using one-way analysis of variance (ANOVA) followed by least significance difference (LSD) multiple comparison tests. The categorical variables were assessed by using the Chi-squared test. The learning curve was evaluated according to operation time, intraoperative blood loss and harvested lymph nodes. All statistical analyses were performed by using SPSS version 22.0. A P-value of <.05 (2-sided) was considered to be statistically significant.

3. Results

3.1. Clinicopathological characteristics of the patients

The clinicopathological characteristics of the 100 consecutive patients are summarized for each group in Table 1. As shown in Table 1, the 5 groups were not statistically significantly different in terms of their various clinicopathologic characteristics, such as age (P=.993), gender (P=.932), BMI (P=.723), ASA score (P=.834), adjuvant chemotherapy (P=.328), main comorbidity (P=.948), method of reconstruction (P=.832), T stage (P=.662), and histological type (P=.675).

3.2. Short-term patient outcomes

The short-term outcomes primarily included the following 8 items: operation time, intraoperative blood loss, conversion to open surgery, harvested lymph nodes, time to ambulation, time to first flatus, postoperative complication and postoperative hospital stay. Table 2 summarizes the short-term outcomes of the 5 groups.

The mean operation time of the 5 groups was 168.2±13.0 minutes. As shown in Table 2, group A had an operation time of 182.8±8.5 minutes, which was longer than the other groups (group B: 167±10.1 minutes; group C: 165.8±5.9 minutes; group D: 165.3±13.1 minutes; group E: 160±13.7 minutes.), which was statistically significantly different (P=.000). However, there were no statistically significant differences among the groups B-E (P>.05). The mean intraoperative blood loss was

Table 2

Short-term patient outcomes.

Factors	Total	Group A	Group B	Group C	Group D	Group E	*P* value
Operation time (min)	168.2±13.0	182.8±8.5	167±10.1	165.8±5.9	165.3±13.1	160±13.7	.000
Intraoperative blood loss (ml)	93.6±29.1	126.5±33.4	93.0±29.1	85.8±21.7	81.5±14.3	81.0±15.2	.000
Conversion to open surgery	1	1	0	0	0	0	.000
Harvested lymph nodes	28.6±4.2	25.4±2.8	28.4±3.4	29.6±4.0	29.0±4.5	30.6±4.7	.001
Postoperative complications	16	4	4	3	2	3	.903
Anastomotic leakage	1	1	0	0	0	0	
Pancreatic fistula	1	0	1	0	0	0	
Abdominal cavity infection	3	0	0	1	1	1	
Pulmonary infection	1	1	0	0	0	0	
Pleural effusion	3	0	1	1	0	1	
Wound infection	7	2	2	1	1	1	
Time to ambulation (days)	2.8±1.1	3.3±1.1	2.6±1.0	3.0±1.1	2.4±1.0	3.0±0.8	.062
Time to first flatus (days)	3.3±0.7	3.5±0.6	3.3±0.6	3.3±0.7	3.0±0.7	3.3±0.7	.236
Postoperative hospital stay (days)	10.5±1.7	11.0±2.5	10.8±1.5	10.2±1.5	10.3±1.5	10.2±1.2	.368

93.6±29.1 ml. For groups A-E, the intraoperative blood loss was 126.5±33.4, 93.0±29.1, 85.8±21.7, 81.5±14.3 and 81.0±15.2 ml, respectively. The patients in group A had more bleeding than the patients in other groups, and this difference was statistically significant ($P=.000$); however, there were no statistically significant differences between the other groups ($P>.05$). Among the 5 groups, the mean number of harvested lymph nodes was 28.6±4.2. The numbers for groups A-E were 25.4±2.8, 28.4±3.4, 29.6±4.0, 29.0±4.5 and 30.6±4.7, respectively, with group A having fewer lymph nodes than the other groups, and this difference was statistically significant ($P=.001$). However, there were no statistically significant differences between the other groups ($P>.05$).

With regard to conversion to open surgery, there was 1 case in group A, which resulted from LGA bleeding, and there were statistically significant differences between the 5 groups ($P=.000$). The mean time to ambulation in the 5 groups was 2.8±1.1 days. The time to ambulation in groups A-E was 3.3±1.1, 2.6±1.0, 3.0±1.1, 2.4±1.0 and 3.0±0.8 days, respectively, with no statistically significant differences between the 5 groups ($P=.062$). The time to first flatus and the postoperative hospital stay, were not statistically significantly different among the 5 groups ($P=.236$, and $P=.368$, respectively).

With regard to postoperative complications, there were 16 overall postoperative complications among the 5 groups. Anastomotic leakage occurred in 1 patient (group A), pancreatic fistula occurred in 1 patient (group B), abdominal cavity infection occurred in 3 patients (1 in group C, 1 in group D, 1 in group E.), pulmonary infection occurred in 1 patient of group A, and pleural effusion occurred in 3 patients (1 in group B, 1 in group C, 1 in group E). Seven patients suffered from wound infection (2 in group A, 2 in group B, 1 in group C, 1 in group D, 1 in group E). For overall postoperative complications, there were no statistically significant differences between the 5 groups ($P=.903$). There were no postoperative mortalities in the 5 groups.

3.3. Calculation of the learning curve

The operative time, intraoperative blood loss and harvested lymph nodes were evaluated to calculate the learning curve. As shown in Fig. 4A, the operative time for group A was significantly longer than those of the other groups ($P=.000$), whereas there were no statistically significant differences between groups B-E ($P > .05$). The learning curve demonstrated a significant downward trend from group A to group B, and showed a flat trend from group B to group E. In terms of intraoperative blood loss, the learning curve trend was the same as the operative time (Fig. 4B). Significantly fewer lymph nodes were harvested in group A than in the other groups ($P=.001$), whereas there were no statistically significant differences between groups B-E ($P > .05$); the learning curve had a significant upward trend from group A to group B, and showed a flat trend from group B to group E (Fig. 4C).

After the first 20 cases, the operative time, and intraoperative blood loss decreased, while the number of harvested lymph nodes increased, which might indicate that the operation skill reached a mature and stable level. Therefore, we thought the learning curve for MLADG might be 20 cases in this study.

4. Discussion

At the present time, the benefits of LADG in gastric cancer surgery are widely accepted. However, the technical difficulty is one of the primary reasons that surgeons may be reluctant to perform it. Particularly for surgeons highly experienced in ODG, learning to perform LADG can be accompanied by a long operative time and the potential risk of severe surgical complications. To reduce the difficulty of operation and standardize the operative procedure, based on the accumulation of experience in LADG, we explored a new operation mode, and named it MLADG.

As a new operation mode, MLADG has the following advantages. First, the complex operative procedure of LADG is divided into 4 simple modularized parts. After completing of the mastery of 1 modularized part, trainees can learn another; which is beneficial in shortening the learning curve. Second, the operative procedure of each modularized part is based on blood vessels, instead of lymph nodes. The separation of the blood vessels and dissection of the lymph nodes are performed simultaneously, which contribute to the en bloc dissection of regional lymph nodes. Third, the trainees stand on the right side, which is the same as they stand for ODG, and the surgical procedure is similar to that of ODG; which lets trainees with abundant experience in ODG easily adapt to laparoscopic surgery. In addition, MLADG avoids exposing the same operation area repeatedly, thus shortens operative time. During many surgical procedures, surgeons do not complete a step of surgical procedure of a certain operation area for some reason,

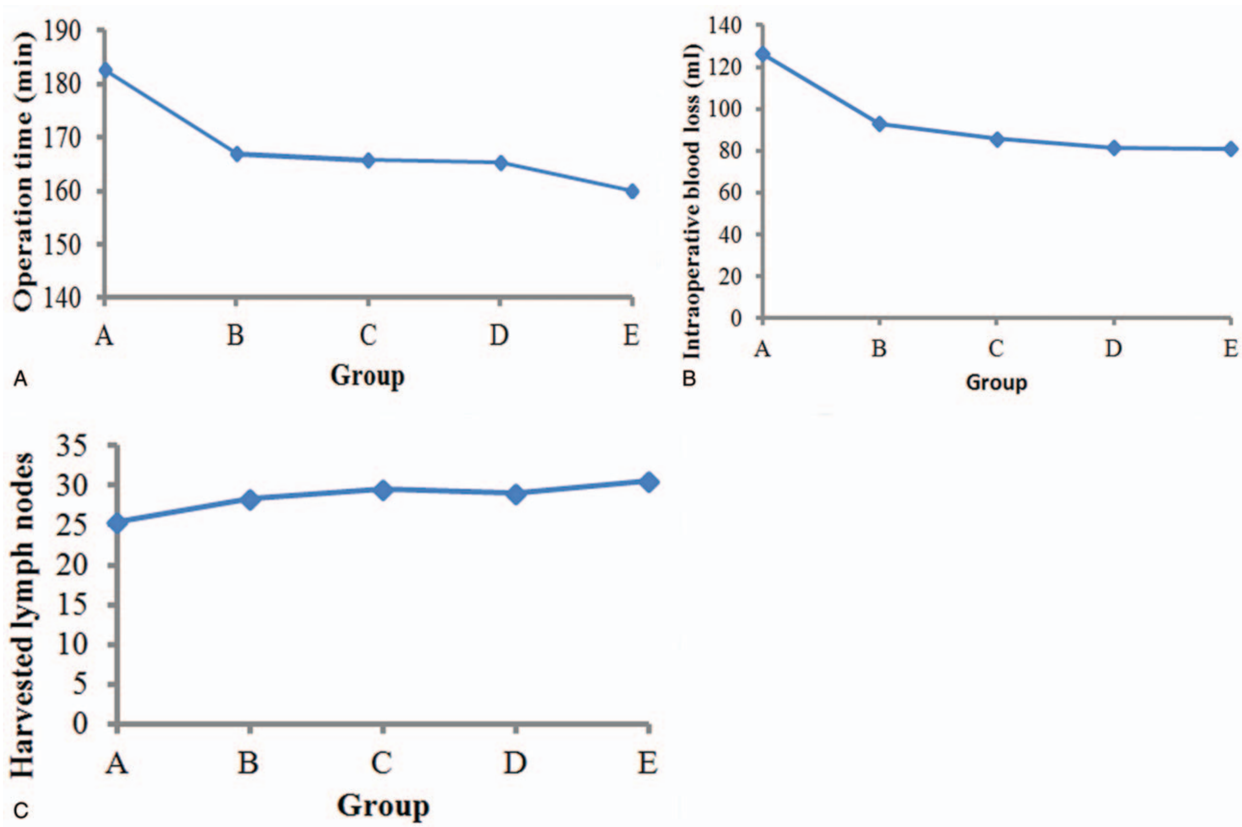

Figure 4. Learning curve of the trainee. (A) The average operation time for modularized laparoscopy-assisted distal gastrectomy (MLADG). (B) The same comparison was performed for intraoperative blood loss. (C) The same comparison was performed for the harvested lymph nodes.

and then jump usually to next operation area to carry on other surgical procedure. After completing the next surgical procedure, surgeons return to the previous operation area to carry on the unfinished step of surgical procedure. In that case, surgeons need to expose the same operation area repeatedly, which leads to a waste of operative time. Based on the operation rules of MLADG, after completing the surgical procedure of 1 modularized part, the trainees perform the next part in order and no longer return to this part. For example, after completing the surgical procedure of part A, the trainees perform the surgical procedure of part B in order, never return back to the surgical procedure of part A. In doing so, repeated exposure to the same operation area is avoided, therefore operative time is shortened.

In our study, 1 major concern throughout the entire MLADG procedure was adequately harvesting lymph nodes for oncological safety. D2 lymph node dissection has been accepted as the standard treatment for advanced gastric cancer. The number of harvested lymph nodes is an important criterion for measuring the thoroughness of radical treatment, and at least 15 lymph nodes are required for correct postoperative N staging.[4,18,19,20] There should be no compromise in the principles of oncological surgery for gastric cancer. Previous studies showed that the number of harvested lymph nodes differed from 28 to 30.[7,21–23] In our study, the mean number of harvested lymph nodes in the 5 groups was 28.6 ± 4.2, and even during the learning period, the mean number was more than 15, which was consistent with the studies mentioned above.

The operation time, intraoperative blood loss, conversion to open surgery and postoperative complication are significant indicators used to evaluate surgical safety. The mean operation time was 168.2 ± 13.0 minutes, and the mean intraoperative blood loss was 93.6 ± 29.1 ml, and these results were lower than the overall study results. [24] Only 1 case (1%) suffered in group A underwent conversion to open surgery, and this incidence was similar to those reported by previous studies.[25,26] There were statistically significant differences between the 5 groups; however, we thought that it had no clinical practical significance due to the low incidence in our study. Postoperative complications occurred evenly among the 5 groups, a total 16 cases (16%) developed, and the incidence was similar to a previous study.[12] In terms of major postoperative complications (2%), 1 patient suffered from anastomotic leakage, and 1 patient suffered from pancreatic fistula, this incidence was slightly higher in our study than in previous studies (1.7%).[6,12,27] However, the incidence was usually considered acceptable. In summary, these results indicate the technical safety of MLADG for advanced gastric cancer.

The time to ambulation, time to first flatus, and postoperative hospital stay were important indices for evaluating postoperative recovery. Consistent with the previous studies,[28,29] in our study, the 3 items were 2.8 ± 1.1, 3.3 ± 0.7, and 10.5 ± 1.7 days, respectively, with no statistically significant differences between the 5 groups. It is well known that postoperative complications delay the postoperative recovery of patients. The postoperative complications were evenly distributed between the 5 groups in our study, which might be partly responsible for the phenomenon. These results indicate that MLADG might greatly improve the postoperative recovery time.

The time required to stabilize the operative time or minimize the number of postoperative complications was used to define the learning curve,[30,31] however, a learning curve analysis based only on operative times may not be completely accurate and sufficient to determine the optimum proficiency for a surgical procedure.[32,33] In this study, the operative time, intraoperative blood loss, and harvested lymph nodes were used to calculate the MLADG learning curve. After the first 20 cases, the operative time, intraoperative blood loss, and harvested lymph nodes plateaued, which implied that the performance of 20 MLADG procedures was required to achieve optimum proficiency. Therefore, we thought that the learning curve for MLADG might be 20 cases in this study. Several LADG learning curve studies have reported that experience in managing 40 to 60 LADG cases are required to achieve proficiency and to reach a learning curve plateau.[31,34–36] The number of MLADG cases needed to overcome the learning curve in our study, was less than that for LADG. Compared with LADG, fewer MLADG cases are needed to overcome the learning curve in our study.

Many factors have influence on the learning curve.[6,37,38] The possible reasons resulting in the reduced learning curve in our study are as follows. Firstly, we think that the advantages of MLADG mentioned above play an indispensable role in the reduced learning period. Secondly, the completion of simulator exercises, together with the completion of training as a first assistant before performing the first case as an operator markedly accelerate the progress. Thirdly, close intraoperative supervision by an expert helps to reduce the learning curve and prevent unexpected postoperative complications, which is necessary during the adoptive period. Fourthly, a solid background in ODG contributes to overcoming the learning curve. Surgeons with ODG experience in more than 50 cases have stable basic surgical skills of upper gastrointestinal surgery, and can continue to complete the operation safely while conversion to open surgery occurs. Therefore, it is easy to overcome the learning curve of MLADG, and safe to perform MLADG during the learning phase for them. Finally, the high-volume at our intuition also partly contributes to the reduction. Having only a few MLADG procedures to perform each month, it is difficult to imagine that a trainee can master the learning curve in a short period.

There are also several limitations to our study. First, due to the retrospective and nonrandomized design, it has the disadvantage of being observational in nature, and the selection criteria bias of the patients is unavoidable. In addition, only short-term outcomes were analyzed in our study due to the lack of long-term follow-up data. Therefore, a long-term follow-up study is required to validate our results. Furthermore, our study is based on a single trainee at our institution, thus, further multicenter research with the participation of more trainees is needed in the future. Moreover, an open question remains to be answered in future research. With the popularity of laparoscopic skills, there will be less opportunity for trainees to perform ODG. For the trainees who are not highly experienced in ODG, what are the learning curve and short-term outcomes of MLADG?

In conclusion, based on the evaluation of short outcomes, our study investigated the oncologic feasibility and technical safety of MLADG for advanced gastric cancer. By calculating the learning curve, for the trainees highly experienced in ODG, the learning curve is considered to be completed after 20 MLADG cases. In addition, MLADG can be safely adopted without increasing surgical risk, even during the learning phase. However, MLADG still should be carefully performed to prevent unexpected postoperative complications.

Acknowledgments

The authors are grateful to Dr. Zhuozhi Shen Chongiqng Center for Disease Control and Prevention, for the substantial work in the statistical methods.

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