福岡大医紀（*Med. Bull. Fukuoka Univ.*）：41(2)，71–75，2014

Early Experience with Laparoscopic Distal Gastrectomy for Gastric Cancer at a Low-volume Institute; Assessment Including CUSUM Analysis in the Initial 55 Cases

Koji MIKAMI, Shinpei NODA, Shugo UWATOKO,
Hiroyuki TAKAHASHI, Nobuharu YAMAMOTO, Kitaro FUTAMI,
Takafumi MAEKAWA

Department of Surgery, Fukuoka University Chikushi Hospital

Abstract

Background: Although there have been many reports regarding the learning curve for laparoscopic distal gastrectomy（LDG）at high-volume centers, few reports have been conducted at low-volume institutions. The present aim was to report the surgical outcomes at our hospital, a low-volume institution, for LDG in patients with early gastric cancer.

Methods: From March 2009 to August 2013, 55 patients underwent laparoscopic distal gastrectomy for early gastric cancer. These operations were performed consecutively by the regular surgeon and an assistant. The cumulative sum method was used to investigate the learning curve in terms of the length of the operation and the amount of intraoperative blood loss. The 55 patients were divided into two groups based on the time period: the first group included the first to 27th patient（period I），while the second group included the 28th to 55th patient（period II）. The two groups were compared with respect to surgical outcomes, postoperative complications and length of hospital stay.

Results: The learning curve with regard to the operation time and the amount of intraoperative blood loss was not completely mastered. There were significant differences in the surgical procedure and lymph node dissection between the two groups divided according to the time period, with totally laparoscopic distal gastrectomy and D2 lymph node dissection being more frequently performed in period II. The incidence of postoperative complications during period II was lower than that observed during period I（3.6% versus 22.2%）. The postoperative hospital stay in period II was shorter than that in period I（12.5 days versus 16.3 days）.

Conclusions: Although the learning curves for the length of the operation and the intraoperative blood loss were not completely mastered, LDG was found to be a feasible modality, and it can be performed safely at low-volume institutions. Further studies are needed to confirm the long-term treatment outcomes.

Key words: Laparoscopy, Gastrectomy, Gastric cancer, Low volume center

Correspondence to: Koji Mikami, Department of Surgery, Fukuoka University Chikushi Hospital, 1-1-1 Zokumyoin, Chikushino City, Fukuoka 818-8502, Japan
Tel: +81-92-921-1011　Fax: +81-92-928-0856　E-mail: mikamikj@fukuoka-u.ac.jp

Introduction

Laparoscopic gastrectomy is now regarded as an oncologically safe procedure, and has become the recommended approach for early gastric cancer [1), 2)]. However, laparoscopic distal gastrectomy (LDG) is a difficult and complex procedure in terms of its technical aspects. Surgeons require extensive surgical experience in order to overcome the learning curve for LDG [3), 4)]. Experience with 50-60 cases of LDG appears to result in satisfactory patient outcomes. However, these learning curve studies were carried out at high-volume centers, and only a few studies have evaluated the learning curve at low-volume institutions [5)]. The total number of patients with early gastric cancer treated at our department is less than 50 per year. Therefore, it is expected that obtaining a satisfactory patient outcome at a low-volume institution, such as our hospital, will take longer. The aims of this study were to describe the LDG learning curve in a low-volume institute and to assess the feasibility and safety to LDG at our hospital.

Patients

Fifty-nine consecutive LDG procedures were performed from March 2009 to August 2013. We enrolled 55 LDG patients after excluding three patients, including two who underwent less than D1 lymph node dissection for liver cirrhosis and one was required combined resection of the colon for ascending cancer. All patients consented to undergo laparoscopic gastrectomy after receiving a comprehensive explanation of the surgical procedure. The operations were performed by the regular surgeon and an assistant. Although the initial indication for LDG was gastric cancer confined to the mucosa or submucosa without lymph node metastasis, it was later extended to include gastric cancers that had invaded the subserosal layer or were associated with lymph node metastasis in the perigastric area.

Surgical procedure

The rules of the Japanese Research Society for Gastric Cancer were used to determine the extent of lymph node dissection that was necessary (D1+ or D2). Although the reconstruction type and approaches was basically selected as an intra-corporeal B-I type, delta-shaped anastomosis, the Roux-en-Y reconstruction was selected when the tumor was located in the upper third of the stomach.

Postoperative management

A soft oral diet was started on postoperative day 2 or 3, without any adverse events. Complications were defined in this study as events of grade 2 or higher according to the Clavien-Dindo classification. Successful cases were defined as those involving patients with no complications and who were discharged within 14 days of the surgery.

Statistical analysis

The data are expressed as the means ± standard deviation (SD) for numerical variables and as the number of cases (percentage) for categorical variables. To assess the differences between the two groups (period I vs. period II), we used an independent two-sample t-test for continuous variables. The Pearson chi-squared test was used to test for statistically significant differences in the distributions of categorical variables. The learning curve was assessed using the cumulative sum method.

Results

The characteristics of the patients are summarized in Table 1. The mean age of the patients was 63.8 years during period I and 65.5 years during period II. There were 16 males and 11 females in periods I and 13 males and 15 females in periods II. The mean body mass (BMI) index, American Society of Anesthesiologists (ASA) score and clinical stage were not significantly different between periods I and II.

Table 1 Characteristics of patients

	Period I	Period II	*p*=
Age	63.8 ± 12.3	65.5 ± 8.3	0.5526
Gender (male : female)	16:11	13:15	0.3407
BMI (kg/m2)	21.6 ± 2.9	22.2 ± 3.1	0.5051
ASA (1: 2,3)	19:8	14:14	0.1232
Clinical stage (stageIA : IB,IIA,IIB)	25:2	21:7	0.1430

BMI: Body mass index
ASA: Amereican society of anesthesis

Table 2 Operative data of patients

	Period I	Period II	p =
Surgical procedure（LADG : TLDG）	15:12	3:25	0.0004
Lymph node dissection（D, D1+ : D2）	27:0	14:14	<.0001
Reconstruction（B-I : R-Y, B-II）	16:11	20:8	0.3427
Operation time（min）	310.2 ± 45.5	294.3 ± 42.1	0.1822
Bleeding（ml）	71.8 ± 77.8	63.0 ± 61.9	0.6445

LADG:laparoscopic assisted distal gastrectomy
TLDG:totally laparoscopic distal gastrectomy
R-Y: Roux en Y

Table 3 Postoperative clinical course

	Period I	Period II	p =
Postoperative complications			0.0511
Abdominal complication			
Stasis	3	1	
Intraabdominal abscess	1	0	
Superficial surgical site infection	1	0	
Cholecystitis	1	0	
Systemic complication			
pneumonia	0	0	
Delirium	0	0	
Postoperative hospital stay（days）	16.3 ± 7.3	12.5± 1.8	0.0100
Surgical outcome（Success:Failure）	17:10	25:3	0.0286

Surgical outcome Success: no complication and 14 and shorter postoperative hospital stay

The surgical procedure and the operative results are summarized in Table 2. During period I, fifteen patients underwent laparoscopic-assisted distal gastrectomy（LADG）and 12 patients underwent totally laparoscopic distal gastrectomy（TLDG）. During period II, three patients underwent LADG and 25 patients underwent TLDG. Lymphadenectomies were performed as D1+ for all twenty-seven patients in period I. Fourteen patients underwent D1+ and 14 patients underwent D2 lymphadenectomy in period II. The surgical procedure and lymphadenectomy were significantly different between periods I and II. In period I, sixteen patients had a B-I reconstruction and 11 patients had a Roux-en-Y reconstruction. In period II, twenty patients had a B-I reconstruction, seven patients had a Roux-en-Y reconstruction and one patient had a B-II reconstruction. The mean length of the operation in periods I and period II was 310.2 minutes and 294.3 minutes, respectively. The mean amount of blood loss in period I was 71.8 ml, while that in period II was 63.0 ml. No patients were converted to open gastrectomy in either period. Postoperative complications occurred in six patients during period I, including three cases of stasis and one case each of an intra-abdominal abscess, superficial surgical site infection and cholecystitis. During period II, one patient developed stasis（Table 3）. The number of successful cases in period II was significantly higher than that observed in period I.

Figure 1 and 2 show the learning curve for the length of the operation and amount of blood loss, as determined according to the cumulative sum（CUSUM）analysis, respectively. The findings showed that the learning curve has not yet been mastered at our institution.

Discussion

In this study, the postoperative hospital stay was significantly shorter in period II than in period I. Although the incidence of postoperative complications was not significantly different between the two periods, there were fewer complications in period II. Our findings indicate that LDG is performed safely with low morbidity at our institute.

As shown in Figure 1, the learning curve for the length of operation and amount of intraoperative blood loss has not yet been mastered. This finding may be the result of two main causes. First, LDG was performed for the patients with different conditions. We began performing LADG for the patients with T1N0M0 and an ASA score of 1. The selection of patients was then extended to

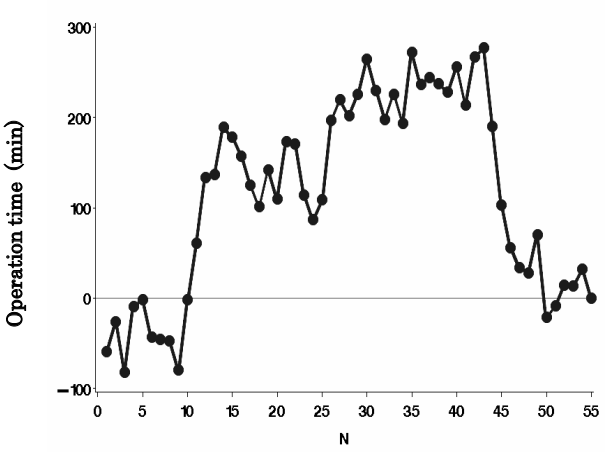

Fig. 1 CUSUM analysis of operation time

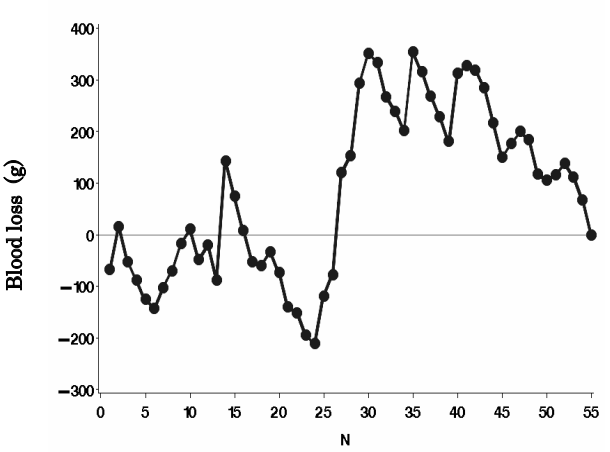

Fig. 2 CUSUM analysis of blood loss

elderly patients with an ASA score of 2 or 3. Hyung et al. suggested that surgeons with limited laparoscopic gastrectomy experience should consider the patient and tumor characteristics to minimize the effects of patient selection on the learning curve [6]. Second, D2 lymph node dissection, which is a more complex and difficult procedure than D1+ lymph node dissection, was performed more often in period II. The use of TLDG also increased in period II. TLDG is considered to be a more technically difficult intra-corporeal anastomosis, and each surgeon and assistant needs to have coordinated movements. Intraoperative identification of the tumor location is a prerequisite for TLDG, because the operator often cannot touch the tumor or marking clip in the abdominal cavity. We often checked the position of the tumor by using an intraoperative endoscope. And we marked the stomach walls at the planned cut lines using crystal violet according to the standard procedure. These procedures slightly increase the length of surgery.

Previous studies have reported significant differences in the mean length of operation between low- and high-volume centers [7]. Low-volume institutions often lack well-trained surgical professionals, such as first assistants and scrub nurses. Furthermore, the postoperative complication rate among patients who undergo LDG at low-volume institutions is higher than that observed at high-volume centers. In order to address these problems, in this study, the regular surgeon and assistant performed LDG, and we established a standardized and suitable procedure for our institution. Consequently, the postoperative complication rate decreased during period II, showing that this aspect of the learning curve had been overcome.

Yang et al. reported that surgeons should have abundant experience in laparotomy, and systemic education and experience as an assistant should be precedent in order to adapt to laparoscopic views [5]. The LDG procedure is technically complex with many difficult steps to master. Surgeons need to understand each procedural step and master the laparoscopy-specific anatomical views as a scopist, and then acquire the skills of handling the laparoscopic devices and hand–eye coordination as an assistant. Improved surgical outcomes of LDG, such as a shorter operative time and reduced amount of blood loss, can be achieved by standardizing the entire laparoscopic procedure, including the roles of the assistant and scopist. Nunobe et al. recommended that the trainees should also study each step of the procedure in every case by watching recorded movies of the actual operation immediately after completing the surgery [8]. A complete understanding of every step of the standardized procedure by the surgeon, assistant and scopist may accelerate the learning curve. We found that examining of the video of the operation was useful for improving the LDG procedure, and we compared our videos with other videos of operative procedures made at high-volume centers. During such examinations, the surgeon and assistants can look at the same image and confirm the characteristics of the laparoscopic devices, the creation of the field of view and the performance of lymph node dissection.

In conclusion, LDG for early gastric cancer is feasible and can be performed safely by several devices even at low-volume institutions, but an experienced surgical team and careful patient selection are necessary to ensure good outcomes.

References

1）Kitano S, Shiraishi N, Uyama I, Sugihara K, Tanigawa N: Japanese Laparoscopic Surgery Study Group. A multicenter study on oncologic outcome of laparoscopic gastrectomy for early cancer in Japan. Ann Surg 245: 68-72, 2007.

2）Kim HH, Hyung WJ, Cho GS, Kim MC, Han SU, Kim W, Ryu SW, Lee HJ, Song KY: Morbidity and mortality of laparoscopic gastrectomy versus open gastrectomy for gastric cancer: an interim report-a phase III multicenter, prospective, randomized Trial（KLASS Trial）Ann Surg 251: 417-20, 2010.

3）Kunisaki C, Makino H, Yamamoto N, Sato T, Oshima T, Nagano Y, Fujii S, Akiyama H, Otsuka Y, Ono HA, et al: Learning curve for laparoscopy-assisted distal gastrectomy with regional lymph node dissection for early gastric cancer. Surg Laparosc Endosc Percutan Tech 18: 236-41, 2008.

4）Zhang X, Tanigawa N: Learning curve of laparoscopic surgery for gastric cancer, a laparoscopic distal gastrectomy-based analysis. Surg Endosc 23: 1259-64, 2009.

5）Yang SJ, Ahn EJ, Park SH, Kim JH, Park JM: The early experience of laparoscopy-assisted gastrectomy for gastric cancer at a low-volume center. J Gastric Cancer 10: 241-246, 2010.

6）Hyung WJ, Song C, Cheong JH, Choi SH, Noh SH: Factors influencing operation time of laparoscopy-assisted distal subtotal gastrectomy: analysis of consecutive 100 initial cases. Eur J Surg Oncol 33: 314-319, 2007.

7）Kim MG, Kwon SJ: Comparison of the outcomes for laparoscopic gastrectomy performed by the same surgeon between a low-volume hospital and a high-volume center. Surg Endosc Jan 1（Epub of print）, 2014.

8）Nunobe S, Hiki N, Tanimura S, Nohara K, Sano T, Yamaguchi T: The Clinical Safety of Performing Laparoscopic Gastrectomy for Gastric Cancer by Trainees after Sufficient Experience in Assisting. World J Surg 37: 424-429, 2013.

（平成 26. 4. 7 受付，平成 26. 6. 12 受理）