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Original Article

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Learning Curve of Pure Single-Port Laparoscopic Distal Gastrectomy for Gastric Cancer

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Conflict of Interest
No potential conflict of interest relevant to this article was reported.

ABSTRACT

Purpose: Despite the fact that there are several reports of single-port laparoscopic distal gastrectomy (SPDG), no analysis of its learning curve has been described in the literature. The aim of this study was to investigate the favorable factors for SPDG and to analyze the learning curve of SPDG.

Materials and Methods: A total of 125 cases of SPDG performed from November 2011 to December 2015 were enrolled. All operations were performed by 2 surgeons (surgeon A and surgeon B). The moving average method was used for defining the learning curve. All cases were divided into 10 cases in a sequence, and the mean operative time and estimated blood loss data were extracted from each group.

Results: Surgeon A performed 68 cases (female-to-male sex ratio, 91.1%:8.82%), and surgeon B performed 57 cases (female-to-male sex ratio, 61.4%:38.5%). The operative time of surgeon B significantly decreased after 30 cases (157.8±38.4 minutes vs. 118.1±34.5 minutes, P=0.003); that of surgeon A did not significantly decrease before and after around 30 cases (160.8±51.6 minutes vs. 173.3±35.2 minutes, P=0.6). The subgroup analysis showed that the operative time significantly decreased in the patients with body mass index (BMI) of <25 kg/m^2 (<25 kg/m^2:≥25 kg/m^2, 159.3±41.7 minutes: 194.25±81.1 minutes; P=0.001).

Conclusions: Although there was no significant decrease in the operative time for surgeon A, surgeon B reached the learning curve upon conducting 30 cases of SPDG. BMI of <25 kg/m^2 was found to be a favorable factor for SPDG.

Keywords: Stomach neoplasms; Laparoscopy; Learning curve; Gastrectomy

INTRODUCTION

Since Kitano et al. [1] first performed laparoscopic gastrectomy for early gastric cancer (EGC) in 1994, the laparoscopic technique has been consistently developed every year. A study conducted in Japan reported that laparoscopic gastrectomy is safe for EGC owing to its short- and long-term oncologic outcomes [2]. In Korea, multicenter prospective randomized controlled trials on the 5-year overall survival from laparoscopic distal gastrectomy (LDG) and open distal gastrectomy for stage 1 gastric cancer are ongoing: Korean Laparoscopic Gastrointestinal Surgery Study (KLASS 01) [3]. Over time, the development of surgical

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techniques and devices in laparoscopic gastrectomy led to the introduction of reduced-port and single-port gastrectomies.

Only a few institutes have produced reports on single-port LDG (SPDG) since it was first reported in 2011 [4]. Recently, 2 comparative studies have illustrated the safety and feasibility of SPDG compared with conventional multiport LDG in EGC [5,6]. Nonetheless, there have been no descriptions of the learning curve of this procedure in any published literature up to date.

The aim of this study is to analyze the learning curve of SPDG and investigate the favorable factors in performing SPDG.

MATERIALS AND METHODS

Patient selection

This was a single-center study using prospectively collected data from 125 consecutive patients who underwent SPDG between November 2011 and December 2015 at Seoul National University Bundang Hospital in Korea. All operations were performed by 2 surgeons, who had experience of more than 2,000 cases of LDG (surgeon A) and 200 cases of LDG (surgeon B) before starting SPDG. SPDG was conducted only for EGC confirmed in the preoperative examination and was excluded if there was evidence of advanced gastric cancer or metastasis to other organs. Previous abdominal surgery itself was not a contraindication to SPDG, except for cases where severe adhesion was expected due to multiple surgical procedures. There was no restriction to patient body mass index (BMI). The surgical procedure of SPDG has already been reported in a previous study [5]. The protocol of this retrospective cohort study was approved by the institutional review board of Seoul National University Bundang Hospital, Seongnam, Korea, an academic hospital affiliated with Seoul National University, College of Medicine (approval No. L-20171194).

Demographics

Baseline characteristics, including patients' age, BMI, comorbidity, and previous operation, were recorded. Before surgery, the patients' conditions were assessed using the American Society of Anesthesiologists (ASA) physical status classification system.

Surgical outcomes

The following variables were analyzed for evaluating the quality of the operations: operative time, estimated blood loss (EBL), number of retrieved lymph nodes (LNs), duration of postoperative hospital stay, and complication rate. The postoperative complications included the 30-day morbidity and mortality. The complications were graded using the Clavien-Dindo classification [7]; those under Clavien-Dindo grade I were not regarded as an event, whereas those with grade II or higher (requiring medical or surgical interventions) were regarded as an event.

Definition of learning curve

There are several statistical methods to evaluate the learning curve, and among them, the moving average method was used. Two sequential variables, i.e., operative time and EBL, were used to define the learning curve. The complication rate was not included, since it was too low to perform reliable statistical analyses [8,9].

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Statistical analysis

Statistical analyses were performed using the SPSS software (version 18.0). All values were expressed as means±standard deviations. The Student's t-test and Mann-Whitney U test were used for continuous variables and the χ^2 test for categorical variables. A P-value of <0.05 was considered statistically significant.

RESULTS

Demographics

The general characteristics of the patients in each group are shown in **Table 1**. SPDG was performed successfully in all 125 cases without any serious intraoperative or postoperative complications. Surgeon A performed 68 (female-to-male sex ratio, 91.1%:8.82%) cases, and surgeon B performed 57 (female-to-male sex ratio, 61.4%:38.5%) cases. No significant differences were observed in age, BMI, ASA score, and history of abdominal operation, except for sex distribution. Surgeon A's patient group had a relatively higher proportion of female patients than surgeon B's patient group.

Learning curve for SPDG

For analyzing the learning curve of each surgeon, cases were extracted from 6 (surgeon A) and 5 (surgeon B) sequential groups. The mean operative time in each group was calculated. The operative time was shorter in the beginning but increased after the middle group with surgeon A (**Fig. 1**). In contrast, surgeon B showed a steady state after 30 cases of SPDG (**Fig. 2**). The "training phase" was defined as the state before proficiency, while the "developed phase" was defined as the state after proficiency, indicating the period that the surgeon had become adept at SPDG.

The surgical quality of the 2 phases for each surgeon was compared (**Tables 2** and **3**). With surgeon B, the first 3 groups were in the training phase, and the following 2 groups were in the developed phase. In the comparison of the operative time according to each phase, it significantly decreased in the developed phase (157.8±38.4 minutes vs. 118.1±34.5 minutes, P=0.003). With surgeon A, as it was difficult to differentiate between the training phase and the developed phase using only the operative time, the entire phase was divided into half to

Table 1. General characteristics of the patients in each group

Variables	Total (n=125)	Surgeon A (n=68)	Surgeon B (n=57)	P-value
Sex				0.012
Male	41 (32)	6 (8.82)	35 (61.4)	
Female	84 (68)	62 (91.1)	22 (38.5)	
Age	56.6±13.8	54.5±13.7	60.0±12.2	0.67
BMI (kg/m^2)	22.3±3.20	21.7±3.3	23.1±3.08	0.35
Operation history (abdomen)	12 (9.6)	10 (14.7)	2 (3.50)	0.067
Comorbidity				0.27
None	76 (73.0)	47 (69.1)	29 (50.8)	
One	32 (20.6)	12 (17.6)	20 (35.0)	
More than two	17 (6.34)	9 (13.2)	8 (14.0)	
ASA score				0.67
1	68 (54.4)	38 (55.9)	30 (52.6)	
2	55 (44.0)	30 (44.1)	25 (43.8)	
3	2 (1.58)	0	2 (3.50)	

Data are shown as mean±standard deviation or number (%).
BMI = body mass index; ASA = American Society of Anesthesiologists.

compare the surgical quality. Only EBL (50.8±55.8 mL vs. 17.9±39.2 mL, P=0.002) decreased in the later phases, while the other variables did not show significant differences. The operative time was similar between the 2 phases (160.8±51.6 minutes vs. 173.3±35.2 minutes, P=0.6).

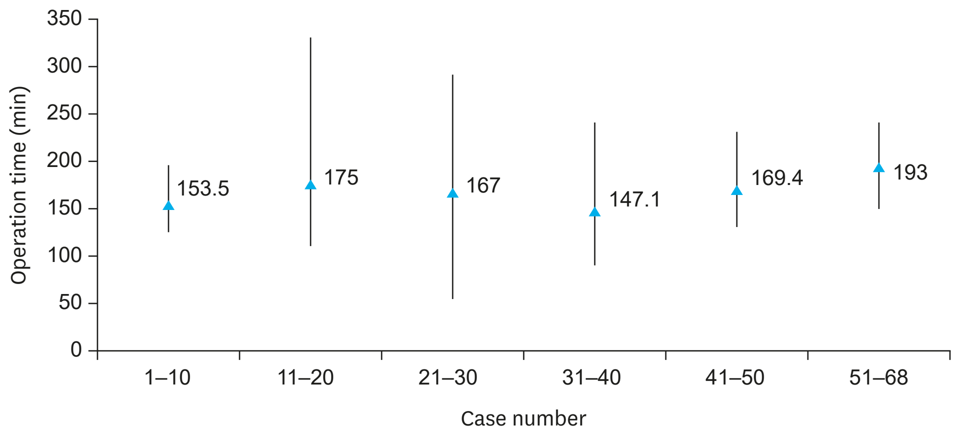

Fig. 1. Learning curve (surgeon A). For analyzing the learning curve of each surgeon, cases were extracted from 6 (surgeon A) sequential groups. The mean operative time in each group was calculated. The operative time was shorter in the beginning but increased after the middle group with surgeon A.

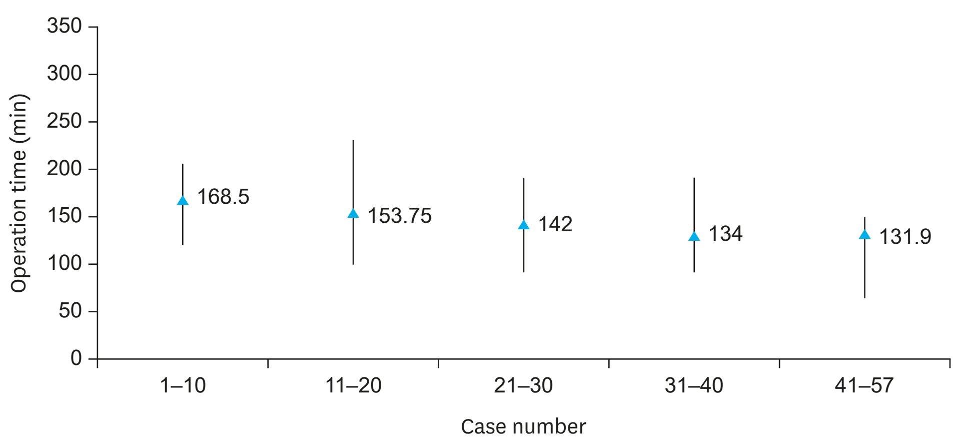

Fig. 2. Learning curve (surgeon B). For analyzing the learning curve of each surgeon, cases were extracted from 5 (surgeon B) sequential groups. The mean operative time in each group was calculated. Surgeon B showed a steady state after 30 cases of single-port laparoscopic distal gastrectomy.

Table 2. Comparison of the variables used to evaluate the operative quality in the 2 phases (surgeon A)

Variables	Phase I (n=34)	Phase II (n=34)	P-value
Operative time (min)	160.8±51.6	173.3±35.2	0.6
Estimated blood loss (mL)	50.8±55.8	17.9±39.2	0.002
Retrieved lymph nodes (No.)	62.1±21.8	65.4±25.6	0.48
Hospital stay (day)	6±4.76	6.88±4.76	0.57

Table 3. Comparison of the variables used to evaluate the operative quality in the 2 phases (surgeon B)

Variables	Phase I (n=30)	Phase II (n=27)	P-value
Operative time (min)	157.8±38.4	118.1±34.5	0.003
Estimated blood loss (mL)	45.9±54.1	40.7±77.4	0.49
Retrieved lymph nodes (No.)	50.7±13.0	56.4±17.4	0.57
Hospital stay (day)	5±2.44	5±1.16	0.53

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Table 4. Early complications after surgery

Case number	Age/sex	BMI (kg/m²)	Complications	Treatment	Clavien-Dindo classification
Surgeon A					
5	62/F	19.2	Gastrojejunostomy narrowing	Laparoscopic gastrojejunostomy	IIIb
15	61/F	25.1	Jejuno-jejunostomy anastomosis leakage	Drainage	IIIa
36	65/F	22.3	Wound dehiscence	Re-suture	IIIa
40	37/F	20.7	Delayed gastric emptying	Conservative care	II
59	57/F	24.3	Duodenal stump leakage	Drainage	IIIa
Surgeon B					
13	46/M	28.2	Delayed gastric emptying	Conservative care	II
23	66/M	20.9	Ileus	Conservative care	II
28	58/M	23.9	Luminal bleeding	Transfusion	II

The early complication rates after surgery are shown in **Table 4**. The complication rate for surgeon A was 7.35%, and that for surgeon B was 5.26%. Complications under Clavien-Dindo grade IV and higher occurred in 4 out of 5 cases with surgeon A; these were not observed with surgeon B.

Further analysis of the operative time

To examine the favorable factors for SPDG, those influencing the operative time were analyzed, and a sub-analysis was conducted for sex and BMI. The operative time between sexes in the entire patient group was similar (male-to-female sex ratio, 173.6±62.1 minutes: 164.2±52.1 minutes; P=0.20), showing no significant difference between the 2 groups. In the analysis of BMI using 25 kg/m^2 as the reference value, which is a standard value for obesity in Korea, the operative time was significantly shorter in the group with a BMI of <25 kg/m^2 (159.3±41.7 minutes vs. 194.25±81.1 minutes, P=0.001). Additional analysis of BMI according to sex was also conducted. The mean BMI was 22.5±3.31 kg/m^2 in the female patients and 22.5±2.60 kg/m^2 in the male patients, showing similar distributions in both groups. The operative time between the female patients with BMIs of <30 and ≥30 kg/m^2 showed a significant difference (156.6±41.1 minutes vs. 196.6±20.5 minutes, P=0.049).

Early complications (<30 days after operation)

No significant differences in the postoperative morbidities were observed between the 2 groups (**Table 4**). The early (<30-day) complication rates for surgeons A and B were 7.35% and 5.26%, respectively (P=0.24). The detailed information on the complications is summarized in **Table 4**. No in-hospital mortality was observed in either group. To assess the severity of postoperative morbidities, early complication cases were graded using the Clavien-Dindo classification. In surgeon B's patient group, complications under grade III and higher did not occur; in surgeon A's patient group, complications under grade III and higher occurred (5.88%).

DISCUSSION

This is the first study that analyzed the learning curve of SPDG and its favorable factors. The results showed that the surgeons who were experienced with conventional multiport LDG reached the learning curve upon conducting 30 cases of SPDG. In addition, a low BMI was a favorable factor for performing SPDG.

Laparoscopic gastrectomy has been widely applied in the treatment of gastric cancer. As experience on LDG is accumulating, many surgeons have shown interest in more minimally invasive surgeries. Recently, the number of reduced-port LDG or SPDG performed is increasing annually [10]. Although there are no data on the long-term outcomes of SPDG, a previous study has revealed that SPDG is feasible, safe, and useful for EGC. Because the incisions are small, patients may have a quicker recovery. Studies show that it reduces potential morbidity associated with postoperative pain and wound size [11,12].

Despite these advantages, SPDG has several technical difficulties. Owing to the limited activity and the difficulty of LN dissections, SPDG can be performed only by skilled surgeons and in a few centers. The purpose of this study is to evaluate how many cases are needed to overcome the learning curve for SPDG and to define the factors that affect the outcomes of the procedure during the learning period.

To evaluate the quality of operation, we used the operative time, EBL, number of retrieved LNs, duration of postoperative hospital stay, and complications. In terms of the general characteristics of the patients, surgeon A preferred female patients (surgeon A, 91.1% vs. surgeon B, 38.5%, sex ratio). Based on the results of the learning curve, the operative time increased from the middle with surgeon A. One possible explanation is that although skillful assistants and scopists participated in the initiation of SPDG with surgeon A, participation of inexperienced fellows and residents after the initiation owing to educational purposes influenced the data. Furthermore, in the initial patient selection, surgeon A favored to perform the operation in the female patients; however, this preference changed towards the end. As relatively consistent personnel performed the operation on various patients with surgeon B, the data from surgeon B were likely to be more reliable for interpreting the learning curve.

We conducted sub-analyses to examine the favorable factors for SPDG. As another study on single-port surgery reported its restriction to patients with low BMIs [13-15], the association of the operative time with BMI and sex was analyzed. The result showed that the operative time was shorter in the female patients, but without a significance. The operative time was significantly longer when the BMI was ≥25 kg/m^2. This suggests that a low BMI will be more favorable for the operation in the initial selection of patients.

For the popularization of SPDG, surgeons must be familiarized with the laparoscopic technique first. Surgeon A had an experience of >2,000 cases of LDG, while surgeon B had >200 cases. When first starting to perform SPDG, selecting patients with a low BMI is one way to overcome the restriction of the small field in single-port surgery.

This study has some limitations. The study has a retrospective nature and was performed in a single center. Further, the patient selection groups with surgeon A were different between the beginning and the end, and there was no consistency in the patients who underwent the surgery. Despite such limitations, it is the first to report the learning curve of SPDG. Although there can be technical difficulties in beginning SPDG, this study showed that it is a safe surgical technique after overcoming the learning curve, especially when it is started on favorable patient groups.

The present study showed that the surgeons who had sufficient experience with conventional multiport LDG reached the learning curve upon conducting 30 cases of SPDG. In addition, a low BMI was a favorable factor for performing SPDG.

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