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Learning curve of laparoscopic surgery for gastric cancer, a laparoscopic distal gastrectomy-based analysis

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Abstract
Background The application of laparoscopic gastrectomy in management of gastric cancer is being propagated rapidly. Training and education play important role during this process. The purpose of this study is to define the learning curve of laparoscopic gastrectomy to obtain an insight into this training process.
Methods All 362 cases of laparoscopic gastrectomy from January 1998 to July 2007 were enrolled and divided into 12 groups of 30 cases each in time sequence. The learning curve was defined with the split group method. Laparoscopic distal gastrectomy was extracted from the 12 groups and the means of operation time and intraoperative blood loss were compared to define the learning curve. Then general data and variables including occurrence of systematic inflammatory response syndrome (SIRS), complications, and conversion to open surgery were compared among the phases of learning curve.
Results A three-phase learning curve of laparoscopic gastrectomy was defined from the laparoscopic distal gastrectomy-based analysis, which included a training phase for the first 120 cases of operation, an intermediate phase for the following 90 cases, and a well-developed phase for the last 152 cases. Learning was considered to be complete after 60–90 operations in the training phase. For most variables, the differences among three phases were statistically significant except for the rate of complications.
Conclusions There was a significant learning curve, composed of three phases. Experience of about 60–90 cases of operation was required for completion of learning.

Keywords Learning curve · Laparoscopic gastrectomy · Gastric cancer

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The laparoscopic technique has been introduced in surgical management of gastric cancer in the last two decades [1]. Its application is being propagated progressively and, especially this century, increasing numbers of surgeons are realizing its numerous merits. In Asian countries such as Japan and Korea, it has become a standard therapy for early-stage gastric cancer [2, 3]. However, due to the complexities of blood supply and lymphatic drainage pattern of the stomach, laparoscopic or laparoscopic-assisted gastrectomy is also recognized as a complicated and difficult procedure when compared with other laparoscopic operations. So a significant learning curve is associated with the development of these operative techniques [4]. To date, several authors have given perfect analyses of the learning curve of laparoscopic gastrectomy to obtain an insight into the progress of training, but these all focused only or mainly on the most popular procedure, laparoscopic distal gastrectomy [4, 5]. Here we aim to perform a further analysis of the learning curve of laparoscopic gastrectomy from a different point of view. We combine all laparoscopic gastrectomy procedures in order to analyze the learning curve of laparoscopic gastrectomy, because we think that different procedures may share the same pattern in terms of technique training. On the other hand, it is almost impossible for an institution to do only one kind of procedure, even over a short period.

Materials and methods

Patients

All 362 gastric cancer patients treated with laparoscopic surgery from 1st January 1998 to 31st July 2007 were enrolled in this study. Patients who accepted laparoscopic exploration only were excluded. Written informed consent was obtained from each patient before operation. To avoid the effect of manipulations besides "pure" laparoscopic gastrectomy, patients with conversion to open surgery or combined procedure for coexistent diseases were excluded in most analysis except for the conversion rate.

Variables

General data

Sex, age, body mass index (BMI), pathological stage, and operative procedures were retrieved from medical reports and reviewed retrospectively.

Operation invasiveness-related variables

The following variables were recorded: operation time; volume of intraoperative blood loss, measured by weight difference between blood-stained gauze and dry gauze and the amount of blood in suction; and occurrence of systematic inflammatory response syndrome (SIRS) on the first postoperative day (POD1), according to the criteria by American College of Chest Physicians and Society of Critical Care Medicine [6]. All complications were recorded.

Operative procedure and postoperative care

In general, the patient received operation under general anesthesia in a supine position with legs apart. A five-port technique was adopted, with a CO_2 pneumoperitoneum pressure of 8–10 mmHg. Mobilization of stomach and dissection of perigastric lymph node were performed following the Japanese Gastric Cancer Association (JGCA) gastric cancer treatment guidelines [7, 8]. Range of gastric resection and extent of lymphatic dissection were determined individually, according to the location of the primary lesion and clinical stage. The type of gastric resection included mucosectomy, wedge resection, segmental gastrectomy, laparoscopic (assisted) pyloric-preserving gastrectomy (LPPG), laparoscopic (assisted) distal gastrectomy (LDG), laparoscopic (assisted) proximal gastrectomy (LPG), and laparoscopic (assisted) total gastrectomy (LTG). Lymphatic dissection included D0, which means no lymphatic dissection or incomplete dissection of group1 lymph nodes; D1, dissection of group 1 lymph nodes; D1 + α, dissection of group 1 lymph nodes plus nos. 7 and 8a lymph nodes if the primary lesion located in the lower third of the stomach; D1 + β, dissection of group 1 lymph nodes plus nos. 7, 8a, and 9 lymph nodes; and D2, which refers to the dissection of all group 1 and 2 lymph nodes. Reconstruction of gastrointestinal tract was performed laparoscopically or via a minilaparotomy.

Postoperative care was performed routinely according to the clinical pathway. In brief, the nasogastric tube was withdrawn on the morning of POD1. Recovery of oral intake was initiated on POD3 with water, followed by a dietary progression from liquid to soft food and finally to solid food. Usually intravenous fluid therapy was terminated on POD5. Preventive antibiotics were administrated intravenously just before operation and continued for 2 days. Postoperative mobilization was encouraged from POD2. Blood routine examination and blood biochemical analysis were performed routinely on POD1, 3, 5, and 7.

For the purpose of standardized operative technique, most of the operations were performed by the same operator (N.T.), and usually with the same laparoscopist and assistant, in the early stage.

Defining learning curve of laparoscopic operation for gastric cancer

Two sequential variables, time of operation and amount of intraoperative blood loss, were used to define the learning curve by using a split group method. As the procedure with the most number of cases, LDG was selected and analyzed to represent laparoscopic gastrectomy. So, all 362 patients were divided into 12 sequential groups of 30 cases each ($n = 32$ only in the last group). LDG of each group was extracted, excluding those with conversion or combined resection. The mean values of operation time and amount of blood loss of LDG in each group were calculated and compared to define the learning curve. In this step, the Student–Newman–Keuls test was used for post hoc multiple comparison of mean values of operation time and amount of blood loss. The means for groups in homogeneous subsets were displayed by this method, and the homogeneous groups in continuous time sequence were defined to form a phase of the learning curve. Then other variables such as occurrence of complications, rate of conversion to open surgery, and operative invasiveness were evaluated among the different phases of the calculated learning curve.

Statistics

All continuous variables are expressed as mean ± standard deviation (SD). One-way analysis of variance (ANOVA), least-significant difference test, and Student–Newman–Keuls test were used for comparison and post hoc multiple comparison of continuous variables. χ^2 test (Pearson chi-square test) was used for analysis of categorical variables.

$p < 0.05$ (two-sided) was considered to be statistically significant. All the statistical analysis was performed with SPSS13.0 software.

Results

Description of patient demographics

From 1st January 1998 to 31st July 2007, 362 patients with gastric cancer were treated with laparoscopic surgery in our department. The general demographics of these 362 patients are shown in Table 1. Most of the operations (303/362, 83.7%) were performed by the same operator (N.T.). There was conversion to open surgery in 13 cases. Combined procedures for coexistent diseases were performed in 26 patients. These 39 patients were excluded from most analysis. Operation-related deaths occurred in three patients due to postoperative complication.

For the remaining 323 patients, 89 had a past history of abdominal operation and 33 of them experienced upper abdominal operations. For 157 patients, history of at least one coexistent systemic disease was recorded. The operation time of these patients was 299.4 ± 82.1 (90–600) min, and volume of blood loss was 79.2 ± 111.8 (5–800) ml. On POD1, 32 patients (9.9%) exhibited SIRS. There were 86 postoperative complications in 75 patients. Among the 86 complications, 51 cases (59.3%) were infectious, including wound infection, peritonitis or intraperitoneal abscess, cholecystitis, respiratory tract infection, and central venous catheter-related infection. Other complications mainly included delayed gastric emptying, stricture of anastomosis, intra-abdominal bleeding, and systemic complications such as liver dysfunction and cardiovascular events. Relaparotomy or interventional radiology therapy were performed 15 times, in 14 patients, for hemostasis or draining intraperitoneal infection. Among these 323 patients 2 died, on POD4 and POD15, respectively. One died from hemorrhagic shock caused by postoperative pancreatitis and anastomotic leakage; the other died from peritonitis with undefined origin on relaparotomy.

Learning curve

Among the 362 patients, 133 cases of eligible LDG were extracted from the 12 consequential groups. For cases of LDG in each group, the mean values of time of operation and volume of blood loss are shown in Fig. 1. Viewing these two variables together, three phases could be defined, with the first four groups constituting the first phase, the following three groups belonged to the second phase, and the last five groups composing the third phase. For the groups forming each phase, mean operation time was statistically homogeneous on Student–Newman–Keuls analysis (Table 2). In the first phase, time of operation of the four groups decreased gradually. On the other hand, volume of blood loss decreased significantly after the first two groups and then stayed at a relatively lower level. So learning was considered to be complete at the end of this phase. Then, after a short intermediate phase, in which time of operation increased to some degree, a well-developed phase emerged with the shortest time of operation and smallest volume of blood loss. When the means of these two variables of LDG of the three phases were compared,

Table 1 Clinicopathological characteristics of all the patients ($n = 362$)

Variable	Cases (%)/mean ± SD (range)
Sex	
Male	245 (67.7%)
Female	117 (32.3%)
Age (years)	63 ± 10.4 (32–92)
BMI (kg/m^2)	22.7 ± 3.0 (15.4–33.9)
Pathological stage	
Stage I	342 (94.5%)
Stage Ia (T1N0M0)	299 (82.6%)
Stage Ib	43 (11.9%)
Stage II	13 (3.6%)
Stage IIIa (T3N1M0)	5 (1.4%)
Stage IV (T3N3M0, T3N2P1)	2 (0.6%)
Operation procedure	
Mucosectomy	2 (0.6%)
Wedge resection	22 (6.1%)
Segmental resection	15 (4.1%)
LPPG	125 (34.5%)
LDG	152 (42.0%)
LPG	38 (10.5%)
LTG	8 (2.2%)
Range of lymph node dissection	
D0	18 (5.0%)
Sd1	10 (2.8%)
D1	6 (1.7%)
D1 + α	107 (29.6%)
D1 + β	111 (30.7%)
sD2	71 (19.6%)
D2	39 (10.8%)

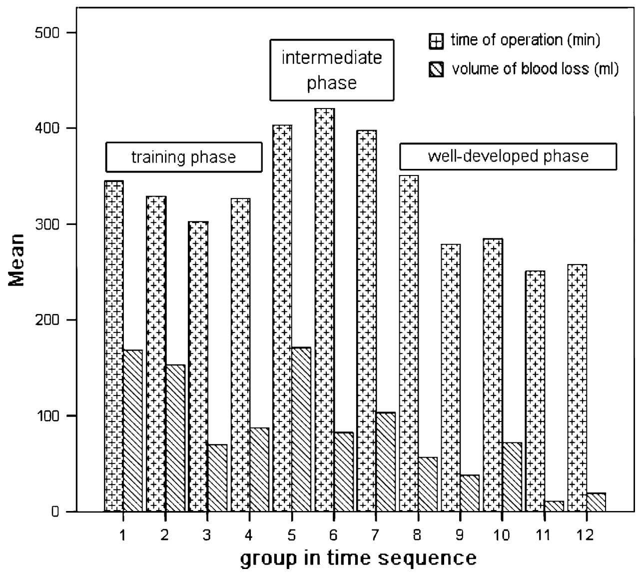

Fig. 1 Time of operation and volume of blood loss for LDG in groups in time sequence. The 12 groups were divided into three phases: (1) the training phase, composed of the first four groups; (2) the intermediate phase, composed of the following three groups, and (3) the well-developed phase, composed of the last five groups

Table 2 Student–Newman–Keuls analysis of time of operation of LDG among 12 groups (min)

Group in time sequence	Groups in homogeneous subset		
	1	2	3
11	251.15[c]		
12	257.86[c]		
9	279.00[c]		
10	285.00[c]		
3	302.69[a]	302.69[a]	
4	327.14[a]	327.14[a]	327.14[a]
2	329.41[a]	329.41[a]	329.41[a]
1	345.00[a]	345.00[a]	345.00[a]
8	351.11[c]	351.11[c]	351.11[a]
7		397.78[b]	397.78[b]
5			403.33[b]
6			420.88[b]
p	0.069	0.050	0.073

[a] Groups defined to be in phase 1, the training phase

[b] Groups defined to be in phase 2, the intermediate phase

[c] Groups defined to be in phase 3, the well-developed phase

the differences were statistically significant, as shown in Table 3.

On further analysis, the 323 cases of laparoscopic gastrectomy were categorized by the three phases calculated based on LDG. The patients in each phase were statistically homogenous in terms of general data, including sex composition, history of abdominal operation ($\chi^2 = 1.593$, $p = 0.810$), coexistent systemic diseases ($\chi^2 = 3.889$, $p = 0.143$), pathological stage ($\chi^2 = 10.442$, $p = 0.235$), and BMI ($p = 0.262$), except for age and composition of procedures. The average age of patients of the three phases was 60.8 ± 10.4 years, 63.5 ± 9.8 years, and 64.0 ± 10.5 years respectively. The distributions of the three main procedures (LPPG, LDG, and LPG, which together accounted for about 90% of all procedures) were homogenous ($\chi^2 = 6.339$, $p = 0.175$). As shown in Table 4, operation time and volume of blood loss of the three phases of learning curve showed the same trends as for LDG. The difference among rates of SIRS was statistically significant. No difference was detected among rates of postoperative complications of the three phases.

To evaluate the conversion rate of different phase of learning curve, the total 362 patients were divided into three groups according to the abovementioned three phases of LDG. As a result, the rate of conversion to open surgery was significantly higher in the first training phase (7.3% versus 1.1% and 0.8% for the later two phases, respectively; $\chi^2 = 10.373$, $p = 0.006$).

Discussion

With progress in early diagnosis and application of population screenings, the incidence of early-stage gastric cancer in Japan has increased to more than 50% of the overall morbidity of gastric cancer in past years [9, 10]. On the other hand, the application of laparoscopic surgery has also propagated at surprising speed in recent decades. Laparoscopic or laparoscopy-assisted gastrectomy was introduced into the field of surgical management of gastric cancer, especially for cases with early-stage cancer. Although its history is no longer than 20 years, laparoscopic gastrectomy for gastric cancer is being accepted by increasing numbers of surgeons and patients for its obvious merits such as less pain, earlier recovery, increased quality of life, and satisfactory short-term oncological outcome. The number of cases and its proportion in gastric cancer surgery have increased significantly, especially in the 21st century [1, 2].

However, due to the complexities of clinical anatomy for radical gastrectomy, laparoscopic or laparoscopic-assisted gastrectomy is sill quite difficult when compared with other laparoscopic operations. It is obvious that a relative longer learning progress is required to master laparoscopic gastrectomy, and that a significant learning curve is associated with this process [4]. It was believed that this learning curve would be helpful in developing strategy for training programs, evaluating the performance of a surgeon or a institution, and even optimizing patient care [5]. On the other hand, to our knowledge, to date there

Table 3 Comparisons of time of operation and amount of blood loss of LDG among the phases of the learning curve

Phase	*N*	Time of operation (min)	Amount of blood loss(ml)
Training phase	52	324.52 ± 75.258*	117.21 ± 144.403
Intermediate phase	35	410.43 ± 66.103*	110.71 ± 157.499
Well-developed phase	46	279.46 ± 75.382*	31.96 ± 47.264*
Total	133	331.54 ± 88.690	86.02 ± 129.503
F		32.368	6.683
p		0.000	0.002

* $p < 0.05$ versus the values of the other two phases

Table 4 Comparisons among the three learning-curve phases of laparoscopic gastrectomy with exclusion of conversion and combined resection

Phase of learning curve	*n*	Time of operation (min)	Volume of blood loss (ml)	SIRS	Complications
Training phase	101	304.30 ± 77.169*	115.50 ± 126.278	17 (16.8%)	23 (22.8%)
Intermediate phase	80	343.38 ± 92.325*	106.31 ± 143.557	7 (8.8%)	25 (31.3%)
Well-developed phase	142	271.52 ± 67.109*	38.11 ± 51.738*	8 (5.6%)	27 (19.0%)
Total	323	299.66 ± 82.145	79.45 ± 112.125	32 (9.9%)	75 (23.2%)
F/χ^2 value		$F = 22.393$	$F = 18.942$	$\chi^2 = 8.451$	$\chi^2 = 4.314$
p		0.000	0.000	0.015	0.116

* $p < 0.05$ versus the values of the other two phases

are only two papers about the learning curve of laparoscopic gastrectomy for gastric cancer, and the objects of their analysis were only or mainly LDG. In our opinion, each case of laparoscopic operation of gastric cancer acts as a chance for training, no matter which kind of procedure it is, or whether there is conversion to open surgery or additional resection for coexistent disease or not. Also, due to the diversity of operative procedures of laparoscopic gastrectomy, it is almost impossible for an institution to do only a certain kind of operation even during a short period. So when we calculated the learning curve, instead of analyzing only a given kind of procedure, we combined all 362 cases of laparoscopic gastrectomy carried out at our institution and divided them into 12 time sequence groups.

Sophisticated approaches such as multivariate regression and the cumulative sum (CUSUM) method have been used in statistical assessment of learning curves of healthy technologies recently. Outcome-related variables, such as conversion to open surgery and occurrence of severe complications, were also evaluated. They were considered to be very useful in monitoring performance [5, 11, 12]. However, in this series, the conversion rate was less than 4%. In terms of complications, about half of them, such as port-site infection, could not be defined as performance-related events. On the other hand, severe complications which required relaparotomy or interventional radiology therapy accounted for less than 5%. As both conversions to open surgery and severe complications were too infrequent for reliable statistical analysis, we preferred to use the commonest, split group, method to define the learning curve of laparoscopic gastrectomy. Two proxies for learning, duration of operation and amount of intraoperative blood loss, were evaluated. To avoid bias caused by different procedures, we analyzed one kind of operation first. As the commonest procedure and as a surrogate for laparoscopic gastrectomy, LDG was extracted from each group and analyzed. As shown by the results of ANOVA analysis, the differences among the two variables between each time-sequential group were statistically significant. Based on this result, we divided the learning curve of laparoscopic gastrectomy into three phases: the training phase for the first four 30-case groups, an intermediate phase for the following three 30-case groups, and the well-developed phase, which began with the eighth 30-case group in the time sequence. Although such a categorization was clearly arbitrary, as shown in Fig. 1 and Table 3, average time of operation of LDG of each group in the same phase formed a homogenous subset. When the 323 "pure" laparoscopic gastrectomy were evaluated, the differences in the means of these two variables of the three phases were statistically significant also. So, we believe that such an arbitrary categorization was indeed, at least to some degree, defined objectively. As an ideal learning curve should be multidimensional and not reflect only duration of operation, other performance-related outcomes such as operative invasiveness, postoperative complication, and conversion rate were evaluated in further tests. The significantly decreased occurrence rate of SIRS and conversion rate in the latter two phases verified again the feasibility of this learning curve. So, such a learning curve, at least to some degree, did reveal the nature of the learning process for laparoscopic surgery for stomach cancer.

During the training phase for the first 120 cases of operation, trends of decreasing volume of blood loss and shortening operative duration were clearly demonstrated. As these two variables reached a steady level in the latter half of this phase, we would like to say that learning was completed in this phase. An experience of about 60–90 cases of laparoscopic gastrectomy, which included LDG for 30–40 cases, was required for training and mastering essential techniques in this field. Blood loss of less than 100 ml was another marker of learning completion, and a further decreased amount of less than 50 ml may indicate the emergence of a well-developed phase. As described in series by other authors, about 60 operative cases for a given kind of procedure were required for completion of training [4]. When compared with these results, the completion of training in our series was slightly earlier. This may be caused by several factors such as the difference of patients' pathological characteristics, selection criteria, institutional performance in other laparoscopic surgeries, experience in open surgery of gastric cancer, etc. A strange feature of the learning curve was observed in this study: elongated duration of operation in the intermediate phase following the completion of learning in the training phase. We think that such an elevated segment of the curve may be mainly caused by the role and character of our institution. As a regional training center for laparoscopic surgery, up to 30 assistants attended the laparoscopic gastrectomy. After the termination of the training phase, education of this operation becomes an important task. In the following period, the assistants were encouraged to attend more in operation. So, such an education process resulted in the elongated duration, and only the duration of operation. After this relatively short intermediate phase, a well-developed phase with shorter operation duration and lower blood loss at a steady level soon emerged and persisted.

In spite of the aforementioned differences among the phases of learning curve, it should be noticed that, when complications of each phase were compared, no statistically significant difference in occurrence rate could be detected among the three phases. As some complications were not manipulation related and the rate of severe complications was quite low, we do not think that this indicates a failure of this learning curve to reveal surgical outcomes. On the other hand, based on our experience with gastric cancer surgery, we speculated that the occurrence of complications may be an accompanying phenomena related to the laparoscopic techniques used nowadays in gastric cancer surgery with a given rate of occurrence, but are not likely to be technique-related events. On the other hand, the rate of conversion to open surgery in the initial training phase was significantly higher than in the later two phases. This may, at least in part, be a reason for the averagely complication rate in the initial phase. So, in the training stage of laparoscopic gastrectomy, conversion to open surgery should be considered in case of difficult manipulation to avoid the occurrence of lethal complication.

Based on our analysis of the 362 cases of laparoscopic gastrectomy of our institution, we would like to conclude that there was a significant learning curve for its application, composed of three phases. Experience of about 60–90 cases of operation was required for completion of learning.

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