

# The Clinical Safety of Performing Laparoscopic Gastrectomy for Gastric Cancer by Trainees after Sufficient Experience in Assisting

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## Abstract

*Background* Laparoscopic gastrectomy (LAG) is increasingly performed to treat gastric cancer. However, the procedure remains complicated, and an optimal system for educating clinicians about LAG has not been established. *Methods* Our training system centers on understanding the anatomical appearance under laparoscopy and the standardized steps of LAG, including the roles of the scopist and the assistant. The trainees participated in LAG procedures as a scopist and an assistant in 30–35 cases, before conducting their first LAG case. The data of 788 consecutive patients with early gastric cancer who underwent LAG were also reviewed.

*Results* During the study period, nine trainees performed a total of 215 LAG (27.3 %) with trainers, while 563 LAG were conducted by the two trainers (71.4 %). The surgical outcomes including operative time, blood loss, and retrieval of lymph nodes were almost equivalent for both the trainers and the trainees. The total experience among the trainees as scopist and as first assistant was 45.0 and 41.4 cases, respectively, and the trainees had experienced 33.8 cases as a scopist and 35.3 cases as an assistant before they performed their first LAG as an operator. After commencing experience as an operator, the average operation time of the trainees reached that of the trainers within six cases and their learning curve reached a plateau.

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*Conclusions* Our training system based on attaining sufficient experience as an assistant and scopist in the simulation of a LAG procedure was effective for ensuring clinical safety for LAG performed by a trainee with experienced surgeons.

## Introduction

Laparoscopic distal gastrectomy (LAG) for early gastric cancer has been widely used since first performed by Kitano et al. in 1991, because of less postoperative pain, an earlier return of bowel function, shorter periods of hospitalization, and better cosmetic results [1]. Many studies have been conducted on the safety, efficacy, and feasibility of this procedure [2–5]. However, the optimal education system of LAG has not been established to date, because the procedure is complex for the trainee [6–9].

The improved surgical outcomes of LAG such as shorter operation time and less blood loss could be achieved by standardization of whole laparoscopic procedures, including assistant and scopist roles [10]. Therefore, a complete understanding by trainees of every step of a standardized procedure might accelerate their learning curve. Although many reports have been issued on the learning curves of LAG, most studies have focused on the numbers of experiences needed as operator to improve the learning curve [6–9], with specific experience as scopist and assistant not well described.

We have developed education in LAG based on the trainee's understanding each standardized step of the procedure [10, 11]. A trainee can learn every procedure step and the associated anatomy as a scopist, and then acquire the required skills of handling laparoscopic devices, field of development, and hand–eye coordination through experience as an assistant.

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We therefore postulated that a minimum level of operator experience, but adequate practice as assistant operator and scopist in a simulated LAG procedure could sufficiently accelerate a trainee's learning. In the present study, we evaluated a simulated training system designed to achieve rapid progress along the learning curve, but with minimal operator experience.

## Material and methods

# Patients

This study reviewed the data of 788 consecutive patients with early gastric cancer who underwent laparoscopic distal gastrectomy (LADG) and laparoscopic pyloruspreserving gastrectomy (LAPPG) in the Department of Gastroenterological Surgery at the Cancer Institute Ariake Hospital, Tokyo, Japan, from February 2005 to December 2009.

All tumors were classified histologically as adenocarcinomas that had invaded only the mucosa or submucosa of the stomach without lymph node metastasis (cT1, cN0). LADG was indicated if the cancer was located in the lower third of the stomach, and LAPPG was the procedure of choice if the lesion was in the middle third of the stomach. We evaluated tumor location and the depth of tumor invasion based on the results of endoscopy, an upper gastrointestinal series, and endoscopic ultrasonography. Distant metastases were evaluated by abdominal ultrasonography and computed tomography. Patients with early gastric cancer not suitable for endoscopic resection, such as patients with submucosal cancer and mucosal cancer that was histologically confirmed as poorly differentiated adenocarcinoma, were treated laparoscopically.

### Surgical procedure

Both LADG and LAPPG were performed by experienced surgeons and some trainees using standardized procedures as previously described [10, 12–14]. Briefly, each step of the lymphadenectomy was standardized, with the assistant playing an important role at each step [10]. The assistant was trained always to provide good tension and counter traction on the membranous surface of the tissue by lifting and expanding it, using both hands with grasper forceps, in the style of a matador (a Spanish bull fighter presenting his red cape to the bull). This action provides a good field of vision for the operator and assistant, and resulted in less bleeding, which might obscure fine procedures. For dissecting the supra-pancreatic lymph nodes, the left-sided approach without duodenal transaction was applied, in a step peculiar to our institute [13]. The assistant gently

pulled up the gastropancreatic fold (the pedicle of the left gastric artery) from the dorsal side and lifted it vertically toward the abdominal wall. The assistant also pulled the pancreas caudally to extend the left gastropancreatic fold. Lymph node stations correspond with specific lymph node tiers named by the Japanese Research Society for Gastric Cancer (JRSGC) [15]. Modified D2 dissection according to en-bloc technique was performed for patients in both LADG and LAPPG. During LAPPG, the lymph node along the root of the right gastric artery was not dissected because it was necessary for maintaining the blood supply to the remnant pyloric cuff. The dissection of first-tier lymph nodes as well as preferential lymph nodes along the left gastric (station 7), common hepatic (station 8), and celiac (station 9) arteries is defined as a modified D2 dissection, and these three stations are defined as selective second-tier stations. The reconstruction method used was the Billroth I, Roux-en-Y, or pylorus-preserving gastrectomy depending on tumor location and the volume of remnant stomach. A stapler was used during the Billroth I or Roux-en-Y reconstruction method.

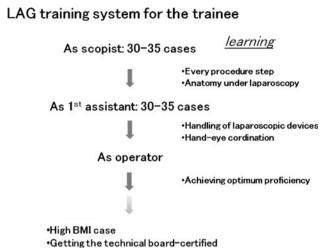
## The trainee and training system

Over 5 years, 16 residents were assigned as trainees for 6 months to 3 years in our department. The surgical outcomes of 9 trainees who had performed more than 5 LAG procedures were compared with the surgical outcomes of the two trainers. These 9 trainees had 7–13 years experience as surgeons after graduation and had performed 20–50 cases of conventional open gastrectomy and 10–30 laparoscopic cholecystectomies.

Our training system focused on understanding the laparoscopy-specific anatomy for gastrectomy under laparoscopy and the standardization of LAG procedures, including the role of scopist and assistant (Fig. 1). The trainees participated in LAG procedures as scopist and assistant in 30–35 cases for each role, and then performed their first case of LAG as an operator. As a first step, each trainee could learn every point of the procedure and the precise anatomy under laparoscopy-specific view as a scopist. As a second step, the trainee would learn handling of laparoscopic devices and develop hand–eye coordination as an assistant. Finally, in the third step for becoming a mature assistant, the trainee could acquire the skills for making a field of development under laparoscopy.

## Clinical analysis

In our training system the learning curve of the trainees was compared based on surgical outcomes of the two trainers and nine trainees. The ratio of the operation case by the trainee was also examined for the ongoing



**Fig. 1** Laparoscopic gastrectomy (LAG) training system in our institute. Our training system focuses on understanding the laparoscopy-specific anatomy for gastrectomy under laparoscopy and standardization of the LAG procedure, including the role of scopist and assistant. The trainees participated in LAG both as scopist and as assistant in 30–35 cases for each role, and then performed their first case of LAG as an operator. As a first step, trainees could learn every procedural step and the precise anatomy under laparoscopy-specific view as a scopist, and as a second step, they could learn handling of laparoscopic devices and develop hand–eye coordination working as an assistant

development of our training system. The following clinical data were obtained from medical records: patient gender, age, body mass index, preoperative complications, and clinical staging of disease. Operative findings, such as type of surgical procedure, operative time, and estimated blood loss, were also recorded. To assess the postoperative clinical course, postoperative complications more than grade III in the Clavien-Dindo classification [16] and length of postoperative hospital stay were recorded. The learning curve of the trainee in operation time was also shown on the basis of the outcome of the trainers. Data were presented as means  $\pm$  standard error (SE). An unpaired t test was used to test the equality between the two means of variables. Fisher's exact test or the  $\chi^2$  test was used to test the independence between the groups. A value of P < 0.050 was considered statistically significant.

# Results

Ratio of the operator cases of LAG by the trainees

The number of patients who underwent LAG in our institute has increased gradually since the introduction of this procedure (Fig. 2). Of 788 LAG cases, 563 (71.4 %) were performed by two trainers, and the numbers experienced by trainees has gradually increased year by year from 4 cases

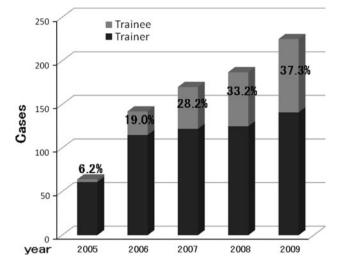


Fig. 2 The number of patients who underwent LAG in our institute gradually increased from the introduction of this procedure. Of 788 LAG cases, 563 (71.4 %) were performed by two trainers, and the numbers of cases performed by trainees has increased gradually year by year

per year (6.2 %) to 84 cases per year (37.3 %) over the past 5 years.

# Patient characteristics

Over the observation period, the nine trainees performed 215 LAG (27.3 %) and the two trainers conducted 563 LAG (71.4 %) (Table 1). Except sex distribution between the groups, there was no significant difference in patient characteristics, including age, body mass index, preoperative co-morbidity, history of laparotomy, and clinical staging.

# Surgical outcomes

The trainees performed significantly more cases of LAPPG over the 5-year period of this study (Table 2). The surgical outcomes, including operative time, blood loss, and retrieval of lymph nodes, were almost equivalent between trainer- and trainee-conducted groups. The postoperative courses were not also significantly different. There was no mortality in the present study.

## Learning curve of the trainees

The total numbers of procedures experienced by the nine trainees as scopist and as first assistant over the study period were 45.0 and 41.4 cases, respectively (Table 3), with 23.9 cases (range: 6–64 cases) performed as LAG operator. The trainees had experienced 33.8 cases as a scopist and 35.3 cases as an assistant before they performed their first case of LAG as an operator. After commencing

| <b>Table 1</b> The differences, by trainer and by trainee, of characteristics in patients who underwent laparoscopic gastrecton | Table 1 | The differences, h | by trainer and b | y trainee, of | f characteristics in | patients who underwent | laparoscopic gastrectom |
|---|---------|--------------------|------------------|---------------|----------------------|------------------------|-------------------------|
|---|---------|--------------------|------------------|---------------|----------------------|------------------------|-------------------------|

|  | By trainer                | By trainee <sup>a</sup>  | P value |
|--|---------------------------|--------------------------|---------|
| Number of cases                        | 563 (71.4 %)              | 215 (27.3 %)             | -       |
| Gender (male/female)                   | 368 (65.4 %)/195 (34.6 %) | 120 (55.8 %)/95 (44.2 %) | 0.017   |
| Age, years                             | $62.2 \pm 0.7$            | $61.6 \pm 0.4$           | 0.546   |
| Body mass index, kg/m <sup>2</sup>     | $22.2 \pm 0.1$            | $22.5 \pm 0.3$           | 0.696   |
| Preoperative co-morbidity <sup>b</sup> | 39 (6.9 %)                | 16 (7.4 %)               | 0.950   |
| History of laparotomy                  | 163 (29.0 %)              | 55 (25.6 %)              | 0.397   |
| Clinical staging                       |                           |                          |         |
| IA                                     | 563 (100 %)               | 215 (100 %)              | -       |
| IB                                     | 0 (0.0 %)                 | 0 (0.0 %)                |         |

Data are presented as mean  $\pm$  SE. An unpaired *t* test was used to test the equality between the 2 means of variables. Fisher's exact test or the  $\chi^2$  test was used to test the independence between the two groups. A value of *P* = 0.050 was considered statistically significant

Body mass index = body weight/height<sup>2</sup> (kg/m<sup>2</sup>)

<sup>a</sup> Trainees who have performed more than 5 cases of laparoscopic gastrectomy

<sup>b</sup> Including respiratory dysfunction, renal dysfunction, ischemic heart disease, liver cirrhoses, and diabetes mellitus

| Table 2 | The differences. | by trainer and by | v trainee, of surgical | outcomes in patients | s who underwent l | aparoscopic gastrectomy |
|---------|------------------|-------------------|------------------------|----------------------|-------------------|-------------------------|
|         |                  |                   |                        |                      |                   |                         |

|                             | By trainer   | By trainee <sup>a</sup> | P value |  |
|-----------------------------|--|-------------------------|---------|--|
| Number of cases             | 563 (71.4 %)   | 215 (27.3 %)            | _       |  |
| Surgical procedure          |  |                         | < 0.001 |  |
| LADG (B-I/RY)               | G (B-I/RY)       383 (68.0 %) [293 (52.0 %)/90 (16.0 %)], 108 (50.2 %) [86 (40.0 %)/22 (10.2 %)] |                         |         |  |
| LAPPG                       | 180 (32.0 %)   | 107 (49.8 %)            |         |  |
| Extension of lymph node dis | section  |                         |         |  |
| D1β/D2                      | 555/8  | 215/0                   | 0.079   |  |
| Surgical outcomes           |  |                         |         |  |
| Operative time              | $230.5 \pm 2.2$  | $229.4 \pm 4.8$         | 0.516   |  |
| Blood loss                  | $60.4 \pm 4.4$   | $64.2 \pm 12.6$         | 0.764   |  |
| Open conversion             | 6 (1.1 %)  | 1 (0.5 %)               | 0.712   |  |
| Retrieval lymph nodes       | $35.9 \pm 0.5$   | $34.9 \pm 0.6$          | 0.504   |  |
| Morbidity <sup>b</sup>      | 29 (5.2 %)   | 14 (6.5 %)              | 0.571   |  |
| Hospital stay, days         | $14.2\pm0.4$   | $13.4 \pm 0.4$          | 0.301   |  |

Data are presented as means  $\pm$  SE. An unpaired *t* test was used to test the equality between the two means of variables. Fisher's exact test or the  $\chi^2$  test was used to test the independence between the two groups. A value of P = 0.050 was considered statistically significant

<sup>a</sup> Trainees who have performed more than 5 cases of laparoscopic gastrectomy

<sup>b</sup> More than grade 3 in the Clavien-Dindo classification

B-I Billroth-I, RY Roux-en-Y

**Table 3** The number of experiences as scopist, as 1st assistant, and as operator by trainee during the learning curve period

|               | Total cases   | Cases to the initial operator <sup>a</sup> |
|---------------|---------------|--|
| Scopist       | $45.0\pm6.7$  | 33.8 ± 6.4                                 |
| 1st assistant | $41.4\pm7.8$  | $35.3 \pm 6.2$                             |
| Operator      | $23.9\pm 6.0$ | 0  |

Data are presented as means  $\pm$  SE

<sup>a</sup> Trainees who have performed more than five cases of laparoscopic gastrectomy

<sup>b</sup> Numbers of scopist and assistant experiences before begining as 1st operator

on the operator role, the average operative time of the trainees reached that of the trainers within 6 cases, and the learning curve reached a plateau at the trainers' average level (Fig. 3).

## Discussion

The LAG procedure is widely performed for early gastric cancer in Japan and Korea [2–5]. Many surgeons plan to conduct LAG as routine surgery; however, the procedure is technically complicated with many difficult steps to master,

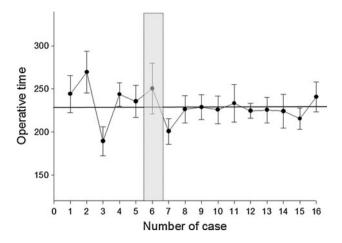


Fig. 3 The learning curve of the trainees. After starting experience as an operator, the average operative time of the trainees reached that of the trainers after 6 cases, and the learning curve reached a plateau at the level of the trainers' average

and each institution thus performs only a limited number of cases each year. Moreover, previous reports showed that surgeons who had performed 40–60 LAG procedures were more likely to have satisfactory outcomes than lesser-trained surgeons, and consequently, trainees were not the subject of the studies [6–9]. It is therefore difficult for young surgeons to start learning the procedure to develop their skills and improve the average learning curve.

The present large-scale study was therefore focused mainly on the trainees, using a training system based on gaining a complete understanding of the whole LAG procedure from the role of both scopist and assistant to accelerate progress along the learning curve. Consequently, with an average of 34 cases as scopist and 35 as assistant, only 6 cases as operator were required for the trainees, who all had substantial conventional basic surgical skills, to achieve optimum proficiency. However, a limitation of the present study was that the surgical outcome of LAG performed by the trainee was only assessed in the presence of experienced surgeons, who were assisting. In fact, in our institute trainees are not permitted to perform surgical procedures without the participation of a staff surgeon. Thus the surgical outcomes in the present study could all have been greatly influenced by the experienced assistance available.

In general, the LAG procedure is not commonly performed nowadays, and the frequency in community hospitals and in the majority of the institutions was only 0.5–2 cases per month [17]. Because of the limited numbers of cases for trainees, a shorter learning curve would be preferable, using a system by which optimal proficiency and surgical outcomes could be achieved quickly with little morbidity. We previously reported that standardizing the LAG procedure for assistants enabled a shorter operative time, reduced blood loss, and led to more accurate lymph node dissection through creating a good field of vision and thus better surgical outcomes [10]. Meanwhile, the trainee could easily 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. Finally, to fully develop proficiency, the trainee could acquire the skill to make a field of development under laparoscopy. The trainees also studied each step of the procedure in every case by recorded movies of the actual operation immediately after completing the surgery.

Although the results can instantly and objectively demonstrate performance in training for basic skills (e.g., using virtual simulators) [18], effectiveness in training for advanced surgery is difficult to measure directly. A learning curve is considered complete when the monitored parameters reach a steady state, and the final results can be compared with published parameters [19]. Most published studies on learning curves for laparoscopic surgery concentrate on operative time, blood loss, the conversion rate to open surgery, major morbidity, and mortality as parameters of operator performance [6-8, 20-22]. The present study included the results of LAG performed by the trainer and the trainee in limited surroundings, and showed that LAG is safe and feasible, has a low conversion rate, and provides favorable short-term outcomes compared with published reports [23-26]. It was difficult to achieve the learning curve in operative time even after 60 LAG procedures, compared with open conventional gastrectomy [8], making this a suitable monitored parameter in learning LAG with acceptable short-term surgical outcomes [7].

Regarding the oncological safety of LAG procedures, because of the length of follow-up, this study did not provide enough data to allow definitive conclusions. The results show that both trainer and trainee could eradicate a sufficient number of lymph nodes, compared with previous studies [8, 9, 24]. This might support the possibility that oncological safety can be maintained for early gastric cancer patients, at least in the short term, in the course of LAG training.

The influence of patient selection on the learning curve should also be evaluated. Hyung et al. suggest that surgeons with limited LAG experience should consider patient and tumor characteristics, such as gender and body mass index, to minimize the effects of patient selection on the learning curve [27]. In the present study, the female patients and the procedure of LAPPG were of higher significance in the trainee group. All conversion cases to open gastrectomy that occurred in the early period of LAG surgical experience were reported in male patients with a relatively large volume of visceral fat [25, 26]. Although there were no definite selection criteria for the patients of

the trainees in our institute, careful patient selection might be one important factor for a successful initial experience with complex LAG procedures.

The senior trainee, who had achieved the optimum learning curve in the training system, even performed LAG on males with relative high BMI. However, laparoscopic total gastrectomy and proximal gastrectomy are considered highly difficult procedures in Japan, and consequently are generally performed only by a LAG specialist. In addition, staff surgeons performed laparoscopic total gastrectomy or proximal gastrectomy in our institute. Trainees in these procedures would therefore need to attain technical board certification by the Japan Society for Endoscopic Surgery as a supervisor of LAG, after acceptance by video examination by two inspectors with 50 % as the passing rate. In the video examination, the LAG procedures, including use of laparoscopic devices, creation of field of view, and performance of lymph node dissection, were evaluated by the point deduction scoring system in detail. To date, 6 of the 9 trainees have already passed the examination, and have joined the leadership of laparoscopic surgical divisions in the community or in the center hospital.

### Conclusions

In conclusion, our training system based on attaining adequate experience as both assistant and scopist was effective in ensuring clinical safety for LAG performed by a trainee with the assistance of experienced surgeons. The standardization and the complete simulation of each step in the LAG procedure through participating in the operation as both assistant and scopist were essential factors in the success of this training system.

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