



Impact of the Endoscopic Surgical Skill Qualification System on the safety of laparoscopic gastrectomy for gastric cancer

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Abstract

Background We hypothesized that the Endoscopic Surgical Skill Qualification System (ESSQS) can shorten operative time, resulting in a decrease in postoperative morbidity. Here, we aimed to clarify whether ESSQS-qualified surgeons could decrease the incidence of complications.

Methods Between January 2009 and June 2019, 1042 patients diagnosed with both clinical and pathological Stage \leq III gastric cancer and undergoing LG were enrolled. In all LG procedures involving ESSQS-qualified surgeons, these served as the operator or the instructive assistant. The short-term outcomes were retrospectively compared between the ESSQS-qualified and the non-ESSQS-qualified surgeons using a propensity-score matched analysis.

Results After propensity-score matching, 321 patients were included in each group. No significant differences were observed in morbidity rate, and length of hospitalization following surgery, although the non-ESSQS-qualified surgeon group had a significantly longer total operative time (Non-ESSQS-qualified group, 368 [170–779] min vs. ESSQS-qualified group, 316 [147–772] min; $p < 0.001$), and larger estimated blood loss (Non-ESSQS-qualified group, 28 [0–702] mL vs. ESSQS-qualified group 25, [0–1069] mL; $p = 0.042$). Multivariate analysis revealed that operative time ≥ 360 min (OR 1.818 [1.069–3.094], $p = 0.027$) was identified as the only significant independent risk factor determining morbidity.

Conclusions The incidence of postoperative morbidity did not differ between patients operated by the qualified and nonqualified surgeons, as long as ESSQS-qualified surgeons provide intraoperative instructions.

Keywords Stomach neoplasms · Gastrectomy · Minimally invasive surgical procedures · Postoperative complications · Education · Endoscopic Surgical Skill Qualification System

Recently, laparoscopic gastrectomy (LG) has gained popularity, especially for early gastric cancer (GC), being minimally invasive and non-inferior to open gastrectomy (OG) with regard to both short- and long-term outcomes [1–6]. However, the disadvantages of LG compared with OG may include prolongation of operative time and a longer learning curve [7, 8]. Furthermore, several recent studies using

the nationwide web-based database in Japan revealed that LG resulted in higher postoperative local complications compared with OG [9–11]. These findings suggest that LG is a technically demanding procedure, and there may be a considerable technical gap between expert and nonexpert surgeons.

With a view to developing a tool for reliable and reproducible evaluation of the surgical techniques of surgeons, the Endoscopic Surgical Skill Qualification System (ESSQS) was launched in 2004 by the Japanese Society for Endoscopic Surgery (JSES) [12], and it has contributed to the improvement and standardization of LG [12, 13]. With the maturation of this system, ESSQS-qualified surgeons are regarded as highly skilled surgeons. However, it remains unknown how the difference in surgical skill might influence on operative time. In addition, it remains unclear whether

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prolongation of the operative time by trainee operators increases the incidence of complications.

Since we demonstrated the comparability of laparoscopic D2 gastrectomy and open D2 gastrectomy with regard to short- and long-term outcomes [14, 15], minimally invasive surgery has been the standard radical procedure for GC at our institute [16]. In addition, recent studies have demonstrated that prolongation of operative time is an independent risk factor for postoperative morbidity [17, 18]. Hence, we hypothesized that ESSQS-qualified surgeons, regarded as skillful surgeons, may be able to shorten the operative time, leading to a decrease of postoperative morbidity. The aim of this study was to clarify whether qualified surgeons could decrease the incidence of complications.

Materials and methods

Patients

Between January 2009 and June 2019, 1716 consecutive patients were referred to our division with primary GC, for which surgical treatment was applicable. Informed consent was obtained from all patients. In the present study, 1,042 patients with both clinical and pathological Stage \leq III GC were enrolled, whereas the remaining 674 patients were excluded because of clinical or pathological Stage IV GC ($n=166$), remnant GC ($n=53$), double cancer ($n=20$), OG ($n=25$), robotic gastrectomy ($n=359$), or palliative or limited lymphadenectomy ($n=51$) due to insufficient physical function. The patient selection process is summarized in Fig. 1. Clinical tumor staging was determined according to the 15th edition of the Japanese Classification of Gastric Carcinoma [19]. Cancer staging was performed based on the findings of contrast-enhanced computed tomography,

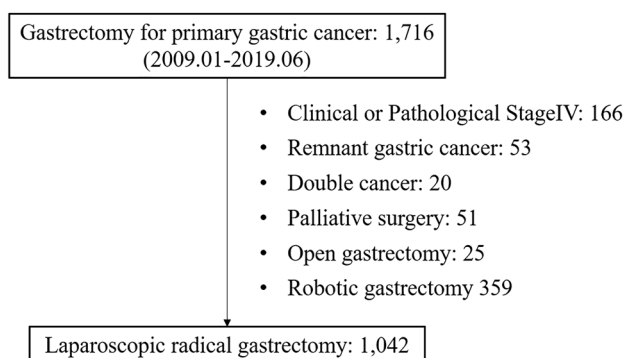


Fig. 1 Flow diagram of the study selection process

gastrography, endoscopy, and endosonography before the beginning of any treatment and when applicable, after the completion of chemotherapy, as previously described [18, 20]. The extent of systematic lymph node (LN) dissection was performed based on the Japanese Gastric Cancer Treatment Guidelines 2018 [21]. Detailed indications for radical gastrectomy, assessment of physical function, operative procedures, perioperative management in radical gastrectomy, extent of gastric resection and LN dissection, type of anastomosis, diagnosis and treatment for pancreatic fistula, and postoperative chemotherapy in addition to oncologic follow-up have previously been reported [14–18, 20, 22–24]. This study was approved by the institutional review board of the Fujita Health University.

Surgical operator selection

In all LG procedures, the ESSQS-qualified surgeons were involved as either the operator or the instructive assistant. When a non-ESSQS-qualified surgeon performed LG, an ESSQS-qualified surgeon, as an assistant surgeon, made his/her best effort to help the operating surgeons safely complete LG. In our institute, the surgeons' skill level and experience vary greatly with regard to OG, LG, and other laparoscopic surgeries, and not all are ESSQS-qualified. Although a uniform or systematic educational program was not established at the initiation of the study, the criteria for selection of surgical operator were determined according to our basic policy, including the following: First step was to learn the surgical procedures by benefiting from the experience of the first assistant or the scope operator in the first year. Second step was to perform laparoscopic distal gastrectomy (LDG) with D1+ dissection in the second year. Third step was to perform LDG with D2 dissection or laparoscopic total gastrectomy (LTG) with D1+ dissection in the third year. Fourth step was to perform LTG with D2 dissection procedures in the fourth year and onwards. The expert gastric surgeon (I.U.), who had performed more than 1500 LG procedures, finally identified the operating surgeon and the assistant surgeons for each patient, supervising all LG procedures. To monitor the operative quality, we had video conferences once a week for every operation using edited surgical videos. Furthermore, surgeons had the opportunity to review full surgical videos for any selected operation once a week.

Measurements

All patients were observed for 30 days following surgery. The clinicopathological characteristics and short-term surgical outcomes, including operative time, surgeon console

time, estimated blood loss, the number of dissected lymph nodes, total morbidity rate, mortality rate, and length of postoperative hospitalization were evaluated as secondary endpoints. All postoperative complications were classified in accordance with the Japan Clinical Oncology Group Postoperative Complication Criteria [25]. The primary endpoint of this single-center retrospective analysis was morbidity (Clavien–Dindo [CD] Grade \geq IIIa) [26]. Total operative time was defined as the time from the beginning of the abdominal incision until the end of complete wound closure. Blood loss was estimated by weighing suctioned blood and gauze pieces with absorbed blood. Intra-abdominal infectious complications included anastomotic leakage, pancreatic fistula, and intraperitoneal abscess. An expert surgeon was defined as a surgeon with an experience of 100 or more LG with D2 dissection. Except three expert surgeons (I.U., S.K., and S.S.), the number of experienced LG cases by each operating surgeon was counted from his/her initial case at our institution, irrespective of the prior LG experience before he/she joined our institution.

Propensity-score matched analysis

Propensity-score matched (PSM) analysis was used to limit confounders and overcome possible patient selection bias. Propensity scores for all patients were calculated using a logistic regression model based on the following variables: age, gender, body mass index (BMI), American Society of Anesthesiologist (ASA) grade, presence of neoadjuvant chemotherapy, history of laparotomy, cT, cN, cStage, pT, pN, pStage, type of gastrectomy, and extent of LN dissection. Consequently, rigorous adjustment for significant differences in the baseline characteristics of patients with propensity-score matching using nearest-neighbor matching without replacement with a caliper width of 0.2 of the standard deviation of the logit of the propensity score was performed. We used the absolute standardized difference (SD) to measure covariate balance, in which an absolute standardized mean difference >0.1 reflected a meaningful imbalance [18].

Statistical analysis

All analyses were performed using IBM SPSS Statistics 23 (IBM Corporation, Armonk, NY, USA). Between-group comparisons were examined by the χ^2 test or the Mann–Whitney *U* test. Univariate χ^2 test and multivariate logistic regression analysis were used to determine the factors contributing to the occurrence of postoperative complications. Data were expressed as medians [range] or odds ratio (OR) [95% confidence interval] unless otherwise noted. A probability (*p*) value <0.05 (two-tailed) was considered statistically significant.

Results

Baseline data on patients receiving LG by non-ESSQS-qualified and ESSQS-qualified surgeons overall and by PSM analysis

In total, 33 surgeons participated in this study. Eight surgeons, including I.U., had already been ESSQS-accredited before the study, 11 surgeons had newly acquired ESSQS qualification, and 14 surgeons remained non-ESSQS-qualified surgeons. The length of surgeon experience was significantly shorter among the non-ESSQS-qualified surgeons than among the qualified surgeons (non-ESSQS-qualified, 11 years [3–27] vs. ESSQS-qualified, 15 years [7–34], $p < 0.001$). The patient characteristics of each cohort are summarized in Table 1. Across the entire cohort, no differences were observed in terms of age, gender, BMI, ASA score, and history of laparotomy between the nonqualified and qualified group; however, significant differences were found in tumor size, cT, cN, cStage, pT, pN, pStage, preoperative chemotherapy, type of resection, extent of lymphadenectomy, and splenectomy. Factors having an SD >0.1 included tumor size, cT, cN, cStage, pT, pN, pStage, use of preoperative chemotherapy, type of resection, extent of lymphadenectomy, and splenectomy (Table 1). To compensate for such differences, PSM analysis was used. The average and standard deviation of the propensity score were 0.543 and 0.200, respectively, thus yielding a caliper width of 0.04 for this study. After propensity-score matching, 321 patients were included in each group. Propensity-score distributions for each case before and after matching are presented in Fig. 2. After matching, the SD for age, gender, BMI, ASA classification, history of laparotomy, tumor size, cT, cN, cStage, pT, pN, pStage, presence of neoadjuvant chemotherapy, type of resection, extent of LN dissection, and splenectomy decreased to <0.10 , indicating that a sufficient balance was achieved (Table 1).

The surgical outcomes of LG by ESSQS-qualified and non-ESSQS-qualified surgeons overall and by PSM analysis

All procedures were completed by each operating surgeon without any severe intraoperative adverse events in this series. The surgical outcomes and short-term postoperative courses of the entire cohort and the PSM cohort are summarized in Table 2. Before PSM, patients operated by non-ESSQS-qualified surgeons had significantly less estimated blood loss and a significantly shorter duration of hospitalization following surgery compared with the

Table 1 Data on patient backgrounds and surgical outcomes of laparoscopic gastrectomy carried out by non-ESSQS-qualified and ESSQS-qualified surgeons

| | Non-ESSQS-qualified (n = 476) | ESSQS-qualified (n = 566) | p-value | ASD | Non-ESSQS-qualified (n = 321) | ESSQS-qualified (n = 321) | p-value | ASD |
|--|----------------------------------|------------------------------|---------|------|----------------------------------|------------------------------|---------|------|
| No. of operators | 25 | 19 | | | 24 | 19 | | |
| Surgeon's experiences (year) | 11 [3–27] | 15 [7–34] | <0.001 | | 11 [3–27] | 15 [7–34] | <0.001 | |
| Age in years | 70 [31–90] | 69 [24–93] | 0.535 | 0.01 | 70 [31–90] | 69 [28–93] | 0.721 | 0.01 |
| Gender (M:F) | 335:141 | 405:161 | 0.681 | 0.02 | 226:95 | 223:98 | 0.863 | 0.02 |
| Body mass index (kg/ m ²) | 22.1 [15.4–33.9] | 22.2 [14.5–37.3] | 0.616 | 0.02 | 22.2 [15.4–33.9] | 22.3 [14.5–37.3] | 0.805 | 0.02 |
| ASA grade (1:2:3) | 157:260:59 | 183:305:78 | 0.805 | 0.01 | 101:178:42 | 107:174:40 | 0.883 | 0.03 |
| History of laparotomy, n (%) | 86 (18.1) | 111 (19.6) | 0.578 | 0.04 | 57 (17.8) | 69 (21.5) | 0.274 | 0.09 |
| Tumor size in mm | 30 [0–180] | 37 [0–150] | <0.001 | 0.31 | 30 [0–180] | 30 [0–150] | 0.245 | 0.06 |
| cT (1:2:3:4) | 320:70:58:28 | 233:119:110:104 | <0.001 | 0.54 | 180:60:53:28 | 183:55:49:34 | 0.803 | 0.02 |
| cN (–: +) | 419:57 | 387:179 | <0.001 | 0.49 | 264:57 | 255:66 | 0.422 | 0.07 |
| cStage (I:II:III) | 375:59:42 | 315:109:142 | <0.001 | 0.52 | 225:54:42 | 220:53:48 | 0.813 | 0.03 |
| pT (1:2:3:4) | 317:59:49:51 | 270:69:83:144 | <0.001 | 0.39 | 196:36:39:50 | 193:42:41:45 | 0.846 | 0.02 |
| pN (0:1:2:3) | 356:48:43:29 | 344:79:70:73 | <0.001 | 0.30 | 224:35:35:27 | 221:40:33:27 | 0.941 | 0.02 |
| pStage (I:II:III) | 337:81:58 | 298:119:149 | <0.001 | 0.38 | 204:62:55 | 209:56:56 | 0.836 | 0.03 |
| Use of preoperative chemotherapy, n (%) | 21 (4.4) | 80 (14.1) | <0.001 | 0.34 | 21 (6.5) | 23 (7.2) | 0.876 | 0.02 |
| Type of resection (DG:PG:TG) | 392:12:72 | 351:35:180 | <0.001 | 0.47 | 237:12:72 | 234:16:71 | 0.774 | 0.02 |
| Extent of lymphad- enectomy (D1+:D2) | 341:135 | 248:318 | <0.001 | 0.59 | 187:134 | 191:130 | 0.810 | 0.03 |
| Splenectomy, n (%) | 6 (1.3) | 28 (4.9) | 0.001 | 0.21 | 6 (1.9) | 6 (1.9) | 1.000 | 0 |

Data are shown as median with range

JCGC Japanese Classification of Gastric Carcinoma, 15th edition, ASD absolute standardized differences, ASA American Society of Anesthesiologist, DG distal gastrectomy, PG proximal gastrectomy, TG total gastrectomy, LNs lymph nodes

patients operated by the ESSQS-qualified surgeon group, although having a lower number of dissected LNs. No significant differences were observed in total operative time, conversion to open procedure, reoperation rate, morbidity rate, intra-abdominal infectious complications rate, or in-hospital mortality (Table 2). After PSM, the non-ESSQS-qualified surgeon group had a significantly longer total operative time (non-ESSQS-qualified group, 368 [170–779] min vs. ESSQS-qualified group, 316 [147–772] min; $p < 0.001$) and a significantly larger estimated blood loss (non-ESSQS-qualified group, 28 [0–702] mL vs. ESSQS-qualified group, 25 [0–1069] mL; $p = 0.042$). No significant differences were observed in the number of dissected LNs, conversion to open procedure, reoperation rate, morbidity rate, intra-abdominal infectious complications rate, the length of hospital stay following surgery, or in-hospital mortality (Table 2).

Postoperative complications

Postoperative complications are summarized in Table 3. Briefly, across the entire cohort, no significant differences were observed in the incidence of total morbidity, intra-abdominal infectious complications, other local complications, and systemic complications. After propensity-score matching, results similar to those for the entire cohort were obtained (Table 3).

Relationship between surgeon experience, the ESSQS qualified rate and morbidity rate as well as operative time

We investigated whether the overall experience and ESSQS qualification of the surgeons influenced on the incidence of postoperative complications in the entire

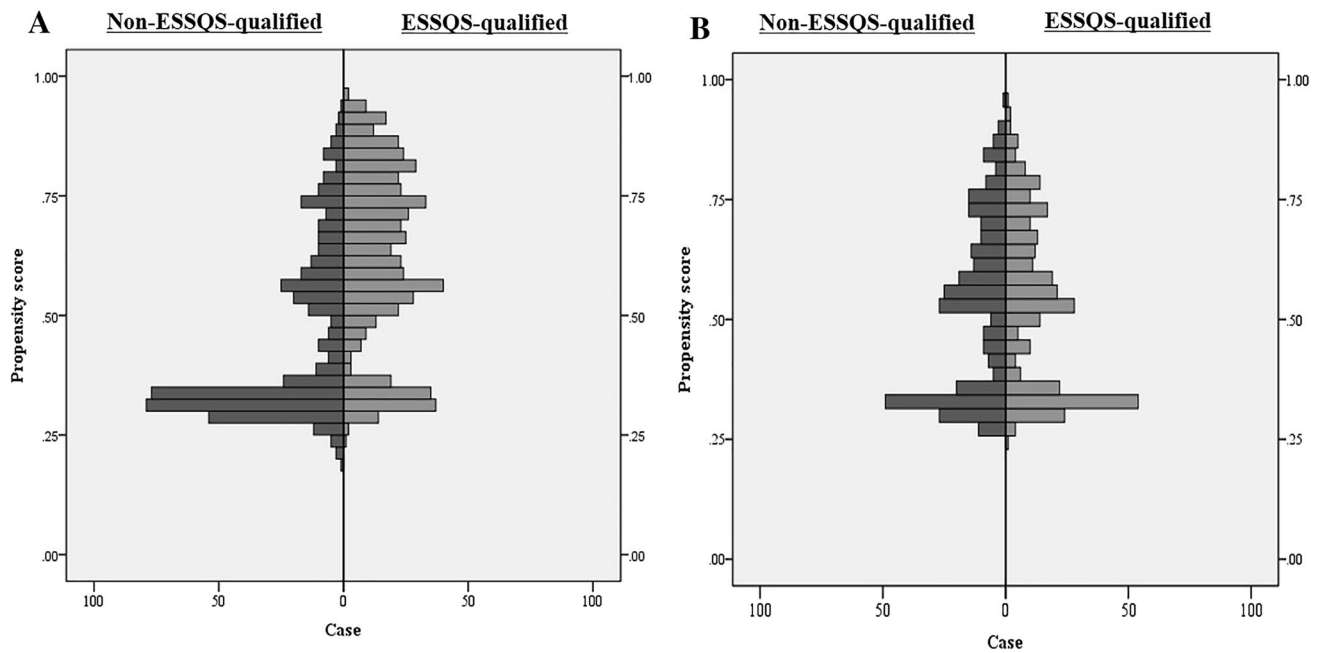


Fig. 2 Mirrored histogram of propensity scores. **A** Before and **B** after matching, showing the distributions of Non-ESSQS-qualified surgeons (black-bar) and ESSQS-qualified surgeons (gray-bar)

Table 2 Surgical outcomes of laparoscopic gastrectomy by non-ESSQS-qualified and ESSQS-qualified surgeons

| | Non-ESSQS-qualified (<i>n</i> = 476) | ESSQS-qualified (<i>n</i> = 566) | <i>p</i> -value | Non-ESSQS-qualified (<i>n</i> = 321) | ESSQS-qualified (<i>n</i> = 321) | <i>p</i> -value |
|--|--|--------------------------------------|-----------------|--|--------------------------------------|-----------------|
| Total operative time (min) | 348 [170–779] | 339 [147–937] | 0.141 | 368 [170–779] | 316 [147–772] | <0.001 |
| Estimated blood loss (mL) | 25 [0–831] | 30 [0–2150] | 0.029 | 28 [0–702] | 25 [0–1069] | 0.042 |
| No. of dissected LNs | 34 [8–109] | 36 [6–114] | 0.002 | 35 [8–109] | 35 [10–114] | 0.166 |
| Conversion to open procedure, <i>n</i> (%) | 0 (0) | 1 (0.2) | 1.000 | 0 (0) | 1 (0.3) | 1.000 |
| Reoperation rate, <i>n</i> (%) | 3 (0.6) | 8 (1.4) | 0.243 | 2 (0.6) | 3 (0.9) | 1.000 |
| Morbidity, <i>n</i> (%) | 39 (8.2) | 53 (9.4) | 0.507 | 27 (8.4) | 23 (7.2) | 0.659 |
| Intra-abdominal infectious complications, <i>n</i> (%) | 31 (6.5) | 35 (6.2) | 0.828 | 19 (5.9) | 13 (4.0) | 0.365 |
| Hospital stay following surgery (days) | 13 [7–144] | 14 [3–177] | 0.005 | 13 [7–144] | 13 [6–177] | 0.354 |
| In-hospital mortality, <i>n</i> (%) | 1 (0.2) | 1 (0.2) | 1.000 | 1 (0.3) | 0 (0) | 1.000 |

Data are shown as median with range

LNs lymph nodes

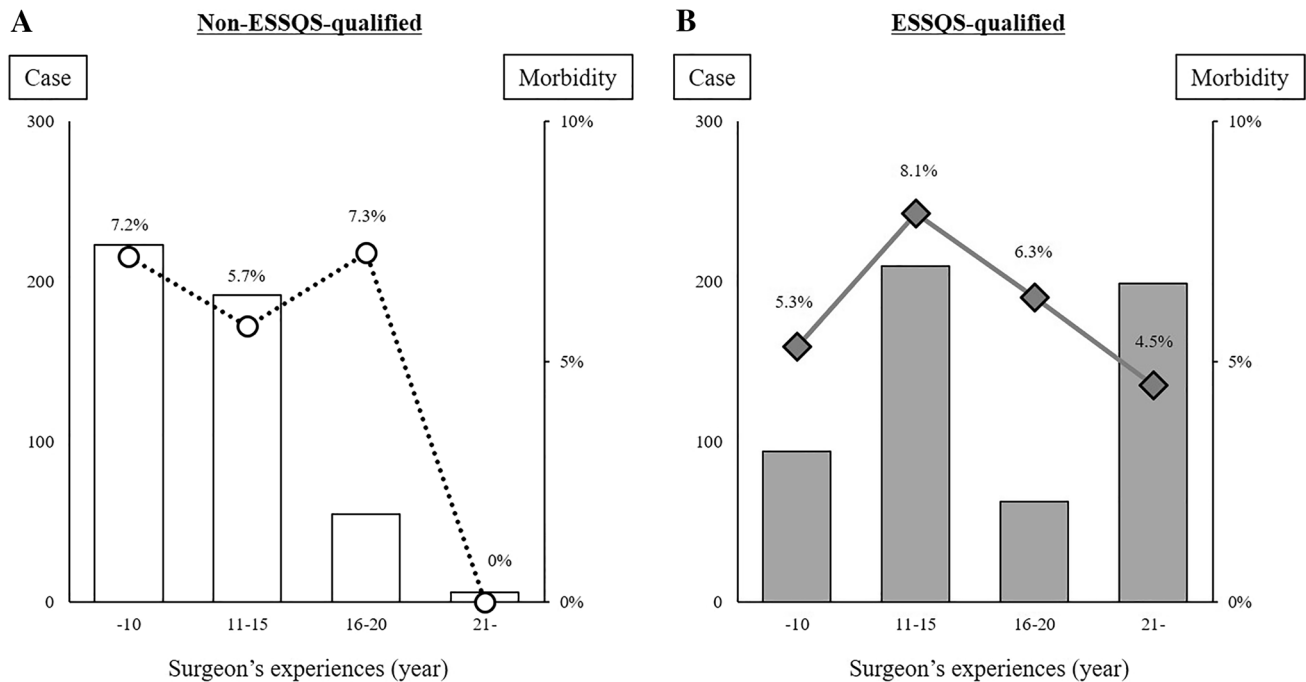
cohort. No obvious relationship was observed between the incidence of complications and the number of years of surgeon experience for both non-ESSQS-qualified and ESSQS-qualified surgeons (Fig. 3). In addition, there were no significant differences in the incidence of complications between the non-ESSQS-qualified surgeons, nonexpert ESSQS-qualified surgeons, and expert ESSQS-qualified surgeons (Fig. 4). Next, the entire cohort was divided into the following three groups based on each operating surgeon's number of LG experience irrespective of the

presence of the ESSQS qualification: each operating surgeon's case 1–20 (Case 1–20), 21–50 (Case 21–50), and 51– (Case 51–). Then, case volume stratified by the type of LG procedure (LDG D1+, LDG D2, and LPG/LTG) in each group was shown as a bar graph (Fig. 5). In addition, the proportion of the patients whom the ESSQS-qualified surgeons operated, as well as operative time and morbidity stratified by the type of LG procedure in each group were also demonstrated (Fig. 5A, B). Consequently, as the number of experienced LGs increased, the proportion

Table 3 Overall and propensity score-matched (PSM) analysis of postoperative complications observed in patients receiving laparoscopic gastrectomy (LG) performed by non-ESSQS-qualified and ESSQS-qualified surgeons, respectively

| | Overall analysis | | | Propensity score-matched analysis | | |
|---------------------------|--|--------------------------------------|-----------------|--|--------------------------------------|-----------------|
| | Non-ESSQS-qualified (<i>n</i> = 476) | ESSQS-qualified (<i>n</i> = 566) | <i>p</i> -value | Non-ESSQS-qualified (<i>n</i> = 321) | ESSQS-qualified (<i>n</i> = 321) | <i>p</i> -value |
| Morbidity | 39 (8.2) | 53 (9.4) | 0.514 | 27 (8.4) | 23 (7.2) | 0.659 |
| Intraabdominal infection | 31 (6.5) | 35 (6.2) | 0.899 | 19 (5.9) | 13 (4.0) | 0.365 |
| Anastomotic leakage | 11 (2.3) | 11 (1.9) | 0.829 | 6 (1.9) | 3 (0.9) | 0.505 |
| Pancreatic fistula | 11 (2.3) | 17 (3.0) | 0.566 | 6 (1.9) | 6 (1.9) | 1.000 |
| Intraperitoneal abscess | 9 (1.9) | 7 (1.2) | 0.453 | 7 (2.2) | 4 (1.2) | 0.545 |
| Other local complications | 4 (0.8) | 10 (1.8) | 0.306 | 4 (1.2) | 7 (2.2) | 0.543 |
| Intraabdominal bleeding | 1 (0.2) | 3 (0.5) | 0.630 | 1 (0.3) | 1 (0.3) | 1.000 |
| Bowel obstruction | 3 (0.6) | 4 (0.7) | 1.000 | 3 (0.9) | 3 (0.9) | 1.000 |
| Anastomotic stenosis | 0 (0) | 3 (0.5) | 0.255 | 0 (0) | 3 (0.9) | 0.249 |
| Systemic complications | 4 (0.8) | 11 (1.9) | 0.219 | 4 (1.2) | 5 (1.6) | 1.000 |
| Pneumonia | 2 (0.4) | 7 (1.2) | 0.192 | 2 (0.6) | 3 (0.9) | 1.000 |
| Renal dysfunction | 0 (0) | 1 (0.2) | 1.000 | 0 (0) | 1 (0.3) | 1.000 |
| Cardiovascular disease | 2 (0.4) | 3 (0.5) | 1.000 | 2 (0.6) | 1 (0.3) | 1.000 |

Data are shown as *n* (%). The χ^2 test was used for between-group comparisons

**Fig. 3** The relationship between surgeon's experience and postoperative morbidity in the entire cohort. For both non-ESSQS-qualified surgeons (A) and ESSQS-qualified surgeons (B), surgeon experience was not significantly associated with morbidity

of ESSQS-qualified surgeons significantly increased ($p < 0.001$), and operative time significantly decreased in each procedure (total: $p < 0.001$, LDG-D1+: $p < 0.001$, LDG-D2: $p < 0.001$, LPG/LTG: $p = 0.008$, Fig. 5a). However, morbidity did not significantly change between the

groups, even in each procedure (Fig. 5b). Regarding procedure type, over 50% in Case 1–20 consisted of LDG D1+, however, in Case 21–50 and Case 51-, the proportions of more complicated procedures including LDG with D2 dissection and LPG/LTG increased (Fig. 5a, b).

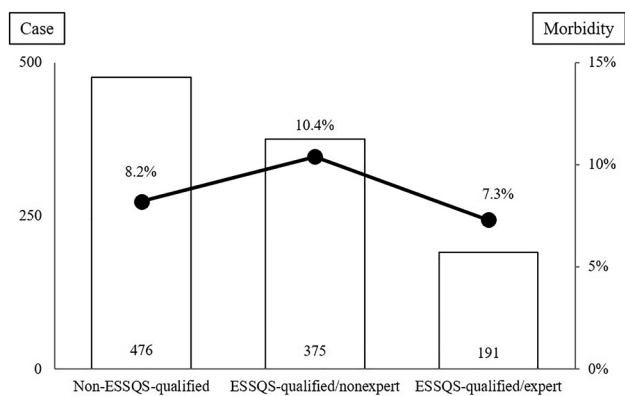


Fig. 4 Incidence of postoperative morbidity according to qualification and expert level of the surgeons in the entire cohort (non-ESSQS-qualified vs. ESSQS-qualified/nonexpert vs. ESSQS-qualified/expert). There were not significantly different in morbidity between these three groups

Factors determining postoperative morbidity after LG in the entire cohort

To identify the factors determining postoperative CD-grade IIIa or higher complications of LG in the entire cohort, univariate and multivariate analyses were performed. Univariate analyses revealed six significant determinants, including male, cStage II or higher, proximal or total gastrectomy, splenectomy, operative time ≥ 360 min, and estimated blood loss ≥ 50 mL (Table 4). Multivariate analyses demonstrated that only operative time ≥ 360 min (OR 1.818 [1.069–3.094], $p=0.027$) was identified as an independent risk factors for morbidity (Table 4).

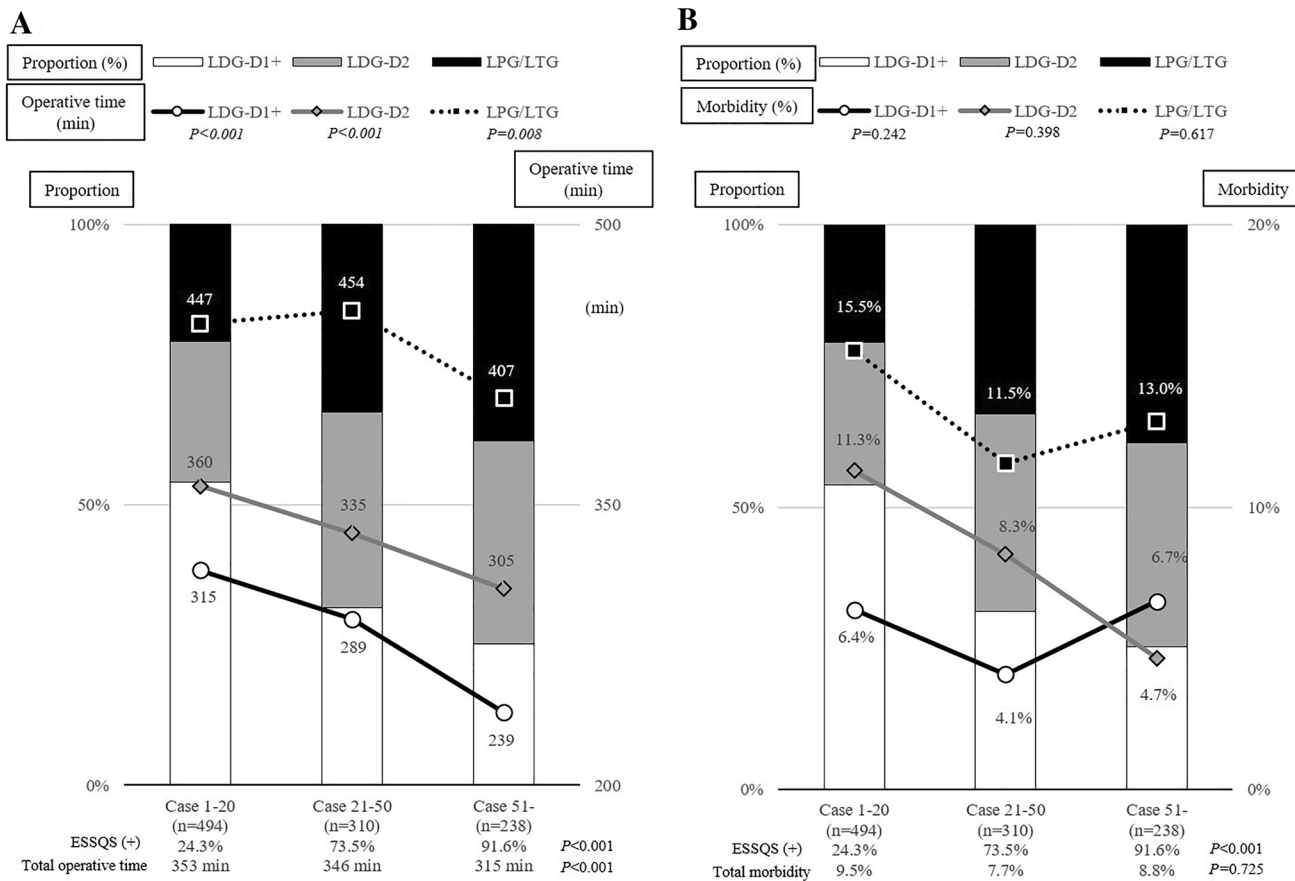


Fig. 5 The relationship between each operating surgeon’s number of LG experienced in our institution, the ESSQS qualified rate, and morbidity rate (A) as well as operative time (B). Case volume stratified

by the type of LG procedure (LDG D1+, LDG D2, and LPG/LTG) in each group was shown as a bar graph

Table 4 Risk factors for postoperative morbidity in the entire cohort ($n = 1042$)

| Factors | Univariate analysis OR (95% CI) | <i>p</i> -value | Multivariate analysis OR (95% CI) | <i>p</i> -value |
|---|------------------------------------|-----------------|--------------------------------------|-----------------|
| Initial 10 cases by each operator | 1.041 (0.668–1.621) | 0.911 | | |
| Operator's experience (≤ 12 year) | 1.034 (0.700–1.528) | 0.913 | | |
| Non-ESSQS-qualified surgeon | 1.158 (0.751–1.784) | 0.514 | | |
| Non-expert (< 100 cases of D2) | 1.276 (0.706–2.306) | 0.482 | | |
| Age ≥ 70 years | 1.099 (0.744–1.625) | 0.663 | | |
| Male | 1.939 (1.150–3.268) | 0.011 | 1.694 (0.958–3.003) | 0.070 |
| Body mass index ≥ 23 kg/m ² | 1.185 (0.769–1.825) | 0.503 | | |
| ASA score ≥ 2 | 1.049 (0.695–1.585) | 0.907 | | |
| History of laparotomy | 1.029 (0.622–1.701) | 1.000 | | |
| cStage-II ^a or higher | 1.734 (1.126–2.671) | 0.015 | 1.334 (0.837–2.129) | 0.226 |
| pStage-II ^a or higher | 1.482 (0.965–2.278) | 0.074 | | |
| Proximal or total gastrectomy | 2.052 (1.327–3.175) | 0.001 | 1.654 (0.658–4.157) | 0.284 |
| D2 dissection | 1.334 (0.869–2.048) | 0.188 | | |
| Splenectomy | 2.815 (1.191–6.656) | 0.025 | 1.419 (0.552–3.645) | 0.467 |
| Operative time ≥ 360 min | 2.601 (1.662–4.070) | < 0.001 | 1.818 (1.069–3.094) | 0.027 |
| Estimated blood loss ≥ 50 mL | 2.035 (1.322–3.134) | 0.001 | 1.279 (0.788–2.077) | 0.320 |
| Use of neoadjuvant chemotherapy | 1.298 (0.667–2.526) | 0.459 | | |

Data are shown as odds ratio (95% confidence interval). The χ^2 test was used for univariate analysis. Multivariate logistic regression analysis was used for factors with *p* value < 0.05 by univariate analysis

ASA American Society of Anesthesiologist

^aJCGC Japanese Classification of Gastric Carcinoma, 15th edition

Table 5 Risk factors for postoperative morbidity in the PSM cohort ($n = 642$)

| Factors | Univariate analysis OR (95% CI) | <i>p</i> -value | Multivariate analysis OR (95% CI) | <i>p</i> -value |
|---|------------------------------------|-----------------|--------------------------------------|-----------------|
| Initial 10 cases by each operator | 1.130 (0.619–2.059) | 0.763 | | |
| Operator's experience (≤ 12 year) | 1.344 (0.776–2.329) | 0.304 | | |
| Non-ESSQS-qualified surgeon | 1.174 (0.688–2.003) | 0.659 | | |
| Non-expert (< 100 cases of D2) | 1.080 (1.413–2.761) | 1.000 | | |
| Age ≥ 70 years | 1.218 (0.712–2.084) | 0.556 | | |
| Male | 1.719 (0.878–3.367) | 0.111 | | |
| Body mass index ≥ 23 kg/m ² | 1.210 (0.694–2.109) | 0.551 | | |
| ASA score ≥ 2 | 1.174 (0.675–2.041) | 0.637 | | |
| History of laparotomy | 1.489 (0.766–2.894) | 0.265 | | |
| cStage-II ^a or higher | 1.872 (1.042–3.363) | 0.038 | 1.357 (0.728–2.528) | 0.336 |
| pStage-II ^a or higher | 1.076 (0.613–1.889) | 0.878 | | |
| Proximal or total gastrectomy | 1.774 (0.974–3.233) | 0.067 | | |
| D2 dissection | 1.354 (0.759–2.415) | 0.369 | | |
| Splenectomy | 2.425 (0.517–11.385) | 0.238 | | |
| Operative time ≥ 360 min | 3.052 (1.648–5.653) | < 0.001 | 2.206 (1.076–4.521) | 0.031 |
| Estimated blood loss ≥ 50 mL | 2.536 (1.414–4.546) | 0.002 | 1.583 (0.827–3.033) | 0.166 |
| Use of neoadjuvant chemotherapy | 1.988 (0.797–4.959) | 0.142 | | |

Data are shown as odds ratio (95% confidence interval). The χ^2 test was used for univariate analysis. Multivariate logistic regression analysis was used for factors with *p* value < 0.05 by univariate analysis

ASA American Society of Anesthesiologist

^aJCGC Japanese Classification of Gastric Carcinoma, 15th edition

Factors determining postoperative morbidity after LG in the PSM cohort

We also investigated the risk factors for postoperative complications of LG in the PSM cohort by uni- and multivariate analyses. Univariate analyses revealed three significant determinants, including cStage II or higher, operative time ≥ 360 min, and estimated blood loss ≥ 50 mL (Table 5). Multivariate analyses demonstrated that only operative time ≥ 360 min (OR 2.206 [1.076–4.521], $p=0.031$) was identified as an independent risk factors for morbidity (Table 5).

Discussion

In this retrospective single-center study, the incidence of postoperative complications did not differ according to the presence and absence of ESSQS qualification both before and after PSM analysis. In addition, the surgeons' experience—both in terms of years and cases—were not significantly associated with an increased incidence of complications. Moreover, multivariate analysis showed that being operated by a non-ESSQS-qualified surgeon was not an independent risk factor for postoperative complications. Therefore, these findings provided evidence that the non-ESSQS-qualified surgeons performed LG safely, without increasing the incidence of postoperative morbidity, in contrast to our hypothesis that ESSQS-qualified surgeons may decrease postoperative morbidity. This result is in line with previous studies showing that the incidence of postoperative morbidity did not differ between highly qualified and less qualified surgeons [27–30]. An important similarity between these studies and our study was that the non-ESSQS-qualified surgeons operated under the guidance of the ESSQS-qualified surgeons. Therefore, it appears that the qualified surgeons could successfully remedy any immature surgical skills of the nonqualified surgeons by providing intraoperative instructions, including advice on the prevention of severe postoperative complications. These findings suggest that the ESSQS is relevant both for improving the skills of the operator, but also for securing better supervision, since ESSQS-qualified surgeons are used as instructive assistants during LG. In the future, we hope that further maturation of the ESSQS will help the trainees overcome the learning curve of LG, which involves at least 40–60 cases [31–34].

With regard to the comparison of the complication rates between the qualified and nonqualified surgeons, all surgeons involved in the operations could understand and carry out the various common surgical concepts and technical principles including outermost layer-oriented LN dissection and intracorporeal anastomosis, which are performed safely and reproducibly in our institute as

previously reported [16, 17, 22, 35–37]; this is achieved via the sufficient experiences of the first assistant, a scope operator, and regular video conferences. Similarly, some previous studies have also reported that the trainees could efficiently achieve a plateau of the operative time in LG and perform LG without significantly increasing the incidence of morbidity after sufficient experience as an assistant and a scope operator or through the systematic education system [27–30]. Therefore, we believe that the operative quality might rely more on sharing the common surgical concepts and technical principles within the surgical team than on the individual operator's skills per se.

Another important finding is that the total operative time in the group of ESSQS-qualified surgeons was significantly shorter than that of the non-ESSQS-qualified surgeons group after compensating for patient demographics, tumor characteristics, and surgical procedure by PSM analysis. In addition, as the number of experienced LGs increased, the proportion of ESSQS-qualified surgeons increased, and operative time decreased in each procedure. These findings suggest that the presence of ESSQS qualification is positively associated with experienced LG cases and the proficiency of LG procedure. Several previous studies also have successfully demonstrated that highly qualified surgeons perform LG in a significantly shorter operative time than the less qualified surgeons [27–29]. Our data strengthen the evidence that ESSQS-qualified surgeons have superior skills of LG compared with non-ESSQS-qualified surgeons. Accordingly, our strategy wherein the ESSQS-qualified surgeons are deemed sufficiently skillful and always involved as the instructive assistant when non-ESSQS-qualified surgeons perform LG seems quite reasonable.

On the other hand, the multivariate analyses of this study showed that only operative time ≥ 360 min was identified as an independent risk factor for postoperative morbidity in both the entire cohort and the PSM cohort, confirming observations from our previous studies [17, 18]. This finding also agreed with previous reports observing that prolongation of the operative time leads to an increased risk of postoperative morbidity [38–40]. Nevertheless, shortening of the operative time by ESSQS-qualified surgeons did not result in a reduced incidence of postoperative morbidity. This might be explained by the possibility that the ESSQS-qualified surgeons performed LG for more patients with large tumor and more advanced disease, who received preoperative chemotherapy, D2 dissection, total or proximal gastrectomy, and splenectomy in this study. Hence, since ESSQS-qualified surgeons were possibly more likely to perform LG requiring these technically demanding procedures, the morbidity risk might thereby be balanced out. In addition, many of these technically demanding procedures were excluded by the PSM analysis. Therefore, postoperative

morbidity risk associated with the qualification of the operating surgeon might have been underestimated in this study. In addition, because we could not identify the factor most associated with an increased incidence of complications among the factors protracting the operative time, further investigation is necessary to clarify the association between protracted operative time and increase of the complications.

In comparison with those previous reports [27–30], our study has strengths in the following three points: First, this study included a lot more operating surgeons (a total of 33 surgeons) and the ESSQS-qualified surgeons (a total of 19 surgeons), whereas the previous studies included only a couple of the trainers or the ESSQS-qualified surgeons. The outcomes of our study are likely to be more reproducible in regard to the impact of ESSQS-qualified surgeons. Second, this study included more complicated procedures including LPG, LTG, and LG after neoadjuvant therapy, whereas the previous studies focused only on LDG. Therefore, our study has determined the impact of ESSQS-qualified surgeons in more advanced setting. Third, apart from the previous studies, this study used propensity score matched analysis to control for confounding. Therefore, we believe our study has determined the impact of ESSQS-qualified surgeons in more reproducible fashion in more advanced setting using more statistically reliable manner.

There were a couple of limitations to the present study. First, this study was analyzed based on a single-center, retrospective, and nonrandomized design. Therefore, several sources of patient bias, especially patient selection bias, could not be excluded, despite compensating for differences in preoperative patients characteristics by propensity-score matching. Further studies including prospective non-inferiority trials are warranted to provide sufficient evidence to accept or refute our hypothesis. Second, our study was limited by operators' bias. Because we were not able to obtain the number of LGs which each operating surgeon conducted before he/she joined our institution from our database, association between the lifetime total number of LGs of each operating surgeon and his/her skills was not determined in this study. In addition, detailed information on the instructive assistants was not available for analysis, while the operators' experience was investigated. Therefore, a detailed analysis of the influence of the joint experience of the operator and the instructive assistant on operative time and postoperative morbidity could not be carried out. As already mentioned, several technically demanding procedures performed by the ESSQS-qualified surgeons were excluded in the PSM analysis in this study. Therefore, the relative contribution of the ESSQS-qualified surgeons to safely performed LG for patients requiring technically demanding procedures should be clarified. Third, the oncological safety could not be investigated in this study because long-term surveillance is still

in development. Due to the small differences in morbidity rate between patients operated by the ESSQS-qualified and non-ESSQS-qualified surgeons, respectively, the long-term oncological outcomes might be expected to be equivalent, if the dissected area was evenly kept between the two groups. Further investigation is warranted to determine the oncological safety of this procedure.

In conclusion, ESSQS qualification might contribute to shortening the operative time of LG. In contrast, the incidence of postoperative morbidity appears not to differ between the ESSQS-qualified and non-ESSQS-qualified surgeons, as long as ESSQS-qualified surgeons provide intra-operative instructions.

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Compliance with ethical standards

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