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ORIGINAL ARTICLE

Safe implementation of robotic distal gastrectomy performed by non–endoscopic surgical skill qualification system-qualified surgeons

Yusuke Umeki[1] · Susumu Shibasaki[1] · Masaya Nakauchi[2] · Akiko Serizawa[1] · Kenichi Nakamura[1] · Shingo Akimoto[1] · Tsuyoshi Tanaka[3] · Kazuki Inaba[2] · Ichiro Uyama[2,3] · Koichi Suda[1,4]

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Abstract

Purpose Robotic gastrectomy (RG) for gastric cancer (GC) was approved for national medical insurance coverage in April, 2018, since when its use has increased dramatically throughout Japan. However, the safety of RG performed by surgeons who are not Endoscopic Surgical Skill Qualification System (ESSQS)-qualified has yet to be established. We conducted this study to verify the short-term outcomes of the initial series of RG procedures performed by non-ESSQS-qualified surgeons.

Methods Between January, 2020 and December, 2021, 30 patients with clinical Stage I and II GC underwent RG performed by four non-ESSQS-qualified surgeons according to the Japan Society for Endoscopic Surgery guideline. We evaluated, retrospectively, the morbidity rates according to Clavien–Dindo (CD) classification grade II or higher.

Results Each operating surgeon completed all procedures without any serious intraoperative adverse events. The median operative time, console time, and estimated blood loss were 413 (308–547) min, 361 (264–482) min, and 25.5 (4–167) mL, respectively. No patient required conversion to laparoscopic or open surgery. Three (10%) patients suffered CD grade II complications postoperatively. The median postoperative hospitalization was 11 (8–51) days.

Conclusion Non-ESSQS-qualified surgeons trained by expert RG surgeons could perform robotic distal gastrectomy safely for initial cases.

Keywords Gastrectomy · Robotic surgical procedure · Minimally invasive procedures

Introduction

The da Vinci Surgical System (DVSS; Intuitive Surgical, Sunnyvale, USA), a novel and promising advanced robotic technology, was developed to overcome laparoscopic surgery limitations, including the restricted range of motion with straight forceps use and hand tremors. Its unique advantages enable surgeons to perform safer, more precise, and more reproducible procedures in a confined surgical field with impressive dexterity [1–3]. In recent years, robotic gastrectomy (RG) using the DVSS has gained increasing popularity worldwide as a more minimally invasive surgical technique for gastric cancer (GC) than laparoscopic gastrectomy (LG) [4]. In Japan, the number of RG procedures has increased dramatically since April, 2018, when RG was approved for national medical insurance coverage.

The Japan Society for Endoscopic Surgery (JSES) has proposed a guideline to prevent severe intraoperative and postoperative complications of robotic surgery, including

✉ Susumu Shibasaki
susumushi48@mist.ocn.ne.jp

1 Department of Surgery, Fujita Health University, 1-98 Dengakugakubo, Kutsukake, Toyoake, Aichi 470-1192, Japan

2 Department of Advanced Robotic and Endoscopic Surgery, Fujita Health University, 1-98 Dengakugakubo, Kutsukake, Toyoake, Aichi 470-1192, Japan

3 Collaborative Laboratory for Research and Development in Advanced Surgical Technology, Fujita Health University, 1-98 Dengakugakubo, Kutsukake, Toyoake, Aichi 470-1192, Japan

4 Collaborative Laboratory for Research and Development in Advanced Surgical Intelligence, Fujita Health University, 1-98 Dengakugakubo, Kutsukake, Toyoake, Aichi 470-1192, Japan

RG, performed by operating surgeons who are unfamiliar with robotic surgery and to introduce robotic surgery to inexperienced institutions safely [5]. Surgeons practicing robotic surgery comply with the Endoscopic Surgical Skill Qualification System (ESSQS) as a criterion for safe performance. In this unique system, which was launched by the JSES in 2004, two judges separately assess the surgeon's skill using an unedited operative video in a double-blinded fashion, according to strict criteria [6]. We described the system in detail in a previous report [6]. Therefore, ESSQS-qualified surgeons are considered highly skillful in Japan, and have contributed greatly to the safe implementation of RG [7]. In March, 2020, these guidelines were revised for further widespread dissemination of robotic surgery. Accordingly, when non-EESQS-qualified surgeons have assisted in ≥ 20 robotic surgeries and can perform robotic surgery under the guidance of a certified proctor, the ESSQS qualification may be excluded from the essential criteria [5]. However, the safety of robotic surgery performed by non-ESSQS-qualified surgeons needs to be established.

We launched RG in 2009 in our institution after having accumulating collective experience of performing LG. Since then, we have established standardized methodologies of radical RG for GC [6]. Thus, we could demonstrate its promising short-term outcomes, focusing on reducing local complications [2, 8] and superior long-term oncological outcomes compared with those of LG [9]. We now recognize RG as the first insured treatment option for GC. To facilitate the efficient learning and acquisition of RG procedures by several second-generation operating surgeons, we developed a systematic training program after a multi-institutional prospective study was conducted in Japan (Senshiniryo-B) [6]. Moreover, in accordance with the JSES guideline revision about robotic surgery, we have extended the operating surgeon criterion of RG to non-ESSQS surgeons, limited to robotic distal gastrectomy (RDG). In this retrospective study, we aimed to confirm the short-term outcomes of the initial series of RDGs performed by non-ESSQS-qualified operating surgeons trained through our program.

Materials and methods

Patients

Between January, 2020 and December, 2021, 255 patients underwent RG for diagnosed GC at our institute. The RG was performed by four non-ESSQS-qualified surgeons (K.I., A.G., Y.U., and Y.T.) in 30 of these patients, who were enrolled in our study. Cancer staging, based on the Japanese Classification of Gastric Carcinoma (15th edition) [10], was performed according to the findings of contrast-enhanced computed tomography, gastrography, endoscopic study, and endosonography before the initiation of any treatment and, when applicable, after chemotherapy completion, as described previously [8]. The indication for endoscopic treatment and radical gastrectomy, including the extent of systematic lymph node (LN) dissection, was determined according to the 2018 Japanese Gastric Cancer Treatment Guidelines [10]. All RDG procedures were performed using the DVSS-Xi, in line with our standardized procedure based on common surgical concepts and technical principles, including the double bipolar method, outermost layer-oriented nodal dissection, and intracorporeal anastomosis, as described previously [2, 3, 5, 11, 12]. The indications for physical function assessment, perioperative radical gastrectomy management, gastric resection and LN dissection extent, and anastomosis type, in addition to oncological follow-up, were based on previous reports [2, 8]. The Institutional Review Board of Fujita Health University approved this study.

Criteria for non-ESSQS-qualified operating surgeons

According to the new JSES guidelines, the criteria for a non-ESSQS-qualified surgeon to operate RG are as follows: [1] The surgeon must be certified to operate a DVSS console of Intuitive Surgical Inc.; [2] they must be certified by the Japanese Society of Gastroenterological Surgery, and [3] they must have performed ≥ 50 RG procedures as an assistant surgeon of four expert RG surgeons with experience of > 50 RG and 100 LG procedures (S.S., K.N., I.U., and K.S.). Before the first RG, all non-ESSQS-qualified operating surgeons had undergone adequate training, comprised of four steps for robotic surgery, according to our educational program to completely utilize the characteristics of the robotic system [6]. Briefly, Step 1 consisted of acquiring certification to operate a DVSS console of Intuitive Surgical Inc. using the DVSS simulator (SimNow™) followed by advanced training for RG using a porcine model; Step 2 comprised bipolar cutting dissection training and anastomotic training for delta-shaped Billroth I anastomosis; Step 3 focused on subclinical RG training using the synthetic training model for gastrectomy; and Step 4 comprised cadaver surgical training using Thiel-embalmed human cadavers. Moreover, the surgical team discussed common surgical concepts and technical principles, and the quality of every operation was assessed at a weekly video conference, as described previously [6, 13]. I.U. finally evaluated the operating surgeons, considering their skill levels and the patients' condition, and supervised all RG procedures. The non-ESSQS-qualified surgeons performed all RG processes using a dual-console system, which allows the expert surgeon to sit at the console simultaneously with the operating surgeon. The proctor stayed primarily to advise on technical tips, demonstrate model manipulations, and help make key anatomies in the operative field

easy to recognize by real-time point-by-point instructions. The non-ESSQS-qualified surgeons performed RDG-D1 + in patients with relatively favorable physical and oncological conditions, including early GC and a low body mass index. After performing five cases of RDG-D1 +, these surgeons could perform RDG-D2 for T1N + or a small tumor (< 3 cm) in patients with T2/T3N0 GC and a BMI of < 22 kg/m^2.

Retrospective video review

To evaluate the reproducibility of these procedures, three expert ESSQS-qualified surgeons (S.S., I.U., and K.S.), who had performed ≥ 50 RG procedures, reviewed the nonedited videos of all cases, retrospectively. The following parameters were also investigated: the success rate for appropriately identifying and tracing the outermost layer; the success rate for anatomically adequate lymphadenectomy, defined by the Japanese Gastric Cancer Association [10]; and the success rate for reconstruction by intracorporeal anastomosis using linear staplers, according to our previously described principles [12].

Measurements

All patients were assessed for 30 days postoperatively. The primary outcome was the morbidity rate. The secondary outcomes were short-term surgical outcomes, such as operative time, surgeon console time, estimated blood loss, dissected LN proportion, complication rate, mortality rate, and postoperative hospitalization duration. All postoperative complications of grade II or more were recorded according to the Clavien–Dindo (CD) classifications [14] and categorized according to the Japan Clinical Oncology Group Postoperative Complications Criteria based on CD classification version 2.0 [15]. The total operative time was the duration from the abdominal incision to complete closure of the wound. The surgeon console time was the duration of DVSS during the surgery, excluding the time to extract the resected specimen from the umbilical incision and redocking for the reconstruction. Blood loss was estimated by weighing the suctioned blood and blood-absorbed gauze.

Statistical analysis

All analyses were conducted using IBM SPSS Statistics 27 (IBM Corporation, Armonk, NY, USA). Data are expressed as median values (range) unless otherwise specified.

Results

Backgrounds of the non-ESSQS-qualified surgeons

All the non-ESSQS-qualified surgeons had performed > 20 LG procedures before performing their first RDG procedure. Those who were enrolled in this study underwent training using SimNow™ for > 20 h and then acquired certification as a DVSS console surgeon certified by Intuitive Surgical Inc. They also undertook Step 2 training at least three times, and Step and Step 4 training at least once under the guidance of a JSES-certified proctor [5] before attempting the first RDG.

Clinicopathological features and surgical outcomes in the entire study

Table 1 summarizes the backgrounds and tumor characteristics of the 30 patients, 17 of whom were men. The median

Table 1 Background characteristics and surgical outcomes of the patients

Clinicopathological characteristics		Surgical outcomes	
Age (years)	66 (41–85)	No. of operators	4
Gender (M:F)	17:13	Extent of lymphadenectomy (D1 + :D2)	24:6
Body mass index (kg/m^2)	21.1 (16.9–30.2)	Total operative time (min)	413 (308–547)
ASA grade (1:2:3)	10:20:0	Console time (min)	361 (264–482)
History of laparotomy, *n* (%)	5 (16.7)	Estimated blood loss (mL)	25.5 (4–167)
Tumor size (mm)	22 (0–45)	No. of dissected LNs	33.5 (17–102)
cT[a] (1:2:3:4a)	22:6:2:0	No. of metastatic LNs	0 (0–5)
cN[a] (− : +)	29:1	Conversion to open procedure, n (%)	0 (0)
cStage[a] (I:II:III)	27:3:0	In-hospital mortality, n (%)	0 (0)
pT[a] (1:2:3:4a)	21:3:3:3	Morbidity (CD grade II), n (%)	3 (10)
pN[a] (0:1:2:3)	23:5:2:0	Morbidity (CD grade ≤ IIIa), n (%)	0 (0)
pStage[a] (I:II:III)	24:3:3	Hospital stay following surgery (days)	11 (8–51)

Data are presented as median with range unless otherwise specified

ASA American society of anesthesiologists, *LNs* lymph nodes, *CD* Clavien-Dindo classification

[a]Japanese Classification of Gastric Carcinoma, 15th edition

age was 66 (41–85) years, and the body mass index was 21.1 (16.9–30.2) kg/m^2. The American Society of Anesthesiologists score was 1 in 10 patients and 2 in the 20 remaining patients. The clinical tumor stages were I and II in 27 and 3 patients, respectively. Table 1 also shows the surgical and short-term outcomes. Twenty-four patients underwent D1 + dissection and 6 patients underwent D2 dissection. The median operative time and console time were 413 (308–547) and 361 (264–482) min, respectively. The estimated blood loss was 25.5 (4–167) mL. Each operating surgeon completed all procedures without inflicting any serious intraoperative injury requiring intervention by the proctor. No steps in the procedure required the proctor to take over from the non-ESSQS surgeon. None of the patients required conversion to laparoscopic or open surgery. Postoperatively, three (10%) patients suffered complications of CD grade II, two suffered delayed gastric emptying, and one suffered pneumonia. The delayed gastric emptying improved after nasogastric tube placement and the pneumonia was diagnosed using computed tomography and resolved with a few days of antibiotic therapy. There was no mortality or morbidity associated with CD grade III or higher. The median duration of postoperative hospitalization was 11 (8–51) days. All patients were discharged within 2 weeks after surgery, except for one of the patients with delayed gastric emptying who required hospitalization for 51 days postoperatively. R0 resection was completed successfully in all patients. When comparing the first 16 cases (n = 16) with the second 14 cases performed by each of the four surgeons, the operative time and console time were significantly shorter in the second group of cases than in the first group of cases (total operative time: 447 (372–547) vs. 402 (308–498), $p = 0.043$; console time: 395 (311–482) vs. 330.5 (264–406), $p = 0.013$).

Assessment of reproducibility via *retrospective video review*

The success rate for identifying and tracing the outermost layer of autonomic nerves was 100%. In both infrapyloric and suprapancreatic nodal dissections, the anatomical landmarks used to precisely identify the outermost layer matched the area of the LN station according to the Japanese Gastric Cancer Association [10].

Discussion

With the rapid increase in the number of RGs being performed, large-scale retrospective studies conducted by propensity score matching analysis have demonstrated a significantly lower incidence of postoperative complications after RG than after LG [8, 16]. Several recent prospective studies and randomized control trials have also demonstrated the potential of RG to reduce the morbidity associated with LG [17–20], as indicated by a 1.1%–5.3% morbidity rate of CD grade IIIa or higher. Conversely, a recent large-scale study conducted using the Japanese National Clinical Database found comparable short-term outcomes of RG and LG performed by ESSQS-qualified surgeons [7]. However, the safety of RG performed by nonexpert surgeons remains unclear. In the current study, we evaluated the competency of four non-ESSQS-qualified surgeons certified by the Japanese Society of Gastroenterological Surgery, who had already performed > 50 RG procedures as assistant surgeons during surgeries lead by specialist surgeons. All four non-ESSQS-qualified surgeons completed RG successfully on all 30 patients, with 10% CD grade II morbidity and no incidence of CD grade IIIa or higher. Furthermore, according to retrospective video reviews by experts, the operative quality of dissection and reconstruction based on our standardized procedure were satisfactory. Although our study was limited to RDG, this finding was not inferior to that of previous studies or of our initial series of RG performed by second-generation surgeons on a study population, with 3% and 0% morbidity rates of CD grade II and IIIa, respectively (Supplementary Table) [6]. Therefore, despite the single-center, small-scale retrospective study design, the current study may contribute to demonstrating the safety of RG performed by non-ESSQS-qualified surgeons. These successful findings are attributable to three factors:

First, before performing their first RG, all our non-ESSQS-qualified surgeons had assisted > 50 RG procedures by specialist surgeons. Although the JSES guideline indicates that experience of assisting at least 20 RG procedures is sufficient to become a console surgeon, our four non-ESSQS surgeons had assisted more than 50 RGs before satisfying the qualification to perform RG as a console surgeon in this study. Such extensive experience might have helped them understand the basic technical principles of the robotic setup and dissection, including the double bipolar method, da Vinci's plane theory, monitor quadrisection theory, and the dissection procedure along the outermost layer [2, 3], before performing their initial RG as a console surgeon. This speculation supports the latest revision of the 2020 JSES guideline in which ESSQS qualification is not essential when surgeons have assisted ≥ 20 robotic surgeries and can perform robotic surgery under the guidance of a certified proctor [5]. Second, regular video conferences accelerated the trainees' learning of the RG procedure through active learning, including self-editing and presenting their surgical video. The video conferences also contributed to the safe introduction of RG performed by the non-ESSQS-qualified surgeons, as well as by the ESSQS-qualified surgeons, as reported previously [6]. Third, the non-ESSQS-qualified surgeons underwent comprehensive off-the-job training based on our systematic DVSS training course before their first RG

case; thus, they had overcome the unique complexities of using the DVSS, like the ESSQS-qualified surgeons in our previous study [6]. Previous studies also demonstrated significantly improved performance of participating surgeons after attending fundamental skill training on robotic surgery [21, 22]. These trainings are essential tools even for inexperienced RG operating surgeons, including non-ESSQS-qualified surgeons and beginner surgeons, to enable them to gain fundamental skills on robotic surgery quickly.

Our evidence shows that factors such as extensive RG experience as an assistant surgeon, video conferencing, and adequate systematic off-the-job training are important for non-ESSQS-qualified surgeons, as well as ESSQS-qualified surgeons, for effective learning on how to perform RG [6]. In Japan, the ESSQS qualification is most important as an indicator of proficiency level. In fact, in line with the safe introduction of RG, an early learning plateau has been achieved by specialist LG surgeons, even in countries without ESSQS [4]. Accordingly, mastering the comprehensive knowledge and skills required for LG by gaining extensive clinical experience will direct the safe implementation of RG. However, the operative time of RG in this study was long, at approximately 7 h. Although this finding is similar to that of the 10 initial cases of RDG performed by ESSQS-qualified surgeons (Supplementary Table) [6], it is still a significant disadvantage and must be improved. A prolonged operative time is significantly associated not only with increased risk of postoperative morbidity [23–25], but also of poor cost-effectiveness and a high burden on medical staff. Hence, further development of an efficient training system is necessary to reduce the operative time.

The present study has several limitations. First, its retrospective, single-center, and nonrandomized design may have introduced data biases. In particular, the effect of selection bias may not be negligible, considering that more patients with favorable conditions may have been selected whereas those requiring technically demanding procedures may have been avoided during enrollment. Second, because the surgeons had experience of performing ≥ 20 LG procedures, we could not clarify whether the safety observed in this study could be extrapolated to RG procedures conducted by a beginner surgeon. Furthermore, it is possible that none of the enrolled surgeons achieved a learning plateau during this study because of the small sample size of patients; therefore, the learning curve of the enrolled surgeons could not be investigated. Accumulating more cases is necessary. Third, given that long-term surveillance is in progress, the oncological outcomes in our study remain inconclusive. Further investigation is warranted to confirm the oncological safety of RG performed by nonexpert surgeons. Fourth, social, institutional, and ethical restrictions to receiving subclinical RG training and cadaver surgical training, which are more common in other countries than in Japan, are also limitations. The hospital volume is also a limitation as few centers perform a high number of RGs in Japan. Therefore, the opportunity to experience many cases of RG as an assistant surgeon in low-volume centers is limited. To address these limitations, we have projected in progress a novel system that provides remote surgical education and remote observation of robotic surgery, as described previously [5]. Establishing this remote system could play a central role in standardizing advanced robotic surgery training for young surgeons in the near future.

In conclusion, non-ESSQS-qualified surgeons who were trained sufficiently by specialist RG surgeons performed their initial cases of RDG safely.

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Author contributions All authors have met the ICMJE authorship criteria as follows: Study design: YU, SS, IU, and KS; Data collection: YU, SS, MN, AS, KN and TT; Statistical analysis and interpretation of results: YU, SS, MN, SA, KI, and KS; Drafting of the manuscript: YU, SS, and KS; Critical revision of the manuscript for important intellectual content: SS, IU, and KS. All authors read and approved the final manuscript. All authors are accountable for ensuring that questions related to the accuracy or integrity of every part of the study were appropriately investigated and resolved.

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Data availability The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Conflict of interest Yusuke Umeki, Susumu Shibasaki, Masaya Nakauchi, Akiko Serizawa, Kenichi Nakamura, Shingo Akimoto, Tsuyoshi Tanaka, Kazuki Inaba, Ichiro Uyama, and Koichi Suda have no commercial association with or financial involvement that might be construed as a conflict of interest in connection with the submitted article. Ichiro Uyama has received lecture fees from Intuitive Surgical, Inc., outside of the submitted work. Tsuyoshi Tanaka and Ichiro Uyama have been funded by Medicaroid, Inc. in relation to the Collaborative Laboratory for Research and Development in Advanced Surgical Technology, Fujita Health University. Koichi Suda has been funded by Medicaroid, Inc. in relation to the Collaborative Laboratory for Research and Development in Advanced Surgical Intelligence, Fujita Health University, and has also received advisory fees from Medicaroid, Inc., outside of the submitted work.

Ethical approval This study was approved by the Institutional Review Board of Fujita Health University (HM18-409) and other participating hospitals. This study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

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