



Safety assessment of robotic gastrectomy and analysis of surgical learning process: a multicenter cohort study

Norihiro Shimoike¹ · Tatsuto Nishigori¹ · Yoshito Yamashita² · Masato Kondo³ · Dai Manaka⁴ · Yoshio Kadokawa⁵ · Atsushi Itami⁶ · Seiichiro Kanaya⁷ · Hisahiro Hosogi⁷ · Seiji Satoh⁸ · Hiroaki Hata⁹ · Takatsugu Kan¹⁰ · Hironori Kawada¹¹ · Michihiro Yamamoto¹² · Eiji Tanaka^{10,13} · Shigeru Tsunoda¹ · Shigeo Hisamori¹ · Koya Hida¹ · Kentaro Ueno¹⁴ · Shiro Tanaka¹⁵ · Kazutaka Obama¹ · on behalf of Kyoto Esophageal and Gastric Surgery Study Group

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Abstract

Background The safety of robotic gastrectomy (RG) for gastric cancer in daily clinical settings and the process by which surgeons are introduced and taught RG remain unclear. This study aimed to evaluate the safety of RG in daily clinical practice and assess the learning process in surgeons introduced to RG.

Methods Patients who underwent RG for gastric cancer at Kyoto University and 12 affiliated hospitals across Japan from January 2017 to October 2019 were included. Any morbidity with a Clavien–Dindo classification grade of II or higher was evaluated. Moreover, the influence of the surgeon's accumulated RG experience on surgical outcomes and surgeon-reported postoperative fatigue were assessed.

Results A total of 336 patients were included in this study. No conversion to open or laparoscopic surgery and no in-hospital mortality were observed. Overall, 50 (14.9%) patients developed morbidity. During the study period, 14 surgeons were introduced to robotic procedures. The initial five cases had surprisingly lower incidence of morbidity compared to the following cases (odds ratio 0.29), although their operative time was longer (+74.2 min) and surgeon's fatigue scores were higher (+18.4 out of 100 in visual analog scale).

Conclusions RG was safely performed in actual clinical settings. Although the initial case series had longer operative time and promoted greater levels of surgeon fatigue compared to subsequent cases, our results suggested that RG had been introduced safely.

Keywords Robotic gastrectomy · Real world · Safe introduction · Learning process

Introduction

Similar to other surgical procedures, laparoscopic gastrectomy (LG) has been widely accepted as a minimally invasive approach with acceptable short and long-term outcomes since its introduction in 1994 [1–6]. Despite the advantages of laparoscopic surgery compare with open surgery, including reduced pain and blood loss, earlier postoperative recovery, and shorter hospital stay [7–9], several inherent limitations, including the fulcrum effect [10], restricted movement

with straight instruments, and tremors in the human hand, have been reported [11].

Nonetheless, surgical robots could overcome these limitations in laparoscopic surgery through articulating instruments [11]. Moreover, the ability to scale motion enables a more precise operation [11]. Although two prospective comparative clinical trials evaluated the clinical benefits of robotic gastrectomy (RG) [12, 13], only expert robotic surgeons participated in those studies. As such, no consensus exists on the safety of RG in actual clinical settings where various surgeons perform surgery for different patients. Furthermore, although unexpected difficulties may occur when introducing new surgical procedures, the process by which surgeons introduced and learned RG is yet to be elucidated.

✉ Tatsuto Nishigori
nsgr@kuhp.kyoto-u.ac.jp

Extended author information available on the last page of the article

Currently, RG is being performed in daily clinical practice throughout Japan given its coverage by the universal health insurance starting in April 2018. This multicenter retrospective study had two aims: (1) to evaluate the safety of RGs in an actual clinical setting and (2) to assess the learning process of surgeons introduced to RG.

Methods

Study design and setting

A retrospective review of a prospectively built multi-institutional database was performed using a research electronic data capture system [14]. The following 13 hospitals participating in the Kyoto Esophageal and Gastric Surgery Study Group (KEGG) attended to the database: Kyoto University Hospital, Kyoto Medical Center, Kyoto City Hospital, Kyoto Katsura Hospital, Shiga General Hospital, Osaka Red Cross Hospital, Kitano Hospital, Tenri Hospital, Amagasaki General Medical Center, Kobe City Medical Center General Hospital, Kobe City Medical Center West Hospital, Nishi-Kobe Medical Center, and Japan Red Cross Wakayama Medical Center. All hospitals were middle- or large-scale designated cancer care hospitals in Japan. This study was approved by the ethics committees of Kyoto University Graduate School (R2345) and Faculty of Medicine, as well as that of each participating hospital.

Patients

We identified patients who underwent RG from January 2017 to October 2019 for pathologically confirmed gastric cancer and esophago-gastric junctional (EGJ) cancer defined as Siewert type 2 [15]. Distal, total, and proximal gastrectomy (DG, TG, and PG) procedures were included.

Surgery

All robotic surgeries were performed using da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA). The extent of gastrectomy and lymph node dissection was determined based on the Japanese gastric cancer treatment guidelines [16]. The type of reconstruction, including Billroth-I, Billroth-II, Roux-en-Y, double-tract, or esophago-gastrostomy, was selected based on the surgeon's preference. A part of our procedures was reported elsewhere [17].

Although RG has been covered by the Japanese universal health insurance since April 2018, the application of the health insurance system has been limited to the following conditions: surgeons with 10 or more RG experience and hospitals capable of managing ≥ 50 gastrectomy procedures per year, including ≥ 20 robot or laparoscopic procedures.

The medical fee for RG was paid by either the hospital or the patient until the national insurance covered it.

RG was introduced and performed in accordance with the Japanese Society of Endoscopic Surgery (JSES) guidelines [18]. Surgeons performing robotic surgery were required to be certified by the Endoscopic Surgical Skill Qualification System of the JSES [19] and to obtain board certification by The Japanese Society of Gastroenterological Surgery. Additionally, surgeons were required to obtain a console surgeon certification for using the da Vinci Surgical System after receiving simulator training and performing animal surgeries. Surgeons and surgical team members of the hospitals were required to observe an experienced surgical team perform RGs before performing the procedure themselves. Initial surgeries were required to be performed under the supervision of proctors certified by the JSES [18].

Among the 13 institutions involved, 10 hospitals were introduced to RG after January 2017. Given that most of the proctors included herein belonged to our study group (KEGG), relatively similar procedures were introduced at each hospital. Moreover, our study group has been performing standardized laparoscopic gastrectomy procedures through video conferences since 2005. Therefore, surgical concepts and technical principles have been shared within our group.

Outcomes

The primary outcome to evaluate the safety of RGs was any morbidity within 30 days after surgery that had a Clavien–Dindo (C–D) classification of grade II or higher [20]. When multiple complications occurred in a patient, the maximum grade of the complications was chosen as the overall grade for the patient, whereas each individual complication was noted separately in the details. The definition of representative morbidities in this study is summarized in Online Resource 1. The secondary outcomes included conversion to open or laparoscopic procedures, intraoperative blood loss, operative time, postoperative hospital stay, and in-hospital mortality.

Moreover, this study examined the influence of the surgeon's accumulated RG experience on surgeon-reported postoperative fatigue, surgical outcomes, and postoperative amylase levels in the drainage fluid among those introduced to robotic surgery during the study period.

Surgeon fatigue was assessed within 1 h after surgery using a 100-mm visual analog scale (VAS) ranging from 0 (minimum fatigue: the best feeling without any fatigue) to 100 (maximum fatigue: the worst feeling of fatigue you have ever felt so far), which has been one of the most frequently used tools to measure total fatigue intensity [21]. The questionnaire survey was performed between June 2018

and October 2019, during which a part of surgeons indicated their fatigue levels.

Experience of RG in each surgeon

To assess the learning process in surgeons introduced to RG, the accumulated experience of each surgeon was divided into three phases. The first phase included the 1st to 5th cases for each surgeon, the 2nd phase included the 6th to 10th cases, and the 3rd phase included the 11th or more cases.

To ensure the consistency of our results, the impact of surgeon experience on the outcomes was evaluated after categorizing the surgeon's experience threshold into tertiles, quartiles, and quintiles, which included any of the three, four, and five points that divided an ordered distribution into three, four, and five parts, each containing a third, fourth, and fifth of the patients, respectively. Moreover, we changed the first phase into the 1st to 3rd cases of each surgeon, the second phase into the 4th to 6th cases, the third phase into the 7th to 9th cases, and the fourth phase into the 10th or more cases.

Data collection

Apart from the outcome measures, the following information was collected as background characteristics of the patients: age; the American Society Anesthesiologists (ASA) physical status; body mass index (BMI); smoking within 1 year; comorbidities such as hypertension, diabetes mellitus, coronary heart disease (CHD), heart failure, chronic obstructive pulmonary disease (COPD), and cerebrovascular disease; and long-term use of corticosteroids.

Information regarding oncological characteristics, including the main location of the tumor, depth of tumor invasion, lymph nodes metastasis, clinical tumor stage (cStage), and preoperative chemotherapy, were also collected. Disease stage was defined according to the Japanese Gastric Cancer Classification [22]. Surgical information comprised the operative procedure, extent of lymphadenectomy, and combined splenectomy. Information on the patients' characteristics, oncological findings, operative findings, and postoperative outcomes were defined before data collection.

In our study group, data on patient enrollment status from the multi-institutional database has been regularly reported at every research meeting which held once every three months. Further, before conducting any analyses were conducted, researchers at each institution confirmed that all patients who underwent RG during the study periods were included in the database and data cleaning was performed by NS.

Statistical methods

For the primary analysis, the safety of RG in the entire cohort was assessed by summing the data. Thereafter, the learning process was analyzed in surgeons introduced to robotic surgery during the study period. Data were described as means with standard deviations, medians with interquartile ranges, or frequencies with percentages, as appropriate.

To assess the learning process, differences in patient background, proctor attendance, and operative procedures (e.g., the extent of resection among the phases) were examined. Associations between surgeon experience and morbidity were examined using logistic regression, whereas associations between operative time and surgeon's fatigue were examined using linear models, accounting for between-surgeon variability and potential confounders. Institution was not regarded as three-level hierarchy because only one or two surgeons performing RG belonged to each institution. Intraclass correlation coefficients (ICCs) were calculated to evaluate the influence of between-surgeon variation. When the ICCs were low, ordinal fix-effects models were used instead of mixed-effects models. The following potential confounders that could affect both the operative indication of RG in the initiation phase and surgical outcomes were selected a priori based on previous literatures [23–29] and clinical knowledge: age, sex, BMI, ASA score, comorbidities (e.g., COPD, diabetes mellitus, and CHD), long-term use of corticosteroids, preoperative chemotherapy, operative procedure, surgeon's experience of LG, cStage, extent of lymphadenectomy, and splenectomy. Comorbidity was not included in the analysis for operative time and surgeon fatigue given that it was less likely to be associated with these outcomes and the sample size was limited. Model fit was assessed using Hosmer–Lemeshow test for logistic regression and the normal Q–Q plot and residual plot for linear regression.

According to the current recommendation on statistics [30, 31], we reported point estimates, 95% confidence intervals, and P values and refrained from binary use of P values. All statistical analyses were performed using Stata version 16.0 (StataCorp, College Station, Texas, USA).

Results

Surgeon and patient characteristics

During the study period, 20 surgeons performed RG for 336 patients with gastric cancer. Among the included surgeons, 8 had over 200 cases, 3 had 101 to 200 cases, 6 had 51 to 100 cases, and 3 had < 51 cases of LG experience. In other words, more than half of the surgeons had over 100 cases of laparoscopic experience. Among the 20 surgeons, 5

operating surgeons performed RG on their own for the first time after previously acting as an assistant surgeon for RG.

The characteristics of the patients are summarized in Table 1. Among the 336 patients, 11 (3.3%) had severe comorbidities with an ASA score ≥ 3 , 12 (3.6%) were

diagnosed with EGJ cancer, and 66 (19.6%) had highly advanced, cStage III or higher cancer. Distal, total, and proximal gastrectomies were performed in 257 (76.5%), 55 (16.4%), and 24 patients (7.1%), respectively, whereas D2 dissection was performed in 164 patients (48.8%).

Table 1 Background characteristics and operative features in patients who underwent robotic gastrectomy

	<i>n</i> = 336
Age, years	70 (63–77)
Sex	
Male	226 (67.3)
Female	110 (32.7)
BMI, kg/m ²	21.9 (20.2–23.9)
ASA score 2/3	231 (69.0) / 11 (3.3)
Comorbidities*	
Hypertension	134 (39.9)
Diabetes mellitus	67 (19.9)
Coronary heart disease,	8 (2.4)
Heart failure	0 (0)
COPD	25 (7.4)
Cerebrovascular disease	13 (3.9)
Long-term use of corticosteroids	4 (1.2)
Smoking within 1 year	74 (22.0)
Preoperative chemotherapy	6 (1.8)
Main location of the tumor	
Upper**/ Middle /Lower third	68 (20.3) / 124 (36.9) / 144 (42.9)
Depth of invasion	
$\leq$ cT1	178 (53.0)
cT2	66 (19.6)
cT3	50 (14.9)
cT4	41 (12.2)
cTX	1 (0.3)
Lymph nodes metastasis	
cN0	247 (73.5)
$\geq$ cN1	87 (25.9)
cNX	2 (0.6)
cStage	
I	225 (67.0)
II	45 (13.4)
III	64 (19.0)
IV	2 (0.6)
Distal/ total/ proximal gastrectomy	257 (76.5) / 55 (16.4) / 24 (7.1)
D2 lymphadenectomy	164 (48.8)
Splenectomy	4 (1.2)

BMI body mass index, *ASA* American Society of Anesthesiology, *COPD* chronic obstructive pulmonary disease

Nominal variables were presented as number (percentage) and continuous variables were expressed median (interquartile range)

*Some patients had multiple comorbidities

**Including esophago-gastric junction cancer

Surgical outcomes

Surgical outcomes are detailed in Table 2. The median operative time was 370 min. No conversion to open or laparoscopic surgery and no in-hospital mortality were observed.

Table 2 Surgical outcomes in patients who underwent robotic gastrectomy

	<i>n</i> = 336
Operation time, minutes	370 (324–445)
Blood loss, ml	0 (0–23.5)
Conversion to open or laparoscopic surgery	0
LHS, days	10 (8–13)
In-hospital mortality	0
Overall complication*	
$\geq$ C–D Grade II	50 (14.9)
$\geq$ C–D Grade III	18 (5.4)
Grade II	
Superficial and deep incisional SSI	3 (0.9)
Organ/space SSI	8 (2.4)
Anastomotic leakage	4 (1.2)
Pancreatic fistula	3 (0.9)
Gastrointestinal bleeding	1 (0.3)
Pneumonia	7 (2.1)
Ileus	2 (0.6)
Delayed gastric emptying	1 (0.3)
Renal dysfunction	1 (0.3)
Urinary tract infection	1 (0.3)
Others	12 (3.6)
Grade III	
Superficial and deep incisional SSI	1 (0.3)
Organ/space SSI	4 (1.2)
Anastomotic leakage	4 (1.2)
Pancreatic fistula	2 (0.6)
Intra-abdominal bleeding	3 (0.9)
Ileus	2 (0.6)
Bowel obstruction	4 (1.2)
Duodenal stump leakage	1 (0.3)
Others	1 (0.3)
Grade V	
Gastrointestinal bleeding	1 (0.3)

LHS length of postoperative hospital stay, *C–D* Clavien–Dindo classification, *SSI* surgical site infection

Nominal variables were presented as number (percentage) and continuous variables were expressed median (interquartile range)

*The total does not add up because of overlapping elements

The incidence of overall morbidity ($C-D \geq$ Grade II) was 14.9% (50/336). Grade II, III, IV, and V complications were observed in 32 (9.5%), 17 (5.1%), 0 (0%), and 1 patient (0.3%), respectively. The only patient with grade V morbidity developed gastrointestinal bleeding on postoperative day 32 after being discharged from the hospital. Despite not satisfying the definition of morbidity in this study, we considered it an important event and included it in the outcomes.

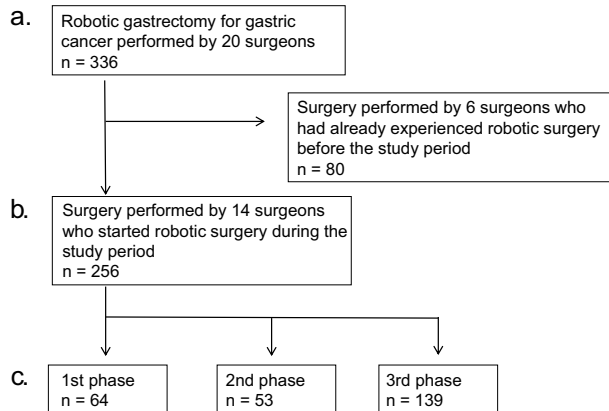


Fig. 1 Flowchart of patient inclusion into this study. **a** The whole cohort in whom the safety of robotic gastrectomy was assessed. **b** The cohort in whom the learning process of initiating robotic gastrectomy was assessed. **c** Patients were divided into the following three phases according to the surgeon's accumulated experience: 1st phase (1st to 5th cases for each surgeon), 2nd phase (6th to 10th cases for each surgeon), and 3rd phase (11th or more cases for each surgeon)

Table 3 Background characteristics of patients who underwent robotic gastrectomy according to surgeon experience

Cases per surgeon	1st phase 1st–5th (n = 64)	2nd phase 6th–10th (n = 53)	3rd phase ≥ 11th (n = 139)
Age, years	70 (66–75)	72 (62–79)	70 (62–77)
Male	46 (71.9)	33 (62.3)	98 (70.5)
BMI, kg/m ²	22.0 (20.4–24.7)	22.0 (20.0–24.4)	21.8 (20.1–23.7)
ASA score ≥ 3	3 (4.7)	1 (1.9)	4 (2.9)
Diabetes mellitus	12 (18.8)	14 (26.4)	22 (15.8)
COPD	7 (10.9)	1 (1.9)	12 (8.6)
Coronary heart disease	2 (3.1)	3 (5.7)	3 (2.2)
Long-term use of corticosteroids	0 (0)	1 (1.9)	2 (1.4)
Preoperative chemotherapy	2 (3.1)	1 (1.9)	3 (2.2)
Distal gastrectomy	58 (90.6)	40 (75.5)	98 (70.5)
Total/proximal gastrectomy	6 (9.4)/ 0 (0)	11 (20.8)/ 2 (3.8)	22 (15.8)/ 19 (13.7)
cStage I	48 (75.0)	36 (67.9)	86 (61.9)
D2 lymphadenectomy	27 (42.2)	27 (50.9)	79 (56.8)
Splenectomy	0 (0)	0 (0)	4 (2.9)
Supervision of proctor	41 (64.1)	15 (28.3)	13 (9.4)

BMI body mass index, ASA American Society of Anesthesiology, COPD chronic obstructive pulmonary disease

Nominal variables were presented as number (percentage) and continuous variables were expressed median (interquartile range)

Surgeon introduction to RG

Among 20 surgeons included herein, 4 had already experienced RG before the study period, whereas 2 started robotic esophagectomy before starting RG. The consecutive cases handle by the 14 surgeons from their initial robotic surgeries were then analyzed. As shown in Fig. 1, 256 patients were divided into 3 groups based on the surgeon's RG experience.

Relationship between surgeon's experience and operative indications for RG

Patient characteristics, such as age, sex, BMI, and ASA performance status, were similar among the three groups of surgeons according to experience (Table 3). However, more complicated surgeries tended to be performed as the surgeons accumulated experience. While most of the cases (90.6%) in the 1st phase were distal gastrectomy, the proportions of total and proximal gastrectomies increased in the 2nd and 3rd phases. As the phases progressed, the proportion of advanced cancers increased, whereas proctor attendance decreased.

Impact of surgeon's experience on morbidity

As shown in Table 4, the incidence of morbidity $\geq$ CD grade II in the first phase was lower than those in subsequent phases. Given that the ICC value for the mixed-effects model was low (0.019), we then considered that

Table 4 Surgical outcomes of patients who underwent robotic gastrectomy and surgeon fatigue according to surgeon experience of RG

Cases per surgeon	1st phase 1st–5th (<i>n</i> = 64)	2nd phase 6th–10th (<i>n</i> = 53)	3rd phase ≥ 11th (<i>n</i> = 139)
Operation time, minutes	452 (340–489)	374 (341–450)	366 (325–422)
Blood loss, ml	18 (0–55)	5 (0–25)	0 (0–15)
Conversion*	0	0	0
Morbidity ≥ Grade II	5 (7.8)	6 (11.3)	30 (21.6)
Morbidity ≥ Grade III	1 (1.6)	3 (5.7)	11 (7.9)
LHS, days	10 (7–12)	9 (7–12)	9 (7–13)
Surgeon fatigue, VAS score	75 (55–82)	59 (50–68)	33 (15–57)

RG robotic gastrectomy, LHS length of postoperative hospital stay, VAS visual analog scale

Nominal variables were presented as number (percentage) and continuous variables were expressed median (interquartile range)

*Conversion to open or laparoscopic surgery

the clustering was irrelevant and instead used ordinary logistic regression, expressed as adjusted odds ratio (OR) with 95% confidence intervals (CIs). After adjusting for covariates using the multivariable logistic regression model, lower odds for morbidity were estimated in the first phase (OR, 0.29; 95% CI, 0.09–0.93) compared to the 3rd phase (Table 5). This analysis also indicated that male sex (OR, 2.71; 95% CI, 1.01–7.29), BMI > 25 kg/m² (OR, 2.62; 95% CI, 1.06–6.48), and COPD (OR, 3.66; 95% CI, 1.09–12.26) had unfavorable impact on the incidence of morbidity.

Due to the low number of events per independent variable included in the analysis, we performed post hoc sensitivity analysis using the bootstrap method with 1000 repeat resamplings, which confirmed that the incidence of morbidity in the 1st phase was lower (Online Resource 2) [32].

Impact of surgeon experience on operative time

Data distribution for operative time is summarized in Table 4. Although the proportion of distal gastrectomies decreased as phases progressed, operative time decreased. Multivariable linear mixed-effects regression showed that the average operative time was longer during the 1st phase (+74.2 min; 95% CI, 43.9–104.4) than that during the 3rd phase (Table 6). Use of a mixed-effects model to account for differences in surgeons was justified based on an ICC value of 0.21, which demonstrated that 21% of the variability in operative time was due to variations between surgeons.

Impact of surgeon experience on postoperative fatigue

During the survey period, 10 surgeons filled out the VAS after 93 RGs. The data distribution is presented in Table 4.

Table 5 Multivariable logistic regression analysis for morbidity of grade II or higher after robotic surgery

	OR (95% CI)	<i>P</i> value
Surgeons' experience of RG		
1st phase	0.29 (0.09–0.93)	0.04
2nd phase	0.55 (0.19–1.61)	0.28
3rd phase	Ref	
Surgeons' experience of LG		
≤ 50 cases	Ref	
51–100 cases	0.34 (0.05–2.48)	0.28
> 100 cases	0.58 (0.13–2.55)	0.47
Age > 70, years	1.13 (0.51–2.50)	0.76
Male	2.71 (1.01–7.29)	0.05
BMI ≥ 25, kg/m ²	2.62 (1.06–6.48)	0.04
ASA score ≥ 3	2.59 (0.40–16.67)	0.32
CHD	0.44 (0.04–5.19)	0.52
COPD	3.66 (1.09–12.26)	0.04
Diabetes mellitus	0.74 (0.28–1.91)	0.53
Long-term use of corticosteroids	1.54 (0.09–26.34)	0.77
Preoperative chemotherapy	0.95 (0.09–9.69)	0.97
TG/ PG	1.23 (0.51–2.96)	0.64
cStage ≥ II	1.80 (0.74–4.39)	0.20
D2 lymphadenectomy	1.09 (0.45–2.62)	0.84
Splenectomy	3.78 (0.37–38.31)	0.26

RG robotic gastrectomy, LG laparoscopic gastrectomy, BMI body mass index, ASA American Society of Anesthesiology, CHD coronary heart disease, COPD chronic obstructive pulmonary, TG total gastrectomy, PG proximal gastrectomy, OR odds ratio, CI confidence interval

Surgeon-reported postoperative fatigue was higher in the 1st (+18.4; 95% CI, 3.7–33.2) than in the 3rd phase after adjusting for covariates (Table 6).

Table 6 Multivariable linear mixed-effect regression for operation time and surgeon-reported postoperative fatigue

	Operation time		Surgeon fatigue	
	Regression coefficient	<i>P</i> value	Regression coefficient	<i>P</i> value
	in minutes (95% CI)		in VAS score (95% CI)	
Surgeons' experience of RG				
1st phase	74.2 (43.9–104.4)	<0.01	18.4 (3.7–33.2)	0.01
2nd phase	12.9 (– 15.7–41.4)	0.38	17.2 (4.1–30.3)	0.01
3rd phase	Ref		Ref	
Surgeons' experience of LG				
≤ 50 cases	Ref		Ref	
51–100 cases	– 43.5 (– 124.7–37.6)	0.29	19.5 (– 2.1–41.1)	0.08
> 100 cases	– 17.7 (– 85.7–50.3)	0.61	3.9 (– 16.6–24.3)	0.71
Age > 70, years	1.9 (– 14.4–18.2)	0.82	– 2.8 (– 10.9–5.4)	0.51
Male	28.6 (11.3–45.8)	<0.01	8.5 (0.1–16.9)	0.05
BMI ≥ 25, kg/m2	4.2 (– -16.7–25.2)	0.69	– 3.2 (– 11.8–5.3)	0.46
ASA score ≥ 3	8.8 (– 36.7–54.4)	0.70	– 7.0 (– 25.4–11.4)	0.45
Preoperative chemotherapy	33.6 (– 19.7–87.0)	0.22	5.9 (– 15.9–27.7)	0.60
TG/ PG	97.8 (76.9–118.6)	<0.01	8.5 (– 0.9–18.0)	0.08
cStage ≥ II	22.1 (1.7–42.6)	0.03	– 4.2 (– 14.2–5.7)	0.41
D2 lymphadenectomy	39.9 (20.9–58.8)	<0.01	5.1 (– 4.0–14.3)	0.27
Splenectomy	73.2 (8.0–138.4)	0.03	NA	

RG robotic gastrectomy, LG laparoscopic gastrectomy, BMI body mass index, ASA American Society of Anesthesiology, DG distal gastrectomy, TG total gastrectomy, PG proximal gastrectomy, CI confidence interval, VAS visual analog scale, NA not applicable

Sensitivity analysis using different thresholds of surgeon experience

Similar to the main findings, the initial phase of the surgeon's experience showed lower morbidity rates, longer operative time, and higher fatigue scores compared to any other threshold (Online Resource 3).

Post hoc analysis to assess the impact of the attendance of a proctor

To assess the impact of the attendance of a proctor on morbidity, we performed a post hoc analysis in which the attendance of a proctor was added as a variable in the multivariable logistic regression model. However, surgeon's experience of RG (phase 1–3) was excluded from the model because of multicollinearity. RGs supervised by a proctor tended to have a low incidence of morbidity (OR, 0.74; 95% CI, 0.25–2.19) (Online Resource 4).

Discussion

The present large-scale multicenter study revealed that RG had been safely performed in actual clinical settings. Notably, postoperative complications occurred in 14.9% of the 336 RGs, which was lower than that reported in a previous

trial (21.2%) [12], which included only surgeons who had experienced at least 20 RGs and excluded patients who had ≥ stage III or EGJ cancer. Despite the expected increase in the incidence of morbidity, the overall morbidity in the present study was rather low. Although the incidence of C–D grade ≥ III complications in the present study (5.4%) was larger than that reported in the aforementioned clinical trial (2.5%) [12], it was lower than or equivalent to the rates reported by a nationwide survey on gastrectomy and leading institutions (6.4–11.5%) [12, 33, 34]. The incidence of postoperative complications following RG may be considered low even in daily clinical settings, although this was not a confirmatory study. One of the major reasons for this might be that only surgeons with LG experience performed RG in accordance with JSES guidelines as stated in the Methods section. To the best of our knowledge, this has been the first multi-institutional study on the safety of RG in daily clinical practice, including the introductory phase of the procedure.

Moreover, the current study clearly demonstrated the trends in surgical outcomes and surgeon fatigue during the introduction process in 14 surgeons using appropriate statistical models. Although a longer operative time and higher surgeon fatigue scores were found in the initial case series, the incidence of morbidity was rather low. These results were confirmed through sensitivity analyses using several cutoff values for surgeon experience. Accordingly, studies have shown that moderate levels of fatigue produce higher

levels of performance impairment compared to proscribed levels of alcohol intoxication [35] and that fatigue may cause medical incidences or accidents [36]. Moreover, evidence has suggested that unexpected challenges tended to emerge with technical immaturity and when introducing a new modality [37, 38]. This study was not designed to evaluate the effect of a proctor and our post hoc analysis did not definitively reveal its impact on the incidence of morbidity. However, RGs supervised by a proctor tended to have lower morbidity; therefore we believe that the attendance of a proctor might have contributed to the reduced incidence of morbidity during the arduous initial series [39, 40]. Although the 2nd and 3rd phases had higher morbidity rates than the first phase, these rates were no worse compared to those presented in the previous studies [12, 33, 34]. However, inviting a proctor may help maintain low rates of morbidity when expanding robotic indications to advanced cases and technically demanding procedures, such as total or proximal gastrectomy.

The current study suggested that individual differences between surgeons had a considerable effect on operative time of RG given the high ICC values during operative time analysis. Despite this natural relationship, only few surgeons had been included in the past studies examining the learning curve of RGs [38, 41–45]. To the best of our knowledge, the 14 surgeons included in the present study is the largest number to have been assessed for the learning process of RG.

Surgical robots are expected to reduce pancreas-related complications by using articulating forceps during suprapancreatic lymph node dissection [46]. The incidence of pancreatic fistula (C–D $\geq$ grade II) in the current study (1.5%) did not differ from that presented in a clinical trial on RG (3.7%) or previous reports on LG (1.9–7.5%) [2, 47, 48]. Moreover, median amylase levels in the drainage fluid on POD1 and POD3 (433 and 166 U/L, respectively) were similar to those reported for RG (374 and 108 U/L, respectively) and lower than those reported for LG (877 and 246 U/L, respectively) [47]. We previously reported higher amylase levels following LG (934.5 U/L) [49]. Although reaching a definitive conclusion without a comparative study design may be difficult, our findings suggest that RG may contribute to reduced pancreas-related complications.

The present study has several limitations worth noting. First, given that this study included only robotic surgeries, comparing RGs with LGs is difficult. However, we believe it clinically meaningful to describe the characteristics and assess the safety of RGs performed in actual clinical settings given the increasing number of RGs expected to be performed in the real world. Second, despite adjusting for all possible confounders obtained from our database to minimize bias, there may have been residual confounding and unmeasured factors, such as the economic status

of the patients, the proctors' experience, and oncological status in the assessment of the learning process. In addition, three of the surgeons were included in only the 1st phase and not in the 2nd and 3rd phases. Although this may have affected the results, the incidence of morbidity in the initial case series was shown to be lower when three surgeons were excluded from the analyses than that in the 2nd and 3rd phases (data not shown). Third, the analyses performed in this study might have limited statistical power to sufficiently account for learning process differences between surgeons. Not all surgeons were evaluated for fatigue. However, this study contains the largest number of surgeons and has been the first to assess surgeon fatigue following 93 RGs by 10 surgeons.

Despite the aforementioned limitations, we believe that our novel findings from multiple institutions on the safety of RGs in actual clinical settings and the learning process, including surgeon fatigue, warrant reporting. Our findings may help surgeons plan for the introduction of RG and take measures, such as inviting an expert robotic surgeon, against long operative time and the high levels of fatigue in the initial phase. Moreover, the introduction of surgeons included herein to RG in clinical practice was done so under the regulations of the government and academic society as described in the Methods section. Our findings may serve as evidence for health policy makers in other countries on the effectiveness of facility and surgeon standards for safe introduction of robotic procedures.

In conclusion, RG had been safely performed in actual clinical settings. Despite the increased operative time and higher levels of surgeon fatigue in initial case series, RG had been safely introduced.

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Author contributions NS and TN designed this study. NS, KU, and ST analyzed the data. NS, TN, KU, and ST interpreted the data. NS drafted the manuscript. Other authors collected the data. All authors revised and approved the final manuscript.

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Declarations

Conflict of interest Yoshito Yamashita, Seiichiro Kanaya, Kazutaka Obama, and Shigeru Tsunoda received lecture fees from Intuitive Surgical G.K. Kazutaka Obama also received consulting fees from Medtronic Corporation and Medtronic Japan Co., Ltd.

Ethical approval All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and later versions.

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Authors and Affiliations

Norihiro Shimoike¹ · Tatsuto Nishigori¹  · Yoshito Yamashita² · Masato Kondo³ · Dai Manaka⁴ · Yoshio Kadokawa⁵ · Atsushi Itami⁶ · Seiichiro Kanaya⁷ · Hisahiro Hosogi⁷ · Seiji Satoh⁸ · Hiroaki Hata⁹ · Takatsugu Kan¹⁰ · Hironori Kawada¹¹ · Michihiro Yamamoto¹² · Eiji Tanaka^{10,13} · Shigeru Tsunoda¹ · Shigeo Hisamori¹ · Koya Hida¹ · Kentaro Ueno¹⁴ · Shiro Tanaka¹⁵ · Kazutaka Obama¹ · on behalf of Kyoto Esophageal and Gastric Surgery Study Group

¹ Department of Surgery, Graduate School of Medicine, Kyoto University, 54 Kawahara-cho Sakyo-ku, Shogoin Kyoto 606-8507, Japan

² Department of Gastroenterological Surgery, Japanese Red Cross Wakayama Medical Center, Wakayama, Japan

³ Department of Surgery, Kobe City Medical Center General Hospital, Kobe, Japan

⁴ Department of Surgery, Kyoto Katsura Hospital, Kyoto, Japan

⁵ Department of Gastrointestinal Surgery, Tenri Hospital, Tenri, Japan

⁶ Department of Surgery, Kobe City Nishi-Kobe Medical Center, Kobe, Japan

⁷ Department of Surgery, Osaka Red Cross Hospital, Osaka, Japan

⁸ Department of Surgery, Kyoto City Hospital, Kyoto, Japan

⁹ Department of Surgery, National Hospital Organization Kyoto Medical Center, Kyoto, Japan

¹⁰ Department of Surgery, Kobe City Medical Center West Hospital, Kobe, Japan

¹¹ Department of Surgery, Hyogo Prefectural Amagasaki General Medical Center, Amagasaki, Japan

¹² Department of Surgery, Shiga General Hospital, Moriyama, Japan

¹³ Department of Surgery, Kitano Hospital, Osaka, Japan

¹⁴ Department of Biomedical Statistics and Bioinformatics, Graduate School of Medicine, Kyoto University, Kyoto, Japan

¹⁵ Department of Clinical Biostatistics, Graduate School of Medicine, Kyoto University, Kyoto, Japan

Gastric Cancer

Safety assessment of robotic gastrectomy and analysis of surgical learning process: a multicenter cohort study

Norihiro Shimoike, Tatsuto Nishigori, Yoshito Yamashita, Masato Kondo, Dai Manaka, Yoshio Kadokawa, Atsushi Itami, Seiichiro Kanaya, Hisahiro Hosogi, Seiji Sato, Hiroaki Hata, Takatsugu Kan, Hironori Kawada, Michihiro Yamamoto, Eiji Tanaka, Shigeru Tsunoda, Shigeo Hisamori, Koya Hida, Kentaro Ueno, Shiro Tanaka, Kazutaka Obama, on behalf of Kyoto Esophageal and Gastric Surgery Study Group

Corresponding author: Tatsuto Nishigori

Department of Surgery, Graduate School of Medicine, Kyoto University

54 Kawahara-cho, Shogoin, Sakyo-ku, Kyoto, 606-8507, Japan

E-mail: nsgr@kuhp.kyoto-u.ac.jp

Online Resource 1. Definition of representative morbidities in this study

Morbidity	Definition
Anastomotic leakage	Detected by radiological findings or drainage of digestive juice from a drain;
Pancreatic fistula	Diagnosed when amylase concentration of drainage fluid was greater than three times the serum amylase concentration after postoperative day 3;
Surgical site infection	Evaluated according to the Centers for Disease Control and Prevention's (CDC)/ the National Healthcare Safety Network (NHSN) surveillance definition of health care-associated infection
Intra-abdominal bleeding	Diagnosed by radiological findings or drainage of blood from a drain
Ileus	Nonmechanical obstruction of bowel
Bowel obstruction	Mechanical obstruction of bowel due to adhesions, mass, or other causes of compression
Pneumonia	Diagnosed by newly developed infiltration on a chest X-ray or computed tomography (CT) accompanied by fever, cough, or purulent sputum
Renal dysfunction	Elevated serum creatinine level 2.0mg/dl more than before surgery
Urinary tract infection	Diagnosed with a positive urine culture or pyuria with fever ($>38^{\circ}\text{C}$), urinary frequency, dysuria, or suprapubic tenderness.

Online Resource 2. Sensitivity analysis with bootstrap of multivariable logistic regression for morbidity of grade II or higher after robotic surgery

	OR (95% CI)	P value
Surgeons' experience of RG		
1st phase	0.29 (0.08–0.99)	0.05
2nd phase	0.55 (0.20–1.52)	0.25
3rd phase	Ref	
Surgeons' experience of LG		
<u>≤50 cases</u>	<u>Ref</u>	
<u>51–100 cases</u>	<u>0.34 (0.00–365.53)</u>	<u>0.76</u>
<u>>100 cases</u>	<u>0.58 (0.00–615.32)</u>	<u>0.88</u>
Age > 70, years	1.13 (0.50–2.54)	0.77
Male	2.71 (0.91–8.08)	0.07
BMI ≥ 25, kg/m ²	2.62 (1.01–6.83)	0.05
ASA score ≥ 3	2.59 (0.38–17.87)	0.33
CHD	0.44 (0.07–2.75)	0.38
COPD	3.66 (0.96–13.98)	0.06
Diabetes mellitus	0.74 (0.22–2.46)	0.62
Long-term use of corticosteroids	1.54 (0.19–12.60)	0.69
<u>Preoperative chemotherapy</u>	<u>0.95 (0.11–7.96)</u>	<u>0.96</u>
TG/ PG	1.23 (0.45–3.36)	0.68
cStage ≥ II	1.80 (0.70–4.65)	0.23
D2 lymphadenectomy	1.09 (0.38–3.10)	0.87
Splenectomy	3.78 (0.70–20.36)	0.12

Abbreviations: RG, robotic gastrectomy; LG, laparoscopic gastrectomy; BMI, body mass index; ASA, American Society of Anesthesiology; CHD, coronary heart disease; COPD, chronic obstructive pulmonary; TG, total gastrectomy; PG, proximal gastrectomy; OR odds ratio; CI, confidence interval.

Supplemental table 3. Sensitivity analyses with different thresholds of surgeon's experience

Case of RG for each surgeon	N	Morbidity ≥ C-D II*		Operation time**			Surgeon fatigue**	
		OR (95% CI)	P value	Regression coefficient (95% CI), in minutes	P value		Regression coefficient (95% CI), in VAS score	P value
Model A								
1–7 (1st tertile)	86	0.31 (0.10–0.89)	0.03	72.7 (31.0–114.3)	<0.01		38.9 (22.9–54.9)	<0.01
8–20 (2nd tertile)	85	0.53 (0.22–1.31)	0.17	22.9 (-14.2–59.9)	0.23		28.8 (14.7–42.9)	<0.01
21– (3rd tertile)	85	Ref		Ref			Ref	
Model B								
1–5 (1st quartile)	64	0.28 (0.08–1.01)	0.05	96.1 (46.9–145.3)	<0.01		30.9 (12.8–49.0)	<0.01
6–12 (2nd quartile)	71	0.49 (0.16–1.52)	0.22	36.6 (-10.1–83.3)	0.12		27.1 (11.0–43.2)	<0.01
12–27 (3rd quartile)	60	1.15 (0.45–2.96)	0.77	2.8 (-37.0–42.6)	0.89		3.1 (-14.2–20.4)	0.73
28– (4th quartile)	61	Ref		Ref			Ref	
Model C								
1–4 (1st quintile)	53	0.26 (0.06–1.07)	0.06	90.6 (33.1–148.2)	<0.01		31.0 (14.1–47.9)	<0.01
5–9 (2nd quintile)	55	0.52 (0.16–1.69)	0.28	51.2 (-4.4–106.9)	0.07		32.9 (17.1–48.6)	<0.01
10–16 (3rd quintile)	50	0.62 (0.19–2.02)	0.43	28.0 (-25.8–81.7)	0.31		21.0 (5.8–36.2)	<0.01
17–33 (4th quintile)	47	0.82 (0.28–2.39)	0.72	-4.1 (-46.6–38.4)	0.85		-9.8 (-26.0–6.3)	0.23
34– (5th quintile)	51	Ref		Ref			Ref	
Model D								
1–3	40	0.10 (0.01–0.85)	0.04	84.2 (52.7–115.6)	<0.01		16.3 (-0.2–32.7)	0.05
4–6	35	0.78 (0.25–2.44)	0.67	42.2 (11.0–73.5)	<0.01		19.9 (4.1–35.7)	0.01
7–9	33	0.74 (0.22–2.54)	0.63	14.8 (-15.5–45.0)	0.34		11.8 (-2.4–26.0)	0.10
10–	148	Ref		Ref			Ref	

*Logistic regression. Model A to D were all adjusted for surgeon's experience of LG, age, sex, BMI, ASA score, COPD, diabetes mellitus, CHD, long-term use of corticosteroids, preoperative chemotherapy, operative procedure, cStage, the extent of lymphadenectomy, and splenectomy.

**Mixed-effects linear regression. Model A to D were all adjusted for surgeon's experience of LG, age, sex, BMI, ASA score, preoperative chemotherapy, operative procedure, cStage, the extent of lymphadenectomy, and splenectomy.

Abbreviations; RG, robotic gastrectomy; LG, laparoscopic gastrectomy; BMI, body mass index; ASA, American Society of Anesthesiology; CHD, coronary heart disease; COPD, chronic obstructive pulmonary disease; VAS, visual analog scale; OR, odds ratio; CI, confidence interval.

Online Resource 4. Post hoc analysis to assess the impact of attendance of a proctor

	<u>OR (95% CI)</u>	<u>P value</u>
<u>Attendance of proctor</u>	<u>0.74 (0.25–2.19)</u>	<u>0.58</u>
<u>Surgeons' experience of LG</u>		
<u>≤50 cases</u>	<u>Ref</u>	
<u>51–100 cases</u>	<u>0.32 (0.04–2.82)</u>	<u>0.31</u>
<u>>100 cases</u>	<u>0.83 (0.16–4.28)</u>	<u>0.83</u>
<u>Age > 70, years</u>	<u>1.15 (0.53–2.51)</u>	<u>0.73</u>
<u>Male</u>	<u>2.67 (1.01–7.04)</u>	<u>0.05</u>
<u>BMI ≥ 25, kg/m²</u>	<u>2.50 (1.03–6.05)</u>	<u>0.04</u>
<u>ASA score ≥ 3</u>	<u>2.45 (0.40–15.15)</u>	<u>0.33</u>
<u>CHD</u>	<u>0.37 (0.03–4.27)</u>	<u>0.43</u>
<u>COPD</u>	<u>3.04 (0.95–9.71)</u>	<u>0.06</u>
<u>Diabetes mellitus</u>	<u>0.72 (0.28–1.84)</u>	<u>0.49</u>
<u>Long-term use of corticosteroids</u>	<u>1.81 (0.11–29.75)</u>	<u>0.68</u>
<u>Preoperative chemotherapy</u>	<u>0.80 (0.08–7.82)</u>	<u>0.85</u>
<u>TG/ PG</u>	<u>1.36 (0.58–3.21)</u>	<u>0.48</u>
<u>cStage ≥ II</u>	<u>1.75 (0.72–4.26)</u>	<u>0.22</u>
<u>D2 lymphadenectomy</u>	<u>1.18 (0.49–2.82)</u>	<u>0.71</u>
<u>Splenectomy</u>	<u>4.27 (0.43–42.58)</u>	<u>0.22</u>

Abbreviations: RG, robotic gastrectomy; LG, laparoscopic gastrectomy; BMI, body mass index; ASA, American Society of Anesthesiology; CHD, coronary heart disease; COPD, chronic obstructive pulmonary; TG, total gastrectomy; PG, proximal gastrectomy; OR odds ratio; CI, confidence interval.