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Received: 7 November 2021 | Accepted: 2 May 2022

DOI: 10.1002/ags3.12579

AGSurg Annals of Gastroenterological Surgery Open Access
WILEY

ORIGINAL ARTICLE

Prevalence and safety of robotic surgery for gastrointestinal malignant tumors in Japan

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Funding information
The Japanese Foundation For Research and Promotion of Endoscopy, Grant/Award Number: NA; National Health Insurance

Abstract

Aim: The National Health Insurance system has reimbursed robotic gastrointestinal surgery since April 2018 in Japan. Additionally, strict facility and surgeon standards were established by the government and the academic society. This study aimed to evaluate the prevalence and safety of robotic surgery using a Japanese nationwide web-based database.

Methods: Patients who underwent the following robotic surgeries for malignant tumors in 2018 were included: esophagectomy (RE), total gastrectomy (RTG), distal gastrectomy (RDG), proximal gastrectomy (RPG), low anterior resection (RLAR), and rectal resections other than RLAR (RRR). The number of cases and surgical mortality rates each month were calculated to evaluate the prevalence and safety of robotic procedures.

Results: A total of 3281 patients underwent robotic gastrointestinal surgery. The monthly number of robotic surgeries nearly doubled in April 2018 when they were initially reimbursed by the National Health Insurance system. Operative mortality rates were 0.9%, 0.4%, 0.2%, and 2.8% for RE (n = 330), RTG (n = 239), RDG (n = 1167), and RPG (n = 109), respectively. No mortality was observed in RLAR (n = 1062) or RRR (n = 374).

Conclusion: Robotic surgery for gastrointestinal malignant tumors was safely introduced into daily clinical practice along with rigorous surgeon and facility standards in Japan.

KEYWORDS
gastrointestinal neoplasms, mortality, registries, robotic surgery, social control

1 | INTRODUCTION

As Japan has a universal health insurance coverage system, if an operation is covered by it, the procedure can be performed without financial hardships. Although the da Vinci surgical system (dVSS, Intuitive Surgical, Sunnyvale, CA, USA) was approved as a medical device in 2009 in Japan, the National Health Insurance system did not reimburse robotic gastrointestinal surgery initially. Since April 2018, however, the health insurance system has covered robotic gastrointestinal surgery, establishing strict facility and operator standards for claim submission. Minimum volume standards were established, as shown in Table S1. In addition, observing the Japanese Society for Endoscopic Surgery (JSES) guidelines is required. For example, surgeons who perform robotic surgery must be certified by the Endoscopic Surgical Skill Qualification System (ESSQS) of the JSES.[1] A JSES-certified proctor must also supervise the initial series.

To date, the prevalence and safety of robotic surgery since the initiation of the health insurance reimbursement have not been determined. The Japanese National Clinical Database (NCD) is a nationwide, web-based data entry system linked to the surgical board certification system.[2,3] The NCD, founded in 2010, now covers almost all surgeries performed in Japan (≥90%) and includes approximately 5000 facilities.[4,5] This study aimed to evaluate the prevalence and safety of robotic gastrointestinal surgery for malignant gastrointestinal tumors, in 2018 in Japan, using the nationwide database.

2 | METHODS

2.1 | Patients

The retrospective study included patients who were registered in the gastroenterological section of the NCD and underwent the following robotic surgeries for malignant tumors between January and December 2018: esophagectomy (RE), total gastrectomy (RTG), distal gastrectomy (RDG), proximal gastrectomy (RPG), low anterior resection (RLAR), and rectal resections other than RLAR (RRR). RRR includes high anterior resection, Hartmann's procedure, abdominoperineal resection of the rectum, and pelvic exenteration. The study excluded patients who underwent esophagectomy without reconstruction, those with only a transhiatal approach, and those who refused to register in the NCD.

2.2 | Data collection

In the NCD, eight procedures, including RE, RTG, RDG, and RLAR, are selected as primary procedures to evaluate medical standards to improve surgical quality.[2,3] Detailed perioperative data have been collected for these procedures.

Preoperative data on patient characteristics, such as age, sex, chemotherapy, or radiation therapy before surgery, and the American Society of Anesthesiologists (ASA) score, were retrieved for all the procedures. Surgical tumor staging that conformed to the 8th edition of the Union for International Cancer Control classification was also used. Additionally, the following additional items regarding RE, RTG, RDG, and RLAR were retrieved: smoking history, drinking history, body mass index (BMI), comorbidities including hypertension, diabetes mellitus, and chronic obstructive pulmonary disease, weight loss of 10% or more within 6 months before surgery, and serum levels of albumin.

2.3 | Outcomes

The primary outcome measure for safety assessment was operative mortality. Operative mortality was defined as death from any cause during the index hospital admission up to 90 days and death after hospital discharge within 30 days after surgery. The secondary outcome measure was postoperative complications ≥grade III according to the Clavien–Dindo (CD) classification.[6]

For all procedures, we evaluated the following intraoperative outcomes: conversion to open surgery, duration of surgery, intraoperative bleeding volume, intraoperative bleeding ≥1000 mL, and intraoperative red blood cell transfusion.

We evaluated specific postoperative complications, surgical site infection (SSI), and sepsis for all procedures. For RE, RTG, RDG, and RLAR, we evaluated anastomotic leakage, pneumonia, atelectasis, pulmonary embolism, peritoneal bleeding, and gastrointestinal bleeding. The RE outcome measures were: recurrent nerve palsy, chylothorax, tracheal tube necrosis, gastric tube necrosis, unexpected intubation, and prolonged mechanical ventilation (≥48 hours). The incidence of pancreatic fistula was evaluated as an outcome of RTG and RDG.

In addition to the primary and secondary outcomes, we included three more factors: complications ≥CD grade II, the length of postoperative hospital stay (LHS), 30-day mortality, and in-hospital mortality. Thirty-day mortality was defined as death within 30 days after surgery regardless of hospitalization status and cause of death. In-hospital mortality was defined as death from any cause during the index hospital admission up to 90 days. For RE, RTG, RDG, and RLAR, we evaluated the incidences of reoperation and readmission within 30 days after surgery.

2.4 | Statistical analysis

We counted the number of robotic procedures performed each month from January to December 2018 to evaluate the prevalence of robotic procedures in Japan.

The frequency of events is presented as numbers and proportions. The distribution of continuous variables is presented as either means with standard deviations or median with interquartile ranges.

No variables used in the data analysis contained frequent (>5%) missing data.

3 | RESULTS

The study included 3281 patients who underwent robotic surgery. The number of robotic surgeries performed each month in 2018 in Japan is shown in Figure 1. As shown in Figure 1A, the number of patients who underwent robotic surgery each month, which remained stable in the low 100s between January and March, nearly doubled in April (n = 221), and quadrupled in October (n = 432). However, by the end of the year it was stable again. Each procedure showed similar changes, as represented in Figure 1B–G.

Table 1 shows patient characteristics. As neoadjuvant chemotherapy is the standard treatment for stage II/III esophageal cancer in Japan, approximately half of the patients undergoing RE received preoperative chemotherapy. Most patients (75%) who underwent RDG and RPG had stage I cancer.

Table 2 summarizes the intraoperative outcomes. The conversion rate in all patients who underwent robotic surgery was 0.8%. No conversion to open surgery was required in robotic rectal surgery. Major bleeding (≥1000 mL) and intraoperative red blood cell transfusion occurred in 32 (0.9%) and 67 (2.0%) of all patients, respectively.

Table 3 lists postoperative complications. Anastomotic leakage, which was the most common major complication after each surgery, occurred in 1.2% (RDG)-13.0% (RE) depending on the surgery type. In patients undergoing RE, the following complications occurred: recurrent laryngeal nerve palsy (n = 60, 18.2%), chylothorax (n = 7, 2.1%), gastric tube necrosis (n = 2, 0.6%), tracheal tube necrosis (n = 0), unexpected intubation (n = 6, 1.8%), and prolonged ventilation (n = 14, 4.2%). Pancreatic fistula after RTG and RDG occurred in 4 (1.7%) and 17 (1.5%), respectively.

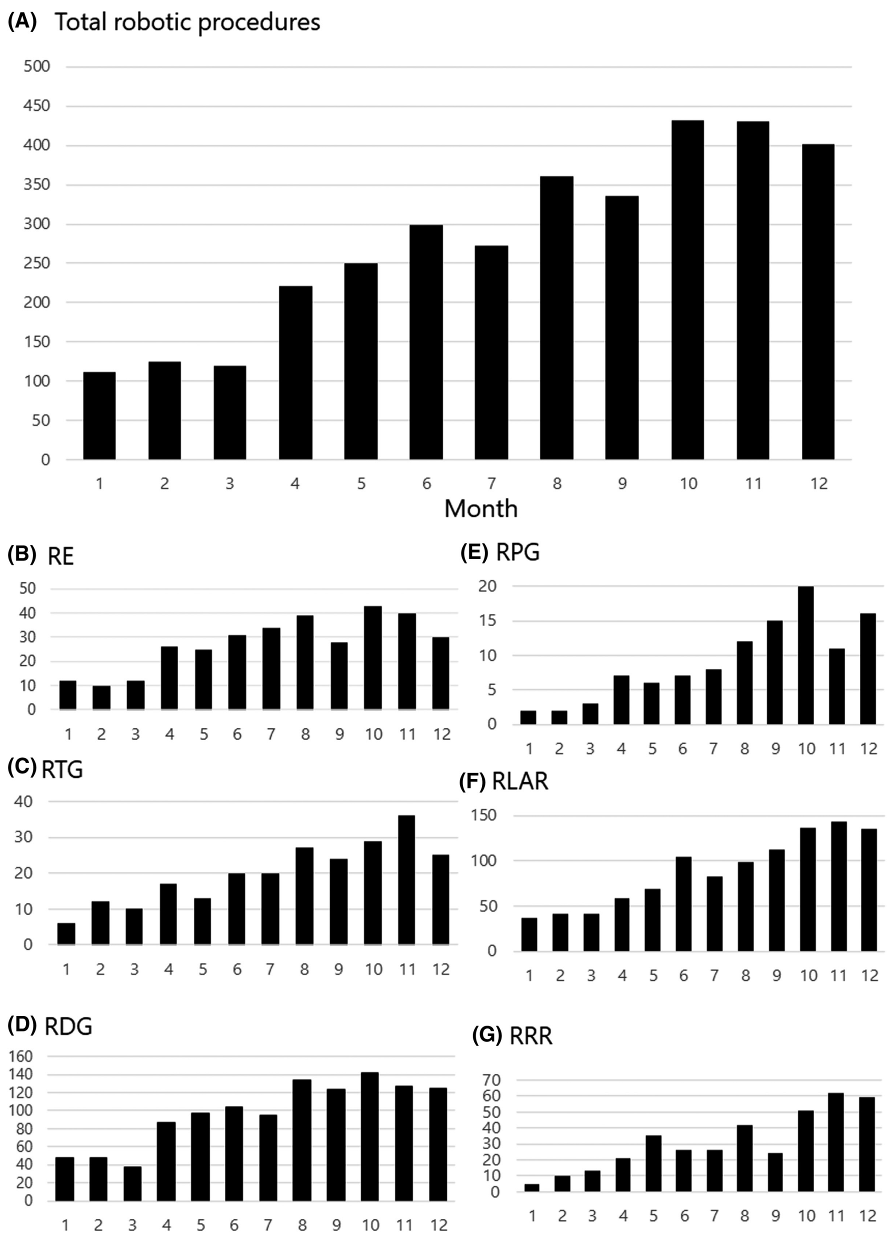

FIGURE 1 The number of total robotic surgeries and each procedure performed each month in 2018 in Japan. (A) Total robotic surgeries, (B) Robotic esophagectomy (RE), (C) Robotic total gastrectomy (RTG), (D) Robotic distal gastrectomy (RDG), (E) Robotic proximal gastrectomy (RPG), (F) Robotic low anterior resection (RLAR), (G) Rectal resections other than RLAR (RRR)

TABLE 1 Patient characteristics

	RE	RTG	RDG	RPG	RLAR	RRR
	n = 330	n = 239	n = 1167	n = 109	n = 1062	n = 374
Age	68 (61–74)	69 (61–75)	70 (61–76)	71 (65–77)	66 (57–72)	69 (61–76)
Sex (female)	73 (22%)	91 (38%)	434 (37%)	18 (17%)	379 (36%)	150 (40%)
Cancer stage ≥II	147 (45%)	119 (50%)	307 (26%)	24 (22%)	621 (58%)	242 (65%)
Preoperative chemotherapy	154 (47%)	19 (8%)	27 (2%)	6 (6%)	120 (11%)	37 (10%)
Preoperative radiotherapy	17 (5%)	1 (0.4%)	0 (0.0%)	1 (1%)	45 (4%)	19 (5%)
ASA score ≥3	16 (5%)	16 (7%)	60 (5%)	8 (7%)	67 (6%)	28 (8%)
Drinking history	265 (80%)	123 (52%)	660 (57%)	N.A.	621 (56%)	N.A.
Smoking history	123 (37%)	41 (17%)	267 (23%)	N.A.	232 (22%)	N.A.
Hypertension	131 (40%)	74 (31%)	450 (39%)	N.A.	372 (35%)	N.A.
Diabetes mellitus	40 (12%)	48 (20%)	190 (16%)	N.A.	172 (16%)	N.A.
COPD	16 (5%)	8 (3%)	61 (5%)	N.A.	49 (5%)	N.A.
BMI (kg/m^2)						
<18.5	51 (16%)	38 (16%)	115 (10%)	N.A.	94 (9%)	N.A.
≥25.0	59 (18%)	50 (21%)	240 (21%)	N.A.	285 (27%)	N.A.
Preoperative weight loss	10 (3%)	6 (3%)	13 (1%)	N.A.	13 (1%)	N.A.
Albumin <4.0 g/dL	133 (40%)	71 (30%)	269 (23%)	N.A.	239 (23%)	N.A.

Abbreviations: ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease; preoperative weight loss is a 10% or greater reduction within 6 months before surgery; BMI, body mass index; RE, robotic esophagectomy; RTG, robotic total gastrectomy; RDG, robotic distal gastrectomy; RPG, robotic proximal gastrectomy; RLAR, robotic low anterior resection; RRR, rectal resections other than RLAR; N.A., not available.

TABLE 2 Intraoperative outcomes

	RE	RTG	RDG	RPG	RLAR	RRR
	n = 330	n = 239	n = 1167	n = 109	n = 1062	n = 374
Conversion to open surgery	5 (1.7%)	11 (4.6%)	13 (1.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Duration of operation (min)	561 (471–663)	432 (364–531)	349 (291–412)	416 (351–510)	355 (267–454)	340 (256–448)
Intraoperative bleeding (mL)	231 ± 275	156 ± 422	53 ± 124	80 ± 110	66 ± 198	100 ± 262
≥1000 mL	7 (2.1%)	7 (2.9%)	4 (0.3%)	0 (0.0%)	9 (0.8%)	5 (1.3%)
RBC transfusion	21 (6.4%)	9 (3.8%)	15 (1.3%)	4 (3.7%)	10 (0.9%)	8 (2.1%)

Note: Duration of operation is presented as medians and interquartile ranges, whereas intraoperative bleeding is presented as means and standard deviations.

Abbreviations: RBC, red blood cell; RDG, robotic distal gastrectomy; RE, robotic esophagectomy; RLAR, robotic low anterior resection; RPG, robotic proximal gastrectomy; RRR, rectal resections other than RLAR; RTG, robotic total gastrectomy.

Table 4 shows operative outcomes. The incidence of postoperative complications ≥grade III ranged from 4.0% (RDG) to 18.2% (RE). Operative mortality rates were 0.9%, 0.4%, and 0.2% in RE, RTG, and RDG, respectively. No mortality occurred after rectal surgery. In contrast, three (2.8%) patients died in the hospital after RPG.

4 | DISCUSSION

This study included 3281 patients who underwent robotic gastrointestinal surgeries; this is one of the largest studies worldwide in this field using a nationwide database with a high coverage rate (>90%) and accuracy. The monthly number of robotic surgeries nearly doubled in April, 2018 and was affected by the National Health Insurance reimbursement. An interesting and unique point of the present study is that the impact of national health policy on individual surgical choice was clearly demonstrated using the nationwide database, with a high coverage rate. Although rigorous comparisons with other surgical approaches were outside the scope of this noncomparative cohort study, we estimated the safety of each procedure by evaluating the acute increase in adverse events compared with the national average.[7] Operative mortality and postoperative complications ≥CD grade III for patients who underwent all surgery types performed nationwide in 2018 were 1.9% and 22.9%

TABLE 3 Specific postoperative complications

	RE	RTG	RDG	RPG	RLAR	RRR
	n = 330	n = 239	n = 1167	n = 109	n = 1062	n = 374
Superficial incisional SSI	15 (4.5%)	8 (3.3%)	12 (1.0%)	0 (0.0%)	21 (2.0%)	0 (0.0%)
Deep incisional SSI	4 (1.2%)	3 (1.3%)	0 (0.0%)	0 (0.0%)	6 (0.6%)	0 (0.0%)
Organ/space SSI	17 (5.1%)	9 (3.8%)	28 (2.4%)	1 (0.9%)	51 (4.8%)	0 (0.0%)
Sepsis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Anastomotic leakage	43 (13.0%)	10 (4.2%)	14 (1.2%)	N.A.	72 (6.8%)	N.A.
Pneumonia	43 (13.0%)	6 (2.5%)	15 (1.3%)	N.A.	10 (0.9%)	N.A.
Atelectasis	13 (3.9%)	1 (0.4%)	3 (0.3%)	N.A.	2 (0.2%)	N.A.
Pulmonary embolism	7 (2.1%)	0 (0.0%)	3 (0.3%)	N.A.	1 (0.1%)	N.A.
Peritoneal bleeding	2 (0.6%)	2 (0.8%)	4 (0.3%)	N.A.	2 (0.2%)	N.A.
Gastrointestinal bleeding	2 (0.6%)	2 (0.8%)	7 (0.6%)	N.A.	0 (0.0%)	N.A.

Abbreviations: N.A., not available; RDG, robotic distal gastrectomy; RE, robotic esophagectomy; RLAR, robotic low anterior resection; RPG, robotic proximal gastrectomy; RRR, rectal resections other than RLAR.; RTG, robotic total gastrectomy; SSI, surgical site infection.

TABLE 4 Operative outcomes

	RE	RTG	RDG	RPG	RLAR	RRR
	n = 330	n = 239	n = 1167	n = 109	n = 1062	n = 374
≥CD grade II	131 (39.7%)	41 (17.2%)	138 (11.8%)	13 (11.9%)	213 (20.1%)	87 (23.3%)
≥CD grade III	60 (18.2%)	16 (6.7%)	47 (4.0%)	6 (5.5%)	80 (7.5%)	34 (9.1%)
Reoperation	19 (5.8%)	7 (2.9%)	20 (1.7%)	N.A.	62 (5.8%)	N.A.
LHS	21 (16–32)	12 (9–16)	10 (8–13)	11 (8–14)	12 (8–16)	11 (8–18)
Readmission	4 (1.2%)	4 (1.7%)	31 (2.7%)	N.A.	31 (2.9%)	N.A.
30-day mortality	2 (0.6%)	1 (0.4%)	1 (0.1%)	2 (1.8%)	0 (0.0%)	0 (0.0%)
In-hospital mortality	3 (0.9%)	1 (0.4%)	2 (0.2%)	3 (2.8%)	0 (0.0%)	0 (0.0%)
Operative mortality	3 (0.9%)	1 (0.4%)	2 (0.2%)	3 (2.8%)	0 (0.0%)	0 (0.0%)

Note: LHS is presented as medians and interquartile ranges.

Abbreviations: CD, Clavien–Dindo classification; LHS, length of postoperative hospital stay; N.A., not available; RDG, robotic distal gastrectomy; RE, robotic esophagectomy; RLAR, robotic low anterior resection; RPG, robotic proximal gastrectomy; RRR, rectal resections other than RLAR.; RTG, robotic total gastrectomy.

for esophagectomy (n = 6207); 2.0% and 11.6% for total gastrectomy (including proximal gastrectomy; n = 13 223); 1.2% and 6.8% for distal gastrectomy (n = 33 988); and 0.7% and 11.9% for low anterior resection (n = 20 636), respectively.[7] Operative mortality rates and postoperative complications associated with each robotic surgery were lower than those for patients who underwent all types of surgeries performed nationwide in 2018.[7] Moreover, these results and the conversion rates of this study are neither inferior nor superior to those observed in previous multicenter studies on robotic procedures, although longer operation time and LHS were observed in this study.[8-13] Konstantinidis et al analyzed the National Cancer Database in the United States and reported that 90-day mortality rates were 6%, 3%, and 1% in robotic esophagectomy, gastrectomy, and rectal resection, respectively.[14] Facility and surgeon standards and guidelines established by the government and academic society might have contributed to the favorable outcomes. For example, surgeons who perform robotic surgery must be certified by the surgical skill qualification system of laparoscopic or thoracoscopic procedure.[1] Additionally, the surgical society-certified proctor must also supervise the initial series. This report might be useful for surgical societies and institutions where the introduction of robotic surgery for gastrointestinal cancer is being planned.

The advantages of robotic surgery over conventional minimally invasive surgery (CMIS) for malignant gastrointestinal tumors have not been confirmed. However, RE is reportedly superior to conventional minimally invasive esophagectomy in terms of short-term outcomes, such as the incidence of pneumonia and vocal cord palsy.[15] Compared with either or both of nationwide NCD surveys on conventional minimally invasive esophagectomy (n = 3515 by Takeuchi et al,[17] n = 12 711 by Yoshida et al[16]), pronounced that the benefits of RE were not observed in the incidences of pneumonia 13% in this study vs 13%–14% in previous studies) and recurrent laryngeal nerve palsy (18% in this study vs 10% in previous studies).[16,17] On the contrary, compared with these previous studies, relatively lower rates of operative mortality (0.9% in this study vs 1.7%–2.5% in previous studies), major bleeding ≥1000 mL (2.1% in this study vs 7.9% in previous studies), and unexpected postoperative intubation (1.8% in this study vs 5.6%–6.8%) were observed in patients undergoing RE. These results indicate that RE may have potential benefits in avoiding serious complications.

According to a large-scale Japanese prospective clinical trial and a meta-analysis, robotic gastrectomy was significantly associated with lower postoperative complications ≥CD grade III rates than CMIS.[19,20] Akagi et al analyzed the NCD and reported outcomes following laparoscopic distal gastrectomy performed by ESSQS-certified surgeons.[21] The incidence of postoperative complications ≥CD grade III and the operative mortality rates were 7.0% and 0.4%, respectively, while these rates were 4.0% and 0.2% in patients undergoing RDG (this study). Etoh et al[22] (n = 512) and Kodera et al[23] (Stage I: n = 3912, Stage II–IV: n = 1771) evaluated laparoscopic total gastrectomy outcomes using the NCD.[22,23] The incidence of postoperative complications ≥CD grade III and the operative mortality rate following conventional laparoscopic total gastrectomy ranged from 7.2%–10.3% and 0.4%–1.7%, respectively (6.7% and 0.4% in this study). Although these results demonstrated the potential benefits of RDG and RTG, the operative mortality rate following RPG was relatively high (2.8%). Since the sample size was small (n = 109) and the cause of death was unclear, safety was difficult to evaluate. RPG safety should be reexamined in the near future. In addition, the conversion rate to open surgery was 4.6% (11/236) in RTG. As the reasons for conversion were unclear, a complicated technique such as an approach around the esophageal hiatus and esophagojejunal anastomosis is needed for total gastrectomy. The conversion rate in RTG should be continuously monitored as well.

In terms of rectal cancer resection, although the advantages of robotic resection over CMIS in terms of open conversion in obese male patients and postoperative sexual dysfunction were reported, there were no significant differences in overall postoperative complications in several meta-analyses.[13,24] Akagi et al reported the outcomes following laparoscopic low anterior resection performed by ESSQS-certified surgeons and registered in the NCD (n = 12 866).[21] The incidence of postoperative complications ≥CD grade III was 15.1% in CMIS and was 7.5% in RLAR (this study). Operative mortality occurred in 0.3% who underwent CMIS and 0% in those who underwent RLAR (this study). Like other procedures, this study also supports the potential benefits of RLAR over CMIS. Currently, a Japanese multicenter prospective trial to evaluate oncological feasibility, such as negative circumferential resection margins following robotic rectal cancer resection, is ongoing (VITRUVIANO trial: UMIN000039685).

We believe that this study contributes to the following: enhancing social accountability of surgical societies, which have a responsibility to protect patients against the potential dangers of a novel procedure, enhancing evidence-based policy-making in the field of surgery, and planning large-scale prospective randomized or non-randomized studies to confirm the benefits of robotic surgery over CMIS. This study showed that in Japan the number of patients who underwent robotic gastrointestinal surgery in 2018 exceeded 3000. Using the data in 2019 from the NCD, we plan to perform a rigorous large-scale comparison of propensity score methods between robotic procedures and CMIS.

Taken together, robotic surgery for malignant gastrointestinal tumors was safely introduced into daily clinical practice along with rigorous surgeon and facility standards in Japan.

ACKNOWLEDGMENTS

We thank all data managers and hospitals for participating in the NCD project and their great effort in entering the data. We also thank all members of the Japanese Society of Gastroenterological Surgery and JSES.

DISCLOSURE

Funding: This study was funded by The Japanese Foundation for Research and Promotion of Endoscopy. The funding source had no role in the design, practice, or analysis of this study.

Conflict of Interest: Authors N.I. and H.M. belong to the Department of Healthcare Quality Assessment, which is a social collaboration department at the University of Tokyo supported by the National Clinical Database, Johnson & Johnson K.K., and Nipro Corporation. Author K.O. received lecture fees from Intuitive Surgical, G.K. Author Y.K. is Editor in Chief of the Annals of Gastroenterological Surgery. Authors M.I. and Y. K. are editorial board members of the Annals of Gastroenterological Surgery.

Ethics statements: The protocol for this research project was approved by a suitably constituted Ethics Committee of the institution and conforms to the provisions of the Declaration of Helsinki; Committee of Kyoto University, Approval No R1764. Informed consent was waived because of the study's retrospective nature.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

How to cite this article: Nishigori T, Ichihara N, Obama K, Uyama I, Miyata H, Inomata M, Prevalence and safety of robotic surgery for gastrointestinal malignant tumors in Japan. Ann Gastroenterol Surg. 2022;6:746–752. doi:10.1002/ags3.12579