








ORIGINAL ARTICLE

The clinical impact of COVID-19 on endoscopic surgery in Japan: Analysis of data from the National Clinical Database

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Abstract

Aim: This study aimed to evaluate the impact of the coronavirus disease (COVID-19) pandemic on elective endoscopic surgeries in Japan using the National Clinical Database.

Methods: We retrospectively analyzed the clinicopathological factors and surgical outcomes of laparoscopic cholecystectomy (LC), laparoscopic distal gastrectomy (LDG), and laparoscopic low anterior resection (LLAR) and compared the monthly numbers of each procedure performed in 2020 with those in 2018 and 2019. The degree of infection in prefectures was classified into low and high groups.

Results: In 2020, the number of LCs (except for acute cholecystitis) was 76 079 (93.0% of that in 2019), the number of LDGs was 14 271 (85.9% of that in 2019), and the number of LLARs was 19 570 (88.1% of that in 2019). Although the number of robot-assisted LDG and LLAR cases increased in 2020, the growth rate was mild compared with that in 2019. There was little difference in the number of cases in the degree of infection in the prefectures. The numbers of LC, LDG, and LLAR cases decreased from

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May to June and recovered gradually. In late 2020, the proportion of T4 and N2 cases of gastric cancer and the number of T4 cases of rectal cancer increased compared with those in 2019. There was little difference between the proportions of postoperative complications and mortality in the three procedures between 2019 and 2020.

Conclusion: The number of endoscopic surgeries decreased in 2020 as a result of the COVID-19 pandemic. However, the procedures were performed safely in Japan.

KEYWORDS

COVID-19, endoscopic surgery, gastric cancer, National Clinical Database, rectal cancer

1 | INTRODUCTION

Coronavirus disease (COVID-19) was reported as a mass infection of pneumonia in Wuhan, China, in December 2019 and spread worldwide.¹ A pandemic was declared on March 11, 2020, by the World Health Organization (WHO). The first positive patients were reported in Japan on January 15, 2020, and the infection spread rapidly.² The Japanese government announced an emergency declaration from April 2020 through May 2020. The COVID-19 pandemic had a major influence on not only normal medical treatment but also surgical treatment.

Endoscopic surgery, such as laparoscopic surgery, causes aerosol development through the pneumoperitoneum and an energy device; therefore, many surgical societies do not recommend endoscopic surgery. The American College of Surgeons recommended that we consider avoiding laparoscopic surgery.³ In the Society of American Gastrointestinal and Endoscopic Surgery and European Association for Endoscopic Surgery joint recommendation for minimally invasive surgeries, the use of devices in filtering the released CO₂ for aerosolized particles should be strongly considered.⁴ Units have cautiously re-established laparoscopy when all criteria are met, as recommended by the Royal College of Surgeons.⁵ According to the Japan Surgical Society guidelines, we should recognize that laparoscopic surgery causes aerosol development, and we should only perform it after confirming the conditions, such as having a highly precise filter and effluent gas device.⁶

During the COVID-19 pandemic, medical materials and surgical instruments necessary for endoscopic surgery were insufficient due to the challenges in transportation. Furthermore, owing to the movement restrictions that exceeded prefecture and entrance restrictions to hospitals, proctors and specialized suppliers could not enter the operating room. Therefore, the introduction and enforcement of new endoscopic surgeries, such as robot-assisted surgery, were difficult.

Considered together, the COVID-19 pandemic was believed to have an influence on endoscopic surgeries. In particular, 2020 was the early stage of spreading the unknown virus, severe acute respiratory syndrome coronavirus 2; no vaccine had been developed against COVID-19, and an emergency was announced for the first time. In addition, movement restrictions were in place, and the distribution of medical supplies was also affected; thus, it was thought that the impact would be large. However, the influence and nature of

the influence of COVID-19 pandemic on endoscopic surgery remain unclear. Therefore, this study aimed to investigate the impact of the COVID-19 pandemic on elective endoscopic surgeries in Japan using the National Clinical Database (NCD).

2 | METHODS

This study was performed by analyzing essential data extracted from the NCD, a nationwide registry system in Japan that has been linked with the surgical board certification system since 2011. Details on data registration in the Japanese NCD system were described previously.⁷ As of 2018, over 5000 institutions had participated in this system, with approximately 1.5 million surgical cases registered annually. All surgical cases are registered in the NCD, and details, including morbidities, comorbidities, postoperative complications, and mortalities, are added to the system.

Cholecystectomy, distal gastrectomy (DG), and low anterior resection (LAR) were selected. The most common endoscopic surgeries in Japan are for the gallbladder, colorectum, and stomach.⁸ Cholecystectomy is a typical operation for benign disease of the gallbladder. DG and LAR were selected as surgical operations for malignant disease. Cholecystectomy was divided into two groups: cholecystectomy for acute cholecystitis and cholecystectomy for reasons other than acute cholecystitis (except acute cholecystitis). In total, 321 131 cases of cholecystectomy, 94 208 cases of DG, and 61 869 cases of LAR were registered in the NCD between 2018 and 2020. Among them, patients aged <18 years and patients who underwent emergent surgeries were excluded from this study. Furthermore, in DG and LAR, benign disease, malignant disease of organs other than the stomach, and diseases in which tumor depth (T) or node metastasis (N) were not clear were excluded from this study. Incomplete data on 48 cases of cholecystectomy, 35 cases of DG, and 18 cases of LAR were also excluded (Figure 1).

2.1 | Classification of prefectures according to the degree of infection

The degree of infection was indicated by the cumulative number of infected people per population of prefectures at the end of 2020.⁹

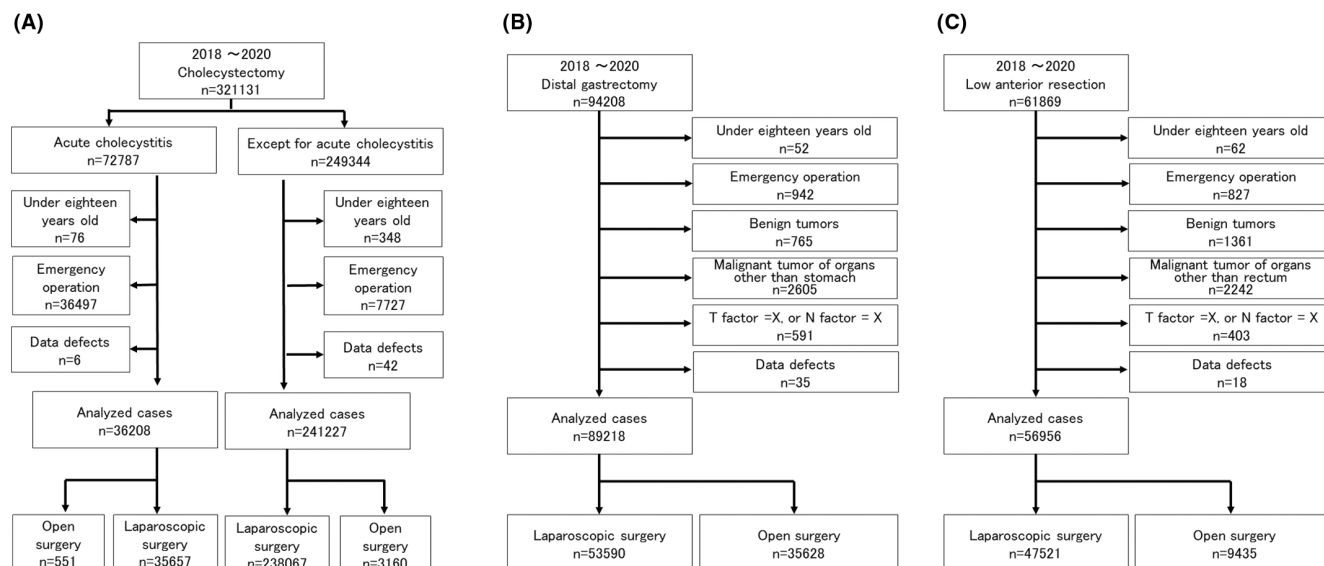


FIGURE 1 Flowchart detailing the patient's selection process. (A) Laparoscopic cholecystectomy. (B) Laparoscopic distal gastrectomy. (C) Laparoscopic low anterior resection.

	Number of operations (2018)	Number of operations (2019)	Number of operations (2020)	Vs. 2018 (%)	Vs. 2019 (%)
Cholecystectomy for acute cholecystitis					
Open	195	188	168	86.2	89.4
Laparoscopic	11800	11744	12131	102.8	103.3
Cholecystectomy except for acute cholecystitis					
Open	1177	1149	834	70.8	72.6
Laparoscopic	80177	81811	76079	94.9	93.0
Distal gastrectomy					
Open	13531	12085	10012	74.0	82.8
Laparoscopic	16895	16610	14271	84.5	85.9
Robot assisted	1159	2102	2553	220.2	121.5
Low anterior resection					
Open	3732	3159	2544	68.2	80.5
Laparoscopic	14308	13977	12316	86.1	88.1
Robot assisted	1012	2448	3460	341.9	141.3

TABLE 1 Numbers of surgeries.

Based on this value, the degree of infection in prefectures was classified into two groups: high and low groups. The high group consisted of 12 prefectures, namely Aichi, Chiba, Fukuoka, Hokkaido, Hyogo, Kanagawa, Kyoto, Nara, Okinawa, Osaka, Saitama, and Tokyo, whereas the low group comprised all other prefectures.

2.2 | Study endpoint

The primary outcome measure of this study was the impact of the COVID-19 pandemic on endoscopic surgery. The total number of each procedure performed in 2020 was analyzed monthly and

compared with those in 2018 and 2019. The secondary outcome was the impact of the COVID-19 pandemic on overall postoperative complications (more than grade-III, according to the Clavien–Dindo classification in cholecystectomy).

2.3 | Clinical factors

The clinical factors included age at surgery (<65, 65–75, and >75 years); sex (male or female); occurrence of preoperative chemotherapy, American Society of Anesthesiologists physical status (ASA-PS: 1, 2, and 3–5); and clinical T, N, and distant metastasis (M)

stages. The 7th edition of the American Joint Committee on Cancer TNM classification was used to extract representative T, N, and M. A comparative analysis was conducted between groups in terms of the duration of surgery, intraoperative blood loss, overall complication, postoperative hospital stays, and operative mortality.

The study protocol was approved by the institutional review board of Oita University (approval number: 2147). This study was conducted in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments.

3 | RESULTS

3.1 | The annual number of each procedure

Table 1 summarizes the number of occurrences of each procedure. The number of open cholecystectomies (OCs) for acute cholecystitis in 2020 was 168 (86.2% of that in 2018 and 89.4% of that in 2019), and the number of laparoscopic cholecystectomies (LCs) for acute cholecystitis in 2020 was 12 131 (102.8% of that in 2018 and 103.3% of that in 2019). Further, the number of OCs (except acute cholecystitis) in 2020 was 834 (70.8% of that in 2018 and 72.6% of that in 2019), and the number of LCs (except for acute cholecystitis) in 2020 was 76 079 (94.8% of that in 2018 and 92.6% of that in 2019). Regarding DG, the number of open surgeries (ODGs) in 2020 was 10 012 (74.0% of that in 2019 and 82.8% of that in 2019). The number of LDGs in 2020 was 14 271 (84.5% of that in 2018 and 85.9% of that in 2019). In addition, the number of robot-assisted distal gastrectomies (RDGs) in 2020 was 2553 (220.2% of that in 2018 and 121.5% of that in 2019). The number of open low anterior resections (OLARs) in 2020 was 2544 (68.2% of that in 2018 and 80.5% of that in 2019), and the number of LLARs in 2020 was 12 316 (86.1% of that in 2018 and 88.1% of that in 2019). The number of robot-assisted low anterior resections (RLARs) in 2020 was 3460 (341.9% of that in 2018 and 141.3% of that in 2019).

3.2 | Comparison of each prefecture according to the degree of infection

Table 2 summarizes the number of each procedure by the degree of infection in the prefectures. In cholecystectomy for acute cholecystitis, cholecystectomy (except acute cholecystitis), distal gastrectomy, and low anterior resection, there was little difference in the number of cases according to the degree of infection in the prefecture.

3.3 | Trends in the monthly volume of each procedure (2018–2020)

The number of OCs for acute cholecystitis decreased in May 2020 and recovered in the following August. The number of LCs for acute cholecystitis did not change (**Figure 2**).

The number of OCs, except acute cholecystitis, decreased after May 2020, while the number of LCs (except acute cholecystitis) decreased in May 2020 and recovered in July 2020.

The number of LDGs decreased from May to July and gradually recovered. In addition, the number of RDGs in 2020 was greater than that in 2019 until April but reached the same number as that in 2019 after May. The number of ODGs slightly decreased in May 2020.

The number of LLARs decreased in May 2020 and gradually recovered, while the number of RLARs increased each year, but the growth rate decreased between May and August 2020. We also observed that the number of OLARs slightly decreased in May 2020.

3.4 | Trends in the monthly proportions of clinicopathological features (2018–2020)

Considering LC for acute cholecystitis, LC (except for acute cholecystitis), and LDG, the proportion of elderly patients and ASA3–5 patients increased in 2020. Each surgery type increased in stages, and the proportion of the increase was the same as that in the previous year. In patients who underwent LLAR, the proportion of elderly patients and ASA3–5 patients did not change in 2020 (**Figure 3**; **Table S1**).

The proportion of patients who underwent LDG with preoperative chemotherapy increased after June 2020. The proportion of those who underwent LLAR with preoperative chemotherapy increased after July 2020 (**Figure 3**).

Further, the proportion of T4a, T4b, or N3b patients who underwent LDG increased in the second half of 2020 (**Figure 4**).

In patients who underwent LLAR, the proportion of T4b patients increased in the second half of 2020.

3.5 | Trends in the monthly proportions of postoperative complications and mortality (2018–2020)

The proportion of complications after undergoing LC, postoperative complications and mortality of LDG, and postoperative complications and mortality of patients who underwent LLAR did not differ in 2019 and 2020 (**Table S2**).

4 | DISCUSSION

Our study showed the impact of the COVID-19 pandemic on endoscopic surgery in Japan using the NCD database. We evaluated the number of endoscopic surgeries, such as LC, LDG, and LLAR, and the postoperative complications of these procedures in 2020, compared with those in 2018 and 2019. In 2020, the number of COVID-19 cases was milder than in 2021, but it seems significant that in the

TABLE 2 Numbers of surgeries according to degree of infection.

	Number of operations (2018)	Number of operations (2019)	Number of operations (2020)	Vs. 2018 (%)	Vs. 2019 (%)
<i>High group</i>					
Cholecystectomy for acute cholecystitis					
Open	111	117	94	84.7	80.3
Laparoscopic	6546	6668	6801	103.9	102.0
Cholecystectomy except for acute cholecystitis					
Open	648	648	472	72.8	72.8
Laparoscopic	46864	47837	43858	93.6	91.7
Distal gastrectomy					
Open	6928	6176	5055	73.0	81.8
Laparoscopic	9844	9585	7931	80.6	82.7
Robot assisted	708	1306	1609	227.3	123.2
Low anterior resection					
Open	1905	1546	1227	64.4	79.4
Laparoscopic	8599	8450	7254	84.4	85.8
Robot assisted	640	1612	2283	356.7	141.6
<i>Low group</i>					
Cholecystectomy for acute cholecystitis					
Open	94	84	71	75.5	84.5
Laparoscopic	6801	5254	5058	74.4	96.3
Cholecystectomy except for cholecystolithiasis					
Open	529	501	362	68.4	72.3
Laparoscopic	33313	33974	32221	96.7	94.8
Distal gastrectomy					
Open	6603	5909	4957	75.1	83.9
Laparoscopic	7051	7025	6340	89.9	90.2
Robot assisted	451	796	944	142.8	118.6
Low anterior resection					
Open	1827	1613	1317	72.1	81.6
Laparoscopic	5709	5527	5062	88.7	91.6
Robot assisted	372	836	1177	316.4	140.8

early days of the COVID-19 pandemic, we had to deal with a lack of knowledge about COVID-19 and vaccines. In the present study, we focused on cholecystectomy, DG, and LAR. In the gastrointestinal surgery subset of the NCD, detailed data are entered for the following eight surgeries: esophagectomy, distal gastrectomy, total gastrectomy, right hemicolectomy, low anterior resection, hepatectomy, pancreaticoduodenectomy, and surgery for acute diffuse peritonitis.¹⁰ DG is a typical procedure in gastric surgery and one of the eight surgeries. The colorectal area includes several typical surgical procedures. Endoscopic surgery is performed more often for rectal cancer than for colon cancer, and robot-assisted surgery for rectal cancer was covered by insurance since 2018.⁸ LAR was selected for the colorectal area, as it is one of the eight surgeries, and there was a need to consider the impact of COVID-19 on robot-assisted surgery.

We found that the number of LCs (except for acute cholecystitis), LDGs, and LLARs decreased in the early stage of the COVID-19

pandemic and gradually recovered, although with no difference in the degree of infection in the prefecture. In late 2020, the proportion of T4 and N2 cases of gastric cancer increased, and the number of T4 cases of rectal cancer increased. Moreover, postoperative complications and mortality did not differ.

During the first wave of the COVID-19 pandemic, non-critical surgeries showed declines in the number of cases, except for oncological and critical surgeries.¹¹ In the analysis from the NCD, the numbers of most oncological procedures decreased in 2020, except for pancreaticoduodenectomy.⁹ During the COVID-19 pandemic, cancer screening using upper gastrointestinal endoscopy and colonoscopy was reported to decrease¹² and was considered to be a reason for the decrease in the number of gastrectomies or anterior resections of the rectum.¹¹ Moreover, surgery for early gastric cancer and rectal cancer decreased due to the detection of early cancer by screening,^{13,14} but the possibility that cancer deaths increased

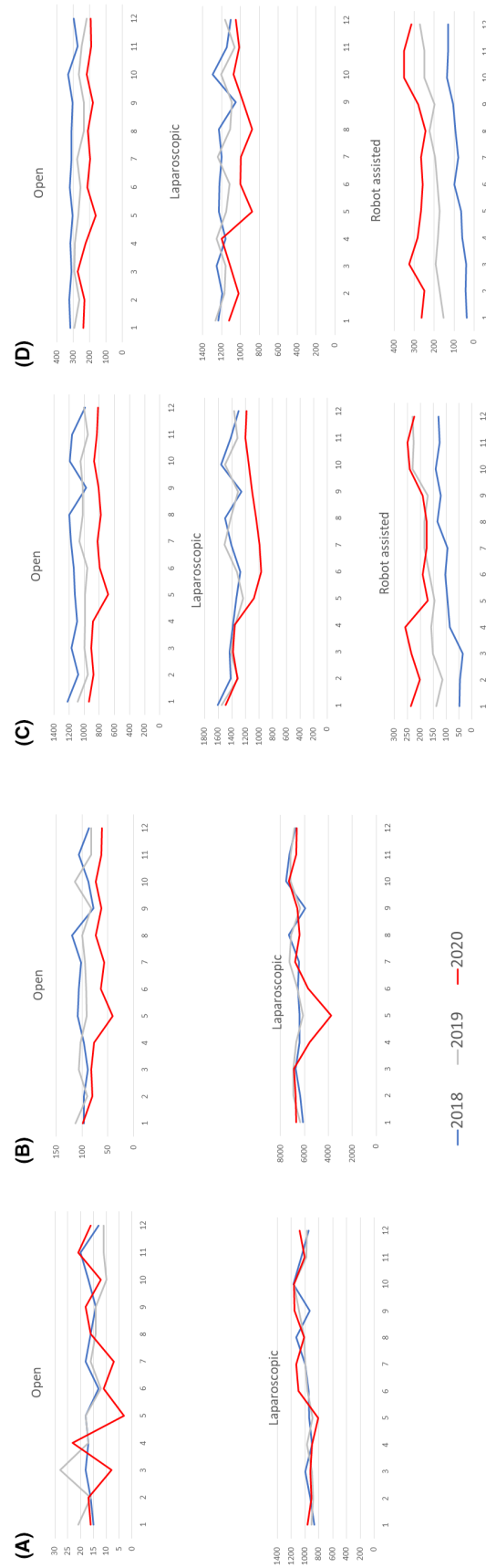


FIGURE 2 The trend in the monthly volume of each procedure. (A) Cholecystectomy for acute cholecystitis. (B) Cholecystectomy except for acute cholecystitis. (C) Distal gastrectomy. (D) Low anterior resection in the high group.

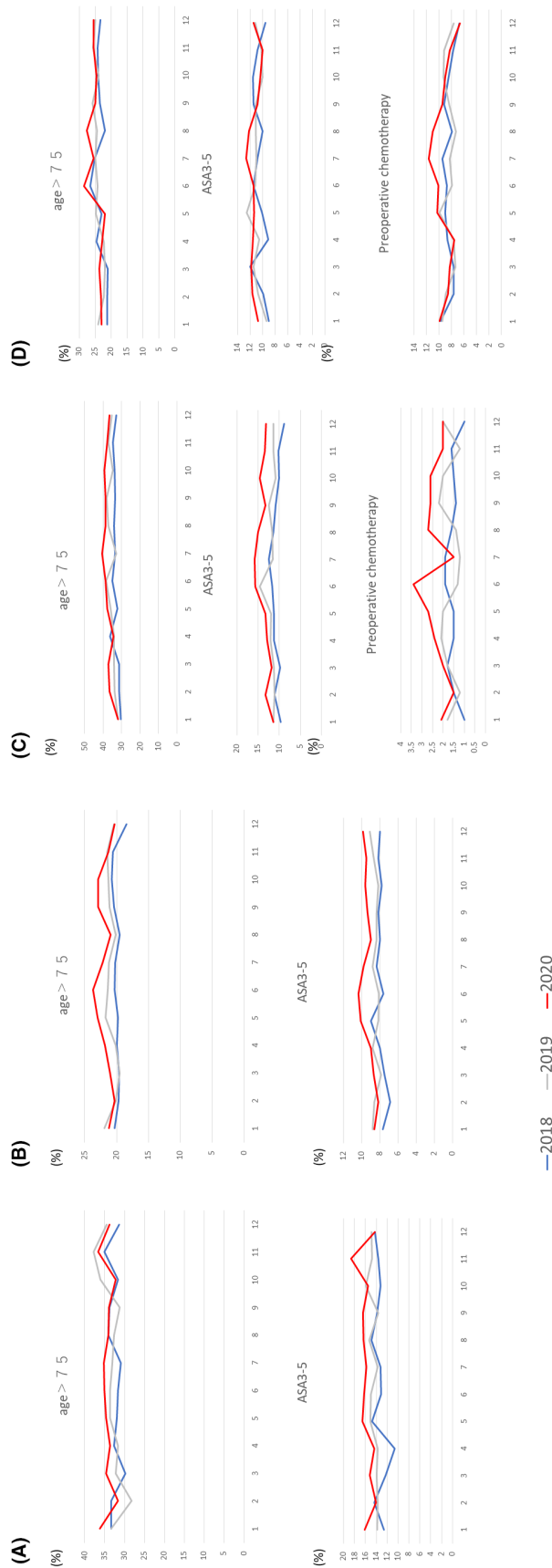


FIGURE 3 The monthly trend of the background of patients. (A) Background of patients with LC (except for acute cholecystitis). (B) Background of patients with LLAR. LC, laparoscopic cholecystectomy; LDG, laparoscopic distal gastrectomy; LLAR, laparoscopic low anterior resection.

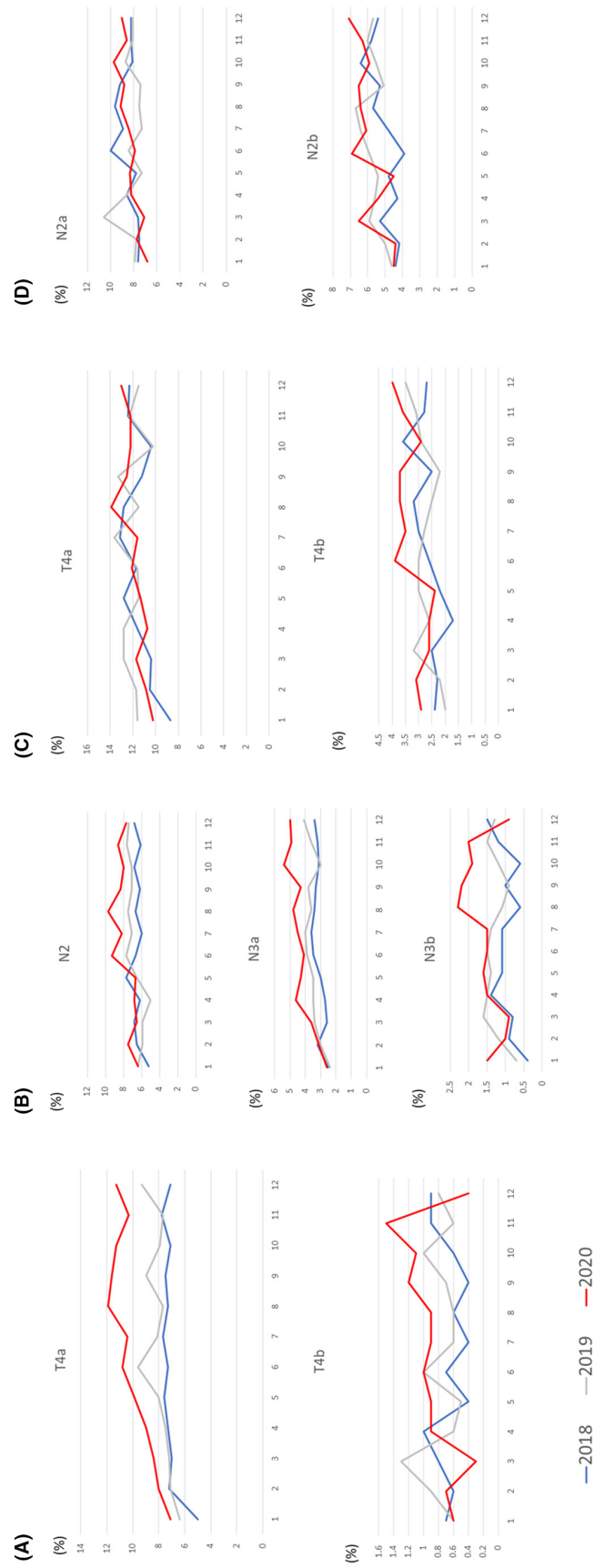


FIGURE 4 The monthly trend of tumor characteristics. (A) T factor of patients with LDG. (B) N factor of patients with LDG. (C) T factor of patients with LLAR. (D) N factor of patients with LLAR. LDG, laparoscopic distal gastrectomy; LLAR, laparoscopic low anterior resection.

due to a delay in diagnosis during the COVID-19 pandemic has been described.^{15,16}

Although the number of LCs (except for acute cholecystitis), LDG, and LLAR decreased in 2020, the number of LCs for acute cholecystitis did not decrease. Regarding cholecystectomy, its number decreased in many countries.¹⁷ One of the reasons for this decrease was considered to be the increase in non-surgical treatment options for acute cholecystitis.^{18,19} On the other hand, LC remains the treatment of choice for acute cholecystitis, even during the COVID-19 pandemic.²⁰ In this study, although the number of LCs (except for acute cholecystitis) decreased, the number of LCs for acute cholecystitis did not decrease. For acute cholecystitis, laparoscopic surgery is widely considered after non-surgical treatment. The number of robot-assisted surgeries slightly increased, but the growth rate was low compared with that of the previous year. In Japan, robot-assisted surgery for gastric cancer and rectal cancer was covered by insurance in 2018. Until 2019, robotic surgery for both gastrectomy and rectal resection was on the rise, while open surgery was on the decline. In DG, ODG and LDG decreased, and RDG increased less. In LAR, OLAR was highly reduced, LLAR was slightly reduced, and RLAR was increased, but the rate of increase was low. In LAR, the transition from OLAR to LLAR and RLAR was more advanced than in DG.

The number of LCs (except for acute cholecystitis), LDGs, and LLARs decreased between May and June 2020. In May 2020, a state of emergency was declared in Japan, the supply of medical materials was affected, and movement restrictions and triage were developed according to the recommendations of an academic society; these were all regarded as major causes of the decrease in the number of surgical procedures. In DG, LDG gradually recovered from May, but RDG showed the same trend as the previous year. It is possible that few new facilities were introduced due to restrictions on the movement of proctors. In LAR, OLAR and LLAR gradually recovered after decreasing, and although RLAR was slightly low from May to August, the number of cases remained higher than in the previous year, possibly because the shift to RLAR was progressing. To deal with this situation, emergency preparedness, such as strategic reserves of personal protective equipment and surgical devices, is considered important. A remote operation supporting system should also be established.

There were slight differences in the degrees of infection in the prefectures. In the early stage of the COVID-19 pandemic, the declaration of a state of emergency, relative shortage of medical supplies, and surgical triage also seemed to be major causes of the increase in the number of infected patients. In the analysis of data from the NCD, the reduction in low anterior resection during the early stage of the COVID-19 pandemic was greater in the high group than in the low group.¹¹ The reason for this finding may be the division into high, medium, and low groups in the study.

Regarding patient characteristics, in LC and DG, the proportion of elderly patients and high-risk patients (ASA3–5) slightly increased in 2020. However, the proportion increased each year, and whether the COVID-19 pandemic affected these ratios remains unknown. Patients who underwent preoperative chemotherapy for gastric and

rectal cancers increased between June and July 2020. The reason for the increase in preoperative chemotherapy may have been attributed to surgeons abiding by COVID-19 guidelines.²¹

In late 2020, the proportion of T4 and N2 cases of gastric cancer in our study increased, and the number of T4 cases of rectal cancer increased; these cases may have increased because patients did not undergo cancer screening or consultation at a hospital during this time period. There were more patients with gastric and rectal cancer who underwent preoperative chemotherapy in 2020 compared with those in 2019.

In Japan, based on the announcement by each surgical society, infection prevention measures and the proper use of medical resources were observed, and surgical triage for the prevention of outcome exacerbation was performed in many hospitals.^{4–6} As a result, although the number of elective laparoscopic surgeries decreased, there was no exacerbation of surgical outcomes.

The proportion of postoperative complications and mortality of patients who underwent laparoscopic surgery ultimately did not differ in 2019 and 2020. Patients with perioperative COVID-19 are at an increased risk of adverse events, including postoperative pulmonary complications and mortality.²² The preoperative screening revealed only a few patients with COVID-19.

This study has some limitations. First, the number of included patients with COVID-19 was unknown; thus, we cannot evaluate the effect of COVID-19 on postoperative complications. In addition, it is unknown whether the healthcare providers were infected, and hence the effect of the aerosol is unknown. However, there seem to be fewer cases of elective surgery in patients with COVID-19 because preoperative screening is typically performed frequently in Japan. Second, all emergency surgeries were excluded, and these data can only be applied to elective surgeries. For locally advanced cancer associated with bleeding or stenosis, emergency surgery may be required. Therefore, surgical outcomes for all locally advanced cancer were not evaluated. Finally, the long-term outcome was not investigated in this study. It is considered that the delay of treatment by a triage of surgery will appear as a prognosis after several years. Thus, further investigation is necessary to precisely evaluate the impact of the COVID-19 pandemic on the outcome of surgeries for gastric and rectal cancer.

In conclusion, the number of endoscopic surgeries decreased in the early stage of the COVID-19 pandemic and gradually recovered, with little difference in the degrees of infection in the prefectures. Furthermore, the shift to robotic surgery is gradually progressing during the COVID-19 pandemic. Patients who underwent preoperative chemotherapy for gastric and rectal cancers increased, and patients with advanced gastric and rectal cancers increased. However, postoperative complications and mortality did not differ.

AUTHOR CONTRIBUTIONS

Study concepts, design, and data interpretation: all authors. Data acquisition and analysis: Hideki Endo, Hiroyuki Yamamoto, Hiroaki Miyata. Article preparation: all authors. Article review: Yoshihiro Kakeji, Yuko Kitagawa, Akinobu Taketomi, Masaki Mori.

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CONFLICT OF INTEREST STATEMENT

HE, HY, and HM are affiliated with the Department of Healthcare Quality Assessment at the University of Tokyo. The department is a social collaboration department supported by National Clinical Database, Johnson & Johnson K.K., and Nipro Corporation. Masafumi Inomata is an Editorial Board Member of *Annals of Gastroenterological Surgery* dealing with the lower digestive tract. Susumu Eguchi is an Editorial Board Member of *Annals of Gastroenterological Surgery* dealing with the hepato-biliary-pancreatic. Yukinori Kurokawa is an Associate Editor of *Annals of Gastroenterological Surgery* dealing with the upper digestive tract. Yoshihiko Kakeji is an Associate Editor of *Annals of Gastroenterological Surgery* dealing with the lower digestive tract. Yuko Kitagawa is an Editor-in-Chief of *Annals of Gastroenterological Surgery*. Masaki Mori is an Emeritus Editor-in-Chief of *Annals of Gastroenterological Surgery*. The remaining authors declare no conflicts of interest for this article.

ETHICS STATEMENT

Approval of research protocol: The study protocol was approved by the institutional review board of Oita University (approval number: 2147). Informed consent: N/A. Registry and the Registration No. of the study/trial: N/A. Animal Studies: N/A.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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