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ORIGINAL ARTICLE

The impact of COVID-19 for postoperative outcomes using a nationwide Japanese database of patients undergoing distal gastrectomy for gastric cancer

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Abstract

Background: The coronavirus disease 2019 (COVID-19) pandemic had resulted in either failure to provide required medical resources or delayed treatment for gastric cancer patients. This study aimed to investigate the impact of COVID-19 on the incidence of postoperative complications using a nationwide Japanese database of patients undergoing distal gastrectomy for gastric cancer.

Methods: We collected the data of patients who underwent distal gastrectomy from January 2018 to December 2021 from the National Clinical Database (NCD), a web-based surgical registration system in Japan. The number of surgical cases, the use of intensive care units, and the incidence of morbidity per month were analyzed. We also calculated the standardized mortality ratio (SMR), defined as the ratio of the number of observed patients to the expected number of patients calculated using the risk calculator established in the NCD, for several morbidities, including pneumonia, sepsis, 30-day mortality, and surgical mortality.

Results: A decrease of 568 gastrectomies was observed from April 2020 to May 2020. Although the absolute number of patients admitted to intensive care units had declined since 2020, the proportion of patients admitted to the ICU did not change before and after the pandemic. Mortality and critical morbidity (such as pneumonia and sepsis) rates were not worse during the pandemic compared to pre-pandemic periods per the SMR.

Conclusions: Surgical management was conducted adequately through the organized efforts of the entire surgery department in our country even in a pandemic during which medical resources and staff may have been limited.

KEYWORDS
COVID-19, gastrectomy, gastric cancer, pandemic, surgical outcome

1 | INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic, which first began in Wuhan, China, rapidly spread worldwide and changed all aspects of daily life.[1] Coronavirus types diversified during the pandemic and still continue to exist worldwide. This dramatically adversely affects the surgical fields. A previous study estimated that 81.7% of operations for benign conditions and 37.7% of operations for malignant conditions will be either canceled or postponed globally during this pandemic.[2] Japan had experienced seven waves of COVID-19 as of November 18, 2022, to date. We faced the first wave in March 2020, and the national government declared the first state of emergency, urging people to avoid unnecessary physical contact and keep a social distance.[3] The Japanese Surgical Society (JSS, which consists of 10 major surgical societies in Japan) announced the importance of surgical triage according to the severity of illness on April 1, 2020. They showed the three urgency levels based on the severity of the surgical intervention and recommend postponing surgical operations if they were not emergencies to save medical resources and prevent nosocomial infections. This resulted in a significant reduction in the number of surgical operations, and an analysis using Japanese nationwide data showed a 10%–15% reduction in the number of gastrointestinal operations during the COVID-19 pandemic.[4,5] Another recent study also reported a marked reduction in the number of surgical operations for gastric and rectal cancer with early T factors.[6]

Gastric cancer is the second-highest cause of cancer-related death all over the world, and the incidence of this malignancy is highest in Eastern Asia, particularly in Japan and Korea.[7] In spite of improvements in non-surgical treatment such as immune checkpoint inhibitors, the most promising curative therapy for gastric cancer to achieve long-term survival is gastrectomy. In Japan, more than 30000 distal gastrectomies are performed annually on gastric cancer patients. However, because of the aging of the population, the number of patients who are elderly and have several comorbidities is increasing, and the operative mortality rate stands at approximately 1.5%.[8]

Undoubtedly, adequate surgical staff and medical resources, including labor, space, and equipment, are necessary to provide adequate perioperative management or to prevent failure to rescue.[9–11] However, the COVID-19 pandemic may have resulted in failure to provide these resources or in the delay of treatment for gastric cancer patients, resulting in worse surgical outcomes. Moreover, previous studies have shown that higher rates of mortality and pulmonary complications were identified in patients with perioperative COVID-19 infection.[12–15] This study aimed to investigate the impact of COVID-19 on medical resources, such as the use of intensive care units, and postoperative complications using a Japanese nationwide database of patients undergoing distal gastrectomy for gastric cancer.

2 | METHODS

2.1 | Patients

We collected the data of patients who underwent distal gastrectomy from January 2018 to December 2021 from the National Clinical Database (NCD), a web-based surgical registration system in Japan. The NCD has much data on not only clinicopathological factors but also patients' short-term outcomes for various fields of surgery. More than 14 million procedures, accounting for more than 90% of all surgical operations performed in our country, have been registered by approximately 5000 hospitals.[4,16] To investigate the impact of the COVID-19 pandemic on gastric cancer treatment, the number of surgical cases, the use of intensive care units, and the incidence of morbidity/mortality per month were analyzed using the NCD. There being no concrete definition of intensive care unit in the NCD, we defined intensive care unit as a ward that can provide the most intensive medical care available in the hospital, as determined by each surgeon. We excluded patients with benign tumors, those with tumors of other organs, those aged <18 years, those who underwent emergency surgery, those with T0 or Tis gastric tumors, and those with missing data from our analysis (Figure S1-S2). We evaluated the prevalence of several causes of morbidity (including pneumonia and sepsis), 30-day mortality, and operative mortality. Pneumonia was diagnosed based on the presence of an abnormal shadow in the chest X-ray or chest computed tomography, or based on postoperative sputum culture positivity. Operative mortality was defined as death within 30 days of surgery or hospitalized death within 90 days. The cancer stage was determined per the TNM classification.[17] The protocol for this study was reviewed and adopted by the Japanese Society of Gastrointestinal Surgery Committee and approved by the Institutional Review Board of Kochi Medical School (ID: 2022–75), and individual written informed consent was waived.

2.2 | Categorization of prefectures according to the degree of infection

In addition to investigations conducted on the data for all 47 prefectures, the data for 12 prefectures (Aichi, Chiba, Fukuoka, Hokkaido, Hyogo, Kanagawa, Kyoto, Nara, Okinawa, Osaka, Saitama, and Tokyo) with a high cumulative number of infections per population (defined as epidemic areas) were also evaluated to clarify the relationship between short-term outcomes and the infectious level in our country.[3] The period of the infectious wave was classified according to changes in the number of people infected on a single day in Japan. The first wave ran from March 1, 2020, to the end of June 2020. This was followed by the period from July 1, 2020, to the end of October 2020, and then from November 1, 2020, to the end of February 2021, from March 1, 2021, to the end of June 2021, and from July 1, 2021, to the end of December 2021 (end of the study

period); these periods were defined as the second, third, fourth, and fifth infection waves, respectively.[18,19]

2.3 | Statistical analysis

The longitudinal graph was visualized using Stata/BE 17 for Mac (StataCorp), and all statistical analyses were performed using R version 4.1.2 (2021; R Foundation for Statistical Computing). Moreover, the standardized mortality and morbidity ratio (SMR) was defined as the ratio of the observed number of patients to the expected number of patients who experienced complications, and this ratio was used to investigate the trend in risk-adjusted outcomes. Expected morbidity and mortality rates for each month were calculated using a risk calculator established by a previous study based on NCD data. In detail, the 30-day and operative mortality models were constructed by 17 and 21 clinical risk factors, respectively. Thirteen factors, including age, activities of daily life before surgery, cerebrovascular disease history, weight loss, uncontrolled ascites, high American Society of Anesthesiologists scores, leukocytosis, anemia, low albuminemia, high alkaline phosphatase levels, high creatinine levels, hyponatremia, and abnormal coagulation, overlapped. The models for pneumonia and sepsis were also constructed using similar variables such as sex, age, activities of daily life before surgery, comorbidities, and abnormal hematological findings based on logistic regression analyses.[20] There is a significant difference between the observed number of patients and the expected number of patients if the 95% confidence interval does not contain 1.

3 | RESULTS

3.1 | The number of patients who underwent gastrectomy

Of all 122450 patients who underwent distal gastrectomy from 2018 to 2021, 115228 patients who met our selection criteria were included in this study. The number of patients who underwent distal gastrectomy is shown in Figure 1 and Table 1. We visually recognized that the number of gastrectomies performed between May 2020 and September 2020 was remarkably lower than the number performed during other periods (Figure 1). In particular, a decrease of 568 cases (22.8%) was observed from April 2020 to May 2020 (2487 cases to 1919 cases), when JSS advocated for hospitals to control the number of surgical operations performed. Subsequently, the declining trend was reversed; however, the numbers have not returned to pre-pandemic conditions. The patients in epidemic areas also demonstrated similar tendencies to those in all prefectures, and a decrease of 354 cases was observed from April 2020 to May 2020 in the epidemic areas (1396 cases to 1042 cases). The proportions of elderly patients aged above 70 years, advanced cancer patients (T2 or higher), and patients at the lymph node stage were also evaluated, and these rates were found to increase significantly between June 2020 and December 2020 (Figure S1-S2).

3.2 | The proportion of admission to intensive care units after surgery

The average proportions of patients who were admitted to intensive care units were 34.7%, 35.5%, 36.1%, and 36.6% in 2018, 2019, 2020, and 2021, respectively. Although the proportion appears to have leveled off, the absolute number of patients admitted to intensive care units reduced significantly since 2020 (10881 patients in 2018, 10843 in 2019, 9634 in 2020, and 9739 in 2021). The whole trend was lower among patients admitted to intensive care units in epidemic areas than among those in all prefectures. The proportions of admitted patients in epidemic areas were also similar between the pre-pandemic and pandemic periods (33.0%, 34.3%, 33.7%, and 34.4% in 2018, 2019, 2020, and 2021, respectively). The graph trend suggests that the decline in ICU use was more critical in epidemic areas than in the prefectures overall. Although similar trends were identified among patients admitted to ICUs for more than 2 days, the proportion was remarkably decreased during the first wave both in all prefectures and in epidemic areas. The data are shown in Table S1-S2 and Figure 2.

3.3 | The standardized mortality and morbidity ratio

The average rates of sepsis, pneumonia, 30-day mortality, and operative mortality were 0.8%, 2.9%, 0.6%, and 0.9%, respectively. No remarkable changes in the rates of morbidity and mortality were observed between the various years. The SMR of these morbidities was calculated for each month to investigate the impact of the COVID-19 pandemic objectively. The incidence of sepsis was significantly higher than expected in November 2020 and September 2021, whereas it was significantly lower than expected in April 2020. The incidence of pneumonia was within expectations, with the exception of May 2020. The 30-day mortality was significantly higher than expected in October 2020 and September 2021, after the pandemic. Although they were not significant, similar tendencies were observed for operative mortality.

Among patients who underwent gastrectomy in epidemic areas, the incidence rates of sepsis and pneumonia were significantly higher than expected in November 2020 and July 2021, respectively, whereas the incidence of pneumonia was significantly lower than expected in May 2020. Although significant differences in the 30-day and operative mortality were observed only in October 2020, there was no significant difference in the observed mortality rate and expected mortality during most periods of the pandemic. The SMR and these 95% confidence intervals are shown in Figures 3 and 4 and Table S1-S2.

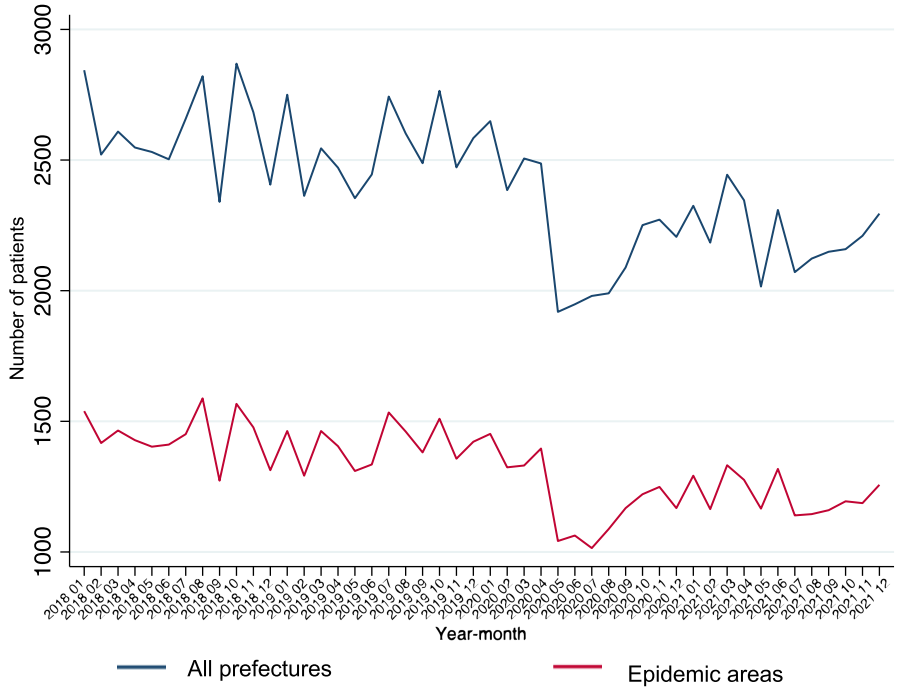

FIGURE 1 Trends in the number of patients undergoing gastrectomy. Blue and red solid lines indicate the number of patients who underwent gastrectomy in all 47 prefectures and the number of patients who underwent gastrectomy in epidemic areas, respectively.

TABLE 1 Number of patients undergoing distal gastrectomy for primary cancers.

		Month											
Year	Total	Jan.	Feb.	Mar.	Apr.	May	Jun	Jul.	Aug	Sep.	Oct.	Nov.	Dec.
All prefectures													
2018	31 333	2844	2521	2609	2548	2531	2503	2658	2821	2340	2869	2683	2406
2019	30 582	2750	2363	2545	2471	2354	2445	2743	2602	2488	2765	2472	2584
2020	26 682	2649	2385	2506	2487	1919	1948	1980	1990	2089	2251	2272	2206
2021	26 631	2325	2184	2444	2346	2016	2309	2071	2123	2149	2159	2210	2295
Epidemic area													
2018	17 332	1539	1417	1465	1428	1403	1411	1451	1588	1273	1567	1477	1313
2019	16 933	1463	1292	1463	1405	1310	1335	1534	1461	1381	1510	1357	1422
2020	14 517	1452	1324	1331	1396	1042	1063	1015	1088	1168	1221	1249	1168
2021	14 631	1292	1164	1332	1276	1166	1318	1140	1145	1160	1194	1187	1257

Note: Epidemic area: Aichi, Chiba, Fukuoka, Hokkaido, Hyogo, Kanagawa, Kyoto, Nara, Okinawa, Osaka, Saitama, and Tokyo, where there is a high cumulative number of infections per population.

4 | DISCUSSION

According to the findings of this study using the NCD, distal gastrectomy could be performed for gastric cancer patients safely without increasing the mortality rate even during a pandemic. Mortality and critical morbidity (such as pneumonia and sepsis) rates were not worse during the pandemic than during pre-pandemic periods, showing that surgical management was conducted adequately despite the limited medical resource and staff that were available during the pandemic. Furthermore, these results did not differ significantly between all 47 prefectures and epidemic areas where there is a high transmission rate of COVID-19. To the best of our knowledge, this is the first study to clarify the appropriate perioperative management for gastrectomy that could be conducted during the pandemic in Japan.

Several studies have demonstrated the negative impact of the COVID-19 pandemic on cancer treatment, including the reduction in the number of gastrectomies.[4,21] Based on survey responses, Tokunaga et al. reported that the number of gastrectomies during the COVID-19 pandemic was less than 80% of the number during the same period of the previous year, and six hospitals in Tokyo were seriously affected by a 50% decrease in the number of gastrectomies.[21] That is because the COVID-19 pandemic may limit medical practice, including both treatment and screening. Indeed, medical resources were diverted to the treatment of COVID-19, resulting in the cancellation of several gastrectomies. Furthermore, the impact

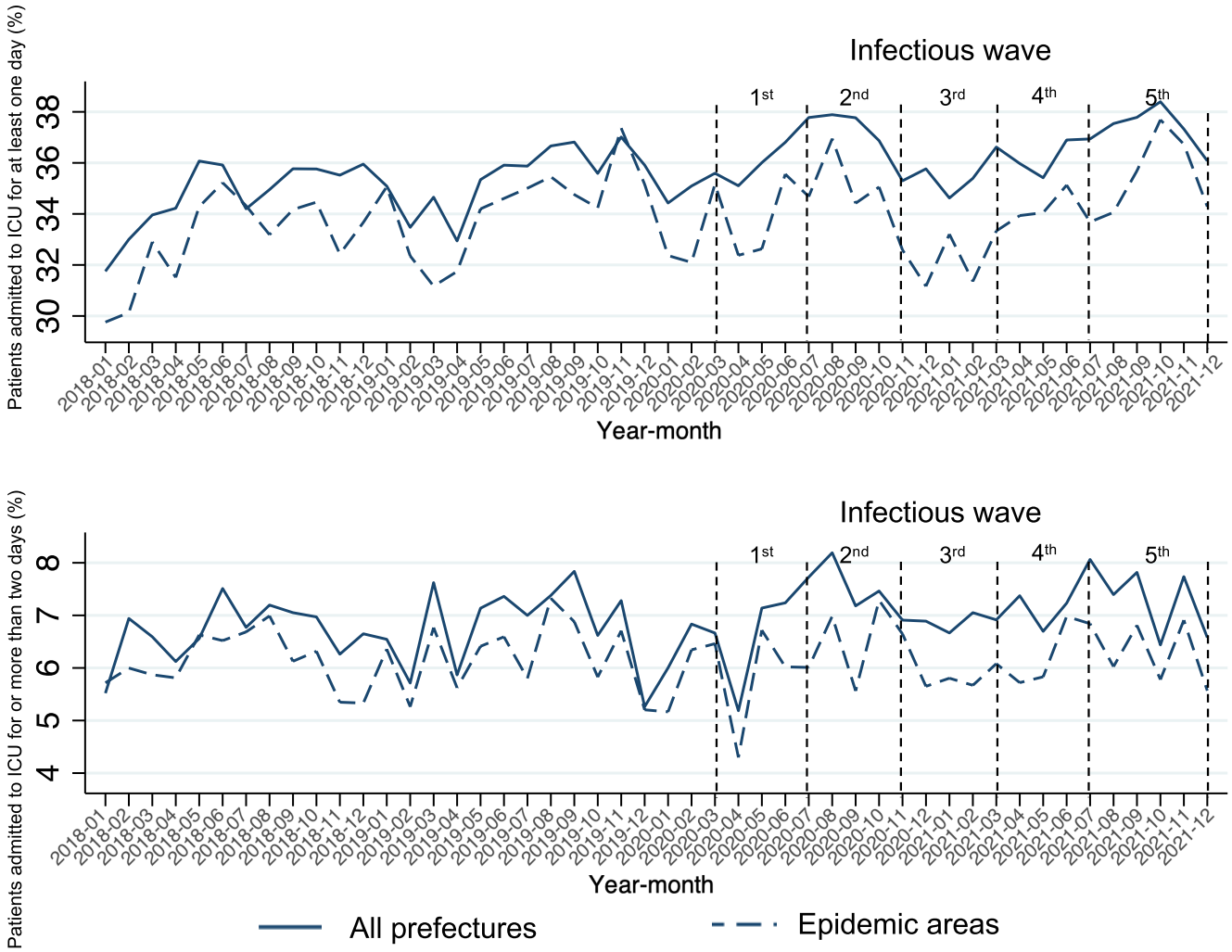

FIGURE 2 Trends in the number of patients admitted to intensive care units. The upper and lower charts indicate the number of patients admitted to intensive care units for at least 1 day and the number of patients admitted to intensive care units for more than 2 days, respectively. Solid and dashed lines indicate the number of patients who underwent gastrectomy in all 47 prefectures and the number of patients who underwent gastrectomy in epidemic areas, respectively. ICU; intensive care units.

of reducing screening on the diagnosis of gastric cancer in Japan was critical because our country has a concrete screening system for gastric cancer via esophagogastroduodenoscopy. Since opportunities for cancer screening via esophagogastroduodenoscopy decreased because it is an aerosol-generating procedure, the total number of endoscopic procedures reportedly decreased by 44% during the pandemic.[22,23] It is consistent with the fact that the rate of diagnosis of advanced-stage cancer was increased due to delayed diagnosis as was reported in a previous study,[24] and even in this study. From these reasons, the number of gastrectomies was significantly reduced because of the pandemic as shown in previous studies and our present findings, especially during the first infectious wave. However, no study has demonstrated the impact of the pandemic on short-term post-gastrectomy outcomes; thus, we investigated the short-term outcomes using the SMR, which is a risk-adjusted objective metric during both pre-pandemic and pandemic periods. Because patients' backgrounds vary, it is important to evaluate the mortality and morbidity rates considering risk-adjusted metrics.

There are some reasons why short-term results were not worsened during the pandemic. First, a gastrectomy is not as highly invasive as an esophagectomy or a pancreatoduodenectomy, which are both known to have severe postoperative complication rates that exceed 20%.[8] Our results showed that mortality was observed only in approximately 1% of cases, and even pneumonia, which is a frequent complication, was observed in only 3% of cases. Therefore, the short-term outcomes did not get worse despite the limited medical resources. In addition, the number of gastrectomies decreased, suggesting that sufficient medical resources were made available for each procedure. Similar studies should be performed on more invasive surgical procedures such as those performed for esophageal cancer or pancreatic cancer in the future. One concern is that SMRs are significantly higher during a particular month of year. For instance, the 30-day mortality and sepsis rates were higher than expected in September 2021. The highest number of patients with severe COVID-19 was recorded during this period (2213 patients were diagnosed with severe COVID-19 in Japan on September 3, 2021)

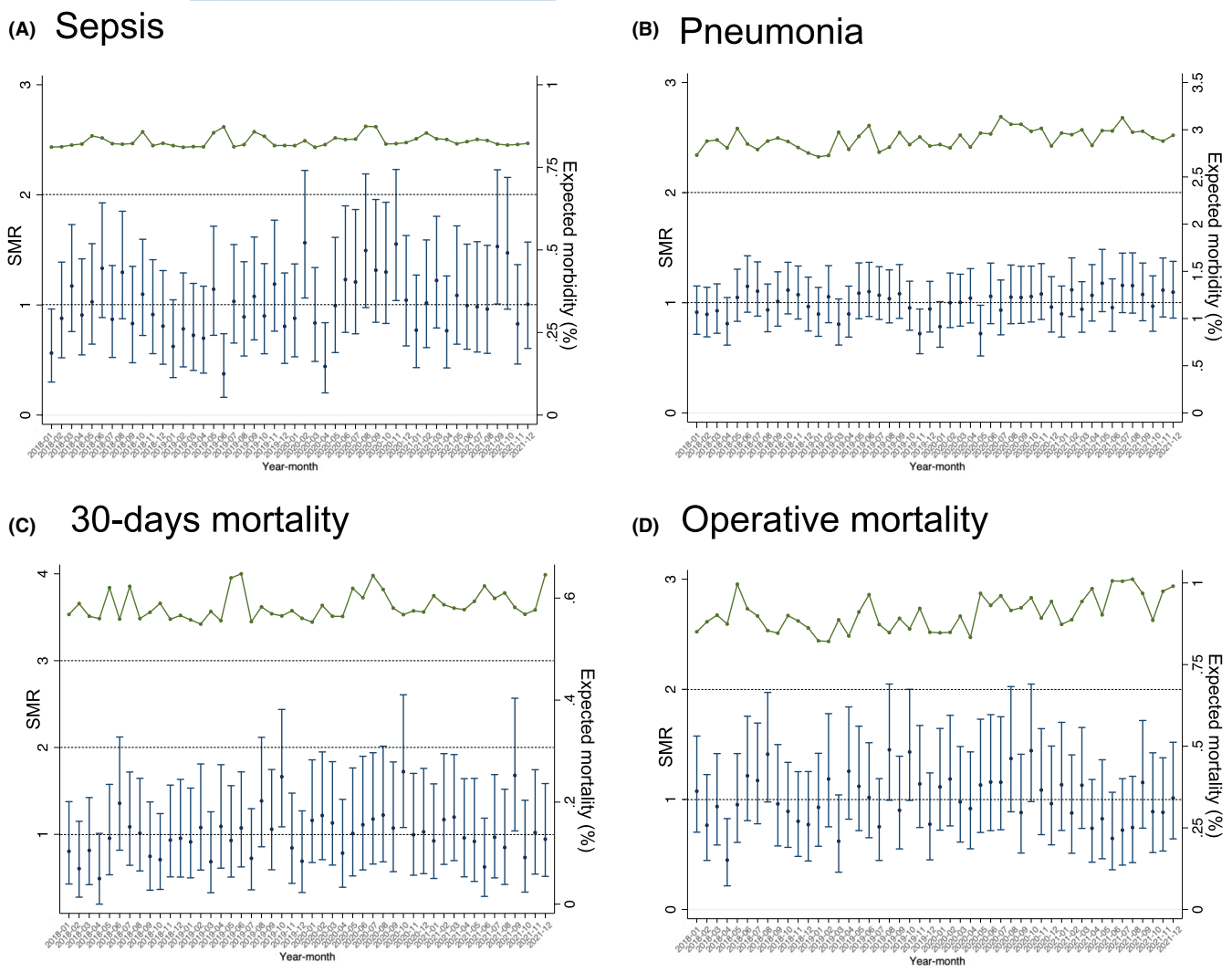

FIGURE 3 The standardized mortality ratio (SMR) during each month for (A) sepsis, (B) pneumonia, (C) 30-day mortality, and (D) operative mortality in all 47 prefectures.

due to the Delta variant surge. Although the relationship between this specific situation and worsening short-term outcomes remains unclear, there is the possibility that a serious shortage of medical resources is associated with adverse surgical outcomes. However, the use of intensive care units was unchanged in that period; thus, more investigation is required.

In our study, the proportion of patients admitted to intensive care units was unchanged during the pandemic. However, the absolute number of patients admitted to intensive care units decreased during the pandemic. This discrepancy can be attributed to the reduction in the number of gastrectomies, suggesting that medical resources were selectively made available to the patients who required intensive care. Furthermore, the proportion of patients who required more than 2 days of admission decreased significantly during the first wave. These showed that early discharge from intensive care units might have been necessary during the early phase of the pandemic. However, intensive care management was recovered after the first wave, resulting in better outcomes. Moreover, the decline of ICU use is more critical in epidemic areas than in other areas, indicating that infection levels might be associated with a decline in medical resources.

The complication rate might be lower in high-volume than in low-volume centers, with the result that areas having many high-volume centers might have better outcomes. However, what is most important is not the comparison of complication rates across regions, but rather the trends in complication rates during the pandemic. We therefore focused on changes in complication rates in all prefectures and epidemic areas, and not on differences in the complication rates between prefectures during the same period.

This study has several limitations. First, this is a retrospective study conducted on an entirely Japanese population, and this could have introduced an element of selection bias. Moreover, since data on long-term outcomes were not available in a nationwide database, only short-term surgical safety during the pandemic could be proven by our analysis. Second, the relationship between the pandemic and cancer treatment could not be determined directly because alternative strategies such as chemotherapy and radiotherapy could be chosen. The outcomes of patients who underwent non-surgical

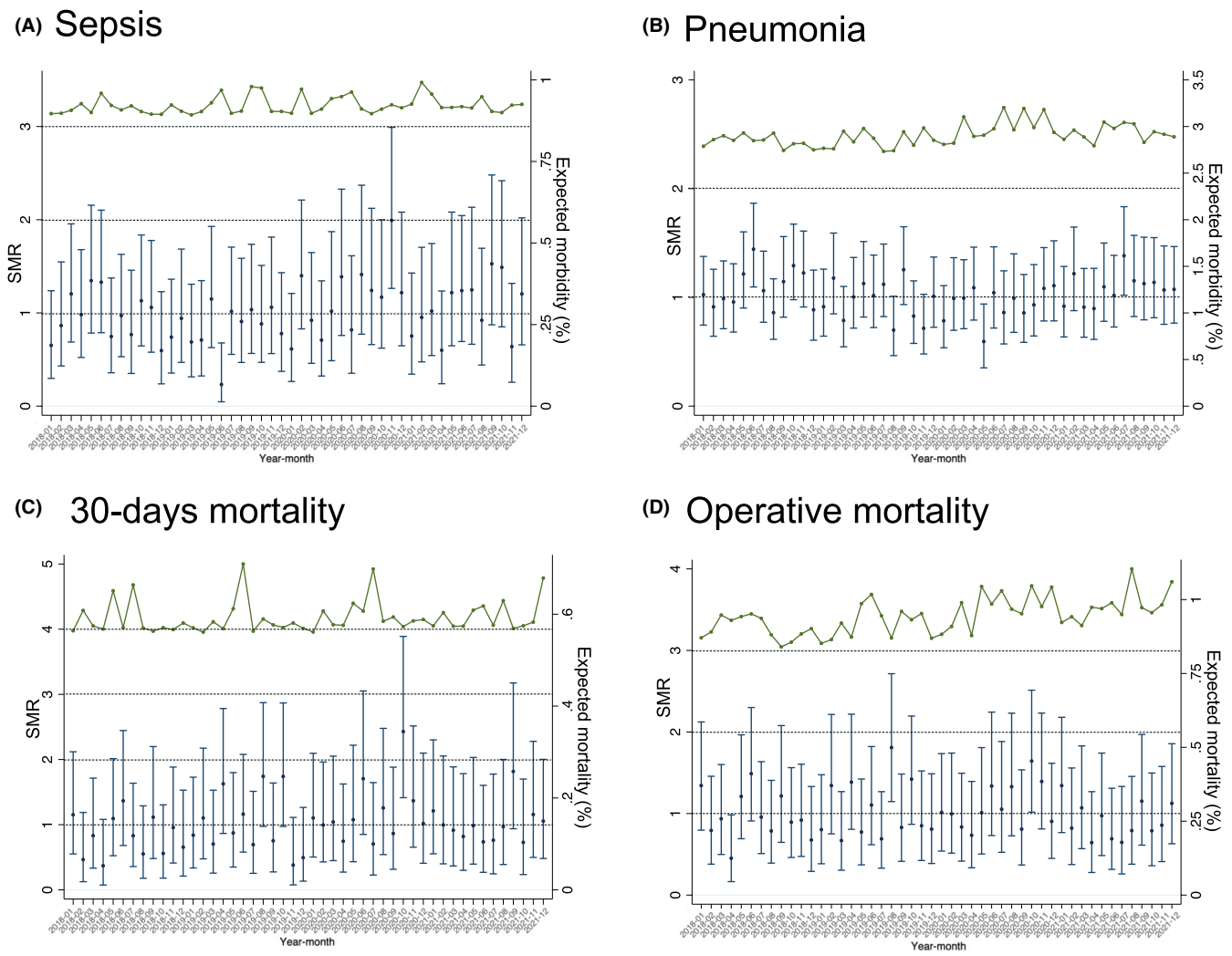

FIGURE 4 The standardized mortality ratio (SMR) during each month for (A) sepsis, (B) pneumonia, (C) 30-day mortality, and (D) operative mortality in epidemic areas.

treatment should be also investigated to clarify the impact of the pandemic on cancer treatment. Third, although the change in the availability of medical resources is a critical issue during the pandemic, only the proportion of patients admitted to intensive care units was evaluated in our present study. Although the intensive care unit was defined as a ward in which the most intensive medical care can be provided in the hospital, this definition varied from one hospital to the next, which constitutes a study limitation. In addition, other factors (e.g., stock of medical appliance) not available in the NCD are good indicators for evaluating medical resources and should be evaluated in the future. In particular, robotic surgery, which has recently become common in various fields, may result in better outcomes. Other factors associated with surgical outcomes, such as facility disparities, could be related to patients' outcomes.

In conclusion, the present study demonstrated that distal gastrectomy could be safely performed for gastric cancer patients without increasing the mortality rate even during the pandemic. These tendencies could be identified even in epidemic areas in Japan. This indicates that surgical management was conducted adequately through the organized efforts of the entire surgery department in our country even in a pandemic during which medical resources and staff may have been limited.

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ETHICS STATEMENTS

Approval of the research protocol: The protocol of this study was reviewed and adopted by the Japanese Society of Gastrointestinal Surgery Committee and approved by the Institutional Review Board of Kochi Medical School with exemption of individual written informed consent owing to the retrospective study design (ID: 2022–75).

Informed Consent: N/A.

Registry and the Registration No. of the study/trial: N/A.

Animal Studies: N/A.

CONFLICT OF INTEREST STATEMENT

Dr. Kitagawa reports grants and personal fees from Asahi Kasei Pharma Corporation; grants, personal fees, and other from Ono Pharmaceutical Co., Ltd.; grants and personal fees from Otsuka Pharmaceutical Factory, Inc.; grants and personal fees from Nippon Covidien Inc.; grants, personal fees, and other from Taiho Pharmaceutical Co., Ltd.; grants, personal fees, and other from Chugai Pharmaceutical Co., Ltd.; grants and personal fees from Kaken Pharmaceutical Co., Ltd.; personal fees from AstraZeneca K.K.; personal fees from Ethicon Inc.; personal fees from Olympus Corporation; personal fees from Shionogi & Co., Ltd.; personal fees and other from Bristol-Myers Squibb K.K.; personal fees from MSD K.K.; personal fees from Smith & Nephew K.K.; personal fees from Aska Pharmaceutical Co., Ltd.; personal fees from Miyarisan Pharmaceutical Co. Ltd.; personal fees from Toray Industries, Inc.; personal fees from Daiichi Sankyo Company, Limited; personal fees from Chugai Foundation for Innovative Drug Discovery Science; personal fees from Nippon Kayaku Co., Ltd.; grants from Yakult Honsha Co. Ltd.; grants from Otsuka Pharmaceutical Co., Ltd.; grants from Tsumura & Co.; grants from Sumitomo Pharma Co., Ltd.; grants and personal fees from EA Pharma Co., Ltd.; grants from Eisai Co., Ltd.; grants from Kyowa Kirin Co., Ltd.; grants from Medicon Inc.; grants from Takeda Pharmaceutical Co., Ltd.; grants from Teijin Pharma Limited.; and personal fees from Intuitive Surgical G.K., outside the submitted work. Hideki Endo, Hiroyuki Yamamoto, and Hiroaki Miyata are affiliated with the Department of Healthcare Quality Assessment at the University of Tokyo. The department is a social collaboration department supported by the National Clinical Database, Johnson & Johnson K.K., Nipro Corporation, and Intuitive Surgical Sàrl. Yuko Kitagawa is a Chief Editor of *Annals of Gastroenterological Surgery*. Masaki Mori is Emeritus Editor-in-Chief of *Annals of Gastroenterological Surgery*. Yasuyuki Seto, Yoshihiro Kakeji, and Hideki Ueno are Associate Editors of *Annals of Gastroenterological Surgery*.

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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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