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ORIGINAL ARTICLE

Impact of COVID-19 pandemic on short-term outcomes after low anterior resection in patients with rectal cancer: Analysis of data from the Japanese National Clinical Database

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Abstract

Aim: The Coronavirus Disease 2019 (COVID-19) pandemic affected the allocation of various medical resources to several areas, including intensive care units (ICUs). However, currently, its impact on the short-term postoperative outcomes of gastrointestinal cancer surgeries remains unclear. We aimed to evaluate the impact of the pandemic on the incidence of complications occurring after low anterior resection in patients with rectal cancer in Japan.

Methods: Data from the Japanese National Clinical Database between 2018 and 2021 were retrospectively examined. The primary outcome of the study was the postoperative morbidity and mortality rates before and after COVID-19 pandemic. Moreover, the postoperative ICU admission rate was assessed. Morbidity and mortality rates were also assessed using a standardized morbidity/mortality ratio (SMR, the ratio of the actual number of incidences to the expected number of incidences calculated by the risk calculator).

Results: This study included 74 181 patients, including 43 663 (58.9%) from COVID-19 epidemic areas. The mean actual incidences of anastomotic leakage (AL) and pneumonia during the study period were 9.2% and 0.9%, respectively. The SMRs of these complications did not increase during the pandemic but those of AL declined gradually. The mean 30-day mortality and operative mortality rates were 0.3% and 0.5%, respectively. Moreover, SMRs did not change significantly in the pandemic or regional epidemic status. The ICU admission rate temporarily decreased, especially in the epidemic areas.

Conclusion: Although the pandemic temporarily decreased the ICU admission rate, its impact on short-term outcomes following low anterior resection in patients with rectal cancer was insignificant in Japan.

KEYWORDS
COVID-19 pandemic, postoperative complication, rectal cancer surgery

1 | INTRODUCTION

The coronavirus disease 2019 (COVID-19), which emerged in Wuhan, China in 2019, has created an overwhelming effect worldwide.[1] Policies were made and strongly implemented in each country to prevent contagion, resulting in a significant impact on overall health care. Japan was no exception, with the number of non–COVID-19-infected patients visiting hospitals decreasing significantly because of the state of emergency declared and outdoor restrictions imposed as soon as the wave of infection began in March 2020.[2] Because of postponing or canceling of scheduled surgeries, most of the oncological surgeries, including low anterior resection (LAR) for rectal cancer, temporarily decreased.[3]

The impact of COVID-19 was not only a change in the number of surgeries. Many medical resources were consumed to treat patients with COVID-19, potentially affecting postoperative management. At the beginning of the pandemic in 2020, some countries recommended changes in surgical procedures for colorectal cancer to reduce workloads in intensive care units (ICUs).[4,5] Even under such circumstances, no significant changes have been noted in the occurrence of complications after colorectal cancer surgery worldwide, including Japan.[6–8] However, the COVID-19 pandemic may have altered the risk of postoperative complications in patients undergoing surgery. To properly assess the frequency of postoperative complications, we need to consider the patient background rather than simply comparing frequencies.

Hence, this study aimed to evaluate the frequency of postoperative complications in rectal cancer surgery during the COVID-19 pandemic in Japan compared with the period before, considering the risk of postoperative complications. Moreover, we evaluated changes in ICU admission rates to examine their relationship with available medical resources.

2 | PATIENTS AND METHODS

2.1 | Data collection

As the primary outcome, the impact of the COVID-19 pandemic on the short-term outcomes following rectal cancer surgery was assessed. Any changes in the patient characteristics and the ICU admission rate were also assessed. All the essential data were extracted from the National Clinical Database (NCD). The NCD is a nationwide web-based surgical patient registration system that enables the collection of data on all surgical procedures performed in Japan, in addition to perioperative factors. Approximately 5000 hospitals have registered more than 14 340 000 procedures, accounting for more than 90% of all surgeries performed in Japan during this period.[9,10] The NCD constructed software for an Internet-based data collection system, and data managers in participating hospitals are responsible for forwarding their data to the NCD office.[9] To reveal the impact of COVID-19 on LAR postoperative outcomes, we used the NCD to investigate any change in the following factors from 2018 to 2021: the number of surgeries performed, use of ICUs, incidence of anastomotic leakage (AL), incidence of pneumonia, 30-day mortality, and operative mortality (death within 30 days or hospitalized death within 90 days). In the present study, LAR involved ultra-low anterior resection and intersphincteric resection with handsewn coloanal anastomosis. ICUs were defined as wards/units that can provide the most intensive medical care in the hospital. Furthermore, patients with benign tumors or those without tumors, those with cancers originating from other organs, those aged <18 years, those who underwent emergency surgery, those with T0 or Tis rectal cancers, and those with missing data were excluded from our analysis (Figure 1). The cancer stage was determined according to the UICC TNM stage classification, 8th edition. Our study protocol 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). All statistical data were analyzed using R version 4.1.2 (2021; R Foundation for Statistical Computing, Vienna, Austria), and graphs were drawn using GraphPad Prism 9 (GraphPad Software, Boston, MA).

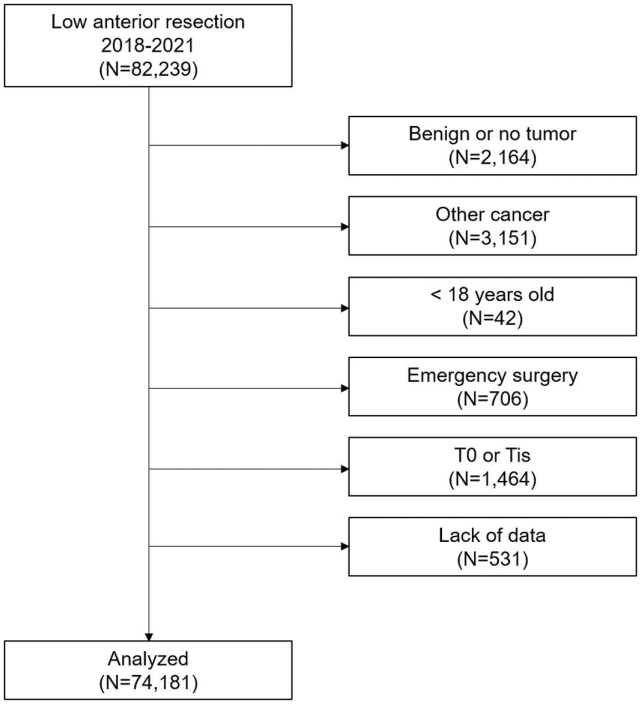

FIGURE 1 The flow diagram of the study.

2.2 | Definition of COVID-19 epidemic areas

We used the cumulative number of infected people per population of prefectures (until the end of 2020) as an index of the degree of infection.[11] Based on this value, the following 12 prefectures were defined as COVID-19 epidemic areas in terms of the degree of infection: Aichi, Chiba, Fukuoka, Hokkaido, Hyogo, Kanagawa, Kyoto, Nara, Okinawa, Osaka, Saitama, and Tokyo. All data were compared between all prefectures and epidemic areas to assess the relationship between infection levels and short-term outcomes.

2.3 | Waves of COVID-19 infection

The waves of COVID-19 infection in Japan were defined according to the number of infections per day as follows: first wave (March 2020–June 2020), second wave (July 2020–October 2020), third wave (November 2020–February 2021), fourth wave (March 2021–June 2021), and fifth wave (July 2021–December 2021) (end of the study period).[12,13] Information regarding the actual number of infections per month was collected from data released by the Ministry of Health, Labour, and Welfare, Japan.

2.4 | Standardized morbidity/mortality ratio (SMR)

The SMR was calculated to accurately evaluate mortality or morbidity by considering the patients' postoperative complication risks.[14] SMR was defined as the ratio of the observed number of patients to the expected number of patients suffering from complications. This ratio was used to investigate the trend in risk-adjusted outcomes. The expected morbidity and mortality rates for each month were calculated using a risk calculator established by a previous study based on NCD data. Briefly, the 30-day and operative mortality models were constructed using 10 and 17 clinical risk factors, respectively. These risk factors included older age, sex (male), body mass index (>30 kg/m^2), respiratory distress, activities of daily living (totally dependent), activities of daily living (partially dependent), ascites, surgical history of peripheral vascular disease, disseminated cancer, preoperative transfusions, serum creatinine (>265.2 μmol/L), low hemoglobin (men, <135 g/L; women, <125 g/L), high hematocrit (men, >0.48; women, >0.42), low platelet (<120000/μL), serum albumin (<25 g/L), AST (>0.67 μkat/L), and hyponatremia (<138 mEq/L). Models for AL and pneumonia were also constructed using similar variables.[15]

3 | RESULTS

3.1 | Number of LARs performed

Overall, 74181 cases were analyzed (Figure 1). Among them, 43663 (58.9%) were from COVID-19 epidemic areas. We first surveyed the trend regarding the number of LARs performed during the study period. Figure 2 shows the number of surgeries per month over time. The first significant change was observed in May 2020 (during the first wave of infection). Compared with the previous month, this month had a decrease of 408 cases nationwide. Additionally, the number of LARs performed was 1270, the lowest during the whole study period, followed by several months with fewer than 1500 during the first and third waves of infection. Since March 2021 (during the fourth wave), the number has been gradually increasing and is returning to the pre-pandemic level. In the epidemic areas, the overall trend regarding the number of LARs was similar.

The proportion of patients aged ≥80 years showed a decrease in March 2020 and an increase in July 2020, whereas the proportion of patients aged <60 years showed an inverse trend (Figure S1). The proportions of advanced cancer (≥T2) and lymph node metastatic cases increased around August 2020 during the second wave (Figure S2). However, there were no differences in age and cancer progression between all prefectures and epidemic areas. Details regarding the number of patients with each clinicopathological factor per month during the study period are shown in Tables S1 and S2.

3.2 | Postoperative ICU admission rate

Figure 3 shows the postoperative ICU admission rate for each month. Nationwide, the proportion of patients admitted to the ICU for at least 1 day was approximately 35% before the pandemic but declined to 32.2% in May 2020 (during the first wave). In the epidemic areas, the rate was approximately 33% before the pandemic but also decreased to 29.2% in May 2020. It then temporarily increased but remained at a low level of approximately 30% during the third and fourth waves. This trend was not the case in all prefectures, which showed a recovery to the pre-pandemic

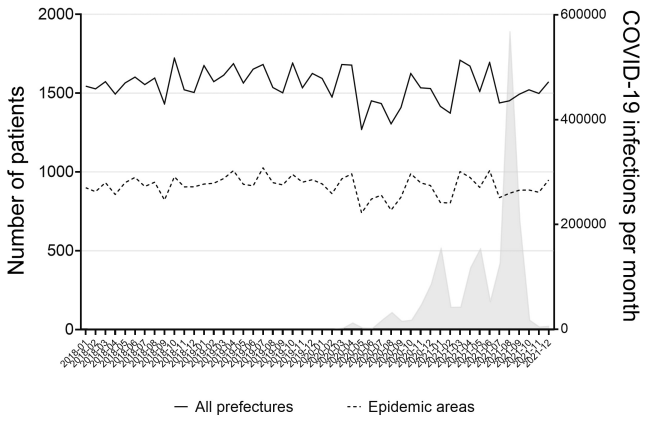

FIGURE 2 Transition of the number of patients undergoing low anterior resection (LAR). Solid lines indicate patients who underwent LAR in all 47 prefectures, and dashed lines indicate patients who underwent LAR in the epidemic areas. Gray-filled line graph indicates the number of COVID-19 infections per month.

level even after the third wave. To address the differences in the impact of ICU admission duration, we investigated the rate of admission for more than 2 days (Figure 3). No major trend changes were observed during the study period, either in all prefectures or in endemic areas.

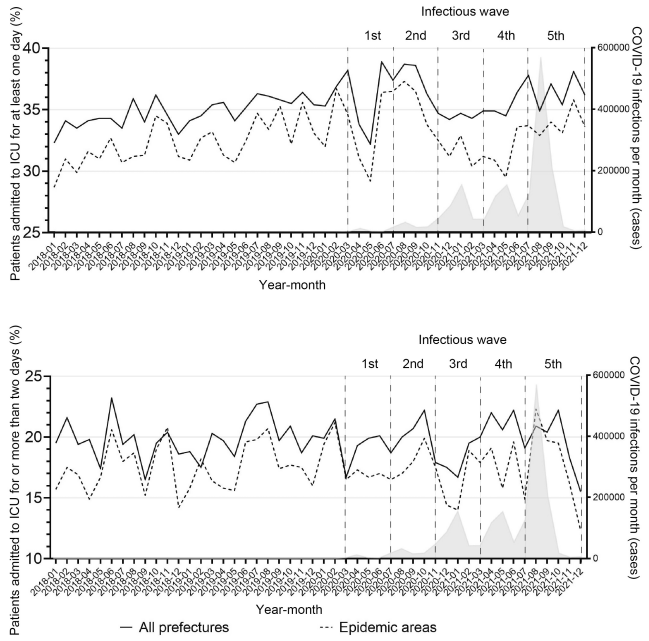

FIGURE 3 Transition of the proportion of patients who were admitted to the intensive care unit (ICU). Upper and lower charts indicate patients who were admitted to the ICU for at least 1 day, and patients who were admitted to the ICU for more than 2 days, respectively. Solid lines denote patients who underwent low anterior resection (LAR) in all 47 prefectures, and dashed lines denote patients who underwent LAR in the epidemic areas. Gray-filled line graph indicates the number of COVID-19 infections per month.

3.3 | Postoperative morbidity

Next, we examined the incidence of postoperative complications. The mean actual incidence rates of AL and pneumonia during the study period were 9.2% and 0.9%, respectively. We then calculated the expected incidence rates adjusted for various patient risks and obtained the SMRs accordingly. Figure 4A,B show the trends of the expected morbidity rate and SMR for AL and pneumonia, respectively. During the study period, the incidence of pneumonia did not change and remained at a level similar to that pre-pandemic. As for AL, the SMR decreased from the baseline of approximately 1.0–0.8 from October 2020, and this trend continued throughout 2021. In the epidemic areas, the mean actual incidence rates of AL and pneumonia were 9.0% and 0.8%, respectively. Figure 4C,D show the expected morbidity rate and SMR for AL and pneumonia in epidemic areas, respectively. The overall trend of the epidemic areas was similar to that of all prefectures.

3.4 | Postoperative mortality

We also assessed postoperative mortality. The mean 30-day mortality and operative mortality rates were 0.3% and 0.5%, respectively. Figure 5A,B show the trends of the expected rate and SMR for 30-day mortality and operative mortality, respectively. The SMR remained at pre-pandemic levels nationwide, similar to that in epidemic areas (Figure 5C,D).

4 | DISCUSSION

Using the Japanese national database, this study demonstrated that during the COVID-19 pandemic, the ICU admission rate after rectal

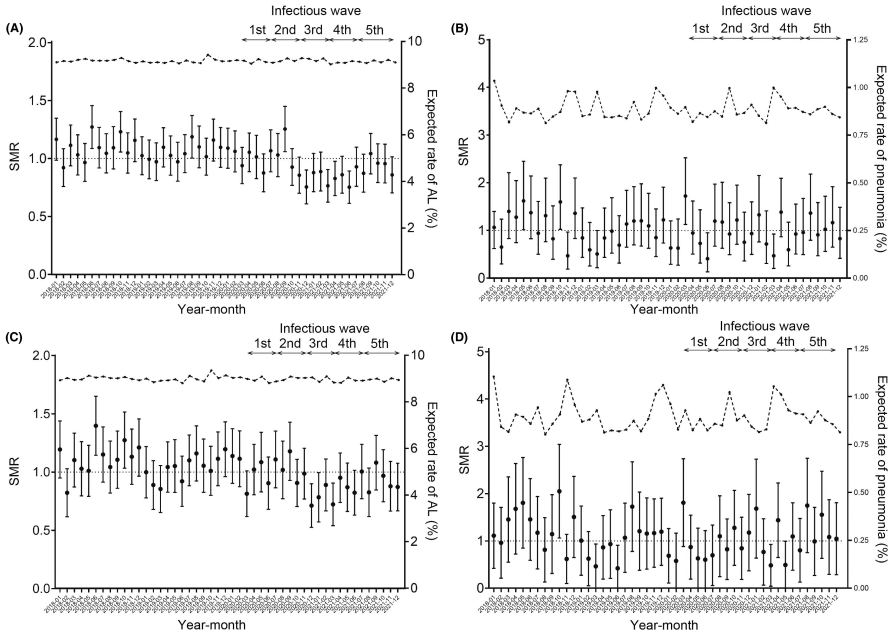

FIGURE 4 The standardized morbidity ratio (SMR) and expected morbidity rate in each month for (A) anastomotic leakage (AL) in all 47 prefectures, (B) pneumonia in all 47 prefectures, (C) AL in the epidemic areas, and (D) pneumonia in the epidemic areas. Vertical lines indicate the SMR with 95% confidential interval, and dashed lines indicate expected morbidity rate.

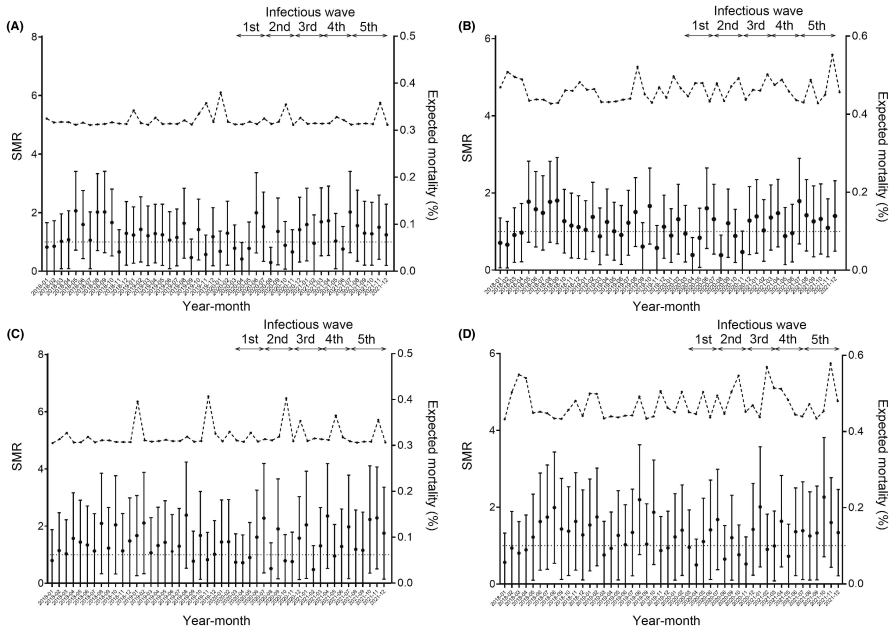

FIGURE 5 The standardized mortality ratio (SMR) and expected mortality rate in each month for (A) 30-day mortality in all 47 prefectures, (B) operative mortality in all 47 prefectures, (C) 30-day mortality in the epidemic areas, and (D) operative mortality in the epidemic areas. Vertical lines indicate the SMR with 95% confidential interval, and dashed lines indicate the expected mortality rate.

cancer surgery temporarily decreased, especially in the epidemic areas. Although limited medical resources during the pandemic could affect postoperative management and lead to an increase in postoperative complications, both mortality and morbidity rates remained at levels similar to those pre-pandemic. Even in the epidemic areas, where more medical resources were spent for COVID-19 treatment, the postoperative complication rate was maintained without a significant increase.

The impact of the COVID-19 pandemic on the postoperative complication risk after colorectal cancer surgery remains controversial. Both mortality and morbidity rates reportedly did not change before and after the COVID-19 pandemic.[6–8,16] An international multi-institutional study has reported that although AL and length of hospital stay have decreased, the mortality rate has increased.[17] Given that the COVID-19 pandemic may have altered the risk of postoperative complications for patients undergoing surgery, analyzing the patients' background rather than simply comparing frequencies is necessary to thoroughly assess their frequencies. The number of endoscopies for cancer screening significantly decreased during the pandemic; consequently, advanced cancers have increased.[18–20] The current study also revealed a period of temporary increase in advanced cancer. In addition, the proportion of older patients also showed significant changes associated with the wave of infections, potentially resulting from the behavioral changes in visiting hospitals.[21] These changes in patient background would have led to a change in the patient's general condition; thus, the present study considered the risk of each patient during the COVID-19 pandemic. Despite such changes, the actual mortality and morbidity rates did not significantly change compared with the patient risk-adjusted expected rates.

The reason why the postoperative complication rate did not increase despite the limited medical resources can be explained by several possibilities. One is the temporal stoma formation to avoid AL and any other critical complications. Although some studies reported no change in the stoma formation rate during the pandemic, others reported an increase in the rate.[6,17,22,23] Our study revealed that the AL rate decreased during the pandemic and maintained at a relatively low level throughout the study period, potentially reflecting this possibility. However, we did not further examine this issue because we did not have data on the number of stoma formations; future studies should clarify this matter. The growing practices of preoperative therapies for advanced rectal cancer may also be a contributing factor. Societies worldwide recommended canceling or postponing surgeries during the pandemic; thus, patients at risk for serious complications may have avoided upfront surgery strategies and received preoperative chemotherapy, radiotherapy, or chemoradiotherapy.[24,25] Morris et al. reported a temporal relative increase of 44% in preoperative radiotherapy use during the pandemic.[22] Future studies should determine how such temporary changes in treatment strategies for preventing postoperative complications have affected long-term survival.

Reports regarding the impact of COVID-19 on the ICU admission rates after colorectal surgery are still limited. Caricato et al. reported that 33.3% of cases with the anticipated need of postoperative ICU were suspended.[26] In the current study, the postoperative ICU admission rate temporarily decreased in all areas of the country during the first wave of infection. In addition, the epidemic areas showed great decreases during the second and third waves, indicating the regional differences in the capacity of postoperative management. Notably, the complication rates did not increase under such circumstances. This study was limited to the cases of rectal cancer, and only data regarding LAR were extracted. Thus, it is not clear whether the same trend can also be observed for other rectal cancer procedures or other diseases. Further studies are expected, especially for more invasive surgeries with a high demand for ICU use.

This study has some limitations. First, the definition of ICU was not universally accepted. According to the data obtained from our study, the ICU admission rates tended to be low in the epidemic areas during the pre-pandemic period. This could be attributed to the higher proportion of young patients or the lower proportion of metastatic cancers. However, the fact that the decision to use ICU, even if the risk was equivalent, was dependent on the institution, and this may have had a significant impact; this is considered one of the limitations of the present study. Second, this study did not consider the recent trend regarding the number of upfront surgery strategies because of the spread of preoperative radiation therapy or chemoradiation therapy. Finally, although the long-term prognosis is one of the most important outcomes in evaluating surgical outcomes in cancer, it was not demonstrated in this study. Future studies should determine the impact of surgery postponement or aggressive preoperative treatment caused by the pandemic.

In conclusion, despite temporary changes in patient characteristics and lower ICU admission rates coincident with the wave of infection, the impact of the COVID-19 pandemic on short-term postoperative outcomes was minimal in Japan nationwide. Surgeons may have exerted tremendous efforts to reduce the risk of complications and perform the surgery safely.

AUTHOR CONTRIBUTIONS

RS and TH developed the main concept, designed the study, and wrote the manuscript. HE, HY, and HM performed data analysis. RS, TH, MT, YN, and HM performed interpretation of data results. AT, YK, YS, HU, MM, and YK contributed to editing and critical revision for important intellectual content.

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CONFLICT OF INTEREST STATEMENT

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ETHICS STATEMENT

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 (2022-75).
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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