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ORIGINAL ARTICLE

Impacts of COVID-19 pandemic on short-term outcomes of low anterior resection performed in hospitals with different surgical volumes

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Abstract

Aim: To evaluate the impact of the coronavirus disease (COVID-19) pandemic on short-term outcomes of low anterior resection (LAR) across hospitals classified by surgical volume.

Methods: Data of patients who underwent elective LAR for rectal cancer between 2018 and 2022 were obtained from the National Clinical Database of Japan. Hospitals were categorized into high-, medium-, and low-volume groups. Each group was constituted to represent approximately one-third of all surgeries performed between 2018 and 2019. The standardized morbidity/mortality ratios (SMRs) of Clavien–Dindo grade ≥3 (CD ≥ 3) complications were the primary endpoint. The secondary endpoints included anastomotic leakage, pneumonia, and surgical mortality.

Results: This study analyzed 91 800 cases of elective LAR, with 10.5% experiencing CD ≥ 3 complications, 8.8% anastomotic leakage, 0.9% pneumonia, and 0.5% surgical mortality. Despite COVID-19, SMRs of CD ≥ 3 complications decreased from 2018 to

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2022 across all groups. However, increases in the rates and SMRs of CD ≥ 3 complications were observed in low-volume hospitals around mid-2020, followed by a decline. Anastomotic leakage showed similar trends. The rates and SMRs of pneumonia and surgical mortality remained unchanged. Notably, anastomotic leakage rates were 7.6%, 8.9%, and 10.0% in high-, medium-, and low-volume hospitals, respectively, indicating superior outcomes in high-volume hospitals.

Conclusion: Early COVID-19 waves may have disproportionately affected low-volume hospitals. However, the decline in SMRs of CD ≥ 3 complications from 2018 to 2022 across all three groups suggests the robustness and resilience of surgical services for rectal cancer in Japan. The potential disparity in short-term outcomes among hospitals is a new concern.

KEYWORDS
anastomotic leak, COVID-19, delivery of health care, rectal neoplasms, treatment outcome

1 | INTRODUCTION

More than 730 000 new cases and 330 000 deaths due to rectal cancer occurred worldwide in 2020,[1] with a projected increase in these numbers.[2] The coronavirus disease 2019 (COVID-19) pandemic affected surgical services for rectal cancer: the number of surgeries decreased while the monthly crude mortality rate remained stable in 2020.[3] The reduction of surgical number for rectal cancer in 2020 has raised concerns about the deterioration of short-term surgical outcomes owing to the excessive burden at the resumption of surgeries. However, an analysis adjusting for the risks of morbidity and mortality revealed that safe surgical treatment for rectal cancer were continuously provided during the pandemic in Japan.[4] Laparoscopic surgeries for rectal cancers were safely performed even during the pandemic.[5] Besides, when the results of the whole country (Japan) were analyzed, the limited negative impact of COVID-19 on short-term outcomes was demonstrated among patients requiring elective surgery for gastric cancer, esophageal cancer, hepatocellular carcinomas,[6–8] and those needing surgical treatment for colorectal perforation.[9]

While these studies demonstrated the strength of the surgical healthcare system across Japan, the mechanism underlying this success remains unclear. With the uncertainty surrounding the transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), anxiety over the shortage of medical supplies, and the restriction of travel, altered inflow and outflow of patients may have occurred. The suspension of cancer screenings and periodic examinations may have occurred to varying degrees among regions and/or facilities. Indeed, a greater reduction in patients with cancers in academic hospitals was reported in the United States.[10] Studies from Japan have shown that the COVID-19 pandemic synchronously affected areas with high infection rates and entire nations.[3,4] However, those investigating the varying impacts of the pandemic across hospitals with different characteristics are limited.[11] Therefore, this study aimed to investigate the surgical outcomes for rectal cancer performed in hospitals with different surgical volumes in Japan. We believe that this study's findings will be valuable in preparing for the spread of emerging infectious diseases.

2 | METHODS

2.1 | Overview

This study aimed to evaluate the effects of COVID-19 on the short-term outcomes of low anterior resection (LAR) in three different groups of hospitals classified by surgical volume. We utilized data from the National Clinical Database (NCD) in Japan, which captures 90%–95% of surgical procedures.[12] The NCD is linked to the certification system of academic societies. The Japanese Society of Gastroenterological Surgery has designated eight surgical procedures to evaluate and improve medical standards,[13] one of which is LAR.

Data of patients who underwent LAR between 2018 and 2022 were analyzed. Patients with benign or no tumors, tumors from other sites, ages <18 years, emergency surgery, T0/Tis tumors, and missing data were sequentially excluded. The primary endpoint of the present study was Clavien–Dindo grade ≥3 complications (CD ≥ 3 complications). Anastomotic leakage, pneumonia, and surgical mortality were also analyzed, and the baseline characteristics of the patients were reported. The study protocol was reviewed and approved by the Institutional Review Board of Kochi University (2023-108).

2.2 | Hospital categories

Due to the absence of an optimal threshold for classifying hospitals based on the number of surgeries for our purpose, and because this study evaluated surgical outcomes over time, we divided the

TABLE 1 Definition of high-, medium-, and low-volume hospitals based on the number of surgeries performed between 2018 and 2019.

		Classifications		
	Total	High volume	Medium volume	Low volume
Number of operations in 2 years, *n* (%)	37 607 (100)	12 783 (34.0)	12 484 (33.2)	12 340 (32.8)
Cutoff value, number of operations in 2 years	NA	52<	25<, 52≥	25≥
Number of included hospitals, *n* (%)	1854 (100)	151 (8.1)	341 (18.4)	1362 (73.5)
Number of surgeries per hospital in 2 years, mean (SD)	20.3 (27.0)	84.7 (50.4)	36.6 (8.0)	9.1 (6.8)
Number of surgeries per hospital in 2 years, median [range]	12 [1–436]	71 [53–436]	35 [26–52]	8 [1–25]

Note: Note that the presented values were calculated using the numbers of surgeries performed in 2 years.

Abbreviations: NA, not applicable; SD, standard deviation.

hospitals into three groups according to surgical volume. First, the sum of surgeries in 2018 and 2019 was calculated for each hospital, and the hospitals were ranked by case volume. In descending order, high-volume hospitals were selected such that approximately one-third of all patients were included. The same sequence was used for medium-volume hospitals. The remaining hospitals, with fewer surgeries, were classified as low-volume hospitals. Based on previous studies in Japan, it was assumed that <10% of the hospitals were classified as high-volume hospitals, and low-volume hospitals would perform <10 cases per year.[14,15]

2.3 | Statistical analysis

We utilized a standardized morbidity/mortality ratio (SMR), calculated by dividing the number of observed and predicted events. An SMR of <1 indicated that the events occurred less frequently than expected. As this study aimed to understand the trends in surgical services, we decided to refrain from performing further statistical comparisons. Statistical data were analyzed using R, version 4.1.2 (2021; R Foundation for Statistical Computing, Vienna, Austria). The graph was plotted using KaleidaGraph Ver. 4.5.2 (Synergy Software, Reading, PA, USA), and edited using Photoshop CS2 (Adobe Systems, San Jose, CA, USA).

3 | RESULTS

3.1 | Overview

Out of 102 396 LARs, 91 800 procedures from 1854 hospitals remained after exclusion (Figure S1). Hospitals were classified into three categories based on 37 607 procedures performed within

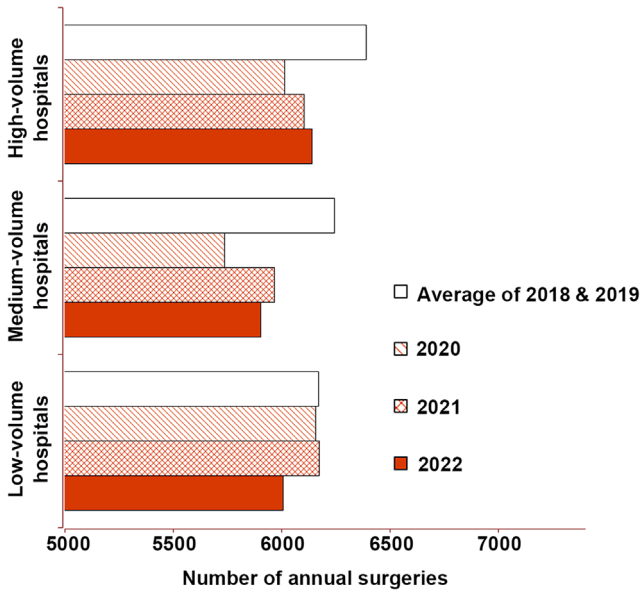

FIGURE 1 Annual surgical volumes (2018–2022). The actual number of surgeries per year in each group is shown. Decreases in the number of surgeries are evident in high- and medium-volume hospitals.

2 years prior to the spread of COVID-19 (Table 1). High-volume hospitals comprised 151 hospitals (8.1%) with 12 783 cases; medium-volume hospitals, 341 hospitals (18.4%) with 12 484 cases; and low-volume hospitals, 1362 hospitals (73.5%) with 12 340 cases.

The annual number of procedures was 18 528 (20.2%) in 2018, 19 079 (20.8%) in 2019, 17 903 (19.5%) in 2020, 18 244 (19.9%) in 2021, and 18 046 (19.7%) in 2022. This reduction in the number of surgeries may be more profound in high- and medium-volume hospitals (Figures 1 and 2). After April 2020, at the beginning of a series of SARS-CoV-2 infection waves, the number of surgeries was

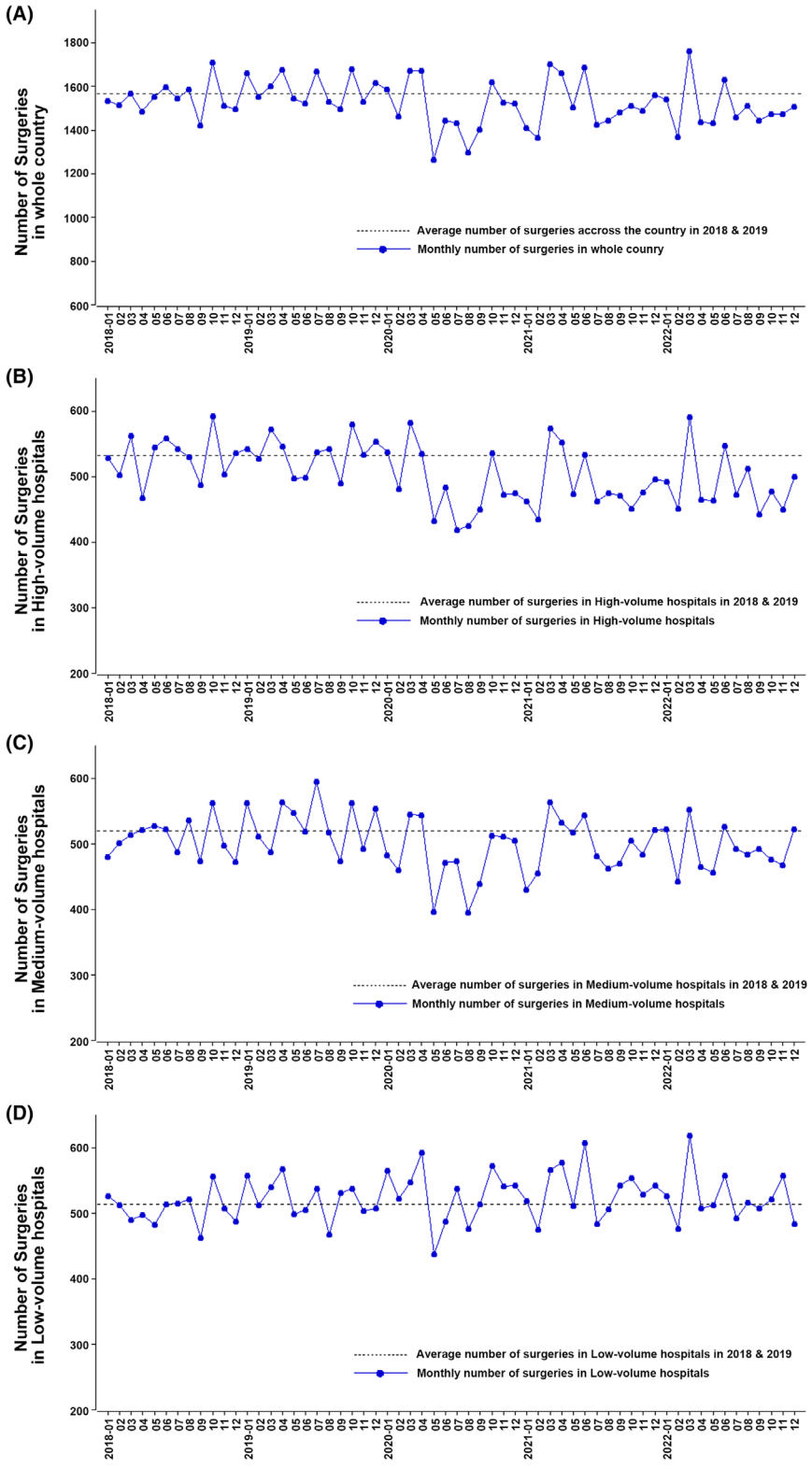

FIGURE 2 Monthly surgical volumes (2018–2022). The transition in monthly surgical volumes is shown. While similar trends are observed across hospital volume groups, the magnitude of fluctuations varies. (A) shows the results for the whole country, (B) for high-volume hospitals, (C) for medium-volume hospitals, and (D) for low-volume hospitals.

frequently below the monthly averages in 2019 and 2020. The monthly surgical numbers increased and decreased similarly in all three groups, and a larger range of fluctuations was observed after the onset of the pandemic (Figure 2). However, an increase in the number of surgeries, which compensates for the decreased surgical numbers in the middle of 2020, has not yet been observed.

3.2 | Background characteristics

The baseline characteristics differed among the three groups, although the trends observed in all three groups were similar. In brief, high-volume hospitals treated younger patients and T1 tumors, whereas low-volume hospitals treated older patients and T3 tumors

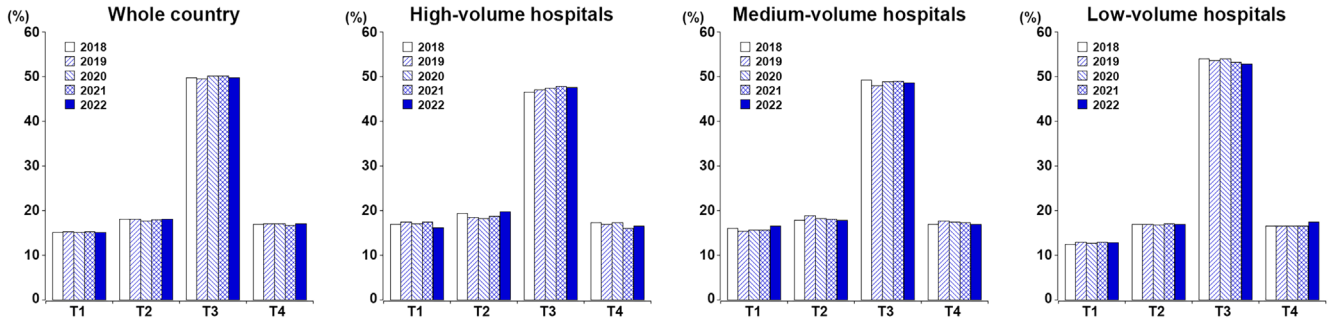

FIGURE 3 T factors during the period 2018–2022. Consistent proportions of T factors are shown from 2018 to 2022.

(Tables S1–S4). Notably, the proportion of T factors was essentially similar before and after the onset of the pandemic when observing the annual trend (Figure 3). Overall, the most frequent T factor was T3 (49.5%–50.2%), followed by T2 (17.7%–18.1%), T4 (16.7%–17.1%), and T1 (15.1%–15.3%).

3.3 | Primary outcome (CD ≥ 3 complications)

CD ≥ 3 complications occurred in 9673 (10.5%) of all procedures. The rate of CD ≥ 3 complications was 11.6% in 2018, 10.6% in 2019, 10.9% in 2020, 10.0% in 2021, and 9.5% in 2022, showing a gradual reduction (Figure 4, Table 2). Although all three groups showed a decrease in the rate from 2018 to 2022, the rate in high-volume hospitals declined markedly between 2021 and 2022. In contrast, the CD ≥ 3 complications rate was highest in 2020 in low-volume hospitals, possibly attributable to the surge between July and September of 2020.

Similar to the complication rate, the monthly SMRs gradually decreased from 2018 to 2022 when evaluated across Japan (Figure 5). Nine months within the period 2020–2022 had significantly lower SMRs, whereas only 1 month fell below 1 within the period 2018–2019. In all three groups, a gradual decrease in SMRs was observed, although the degree of change appeared large in high- and medium-volume hospitals. Meanwhile, the decrease in SMRs of CD ≥ 3 complications from 2018 to 2022 appeared blunt in low-volume hospitals. In addition, the increase in the SMR around September 2020 coincided with its crude rate (Figures 4D and 5D).

3.4 | Secondary outcomes

Overall, a gradual decrease in anastomotic leakage was observed from 2018 to 2022 (Table 2). However, the differences in SMRs among the three groups were more evident than those observed in CD ≥ 3 complications (Figure S2). In high-volume hospitals, 20 out of 60 months had significantly lower SMRs, the majority of which accumulated in the later years of the study. In medium-volume hospitals, 11 months had SMRs below 1, with the majority also observed during the later study period. Less frequently, 5 out of 60 months with lower SMRs were observed in low-volume hospitals during the COVID-19 pandemic. Meanwhile, months with SMRs higher than 1 were observed during the early study periods in medium-volume hospitals and the early periods of the pandemic in low-volume hospitals.

The surgical mortality rate of LAR in Japan was as low as 0.4%–0.5% (Table 3). A disparity in surgical mortality was observed, with low mortality in high-volume hospitals. The SMR for mortality showed a lower tendency in high-volume hospitals than in low-volume hospitals (Figure S3). The rate and SMRs of pneumonia were similar to those of surgical mortality (Figure S4).

4 | DISCUSSION

This study hypothesized that hospitals with different surgical volumes could be impacted differently by the COVID-19 pandemic. Using data from the NCD, one of the largest clinical databases in Japan, we delineated the overall experiences of institutions across the nation. The following intriguing findings emerged. The monthly surgical numbers showed similar fluctuations across all three groups. The baseline characteristics of the patients and tumors were different among the three groups (i.e., a higher proportion of older patients and T3 tumors in low-volume hospitals). Despite the pandemic, the rates and SMRs of complications showed a gradual decline in all three groups. Months with high SMRs were found around the middle of 2020 in low-volume hospitals. In addition, high-volume hospitals appeared to have better short-term outcomes.

First, the increases and decreases in monthly surgical numbers were similar in all three groups, although their extents differed. A study from the northeastern region of Japan (Tohoku region) reported that colonoscopies were performed less frequently immediately after the state of emergency in April 2020. This resulted in a 7.9% reduction in colonoscopies and a 2.7% reduction in cancer detection in 2020.[16] The authors also demonstrated a smooth recovery of examinations to a level similar to that of the previous year, and the number of colonoscopies was maintained until the end of the study period. Considering the approximately 4-week interval between the diagnosis and treatment of colorectal cancers,[17] the drop in surgical numbers around the middle of 2020 in our study aligns with their results. Because the fluctuation range of the surgical numbers appeared large after the onset of the pandemic, we consider that a decrease in colonoscopies, delay in referral and hospital visits, and

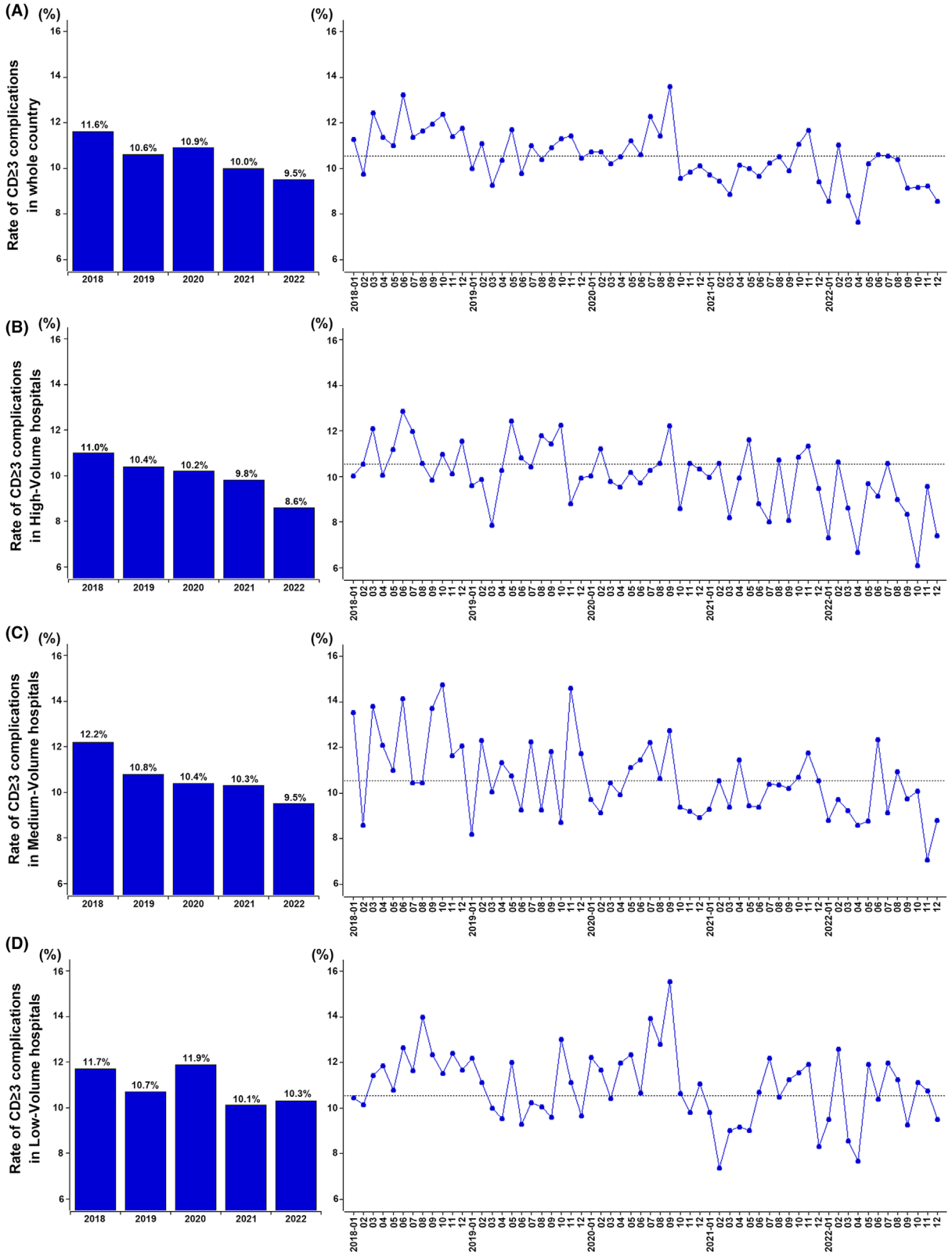

FIGURE 4 Annual and monthly rates of CD ≥ 3 complications. A gradual decline in the annual and monthly rates of CD ≥ 3 complications is evident. However, the rates were higher in 2020 among low-volume hospitals. (A) shows the results for the whole country, (B) for high-volume hospitals, (C) for medium-volume hospitals, and (D) for low-volume hospitals.

restriction of surgeries during the pandemic waves similarly affected all three groups. However, the annual decline in surgical numbers was marginal.

It was anticipated that the delay in the diagnosis and treatment of gastrointestinal cancer after a marked reduction of surgical numbers in the middle of 2020 would result in a rebound in the following

TABLE 2 Numbers and proportions of patients with CD > 3 complications and anastomotic leakage.

		Year of operations				
	Total	2018	2019	2020	2021	2022
CD > 3 complications, *n* (%)						
Whole country	9673 (10.5)	2158 (11.6)	2030 (10.6)	1943 (10.9)	1832 (10.0)	1710 (9.5)
High-volume hospitals	3041 (10.0)	701 (11.0)	670 (10.4)	595 (10.2)	572 (9.8)	503 (8.6)
Medium-volume hospitals	3202 (10.6)	744 (12.2)	692 (10.8)	594 (10.4)	614 (10.3)	558 (9.5)
Low-volume hospitals	3430 (10.9)	713 (11.7)	668 (10.7)	754 (11.9)	646 (10.1)	649 (10.3)
Anastomotic leakage, *n* (%)						
Whole country	8098 (8.8)	1852 (10.0)	1827 (9.6)	1612 (9.0)	1447 (7.9)	1360 (7.5)
High-volume hospitals	2291 (7.6)	532 (8.4)	539 (8.4)	446 (7.7)	403 (6.9)	371 (6.3)
Medium-volume hospitals	2672 (8.9)	650 (10.7)	608 (9.5)	487 (8.5)	477 (8.0)	450 (7.6)
Low-volume hospitals	3135 (10.0)	670 (11.0)	680 (10.9)	679 (10.7)	567 (8.8)	539 (8.6)

years. However, a compensatory increase in the number of surgeries, coupled with alterations in the TNM stage of rectal cancer, was not observed in 2021 and 2022. Instead, surgery volumes across the country slightly reduced by 4.8% in 2020, 3.0% in 2021, and 4.1% in 2022, compared to the averages in 2018 and 2019. In addition, the proportion of TNM stages before and after the pandemic remained essentially unchanged. Therefore, the delay in diagnosis may be limited, and its impact on tumor progression and long-term survival may not be profound. In other words, due to the declining population in Japan,[18] the natural decrease in colorectal cancer across the country could have occurred in the period 2020–2022. However, the ongoing effects of the COVID-19 pandemic have not been ruled out. Utilizing data from the United States National Cancer Database, Janczewski et al. demonstrated the possibility that cancers undiagnosed in 2020 may not have been identified in subsequent years,[19] assuming an increase in cancer diagnoses. Furthermore, their research did not identify any alterations in the TNM classifications of the diagnosed cancers. Their findings are alarming, aligning with those of our study, and further research utilizing other databases is necessary for a comprehensive understanding of these findings.

An unexpected finding of the present study was the steady decrease in monthly rates and SMRs of CD ≥ 3 complications in all three groups, despite the COVID-19 pandemic. Anastomotic leakage after LAR occurs in nearly 10% of cases and often necessitates drainage tube management (placement/exchange of tubes). Thus, the major factor contributing to this finding could be the reduction in the anastomotic leakage rate. Seishima et al. investigated the short-term results of LAR for rectal cancer between 2018 and 2021, suggesting a decline in anastomotic leakage in Japan[4] possibly due to stoma creation. A Swedish database study demonstrated an increase in the use of ostomies in colon surgery, probably aimed at reducing postoperative complications.[20] In addition, the increasing utilization of robotic surgery may explain the decreasing trend in complications. The proportion of robotic surgery increased from 5.3% of all LARs in 2018 to nearly 20% in 2020.[21] A review of literature from various countries suggested that robotic surgery could yield better short-term outcomes owing to several advantages, including instruments with multiple wrists and three-dimensional views.[22] Recently, similar findings have been increasingly reported in Japan.[23,24] Considering that the introduction of robotic surgery is hampered by its cost and the absence of insurance reimbursement in hospitals with low case volumes, the disparities in short-term outcomes among the three groups strengthen this hypothesis.

Besides CD ≥ 3 complications, no evident increase in postoperative pneumonia was identified. The relationship between COVID-19 infection and postoperative pneumonia has been reported in various studies.[25,26] It is suggested that there is a relationship not only with pneumonia but also with other complications.[25] In particular, the risk increase is thought to be highest within 4 weeks, and the effect lasts up to 8 weeks. The early publication of such results[26] may have led to the provision of safer treatment in surgical procedures, but this cannot be clarified in this study.

Although the three groups demonstrated decreasing trends of monthly SMRs for CD ≥ 3 complications, a concern is that the actual rates and SMRs in low-volume hospitals were high around September 2020. In addition, the incidence rate of CD ≥ 3 complications in 2020 was the highest among the 5 years studied (Figure 5). This period also saw the emergence of a second wave of COVID-19 in Japan and an increase in the proportion of older people and patients with more advanced cancer.[4] COVID-19 may have had a greater impact on low-volume hospitals due to their typically lower staffing levels, lower number of or lack of ICU beds, and limited material resources. Besides, low-volume hospitals could have been adversely affected by the phenomenon that the surgical volume remained largely unchanged (Figure 2). However, the SMR decreased immediately without a similar surge in rates and SMRs during subsequent intensified infection waves. This observation may suggest that such data fluctuations may have occurred by chance and warrant further investigation.

While studies investigating the impact of surgical volumes on the short-term outcomes of rectal cancer surgery are scarce, our study demonstrated the possibility of fewer complications in hospitals with higher caseloads. In contrast to previous studies[27–29] and ours, a different conclusion was drawn in a study focusing on a specific

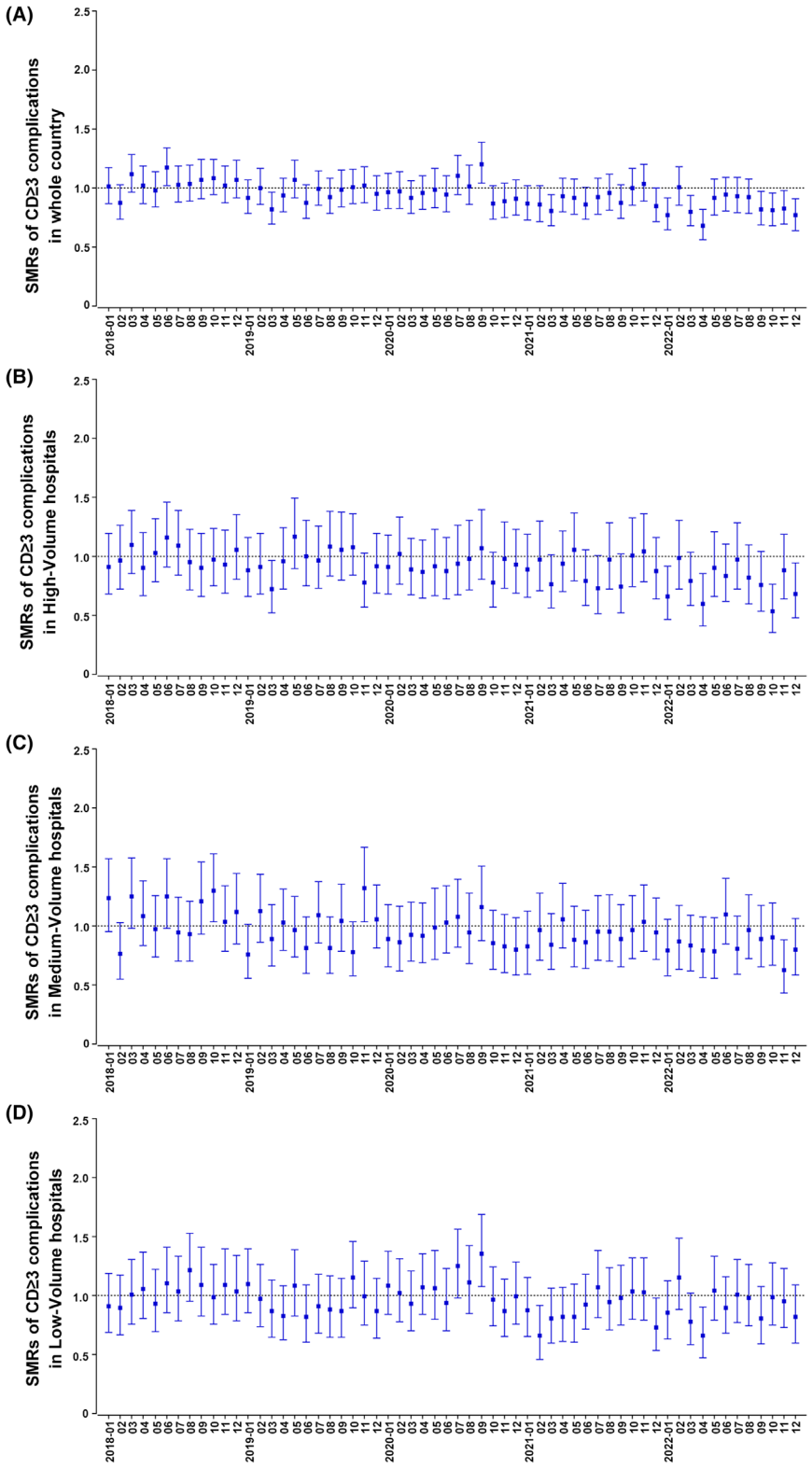

FIGURE 5 SMRs for CD ≥ 3 complications. (A) shows the results for the whole country, (B) for high-volume hospitals, (C) for medium-volume hospitals, and (D) for low-volume hospitals. Although a statistical difference was not observed in most months, a decreasing trend in SMRs is visible in all three groups. Compared with high- and medium-volume hospitals, the decrease in SMRs was slower in low-volume hospitals.

region of Japan. That study also utilized NCD data between 2013 and 2015 and examined the effect of surgical volumes on postoperative outcomes of LAR in relation to patient's commuting distance.[14] They focused on an area of Japan characterized by geographic isolation, where most hospitals had low surgical volumes despite covering broad areas. Consequently, they did not find a significant difference in postoperative results between groups classified by surgical volume and patients' hospital travel time. The discrepancy between that study and ours could be attributed to regional peculiarities as well as multiple factors raised by Kunisawa et al.[14] In addition, the increasing adoption of robotic surgery may contribute to the differences in short-term results among different caseloads.

TABLE 3 Numbers and proportions of surgical mortality and patients with postoperative pneumonia.

		Year of operations				
	Total	2018	2019	2020	2021	2022
Surgical mortality, *n* (%)						
Whole country	422 (0.46)	93 (0.50)	81 (0.42)	67 (0.37)	94 (0.52)	87 (0.48)
High-volume hospitals	55 (0.18)	14 (0.22)	9 (0.14)	10 (0.17)	12 (0.20)	10 (0.17)
Medium-volume hospitals	118 (0.39)	28 (0.46)	32 (0.50)	17 (0.30)	23 (0.39)	18 (0.30)
Low-volume hospitals	249 (0.80)	51 (0.84)	40 (0.64)	40 (0.63)	59 (0.92)	59 (0.94)
Postoperative pneumonia, *n* (%)						
Whole country	824 (0.90)	192 (1.04)	157 (0.82)	149 (0.83)	156 (0.86)	170 (0.94)
High-volume hospitals	200 (0.66)	39 (0.61)	40 (0.62)	39 (0.67)	40 (0.68)	42 (0.72)
Medium-volume hospitals	235 (0.78)	67 (1.10)	49 (0.77)	37 (0.65)	36 (0.60)	46 (0.78)
Low-volume hospitals	389 (1.24)	86 (1.42)	68 (1.09)	73 (1.15)	80 (1.25)	82 (1.31)

Robotic surgery has shown favorable short-term outcomes compared to laparoscopic surgeries,[23,24,30] although only a favorable tendency was suggested in terms of anastomotic leakage (8.8% vs. 7.8%, $p=0.172$).[30] Insurance reimbursement for robot-assisted laparoscopic LAR started in 2018, and the number of these surgeries is increasing yearly.[21] We speculate that the introduction of robotic surgery is hindered in hospitals with low case volumes due to restrictions of insurance reimbursement and high introduction costs, which may be reflected in the difference in surgical outcomes in the present study. Our findings and the referenced literature suggest that centralization is likely a necessary step to further improve surgical outcomes nationwide. However, this process must be balanced with regional characteristics, accessibility, patients' travel burden,[31] and surveillance of tumor recurrence and late complications.

4.1 | Strengths and limitations

The main strength of this study is the utilization of data from the NCD, known for its large dataset and high reliability.[32] Under this condition, SMRs were calculated using relevant clinical factors, including activities of daily living, medical history, blood test results, and tumor factors.

The present study had some limitations. First, the lack of data regarding endoscopic resection, preoperative chemoradiation, postoperative adjuvant therapy, and chemotherapy limited the comprehensive understanding of the treatment alterations in rectal cancer during the pandemic. Second, the lack of information concerning the participation of board-certificated surgeons,[33] patients' frailty,[34] stoma creation, surgical approaches, and tumor location (Ra/Rb) could be considered limitations of the present study. Third, the present study focused on elective surgery because evaluating the safety of surgery among different hospital groups during the pandemic was one of our main objectives. Emergency surgery was excluded because it is generally characterized by much higher mortality and morbidity and should be analyzed as a different surgical context. Indeed, the substantially lower mortality rate in the present study compared with that in other studies[29,35] could be attributed to the exclusion of emergency surgeries. Additional studies focusing on emergency surgery may reveal different aspects of the impact of the COVID-19 pandemic. Fourth, although we divided the patients into three groups based on the surgical volume, the cutoffs utilized in the present study can be optimized to more clearly separate the surgical outcomes. Fifth, the present study did not investigate the reasons for the gradual decline in complications, although this aspect was carefully discussed with reference to prior studies. Sixth, long-term outcomes must be quantified to determine whether the quality/efficacy of surgery was fully maintained during the pandemic. In addition to these limitations, we should note that this study only suggested a potential association between hospital groups divided by surgical volume and prognosis but could not elucidate the underlying mechanism.

5 | CONCLUSION

Low-volume hospitals may have been more affected early in the COVID-19 pandemic. However, across all three hospital volume groups, SMRs of CD ≥ 3 complications and anastomotic leakage rates declined from 2018 to 2022, indicating the consistent provision of safe surgical treatment. Surprisingly, we discovered that the rates and SMRs of complications differed among the three hospital groups, suggesting disparities in short-term outcomes according to surgical volume and the need for further studies.

AUTHOR CONTRIBUTIONS

Hiromichi Maeda: Conceptualization; investigation; methodology; project administration; visualization; writing – original draft. **Hideki Endo:** Conceptualization; data curation; formal analysis; investigation; methodology; writing – review and editing. **Ryo Seishima:** Conceptualization; investigation; methodology; project administration; writing – review and editing. **Taizo Hibi:** Conceptualization; funding acquisition; investigation; methodology; project administration; resources; supervision; writing – review and editing. **Masashi**

Takeuchi: Conceptualization; investigation; methodology; writing – review and editing. **Yusuke Takemura:** Conceptualization; investigation; methodology; writing – review and editing. **Hiroyuki Yamamoto:** Conceptualization; data curation; formal analysis; investigation; methodology; software; writing – review and editing. **Akinobu Taketomi:** Conceptualization; investigation; methodology; supervision; writing – review and editing. **Yoshihiro Kakeji:** Conceptualization; investigation; methodology; supervision; writing – review and editing. **Yasuyuki Seto:** Conceptualization; investigation; methodology; supervision; writing – review and editing. **Hideki Ueno:** Conceptualization; investigation; methodology; supervision; writing – review and editing. **Masaki Mori:** Conceptualization; investigation; methodology; supervision; writing – review and editing. **Ken Shirabe:** Conceptualization; investigation; methodology; supervision; writing – review and editing. **Yuko Kitagawa:** Conceptualization; funding acquisition; investigation; methodology; supervision; writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

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ETHICS STATEMENT

Approval of the research protocol by an Institutional Reviewer Board: The study protocol was reviewed and approved by the Institutional Review Board of Kochi University (2023-108).
Informed Consent: Written informed consent was waved due to the retrospective nature of this study.
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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