

# Assessing the Impact of COVID-19 on Incident Reporting and Elucidating the Characteristics of Incident Reports for COVID-19 Patients at the Critical Care Center of a Tertiary-Care Teaching Hospital in Japan

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The global coronavirus disease 2019 (COVID-19) pandemic has necessitated the establishment of new medical care systems worldwide. Medical staff treating COVID-19 patients perform their care duties in highly challenging and psychologically demanding situations, raising concerns about their impact on patient safety. Therefore, this study aimed to investigate and characterize incident reports related to COVID-19 patients to clarify the impact of COVID-19 on patient safety. The study included data from 557 patients admitted to the Critical Care Center of a tertiary-care teaching hospital in Osaka, Japan, from April 2020 to March 2021. The patients were divided into two groups: COVID-19 (n = 106) and non-COVID-19 (n = 451) and compared based on various characteristics, incident reporting rates, and the content of incident reports. The findings indicated a significantly higher rate of patients with incident reports in the COVID-19 group compared to the non-COVID-19 group (49.1% vs. 24.4%, P < 0.001). In addition, quantitative text analysis revealed that the topic ratio, consisting of "respiration," "circuit," "settings," "connection," "nursing," "ventilator," "control," "tape," "Oxylog®," and "artificial nose" was significantly higher in the incident reports of the COVID-19 group (P = 0.003). In conclusion, COVID-19 patients are more susceptible to adverse incidents and may face a higher risk of patient safety issues. The characteristic topics in incident reports involving COVID-19 patients primarily revolved around ventilator-related issues. In the future, the methodology used in the current study may be utilized to identify incident characteristics and implement appropriate countermeasures in the event of unknown patient safety issues.

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# Introduction

The coronavirus disease 2019 (COVID-19), declared a "pandemic" by the World Health Organization (WHO) on March 12, 2020, has led to significant changes in healthcare systems worldwide. In Japan, the first case of COVID-19 was reported in January 2020, and it was classified as a designated infectious disease in February 2020. Since March 2020, there has been a rise in community-acquired COVID-19 infections, accompanied by frequent mutations of the

virus strain.

Hospitals admitting COVID-19 patients have had to adapt their nosocomial infection control systems, medical treatment protocols, ward organization, and rules, resulting in a healthcare landscape distinct from the pre-pandemic. Despite taking significant precautions to avoid infection, medical staff constantly fear contracting the virus themselves and the subsequent risk of spreading it to their families, other medical staff, and patients. As such, medical staff have been required to operate in psychologically

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unstable conditions during the COVID-19 crisis (Rangachari and L. Woods 2020). Psychological distress among medical staff related to COVID-19 has been reported to have a deleterious impact on patient safety (Rangachari and L. Woods 2020; Al-Shaya et al. 2021).

Incident reports serve as tools for assessing and improving patient safety (Tricarico et al. 2017; Pauletti et al. 2022). Therefore, conducting a thorough analysis of incident reports during the COVID-19 pandemic can help elucidate its impact on patient safety. Previous studies have investigated incident reporting during the COVID-19 pandemic; however, there is no consensus on whether incident reporting has decreased or increased during the pandemic (Denning et al. 2020; Al-Shaya et al. 2021; Pauletti et al. 2022). While some comparisons have been made between the COVID-19 and pre-COVID-19 periods, no studies have compared incident reports between COVID-19 and non-COVID-19 patients or identified incident reports characteristic of COVID-19 patients. One study reported an increase in the frequency of laboratory-related and medical equipment issues mentioned in the incident reports prepared during the COVID-19 period (Al-Shaya et al. 2021). However, the characteristic features of incident reports involving COVID-19 patients remain unclear. Therefore, this study aims to investigate and characterize incident reports involving COVID-19 patients, ultimately clarifying the impact of COVID-19 on patient safety.

#### **Materials and Methods**

#### Study design and data collection

This single-center retrospective study was conducted at the Trauma and Critical Care Center of Osaka Metropolitan University Hospital in Osaka, Japan. In Osaka, the phases of the COVID-19 pandemic were divided into four waves: the first (January 2020-June 2020), second (June 2020-October 2020), third (October 2020-February 2021), and fourth (March 2021-April 2021) waves (Kurahara et al. 2021). The Trauma and Critical Care Center of the Osaka Metropolitan University Hospital began admitting severely ill COVID-19 patients in April 2020 and adjusted its operations by establishing a COVID- 19 physician-support team and periodically closing and reopening wards depending on the number of severely ill COVID-19 patients in Osaka.

The study enrolled patients admitted to the Trauma and Critical Care Center between April 2020 and March 2021. The study excluded deaths occurring in the initial treatment room immediately after admission. Patients were categorized into the COVID-19 and non-COVID-19 groups based on their COVID-19 test results. The assessment focused on patient characteristics such as age, sex, duration of hospitalization, diseases on admission, and any incident reporting. Incident reports were assessed based on the number of reported patients, the number of reports, patient impact level, categories, occupation of the reporter, and a summary of the incident. The evaluation period of the study was limited to the duration of hospitalization at the Trauma and Critical Care Center only; hospitalization in other wards was not included in the study. The incident summary provided a free-text description of the occurred or potential incident. The primary endpoint was the rate of incident reporting, while secondary endpoints included the patient impact levels, the occupations of the reporters, categories, and descriptions of the incident reports between the two groups.

The rate of patients with incident reports was calculated as the percentage of patients who had incident reports out of the total number of patients. The rate of incident reporting per 1,000 hospitalization days was calculated by multiplying the number of patients who were incident reported divided by the total number of inpatient days of eligible patients by 1,000. The number of incident reports per 10 hospitalization days was calculated by multiplying the number of incident reports divided by the number of days of hospitalization for each eligible patient by 10. The patient impact level in the incident report was divided into eight levels based on the injury level of the patient: 0, 1, 2, 3a, 3b, 4a, 4b, and 5 (Table 1). Incident reports were further categorized into medication, medical equipment, nursing care, catheter-related incidents, laboratory incidents, nutrition/food services, patient management, medical records/documentation management, treatment-related inci-

Table 1. Patient impact levels.

Patient impact level	Details of injury
0	Errors and medical equipment malfunctions observed; no incorrect medications provided to patients.
1	No actual harm to the patient; potential impacts not ruled out.
2	No treatment or therapy administered; required enhanced patient observation or tests to confirm safety and monitoring minor changes in vital signs.
3a	Required simple procedures or treatments (e.g., disinfection, compresses, skin stitches, and administration of analgesics).
3b	Required intensive care or treatment (e.g., advanced changes in vital signs, ventilator placement, surgery, extended hospital stay, outpatient hospitalization, and fractures).
4a	Permanent disability or sequelae, without significant functional impairment or cosmetic issues.
4b	Permanent disability or sequelae, with significant functional impairment and cosmetic issues.
5	Death (excluding death due to natural course of underlying disease).

dents, falls/collisions, and other situations. The occupations of the reporters were categorized as physicians, nurses, and others.

Approval for this study was obtained from the ethics committee of Osaka Metropolitan University (approval number 2021-008). This study was conducted per the ethical standards formulated in the Helsinki Declaration of 1964, and in compliance with the "Ethical Guidelines for Medical and Health Research Involving Human Subjects" (Ministry of Health, Labour and Welfare 2015). Information regarding the implementation of the study was published, and both the patients and the medical staff were provided with the option to decline participation. However, no cases of refusal were encountered, and informed consent was obtained from all participants.

#### Quantitative text analysis of incident report summary

To define the characteristic summaries of incident reports involving the COVID-19 group, we utilized KH Coder 3 software, a free tool for quantitative text analysis (Higuchi 2016, 2017). First, using KH Coder 3, we conducted hierarchical cluster analysis to analyze incident summaries from both groups and extract characteristic words found within the incident summaries. These words were then used to create a specified number of clusters based on their similarity. Next, we conducted a topic ratio analysis, which calculates the percentage of each incident summary that contains the characteristic word groups of the clusters created by the hierarchical cluster analysis. The topic ratio is a value that describes the distributional weighting of how often each cluster created by the hierarchical cluster analysis is included in the content of each incident summary. In other words, it represents the rate of frequency of appearances of a specific number of clusters in one report. By comparing the topic ratios between the two groups, we were able to identify the topics that exhibit specific characteristics within the COVID-19 group.

#### Statistical analysis

The statistical analysis was performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan) (Kanda 2013), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). Specifically, EZR is a modified version of R commands that includes commonly used statistical functions in biostatistics.

Nominal variables of the two groups were compared using the Chi-square test, while continuous variables were compared using the Mann-Whitney U test. Differences were considered statistically significant at a *P*-value of < 0.05. This study did not adjust the  $\alpha$  level for simultaneous multiple comparisons.

#### Results

# Patient characteristics

A total of 700 patients were admitted to the Trauma

and Critical Care Center during the study period. Among them, 557 patients were included in the study after excluding 143 patients who had died in the initial treatment room immediately after admission. There were 106 and 451 patients in the COVID-19 and non-COVID-19 group, categorized based on their COVID-19 test results. Regarding patient characteristics, there were no significant differences in sex between the two groups. However, the median age of patients in the COVID-19 group was higher compared to the non-COVID-19 group (72.0 years [interquartile range, IQR: 61.0-78.0] vs. 61.0 years [IQR: 44.3-75.8], P < 0.001). It is important to note that the non-COVID-19 group included one patient with an unknown age. There were no significant differences in the number of patients aged 18 years or less between the two groups. Among the non-COVID-19 group, trauma (29.9%) was the most common condition observed during admission, followed by severe infection (11.8%). Furthermore, the duration of hospitalization at the Trauma and Critical Care Center was significantly longer in the COVID-19 group (12.0 days [IQR: 7.0-17.0] vs. 4.0 days [IQR: 2.0-9.0], P < 0.001). Mortality was 13.2% (14/106) in the COVID-19 group and 12.0% (54/451) in the non-COVID-19 group, with no significant difference between the two groups.

#### Comparison of incident reports

The COVID-19 group had 52 patients with 135 incident reports. In contrast, the non-COVID-19 group had 110 patients with 189 incident reports. The rate of patients with incident reports was significantly higher in the COVID-19 group at 49.1% (52/106) compared to 24.4 % (110/451) in the non-COVID-19 group (P < 0.001). The rate of incident reporting per 1,000 hospitalization days was 38.7‰ in the COVID-19 group and 32.8‰ in the non-COVID-19 group. The number of incident reports per 10 hospitalization days was also significantly higher in the COVID-19 group at 0.0 [IQR 0.0-1.4] reports, compared to 0.0 [IQR 0.0-0.0] reports in the non-COVID-19 group (P < 0.001). The results of the characteristics of patients and comparison of incident reports are presented in Table 2.

There were no significant differences in the occupations of incident reporters between the two groups. The impact level of incident reports was significantly higher in the non-COVID-19 group for level-0 reports [29 reports (21.5%) vs. 67 reports (35.4%), P = 0.010] and significantly higher in the COVID-19 group for level-3a reports [27 reports (20.0%) vs. 18 reports (9.5%), P = 0.012]. Regarding the categorization of incident reports, the non-COVID-19 group had significantly more reports pertaining to treatment-related issues compared to the COVID-19 group [0 reports (0.0%) vs. 13 reports (6.9%), P = 0.005]. The results of incident reporters, patient impact level, and incident report categories are presented in Table 3.

# Quantitative text analysis of incident report summaries Hierarchical cluster analysis and topic ratio calcula-

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Table 2. Characteristics of patients and comparison of incident reports.

	COVID-19 group (n = 106)	Non-COVID-19 group $(n = 451)$	P-value
Sex (male/female), n	74/32	297/154	0.051 <sup>a)</sup>
Age (years), median [IQR]	72.0 [61.0-78.0]	61.0 [44.3-75.8]	$< 0.001^{b}$
Under 18 years, n (%)	0 (0)	16 (3.5)	0.051 <sup>a)</sup>
Diseases on admission, n (%)			
COVID-19	106 (100)		
Trauma		135 (29.9)	
Severe infection		53 (11.8)	
Cardiopulmonary arrest		37 (8.2)	
Acute toxicity		29 (6.4)	
Gastrointestinal disease		29 (6.4)	
Respiratory disease		28 (6.2)	
Cerebrovascular disease		28 (6.2)	
Cardiovascular disease		16 (3.5)	
Burns		13 (2.9)	
Others		83 (18.4)	
Mortality, n (%)	14 (13.2)	54 (12.0)	0.742 <sup>a)</sup>
Number of days hospitalized, median [IQR]	12.0 [7.0-17.8]	4.0 [2.0-9.0]	$< 0.001^{b}$
Number of patient incidents reported, n (%)	52 (49.1)	110 (24.4)	$< 0.001^{a}$
Incident report rate per 1,000 hospitalization days (‰)	38.7	32.8	-
Number of incidents reported	135	202	-
Number of incidents reported per 10 hospitalization days, median [IQR]	0.0 [0.0-1.4]	0.0 [0.0-0.0]	< 0.001 <sup>b)</sup>
Number of incidents reported per patient with incident reported only, n median [IQR]	2.0 [1.0-3.3] (n = 52)	$\begin{array}{c} 1.0 \ [1.0-2.0] \\ (n = 110) \end{array}$	0.007 <sup>b</sup>

<sup>a)</sup>Chi-square test, <sup>b)</sup>Mann-Whitney U test.

Data are presented as number of patients (%) or median [IQR; interquartile range].

tions were performed on 324 incident report summaries. In the hierarchical cluster analysis, the recommended number of clusters for this study was 13 clusters, with each cluster comprising 10 characteristic words extracted per cluster.

The extracted words for Cluster 4 included "respiration," "circuit," "settings," "connection," "nursing," "ventilator," "control," "tape," "Oxylog<sup>®</sup>" (a transport ventilator), and "artificial nose." The topic ratio for Cluster 4 was significantly higher in the COVID-19 group (0.066 [IQR 0.056-0.091] vs. 0.062 [IQR 0.055-0.071], P = 0.008).

In contrast, the topic ratios for Clusters 2, 5, and 9 were significantly higher in the non-COVID-19 group (Cluster 2: 0.068 [IQR 0.059-0.084] vs. 0.077 [IQR 0.062-0.092], P = 0.013; Cluster 5: 0.062 [IQR 0.053-0.081] vs. 0.065 [IQR 0.055-0.096], P = 0.041; Cluster 9: 0.064 [IQR 0.057-0.080] vs. 0.069 [IQR 0.061-0.090], P = 0.003). The results of Clusters, characteristic words or phrases, and comparison of topic ratios are presented in Table 4.

# Discussion

This study aimed to investigate and characterize incident reports related to COVID-19 patients to clarify the impact of COVID-19 on patient safety. To the best of our knowledge, this study is the first to report on the contents and characteristics of incident reports specifically related to COVID-19 patients admitted to a tertiary-care teaching hospital in Japan. The findings of this study revealed an increased rate of incident reporting among COVID-19 patients. Notably, the incident reports involving COVID-19 patients often focused on topics such as "respiration," "circuit," "settings," "connection," "nursing," "ventilator," "control," "tape," "Oxylog<sup>®</sup>," and "artificial nose," indicating a predominant association with ventilator-related issues. This study also utilized quantitative text analysis, a novel approach to identifying the characteristic contents of incident reports involving COVID-19 patients.

The current investigation primarily focused on incident reports within a single ward over a period of one year, and it was observed that COVID-19 patients reported significantly more incidents compared to non-COVID-19 patients. Throughout the study period, the patients hospitalized in the ward under observation were either severely ill COVID-19 patients requiring ventilator management or extracorporeal membrane oxygenation treatment, or general tertiary care emergency patients. Since this study was conducted in a single ward, the medical staff involved in the study were the same for both the COVID-19 and non-COVID-19 groups.

Table 3.	Incident repo	orters, patien	t impact leve	el. and incident	report categories.

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	$\begin{array}{c} \text{COVID-19 group} \\ (n = 135) \end{array}$	Non-COVID-19 group $(n = 189)$	P-value	
Occupation of incident reporters				
Physicians	5 (3.7)	13 (6.9)	0.325	
Nurses	127 (94.1)	172 (91.0)	0.418	
Others	3 (2.2)	4 (2.1)	1.000	
Patient impact level				
0	29 (21.5)	67 (35.4)	0.010	
1	59 (43.7)	68 (36.0)	0.197	
2	20 (14.8)	36 (19.0)	0.398	
3a	27 (20.0)	18 (9.5)	0.012	
3b-5	0 (0)	0 (0)	-	
Incident report categories				
Medication	47 (34.8)	58 (30.7)	0.508	
Medical equipment	30 (22.2)	27 (14.3)	0.089	
Nursing care	27 (20.0)	22 (11.6)	0.056	
Catheter-related	17 (12.6)	30 (15.9)	0.505	
Laboratory	4 (3.0)	13 (6.9)	0.192	
Nutrition/food service	4 (3.0)	2 (1.1)	0.403	
Patient management	3 (2.2)	10 (5.3)	0.271	
Medical record/documentation management	2 (1.5)	2 (1.1)	1.000	
Treatment-related	0 (0)	13 (6.9)	0.005	
Fall/collision	0 (0)	2 (1.1)	0.632	
Others	1 (0.7)	10 (5.3)	0.055	

Data are presented as number of reports (%).

Chi-square test.

Regarding patient characteristics, a notable age difference was observed between the two groups, with the COVID-19 group having a significantly older population. This aligns with the general clinical epidemiology of COVID-19 in Japan, where older age has been identified as a risk factor for severe COVID-19 cases (Matsunaga et al. 2021). The COVID-19 group in this study exclusively consisted of severe cases, which further supports the correlation between older age and severity. In our research, there were limited reports indicating an explicit association between patient age and the rate of incident reporting. Elnahal et al. (2016) found that patients under 18 years of age reported incidents more frequently compared to adult patients. Similarly, another study reported that pediatric patients are associated with an increased rate of incidents (Chang et al. 2014). In the present study, the non-COVID-19 group included 16 patients under the age of 18, whereas the COVID-19 group had no patients in this age range. Nevertheless, the higher incident-report rate observed in the COVID-19 group cannot be solely attributed to age-related factors.

In addition, the COVID-19 group had a longer duration of hospitalization at the Trauma and Critical Care Center in our study. Launay et al. (2021) reported that the duration of hospitalization affects the occurrence of adverse events among older emergency patients. This finding suggests that a longer duration of hospitalization may result in a higher frequency of incident reporting. Therefore, this study made adjustments for the rate of incident reporting and the number of incident reports based on the duration of hospitalization. The rate of incident reporting per 1,000 hospitalization days was higher in the COVID-19 group. The number of incident reports per 10 hospitalization days was also significantly higher in the COVID-19 group. These findings suggest that the rate of incident reporting may have been higher in the COVID-19 group in this study, regardless of the duration of hospitalization.

Several studies have investigated the relationship between COVID-19 and incident reports. Denning et al. (2020) reported a significant decrease in the ratio of incident reports during the COVID-19 pandemic compared to before the pandemic. They attributed this decrease to factors such as the increased workload of medical staff, a shift in perception regarding the importance of errors, and decreased opportunities for incidents due to the discontinuation of routine operations (Denning et al. 2020). However, the findings of the current study differ from theirs. Our study was conducted within a single ward during the same period, and we consider that factors such as medical staff workload, perception of the importance of errors, and the

Table 4. Clusters, characteristic words or phrases, and comparison of topic ratios.

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Clusters	Characteristic words or phrases	COVID-19 group (n = 135)	Non-COVID-19 group $(n = 189)$	P-value	r score
1	Medicine, dose, prepare, saline solution, syringe, audit, continuous, intravenous drip, fentanyl, injection	0.060 [0.052-0.076]	0.063 [0.055-0.079]	0.157	1.8
2	Confirmation, report, notification, medical record, order, communicate, implement, charting, in charge, administration	0.068 [0.059-0.084]	0.077 [0.062-0.092]	0.013	1.8
3	Patient, receive, ward, storage, bed, imagine, high, use, possible, confirmation	0.068 [0.057-0.082]	0.069 [0.059-0.086]	0.200	1.8
4	Respiration, circuit, settings, connections, nursing, ventilator, management, tape, Oxylog <sup>®</sup> , artificial nose	0.066 [0.056-0.091]	0.062 [0.055-0.071]	0.008	1.5
5	Fitting, observation, use, state, insertion, removal, arterial line, think, self, risks	0.062 [0.053-0.081]	0.065 [0.055-0.096]	0.041	1.8
6	Line, exchange, check, night shift, day shift, hand over, point out, forget, central venous, in charge	0.062 [0.055-0.086]	0.066 [0.057-0.084]	0.275	1.7
7	Implementation, examination, finding, insufficient, samples, detection, nursing, blood sampling, work, right	0.066 [0.057-0.080]	0.069 [0.058-0.083]	0.243	1.7
8	Instructions, patient, information, acute, measurement, system, severe, blood sugar, error, wrong	0.063 [0.056-0.079]	0.065 [0.057-0.081]	0.334	1.7
9	Confirmation, doctor, change, instructions, rate of administration, entering room, nursing, description, order, check	0.064 [0.057-0.080]	0.069 [0.061-0.090]	0.003	1.9
10	Nursing, doctor, leader nurse, surgery, emergency, initiation, out, necessary, termination, in charge	0.068 [0.058-0.082]	0.069 [0.061-0.089]	0.060	1.8
11	Possible, time, report, transfer, alarm, monitor, progress, correspond, necessary, insufficient	0.065 [0.057-0.083]	0.066 [0.057-0.082]	0.760	1.7
12	Fixation, supine position, found, intubation, tube, decompression, redness, location, attachment, anchor fast	0.062 [0.050-0.108]	0.063 [0.054-0.075]	0.671	1.7
13	Administration, preparation, internal administration, time, leftover medicine, take orally, procedure, plan, notice, prescription	0.063 [0.056-0.085]	0.065 [0.056-0.079]	0.879	1.7

Data are presented as median [IQR; interquartile range]. Mann-Whitney U test.

discontinuation of routine operations did not vary between the COVID-19 and non-COVID-19 groups. Consequently, these factors did not impact the results of our study, which explains the disparity with the findings of Denning et al. (2020).

In this study, we observed an increased rate of incident reporting among COVID-19 patients. We propose two reasons to explain this phenomenon. First, the increase in incident reports could be attributed to heightened anxiety among medical staff who suddenly found themselves involved in the treatment of an unknown infectious disease. Many reports indicate that medical staff are at an increased risk of contracting COVID-19 (Shah et al. 2020; Nguyen et al. 2020; Chou et al. 2020). The COVID-19 pandemic placed extreme stress and anxiety on medical staff. For healthcare providers, incident reports can serve as valuable learning opportunities to protect patients against future risks. In addition, utilizing data from incident reports can help reduce anxiety levels among medical staff. Al-Shaya et al. (2021) reported an increase in the number of incident reports during the COVID-19 period, compared to before and after the pandemic, when medical staff were aware of the importance of incident reporting. This finding is consistent with the findings of our study. Second, we suggest that the increase in incident reports during the COVID-19 pandemic may be attributed to the implementation of specific treatment protocols for COVID-19 patients. In this study, we conducted quantitative text analysis on incident report summaries from the COVID-19 and non-COVID-19 groups. Consequently, we found that the incident report summaries characteristic of the COVID-19 group included words such as "respiration," "circuit," "settings," "connections," "nursing," "ventilator," "management," "tape," "Oxylog®," and "artificial nose." This suggests that incident report summaries regarding ventilator-related incidents were more prominent in the COVID-19 group. A comparison of incident report categories showed no significant differences between the two groups in medical equipment. For this reason, a quantitative textual analysis of incident reports may reveal evidence that univariate analysis comparisons could not. Our hospital developed specific rules for the treatment of COVID-19 patients, including setting the FiO<sub>2</sub> (fraction of inspiratory oxygen) of the Oxylog<sup>®</sup> transport ventilator to 100% when transferring a COVID-19 patient to a laboratory or another site to prevent coronavirus contamination of the transport ventilator. The adoption of similar rules has also been reported in other healthcare facilities (Notz et al. 2020). Conversely, when transferring a non-COVID-19 patient with Oxylog®, the FiO<sub>2</sub> setting should match the current setting of the patient. In addition, ventilator management is essential for treating severely ill COVID-19 patients (Umakanthan et al. 2020). Against this background, we believe that incident reports involving ventilator-related, were more prevalent among COVID-19 patients. Incident reports of patients at impact level 3a were also more common in the COVID-19 group, indicating a higher probability of actual harm among these patients. It is important to note that incident reporting relies on voluntary reporting from medical staff, and further examination is required to determine whether incidents resulting in disabilities occurred in COVID-19 patients. However, the increase in incident reports must be considered a positive aspect. A comprehensive analysis of incident reports can help mitigate similar risks in the future (Abraham et al. 2021). Furthermore, we believe that avoiding the risk of incidents will contribute to alleviating anxiety among medical staff. Therefore, it is important to improve patient safety by implementing the lessons learned and experiences gained from incident reports within the healthcare field.

Although the present study reveals important findings, it has several limitations. First, it was a retrospective study conducted among a limited number of patients in a single institution. Second, given the study's design, it was not possible to assess the psychological well-being of the Trauma and Critical Care Center staff during the study period. Third, because incident reporting is a voluntary reporting system for medical staff, there may be a discrepancy between the actual number of incidents and the number of incidents reported. This study revealed very few incident reports related to exposure to infectious materials or non-compliance with infection prevention rules, other than ventilators. It is not sufficiently clear whether there were no infection management problems or no reported infection management incidents. Fourth, the study period encompassed the first year after the outbreak of the COVID-19 pandemic. Given that the severity and infectivity of the disease have varied depending on the different severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants (Akaishi et al. 2022; Lundberg et al. 2022), the management of COVID-19 in healthcare facilities has also evolved. Therefore, further research is necessary to determine whether the results of this study remain specific to COVID-19 patients.

In conclusion, the findings of this study demonstrate an increase in incident reports among COVID-19 patients, influenced by increased of uncertainty among medical staff and the implementation of protocols specific to COVID-19 patients. Using quantitative text analysis of incident reports, the findings highlighted that ventilator-related incident reports are characteristic of COVID-19 patients. Employing the same methodology as in this study may enable the prompt identification of incident characteristics and facilitate the implementation of appropriate measures in the face of unknown patient safety issues in the future.

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#### **Author Contributions**

H. Kawaguchi and E.N. Yamaguchi developed the study protocol; H. Kawaguchi and E.N. Yamaguchi performed the data analysis; H. Kawaguchi., H. Kakeya, and E.N. Yamaguchi wrote the manuscript. All authors critically reviewed the manuscript and approved its publication.

#### **Conflict of Interest**

The authors declare no conflict of interest.

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