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RESEARCH ARTICLE

REVISED Comparison of clinical characteristics and outcomes between COVID-19 survivors and non-survivors: a retrospective observational study

[version 3; peer review: 2 approved]

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Abstract

Background

To compare the clinical characteristics of COVID-19 survivors and non-survivors who were transferred from general wards to the critical care units in four tertiary hospitals of Nepal.

Methods

This study utilized electronic data from the National Intensive Care Unit (ICU) registry managed by the Nepal Intensive Care Research Foundation (NICRF). A retrospective observational study was conducted among 78 eligible COVID-19 patients admitted to the intensive care units of four different hospitals between 2020 and

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2022. The Mann-Whitney U test was used to compare each continuous variable between the survivors and non survivors, while Pearson's chi-squared test was used to examine the association between each categorical variable and outcome.

Results

Among 78 cases of COVID-19 studied, 29 (37.1%) had died, and 49 (62.8%) had recovered. The median age of the patient was 57.5 years, with a higher percentage of males (66.6%). Hypertension (41%) and diabetes (26.9%) were common comorbidities, whereas pneumonia (41%) and acute respiratory distress syndrome (19.2%) were common complications. Most patients required oxygen therapy (96.2%). Corticosteroids (76.9%) and anticoagulants (83.3%) were commonly administered medications. Median of mean arterial pressure was 85 mm Hg [IQR- 79.2-99.5] in non-survivors and 93.3 mm Hg [IQR-86.6-102.6] in survivors which was significantly different between the two groups (p = 0.04). Nine of the patients had cardiac dysfunction on ICU admission, of which none survived (p = 0.001). Out of ten patients requiring inotropes or vasopressors, only two survived (p = 0.001).

Conclusions

Non-survivor COVID patients had lower mean arterial pressure on admission to intensive care units. A higher proportion of patients with cardiac dysfunction and requiring inotropes or vasopressors could not survive.

Plain language summary

This study aimed to compare the clinical features of COVID-19 patients who survived and those who did not after being transferred from general wards to critical care units in four major hospitals in Nepal. Data from 78 patients, gathered from the National Intensive Care Unit registry, were analysed. Among these patients, 37.1% did not survive, while 62.8% recovered. The analysis revealed that non-survivors had lower mean arterial pressure upon admission to intensive care units compared to survivors. Patients with cardiac dysfunction on admission and those requiring inotropes or vasopressors had a higher likelihood of not surviving. The study emphasizes the importance of understanding these clinical factors in managing severe COVID-19 cases.

Keywords

COVID-19 mortality, clinical characteristics, Nepal



This article is included in the Coronavirus (COVID-19) collection.

Research & Development, Stevenage, UK

Any reports and responses or comments on the article can be found at the end of the article.

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REVISED **Amendments from Version 2**

The revised version includes key improvements in response to reviewer comments. The Methods section now clearly defines the "comprehensive" registry data and adds temporal context of admissions (2020–2022), while acknowledging missing data on SARS-CoV-2 sequencing and timing of symptom onset to admission as limitations. The statistical analysis has been clarified as unadjusted, with no multivariable analysis due to small sample size, and the risks of type II error and absence of power calculation are now stated. Interpretation of the violin plot has also been improved. Data transparency has been strengthened by sharing de-identified data in Figshare. The interpretation of findings has been revised to avoid overstatement: vasopressor use is now described as reflecting underlying shock rather than causing mortality, and conclusions on vaccination have been removed due to incomplete data and limited power. The limitations section has been expanded accordingly.

Any further responses from the reviewers can be found at the end of the article

Introduction

The global outbreak of the novel coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has presented an unprecedented challenge to healthcare systems worldwide. Since its emergence in late 2019, COVID-19 has rapidly spread, affecting millions of people worldwide, including Nepal. As of September 2023, Nepal has reported 1,003,431 confirmed cases of COVID-19 and 12,031 deaths.[1] Numerous studies have identified predictors of severity and mortality in COVID-19 patients. Factors such as age, underlying health conditions, and elevated inflammatory markers, including White Blood Cell Counts, Neutrophil-to-Lymphocyte ratio, Serum Glutamic Oxaloacetic Transaminase (SGOT), sodium, and potassium levels, are commonly associated with COVID-19 severity.[2] Early assessment and monitoring of these laboratory parameters have been shown to be critical in halting disease progression and preventing fatalities.[3] Recent studies have also focused on molecular biomarkers like IL-6, IL-8, and SP-D, which may offer early indications of disease severity and progression.[4] Additionally, elevated levels of creatinine, D-dimer, lactate, and potassium in a patient's blood, a low PaO2/FiO2 ratio, and a rapidly increasing alveolar-arterial gradient have been identified as predictors of mortality in critically ill patients.[5]

COVID-19 can be complicated by severe acute respiratory illness (SARI), often necessitating hospitalization and intensive medical care.[6,7] Early recognition and comprehensive management of SARI in COVID-19 patients are crucial for improving outcomes. This study aimed to compare the clinical characteristics of COVID-19 survivors and non-survivors who were transferred from general wards to the critical care units in four tertiary hospitals in Nepal. During COVID-19 surge, these general wards were utilized as isolation units for the infected patients. Patients who were initially admitted in general wards were non-severe COVID-19 patients. These patients were shifted to intensive care units either based on progression to severe COVID or physician discretion. The characteristics of patients presenting with severe COVID-19 in the hospital may differ from the patients who present with non-severe illness and become severe during the hospital stay. So this study only included those patients who were non severe on presentation to the hospitals.

Methods

Study design, setting and population

This study employed a retrospective observational design and utilized medical records from four hospitals within the national Intensive Care Unit (ICU) registry managed by the Nepal Intensive Care Research Foundation (NICRF). The registry utilized Case Report Form[8] and contained comprehensive information on all patients admitted to the ICU including demographic, clinical, laboratory, treatment, and outcome variables, from admission until discharge. The study accessed raw data from the registry covering the period from 2020 to 2022. There were 31 (39.7%) ICU admissions in 2020, 25 (32.1%) in 2021, and 22 (28.2%) in 2022, reflecting different phases of the COVID-19 pandemic and considered registered patients who met the following inclusion criteria: (i) Patients aged 18 years or above (ii) having laboratory confirmed SARS-CoV-2 infection; and (iii) initially admitted in general wards. The exclusion criteria were: (i) Patients without lab confirmed COVID-19 (ii) Patients brought to Emergency Department or directly admitted to ICU; and (iii) Patients transferred from another health facility. Data on SARS-CoV-2 variant sequencing and timing from symptom onset to hospital or ICU admission were not available in the registry.

From 122 records initially identified, 91 were screened for completeness (Figure 1). Out of them, 78 were eligible for inclusion after excluding irrelevant records and patients transferred to another health facility. The final analysis included a total of 49 survivors and 29 non survivors.[8]

The study collected demographic data, clinical characteristics, laboratory parameters, treatments, and outcomes for all patients.

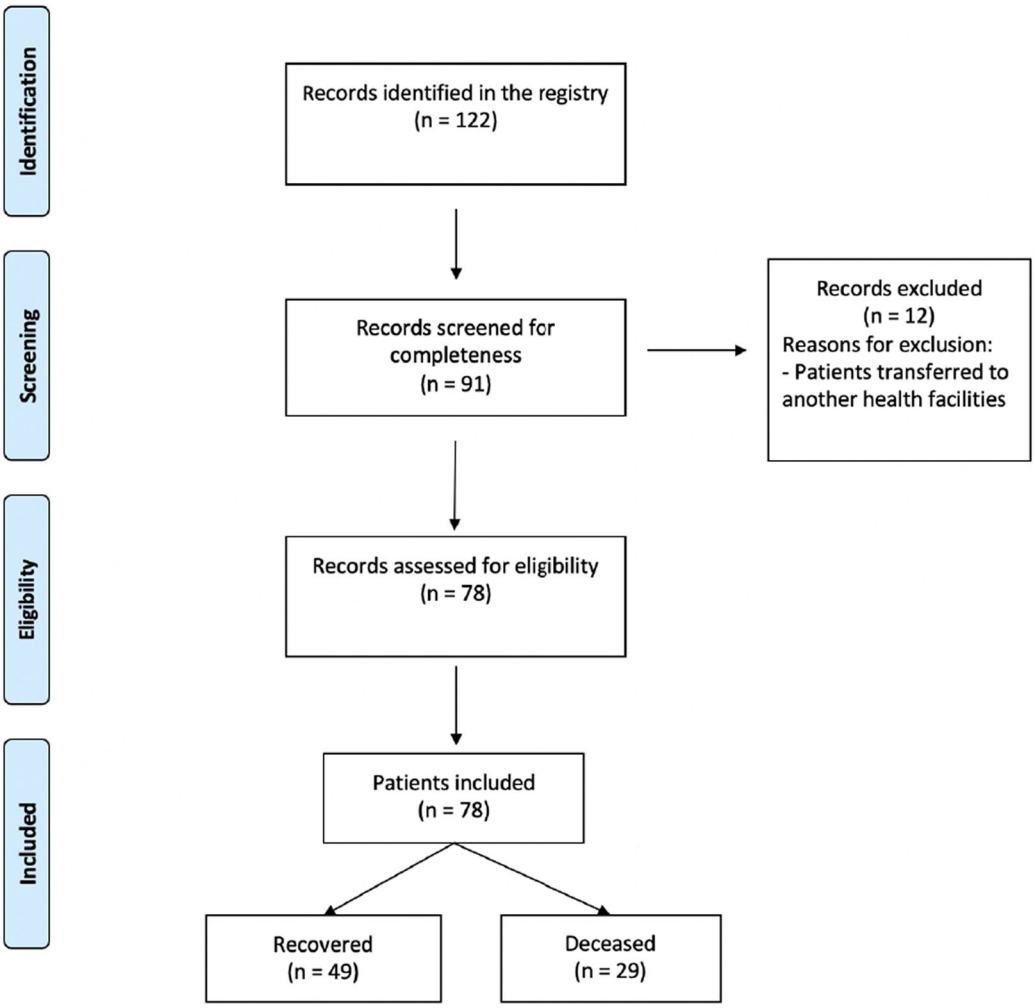


Figure 1. Flowchart of study of the selected patients with COVID-19.

Data analysis

The statistical analysis involved tabulating continuous variables as median and interquartile range [IQR]. The Mann-Whitney U test was used to compare continuous variables between the survivors and non-survivors, while Pearson's chi-squared test was used to examine the association between categorical variables and outcome. In cases where the expected frequency in any cell of the contingency table was less than 5, Fisher's exact test was used. All analyses were unadjusted, and no multivariable analysis was performed due to the limited sample size. The significance level was set at 5%, (alpha = 0.05). All statistical analysis was conducted using IBM Statistical Package for the Social Sciences (SPSS) software, version 25.

The study was conducted after obtaining ethical clearance from Nepal Health Research Council (Ref No. 1698/2022) on 23rd January 2023. We received exemption from review of secondary data which was de-identified and did not involve direct patient participation.

Results

Socio-demographic and clinical characteristics

Table 1[8] presents the socio-demographics and clinical characteristics of hospitalized patients with COVID-19. The patients had a median age of 57.5 years (IQR 48–68.7), with 66.6% being male, and among 29 who died, 20 were males. Upon admission, no significant differences in temperature, heart rate, or respiratory rate were found between the non survivors and survivors. The median peripheral oxygen saturation (SpO2) was lower in both groups (<94%), but this difference was not statistically significant. However, the mean arterial pressure was significantly lower in non-survivor

Table 1. Socio-demographics and clinical characteristics of hospitalized patients with COVID-19.

Characteristics	Total (n = 78)	Non- Survivor (n = 29)	Survivor (n = 49)	P-value
Age years, Median [IQR]	57.5 [48–69.25]	58 [48–71]	57 [48–68]	0.702
Sex n (%)				
Female	26 (33.3)	9 (31)	17 (34.7)	0.740
Male	52 (66.6)	20 (69)	32 (65.3)	
Vitals at admission				
Temperature degree Celsius	36.8 [36.3–37.7]	36.7 [36.1–37.6]	36.8 [36.3–37.8]	0.348
Heart rate beats per minute	95 [80–110]	100 [76–111]	93 [80–110]	0.676
Respiratory rate breaths per minute	24 [22–28]	24.5 [22–30]	24 [20–25.5]	0.059
Peripheral oxygen saturation (SpO2)	91 [85.7–94]	91 [83–93]	90 [86–94]	0.800
Mean Arterial Pressure mm Hg	90 [83.3–100.3]	85 [79.2–99.5]	93.3 [86.6–102.6]	**0.044***
Comorbidities n (%)				
Hypertension	32 (41.0)	11 (37.9)	21 (42.9)	0.669
Diabetes Mellitus	21 (26.9)	9 (31.0)	12 (24.5)	0.529
Renal disease	9 (11.5)	5 (17.2)	4 (8.2)	0.225
COPD/pulmonary disease	8 (10.3)	2 (6.9)	6 (12.2)	0.452
Hypothyroidism	8 (10.3)	5 (17.2)	3 (6.1)	0.118
Cardiovascular disease	5 (6.4)	2 (6.9)	3 (6.1)	0.893
Symptoms n (%)				
Fever	54 (69.2)	19 (65.5)	35 (71.4)	0.585
Shortness of Breath (SOB)	50 (64.1)	18 (62.1)	32 (65.3)	0.773
Cough (non- productive)	33 (42.3)	10 (34.5)	23 (46.9)	0.282
Cough (productive)	19 (24.4)	10 (34.5)	9 (18.4)	0.109
Fatigue/Malaise	9 (11.5)	4 (13.8)	5 (10.2)	0.428
Vaccination Status n (%)		.		
Yes	15 (19.2)	5 (17.2)	10 (20.4)	0.190
No	30 (39.7)	8 (27.6)	22 (44.9)	
Unknown	33 (41.0)	16 (55.2)	17 (34.7)	

*p < 0.05, n = number of patients, IQR = Interquartile Range, COPD = Chronic Obstructive Pulmonary Disease.
(Note: Body Mass Index (BMI) was not calculated due to incomplete entries in the registry).

(85 [79.2–99.5]) compared to the survivor (93.3 [86.6–102.6]) with a p-value of 0.044. While the medians of systolic and diastolic blood pressure are similar between COVID-19 survivors and non-survivors, the independent values are clustered around the median for survivors but widespread for non-survivors (Figure 2). Hence the non-survivors showed a higher range of blood pressure values compared to survivors.

The violin plot illustrates the distribution and variability of systolic and diastolic blood pressure values, with greater dispersion observed among non-survivors. The embedded box plot represents the median and interquartile range. In terms of comorbidities, hypertension was the most common comorbidity at 41%, followed by diabetes mellitus (26.9%) and renal disease (11.5%). The most common symptoms were fever (69.2%) and shortness of breath (64.1%). Out of 78 patients, 45 had known vaccination status, and of those 15 (19.2%) were vaccinated.

Laboratory tests at ICU admission

Table 2 summarizes the laboratory findings of patients upon admission to the ICU. Upon admission to the ICU, the majority of patients (n = 48; 61.5%) had decreased lymphocyte counts. Non-survivors had slightly higher levels of AST/SGOT, CRP, LDH, and D-dimer but the differences were not statistically significant. Arterial blood gas analysis also did not reveal any significant differences between the two groups.

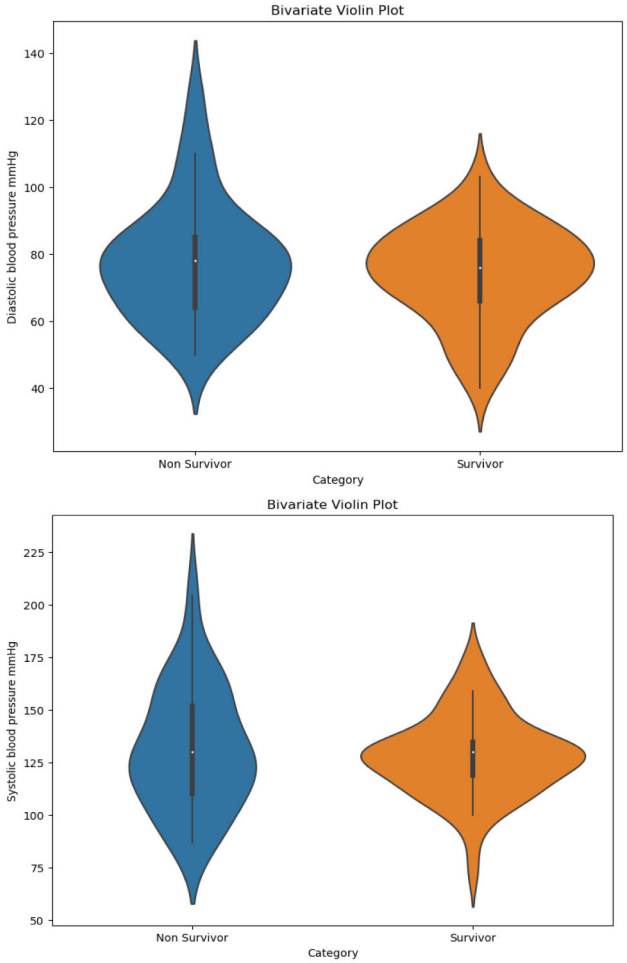


Figure 2. Violin plot of systolic and diastolic blood pressure distribution between COVID-19 non-survivors and survivors.

Table 2. Laboratory tests at ICU admission of hospitalized patients with COVID-19.

Laboratory tests	Total (n = 78)	Non-Survivor (n = 29)	Survivor (n = 49)	P-value
Haemoglobin (g/dL) (median [IQR])	13.1 [10.9–14.3]	13.8 [11.4–14.6]	12.8 [10.5–13.8]	0.146
WBC count (x10^9/L)				
< 4.0	5	3	2	0.596
4.0—12.0	42	16	26	
> 12.0	25	9	16	
Lymphocyte count (%)				
<20	48	16	32	**0.045***
20–50	11	7	4	
>50	0	0	0	

Table 2. *Continued*

Laboratory tests	Total (n = 78)	Non-Survivor (n = 29)	Survivor (n = 49)	P-value
Neutrophil count (%)				
<50	1	0	1	0.723
50–79	15	6	9	
>80	38	15	23	
Platelets (10^9/L)				
<150	12	7	5	0.287
150–450	51	18	33	
>450	7	2	5	
ALT/SGPT (U/L)	45 [22–56.5]	48 [27–54.5]	41.5 [21.2–64.2]	0.662
Total bilirubin (mg/dl)	0.7 [0.5–0.8]	0.7 [0.54–0.8]	0.5 [0.3–0.9]	0.049
AST/SGOT (U/L)	41 [26.7–64]	47 [32.7–74.2]	35.5 [22.2–48.2]	0.051
Glucose (mg/dl)	130 [101–170]	139 [75.5–181.2]	122 [102–155]	0.355
Urea (mg/dl)				
< 20 mg/dl	23	11	12	0.350
>20	47	17	30	
Na (mequ/l)				
<135	26	12	14	0.666
135–145	45	16	29	
>145	1	0	1	
K (mequ/l)				
<3.5	12	4	8	0.407
3.5—4.5	46	16	30	
>4.5	15	8	7	
Procalcitonin (ng/mL)	0.5 [0.1–4.6]	0.9 [0.5–8.4]	0.1 [0.1–4.6]	0.123
CRP (mg/L)	49 [15–82.5]	75 [17.5–7362]	40.5 [13.5–57.2]	0.342
LDH (U/L)	519 [270–951]	855.5 [275–1000]	396 [266–746]	0.301
D-dimer (mg/L)	240.5 [23.6–557]	19.4 [2.7–980.9]	290.7 [176–538.7]	0.307
Ferritin (ng/mL)	1000 [428.1–1000]	1000 [724.3–1470.5]	617 [349.9–1000]	0.164
Arterial blood gas analysis				
*pH	7.46 [7.41–7.48]	7.44 [7.4–7.4]	7.46 [7.41–7.4]	0.458
*paO2/FiO2, mm Hg	128.3 [91.6–178]	123.5 [68.8–187.4]	129 [95.1–178]	0.266
*pCO2, mmHg	31.3 [28.7–34.5]	30.4 [27.5–37.2]	31.4 [29–34.6]	0.477
*HCO3-, mmol/L	22.5 [19.7–24]	21.9 [19.5–26.4]	22.8 [19.8–23.9]	0.616
Imaging				
Chest X-ray infiltrates n (%)	65 (83.3)	24 (82.8)	41 (83.7)	0.999
CT-scan infiltrates n (%)	27 (34.6)	8 (27.6)	19 (38.8)	0.999

*p < 0.05, n = number of patients, IQR = Interquartile Range, WBC = White Blood Cell, ALT/SGPT = Alanine Aminotransferase/ Serum Glutamate Pyruvate Transaminase, AST/SGOT = Aspartate Aminotransferase/Serum Glutamic Oxaloacetic Transaminase, Na = Sodium, K = Potassium, CRP = C-Reactive Protein, LDH = Lactate Dehydrogenase, paO2/FiO2: Ratio of Partial Pressure of Oxygen to Fraction of Inspired Oxygen, pCO2: Partial Pressure of Carbon Dioxide, HCO3- = Bicarbonate, CT = Computed Tomography.
[*Note: The laboratory values which had the low number of observations such as interleukins, creatinine, creatine kinase, lactate, activated partial thromboplastin time (APTT), activated partial thromboplastin ratio (APTR), prothrombin time (PT), and international normalized ratio (INR) were not included in the analysis*].

Table 3. Complications, treatments, and medications in hospitalized patients with COVID-19.

Characteristics	Total (n = 78) n %	Non-Survivor (n = 29)	Survivor (n = 49)	P-value
Complications n (%)				
Pneumonitis	32 (41.0)	16 (55.2)	16 (32.7)	0.051
ARDS	15 (19.2)	8 (27.6)	7 (14.3)	0.150
Cardiac dysfunction	9 (11.5)	9 (31)	0 (0.0)	**<0.001***
Sepsis	5 (6.4)	4 (13.8)	1 (2.0)	0.061
Renal failure	3 (3.8)	3 (10.3)	0 (0.0)	**0.048***
Treatment n (%)				
Oxygen therapy	75 (96.2)	29 (100)	46 (93.9)	0.290
Invasive	9 (11.5)	6 (20.7)	3 (6.1)	0.071
Non-invasive	23 (29.5)	12 (41.4)	11 (22.4)	0.142
Prone positioning	29 (37.2)	9 (31)	20 (40.8)	0.578
Antiviral medication	45 (57.7)	18 (62.1)	27 (55.1)	0.547
Remdesivir	44 (56.4)	18 (62.1)	26 (53.1)	0.438
Tocilizumab	3 (3.8)	0 (0.0)	3 (6.1)	-
Antibiotic medication	63 (80.7)	26 (89.7)	37 (75.5)	0.137
Corticosteroids	60 (76.9)	24 (82.8)	36 (73.5)	0.188
Dexamethasone	54 (69.2)	23 (79.3)	31 (63.3)	0.138
Hydrocortisone	5 (6.4)	1 (3.4)	4 (8.2)	0.646
Methylprednisolone	12 (15.4)	6 (20.7)	6 (12.2)	0.346
Anticoagulant	65 (83.3)	24 (82.8)	41 (83.7)	0.999
Enoxaparin	61 (78.2)	22 (75.9)	39 (79.6)	0.700
UFH	3 (3.8)	1 (3.4)	2 (4.1)	-
Rivaroxaban	1 (1.3)	1 (3.4)	0 (0.0)	-
Inotropes/Vasopressors	10 (12.8)	8 (27.6)	2 (4.1)	**0.001***
Length of ICU stay, median [IQR], days	5.5 [3–10]	8 [3–13.5]	4 [3–9.5]	0.121

*$p < 0.05$, n = number of patients, ICU = Intensive Care Unit, IQR = Interquartile Range.

Complications, treatments, and medications

The most common complications were pneumonia (41%), followed by acute respiratory distress syndrome (ARDS) (19.2%) and cardiac dysfunction (11.5%) (Table 3). Sepsis and renal failure were less common, occurring in 6.4% and 3.8% of patients, respectively. Notably, all patients with cardiac dysfunction (n = 9) died and the analysis showed a significant association between cardiac dysfunction and mortality ($p < 0.001$). Similarly, renal failure also showed significance ($p = 0.04$) but the number of patients with renal failure was low. In terms of treatments, the majority of patients (96.2%) required oxygen therapy. 11.5% required invasive methods, while 29.5% were managed with non-invasive approaches. Regarding medications, corticosteroids and anticoagulants were widely utilized, with usage rates of 76.9% and 83.3% respectively. Antibiotics were given to 80.7% of patients, and 57.7% received antiviral agents, with Remdesivir being the most commonly used (56.4%). Furthermore, out of 10 patients who received inotrope or vasopressors, eight died, which was statistically significant ($p = 0.001$). However, the use of inotropes or vasopressors likely reflects the presence of shock and clinical deterioration rather than being independently associated with mortality. Lastly, the length of ICU stay was longer for non-survivor (median of 8 [3–13.5] days) compared to survivor (median of 4 [3–9.5] days).

Discussion

In this retrospective observational study, we aimed to explore the clinical characteristics and outcomes of COVID-19 patients who were transferred from the general wards and got admitted to the critical care unit for further management. Although SARS-CoV-2 variant data were not available, the distribution of admissions across multiple years suggests that

patients were exposed to different circulating variants during the study period, which may have influenced clinical characteristics and outcomes.

The median age of the patients was 57.5 years. While the mean age of COVID-19 patients varies across different studies and locations,[9–13] previous reports consistently highlighted the susceptibility of older age groups to severe COVID-19 outcomes.[14–16] Moreover, we observed that among those who died, 69% were males, aligning with existing evidence suggesting a higher mortality rate in males compared to females.[17–21] Upon admission, we observed no significant disparities in temperature, heart rate, respiratory rate, or symptoms such as fever, shortness of breath, and cough between the survivors and non-survivors, suggesting that initial vital signs and symptoms may not be sufficient markers of disease progression in COVID-19. However, mean arterial pressure (MAP) was different between the two groups, with the non-survivor exhibiting lower MAP values than survivor. This finding may be associated with age and the presence of hypertension, as previous studies have indicated that pre-existing comorbidities can exacerbate COVID-19 severity and increase the risk of mortality.[22–24] Notably, hypertension and diabetes mellitus were the most prevalent comorbidities among the hospitalized patients. Other studies have also suggested that MAP is a valuable marker for predicting poor prognosis in COVID-19 patients with hypertension.[25,26]

One third of our study patients (5 out of 15) died despite being vaccinated against COVID-19. Due to the lack of data on vaccination status completeness and timing, as well as the substantial proportion of missing data, small sample size, and the associated lack of power, no conclusions can be drawn regarding the association between vaccination status and outcomes in this study. Factors such as pre-existing comorbidities, breakthrough infections, new variants of the virus, and non-clinical factors like quality of clinical care can contribute to severe outcomes in vaccinated individuals. We also examined the use of biomarkers such as CRP, LDH, and D-dimer, which are frequently used to assess inflammation and coagulopathy in COVID-19 patients.[27] However, the number of cases in our study were very few to make any definitive conclusions. Use of oxygen, corticosteroids, and anticoagulants was high in our study cases. Oxygen therapy was administered to the majority of patients (96.2%), which was plausible as acute respiratory distress is commonly seen in COVID-19 cases. Antibiotics were used in nearly 70% of cases, regardless of clear indication. Our study has several limitations. Firstly, its retrospective design, relying on data from the National ICU Registry, introduces the potential for data inaccuracies and missing information. Secondly, the relatively small sample size of 78 patients restricts the generalizability of our findings. The small sample size increases the risk of type II error, potentially limiting the ability to detect true associations and reducing statistical power. Thirdly, as we included four ICUs in the study, variations in admission criteria across these ICUs may have influenced patient characteristics and outcomes. Additionally, incomplete data on vaccination status, including timing and completeness of vaccination, limited the ability to assess its association with clinical outcomes. Furthermore, data on SARS-CoV-2 variant sequencing and timing from symptom onset to hospital or ICU admission were not available, which may have influenced the interpretation of disease severity and outcomes. Finally, as all analyses were unadjusted, the potential influence of confounding variables cannot be excluded.

Conclusion

Our findings provide valuable insights into the clinical characteristics and outcomes of COVID-19 patients seen in health facilities of Nepal. Most of the patients were males, with hypertension being a common comorbidity. Quality of care in general wards can be improved to prevent common complications like pneumonitis, ARDS and cardiac dysfunction which are also the cause of death in COVID-19 patients in low-resource settings. The study also emphasizes proactive monitoring and management of mean arterial pressure (MAP).

Ethics and consent

The study was conducted after obtaining ethical clearance from Nepal Health Research Council (Ref No. 1698/2022) on 23rd January 2023. We received a waiver of consent from Nepal Health Research Council, Review Board for our study as this is a review of secondary data which was de-identified and did not involve direct patient participation.

Data availability

Underlying data

Figshare: Comparison of Clinical Characteristics and Outcomes between COVID-19 Survivors and Non-Survivors: A Retrospective Observational Study.

https://doi.org/10.6084/m9.figshare.25040621.[8]

The project contains the following underlying data:

Characteristics and Outcomes_COVID-19_DATA.

Extended data

Figshare: Comparison of Clinical Characteristics and Outcomes between COVID-19 Survivors and Non-Survivors: A Retrospective Observational Study. https://doi.org/10.6084/m9.figshare.25040621.[8]

The project contains the following extended data:

CRF-COVID-19-CORE-CRF_2024 and Figure 1_Flow chart of study of the selected patients with COVID-19.

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

Acknowledgements

We thank all the involved hospitals and healthcare professionals of the ICUs who provided valuable information in the registry.

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Open Peer Review

Current Peer Review Status: ✔ ✔

Version 3

Reviewer Report 28 April 2026

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✔ **Daniel C Gibbons**
Real-World Data, Measurement & Analytics, Development Sciences, GlaxoSmithKline Research & Development, Stevenage, Hertfordshire, UK

Thanks to the authors for their revisions. No further comments.

Competing Interests: I am an employee of, and shareholder in, GSK plc.

Reviewer Expertise: Epidemiology, biostatistics, COVID-19, clinical medicine.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 2

Reviewer Report 19 December 2024

https://doi.org/10.21956/wellcomeopenres.25779.r113813

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✘ **Daniel C Gibbons**
Real-World Data, Measurement & Analytics, Development Sciences, GlaxoSmithKline Research & Development, Stevenage, Hertfordshire, UK

Is the study design appropriate and is the work technically sound?
Whilst the study design - essentially an observational retrospective registry review - is appropriate,

it would be good to understand what the authors mean by 'comprehensive' data. For example, as all cases are lab confirmed, are sequencing data on SARS-CoV-2 available?

Even if sequencing data are not available, I would recommend that the authors provide summary information on the timing of hospital admission for this cohort of patients (even if it is as broad as, for example, Q2 2021). This may be a reasonable proxy, albeit one prone to ecological bias, to postulate the likely dominant SARS-CoV-2 variant circulating at that point in time.

Under the assumption that such data are available, I would also recommend that the authors report the delay from symptom onset to hospital and ICU admission for each group.

If applicable, is the statistical analysis and its interpretation appropriate?
Due to the small sample size in this study, I appreciate that multivariate analyses are unlikely to be adequately powered. That being said, I would recommend that the authors note that their point estimates and associated significance are unadjusted.

As the sample size is small, there is also a risk of type II error. I recommend that the authors perform power calculations to estimate this risk.

I welcome the addition of the violin plot in Figure 2 to visualise SBP and DBP between groups; I would recommend that some explanatory text is added to aid readers in interpreting box plot component of this graph.

Are all the source data underlying the results available to ensure full reproducibility?
Whilst I applaud the journal's desire to have all source data for a publication available for the purposes of transparency and reproducibility, providing the full raw data for this study would potentially put patient confidentiality at risk.

Are the conclusions drawn adequately supported by the results?
The authors comment that eight of the ten patients who received inotropes and/or vasopressors died - and that this difference was statistically significant. I would recommend that the authors note that such treatment decisions were made in response to the deteriorating clinical state of these patients - and may be a proxy of the presence of shock rather than being associated with poor clinical outcomes in and of themselves.

The authors also note that one-third of patients who died were vaccinated; however, a greater proportion of survivors were vaccinated compared to non-survivors (20.4% vs. 17.2%) and a substantial proportion of patients had unknown vaccination status (41% overall, 55.2% of non-survivors, 34.7% of survivors). No data presented on whether patients had a complete course of vaccination, or what the timing of their last course of vaccination was relative to symptom onset. In addition to the lack of data accurately describing vaccination status and timing, the small sample size may also risk Type II error.

Taking these factors into account, I am uncomfortable that the authors suggest *'Although vaccination is considered the best approach to protect oneself... it alone may not be effective in preventing severe outcomes...'* on the basis of their analyses.

It would be more appropriate to note the lack of data on vaccination administration, its timing and

completeness in this study and that a small sample size, and the associated lack of power, precludes the ability to draw any conclusions on the association of vaccination status and outcomes in this study.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
No

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: I am an employee of, and shareholder in, GSK plc.

Reviewer Expertise: Epidemiology, biostatistics, COVID-19, clinical medicine.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Author Response 28 Mar 2026

Subekshya Luitel

1. Is the study design appropriate and is the work technically sound? Whilst the study design - essentially an observational retrospective registry review - is appropriate, it would be good to understand what the authors mean by 'comprehensive' data. For example, as all cases are lab confirmed, are sequencing data on SARS-CoV-2 available? Even if sequencing data are not available, I would recommend that the authors provide summary information on the timing of hospital admission for this cohort of patients (even if it is as broad as, for example, Q2 2021). This may be a reasonable proxy, albeit one prone to ecological bias, to postulate the likely dominant SARS-CoV-2 variant circulating at that point in time. Under the assumption that such data are available, I would also recommend that the authors report the delay from symptom onset to hospital and ICU admission for each group.
Response: Thank you for the comment. We have clarified the registry variables in the Methods section by expanding “comprehensive” with a description of included data (demographic, clinical, laboratory, treatment, and outcome variables). SARS-CoV-2

sequencing data were not available. To provide temporal context, we have added admission timing: 31 (39.7%) in 2020, 25 (32.1%) in 2021, and 22 (28.2%) in 2022. We have also added a statement in the Discussion noting that admissions across multiple years likely reflect exposure to different circulating variants. Data on symptom onset to hospital/ICU admission were not available and are acknowledged as a limitation.

2. If applicable, is the statistical analysis and its interpretation appropriate? Due to the small sample size in this study, I appreciate that multivariate analyses are unlikely to be adequately powered. That being said, I would recommend that the authors note that their point estimates and associated significance are unadjusted. As the sample size is small, there is also a risk of type II error. I recommend that the authors perform power calculations to estimate this risk. I welcome the addition of the violin plot in Figure 2 to visualise SBP and DBP between groups; I would recommend that some explanatory text is added to aid readers in interpreting the box plot component of this graph.
Response: Thank you for these valuable suggestions. We have clarified in the Methods section that all analyses were unadjusted and no multivariable analysis was performed due to the limited sample size. We have also added in the limitations that the small sample size increases the risk of type II error and that findings should be interpreted with caution. Formal power calculations were not performed and this has been acknowledged as a limitation. We have added explanatory text to Figure 2 to aid interpretation of the violin plot and its embedded box plot.

3. Are all the source data underlying the results available to ensure full reproducibility? Whilst I applaud the journal's desire to have all source data for a publication available for the purposes of transparency and reproducibility, providing the full raw data for this study would potentially put patient confidentiality at risk.
Response: The dataset used in this study has been shared in Figshare in accordance with journal requirements. All data were de-identified prior to sharing to ensure patient confidentiality, and no personally identifiable information is included.

4. Are the conclusions drawn adequately supported by the results? The authors comment that eight of the ten patients who received inotropes and/or vasopressors died - and that this difference was statistically significant. I would recommend that the authors note that such treatment decisions were made in response to the deteriorating clinical state of these patients - and may be a proxy of the presence of shock rather than being associated with poor clinical outcomes in and of themselves. The authors also note that one-third of patients who died were vaccinated; however, a greater proportion of survivors were vaccinated compared to non-survivors (20.4% vs. 17.2%) and a substantial proportion of patients had unknown vaccination status (41% overall, 55.2% of non-survivors, 34.7% of survivors). No data presented on whether patients had a complete course of vaccination, or what the timing of their last course of vaccination was relative to symptom onset. In addition to the lack of data accurately describing vaccination status and timing, the small sample size may also risk Type II error. Taking these factors into account, I am uncomfortable that the authors suggest 'Although vaccination is considered the best approach to protect oneself... it alone may not be effective in preventing severe outcomes...' on the basis of their analyses. It would be more appropriate to note the lack of data on vaccination administration, its timing and completeness in this study and that a small

sample size, and the associated lack of power, precludes the ability to draw any conclusions on the association of vaccination status and outcomes in this study.
Response: Thank you for this valuable observation. We have revised the interpretation to clarify that the use of inotropes and vasopressors likely reflects underlying shock and clinical deterioration rather than being independently associated with mortality. We have also revised the interpretation of vaccination findings. Due to incomplete data on vaccination status, timing, and dosage, as well as the small sample size and associated limited power, we have removed causal statements and now state that no conclusions can be drawn regarding the association between vaccination and outcomes in this study. These limitations have been explicitly acknowledged in the revised manuscript.

Competing Interests: No competing interests were disclosed.

Reviewer Report 11 November 2024

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Tomokazu Konishi
Akita Prefectural University, Akita, Japan

As I am seeing the data, Peripheral Oxygen Saturation- ICU Admission and Respiratory Rate per minute - ICU Admission has clear differences between the groups. Please make violin plots for those classes, not the blood pressures. Those could be convenient tools.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: bioinformatics

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 23 September 2024

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?

Tomokazu Konishi
Akita Prefectural University, Akita, Japan

There has always been concern that patients with heart disease might be more likely to develop severe COVID, and this is a straightforward result of that. We believe that this is an important result for future care. The data is reliable and the way it was compiled is highly valid. On that basis, I have only one request to make

Regarding the mean arterial pressure:
The mean arterial pressure: There was probably a large variation between individual patients. The way Table 2 is presented only shows the average value. This is a great pity. Some patients would have been hypertensive, while others would have had significantly lower blood pressure. These should be considered separately. Hypertension is considered to be one of the symptoms of COVID, but was it mainly patients with heart disease whose blood pressure fell?

One additional figure should be added for this. I would like you to create a violin plot for each systolic and diastolic blood pressure, based on the data from each patient. If this is difficult, then please create histograms for survivors and deaths for each of them and show them.

That's all I have to ask for.

Incidentally, but there are reports that vaccines are no longer lowering mortality.
https://www.mdpi.com/2673-8112/4/2/12

There are also a number of reports, particularly for mRNA vaccines, that these induce IgG4, which in turn impairs immunity. This result confirms such reports.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: bioinformatics

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 05 Nov 2024

Subekshya Luitel

1. Regarding the mean arterial pressure:
The mean arterial pressure: There was probably a large variation between individual patients. The way Table 2 is presented only shows the average value. This is a great pity. Some patients would have been hypertensive, while others would have had significantly lower blood pressure. These should be considered separately. Hypertension is considered to be one of the symptoms of COVID, but was it mainly patients with heart disease whose blood pressure fell?
Response: There are only five patients with cardiac disease. Hence, it could not be assessed if only the patients with cardiac disease had a fall in blood pressure.

2. One additional figure should be added for this. I would like you to create a violin plot for each systolic and diastolic blood pressure, based on the data from each patient. If this is difficult, then please create histograms for survivors and deaths for each of them and show them.
Response: We have added Figure 2, which displays the violin plot of systolic and diastolic blood pressure distribution between COVID-19 survivors and non-survivors.

Competing Interests: No competing interests were disclosed.