



# A Report on the Relationship between Vaccination Status, Viral Loads and Patient Outcomes among Hospitalized Patients during the COVID-19 Omicron Variant's Surge in Tehran, Iran

Shirin Esmaeili<sup>1</sup>, Arezoo Salami Khaneshan<sup>2</sup>, Parvaneh Ebrahimi Alavijeh<sup>2</sup>, Kiavash Semnani<sup>1</sup>, SeyedAhmad SeyedAlinaghi<sup>3</sup> and Marjan Sohrabi<sup>2\*</sup>

1. School of Medicine, Tehran University of Medical Sciences, Tehran, Iran

2. Department of Infectious Diseases, Tehran University of Medical Sciences, Tehran, Iran

3. Iranian Research Center for HIV/AIDS, Tehran University of Medical Sciences, Tehran, Iran

## \* Corresponding author

**Marjan Sohrabi, MD**

Department of Infectious Diseases,  
School of Medicine, Tehran University  
of Medical Sciences, Tehran, Iran

**Email:** sky98194@gmail.com

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## Abstract

**Background:** The present study explored patient outcomes and factors possibly associated with these outcomes among patients hospitalized with severe COVID-19 during the Omicron variant's surge in a tertiary care center in Tehran, Iran.

**Methods:** The study design was a retrospective observational study conducted on adults hospitalized with severe COVID-19 in a tertiary care center in Iran, from 22 December 2021 to 22 April 2022. Patients with major comorbidities were excluded. Demographics, Cycle threshold (Ct) value at diagnosis, and outcomes (length of stay, ICU admission, and mortality) were obtained from hospital archives. Vaccination status was retrieved from a national registry. The relationship between proposed prognostic factors and patient outcomes was analyzed.

**Results:** Data from 212 in-patients with severe COVID-19 was analyzed. Patients were aged  $54.7 \pm 18.6$  years old. 11.3% of patients were admitted to the ICU, and overall mortality was 14.1%. Average length of stay was 6.27 days. 70.8% of patients were fully vaccinated, and 11.3% had received a booster dose. Vaccination was associated with significantly less hospital stay ( $p=0.006$ ), ICU admissions ( $p=0.018$ ), and mortality ( $p=0.024$ ). Higher viral burden was associated with mortality ( $p=0.01$ ), but not ICU admission or longer stay.

**Conclusion:** The present study findings restate the protective role of vaccines against adverse outcomes of COVID-19 infection. However, an alarming rate of poor outcomes during the peak circulation of the Omicron variant was found – warranting further consideration.

**Keywords:** Adult, COVID-19, Intensive care units, Iran, Humans, Length of stay, Prognosis, Vaccination, Vaccines, Viral load

## Introduction

Iran experienced the first wave of the pandemic in February 2020 (1), followed by the devastating fourth and fifth waves associated with the delta variant in late 2021 (2). During this period Iran became a “major epicenters” for the COVID-19 pandemic (3).

However, the following rise of the Omicron variant was postulated to be associated with significantly less severe adverse outcomes (4).

However, even beyond the pandemic, COVID-19 entails a major hazard of morbidity and mortality exceeding that of its longstanding comparator-the seasonal flu (hazard ratio=1.35; confidence interval 95% 1.10 to 1.66) (5). This continued need for battling COVID-19 is further complicated by the public’s fatigue and concerns regarding vaccine efficacy-specifically those from certain available manufacturers in Iran (6). These highlight the need for further local research and the use of such research in policy-making including public information campaigns.

In the current report hospitalization outcomes for patients with severe COVID-19 caused by the Omicron variant of the virus was evaluated. The aim was to compare the findings of this study with previous literature to examine the assumption of diminished concern for negative consequences of COVID-19 associated with newer variants. Additionally, the association between vaccination status and patient outcomes was explored to determine the effect of vaccination under regional protocols, and gauge the possible need for future reinforcement of vaccination programs in battling the now endemic of COVID-19.

## Materials and Methods

### Strategy and design

A retrospective observational study was conducted on patients hospitalized due to severe COVID-19 infection during the Omicron (BA.1 and BA.2) variant’s surge (22 December 2021 to 22 April 2022) (3). Diagnoses were confirmed by a Reverse Transcription Polymerase Chain Reaction (RT-PCR) test. Patient outcomes were defined as recovery, ICU admission and mortality.

### Inclusion and exclusion criteria

Adult (18 years or older) patients with severe

COVID-19-defined as a Respiratory Rate $\geq$ 30, Spo<sub>2</sub> <94% or evidence of sepsis/shock-were eligible for study. Patients with major comorbidities affecting outcomes were excluded. Comorbidities warranting exclusion were: Hypertension (HTN), Diabetes Mellitus (DM), Cardiovascular Disease (CVD), chronic pulmonary diseases, Chronic Kidney Disease (CKD), and cancer.

### Data collection

Demographic data, Ct value at diagnosis, and outcomes were retrieved from hospital records. Ct values had been obtained *via* RNA extraction using a column-based kit (BehGene, Iran), followed by amplification and quantification using RT-PCR with the COVITECH (Iran) kit. Vaccination status was extracted from the SIB Integrated Health System.

### Data analysis

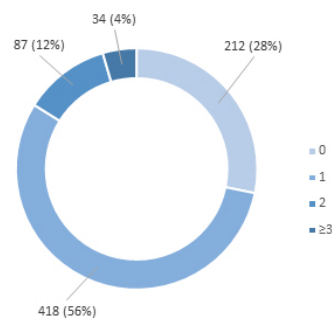
Statistical analysis was performed using IBM SPSS version 25. Chi-square, independent T-test and Pearson correlations were used to examine association between pairs of data. Relative Risks (RR) and corresponding 95% Confidence Intervals (CI95%) were calculated and reported for factors associated with mortality.

## Results

During the study period 807 patients were hospitalized due severe COVID-19 in the tertiary care center. 29 were younger than 18 years old-with a median age of 14 years old (IQR=10-15). Adults were 57.4 $\pm$ 18.7

**Table 1.** Distribution of comorbidities among adults hospitalized with severe COVID-19

Comorbidity	Frequency (percentage)
Hypertension	228(30.3)
Cardiovascular diseases	161(21.4)
Diabetes	136(18.1)
Malignancies	89(11.8)
Pulmonary diseases	58(7.7)
Chronic kidney disease	43(5.7)



**Figure 1.** Number of comorbidities in each adult hospitalized with severe COVID-19.

years old (range=18-98, IQR=42-71). 539 patients (71.8%, Figure 1.) were excluded from analysis due to identification of at least one major comorbidity. The most common comorbidities were HTN, CVD, and DM (Table 1). Data from 212 patients was analyzed. 52.8% of the study sample were males. Gender was not associated with mortality (p-value= 0.95) or ICU admission (p-value=0.47). Patients in the present study sample were aged  $54.7 \pm 18.6$  years old (range=18-91, IQR=40-69)–significantly younger than all patients hospitalized with severe COVID-19 (p-value=0.04). Deceased patients were  $61.6 \pm 14.1$  years old compared to survivors being  $53.5 \pm 19$  years old (p-value<0.001, CI 9% for age difference=2.2-13.9). Patients admitted to the ICU were also older, however, this association was non-significant (p-value=0.38).

The overall mortality rate was 14.1%. 11.3% of patients had been admitted to the ICU during the course of their hospitalization; of these 58.3% had expired (p-value<0.001). The median length of stay was 6 days (IQR=3-10). Patients admitted to the ICU spent a median of 5.5 days (IQR=3-9) in the ward. Length of stay was weakly correlated with age (Pearson correlation=0.23) and had no significant association with gender (p-value=0.938).

A majority (70.8%) of patients were fully vaccinated with two or more doses of a COVID-19 vaccine. 11.3% had received a single dose of vaccine, while 26.4% had received a third “booster” dose. Those receiving the booster dose were significantly (p-value<0.001,  $63.1 \pm 17.3$  years old) older than their counterparts ( $52.2 \pm 17.8$  years old). The Sinopharm vaccine was most commonly used (82.7%), followed by the Astrazeneca (11.5%), Barekat (5%), and Sputnik V (one patient) vaccines.

Vaccination with at least two doses of a COVID-19

vaccine was associated with significantly less mortality (RR=0.47; CI95% 0.25 to 0.91, p-value=0.02) and ICU admission (RR=0.41; CI95% 0.20 to 0.87, p-value=0.02). Decreased mortality with vaccination was a persistent finding when adjusting for other factors (age and Ct values) found likely associated with mortality (adjusted RR=0.31; CI95% 0.13 to 0.73). Among the deceased, the unvaccinated were significantly younger (p-value=0.008)–with an average age of  $54.57 \pm 14$ , while their unvaccinated counterparts were aged  $67.8 \pm 11.2$  years old. Length of stay was also significantly shorter among those fully vaccinated. Vaccinated patients had a length of stay of  $5.6 \pm 4$  days compared to their counterparts’ stay of  $8 \pm 5.5$  days (p-value=0.006).

No association was found between patients’ age (p-value=0.15), gender (p-value=0.32), or vaccination status (p-value=0.66) and Ct values at diagnosis. However, a statistically non-significant (p-value=0.45) difference in Ct values was observed when comparing those receiving a booster dose to those who had received no vaccine ( $25.52 \pm 5.3$  vs.  $24.66 \pm 5.6$ ). Ct values and length of stay were weakly correlated (Pearson correlation=0.09) and no significant association was found between Ct values and ICU admission (p-value=0.58). On the other hand, higher Ct values were found to be significantly associated with less mortality (p-value=0.01; CI 95% for difference=0.69-4.92).

## Discussion

The current study aimed to re-examine outcomes of hospitalization during the COVID-19 Omicron variant’s surge. The present study population (aged  $57.4 \pm 18.7$  years old) manifested demographics similar to other studies from Iran (3,7); while studies

from developed countries reported a more advanced age upon hospitalized due to COVID-19 (8,9). The present study found 28% to have been admitted without comorbidities. This finding is akin to that of a multinational cohort reporting the absence of comorbidities in only 20.6% of patients hospitalized due to the Omicron variant (9). However previous reports from Iran had suggested a larger proportion (40.2%) of hospitalizations among otherwise healthy individuals (3).

Inpatient mortality in the present study was 14.1%. A multi-national cohort reported 9% overall in-hospital mortality (8). Similarly, in-hospital mortality during the Omicron wave was found to be 5.7% in a recent meta-analysis (10). Even though only severe cases were evaluated—considering none of these studies excluded patients with comorbidities—the reported mortality rate constitutes an alarming discovery. The present study findings, however, are not unprecedented. Close to 13% mortality during the early Omicron surge has been reported in Iran (7). A prospective study conducted in the same center, during later waves of Omicron, found the mortality rate for hospitalized patients on day 14 to be 6% (11)—which is comparable to the present study finding of 8.4% 14-day mortality. This may suggest a sinister rate of in-hospital complications in the present study's population. Supporting this proposition, length of stay (median of 5 days, IQR=3-10) was prolonged compared to previous reports (median 4 days, IQR=3-7 over 26 months in Iran) (12). Conversely, overall mortality was far lower than that reported with the alpha and delta variants under similar circumstances (13), a smaller proportion (11.3%) of patients were admitted to the ICU (14), and ICU mortality (58.3%) was lower in contrast to previous COVID-19 surges (68.8%) (2).

Most patients (82.1%) were vaccinated with at least one dose of a COVID-19 vaccine. Patients had overwhelmingly (82.7%) received the Sinopharm inactivated vaccine. This finding is consistent with reports from the Iranian population (1). However different regions have reported a full vaccination coverage as low as 39.5% (5), and vaccine coverage differed exceedingly from that in high socioeconomic countries (14). Consistent with the bulk of present global literature, vaccination was found to be

associated with significantly less mortality (10.6 vs. 22.6%) and ICU admission (8 vs. 19.3%) (15)—a finding some previous reports from Iran had failed to demonstrate (1,11).

The results of the present study findings, support the role of vaccination in preventing adverse outcomes of COVID-19 including hospital stay, ICU admission, and mortality. This proposition seems true despite concerns of limited access to standard vaccination protocols and less-studied vaccines. However, the finding of a high mortality rate in the dominance period for a “less threatening” variant of COVID-19 warrants further contemplation—more so, the presence of this finding in exclusion of patients routinely considered to be high-risk for COVID-19 complications (*i.e.* those with comorbidities). If replicated and found true for later variants of COVID-19, this finding may necessitate further care for COVID-19 prevention efforts such as booster doses of the vaccine—even in the general population. Conversely, if found to be unique to healthcare providers, these results justify a detailed investigation of possible causes (and subsequent solutions) for this unexpected rate of complications in this center as well as those providing care under similar circumstances. The latter is crucial not only for ongoing COVID-19 cases, but possibly for management of future respiratory outbreaks.

### **Limitations**

The current study suffers selection bias by enrolling patients from a tertiary care center. The retrospective study design is also limited by the accuracy of documentation. Absence of data regarding variant confirmation leaves us to presume a dominance of Omicron BA.1 and BA.2 in the study period. We also did not explore the role of treatments received in each case.

### **Ethic approval**

This study was approved by the Imam Khomeini Hospital Complex's ethics committee (IR.TUMS.IKHC.REC.1401.274) as part of the first author's thesis in partial fulfillment of the requirements for the degree Doctor of Medicine. Verbal or written consent were waived due to the retrospective nature of the study. Patients' identifying data were not collected; all data point were anonymized prior to storage.

### Funding statement

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### Conflict of Interest

There was no conflict of interest in this manuscript.

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