

Original Research Article

Vaccination hesitancy as a cause of COVID-related mortality

Jehat Kiliç^{1*}, M. Serdar Yıldırım¹, Ömer Faruk Alakuş¹, Delyadil Karakaş Kiliç²,
Nurettin A. Y.¹, Berat Ebik¹

¹Department of Internal Medicine, Gazi Yaşargil Training and Research Hospital, Diyarbakır, Turkey

²Department of Internal Medicine, Halis Toprak Lice State Hospital, Diyarbakır, Turkey

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*Correspondence:

Dr. Jehat Kiliç,

E-mail: Jehat_kilic@outlook.com

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ABSTRACT

Background: In this study, our aim was to draw attention to the vaccine hesitation as a cause of unvaccination and evaluate the vaccinated and unvaccinated patients in the intensive care unit in terms of morbidity and mortality.

Methods: A hundred and ninety-nine patients between the May 2021-September 2021 admitted to the intensive care units in our hospital were included in this study. We included the patients with COVID-19 infection as assessed by reverse-transcriptase-polymerase-chain-reaction (RT-PCR) assay.

Results: Despite the availability of eligible vaccines in our region, the most of included patients in this study were unvaccinated (n:119). Eighty patients were vaccinated. The vaccinated patients were divided into six groups according to their vaccination status such as subgroup 1: one-dose Coronavac, subgroup 2: two-doses Coronavac, subgroup 3: three-doses Coronavac, subgroup 4: 2-doses Coronavac+ One-dose BNT162b2, subgroup 5: one-dose BNT162b2, subgroup 6: two-doses BNT162b2 (Numbers of patients: 7-61-3-1-10-0 respectively for each group). Between the vaccinated and unvaccinated groups, there was no significant difference in terms of mortality ($p>0,05$). The majority of patients in the vaccinated group were the patients vaccinated with Coronavac (subgroup 2:59), and there was no full dose vaccinated patient with BNT162b2.

Conclusions: While both vaccines are effective to reduce the morbidities and mortality related to COVID-19, there might not be efficacy in these vaccines, particularly Coronavac, following the admission to the intensive care unite in the more vulnerable population. And despite the availability of vaccines, vaccine-hesitancy may be one of the significant reasons for the hospitalization process.

Keywords: COVID-19, ICU, Vaccination hesitancy, Vaccine

INTRODUCTION

At the end of 2019, a novel coronavirus causing severe acute respiratory syndrome was identified in Wuhan as a cause of pneumonia. It has spread inside the country and across the world with the accelerating effect of globalization. In the middle of February, a pandemic was declared by World Health Organization (WHO) due to the unpreventable spread of COVID-19.¹

Since the beginning of the pandemic by now, it is believed that the most promising way developed to curb

the disease or to reduce the morbidity and mortality caused by disease is to vaccinate the majority of the population with effective and safe vaccines.² Biontech (BNT162b2) and Sinovac (Coronavac) are among these vaccines in Turkey, which are in use to contain the virus. The effectivity of BNT162b2 against COVID-19 is high approximately 95%, which is declined to 88% with the surge of the delta variant after a full dose of vaccination.³ Coronavac is an inactivated vaccine developed in China. The different studies suggest the different rates of neutralizing activity against COVID-19. In a study in Turkey, its effectivity is 83.5% among 10.000

participants, however, lower effectivity has been reported in Brazil by 50% against COVID-19. This rate has been declined with the emergence of variant B.1.351 (Beta) and B.1.617.2 (Delta) variants.⁴⁻⁷

Although vaccines are effective against the COVID-19 infection to reduce hospitalizations and mortality, it is unclear if they are effective for the vaccinated population after hospital admission or if there are any differences between the vaccinated and unvaccinated patients in terms of morbidities and mortalities.⁸ Besides this, one of major obstacles in the vaccination process might be vaccination hesitancy, which reasons vary across time, places, and vaccines.⁹

In this study, we aim to define characteristic features, morbidities and vaccination status of the patients admitted to the intensive care unit (ICU) and draw attention to that vaccine or vaccination hesitancy might be one of the biggest obstacles despite the effectiveness and safety of vaccines.

What is known?

Vaccines are highly effective and protective against COVID-19 infection. Vaccination can reduce COVID-19 related morbidities and mortality.

What is new?

Although vaccination is protective against the infection, there might be no difference between the vaccinated and unvaccinated patients after admission to intensive care units. Despite the availability of vaccines, vaccination hesitancy might prevent people from getting vaccinated and can cause COVID-19-related morbidities and mortality.

METHODS

This study retrospectively has been designed and 199 patients between the May 2021-September 2021 were included in the Gazi Yaşargil Training and Research Hospital. The ethical approval was obtained from the ethical committee of our hospital.

Inclusion criteria

We included the laboratory-confirmed patients with COVID-19 infection as assessed by reverse-transcriptase-polymerase-chain-reaction (RT-PCR) assay which was confirmed by computerized tomography (CT) of the thorax.

Demographic data, age, and gender of the patients were recorded. Vaccination status was obtained from the digital data of patients. The patients were hospitalized in the intensive care unit and were selected in accordance with the criteria for admission to the ICU. The patients who have dyspnea, frequent respiratory rate (>30

per/min), oxygen saturation <93%, PO₂/FiO₂<300 and infiltrates more than 50% in CT were considered as severe infection to admit to ICU. The length of stay (LOS) in the ICU and whether they were intubated were evaluated.

Information about the vaccination status of intensive care patients was obtained from the digital health data of the patients. It was determined how many doses of each vaccine were used. The vaccination status of the patients was evaluated considering the 12 days following the last dose. Vaccine doses within 12 days were not considered as administered doses.

Exclusion criteria

Patients younger than 16 years of age, immunosuppressed patients, patients using immunosuppressive drugs, and patients with malignancy were not included in this study. Immunosuppressive diseases and malignancy, along with drugs, were excluded from the study because they may affect the immune response and affect the efficacy of the vaccine.

Patients were divided into two groups as vaccinated and unvaccinated. Group 1 was determined as unvaccinated patients and group 2 as vaccinated patients. Patients who received at least a single dose of vaccine were also considered vaccinated. Group 2 was divided into 6 subgroups according to the number of vaccines and type of vaccine. Subgroup 1: a single dose of Coronavac, subgroup 2: a double dose of Coronavac, subgroup 3: 3 doses of Coronavac, subgroup 4: 2 doses of Coronavac+1 dose of BNT162b2, subgroup 5: a single dose of BNT162b2, subgroup 6: 2 doses of BNT162b2.

In addition, the patients were evaluated in terms of comorbid diseases; diabetes mellitus (DM), hypertension (HT), chronic kidney disease (CKD), coronary artery disease (CAD), and chronic obstructive pulmonary disease (COPD). Comorbid diseases were evaluated between the vaccinated and unvaccinated groups. Mortality and comorbid diseases were evaluated between unvaccinated patients and subgroup 2, which constitutes the majority within the vaccinated group.

Statistical analysis

Kolmogorov-Smirnov, Shapiro-Wilk test, coefficient of variation, skewness, and kurtosis methods were used to control the normal distribution of patient data. Continuous variables were expressed as mean and standard deviation values, while categorical variables were expressed as percentage. An independent t-test was used to determine the difference between age, gender, and laboratory parameters in vaccinated and unvaccinated patient groups. Independent samples t-test or Mann Whitney U test was used to determine the difference in terms of comorbid diseases between patients who survived and died of COVID-19. One-way ANOVA test

was applied in groups with homogeneous variances, and Chi-square test was used in groups whose variances were not homogeneously distributed. All tests were bilateral and p value <0.05 was considered statistically significant. Statistical analyzes were performed using the SPSS24.0 for Windows (SPSSInc.Chicago, IL, USA) package program.

RESULTS

One hundred-ninety nine patients were included in this study. The mean age of the patients was 68.34±15.12 years(p:0.004). Ninety-nine of the patients were male, and 100 were female (p>0.05) (Table 1). The patients were divided into two groups as vaccinated and unvaccinated. Vaccinated patients were also divided into 6 groups. The vaccinated group was classified as group 1 a single dose of Coronavac, group 2 as 2 doses of Coronavac, group 3 as 3 doses of Coronavac, group 4 as 2 Coronavac+1 BNT162b2, group 5 as 1 dose of BNT162b2 group 6 as 2 doses of BNT162b2. Of 199 patients, 119 were unvaccinated and 80 were vaccinated (number of patients in group 1: 7, group 2: 59, group 3: 3, group 4: 1 group 5: 10 group 6: 0) (Table 4).

Table 1: Demographic and clinical data of patients.

	Discharged (n:47)	Exits (n:152)	P value
Age	61.9±17.8	70.3±13.6	0.004
Gender			
Female/	26 (55.3%)/	74 (48.7%)/	0.505
Male	21 (44.7%)	78 (51.3%)	
LOS (days)	11.3±6.7	5.6±6.4	>0.001
Comorbid diseases			
DM	13 (27.6%)	56 (36.8%)	0.295
HT	29 (61.7%)	129 (84.8%)	0.007
CAD	15 (31.9%)	70 (46.0%)	0.060
CKD	5 (10.6%)	31 (20.3%)	0.093
COPD	4 (8.5%)	25 (16.4%)	0.131

Table 2: The relationship between the time from the last vaccine and mortality rates in previously vaccinated patients with COVID-19.

Parameters	Discharged (n=19)	Exits (n=61)	P value
1-3 months	9 (47.4%)	25 (41.0%)	0.271
3-6 months	8 (42.1%)	36 (59.0%)	
>6 months	2 (10.5%)	0 (0.0%)	

The majority of the patients consisted of the population over 65 years of age, and these patients comprised 136 (68.3%) of 199 patients. The age-mortality relationship was found to be statistically significant (p<0.005). In addition, no significant correlation was found between the time interval from vaccination and mortality (Table 2).

Table 3: Mortality rates of vaccinated and unvaccinated patients in ICU due to COVID-19.

	Discharged (n=47)	Exits (n=152)	P value
Unvaccinated	28 (23.6%)	91 (76.4%)	0.650
Vaccinated	19 (23.8%)	61 (76.2%)	

Table 4: Vaccination status of patients.

Vaccination status	Discharged	Exits	Total
Unvaccinated	28	91	119
Vaccinated			
Subgroup 1	1	6	7
Subgroup 2	17	42	59
Subgroup 3	0	3	3
Subgroup 4	0	1	1
Subgroup 5	1	9	10
Subgroup 6	-	-	-
Total	47	152	199

Subgroup 1: One-dose Coronavac, Subgroup 2: 2-doses Coronavac, Subgroup 3: 3-doses Coronavac, Subgroup 4: 2-doses Coronavac+ 1-dose BNT162b2, Subgroup 5: 1 dose-BNT162b2, Subgroup 6: 2-doses-BNT162b2

Between the unvaccinated group, and the vaccinated group, which subgroup 2 patients with 2 doses of Coronavac constituted the largest group in the vaccinated group, there was no significant difference in terms of mortality (Table 3). Unvaccinated and vaccinated patients were compared in terms of comorbidities, and there was no statistical significance although the rate of comorbidities is higher in group 2 (comorbidities in vaccinated (group 2) and unvaccinated groups respectively: DM: 44-29.4%, HT: 94.9-67.2%, CKD: 18.6-15.9%, CAD: 62.7- 35.2%, COPD: 25.4-10%).

DISCUSSION

This study was designed to investigate the vaccine status, comorbidities, the effect of the vaccine status of the patients on mortality after hospitalization in the ICU, and the factors that may affect mortality in vaccinated and unvaccinated patients of 199 patients hospitalized in the ICU of our hospital, which is a pandemic hospital, between May 2021 and August 2021.

As of November 2021, the best preventive method used to reduce the COVID-19-related morbidity and mortality is to vaccinate the largest populations eligible for vaccination.¹⁰

So far, many vaccines have been developed on the vaccine front and these vaccines have been used in many countries of the world. And many new vaccine and treatment studies continue and give hope in preventing and treating the disease.¹¹ In Turkey, the Coronavac vaccine has been approved for use since December 2020

and the BNT162b2 vaccine has been used since April 2021 by the Ministry of Health.¹²

As it is known, BNT162b2 and Coronavac vaccines used in Turkey are highly effective vaccines in reducing morbidity and mortality associated with COVID-19. BNT162b2 was found to be 95% effective against COVID-19 in a study conducted on people over the age of 16, and Coronavac was found to be 65.9% effective in a study conducted in Chile.¹³ The emergence of new variants such as Delta has the potential to reduce the effectiveness of vaccines which are still an effective method in reducing hospitalizations and mortality.^{14,15}

In this study, 199 patients were hospitalized in the ICU, and the majority of our patients were unvaccinated despite the vaccine availability in our country (119 patients). Vaccinated patients were found at a lower rate (80 patients). Despite the fact that vaccination with Coronavac started in 2020, the majority of unvaccinated patients in the ICU brings to mind the hesitancy of vaccination. Vaccine hesitancy is defined as a delay in acceptance or rejection of vaccination despite the availability of vaccination services.¹⁶ Vaccine hesitation differs from country to country, and in a study conducted on 13,426 patients from 19 countries, 72% of the participants stated that they would use a safe vaccine with proven efficacy. In a study conducted with 759 people in Turkey, the rate of patients who were hesitant about vaccination was found to be 50.3%.^{17,18} Our hospital is located in the southeast part of Turkey and has been at the bottom of vaccination rates since the day the vaccination started in the country.¹⁹ This situation partially explains the rate of unvaccinated patients in intensive care patients due to vaccine hesitancy. Although this situation may be related to social, cultural, and economic experiences compared to regions with better vaccination rates, unfortunately, there is no study on this subject. In a study conducted in our region, it is known that vaccination rejection of parents in the 0-2 group and the 5-year-old group is higher than in other regions.²⁰ There is no scientific study on the causes of this situation. On the other hand, studies on hepatitis B in Turkey show regional differences in terms of hepatitis B prevalence in the country, varying between 4-5%. The prevalence of hepatitis B is higher in our region compared to other regions. This, albeit partially, gives information about the fact that vaccine hesitancy may be higher in our region compared to other regions. The Turkish Ministry of Health declared the incidence of hepatitis B infection to be 8.26 by 2002 and 4.2 by 2010 per 100 000 people. And the prevalence of hepatitis B in the country has decreased to 2% in recent years with national campaigns conducted across the country. Despite the decrease in the prevalence of hepatitis B, regional differences remain, and there may be many economic and cultural reasons for this. For this reason, campaigns related to vaccine persuasion are important in preventing vaccine hesitancy.²¹⁻²⁴ According to the World Health

Organization, vaccine hesitation is among the top 10 global causes threatening the world.²⁵

In the vaccinated patients' arm of our study, the largest group was the double dose vaccinated Coronavac group (group 2) (59 patients). The higher number of Coronavac-vaccinated patients in our ICU and the absence of any double-dose BNT162b2 vaccinated patients may be due to factors such as the less effectiveness of the Coronavac vaccine, the long duration time from the first shot of Coronavac vaccine, and the recent history of BNT162b2 vaccination.^{26,27} There was no patient with double dose BNT162b2 among the patients in the ICU. The absence of BNT162b2 double-dose patients also gives some information about the effectiveness of the vaccine.

Additionally, comorbidities were found to be higher in vaccinated patients (group 2) than unvaccinated groups (subgroup 2) in our study. This shows similarity to a study conducted on 152 vaccinated patients and 10,021 unvaccinated patients, which shows a higher rate of comorbidities in the vaccinated group (DM: 48-27.9%, HT 71-55.6%, CKD 27-22%, heart failure 32-19.6%, Chronic lung disease 24-13.6%).^{28,29}

In our study, the mortality rate was 76.4% in the unvaccinated group, and 76.2% in the vaccinated group and there was no statistical difference in terms of mortality between these 2 groups. Overall mortality was found to be 76.3%. This shows similarity to the study conducted by Petrilli et al on 5279 patients in ICU which shows a 60.4% mortality rate in ventilated patients.³⁰

In our study, the absence of patients with full-dose BNT162b2 in intensive care, mostly the presence of patients with Coronavac, partially demonstrates the effectiveness of the BNT162b2 vaccine in reducing intensive care admissions. The absence of BNT162b2 vaccinated patients did not allow the comparison between Coronavac and BNT162b2 vaccinated in terms of morbidity and mortality. However, larger studies are needed to evaluate the morbidity and mortality of vaccinated patients after admission to the ICU. There was no data in our hands on why unvaccinated patients were not vaccinated. Due to the retrospective character of our study and the high mortality rate, data on why the unvaccinated were not vaccinated could not be obtained.

Limiting factors of our study are the low number of patients, the absence of double-dose Biontech patients, the non-normal distribution of vaccinated patient groups, and the lack of data on why patients hesitate about vaccination.

CONCLUSION

There was no difference in mortality after admission to the ICU between vaccinated and unvaccinated patients. The absence of patients with double-dose BNT162b2 in the ICU provides information regarding the effectiveness

of the vaccine, including new mutations. Additionally, management of vaccine hesitancy in the management of the COVID-19 pandemic may affect hospital admissions and mortality. For this reason, studies that will eliminate the vaccine hesitation gain importance.

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