



# Side Effects Related to BNT162b2 and CoronaVac Vaccine Requiring Emergency Department Visit

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## Abstract

**Background** Currently, the most effective method in the fight against coronavirus disease 2019 (COVID-19) is vaccination against the disease. However, there are hesitations among society concerning the safety and side effects of COVID-19 vaccines. We aimed to determine the observed side effects that require an emergency room visit after taking the BNT162b2 and CoronaVac vaccines.

**Methods** This prospective observational study was conducted with patients who presented to the emergency department due to vaccine-related complications after COVID-19 vaccination. The patients' symptoms at the time of presentation, time from vaccination to the onset of symptoms, and dose of the vaccine administered were determined. In addition, the demographic characteristics of the patients, whether they had a history of COVID-19 infection, and their vital signs at the time of presentation were recorded. The variables were compared according to the type of vaccine administered.

**Results** The study included 182 patients who presented to the emergency department over a 6-month period. It was determined that 166 of these patients (91.2%) had received the BNT162b2 vaccine and 16 (8.8%) had received the CoronaVac vaccine. The majority of the patients did not have a history of COVID-19 infection (70.3%), and most presented to the hospital with complications after the second dose (61%). The onset of vaccine-related symptoms was mostly within 1 to 12 hours (39%). The majority of patients (97.8%) were discharged from the emergency department. The most common symptoms after vaccination were fatigue ( $n=70$ ), followed by muscle/joint pain ( $n=52$ ), headache ( $n=33$ ), and fever ( $n=32$ ). The rate of dizziness was found to be statistically significantly higher in the CoronaVac vaccine group than in the BNT162b2 vaccine group ( $p=0.008$ ). There was no statistically significant difference between the two vaccine groups in relation to the remaining symptoms ( $p>0.005$ ).

**Conclusion** There were no serious complications related to the BNT162b2 or CoronaVac vaccine. The most common symptom after both vaccines was fatigue; therefore, the BNT162b2 and CoronaVac vaccines can be safely administered.

## Keywords

- COVID-19
- vaccine
- adverse effects
- BNT162b2
- CoronaVac

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## Introduction

The coronavirus 2019 (COVID-19) pandemic has gravely affected the whole world and caused the death of millions of people. There is currently no definitive treatment for the disease, and the best method to prevent its spread is vaccination. Vaccine studies for the COVID-19 disease were started promptly, and approved vaccines have been started to be administered across the world.<sup>1,2</sup> An ideal vaccine is the one that has the least side-effect profile and high efficacy. However, the rapid development of vaccines has led to hesitations in society concerning the safety of their application.<sup>3,4</sup>

Vaccine studies in the world have been implemented under five different main platforms: live attenuated, mRNA-based, DNA-based, inactivated, and viral vector-based. Among these, the mRNA-based “BNT162b2” developed by Pfizer/BioNTech company is one of the first approved vaccines and administered in many countries. Phase 4 studies of this vaccine continue after approval.<sup>5</sup> In Turkey, two types of vaccines are currently administered: the “BNT162b2” and the “CoronaVac” vaccine developed by Sinovac Biotech.<sup>6</sup> BNT162b2 is a genetic mRNA-based vaccine that creates an immune response by injecting the genetic code encoding the spike protein of the genome of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus into the human body in lipid nanoparticles.<sup>7</sup> CoronaVac is an inactive viral vaccine. In both these vaccines, two doses are administered at an interval of 28 days.<sup>8</sup>

Allergic reactions related to the content of COVID-19 vaccines are the most reported side effects. In addition, it has been reported that vaccines developed for COVID-19 can cause serious complications, such as myocarditis, thrombocytopenia, and cerebral venous thrombosis.<sup>5,9–11</sup> Although studies have been conducted to investigate the efficacy of COVID-19 vaccines, there is not sufficient research on their side effects. There are also limited studies on patient presentations to the emergency department due to vaccine side effects and the approach to the management of these patients. Therefore, in this study, we aimed to determine the symptoms of patients who presented to the emergency department with adverse reactions after COVID-19 vaccination. We investigated whether these symptoms were seen more frequently depending on the type and dose of the vaccine administered.

## Methods

### Study Design and Setting

This prospective observational study was conducted in the emergency department of a tertiary hospital over a 6-month period from May 1, 2021, through November 1, 2021. Prior to the study, ethical approval was obtained from the local ethics committee, and permission was granted by the Turkish Ministry of Health. The study was performed in accordance with the tenets of the Declaration of Helsinki. Informed consent was obtained from all participants. The study followed the Strengthening the Reporting of Observational

Studies in Epidemiology (STROBE) reporting guidelines for cross-sectional studies.<sup>12</sup>

### Selection of Participants

Patients who presented to the emergency department with vaccine-related complications after COVID-19 vaccination were included in the study. Patients who did not agree to participate in the study, those with a respiratory tract infection before vaccination, and those who were determined to have symptoms related to other diseases were excluded from the study. At the time of presentations, the patients' symptoms and vital signs (mean arterial pressure [MAP], heart rate, body temperature, and oxygen saturation [SpO<sub>2</sub>]) were determined. In addition, the demographic characteristics of the patients, the type and dose of vaccine administered, and the time from vaccination to the onset of symptoms were recorded in prepared forms.

In Turkey, everyone over the age of 18 years was included in the vaccination program at the time of the study. Currently, two types of vaccines are administered. The BNT162b2 is available in six doses in a 0.3-mL vial. One vial is administered to six patients in an equally divided dose. The CoronaVac is administered as a single dose in a 0.5-mL vial. Individuals are free to choose either vaccine but the type administered as the second dose must be the same as the first dose.

### Statistical Analysis

Data analysis was performed using the Statistical Package for the Social Sciences for Windows, version 17 (SPSS Inc, Chicago, IL, United States). Data were expressed as mean  $\pm$  standard deviation for continuous variables, and frequencies and proportions for categorical variables. Student's *t*-test was used to analyze the mean differences between the groups. Categorical data were analyzed using Pearson's chi-square test.

## Results

A total of 206 patients were evaluated for the study. Sixteen patients with respiratory tract infections before vaccination and eight patients with symptoms related to other diseases were excluded from the study. Finally, the study included 182 patients who presented to the emergency department with symptoms after COVID-19 vaccination over a 6-month period. The BNT162b2 vaccine had been administered to 166 (91.2%) of these patients and the CoronaVac vaccine to the remaining 16 (8.8%) patients. Considering the age and gender distribution in all cases, the rate of women was higher (57.7%), and 45.5% of the patients were aged 18 to 40 years. The vast majority of the patients (70.3%) did not have a history of COVID-19 infection, and the rate of presentation was higher after the second dose (61%). The time of onset of vaccine-related symptoms was mostly within 1 to 12 hours (39%). In addition, the majority of patients (97.8%) were discharged from the emergency department ([Table 1](#)).

When the presentation symptoms of the patients after vaccination were examined, it was determined that the most

**Table 1** Demographic characteristics of the patients

	N	%
Gender		
Male	77	42.3
Female	105	57.7
Age (y)		
18–40	81	44.5
41–60	78	42.9
> 61	23	12.6
Type of vaccine		
BNT162b2	166	91.2
CoronaVac	16	8.8
Dose of vaccine		
First	54	29.7
Second	111	61
Third	15	8.2
Fourth	2	1.1
History of COVID-19		
Present	54	29.7
Absent	128	70.3
Onset of complaints after vaccination		
< 1 h	13	7.1
1–12 h	71	39
13–48 h	69	37.9
> 48 h	29	15.9
Hospitalization		
Present	4	2.2
Absent	178	97.8

Abbreviation: COVID-19, coronavirus disease 2019.

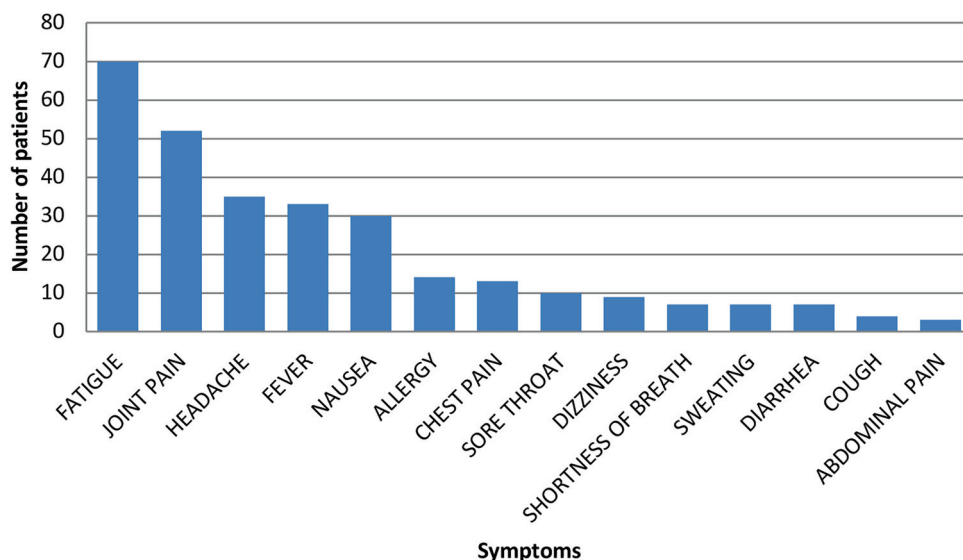
common complaint was fatigue ( $n=70$ ), followed by muscle/joint pain ( $n=52$ ), headache ( $n=33$ ), and fever ( $n=32$ ) (►Fig. 1).

Considering the relationship between symptoms and vaccine type, for the patients vaccinated with BNT162b2, the most common symptom was fatigue ( $n=61$ , 36.7%), followed by joint pain ( $n=47$ , 28.3%) and headache ( $n=32$ , 19.3%). In the CoronaVac vaccine group, the most common symptom was similarly fatigue ( $n=9$ , 56.3%), followed by muscle/joint pain ( $n=5$ , 31.3%), headache ( $n=3$ , 18.8%), fever ( $n=3$ , 18.8%), and dizziness ( $n=3$ , 18.8%). The rate of dizziness was statistically significantly higher in the CoronaVac vaccine group than in the BNT162b2 vaccine group ( $p=0.008$ ). However, there was no statistically significant difference between the two groups in relation to the remaining symptoms ( $p>0.005$ ). In addition, no relationship was found between the type and dose of vaccine and whether the patients had a history of COVID-19 infection and onset of symptoms after vaccination ( $p>0.05$ ; ►Table 2).

In the BNT162b2 vaccine group, the mean values for the vital signs of the patients were determined as follows: body temperature,  $36.55 \pm 0.45^\circ\text{C}$ ; heart rate,  $96.77 \pm 13.68/\text{min}$ ; MAP,  $89.69 \pm 9.42$  mm Hg; and  $\text{SpO}_2$ ,  $96.22 \pm 1.83\%$ . In the CoronaVac vaccine group, the mean vital signs were  $36.6 \pm 0.37^\circ\text{C}$  for body temperature,  $100.2 \pm 22.92$  for heart rate,  $86.87 \pm 12.78$  for MAP, and  $96.22 \pm 9.42$  for  $\text{SpO}_2$ . There was no statistically significant difference between the two vaccines in terms of vital signs ( $p>0.05$ ; ►Table 3).

## Discussion

Vaccination against COVID-19 is the most important approach in preventing the disease. However, some individuals have hesitations concerning the safety of COVID-19 vaccines. Side effects and postvaccination symptoms are the main reasons for avoiding vaccination.<sup>13,14</sup> To our knowledge, there is no study comparing the side effects of the BNT162b2 and CoronaVac vaccines. In general, previous

**Fig. 1** Distribution of symptoms.

**Table 2** Comparison of variables between the two vaccine groups

	BNT162b2 n = 166 (%)	CoronaVac n = 16 (%)	p-Value
Gender			
Female/male	94 (56.6)/72 (43.4)	11 (68.7)/5 (31.3)	0.349
Complaint <sup>a</sup>			
Fatigue	61 (36.7)	9 (56.3)	0.126
Joint pain	47 (28.3)	5 (31.3)	0.804
Headache	32 (19.3)	3 (18.8)	0.959
Fever	30 (18.1)	3 (18.8)	0.946
Nausea	28 (16.9)	2 (12.5)	0.653
Allergy	14 (8.4)	0 (0)	0.227
Chest pain	12 (7.2)	1 (6.3)	0.885
Sore throat	10 (6)	0 (0)	0.313
Sweating	7 (4.2)	0 (0)	0.402
Diarrhea	7 (4.2)	0 (0)	0.402
Dizziness	6 (3.6)	3 (18.8)	<b>0.008</b>
Shortness of breath	6 (3.6)	1 (6.3)	0.601
Cough	4 (2.4)	0 (0)	0.530
Abdominal pain	3 (1.8)	0 (0)	0.588
Other <sup>b</sup>	4 (2.4)	0 (0)	0.530
Onset of complaints after vaccination			
< 1 h	11 (6.6)	2 (12.5)	0.058
1–12 h	67 (40.4)	4 (25)	
13–48 h	65 (39.2)	4 (25)	
> 48 h	23 (13.9)	6 (37.5)	
Dose of vaccine			
First	50 (30.1)	4 (25)	0.87
Second	101 (60.8)	10 (62.5)	
Third	13 (7.8)	2 (12.5)	
Fourth	2 (1.2)	0	
History of COVID-19			
Present	52 (31.3)	4 (25)	0.779
Absent	114 (68.7)	12 (75)	

Abbreviation: COVID-19, coronavirus disease 2019.

<sup>a</sup>Multivariable.<sup>b</sup>Includes dry mouth, palpitations, and visual impairment.**Table 3** Relationship between the type of vaccine and vital signs

Vital signs	BNT162b2	CoronaVac	Mean difference (%95 CI)	p-Value
MAP, mean $\pm$ SD (mm hg)	89.69 $\pm$ 9.42	86.87 $\pm$ 12.78	2.81 (–2.22 to 7.85)	0.271
Heart rate, mean $\pm$ SD (beats per minute)	96.77 $\pm$ 13.68	100.2 $\pm$ 22.92	–3.43 (–15.78 to 8.92)	0.564
Body temperature, mean $\pm$ SD (°C)	36.55 $\pm$ 0.45	36.60 $\pm$ 0.37	–0.049 (–0.312 to 0.214)	0.713
Oxygen saturation, mean $\pm$ SD (%)	96.22 $\pm$ 1.83	96.22 $\pm$ 1.51	0.005 (–0.926 to 0.937)	0.991

Abbreviations: CI, confidence interval; MAP, mean arterial pressure; SD, standard deviation.

studies indicate no serious side effect associated with COVID-19 vaccines.<sup>15–17</sup> In a study by Baden et al<sup>18</sup> on the efficacy and safety of an mRNA-based vaccine, only local complications were observed after vaccination. However, there are also publications reporting serious complications, such as myocarditis after mRNA vaccination.<sup>11,19</sup> In the current study, only four patients required hospitalization, who were all discharged with full recovery after treatment, and no serious side effects were observed.

In the literature, side effects have been reported to occur at a higher rate after the administration of mRNA-based vaccines compared with inactivated vaccines.<sup>9,10,18,20</sup> In our study, the majority of the patients (91.2%) had received the BNT162b2 vaccine. However, when the variables were compared according to the vaccine type, there was no significant difference between the two vaccine groups. The only significant difference was observed in relation to the complaint of dizziness, which was at a higher rate among the patients who had received the CoronaVac vaccine.

In studies investigating symptoms observed after COVID-19 vaccination, the most common complaint was reported to be headache by Li et al,<sup>21</sup> and fatigue, headache, muscle pain, and injection-site pain by Sadoff et al.<sup>22</sup> Similarly, in the current study, the most common complaint was fatigue in both the vaccine groups.

The literature contains no study evaluating the relationship between vaccine-related side effects and a history of COVID-19. In this study, we determined that the majority of the patients (70.3%) had not contracted COVID-19. It can be suggested that COVID-19 vaccines show more symptoms in those who have not had the disease.

There is also no previous study exploring the relationship between the vaccine dose administered and the occurrence of symptoms. Previous studies have shown that vaccines increase humoral and T-cell immunity. Li et al reported that T-cell and humoral immunity were higher in patients who had received mRNA vaccination.<sup>21</sup> In our study, the rate of patient presentation due to vaccine-related side effects was higher after the second dose of vaccination, which may be due to type 2 sensitivity reactions. There is a need for further research on this subject.

### Limitations

The main limitation of the study is its observational cross-sectional design. This study has a small number of participants. Consequently, this limited our ability to conduct multiple subanalyses and generated wide results. In addition, this study was conducted on a single center. Another limitation is that this study only included patients presenting to the emergency department.

### Conclusions

We determined that patient presentation to the emergency department due to side effects after vaccination with BNT162b2 was higher compared with those after vaccination with CoronaVac. Fatigue was the most common symptom in

both vaccine types. The rate of postvaccination hospitalization was very low, and no serious problems were observed related to either vaccine; therefore, the BNT162b2 and CoronaVac vaccines can be safely administered.

### Authors' Contributions

E. Y. and K. T. conceived and designed the project. U. G., E. A., and I. A. acquired, analyzed, and interpreted the data. C. S. and O. O. wrote the original draft manuscript. E. Y., K. T., and U. G. wrote, revised, and edited the manuscript.

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### Conflict of Interest

None declared.

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