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Coronavirus Pandemic

Real-life evaluation of incidence and clinical outcomes of COVID-19 among healthcare workers during pre-vaccination and post-vaccination periods: A cross-sectional impact study

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Abstract

Introduction: We aimed to evaluate the prevalence and clinical outcomes of COVID-19 in healthcare workers (HCWs) in the pre-vaccination and post-vaccination periods. In addition, we determined factors associated with the development of COVID-19 after vaccination.

Methodology: In this analytical cross-sectional epidemiological study, HCWs who were vaccinated between January 14, 2021, and March 21, 2021, were included. HCWs were followed up for 105 days after the 2 doses of CoronaVac. Pre-vaccination and post-vaccination periods were compared.

Results: A total of 1,000 HCWs were included, 576 patients (57.6%) were male, and the mean age was 33.2 ± 9.6 years. In the last 3 months during the pre-vaccination period, 187 patients had COVID-19, and the cumulative incidence of COVID-19 was 18.7%. Six of these patients were hospitalized. Severe disease was observed in three patients. In the first 3 months post-vaccination period, COVID-19 was detected in 50 patients, and the cumulative incidence of the disease was determined to be 6.1%. Hospitalization and severe disease were not detected. Age (p = 0.29), sex (OR = 1.5, p = 0.16), smoking (OR = 1.29, p = 0.43), and underlying diseases (OR = 1.6, p = 0.26) were not associated with post-vaccination COVID-19. A history of COVID-19 significantly reduced the likelihood of the development of post-vaccination COVID-19 in multivariate analysis (p = 0.002, OR = 0.16, 95% CI = 0.05-0.51).

Conclusions: CoronaVac significantly reduces the risk of SARS-CoV-2 infection and alleviates the severity of COVID-19 in the early period. Additionally, HCWs who have been infected and vaccinated with CoronaVac are less likely to be reinfected with COVID-19.

Key words: COVID-19; CoronaVac; healthcare workers.

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Introduction

The coronavirus disease 2019 (COVID-19) pandemic has caused an unprecedented public health problem worldwide, leading to approximately 6,401,046 deaths as of August 3, 2022 [1]. Since an effective treatment for COVID-19 has not yet been discovered, disease prevention approaches have gained more importance [2]. However, effective vaccines against the disease have been developed and approved in a short period. Moreover, various new vaccine studies are in the final stages of clinical trials [3]. Currently, ten COVID-19 vaccines have been approved by the World Health Organization, and 34 COVID-19 vaccines have been approved by at least one country [4]. While vaccination rates vary by country, as of July 25, 2022, 60.6% of the world's population had been fully vaccinated against COVID-19, and 5.8% had been partially vaccinated [1].

CoronaVac (Sinovac Biotech), an inactivated whole virus vaccine, has been approved by 47 countries and used as part of vaccination campaigns in some countries [4]. In phase 3 clinical trials of CoronaVac conducted in Turkey, its effectiveness in preventing symptomatic COVID-19 was 83.5% (95% CI 65.4-92.1; $p < 0.0001$). It was also found to be 100% effective in preventing COVID-19-related hospitalization (p = 0.0344) [5]. In

a phase-3 clinical study conducted in Brazil, CoronaVac was 51% effective in preventing symptomatic COVID-19 infection and 100% effective in preventing severe illness and hospitalization [6].

CoronaVac is the first vaccine approved for use in Turkey, and it started to be applied on January 14, 2021. Turkey aimed to vaccinate risky groups. Healthcare workers (HCWs) and older adults were the first to receive the vaccine. The second dose of vaccines started to be administered 4 weeks after the first dose on February 11, 2021. On April 12, 2021, the administration of the Pfizer-Biotech vaccine started in Turkey [7].

In Istanbul, Turkey's most populated city, two hospitals were urgently built to mitigate the burden of the COVID-19 pandemic. One of these hospitals, Professor Doctor Murat Dilmener Emergency Hospital with a capacity of 1008 beds, was completed on May 31, 2020, and provided healthcare services to patients.

We aimed to compare the cumulative incidence and clinical outcomes of COVID-19 in healthcare workers (HCWs) in the pre-vaccination and post-vaccination periods. In addition, we aimed to determine factors affecting the development of COVID-19 in the post-vaccination period. In addition, we determined factors associated with the development of COVID-19 after vaccination.

Methodology

Study Design

This is an analytical, cross-sectional, and epidemiological study. Frontline HCWs (doctors and nurses) who applied to Professor Doctor Murat Dilmener Emergency Hospital to be vaccinated between January 14, 2021, and March 21, 2021. Demographic characteristics of HCWs, vaccination status, and clinical results of HCWs with COVID-19 were obtained from the hospital electronic data registration system and follow-up forms. HCWs were followed up for 105 days after the 2 doses of the CoronaVac vaccine.

Prevaccination period was determined as the 3-month period before the first vaccination (between 14 October 2020 and 14 January 2021). Postvaccination period was defined as the 3-month period from 15 days after the second dose of vaccination (between 1 March 2021 and 1 June 2021). Pre-vaccination and post-vaccination periods were compared.

Inclusion Criteria

In this study, 1000 healthcare workers between the ages of 18-65 years who received two doses of CoronaVac at 4-week intervals in our hospital's vaccination outpatient clinic were included. The sampling method was a nonprobability and consecutive random sampling method.

Exclusion Criteria

Patients with positive SARS-CoV-2 real-time polymerase chain reaction (RT–PCR) test results between the 1st dose and 2nd dose of the CoronaVac (seven patients) and within the first 14 days after the 2nd dose (nine patients) were excluded from the study.

The independent variables were sex, age, smoking habits, underlying diseases, and previous diagnosis/history of COVID-19.

The primary outcome was the development of COVID-19. Secondary outcomes were the severity of COVID-19, COVID-19-related hospitalization, intensive care unit admission, and death. Additionally, we performed a subgroup analysis by excluding HCWs with a previous history of COVID-19.

Death was defined as in-hospital mortality.

The disease severity was stratified as critical, severe, and non-severe. The evaluation of disease severity was based on the recommendations of the WHO severity definitions [8]. The following criteria were used to identify the patients' severity:

- Severe COVID-19: defined by any of the following: oxygen saturation < 90% on room air; respiratory rate > 30 breaths/min; or signs of severe respiratory distress (accessory muscle use, inability to complete full sentences).
- Non-severe COVID-19: defined as the absence of any criteria for severe or critical COVID-19.
- Critical COVID-19: Defined by the criteria for acute respiratory distress syndrome (ARDS), sepsis, septic shock, or other conditions that would normally require the provision of life-sustaining therapies such as mechanical ventilation (invasive or non-invasive) or vasopressor therapy

Daily Case Frequency in Turkey

To determine the peak dates of the cases in Turkey, daily case graphs were drawn using Microsoft Excel 2016, and the data were obtained from https://covid19.saglik.gov.tr/TR-66935/genel-koronavirus-tablosu.html. Data before November 25, 2020, were calculated by proportioning to patient data.

Statistical analysis

Quantitative variables were expressed as the mean and standard deviation when they included continuous data. The normal distribution of the data questioning the

necessity of using the parametric test was decided by evaluating the Kolmogorov–Smirnov test results, box plot distributions, median, mean proximity, skewness, kurtosis results, and histogram curves altogether. Student's t-test was used for normally distributed continuous data. Nonparametric tests were used for nonnormally distributed data. The Kruskal–Wallis test (with Bonferroni correction, if necessary) was used in the analysis of continuous and more than two independent nonparametric groups. The Mann–Whitney U test was used for post hoc analysis. Those with categorical data were expressed as a percentage (%) and frequency (n). The comparison of qualitative variables was analysed with the Pearson χ^2 test. Univariate logistic regression analysis was performed to question the factors leading to post-vaccination COVID-19. All factors with $p < 0.05$ and factors considered important in the literature were included in the multivariate logistic regression analysis.

The results were evaluated in a 95% confidence interval, and the statistical significance level was considered to be $p < 0.05$. The analyses were made by using the IBM SPSS-21 (Statistical Package for Social Sciences, Armonk, NY, USA) package program.

Power Analysis

We performed a prior power analysis to determine the minimum required sample size for the study. We accepted the effect size as d = 0.03. In addition, the Type I error and prior power level were accepted as 5% and 80%, respectively. Based on this information, the suitable sample size was calculated as 785.

Ethical Approval

This study was approved by the local ethics committee (Decision No: 2021-21, Date: 01.11.2021) and the Ministry of Health Scientific Research Commission (Decision No: 2021-10-15T22_24_17 Date: 19.10.2021). Written informed consent was waived, given the retrospective nature of this study.

Results

A total of 1000 HCWs were included in the study. Five hundred seventy-six patients (57.6%) were male, and the mean age was 33.2 ± 9.6 years. The mean ages of the male and female patients were 34.6 ± 10.1 and 32.1 ± 9.6 years, respectively ($p = 0.02$). Two hundred eighty-three (28.3%) HCWs were current smokers. One hundred eleven (11.1%) HCWs had at least one comorbidity. The most frequent comorbidities were hypertension (n = 45, 4.5%), diabetes (n = 34, 3.4%), coronary artery disease (n = 22, 2.2%), and asthma/chronic obstructive pulmonary disease (n = 19, 1.9%). Two hundred ninety-two (29.2%) patients had a history of COVID-19 before vaccination. COVID-19 was detected in 50 (5%) patients between 15-105 days after two doses of the CoronaVac vaccine (Table 1). Post-vaccination COVID-19 occurred between days 16 and 101, and the median duration was 53 days. There was no significant difference between the post-vaccination COVID-19 and non-COVID-19 groups in terms of age ($p = 0.29$), sex (OR = 1.5, $p = 0.16$), smoking (OR = 1.29, $p = 0.43$), or underlying diseases (OR = 1.6, $p = 0.26$). There was a statistically significant difference between the two groups in terms of the history of COVID-19 (OR = 0.32, $p = 0.01$) and

Table 1. Demographic characteristics of healthcare workers.

	Total (n = 1000)	Post-vaccine COVID-19 (n = 50)	Post-vaccine non-COVID (n = 950)	*p*	OR
Age (mean ± sd)	33.2 ± 9.6	34.2 ± 8.7	33.1 ± 9.6	0.29	
Sex				0.16	1.50
Male, n (%)	424 (42.4)	26 (52)	398 (41.9)		
Female, n (%)	576 (57.6)	24 (48)	552 (58.1)		
Smoking				0.43	1.32
Yes, n (%)	283 (28.3)	17 (34)	266 (29.5)		
No, n (%)	717 (71.7)	33 (66)	684 (70.5)		
Comorbid Diseases	111 (11.1)	8 (16)	103 (10.8)	0.26	1.56
Hypertension, n (%)	45 (4.5)	4 (8)	41 (4.3)	0.81	1.92
DM, n (%)	34 (3.4)	2 (4)	32 (3.4)	0.22	1.19
CAD, n (%)	22 (2.2)	0 (0)	22 (2.3)	0.54	0.40
Asthma/COPD, n (%)	19 (1.9)	2 (4)	17 (1.8)	0.27	2.28
Hypothyroid, n (%)	10 (1.0)	1 (2)	9 (0.9)	0.47	2.13
Others, n (%)	13 (1.3)	1 (2)	12 (1.3)	0.65	1.59
Pre-vaccine COVID-19 history (before the last 3-month)	292 (29.2)	6 (12)	286 (30.1)	0.01	0.31
Prevaccine COVID-19 status (last 3 months)	187 (18.7)	0 (0)	187 (19.7)	0.02	0.04

DM: Diabetes mellitus; CAD: Coronary Artery Disease; COPD: Chronic obstructive pulmonary disease; sd: standard deviation.

having COVID-19 in the last three months (OR = 0.27, $p = 0.02$).

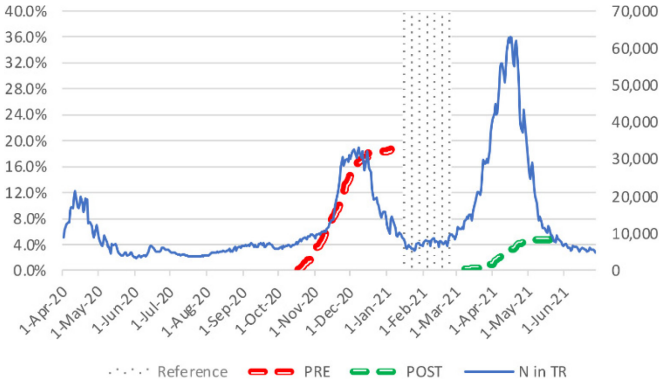
Univariate and multivariate regression analyses were performed to evaluate the factors affecting the development of COVID-19 in HCWs who received two doses of the CoronaVac vaccine. A history of COVID-19 significantly reduced the likelihood of the development of post-vaccination COVID-19 in multivariate regression analysis ($p = 0.002$, OR = 0.16, 95% CI = 0.05-0.51). Gender ($p = 0.069$, OR = 1.72), age ($p = 0.453$, OR = 1.01), smoking ($p = 0.443$, OR = 1.28), and any comorbidity ($p = 0.190$, OR = 1.69) were not associated with post-vaccination COVID-19 development in multivariate analysis (Table 2).

The comparison of the number of COVID-19 patients in the general population in Turkey and the number of COVID-19 HCWs during the study period is shown in Figure 1. The last three months before the vaccination and 15-105 days after the vaccination was compared in HCWs. In the pre-vaccination period, 187 patients were diagnosed with COVID-19, and the cumulative incidence of COVID-19 was 18.7%. Six of these patients were hospitalized due to COVID-19. Severe disease was observed in only three patients. Critical illness, intensive care unit admission, and death were not detected. In the post-vaccination period, 813 HCWs who did not have COVID-19 in the last three months were evaluated. In a 3-month period, COVID-19 was detected in 50 HCWs, and the cumulative incidence was determined to be 6.1%. No hospitalization, severe illness, intensive care unit admission, or death due to COVID-19 was detected in these 50 patients (Table 3). In the subgroup analysis after excluding HCWs with a previous history of COVID-19, the incidence of COVID-19 was 26.4% (n = 187/708) in the pre-vaccination period and 8.4% (n = 44/521) in the post-vaccination period ($p < 0.001$) (Table 4).

Discussion

In this study, we presented a cross-sectional analysis of 1,000 HCWs vaccinated with CoronaVac.

Figure 1. Cumulative incidence of COVID-19 in HCWs and number of COVID-19 in the community.



We found that the CoronaVac vaccine reduced the incidence of COVID-19 in HCWs by approximately two out of three. CoronaVac also significantly decreased the COVID-19-related hospitalization requirement within 15-105 days after vaccination.

Different epidemiological studies, especially on HCWs, have been reported with the use of the CoronaVac vaccine [9-13]. In the study of Palacios *et al*., it was reported that the CoronaVac vaccine was 50.7% effective in preventing symptomatic COVID-19 and 100% effective in preventing severe disease in HCWs [9]. In the study of Hitchings *et al*., the efficacy of the vaccine against the gamma variant in HCWs was estimated at 56.2% in the adjusted analysis [10]. Faria *et al.* reported that the estimated effectiveness of CoronaVac in HCWs was 50.7% after two weeks and 73.8% after five weeks [11]. Copur *et al.* in Turkey found the adjusted effectiveness of CoronaVac as 65% [12]. In another study, a 62% reduction in the incidence of COVID-19 in HCWs by CoronaVac and ChAdOx1 was reported [13]. In our study, the pre-vaccination and post-vaccination 3-month periods were compared. In the post-vaccination period, a 67% reduction in the incidence of COVID-19 was detected in HCWs in the pandemic hospital. It also prevented the COVID-19-related hospitalization requirement by 100% (n = 6/1000 vs n = 0/813). It is noteworthy that the present

Table 2. Univariate and multivariate regression analyses in post-vaccine COVID-19.

	Univariate Regression Analysis			Multivariate Regression Analysis		
	OR	**95% CI**	***p***	**OR**	**95% CI**	***p***
Sex	1.72	0.96-3.11	0.069	1.74	0.96-3.16	0.067
Age	1.01	0.98-1.04	0.453			
Smoking	1.28	0.68-2.43	0.443			
Pre-Vaccine COVID-19	0.15	0.05-0.51	0.002	0.16	0.05-0.51	0.002
Any Comorbidity	1.69	0.77-3.72	0.190	1.63	0.73-3.62	0.228
Hypertension	2.07	0.71-6.04	0.183			
DM	1.27	0.30-5.51	0.741			

DM: Diabetes mellitus; sd: standard deviation.

promising results were obtained when the pandemic was more severe and although the dominant variant was more virulent. Similarly, in the study of Shoukat *et al.*, which compared the pre-vaccination and post-vaccination periods, COVID-19 development, COVID-19-related hospitalization, and death decreased by 30%, 51%, and 48%, respectively [14]. Li *et al.* also found that the number of daily COVID-19 cases decreased by approximately 50% between 3-4 weeks following vaccination [15]. In a previous study by Surme *et al.*, the number of COVID-19 cases and COVID-19-related poor clinical outcomes decreased in the post-vaccination period compared to the pre-vaccination period [16]. Considering the similar findings in different studies, it can be stated that CoronaVac has a positive impact against COVID-19 in the early period (first 3 months). However, it is unknown how long this promising effect will continue.

In different studies, it has been reported that antibody titers after CoronaVac vaccination are higher in people with a history of COVID-19 than in those without [17-18]. In our study, the presence of a previous diagnosis of COVID-19 was a protective factor against new SARS-CoV-2 infections among vaccinated HCWs ($p = 0.002$, 95% CI = 1.96-20.72, OR = 6.38). Similarly, Toniasso *et al.* reported that the prevalence of COVID-19 decreased by 65% in the post-vaccination period in people with a previous history of COVID-19 ($p < 0.05$, 95% CI: 0.18–0.67, OR = 0.35) [13]. In another study, a previous positive RT–PCR or antigen detection test ($p = 0.01$, 95% CI 0.17-0.79, OR=0.36) and female sex ($p < 0.001$, 95% CI 0.37-0.78, OR = 0.54) were shown to protect against the development of COVID-19 after vaccination with the CoronaVac vaccine [10]. It is noteworthy that patients who had COVID-19 may have re-infection. In a meta-analysis conducted by Flacco *et al.*, COVID-19 vaccination reduced the risk of reinfection with COVID-19 [19].

This study had several strengths. First, variables such as age, sex, smoking status, underlying disease, and history of COVID-19 were included to evaluate the factors affecting the development of COVID-19 in the post-vaccination period. Second, in addition to the factors associated with the development of COVID-19, disease severity, COVID-19-related hospitalization, intensive unit care admission, and death were evaluated. Third, to mitigate the possible effect of the prior SARS-CoV-2 infection on cases, we performed a

Table 3. Comparison of pre-vaccination and post-vaccination period in terms of COVID-19 development and the disease severity.

	Pre-vaccination period (n = 1000)		Post-vaccination period (n = 813)		*p*	OR
	n	%	n	%		
COVID-19						
Yes	187	18.7	50	6.1	<0.001	3.51
No	813	81.3	763	94.9		
COVID-19 related hospitalization						
Yes	6	0.6	0	0	0.107	10.63
No	994	99.4	813	100		
Severe COVID-19						
Yes	3	0.3	0	0	0.249	5.70
No	997	99.7	813	100		
Critical illness, intensive care unit admission, and death						
Yes	0	0	0	0	0.917	0.81
No	1000	100	813	100		

Table 4. Subgroup analysis of pre-vaccination and post-vaccination period in terms of COVID-19 development and the disease severity.

	Pre-vaccination period (n = 708)		Post-vaccination period (n = 521)		*p*	OR
	n	%	n	%		
COVID-19						
Yes	187	26.4	44	8.4	< 0.001	3.89
No	521	73.6	477	91.6		
COVID-19 related hospitalization						
Yes	6	0.8	0	0	0.122	9.65
No	702	99.2	521	100		
Severe COVID-19						
Yes	3	0.4	0	0	0.277	5.17
No	705	99.6	521	100		
Critical illness, intensive care unit admission, and death						
Yes	0	0	0	0	0.878	0.73
No	708	100	521	100		

subgroup analysis after excluding HCWs with a previous history of COVID-19 in the last three months. However, there were some limitations. First, this was a single-center retrospective study. Second, our study had a small sample size. Therefore, the effect of the vaccination on poor outcomes such as the need for intensive care and death could not be evaluated. Third, there was no control group with unvaccinated HCWs. Thus, we did not measure the efficacy or effectiveness of COVID-19 vaccination.

Conclusions

In conclusion, the CoronaVac vaccine significantly reduces the risk of developing SARS-CoV-2 infection in the early period (first 3 months) and alleviates the clinical severity of COVID-19. Additionally, individuals infected and vaccinated with the CoronaVac vaccine are less likely to be reinfected with COVID-19. However, individuals infected with COVID-19 are at risk for re-infection after 3 months. For this reason, even if people have a history of COVID-19, they should be vaccinated.

Authors' Contributions

Yusuf Emre Ozdemir and Kadriye Kart Yasar proposed the concept, designed the study, wrote the protocol, and managed the study. Yusuf Emre Ozdemir, Aysegul Inci Sezen, Meryem Sahin Ozdemir, Osman Faruk Bayramlar performed the statistics, interpreted the data, and wrote the manuscript. Serkan Surme, Emine Ilay Duman, Nomin Bold, and Zuhal Yesilbag were involved in collecting the data. Sevtap Senoglu, Habip Gedik, and Kadriye Kart Yasar performed a critical review of the manuscript. All authors provided input for revision of the manuscript. Yusuf Emre Ozdemir communicated with the journal and addressed comments from reviewers. All authors contributed to data acquisition, data analysis and interpretation, and reviewed and approved the final version.

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