

Retrospective analysis of healthcare workers admitted to emergency department due to side effects of the inactivated COVID-19 vaccine^{*}

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ABSTRACT

Objective: This study aimed to evaluate the clinical characteristics and outcomes of healthcare workers who presented to the emergency department with vaccine-related reactions following the first dose of the CoronaVac vaccine.

Materials and Methods: A retrospective analysis was conducted in Ankara Bilkent City Hospital's Emergency Department between 13.01.2021 and 13.02.2021, encompassing healthcare workers aged 18 and above who experienced Vaccine Adverse Effects after CoronaVac vaccination. Data regarding demographics, medical history, symptoms, treatments, and outcomes were extracted from the hospital management system and analyzed using SPSS Version 24.

Results: Of the 43 healthcare workers presenting with Vaccine Adverse Effects, 76% were female. Known history of anaphylaxis/urticaria was recorded in 32.6% of the patients, while 11.6% had a prior history of COVID-19. Common presenting symptoms included chest pain (16.3%) and headache (14%). A majority (58.1%) required no treatment, though two patients received adrenaline for anaphylaxis, with one requiring hospitalization. The median time from vaccination to symptom onset was approximately 16 hours.

Conclusion: The study demonstrates a higher incidence of Vaccine Adverse Effects among female healthcare workers and those with a history of anaphylaxis/urticaria, although most reactions were mild and did not necessitate treatment. This analysis sheds light on the CoronaVac vaccine's safety profile among healthcare workers and provides a foundation for addressing vaccine-related concerns in preparation for future mass vaccination endeavors against emerging COVID-19 variants or new pandemics.

Keywords: COVID-19, COVID-19 vaccines, adverse effects, emergency department.

INTRODUCTION

The COVID-19 pandemic, stemming from the first reported case in Wuhan province, China, in 2019, has emerged as one of the most pivotal events of the 21st century, spreading rapidly worldwide. Initial high mortality rates persisted until the development of initial treatments and preventive measures. As per current World Health Organization data, it has led to approximately 7 million deaths [1].

Vaccination stands out as a paramount defense against viral infections [2]. Various vaccines, including mRNA, inactivated, and adenovirus vector-based, have been devised to combat COVID-19 [3]. One such vaccine, CoronaVac, an inactivated SARS-CoV-2 vaccine developed by Sinovac/Biotech, China, obtained global emergency use approval [4]. Owing to limited production and the urgent need in vaccination programs, priority has been rightly accorded to vaccinating high-risk individuals globally, with healthcare workers prominently featured among them.

Commencing on January 13, 2021, healthcare workers and individuals above the age of 65 began mass vaccinations with CoronaVac, the inaugural COVID-19 vaccine receiving emergency use approval in Turkey [5]. In Turkey, hospitals have been designated as mass vaccination centers, facilitating the provision for vaccinated individuals to seek assistance from the emergency department in case of adverse reactions. Side effects linked to inactivated vaccines typically manifest as local symptoms or exhibit mild to moderate severity, encompassing fever, fatigue, headache, and pain/redness at the injection site [6]. In our study, we undertook an evaluation of the clinical characteristics and outcomes of healthcare workers who presented to the emergency department following vaccine-related reactions subsequent to the administration of the first dose of the CoronaVac vaccine.

METHODS

Our study follows a prospective, observational design and was conducted within the Emergency Department of Ankara Bilkent City Hospital. Ethical approval was obtained from the Ethics Committee

for Clinical Research, chaired by the Institutional Review Board of Ankara City Hospital, specifically from Research Ethics Committee No. 2. Located in Ankara, the capital of Turkey, Ankara Bilkent City Hospital served as a crucial center during the pandemic, functioning both as a pandemic center hospital and a vaccination center in the city. The Emergency Department of Ankara Bilkent City Hospital attends to approximately 360,000 patients annually. The study period spanned from January 13, 2021, to February 13, 2021, corresponding to the administration of the first dose of the vaccination.

The study cohort comprised healthcare workers exhibiting complaints subsequent to receiving the CoronaVac vaccine and seeking care in the emergency department. Vaccine Adverse Effect (VAE) was defined as "any adverse medical event occurring after vaccination and thought to be related to a vaccine (including known or unknown vaccine effects)." Inclusion criteria involved healthcare workers aged 18 and above, providing informed consent for participation, and presenting to the emergency department with VAE. Key data, including gender, age, chronic diseases, COVID-19 history, anaphylaxis/urticaria history, vaccine-symptom interval, presenting symptoms, emergency department treatments, and outcomes, were systematically recorded.

Statistical analysis employed the SPSS statistical package program. Descriptive findings for categorical variables were presented as numbers and percentages, while continuous variables were expressed as mean \pm standard deviation for normally distributed data and median (minimum, maximum) for non-normally distributed data. The normal distribution of continuous variables was assessed through visual (histogram and probability graphs) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk tests). Pairwise comparisons utilized Mann-Whitney U and Chi-square tests, with statistical significance set at $P < 0.05$.

RESULTS

A total of 43 healthcare workers sought admission to the emergency department with Vaccine Adverse Effect (VAE). Among them, 76% ($n=33$)

were female. Notably, 32.6% (n=14) had a known history of anaphylaxis/urticaria, while 11.6% (n=5) reported a previous episode of COVID-19. The distribution of patients concerning medical history and gender is detailed in Table 1.

Table 2 provides insights into the age distribution of patients and the time elapsed after vaccination until the manifestation of symptoms.

The most prevalent presenting symptoms were chest pain, reported by 16.3% (n=7), and headache, reported by 14% (n=6). A significant portion of patients (58.1%) successfully completed the follow-up period without necessitating treatment. Only two patients received adrenaline, with one of them requiring hospitalization for further observation, as outlined in Table 3.

DISCUSSION

In the context of pandemics, safeguarding healthcare workers, who are at high risk due to increased healthcare demands and heightened exposure to the infectious agent, is of paramount importance. Vaccination stands out as the most

effective measure for their protection against pandemics. Despite being healthcare workers, concerns about vaccine side effects persist [4-7-8-9].

Our study revealed a notable predominance of females among patients seeking admission to the emergency department with Vaccine Adverse Effect (VAE). This observation aligns with existing literature trends [10-12]. Considering that the majority of admissions were linked to immune response-related reasons, a gender-based influence might be at play [13]. Additionally, the presentation habits of women could contribute to this phenomenon [14].

Approximately 33% of patients had a history of anaphylaxis, surpassing figures reported in the literature [15,16]. Notably, patients with a history of anaphylaxis and allergy exhibited a higher incidence of side effects [12].

Common reactions to inactivated vaccines, such as VAE, typically involve local pain, rash, headache, fever, and malaise [9]. Our study corroborates the high incidence of headache. Notably, there were no admissions related to pain, redness, or fever, possibly attributed to patients with such

Table 1. Gender distribution and medical history of patients

		(n)	(%)
Sex	Male	10	23,3%
	Female	33	76,7%
Chronic Disease	Hypertension	6	14,0%
	Hypothyroidism	6	14,0%
	Asthma	2	4,7%
	Rheumatological disease	2	4,7%
Anaphylaxis/ Urticaria History	Yes	14	32,6%
	No	29	67,4%
COVID 19 History	Yes	5	11,6%
	No	38	88,4%

Table 2. Analysis of patients' age and time from vaccination to symptom onset

	Mean	SD	Median	Percentile 25	Percentile 75
Age (years)	35	11	35	26	41
Vaccine symptom interval (hours)	16,4	15,5	23,0	1,0	24,0

Table 3. Clinical features and outcomes of patients

		(n)	(%)
Symptoms	Headache	6	14,0%
	Dizziness	2	4,7%
	Nausea	2	4,7%
	Palpitation	2	4,7%
	Urticaria	4	9,3%
	Joint pain	3	7,0%
	Chest pain	7	16,3%
	Fatigue	3	7,0%
	Diarrhea	2	4,7%
	Pruritus	5	11,6%
	Dyspnea	4	9,3%
	Paresthesia	1	2,3%
	Finger swelling	1	2,3%
	Syncope	1	2,3%
Treatment	Nontreatment	25	58,1%
	Antihistamines +steroid	9	20,9%
	Analgesic (NSAID)	7	16,3%
	Adrenaline	2	4,7%
Hospitalized	Hospital admission	1	2,3%
	Discharged	42	97,7%

complaints not seeking emergency department care for relatively simple side effects.

The median time from vaccination to emergency department presentation was approximately 16 hours, with 25 patients undergoing observation without requiring treatment. This aligns with the prevailing understanding that the majority of COVID VAE occurs within the initial 48 hours [3-14].

Of significance, only 2 patients received adrenaline for anaphylaxis, and one necessitated hospitalization. Both patients, females, presented with dyspnea, were promptly attended by the code team from the vaccination center within the hospital, and received intramuscular adrenaline. Symptoms regressed without further intervention (intravenous adrenaline, vasopressors, etc.). Despite the incidence of anaphylaxis after routine vaccination being reported as approximately 1 in a million [10], our study indicates a higher rate compared to routine vaccination. This heightened risk is consistent with existing literature on COVID-19 vaccines [17,18]. However, considering the protective benefits and the low incidence of severe side effects, applying COVID-19 vaccination is deemed logical [9-14].

CONCLUSION

Our investigation reveals a higher incidence of Vaccine Adverse Events (VAE) associated with CoronaVac in females and individuals with a history of allergies. Importantly, the majority of these cases were uncomplicated and did not necessitate follow-up. As new variants of COVID-19 with the potential to evade existing vaccines and unforeseen pandemics may emerge in the future,

preparations for novel mass vaccination strategies will be crucial. We anticipate that the insights from our study will serve as a valuable guide in shaping these preparations.

Limitations

Our study is not without limitations. First, we lack follow-up data for patients discharged from the emergency department, preventing an assessment of the duration of their symptoms and their resolution over time. Additionally, information about the specific units or departments where the healthcare workers, participants in our study, were employed is not available. These limitations warrant consideration when interpreting the results and may provide avenues for further investigation in future research endeavors.

Author contribution

Study conception and design: ÇY, Nİİ; data collection: ÇY, Nİİ; analysis and interpretation of results: ÇY, Nİİ; draft manuscript preparation: ÇY, Nİİ. All authors reviewed the results and approved the final version of the manuscript.

Ethical approval

The study was approved by the Ethics Committee No. 2 of Ankara City Hospital (Protocol no. E2-21-120/10.02.2021).

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Conflict of interest

The authors declare that there is no conflict of interest.

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