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Evaluation of patients admitted to the emergency department after Coronavac (Sinovac) vaccination?

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Abstract

To evaluate the symptoms and laboratory parameters of patients admitted to the emergency department after CoronaVac (Sinovac) vaccination. Complaints, demographic characteristics, laboratory tests, interventions, and outcomes of patients admitted to the emergency department within seven days of receiving the CoronaVac (Sinovac) were all evaluated. Pain at the injection site, swelling, redness, and pain in the injected arm were expected side effects of the vaccination. In this study, a total of six people had syncope following the vaccination, one of whom developed an allergic reaction. The most common adverse events in non-geriatrics were fatigue, headache, fever, and abdominal pain, while in geriatric patients' fatigue, headache, chest pain, and dyspnea were most common, with fever falling in the last place. Rare symptoms following vaccination included syncope and urticaria. It is necessary to be prepared for the side effects that may occur during mass vaccination against COVID-19. In this study, the body's response to the vaccine in geriatric patients was atypical in vital signs and laboratory values.

Keywords: vaccine, side effect, COVID-19, CoronaVac, SARS-CoV-2

1. Introduction

The coronavirus disease COVID-19 started in Wuhan in December 2019. It spread rapidly around the world and was declared a pandemic. It causes severe acute respiratory syndrome in patients. The mortality of the disease varies between 0.4% and 7% (1). Vaccine studies have accelerated due to the increased mortality rates, especially with the delta variant.

On the other hand, the fact that the immunity of those who had the disease is not permanent and the reinfection rates are high revealed the importance of community immunity in order to end the pandemic (2). Vaccines are obtained using antigenic substances produced from the disease-causing agent, in order to create a defense mechanism against diseases and to produce antibodies (3). In line with the COVID-19 Vaccine Implementation Strategy (in the study's country of origin), on January 14, 2021, the vaccination of those aged 65 and over—primarily healthcare workers—began. The plan is to vaccinate all individuals by dividing them into age groups, according to the COVID-19 vaccination calendar from the Ministry of Health of Turkey. The vaccine made in the study's country of origin is the CoronaVac (Sinovac) vaccine. CoronaVac was obtained by producing and inactivating the live SARS-CoV-2 virus in a laboratory, using the traditional vaccine production method (4). The country and healthcare system aim to be prepared for the potential side effects following the COVID-19 vaccination. The most common post-vaccine side effects are reported by the World Health Organization as pain at the injection site, headache, fatigue, and myalgia (5).

As the vaccination process reaches the stage of comprehensive vaccination in the wider community, an awareness of the potential side effects makes it possible to decide where and how the vaccine will be administered, considering the gender and age of the recipient and whether they suffer from any chronic diseases (6-8).

Data on adverse events following the initial vaccination are valuable, as they can inform the healthcare system in advance of the potential side effects in preparation for mass vaccination. In turn, this allows both patients and health institutions to act more cautiously when administering the vaccine and encountering side effects, and it enables adequate preparation for the potential side effects following the COVID-19 vaccination. At the stage of comprehensive vaccination of the wider community, the location and method of vaccination can be determined, considering the gender and age of the recipient and whether they suffer from any chronic diseases.

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2. Material and Methods

The study was conducted retrospectively and included patients aged 18 and over who applied to the Emergency Department (ED) between January 11, 2021, and February 11, 2021.

Vaccination is carried out by appointment, and specific conditions must be established for patients to receive the vaccination: It is not administered to patients with a fever of 38 °C or above, those with undiagnosed acute disease, or those who are experiencing a period of acute attack from a chronic illness.

The COVID-19 disease status of the patient is checked. If they are found to have the disease, the vaccine is not administered. Being in contact with a confirmed COVID-19 case in the last ten days is checked, and if so, the vaccine is not administered. It is also checked whether the patient has received other vaccines in the month prior: Those who have received seasonal influenza, pneumococcal, meningococcal, and other inactivated vaccines must wait two weeks to make an appointment to receive the COVID-19 vaccine. Complaints, demographic characteristics, laboratory tests, and the interventions and outcomes of the patients admitted to the ED within seven days of receiving the vaccination were all evaluated. All patients admitted to the ED following the CoronaVac (Sinovac) vaccination were included in the study.

Laboratory tests, including those for white blood cells, lymphocytes, neutrophils, platelets, hemoglobin, alanine aminotransferase, aspartate aminotransferase, bilirubin, fasting blood glucose, and creatinine, are investigated to assess for any post-vaccination side effects. The data is obtained from NUCLEUS MBS—the patient clinical information system of the Medical Faculty Hospital.

2.1. Statistical analysis

The statistical analyses were performed using SPSS, version 22 (IBM SPSS Statistics for Windows, Armonk, NY; IBM Corp., 2013). First, a Kolmogorov-Smirnov test was used to determine which variables should be included in the data analysis and whether the data for the variables were normally distributed, but the data were not normally distributed. Therefore, non-parametric tests were used. The Mann-Whitney U test was used to compare continuous variables across the groups. The Wilcoxon signed Ranks Test was used to compare two dependent variables. The mean ± standard deviation, frequency, and percentage were reported as descriptive statistics. The statistical significance level was set to $p < 0.05$.

2.2. Ethics

Approval was obtained from The Bezm-i Alem Foundation University local ethics committee with dated 29.04.2021 and number 09. Due to the retrospective design of the study and its relationship with public health, consent was not obtained from the patients within the knowledge of the ethics committee.

3. Results

A total of 66 patients were admitted to the ED following CoronaVac (Sinovac) vaccination, with a mean age of 51.2±23.4 years and a median age of 47.5 years (25–90). Twenty-eight (42.4%) patients were female and 38 (57.6%) were male. The number of geriatric patients totaled 43 (65.4%). Of the 66 patients, hypertension was witnessed in 20 (30.3%), coronary artery disease in 14 (21.2%), diabetes mellitus in 12 (18.2%), chronic obstructive pulmonary disease in 12 (18.2%), and nine (21.2%) suffered from congestive heart failure. Of the 66 patients, 51 (77.3%) were discharged from the ED, 12 (18.2%) were admitted onto a ward, two (3%) were admitted to the intensive care unit, and one patient (1.5%) died (Table 1). In terms of complaints, 33 (50%) patients suffered from fatigue, 27 with headaches (40.9%), 17 with fever (25.8%), 15 with shortness of breath (22.7%), 14 with joint pain (21.2%), 14 with abdominal pain (21.2%), 11 with a cough (16.7%), 10 with nausea and/or vomiting (15.2%), eight with dizziness (12.1%), eight with chest pain (12.1%), eight with diarrhea (12.1%), six with syncope (9.1%), and two with urticaria (3%) (Table 2). Two geriatric patients experienced fever (8.7%), compared to 15 of the non-geriatric patients (34.9%) (p=0.02). Fatigue was present in nine (39.1%) of the geriatric patients, compared to 24 (55.8%) of the non-geriatric patients (p=0.196). Dyspnea was present in six (26.1%) geriatric patients, compared to nine (20.9%) of the non-geriatric patients (p=0.634). Headaches were experienced by nine (39.1%) of the geriatric patients, compared to 18 (41.9%) of the non-geriatric patients (p=0.830). Of the geriatric patients, four (17.4%) suffered from joint pain, compared to ten (23.3%) of the non-geriatric patients (p=0.755). Nausea and/or vomiting was experienced by four (17.4%) of the geriatric patients, compared to six (14%) of the non-geriatric patients (p=0.730). Cough was present in five (1.7%) of the geriatric patients, compared to six (14%) of the non-geriatric patients (p=0.495). Abdominal pain was experienced in three (13%) of the geriatric patients, compared to 11 (25.6%) of the non-geriatric patients (p=0.346). Syncope was present in four (17.4%) of the geriatric patients, compared to two (4.7%) of the non-geriatric patients (p=0.172). Of the geriatric patients, three (13%) suffered from dizziness, compared to five (11.6%) of the non-geriatric patients (p=0.867). Chest pain was experienced by seven (30.4%) of the geriatric patients but only one (2.3%) non-geriatric patient (p=0.002). Diarrhea was present in three (13%) of the geriatric patients, compared to five (11.6%) of the non-geriatric patients (p=0.867). Urticaria was only witnessed in two (8.7%) of the geriatric patients, and not at all in the non-geriatric patient sample (Table 2). Anaphylactic shock developed in one female patient, who also experienced syncope and was non-geriatric. Vital and laboratory parameters of the enrolled patients and their comparison between the geriatrics and non-geriatrics groups are presented in table 3.

Table 1. Demographics and baseline characteristics of simple

Variables		n (%)
Gender	Female	28 (42.4%)
	Male	38 (57.6%)
Age		51.2±23.4
	<65 years	43 (65.2%)
	≥65 years	23 (34.8%)
Comorbidities	Hypertension	20 (30.3%)
	Chronic obstructive pulmonary disease	12 (18.2%)
	Congestive heart failure	9 (13.6%)
	Coronary artery disease	14 (21.2%)
	Diabetes mellitus	12 (18.2%)
Outcome	Discharge	51 (77.3%)
	Service	12 (18.2%)
	Intensive care	2 (3%)
	Death	1 (1.5%)

Table 2. Symptoms of the enrolled patients and their comparison between the geriatrics and non-geriatrics groups

	Non-geriatrics	Geriatrics	p
	n (%)	n (%)	
Fever	15 (34.9%)	2 (8.7%)	**0.02**
Fatigue	24 (55.8%)	9 (39.1%)	0.19
Dyspnea	9 (20.9%)	6 (26.1%)	0.63
Headache	18 (41.9%)	9 (39.1%)	0.83
Join-muscle pain	10 (23.3%)	4 (17.4%)	0.75
Nausea-vomiting	6 (14%)	4 (17.4%)	0.73
Cough	6 (14%)	5 (21.7%)	0.49
Abdominal pain	11 (25.6%)	3 (13%)	0.34
Syncope	2 (4.7%)	4 (17.4%)	0.17
Dizziness	5 (11.6%)	3 (13%)	0.86
Chest pain	1 (2.3%)	7 (30.4%)	**0.02**
Diarrhea	5 (11.6%)	3 (13%)	0.86
Urticaria	0	2 (8.7%)	0.11

Table 3. Vital and laboratory parameters of the enrolled patients and their comparison between the geriatrics and non-geriatrics groups

		Non-geriatrics	Geriatrics	p
Vital signs	Fever	36.7±0.7	36.2±0.4	**0.01**
	Blood pressure (mm/Hg)	121±17.8	145.7±22.6	0.02
	Respiratory rate (/min)	19.5±2.1	20.8±1.7	0.23
	Heart rate (/min)	95.9±12.1	81.8±12.3	0.17
	Oxygen saturation	96.3±1.6	93.9±3.5	**<0.001**
Laboratory parameters	*White blood cell count (10^3/μL)*	6.1±1.2	8.6±3	**<0.001**
	Hemoglobin (g/dL)	13.8±1.3	11.9±2	0.16
	Platelet count (10^3/μL)	197.3±79	188±39.4	**<0.001**
	Troponin I (ng/dL)	3.9±6.4	348±1073	**<0.001**
	Prothrombin time	13.5±1.5	14.9±3.1	**<0.001**
	Partial Thromboplastin Time	27.9±7.4	32.1±7.1	0.91
	International normalized ratio	0.9±0.15	1.1±0.27	<0.001
	D-Dimer (ng/mL)	203±88.1	481±300	<0.001
	C-Reactive Protein (mg/dL)	13.3±27.4	6.5±8.2	0.05
	Lactate dehydrogenase (mg/dL)	211±71.7	380±374	**<0.001**
	Blood urea nitrogen (mg/dL)	18.9±10	32.6±14.9	0.12
	Creatinine (mg/dL)	0.8±0.2	1.6±1.4	**0.01**
	Aspartate transaminase (U/L)	31.3±23.8	64.2±144	**0.01**
	Alanine transaminase (U/L)	35.5±37.8	45.9±92	0.05
Outcome	Discharge	36 (83.7%)	15 (65.2%)	**0.08**
	Hospitalization to ward	7 (16.3%)	5 (21.7%)	
	Intensive care unit admission	0	2 (8.7%)	
	Death	0	1 (4.3%)	

4. Discussion

In the study's country of origin, health workers and patients over 65 years of age were included in the scope of the initial stage of the COVID-19 vaccination program. It aimed to vaccinate the majority of the population in order to create social immunity.

The most important risk factor for COVID-19-related mortality was advanced age. Immunization programs around the world started with health workers and the elderly, who are at risk groups (9) The goal of herd immunity is particularly important in the case of COVID-19, due to its deadly nature and limited treatment options (10). However, many people are concerned about whether vaccines protect them, whether vaccines are safe, and what the possible side effects are. In a previous study, it was shown that 29% of participants were not willing to get vaccinated, and 44% believed that COVID-19 vaccines could have serious side effects that could affect their health (11).

The most common symptoms associated with COVID-19 were fever, shortness of breath, and muscle and joint pain. Vaccination-related symptoms are similar to disease symptoms (12). Convincing people to get vaccinated can only be achieved with the help of scientific studies. Following vaccination, pain at the injection site, swelling, redness, and pain in the arm injected are all expected side effects (13). Those side effects most feared, however, are those related to allergic reactions

and the degree of involvement of vital organs (e.g., myocarditis). Mild to moderate reactions can be seen as "a sign of the immune system's response to the vaccine" (14); however, these symptoms normally only last a short time and subside on their own. In this study, a total of six patients suffered from post-vaccine syncope, and only one developed an allergic reaction. Hypotension, tachycardia, and angioedema were observed in the first five minutes following vaccination. It was discovered that this patient, whose condition improved with intervention, had a previous history of allergic reaction. It should be accepted that those with a history of allergies are potentially at risk (15). Anaphylaxis is a life-threatening allergic reaction that occurs in rare situations following vaccination, with a typical onset of minutes to several hours (16, 17). There are existing studies reporting that anaphylaxis is a risk following a COVID-19 vaccination (18); however, the prognosis of anaphylaxis is good when diagnosed and treated in a timely and correct manner (19). Vaccination centers should be equipped with the necessary materials and equipment for the treatment of anaphylaxis. In this study, the most common side effect following a COVID-19 vaccination was fatigue (50%), the second most common was a headache (40.9%), and the third most common was fever (34.9%). However, in the geriatric group, fever ranked last (8.7%), and there was a statistically significant difference between the geriatric and non-geriatric groups (p=0.02)—high fever may not always be observed in geriatric patients, even in the presence of severe infection (20). Abdominal pain was more common in those under 65 years of age (25.6%). Normal physiological changes (such as the absence of fever and leukocytosis) and physical examination can be seen in geriatric individuals, even with significant abdominal pathologies (21). While chest pain was seen at a rate of 30.4% in people over 65 years of age, it was among the rarer symptoms in the non-geriatric group. In connection with this complaint, the troponin value was found to be higher in the geriatric age group. According to these results, there is a need for further studies focusing on the relationship between vaccines and myocarditis. Complaints of chest pain in those under the age of 65 were 2.3% and troponin values were within the normal range. Common side effects listed by the World Health Organization (WHO) for the COVID-19 vaccine included fever, weakness, headache, muscle pain, and nausea (22). In this study, diarrhea, syncope, urticaria, and chest pain were added to these complaints. Post-vaccination, 77.3% of the patients admitted to the ED were discharged following clinical evaluations and only two (3%) were admitted to the ward. One patient in the geriatric age group, also suffering from additional diseases, died: They had been admitted to the ED in arrest the day following their vaccination, despite having no active complaints prior to this. The most significant laboratory parameter for this patient was a platelet count of 25,000. In a similar study, death after vaccination was associated with a low blood platelet count. In a study conducted in Norway, 23 geriatric deaths following vaccination were reported (23).

Vaccination against SARS-CoV-2, the cause of COVID-19, is the most important global strategy for controlling the pandemic. In order to achieve herd immunity, it is crucial to persuade those who are currently opposed to the vaccination; in order to successfully achieve this, scientific data should be applied. It is also particularly important to consider the potential side effects when performing mass vaccination against COVID-19. A patient who has previously experienced a severe allergic reaction should be prepared for post-vaccine anaphylactic shock. This study has also shown that post-vaccine geriatric patients may experience atypical vital signs and laboratory values, and there were statistically significant differences between the geriatric and non-geriatric groups. As a result, adverse reactions may develop in the body's response to the vaccine in geriatric patients, particularly when combined with the effects of an underlying disease.

There are several important limitations to our study. The retrospective design is the most important limitation. Secondly, to better interpret the changes in laboratory values of patients admitted to the ED post-vaccination, the same parameters should also be measured in blood samples taken prior to vaccination. The limited sample and single-center design can be considered as other limitations that could limit the generalizability of our findings.

As a conclusion, it is necessary to be prepared for the potential side effects when conducting mass vaccination against COVID-19. The results of this study can be used as evidence-based scientific data that addresses the side effects of CoronaVac (Sinovac). Thus, it can be used to increase public engagement in the vaccination program by raising awareness about CoronaVac (Sinovac).

Ethical statement

Approval was obtained from The Bezm-i Alem Foundation University local ethics committee with dated 29.04.2021 and number 09.

Conflict of interest

There are no conflicts of interest.

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None to declare.

Authors' contributions

Concept: B.T., E.S., S.Ö., Design: B.T., E.S., S.Ö., Data Collection or Processing: B.T., E.S., S.Ö., Analysis or Interpretation: B.T., E.S., S.Ö., Literature Search: B.T., E.S., S.Ö., Writing: B.T., E.S., S.Ö.

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