Original Article

The Adverse Events Following Immunization (AEFI) of Sinovac Vaccine among Lecturer and Teaching Staff at Syarif Hidayatullah State Islamic University Jakarta Indonesia

Hari Hendarto[1], Risahmawati[2], Nurin Nadzifatil Fitriyah[3], Femmy Nurul Akbar[1]

[1]Internal Medicine Department, Faculty of Medicine, Univesitas Islam Negeri Syarif Hidayatullah Jakarta, Banten, Indonesia.

[2]Community Medicine Department, Faculty of Medicine, Universitas Islam Negeri Syarif Hidayatullah, Jakarta, Banten, Indonesia.

[3]Biology Department, Faculty of Medicine, Universitas Islam Negeri Syarif Hidayatullah, Jakarta, Banten, Indonesia.

Abstract

Background: Information about the incidence of adverse events after the administration of COVID-19 vaccine has an important effect on the level of public confidence in the vaccination program in Indonesia. The rejection occurred was caused by the lack of knowledge about the benefits of the vaccination as well as the adverse events. Therefore, this study aims to determine the vaccine safety in response to the community's vaccination hesitancy.

Methods: This is a cross-sectional survey study, was carried out from March to April 2021 by collecting data on the adverse events following immunization (AEFI) of Sinovac vaccination among lecturers and teaching staff at Syarif Hidayatullah State Islamic University Jakarta. The vaccines were injected twice, with an interval of 2-4 weeks.

Results: A total of 518 participants filled in the questionnaire. Furthermore, pain at injection site fatigue, headache, drowsiness, chills, and hunger were the most common AEFI after the first and second doses. All the AEFI that occurred were generally mild, and none of them needed special medical treatment or to be hospitalized. The AEFI disappeared within a week and were resolved without additional problems.

Conclusions: The data in this study showed the occurrence of lower AEFI of first and second doses immunization using the Sinovac vaccine. All the reactions were mild and disappeared within a week without further problems. These results are expected to increase public confidence in the safety of COVID-19 vaccination without significant adverse events, thereby increasing the coverage of the program.

Keywords: COVID-19, Sinovac vaccine, AEFI, Vaccine hesitancy, Vaccine safety.

INTRODUCTION

The World Health Organization (WHO) officially declared the Coronavirus disease 2019 (COVID-19) as a pandemic on March 11, 2020. In April 2021, the global pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has spread to several countries and infected more than 3 million people.1

Address for correspondence: Hari Hendarto
Internal Medicine Department, Faculty of Medicine, Univesitas Islam Negeri Syarif Hidayatullah Jakarta, Banten, Indonesia.
Email: hari.hendarto@uinjkt.ac.id com

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The unavailability of an effective treatment promoted all countries to fight the virus collectively. In Indonesia, different prevention strategies, such as wearing masks, social distancing, avoiding crowds, and limiting unnecessary travel were implemented from the emergence of the virus. These measures were taken to curtail its spread, but the lack of public discipline in adhering to them has increased the number of infected people. Although the government implemented a limited lockdown, the fatigue caused by the unending pandemic has reduced public compliance. Restrictions on people's daily activities also increased the community's economic burden, hence, it is not a long-term solution. This indicates that the development of a vaccine is the best solution to stop the pandemic. Therefore, this study aims to determine the safety of the Sinovac vaccine among lecturers and teaching staff at Syarif Hidayatullah State Islamic University Jakarta. The safety of vaccines against COVID-19 also needs to be assessed in a real post-licensure study.

The announcement of the successful discovery of a corona vaccine in China has given the community new hope. Some of the vaccines developed have received approval for emergency use in China and other countries. Meanwhile, a Chinese state-owned company, Sinopharm, has worked on two different types of vaccination using an inactivated form of SARS-CoV-2. The first was developed at the Beijing institute, while the second was at Wuhan City. The third vaccine was developed by a Beijing-based pharmaceutical company, Sinovac, which also used an inactivated SARS-CoV-2 as the main ingredient.2,3 The Sinopharm vaccine has received emergency use approval in approximately 30 countries including Bahrain, Guyana, Hungary, Serbia, and the UAE. Hungary is the first European Union country to approve its usage, while other countries, such as Brazil, Chile, Turkey, and Indonesia, where it has been tested also approved the emergency use.2

The Strategic Advisory Group of Experts (SAGE) on immunization issued an emergency use permit for the Sinovac vaccine on 7 May 2021, approximately 4 months after the Chinese authorities announced its approval on 31 December 2020.4 Several reports showed that it is well tolerated and capable of triggering a humoral response to SARS-CoV-2. In January 2021, the vaccine showed an effectiveness of 50.4%5 based on the results of the trials in Brazil, while it was 67%6 and 83.5%7 in Chile and China, respectively. The Indonesian Food and Drug Supervisory Agency (BPOM) in January 2021 also issued an emergency use permit after it showed an effectiveness of 65.3% in phase three clinical trials, which is the final stage before a vaccine can be distributed and released to the wider community.8

According to WHO, Adverse Events Following Immunization (AEFI) are detrimental medical events that occur after vaccination, and they are not always causally related. When effective treatments are not immediately applied, they can undermine public confidence in the usefulness of vaccines. This ultimately has negative consequences for immunization coverage and the incidence of the disease. Therefore, it is necessary to conduct a strict monitoring and safety reporting process for the vaccine, as well as record all reactions that occurred by implementing officers to determine the occurrence of AEFI. A Serious Adverse Event (SAE) is any medical event that causes hospitalization, disability, death, and unrest in the community after immunization. Mild Adverse Event (MAE) is a medical event, which poses no risk to the health of the recipient after a vaccine is received.

An analysis of the global community's perspectives on the use of vaccines against COVID-19 showed that most people have more neutral opinions. A previous study also showed that most Indonesians have neutral opinions on the vaccination, which started in January 2021.9 This indicates that public enthusiasm for the program is still considered mediocre and has not become a top priority as a weapon to fight the pandemic. The rejection was caused by a lack of knowledge about vaccines and their benefits as well as concerns about the risks.10 Therefore, acceptance by the wider community is an important factor in the success of the national vaccination program. A previous study stated that effective vaccines have been introduced to prevent certain diseases and are widely circulated, but there were some cases of AEFI reactions. This reduced the confidence in immunization due to public concern, specifically when it is strengthened by the mass media reporting cases of AEFI.11

The government has the responsibility to ensure herd immunity is achieved, which is a condition where the majority people are immune to certain diseases through vaccination, thereby making transmission difficult. In Indonesia, to fulfill the requirements for the formation of herd immunity, approximately 181.5 million people or 70% of the total population must be vaccinated.12 Meanwhile, lack of local information about AEFI influences the community’s perception of vaccine safety, which leads to hesitation in vaccination recommendations to family, friends, and the environment, and this indirectly delays national coverage targets. Information about the incidence of AEFI has an important impact on the level of public confidence in the benefits of vaccination and participation in supporting its implementation.

MATERIAL AND METHODS

Participants

This is a cross-sectional study with a survey method, which was carried out between March and April 2021, by collecting data on the adverse effects of the Sinovac vaccine among lecturers and teaching staff at Syarif Hidayatullah State Islamic University Jakarta through questionnaires.

Study Population

The inclusion criteria were all teaching staff aged 18 years

and above who have received the complete doses of the Sinovac vaccine. Meanwhile, the exclusion criteria were those who had received vaccinations other than Sinovac.

Assessment tools

Based on the recommendation, the vaccination was carried out twice, where the second dose was administered within 2 to 4 weeks after the first.4 In this study, information was obtained by filling out a self-administered and validated questionnaire using a multiple-choice model, which includes basic demographic information, such as age, gender, education, occupation, health status, and vaccination history. Existing reactions or complaints were evaluated within 30 minutes, 24 hours, and 3 days after the first and second vaccinations. Almost all the question models were marked, with a checkbox provided to select an answer. It also contained an explanation of the aim, the expected benefits of this study and informed consent. The data was analyzed statistically using Microsoft Excel 2019 and SPSS 22.0. The Chi-square test was used for the statistical analysis with the p-values less than 0.05 is statistically significant.

This study was carried out based on the Indonesian Medical Research Ethics Guidelines. It also received ethical clearance from the Medical Research Ethics Committee, Faculty of Medicine, Syarif Hidayatullah State Islamic University, Jakarta, Indonesia with registry number B-008/F12/KEPK/TL.00/06/2021. All data obtained were treated confidentially and used solely for this study.

RESULTS

A total of 518 participants completed the questionnaire and have received the two doses of the vaccine. The response rate was 32% (518/1589) during the vaccination period in March and April 2021. The participants consisted of 43% female and 57% male with an age range of 20 to 76 years, as shown in Tables 1 and 2.

Table 1. Number of study participants by gender

Gender	Numbers	%
Male	295	57
Female	223	43
N	518	100

Table 2. Number of participants classification by age

Age (years old)	Numbers	%
17 – 25	16	3.09
26 – 35	127	24.52
36 – 45	160	30.89
46 – 55	162	31.27
56 – 65	47	9.07
> 65	6	1.16

The most common complaints within 30 minutes, 24 hours, and 3 days after the first vaccination were without AEFI (55.98%, 48.26%, 71%), pain at the injection site (26.83%, 18.53%, 8.11%), fatigue (2.12%, 10.62%, 7.53%), headache (2.9%, 5.02%, 4.25%), drowsiness (19.5%, 27.03%, 10.81%), fever (0.58%, 4.25%, 1.74%), and hunger (1.54%, 1.16%, 0.97%). Meanwhile, the complaints within 30 minutes, 24 hours, and 3 days after the second vaccination include without AEFI (52.92%, 65.44%, 73.94%), pain at the injection site (32.24%, 17.95%, 11.58%), fatigue (6.95%, 7.14%, 7.34%), headache (2.7%, 3.86%, 3.47%), drowsiness (15.44%, 13.32%, 7.92%), fever (0.58%, 3.09%, 1.74%), and hunger (0.39 %, 0.58%, 0.39%), as shown in Table 3.

Table 3. The most common adverse events of Sinovac vaccine

	First vaccination %			Second vaccination %		
AEFI	30 min	24 hours	3 days	30 min	24 hours	3 days
No side effects	55.98	48.26	71	52.9	65.44	73,94
Pain at injection site	26.83	18.53	8.11	32.24	17.95	11.58
Drowsiness	19.5	27.03	10.81	15.44	13.32	7.92
Fatigue	2.12	10.62	7.53	6.95	7.14	7.34
Headache	2.9	5.02	4.25	2.7	3.86	3.47
Chills	0.58	4.25	1.74	0.58	3.09	1.74
Hunger	1.54	1.16	0.97	0.39	0.58	0.39

The statistical analysis showed that there were no significant differences in the number of side effects between male and female, as shown in Table 4.

Table 4. Number of side effects of Sinovac vaccine by gender

	First vaccination %			Second vaccination %		
Gender	30 min	24 hours	3 days	30 min	24 hours	3 days
Male	23	25.3	13.5	25.5	20.7	14.3
Female	21	26.6	15.1	21	19.9	16.8

All the general side effects were more prevalent among the 26-55 years old group, and their duration was mainly within 24 hours after the vaccine, as shown in Figures 1 and 2.

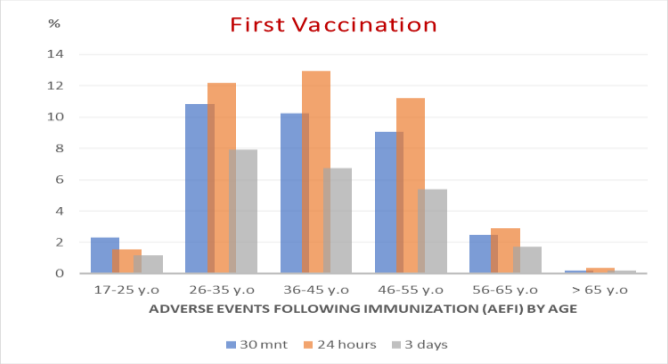

Figure 1. Adverse events following immunization (AEFI) of first dose of Sinovac vaccination by age

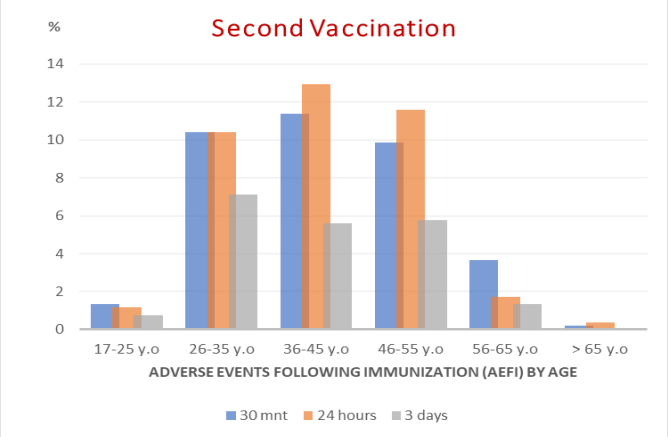

Figure 2. Adverse events following immunization (AEFI) of second dose of Sinovac vaccination by age

All reported AEFI was generally mild and none of them required special medical treatment or hospitalization. Most of the reactions were felt within the first 3 hours after vaccination and completely disappeared within a week without further problem

Discussion

The strategy for implementing the vaccination program was to protect groups of individuals with a high risk of being infected with COVID-19, such as health workers, the elderly with comorbidities, and the vulnerable populations including frontline officers, and educators.5 In this study, the target groups include lecturers and teaching staff at Syarif Hidayatullah State Islamic University Jakarta, who are expected to help in the dissemination of information about the benefits and safety of vaccination to the public. Between March and April 2021, mass vaccination using Sinovac was carried out on 1589 lecturers and teaching staff. Based on this description, it is necessary to conduct a study on the incidence of AEFI during the program as an effort to support data collection in Indonesia.

Out of the 1589 people who received complete vaccination, 518 (32%) were willing to participate in this study by filling out a questionnaire and fulfilling the inclusion criteria. Meanwhile, the majority people who were fully vaccinated and did not participate stated the reason for not experiencing AEFI. The WHO recommended that all vaccinated individuals must receive two doses (0.5 ml) intramuscularly into the deltoid muscle, with an interval of 2 to 4 weeks.4

The results showed that only 7.4% of AEFI were reported after the first vaccination, which indicated that most of the participants had mild adverse effects. Furthermore, 59% occurred within the first 30 minutes, while 33.8% was felt between 1 to 3 days. Approximately 6.5% felt the presence of AEFI for more than 3 days, but not up to 1 week after the vaccination. The symptoms are in line with a previous study in China, which showed that the most common side effects were mild.13

The most common AEFI felt after vaccination among lecturers and teaching staff at Syarif Hidayatullah State Islamic University Jakarta, was pain at the injection site, fatigue, headache, drowsiness, chills, and hunger. These results are not significantly different from the safety data cited by WHO at three clinical trials, which involved 16,671 people. The most common side effects include pain at the injection site, headache, and fatigue4. Previous studies also showed that the most dominant AEFI was pain at the injection site by 9.6%, after the first vaccination and 10.7% after the second. Meanwhile, other side effects that often occur include fatigue, headaches, and muscle aches.13

Female complained of more severe vaccine side effects than male because they have stronger immune responses and are less susceptible to viral infections.14 However, male patients are more prone to infection, and it is independent of age, compared to females.15 In this study, there were no significant differences in the adverse events found between male and female. This indicated that most of the participants did not experience any side effects.

The result also showed the occurrence of lower adverse events after the first dose immunization with Sinovac vaccine, among 10.23 % elderly population (56 years and above) compared to the productive age group. Similar observation was also made in the second dose vaccination, where aged people showed lower number of side effects. The elderly is more vulnerable to COVID-19, but most of the elderly population in Indonesia including in this study are retired that have low mobility and spend more time at home. These behaviors can cause a lower perceived risk of being infected with COVID-19, and eventually lead to lower acceptance of the vaccination program. However, several studies showed that elderly, specifically those with comorbidities, have a higher risk of contracting COVID-19 infection, and must be the main priority to be vaccinated.16

Conclusion

Based on the results, the most common AEFI obtained after vaccination using Sinovac among lecturers and teaching staff at Syarif Hidayatullah State Islamic University Jakarta, include pain at the injection site, fatigue, headache,

drowsiness, chills, and hunger. Meanwhile, all reactions were mild and disappeared within a week without further problems. These results are expected to increase public confidence in the safety of COVID-19 vaccination without significant adverse events, thereby increasing the coverage of the program.

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