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Adverse Events Following Immunization Report and Vaccine Effectiveness of Sinovac. An Interim Report

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ABSTRACT

Vaccination is a prevention of transmission and spread and in order to establish herd immunity against the Covid-19 pandemic. Indonesia chose the Sinovac vaccine, which uses weakened viruses. The objective of the study was to measure the Adverse Events Following Immunization (AEFI) 24-72 hours post-vaccination and its effect at three months after vaccination. An online survey was distributed to 1574 subjects who received the first dose, and 530 respondents (response rate 33.6%) who answered the questionnaire were sent the form again for the second dose, and 249 subjects responded (response rate 46.9%). From the first dose: 322 female (60.9%), 207 male (39.1%). There were 22 respondents who had fever on the first day and only five respondents on the second day. In addition, 147 (27.8%) felt pain in the injection site, nausea 30 respondents (5.7%), vomiting six persons, bloating 35 respondents (6.6%), and diarrhea ten respondents (1.9%). Fifty-nine respondents who got mild adverse events did nothing to ease their adverse events, 18 respondents took self-medication, 15 respondents consulted the doctors in the vaccination site. Only one respondent went to the nearby hospital for further therapy. Results from the second dose: As many 249 respondents (131 female, 108 male) answered respondents. The AEFI's pattern was quite the same as the first dose.

Keywords: *AEFI, Sinovac, Covid-19*

1. INTRODUCTION

Covid-19 was firstly identified in Wuhan, Hubei province – China. Vaccination is useful to prevent the transmission and spread of the disease while forming herd immunity against the Sars-Cov2 or Covid-19 pandemic. Due to the epidemic that immediately spread worldwide, many countries, research bodies, and pharmaceutical companies developed vaccines. Due to the urgent need for vaccination, clinical trials were carried out quickly, and the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and World Health Organization (WHO) issued Emergency Use Authorization (EUA). All countries, including Indonesia, are currently focusing on organizing mass vaccinations for their communities. From the various vaccines available and those currently in development, Indonesia firstly chose Sinovac, which is based on inactivated viruses, not the mRNA vaccine. The Sinovac vaccine used by Indonesia for mass vaccination programs is an inactivated virus. Its phase III clinical trials have been conducted in Indonesia, Brazil, and China, with good efficacy results. [1], [2] Aside the efficacy of the vaccine, adverse event following immunization (AEFI) is also important, and that usually occurs shortly after vaccination up to approximately 24-72 hours. Still, some reactions were sustained for up to 14 days. [3]

The Sinovac vaccine contains 3 ug/0.5 mL (equivalent to 600 SU per dose) of inactive viruses with aluminum hydroxide adjuvant (Al_2OH_3). The canyoned adjuvant can also give a crossroads effect.

Universitas Kristen Indonesia/Christian University of Indonesia (UKI) and the Alumni Association, Faculty of Medicine, and UKI's Teaching Hospital organized a mass vaccination program. The vaccine was supplied by the Community Health Center of Kramat Jati. Vaccination was carried out for three days in March-April 2021.

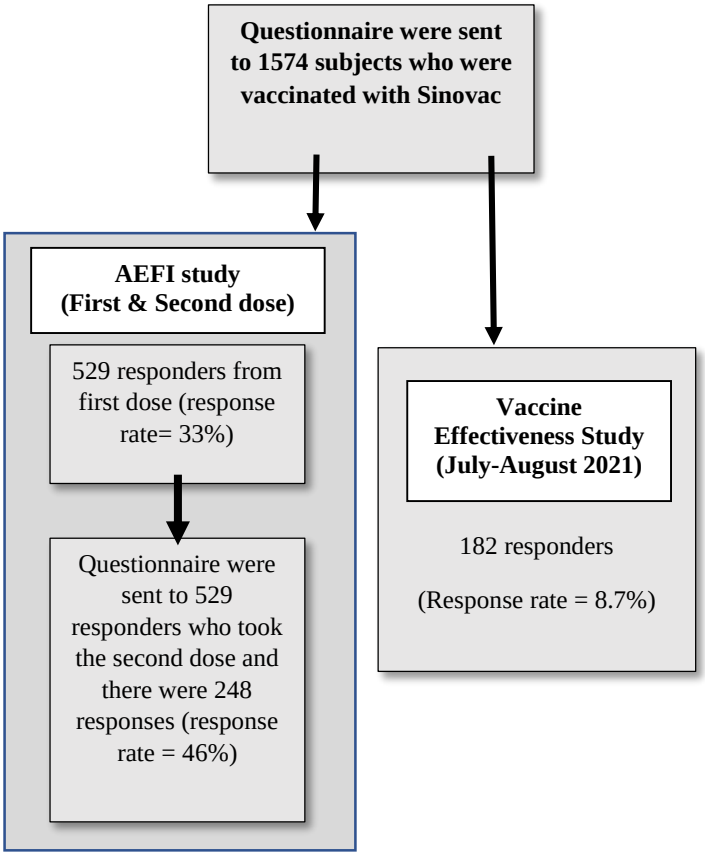

Figure 1 The recruitment scheme of respondents

2. METHODS

An online questionnaire using Microsoft Form was distributed to all vaccine recipient respondents recorded by the committee via Whatsapp (WA).

The questionnaire consists of 14 questions consisting of related questions:

a. Demographics: gender, age, and ID card number.
b. Adverse reaction divided into nervous system and brain, skin system, and digestive system
c. Other adverse reactions they might had which can be freely written in the questionnaire.
d. Actions taken by respondents when experiencing adverse reactions.

Subjects who had been vaccinated at the first dose and second dose were directly sent the questionnaire of AEFI by WhatsApp (WA).

The second questionnaire was developed to explore whether the respondents were infected or being infected as they received the questionnaire. In addition, we also asked about their compliance with health protocols that in Indonesia consist of 6 things: wearing masks, washing hands, maintaining distance, staying away from crowds, reducing mobility, and not eating together in restaurants.

The survey was approved by the Ethical Committee: No. 15/Etik Penelitian/FKUKI/2021.

3. RESULTS AND DISCUSSION

Figure 1 shows the responders' recruitment for assessment of AEFI and monitoring the efficacy of vaccination in the real world. The questionnaires were sent only to the subjects who responded to the first dose questionnaire at the second dose assessment. The response rates were 33% and 45%, respectively, from the first and the second dose. Thus, the response rate of vaccine effectiveness was quite low, 182 respondents (8.7%), although the questionnaires were sent to all 1547 who had been vaccinated. Response rates in such studies are generally low. Maybe the respondents, because they have many WA groups, often missed or deleted chats that seemed to consume their cellphone memory, therefore sending the questionnaire via WA needs to be repeated many times. Since this study is still ongoing, we hope there will be enough additional respondents in the near future.

Table 1. Demographic and AEFIs reported by respondents at the first and second dose of Sinovac

	Respondents from first dose vaccine (n=529)		Respondents from second dose vaccine (n=248)	
Women	321 (61%)		131 (52%)	
Male	208 (39%)		107 (48%)	
Age (mean ± SD)	45 ± 15		47 ± 16	
Min-Max of age	17 years – 76 years			
	Yes	No	Yes	No
Fever on the first day of vaccination	22 (4.2%)	507 (95.8%)	6 (2.5%)	230 (97.5%)
Fever in the second day of vaccination	5 (.9%)	16 (3.0%)	3 (.6%)	3 (.6%)
Took drug against fever	6 (1.1%)	15 (2.8%)	0 (0%)	6 (100%)
Pain in injection site	146 (27.5%)	383 (72.5%)	78 (31.4%)	158 (68.6%)
Swelling at the injection site	22 (4.2%)	507 (95.8%)	7 (2.5%)	229 (97.5%)
Nausea	30 (5.7%)	499 (94.3%)	18 (7.5%)	218 (92.5%)
Vomiting	6 (1.1%)	523 (98.9%)	2 (0.8%)	234 (99.2%)
Flatulence	35 (6.6%)	494 (93.4%)	16 (6.7%)	220 (93.3%)
Diarrhea	10 (1.9)	519 (98.1%)	5 (2.1%)	231 (97.9%)
Drowsiness	64 (12%)	465 (88%)	33 (13.3%)	215 (86.7%)

As shown in Table 1, the AEFIs from the first dose and second dose vaccine were enlisted, and the most frequent adverse events reported by respondents were pain at the injection site: 146 (27.5%), and 78 (31.4%), respectively. The second most frequent adverse events were drowsiness: 64 (12%), 33 (13.3%), respectively. Table 2 shows actions taken by respondents while they experienced AEFIs. The AEFI pattern that appears in our study confirms what Zhang et al. reported in the Sinovac phase 1/2 clinical trial. [4] Although there were 146 (27.5%) respondents and 78 (31.4%) respondents at the first dose and the second dose who felt pain at the injection site and also felt fever even though there were not many, many did not take action against it. This may be due to pain at the injection site, or fever that they feel was only mild. However, some respondents took a pain killer. For example, in the first dose group, there were 8 respondents who consulted AEFI to the nearest hospital, while in the second dose group only one person

Table 2. Actions taken by respondents against AEFIs

	Respondents from first dose vaccine with adverse reactions (n=249)	Respondents from second dose vaccine with adverse reactions (n=96)
No actions were taken	149 (59.8%)	59 (61.4%)
Self-medicated	56 (22%)	18 (18%)
Consulted the doctors in vaccination's site	28 (11%)	15 (15.6%)
Consulted to the nearby Public Health Centre	3 (1%)	2 (2%)
Consulted to the nearby doctor	4 (1.6%)	1 (1%)
Consulted to the nearby allied health personnel	0 (0%)	0 (0%)
Consulted the nearby hospital	8 (3%)	1 (1%)

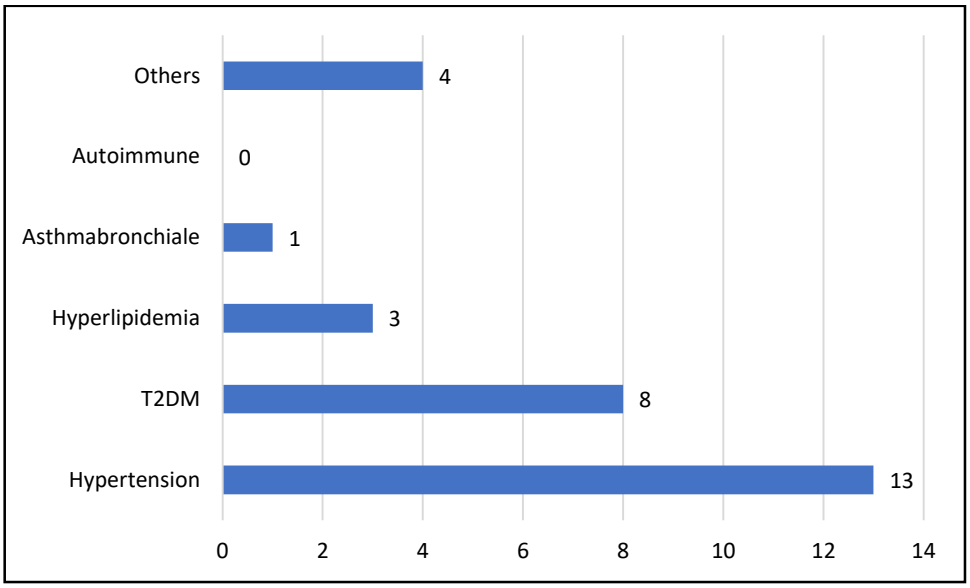

Figure 2 Comorbidities that some respondents have

Some respondents had comorbidities, as depicted in Figure 2, but they were still allowed to be vaccinated because their disease was controlled, and health workers checked their condition shortly before vaccination. The vaccine will also be given to subjects who have a comorbidity, and this is challenging because people with comorbidity do not necessarily have an optimal immune response. Therefore, in every vaccination, for people who have comorbidity, the disease must be well controlled if to be vaccinated. Another aspect that is also studied is old age. Advanced age is also associated with a decreased immune response; therefore, they are included in priority vaccinations. However, a comparison study of the Sinovac vaccine effectiveness between older (78.85 ± 12.56) and relatively young health care workers (age 48.37 ± 11.37) done by Özsezikli et al. showed that in the older group, there was a significant increase of the antibody (IgG >1) from 61.8% at the vaccination I to 85.3% at the vaccination II (p = 0.003), respectively. However, this was lower compared to the young health care workers, which was from 69.2% to 97.4%, respectively (p = 0.000)[5]

3. 1. Vaccine Effectiveness

Figure 3 shows the proportion of respondents who got infected, infected, and not infected three months after vaccination. There were 154 (84%) respondents who reported that they had not been infected, and 18 (10%) had been infected, whereas 11 (6%) respondents were being infected as they fill-out the questionnaire. Twenty respondents (69%) reported they had infected or been infected with symptoms, and the rest (9 persons, 31%) were without symptoms. These results were quite higher compared to a study by Jara et al., who reported the effectiveness of the Sinovac vaccine given to the Chilean population.[6] But our results match those reported by Özsezikli et al., that's the 40s age group. [5]

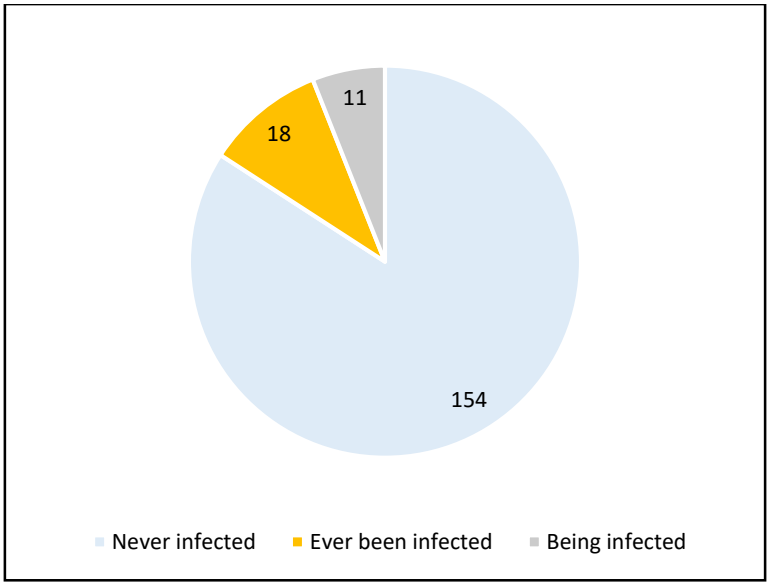

Figure 3 Respondents who got infected, being infected, and had never infected post-vaccination

3.2. Post-covid syndrome

Although many Covid-19 patients are cured, some case reports indicate a "long-covid" phenomenon that according to some reports could last up to 60 days[7], [8] and show many difficult symptoms. However, fatigue appears as a prominent features aside from shortness of breath.[9], [10] Our study also showed the same symptoms (shown in Figure 4). Although some respondents reported they had long-covid experiences, they ignored it and did not go to health facilities to get treatment.

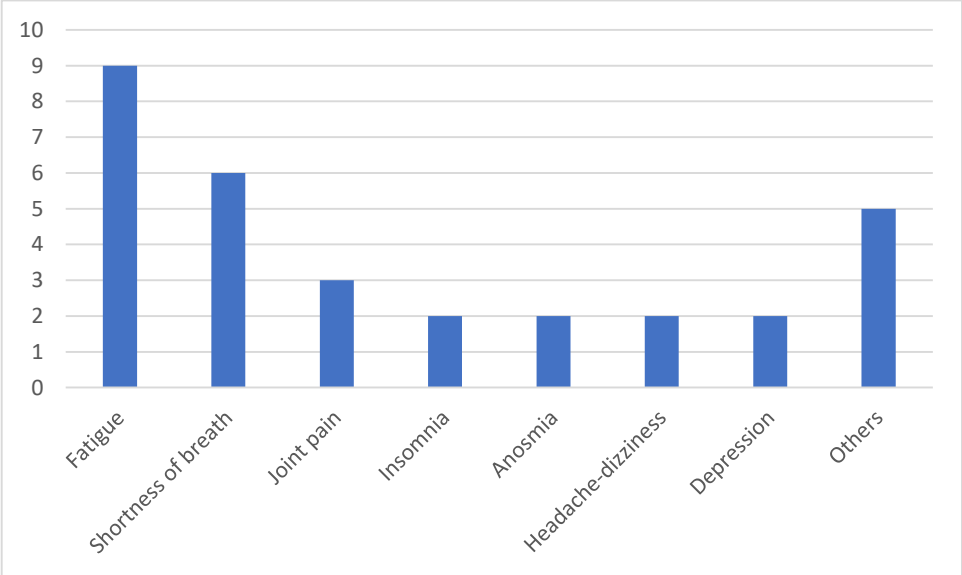

Figure 4 Long-covid symptoms reported by respondents

4. CONCLUSION

Our study shows results from the real-world experience of the use of the Sinovac vaccine. The AEFI of Sinovac in our respondents was low and tolerable. The vaccine effectiveness is also in accordance with the clinical trials done as a basis for the determination by WHO to be used by issuing Emergency Authorization Use (EAU). However, our study is also subject to limitation. Firstly, we did not measure the neutralizing antibody level of respondents, which is not yet regularly done in such studies. It was stated also in the method, the data collected in the study was solely rely on the respondents' self-report. Data from respondents continues to come in so we will later report the results more comprehensively.

AUTHORS' CONTRIBUTIONS

Abraham Simatupang: Head of research team, who instilled the main idea and wrote the research proposal, and wrote the manuscript.

Robert H Sirait: research team member, partly contributed in writing the research proposal.

Forman Erwin Siagian: research team member, partly contributed in writing the research proposal.

Yunita RMB Sitompul: research team member, vaccinator and monitoring the AEFI.

Luana Natingkaseh: research team member, vaccinator and monitoring the AEFI.

Sudung Nainggolan: research team member, partly contributed for developing the research proposal, and conducted the statistical analysis.

Conflicts of Interest: The authors declare that they have no competing interests.

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Vaccination is a prevention of transmission and spread and in order to establish herd immunity against the Covid-19 pandemic. Indonesia chose the Sinovac vaccine, which uses weakened viruses. The objective of the study was to measure the Adverse Events Following Immunization (AEFI) 24-72 hours post-vaccination and its effect at three months after vaccination. An online survey was distributed to 1574 subjects who received the first dose, and 530 respondents (response rate 33.6%) who answered the questionnaire were sent the form again for the second dose, and 249 subjects responded (response rate 46.9%). From the first dose: 322 female (60.9%), 207 male (39.1%). There were 22 respondents who had fever on the first day and only five respondents on the second day. In addition, 147 (27.8%) felt pain in the injection site, nausea 30 respondents (5.7%), vomiting six persons, bloating 35 respondents (6.6%), and diarrhea ten respondents (1.9%). Fifty-nine respondents who got mild adverse events did nothing to ease their adverse events, 18 respondents took self-medication, 15 respondents consulted the doctors in the vaccination site. Only one respondent went to the nearby hospital for further therapy. Results from the second dose: As many 249 respondents (131 female, 108 male) answered respondents. The AEFI's pattern was quite the same as the first dose.

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