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Original Article

Adverse Events Following Immunization of mRNA And Inactivated Vaccines Against Covid-19 at The University of Indonesia Hospital: A Cross-Sectional Study

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Abstract

Background: The coronavirus that causes severe acute respiratory syndrome (COVID-19) is coronavirus 2 (SARS-CoV- 2). This virus has caused a global pandemic. The adverse impact of this virus in the past two years has resulted in efforts to build herd immunity through vaccination. This study aims to identify the side effects after getting the Pfizer and Sinovac vaccines at the University of Indonesia Hospital and the risk factors for Adverse Events Following Immunization (AEFI).

Methods: This observational study used a descriptive non-experimental method with a cross-sectional design. Data were collected using Google Forms.

Results: AEFI symptoms are commonly found at an onset of 15 minutes – 24 hours. The common AEFI symptoms were pain at the injection site, fatigue, muscle aches, and joint pain. The AEFI severity was mostly at the mild level and only a few participants took medication. Results from this study showed that female participants, participants with comorbidities and allergies, previous medication history within the last 6 months, experience with COVID-19 had a higher risk for AEFI with a statistically significant effect ($p<0.005$).

Conclusion: This study reveals that Pfizer and Sinovac Covid-19 vaccines are safe to administer as AEFIs are mostly mild and automatically disappear and decrease after 1 to 3 days.

Keywords: Covid-19; AEFI; Pfizer; Sinovac; Vaccine.

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INTRODUCTION

The coronavirus that causes severe acute respiratory syndrome (COVID-19) is coronavirus 2 (SARS- CoV-2). Global pandemic brought on by this virus. There were 27 people with pneumonia in Wuhan, Hubei Province, China, in late 2019. The virus spread quickly across the globe (1). Indonesia recorded zero cases from December 2019 to February 2020, when China was severely affected by the novel coronavirus SARS- CoV2. On March 2, 2020, President Joko Widodo announced Indonesia's initial two COVID-19 infections. Given that Indonesia has the fourth-highest population in the world, more hardship is anticipated there than in other, less crowded nations (2).

The severe impact of COVID-19 in the past two years has resulted in global efforts to build herd immunity starting from the individual level to the population level (3). Referring to national data, a total of 202,623,385 people (97%) have received the first dose of vaccine, while a total of 170,201649 people (81%) have received the second dose, and a total of 56,829,093 people (24%) have received the third dose (updated on August 4, 2022At least 70-85% of the population must receive vaccinations in order to acquire herd immunity. Public perceptions changes along with the changing condition of the pandemic (4).

There is currently no licensed coronavirus vaccine for human use. Therefore the rapid research and

development cycle and the scant post-vaccination monitoring raise significant public concerns regarding the safety of the COVID-19 vaccine candidate, particularly for the new platform like RNA vaccines. A common defence for not having the immunization is that there are "concerns regarding the safety of the vaccine in development" and "potential harmful effects". Adverse events following immunization (AEFI) have increased since the widespread use of vaccination, especially the infrequent one (5). Based on the Indonesian Society of Internal Medicine (PAPDI), AEFI should be monitored due to at least four reasons. First of all, no vaccine is completely risk-free and safe. Second, it's critical to understand the dangers and how to manage them as they manifest. Third, to preserve public confidence in the immunization program, it is crucial to notify the public about AEFIs appropriately. Lastly, monitoring AEFIs contributes to better service quality (6).

In consideration of the COVID-19 history, certain unfriendly public impressions surrounding the vaccine's side effects, the low level of AEFI reports, and limited scientific evidence of AEFI in Indonesia, based on the severity of AEFIs at the University of Indonesia Hospital, researchers are motivated to conduct this research to discover the potential risks that influence the vaccine's efficacy.

METHODS

Study Design and Population

This observational study assessed the effectiveness of the Pfizer and Sinovac vaccines using a non-experimental, descriptive, cross-sectional study design. Research participants who received vaccinations at the University of Indonesia Hospital were directly interviewed to gather data prospectively. Besides, this study used online forms to collect the required information from participants. The information was then categorized and monitoring was done for 28 days. This research was conducted at the University of Indonesia Hospital in August - September 2022. Data monitoring was done successively based on the following timeline. A Google Form in Indonesian was created with a 5-minute completion time for the questionnaire to evaluate AEFI. Therefore, according to the timeframe for the research at the University of Indonesia Hospital, the questionnaire covered an AEFI evaluation with five steps.

Data Collection and Analysis

Participants completed a survey in the form of a Google Form containing personal identity, medical conditions, and perceived AEFI complaints. Questionnaire data were filled in 5 stages according to the timeline. Personal data in the questionnaire covered name, gender, telephone number, date of birth, weight and height, blood type, occupation, the previous dose of vaccine and the dose received during vaccination at the University of Indonesia Hospital during recruitment. The questionnaire's medical information also includes comorbidities, allergy and covid-19 histories, hospitalizations in the last three months, and drug use in the previous six months. The questionnaire had closed-ended inquiries concerning AEFI concerns. The questionnaire sheet used in the survey is shown in the **Supplementary Data 1**. The information from the questionnaire was entered into a Microsoft Excel sheet and statistically examined using SPSS 25 and Microsoft Excel. The incidence of AEFI was compared with gender, age, BMI, comorbidities, vaccine types, history of allergies, prior COVID-19, history of hospital admission in the previous three months, and history of medication in the last six months using the Chi-square test. The significance level ($p = 0.05$) was used to perform statistical comparisons.

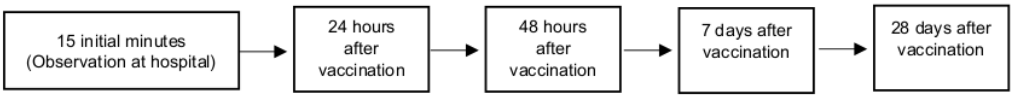

Figure 1. Research Data Monitoring Timeline

Ethical Clearance

The University of Indonesia Hospital Ethics Committee has accepted this study under approval number S-033/KETLIT/RSUI/VIII/2022 with protocol number 2022-07-165.

RESULTS

Demographic characteristics

In total, 272 participants were surveyed to obtain a minimum sample of 137 participants. However, only 261 subjects agreed to participate in the study by completing the given online form and meeting the inclusion and exclusion criteria. Of the total 261 participants, the mean age was 29.88 ± 10.86 years (mean ± standard deviation (SD)). The participants consisted of 148 (57%) females and 113 males (43%). The average body mass index (BMI) was 2.29 ± 0.86 with the highest BMI category of Underweight - Normal (<18,5 - 24,9) with a total of 187 participants (72%). Two groups were formed from the participants. The first group had 149 people (57%) who received the Pfizer (BNT162b2) vaccination, while the second group had 112 individuals (43%) who received the Sinovac vaccine. Only 31 participants (12%) had comorbidities and 54 participants (21%) took medication in the last 6 months. A total of 13 participants (5%) experienced a hospitalization within the past three months. Meanwhile, participants who had a history of allergies and Covid-19 were 31 participants (12%) and 81 participants (31%) respectively. **Table 1** describes the specific participant characteristics in detail.

Table 1. Characteristics of the Participants

Variable	Category	Frequency	Percentage
Age	**Mean ± SD**		29.88 ± 10.86
	Adolescence aged ≤25 years	116	44%
	Adulthood aged 26-45 years	109	42%
	Elderly aged <45 years	36	14%
Gender	Female	148	57%
	Male	113	43%
Body Mass Index (BMI)	**Mean ± SD**		2.29 ± 0.86
	Underweight - Normal (<18,5 - 24,9)	187	72%
	Overweight - Obese (25 - ≥ 27)	74	28%
Vaccine types	BNT162b2 (*Pfizer*)	149	57%
	Sinovac	112	43%
Vaccine variation	Pfizer	8	3%
	Pfizer + Pfizer	14	5%
	Sinovac + Sinovac	11	4%
	Sinovac + Sinovac + Sinovac	91	35%
	Sinovac + Sinovac + Pfizer	23	9%
	Pfizer + Pfizer + Pfizer	23	9%
	Astrazeneca + Astrazeneca + Pfizer	19	7%
	Moderna + Moderna + Pfizer	8	3%
	Sinovac + Sinovac + Sinovac + Sinovac	10	4%
	Sinovac + Sinovac + Pfizer + Pfizer	14	5%
	Sinovac + Sinovac + Moderna + Pfizer	34	13%
	Astrazeneca + Astrazeneca + Pfizer + Pfizer	6	2%
Dose	1st dose Pfizer	8	3%
	2nd dose Pfizer	14	43%
	3rd dose Pfizer	73	28%
	4th dose Pfizer	54	43%
	2nd dose Sinovac	11	43%
	3rd dose Sinovac	91	35%

	4th dose Sinovac	10	43%
Comorbidity	No	230	88%
	Yes	31	12%
History of allergy	No	229	88%
	Food allergy	28	11%
	Drug allergy	4	2%
Hospitalization in the last 3 months	No	248	95%
	Yes	13	5%
History of medication in the last 6 months	No	207	79%
	Yes	54	21%
History of Covid	No	180	69%
	Yes	81	31%

Adverse Event Following Immunization (AEFI)

Overall, the AEFI is divided into 4 monitoring period, namely the initial 15 minutes during hospital observation, 15 minutes – 24 hours, 24 hours – 48 hours, and 48 hours – 7 days. In the initial 15 minutes, a total of 197 participants (75%) experienced AEFI. Then, in the 15 minutes – 24 hours monitoring, a total of 215 participants (82%) experienced an increase in AEFI from the previous monitoring. In the 24-48 hours monitoring and 48 hours – 7 days monitoring, the incidence of AEFI decreased to 133 participants (50%) and 57 participants (21%) (**Figure 2**).

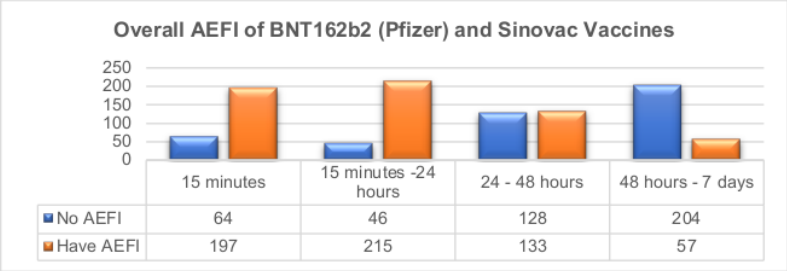

Figure 2. Overall AEFI of BNT162b2 (*Pfizer*) and Sinovac Vaccines

Table 2 shows that in the initial 15 minutes after vaccination, participants reported 3 main complaints, namely 130 participants (39.5%) experienced pain at the injection site; 70 (26.8%) participants experienced fatigue, and 44 (16.9%) participants experienced myalgia with mild severity based on the Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials issued by the Food and Drug Administration **(Supplementary 2)**. At moderate severity in the initial 15 minutes, the main complaint felt by participants was fatigue with 27 participants (10.3%) followed by pain at the injection site and myalgia. At severe severity in the initial 15 minutes, there was 1 participant in each AEFI category, namely swelling/induration, headache, fatigue and joint pain. At 15 minutes – 24 hours of monitoring (**Table 2**), there was an increase in the incidence of AEFI with mild severity where 134 participants (51.3%) experienced pain at the injection site, 91 participants (34.9%) experienced fatigue, and 20.7% of the participants experiencing myalgia and joint pain. **Table 3** shows the incidence of AEFI at 24 hours – 48 hours and 48 hours – 7 days of monitoring. In 24 hours - 48 hours of monitoring, there was a decrease in the incidence of AEFI from 134 participants (51.3%) to 72 participants (27.6%) experiencing pain at the injection site. Then,

participants experiencing fatigue with mild severity decreased from 91 participants (34.9%) to 49 participants (18.8%). At moderate severity, there was a decrease from 28 participants (10.7%) to 10 participants (3.8%). On monitoring 48 hours – 7 days (**Table 3**), there was no longer any AEFI at the injection site. The main complaints during monitoring for 48 hours – 7 days were headache, fatigue and joint pain. The detailed information is presented in the following table.

Table 1. AEFIs and the severity levels in the initial 15 minutes observation at the hospital and 15 minutes – 24 hours

AEFI	15 minutes								15 minutes – 24 hours							
	Mild		Moderate		Severe		PLT		Mild		Moderate		Severe		PLT	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Local Adverse Events																
Pain at the injection site	103	39.5%	24	9.2%	0	0.0%	0	0.0%	134	51.3%	25	10%	0	0.0%	0	0.0%
Redness/Erythema	4	1.5%	0	0.0%	0	0.0%	0	0.0%	17	6.5%	2	1%	0	0.0%	0	0.0%
Swelling/induration	19	7.3%	2	0.8%	1	0.4%	0	0.0%	24	9.2%	6	2%	1	0.4%	0	0.0%
Itching/Pruritus associated with injection	6	2.3%	0	0.0%	0	0.0%	0	0.0%	17	6.5%	1	0%	0	0.0%	0	0.0%
Systemic Adverse Events										0.0%		0%	0	0.0%	0	0.0%
Pain in the legs	24	9.2%	4	1.5%	0	0.0%	0	0.0%	34	13.0%	5	1.9%	0	0.0%	0	0.0%
Fever	36	13.8%	0	0.0%	0	0.0%	0	0.0%	43	16.5%	2	0.8%	0	0.0%	0	0.0%
Nausea/ Vomiting	4	1.5%	0	0.0%	0	0.0%	0	0.0%	9	3.4%	0	0.0%	0	0.0%	0	0.0%
Headache	31	11.9%	8	3.1%	1	0.4%	0	0.0%	37	14.2%	8	3.1%	1	0.4%	0	0.0%
Fatigue	70	26.8%	27	10.3%	1	0.4%	0	0.0%	91	34.9%	28	10.7%	1	0.4%	0	0.0%
Myalgia	44	16.9%	15	5.7%	0	0.0%	0	0.0%	54	20.7%	18	6.9%	0	0.0%	0	0.0%
Acute Allergic Reaction	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Rash	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Joint pain	34	13.0%	14	5.4%	1	0.4%	0	0.0%	54	20.7%	17	6.5%	3	1.1%	0	0.0%
Other Adverse Event	1	0.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%

PLT:** ***Potentially Life-Threatening

Table 3. AEFIs and the severity levels at 24 – 48 hours and 48 hours – 7 days

AEFI	24 - 48 hours								48 hours - 7 days							
	Mild		Moderate		Severe		PLT		Mild		Moderate		Severe		PLT	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Local Adverse Events																
Pain at the injection site	72	27.6%	3	1.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Redness/Erythema	7	2.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Swelling/induration	13	5.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Itching/Pruritus associated with injection	9	3.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.4%	0	0.0%	0	0.0%
Systemic Adverse Events																
Pain in the legs	16	6.1%	1	0.4%	0	0.0%	0	0.0%	7	2.7%	0	0.0%	0	0.0%	0	0.0%
Fever	26	10.0%	0	0.0%	0	0.0%	0	0.0%	9	3.4%	0	0.0%	0	0.0%	0	0.0%
Nausea/ Vomiting	4	1.5%	1	0.4%	0	0.0%	0	0.0%	2	0.8%	0	0.0%	0	0.0%	0	0.0%
Headache	32	12.3%	5	1.9%	0	0.0%	0	0.0%	16	6.1%	4	1.5%	0	0.0%	0	0.0%
Fatigue	49	18.8%	10	3.8%	1	0.4%	0	0.0%	16	6.1%	2	0.8%	1	0.4%	0	0.0%
Myalgia	36	13.8%	3	1.1%	0	0.0%	0	0.0%	15	5.7%	0	0.0%	0	0.0%	0	0.0%
Acute Allergic Reaction	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Rash	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Joint pain	31	11.9%	4	1.5%	0	0.0%	0	0.0%	16	6.1%	1	0.4%	0	0.0%	0	0.0%
Other Adverse Event	3	1.1%	0	0.0%	0	0.0%	0	0.0%	1	0.4%	0	0.0%	0	0.0%	0	0.0%

PLT:** ***Potentially Life-Threatening

Tabel 4. Risk factors affecting AEFI in the initial 15 minutes and 15 minutes – 24 hours

Risk factor	AEFI 15 minutes						AEFI 15 minutes - 24 hours					
	NO AEFI	AEFI	p-value	OR	95 % CI		NO AEFI	AEFI	p-value	OR	95 % CI	
	n (%)	n (%)			Lower	Upper	n (%)	n (%)			Lower	Upper
Gender												
Female	27 (18.2)	121 (81.8)	**0.009**	0.458	0.258	0.813	16 (10.8)	132 (89.2)	**0.002**	0.335	0.172	0.653
Male	37 (32.7)	76 (67.3)					30 (26.5)	83 (73.5)				
Age												
≤ 25 tahun	27 (23.3)	89 (76.7)	0.215	-	-	-	20 (17.2)	96 (82.8)	0.071	-	-	-
26– 45 tahun	24 (22.0)	85 (78.0)					15 (13.8)	94 (86.2)				
tahun	13 (36.1)	23 (63.9)					11 (30.6)	25 (69.4)				
Body Mass index (BMI)												
Underweight - Normal (<18,5 - 24,9)	35 (18.7)	152 (81.3)	**0.001**	0.357	0.197	0.647	29 (15.5)	158 (85.5)	0.155	0.615	0.315	1.204
Overweight - Obese (25 - ≥ 27)	29 (39.2)	45 (60.8)					17 (23.0)	57 (77.0)				
Vacccine type												
Pfizer	24 (16.1)	125 (83.9)	**<0.001**	2.894	1.615	5.185	15 (10.1)	134 (89.9)	**<0.001**	3.419	1.74	6.717
Sinovac	40 (35.7)	72 (64.3)					31 (27.7)	81 (72.3)				
Comorbidities												
No	62 (27)	168 (73)	**0.013**	5.351	1.24	23.093	45 (19.6)	185 (80.4)	**0.023**	7.297	0.969	54.945
Yes	2 (6.5)	29 (93.5)					1 (3.2)	30 (96.8)				
History of allergic reactions												
No	62 (27.1)	167 (72.9)	**0.008**	5.569	1.292	23.997	45 (19.7)	184 (80.3)	**0.023**	7.582	1.008	57.028
s	2 (6.3)	30 (93.8)					1 (3.1)	31 (96.9)				
Acute infection/hospitalization in the last 3 months												
No	62 (25)	186 (75)	0.741	1.833	0.395	8.499	45 (18.1)	203 (81.9)	0.476	2.66	0.337	20.984
s	2 (15.4)	11 (84.6)					1 (7.7)	12 (92.3)				
History of medication in the last 6 months												
No	58 (28)	149 (72)	**0.012**	3.114	1.264	7.669	43 (20.8)	164 (79.2)	**0.008**	4.457	1.327	14.975
Yes	6 (11.1)	48 (88.9)					3 (5.6)	51 (94.4)				
History of Covid-19												
No	54 (30)	126 (70)	**0.002**	3.043	1.459	6.344	38 (21.1)	142 (78.9)	**0.034**	2.442	1.083	5.506
Yes	10 (12.3)	71 (87.7)					8 (9.9)	73 (90.1)				

* p-value < 0.05

Table 5. Risk factors affecting AEFI at 24 – 48 hours and 48 hours – 7 days

Risk factor	AEFI 24 - 48 hours						AEFI 48 hours - 7 days					
	NO AEFI n (%)	AEFI n (%)	p-value	OR	95 % CI Lower	95 % CI Upper	NO AEFI n (%)	AEFI n (%)	p-value	OR	95 % CI Lower	95 % CI Upper
Gender												
Female	57 (38.5)	91 (61.5)	**<0.001**	0.371	0.224	0.614	109 (73.6)	39 (26.4)	0.05	0.53	0.284	0.987
Male	71 (62.8)	42 (37.2)					95 (84.1)	18 (15.9)				
Age												
≤ 25 tahun	56 (48.3)	60 (51.7)	**0.023**	-	-	-	101 (87.1)	15 (12.9)	**0.006**	-	-	-
26– 45 tahun	47 (43.1)	62 (56.9)					76 (69.7)	33 (30.3)				
> 45 tahun	25 (69.4)	11 (30.6)					27 (75.0)	9 (25.0)				
Body Mass index (BMI)												
Underweight - Normal (<18,5 - 24,9)	87 (46.5)	100 (53.5)	0.218	0.7	0.408	1.203	143 (76.5)	44 (23.5)	0.323	0.693	0.348	1.377
Overweight - Obese (25 - ≥ 27)	41 (55.4)	33 (44.6)					61 (82.4)	13 (17.6)				
Vacccine type												
Pfizer	67 (59.8)	45 (40.2)	**0.003**	2.148	1.304	3.539	107 (71.8)	42 (28.2)	**0.004**	2.538	1.325	4.864
Sinovac	61 (40.9)	88 (59.1)					97 (86.6)	15 (13.4)				
Comorbidities												
No	118 (51.3)	112 (48.7)	0.056	2.213	0.998	4.905	187 (81.3)	43 (18.7)	**0.002**	3.581	1.64	7.822
Yes	10 (32.3)	21 (67.7)					17 (54.8)	14 (45.2)				
History of allergic reactions												
No	118 (51.5)	111 (48.5)	**0.038**	2.339	1.06	5.159	184 (80.3)	45 (19.7)	**0.037**	2.453	1.117	5.386
Yes	10 (31.3)	22 (68.8)					20 (62.5)	12 (37.5)				
Acute infection/hospitalization in the last 3 months												
No	125 (50.4)	123 (49.6)	0.085	3.388	0.91	12.605	197 (79.4)	51 (20.6)	**0.041**	3.311	1.066	10.281
Yes	3 (23.1)	10 (76.9)					7 (53.8)	6 (46.2)				
History of medication in the last 6 months												
No	106 (51.2)	101 (48.8)	0.221	1.527	0.832	2.802	166 (80.2)	41 (19.8)	0.139	1.705	0.866	3.354
Yes	22 (40.7)	32 (59.3)					38 (70.4)	16 (29.6)				
History of Covid-19												
No	96 (53.3)	84 (46.7)	**0.045**	1.75	1.027	2.982	142 (78.9)	38 (21.1)	0.746	1.145	0.612	2.142
Yes	32 (39.5)	49 (60.5)					62 (76.5)	19 (23.5)				

* p-value < 0.05

Table 4 shows that the incidence of AEFI in the first 15 minutes is affected by gender, BMI, vaccine types, comorbidities, history of allergic reactions, taking medication during the past 6 months and prior COVID-19 infection with p-value <0.05. Meanwhile, monitoring at 15 minutes – 24 hours showed that the incidence of AEFI was affected by risk factors of gender, vaccine types, comorbidities, history of allergic reactions, taking medication during the past 6 months and prior COVID-19 infection with a p-value <0, 05. In the 24-48 hours monitoring, the incidence of AEFI was affected by gender, age, vaccine types, history of allergic reactions and previous COVID-19 infection with a p-value <0.05 as presented in Table 5. Monitoring of AEFIs at 48 hours – 7 days (**Tabel 5)** showed that the incidence of AEFI was affected by age, vaccine types, comorbidities, history of allergic reactions and hospitalization in the last 3 months with a p-value <0.050

Table 6. Vaccine combination variations on the incidence of AEFI

Vaccine combination variations	AEFI 15 minutes		AEFI 15 minutes - 24 hours		AEFI 24 hours - 48 hours		AEFI 48 hours - 7 hours	
	No	Yes	No	Yes	No	Yes	No	Yes
Pfizer	25%	75%	13%	88%	63%	38%	75%	25%
Pfizer + Pfizer	7%	93%	14%	86%	43%	57%	79%	21%
Sinovac + Sinovac	18%	82%	9%	91%	9%	91%	73%	27%
Sinovac + Sinovac + Sinovac	38%	62%	31%	69%	68%	32%	89%	11%
Sinovac + Sinovac + Pfizer	30%	70%	13%	87%	26%	74%	78%	22%
Pfizer + Pfizer + Pfizer	22%	78%	13%	87%	35%	65%	65%	35%
Astrazeneca + Astrazeneca + Pfizer	16%	84%	11%	89%	42%	58%	74%	26%
Moderna + Moderna + Pfizer	0%	100%	13%	88%	25%	75%	25%	75%
Sinovac + Sinovac + Sinovac + Sinovac	30%	70%	20%	80%	40%	60%	80%	20%
Sinovac + Sinovac + Pfizer + Pfizer	0%	100%	7%	93%	36%	64%	57%	43%
Sinovac + Sinovac + Moderna + Pfizer	18%	82%	6%	94%	50%	50%	79%	21%
Astrazeneca + Astrazeneca + Pfizer + Pfizer	0%	100%	0%	100%	67%	33%	100%	0%

Table 6 shows the relationship between the vaccine combination variations vaccines received by participants and the level of AEFIs. In the first 15 minutes, the combination with the highest percentage of AEFIs was the combination of Moderna + Moderna + Pfizer, Sinovac + Sinovac + Pfizer + Pfizer, Astrazeneca + Astrazeneca + Pfizer + Pfizer in which 100% of participants experienced at least 1 type of AEFIs in the 15 minutes monitoring. Meanwhile, at 15 minutes – 24 hours monitoring, the highest incidence of AEFI was in the combination of the Astrazeneca + Astrazeneca + Pfizer + Pfizer vaccine in which 100% of the participants experienced AEFIs, followed by the combination of Sinovac + Sinovac + Moderna + Pfizer with AEFI percentage increased from 82% to 94%, and the combination of Sinovac + Sinovac + Pfizer + Pfizer decreased from 100% to 93% participants with least 1 type of AEFIs. In 24-48 hours of monitoring, the highest AEFI incidence was in the combination of Sinovac + Sinovac vaccine in which 91% of participants experienced AEFIs. This combination of Sinovac + Sinovac vaccine was higher than other combinations, followed by the combination of Moderna + Moderna + Pfizer and Sinovac + Sinovac + Pfizer with 75% and 74% participants. In 48 hours – 7 days of monitoring, all vaccine combinations had decreased AEFIs. Of all combinations, only the Moderna + Moderna + Pfizer had an AEFI level higher than 50% in which 75% of participants experienced at least 1 type of AEFIs.

Figure 3 shows the level of therapy used in participants who experienced at least 1 type of AEFI. In the 15 minutes of monitoring, 25 participants used therapy to relieve AEFI. In the 15 minutes - 24 hours, there was an increase in 4 participants who used therapy. Meanwhile, at 24-48 hours monitoring and

48 hours - 7 days monitoring, the participants who used therapy decreased by 3 participants at each monitoring time. The detailed information is presented in Figure 4.

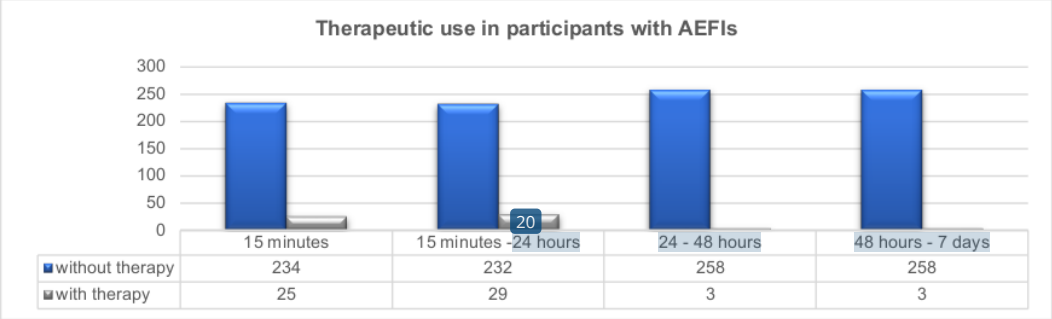

Figure 3. Therapeutic use in participants with AEFIs

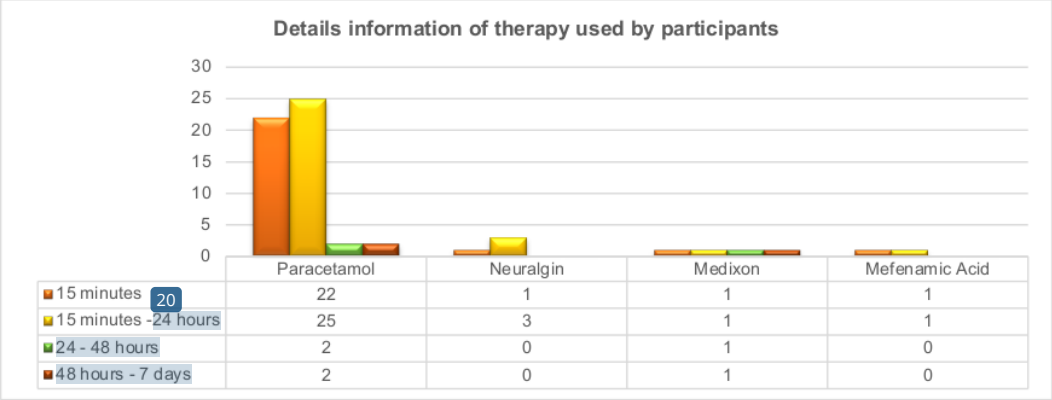

Figure 4. Details information of therapy used by participants

DISCUSSION

In this study, the highest level of AEFI was found in 15 minutes – 24 hours monitoring in which 215 participants (82%) experienced AEFI. This number increased from the previous monitoring with 197 (75%) participants experiencing AEFI. Then, it decreased within 24-48 hours of monitoring with 133 participants (50%). In the 48 hours-7 days of monitoring, the decline in AEFI was very large with 57 participants (21%) experiencing AEFI. This incident is in line with Mohsin et al who reported an average of only 1-3 days of adverse events and the study did not identify any examples of serious effects or hospitalizations (7). Moreover, Lai et al compared AEFI in CoronaVac and Comirnaty vaccines and revealed that the proportion of AEFI reached its peak on the first day after vaccination and gradually decreased (8).

In this study, 130 participants (39.5%) reported discomfort at the injection site, the highest prevalence of AEFI symptoms in the first 15 minutes after immunization. Then, 44 individuals (16.9%) and 70 people (26.8%) reported having myalgia. Phase 3 research from the United States revealed that following the first and second doses of the mRNA-1273 vaccination, systemic and injection site-related side events occurred more frequently in the mRNA-1273 vaccine group than in the placebo group. Additionally, soreness at the injection site is the most prevalent adverse event connected to the site of injection, which is similar with a previous research by Bostan et al. in which a local injection site response was the most often seen side effect (9). In this study,

the perceived severity of AEFI was dominated by mild severity, while moderate, severe, and potentially life-threatening occurred in a few cases only. This is consistent with the findings of Bostan et al.. They found that the modest, self-limiting responses to the Sinovac-CoronaVac and Pfizer-BioNTech COVID-19 vaccines are both systemic and local. No study participants had severe or life-threatening systemic or local side effects that would have stopped them from getting subsequent vaccines (9). The findings of this study are also in line with Aryal et al that the most common local reaction is pain at the injection site and rarely swelling, while the most common systemic reactions are lethargy, headache, and muscle pain. These results align with preliminary safety data analyses carried out in China, Bahrain, Egypt, Jordan, and the United Arab Emirates, which found that injection site pain, rash, swelling, induration, and itching were the most frequently reported local reactions. At the same time, headache, fever, myalgia, fatigue, arthralgia, cough, dyspnea, nausea, and diarrhea were the most frequently reported systemic reactions (10). Global side effects following COVID-19 vaccination varied by vaccine type, according to research by Anjorin et al. However, the most frequently reported symptoms were fatigue, headache, muscle and joint pain, allergic skin reactions, and chills. Symptoms that appeared several days after vaccination were more frequently light fever, fever, and pain or redness at the injection site (11).

Different demographic profiles have been investigated in this study and are associated with existing AEFIs. In this study, the age category was divided into 3 groups. The level of AEFI complaints was dominated by the age group of 17-35 years than 45 years and over. According to Le et al., participants between the ages of 18 and 55 were more likely than participants over 55 to suffer AEFI. Persons between 18 and 55 were 1.9 times more likely than participants over 55 to develop AEFIs (12). Moreover, this study is also in line with Parida et al that the majority of AEFIs were mild. The most frequent AEFI is now pain at the injection site, followed by fever and myalgia. Younger persons than elders reported AEFIs more frequently. Participants aged 18-29 years (younger) reached 34.6%, while in South India, it was 48.4%, and most AEFIs were reported among the younger age group (13). In comparison to the elder demographic, Ripabelli noted that adverse effects were recorded by 70% of young persons aged 55. In addition to having a stronger immune system than older people, older people have a reduced capacity to respond effectively to vaccination, as evidenced by a lower frequency of neutralizing antibodies following the Comirnaty vaccination (14).

In this study, the percentage of AEFI incidence was higher in female than in male participants. In the 15 minutes of monitoring, the AEFI in female participants was significantly higher (p=0.009) compared to that in males. It also occurs in the 15-24-hours monitoring (p=0.002), 24-48 hours monitoring, and 48 hours -7 days monitoring which significantly differs (p<0.001 & p=0.050). This is in line with Ripabelli et al that most female vaccine recipients report adverse events with a twofold increase in the likelihood of reporting reactions compared to men. It's not news that there may be gender-specific variations in vaccine side effects. Studies on different vaccines show that the cellular immune response in men is generally suppressed compared to women. The significant biological link between sex and immunological response and its implications on disease susceptibility, transmission, and vaccination outcome can be used to explain this discrepancy. The primary sex hormones appear to oppose the innate and adaptive immune systems; for example, rising estradiol and testosterone levels reduce the antibody responses elicited by vaccination. Additionally, behavioural attitudes toward reporting side effects and autoimmune illnesses were recorded more commonly in women than men. Finally, women are more likely to have side effects due to their larger body fat percentage, which influences the drug's volume of distribution and clearance rate (14). Chakraborty et al found that the number of women with AEFI was higher than that of men for both local and systemic reactions (15). Parida et al. also demonstrated that, with statistically significant

differences (p = 0.010), AEFI was 1.30 times more common in women than in males (13).

Body Mass Index (BMI) does not significantly affect the level of AEFI in this study, only in the 15 minutes of monitoring, the AEFI in Underweight - Normal (<18,5 - 24,9) participants was significantly higher (p=0.001) compared to that in Overweight - Obese (25 - ≥ 27), but the percentage of participants in the normal weight category (≥ 18.5− < 24.9) is higher than those with overweight and obese categories. This supports the finding by Hidayat et al. that those with BMIs under 25 kg/m2 (underweight/norm weight) are more likely to have AEFIs than those with BMIs above 25 kg/m2 (overweight) (16). Iguacel et al. discovered that people in the underweight and normal weight groups had a higher likelihood of experiencing COVID-19 adverse effects (fever, vomiting, diarrhea, and chills) than people who are overweight (including obese) (17).

In this study, the Pfizer vaccine type had a higher AEFI percentage than the Sinovac vaccine. In the first 15 minutes and 15 minutes – 24 hours, the AEFI percentage of Pfizer was significantly (p<0.001) higher than the Sinovac vaccine. In 24-48 hours of monitoring, Pfizer showed significantly higher AEFIs than Sinovac (p=0.003) and so does in 48 hours – 7 days of monitoring (p=0.004). This is in line with Bostan et al that the Pfizer-BioNTech vaccine in the first and second doses has a statistically higher rate of systemic and local side effects than the Sinovac-CoronaVac vaccine (9). Additionally, Chen et al. found that the incidence of AEFI was 23.0% (95% CI 20.0-26.0%, I2 = 55.71%), 48.0% (95% CI 28.0-84.0%, I2 = 99.99%), and 76.0% (95% CI 69.0-84.0%, I2 = 84.46%), respectively, from inactivated vaccines, mRNA-based vaccines, and viral vector vaccines [18]. Pfizer-BioNTech recipients demonstrated a 5.37 times (95% CI: 2.57-11.22) higher likelihood of side effects than Sinopharm recipients, according to Mohsin et al. (7). The related claim that CoronaVac has less reactogenicity than Comirnaty was supported by Lai et al. They also noted that those who received CoronaVac as opposed to Comirnaty had a considerably decreased probability of adverse responses (global, local, and systemic) two weeks after immunization (8).

Comorbidity had a big impact on AEFI level in this study. According to Parida et al., People with comorbidities are 2.08 times more likely than healthy individuals to suffer AEFI (p<0.001) (13). A history of COVID-19 infection and allergies greatly impacts AEFI levels. This is consistent with the research of Parida et al. that AEFI symptoms and a history of allergies are strongly correlated (13). Based on studies by Juliane et al., multivariate analysis in this study identified co-morbidities, including chronic lung disease, chronic kidney disease, and cardiovascular disease, that had a substantial association with a high risk of mortality. According to multiple research, COVID-19 patients with chronic comorbidities had an increased risk of COVID-19 events, including death Similar to the relationship with AEFI events, comorbidities increase the incidence of AEFI in patients (18). Significant predictors of AEFI, in addition to gender, were comorbidities, a history of using steroids, a history of allergies, a history of using drugs within the previous six months, and a history of being hospitalized within the previous three months (13). Additionally, the history of medication use over the previous six months greatly impacts AEFIs.

The level of AEFI is greatly impacted by Covid-19 history. This is consistent with Ossato et al., who found that previously immunized individuals with Covid-19 infection have a considerably greater antibody response following a single vaccination döşe (19). All 18 COVID-19 patients who had previously been diagnosed had mild reactions, and nine of them reported moderate reactions, which were connected to a history of SARS-CoV-2 infection, according to Ripabelli et al. This correlation may be explained by increased immunogenicity in those who have had an infection and have antibodies against healthy individuals, as well as heightened concern about side effects, even in those who only have minor symptoms (14).

Based on the different combinations, the Pfizer vaccine combination had a higher AEFI than the Sinovac vaccine. During the initial 15 minutes of monitoring and the next 24-48 hours of monitoring,

the second dosage of the Pfizer vaccine in this trial showed a larger AEFI than the first dose. This is consistent with the FDA analysis, which found that after the second dosage of the vaccine, local adverse effects were slightly more common than they were after the first dose (20). This is consistent with research by Ripabelli, which found that about 80% of people who participated in active surveillance disclosed at least one AEFI after the first or second dose. Additionally, it is consistent with earlier national studies for mRNA-based vaccinations, highlighting the lack of a significant difference between the two dosages. However, as seen elsewhere, some reactions commonly happen after the second döşe (14). The investigation by Maruyama et al. into the Pfizer vaccine related to AEFI revealed that the incidence of systemic reactions increased following the second dose, which is consistent with the results of the earlier study (21). In contrast, it cannot further examine which vaccination combination substantially impacts the occurrence of AEFI due to the less widespread distribution of the vaccine variety.

In this research, some participants who experienced AEFIs took medication independently. The most consumed drug by participants to relieve AEFI symptoms is Paracetamol. This is consistent with Ripabelli et al., who found that 141 participants (50.2%) reported adverse effects after receiving Pfizer's second dose (n = 281). These participants were treated for their symptoms mostly with paracetamol (n = 101, 71, 6%), followed by NSAIDs (n = 21, 14.9%) (14). According to Mohsin et al., more than 70% of responders who had Pfizer and Moderna vaccine adverse effects took medicine. On the other hand, only 9.87% of individuals took medication and had side effects after getting Sinopharm vaccinations (7).

LIMITATION

This study has some limitations. Following the vaccine, we only conducted a one-week follow-up. To evaluate late symptoms of immunization, long-term follow-up is required. Despite the fact that a high quality of data was acquired due to the target population's degree of knowledge and skills about health concerns and their ability to recognize post-vaccination symptoms, the use of self-reported data might potentially create misclassification bias. Additionally, we didn't conduct immunological testing to demonstrate the respondents' immune responses.

CONCLUSION

This study reveals that Pfizer and Sinovac Covid-19 vaccines are safe to administer as AEFIs are mostly mild and automatically disappear and decrease after 1 to 3 days. This study shows that Pfizer and Sinovac Covid-19 vaccines are safe to use because AEFIs are often mild and gradually disappear within 1 to 3 days. This research offers a thorough analysis of the variables influencing AEFIs in immunization participants at the University of Indonesia Hospital. The findings of this study demonstrated that female participants with comorbidities, prior allergy history, history of medication use during the past six months, and history of covid-19 have a higher risk of AEFI and a statistically significant effect ($p < 0.005$). Additionally, people getting mRNA immunization should have more close monitoring than those receiving inactivated vaccines because the Pfizer vaccine dramatically worsens side effects than the Sinovac vaccine.

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Conflict of Interest

The authors affirm that no material competing interests—financial, professional, or personal—might have impacted how the work described in this publication was performed or presented.

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