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Research

CHARACTERISTICS OF ADVERSE EVENTS OF CORONAVIRUS DISEASE 2019 VACCINES FIRST, SECOND AND BOOSTER

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ABSTRACT

Background Coronavirus Disease 2019 (COVID-19) was a new type of highly contagious disease that had a high risk of developing Acute Respiratory Distress Syndrome (ARDS). According to the World Health Organization (WHO), COVID-19 can be transmitted mainly through aerosol particles contiguous to another human in one meter. To cope with this pandemic, the government programmed vaccinations around the world, including in Indonesia.

Objective This study provided new information about the description of the characteristics of adverse events following vaccination participation in vaccination COVID-19 first, second and booster doses.

Method This descriptive research was conducted using a cross-sectional method. Subjects were populations with various characteristics at Bethesda Hospital, Bethesda Lempuyangwangi Hospital, and the Jawa Dayu Christian Church who had received the COVID-19 vaccine. The data were univariately presented as a distribution table using the IBM SPSS - Statistical Program for Social Science Statistics 23.

Result From 400 respondents, the most common types of vaccine received during the first dose were Sinovac, the second dose of Sinovac, and the Moderna for booster dose.

Conclusion The first dose was the same as the second dose. Most felt drowsiness 87.9%, swelling and pain at the injection site 77.9%, and weakness at 60.4%. In phase 1 clinical research of the mRNA vaccine from Moderna, side effects occurred in more than 50% of vaccination participants in the form of fatigue, chills, headache, myalgia, and pain at the injection site, especially at higher doses.

Keywords: adverse events, COVID-19, SARS-COV-2, vaccination, vaccines

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INTRODUCTION

Coronavirus Disease 2019 (COVID-19) is a new type of disease that has never been identified before, starting in Wuhan, China. Globally, this virus shows a very high transmission rate. As of October 18th, 2023, it was estimated that there were 202,608,306 infections and 4,293,591 deaths.[1] COVID-19 is a highly contagious virus and has a high risk of developing Acute Respiratory Distress Syndrome (ARDS). According to the World Health Organization (WHO), COVID-19 can be transmitted mainly through aerosol particles contiguous to another human in one meter.[1,2]

To cope with this pandemic , the government programmed vaccinations around the world, including in Indonesia. COVID-19 vaccination had undergone a long trip to ensure security and potency through various studies and tests. Vaccination programs were considered the key to ending the pandemic as they can reduce morbidity and mortality rates and form herd immunity against the COVID-19 virus.[2] World Health Organization recommended several types of vaccines that had been in evaluation and were safe for use, among them COVID-19

mRNAs- BNT162b2 (Pfizer), vaccine mRNA -1273 (Modern), ChAdOx1 nCoV vaccine -19 /AZD1222 (AstraZeneca), Ad26.COV2.S (Jessen), Sinopharm, and finally Sinovac vaccine.[1] In Indonesia, the six vaccines used were Sinovac, AstraZeneca, Sinopharm, Moderna, Pfizer, and Novavax. The vaccine provided was a vaccine whose safety and effectiveness have been confirmed. The platforms used were different, namely inactivated viruses, RNA-based, viral-vector, and protein sub-units.[2,3]

Adverse effects were associated with every vaccination. Some risks were associated with COVID-19 vaccinations. The most common symptoms were localized pain and swelling at the injection site, fever, headache, myalgia, and chills. Serious adverse events were rare such as myocarditis, glomerular diseases, and cutaneous eruptions, are seen with the mRNA vaccines.[4,5]

Each COVID -19 vaccine had a mechanism for administering it, from the number of doses and the administration interval to the different vaccine platforms. Many people did not believe in using vaccines as a solution to end a pandemic. The reasons behind the refusal and doubts about the vaccine were very diverse, such as not being sure of the vaccine's safety, doubting the vaccine's effectiveness, fear of vaccine side effects, not believing in the vaccine's usefulness, and religious beliefs.[6] Therefore, this study provided information about the description of the characteristics of adverse events following vaccination participation in vaccination COVID-19 first, second and booster doses.

METHOD

This research was a descriptive study. The research subjects were populations with various characteristics at Bethesda Hospital, Bethesda Lempuyangwangi Hospital, and the Jawa Dayu Christian Church who had received the COVID-19 vaccine. Data was collected by the Google Forms application by respondents from June to November 2022.

The contents of this questionnaire were just a survey about the adverse effects. There was no authority that the questioner must complete on the same day as they got vaccinated. However, they had to complete the questionnaire promptly and recall the adverse effects. Unfortunately, this could cause a recall bias because they already had the first dose in one year or more.

The form was about the demographic data such as age, gender, and education level, the type of vaccine received at doses of 1, 2 and boosters, complaints after each vaccine, duration such as pain at the injection site, fever, nausea, sleep disturbance, vomiting, rash, and history of comorbidities. The inclusion criteria for this study were patients who had received at least one dose of vaccine with any vaccine. The exclusion criterion was that the subject does not submit a Google form. The data were univariately presented as a distribution table using the IBM SPSS - Statistical Program for Social Science Statistics 23 application.

This study already had ethical approval from the Ethics Committee Faculty of Medicine Duta Wacana Christian University with registration numbers 1521/C.16/FK/2023.

RESULTS

Responses to this study were varied in age, occupation, number of vaccines, and comorbid history. Respondent characteristics were presented in Table 1. The demographic distribution of respondents could be grouped based on age, gender, occupation, education level, comorbidities, history of being infected with COVID-19, and the number of doses and type of vaccine received.

Based on Table 1, the ages were grouped into ages <20, 21-29, 30-39, 40-49, 50-59, and >60 years with the most age group being 20-29 years, namely 155 people. Based on gender, there were more female respondents than male respondents, namely as many as 245 people; as many as 138 people were health workers, while the rest were not health workers. The education level of most respondents was at the bachelor level, namely 230 people. Four hundred respondents received two vaccine doses, with 342 people receiving booster doses. The most common types of vaccine received during the first dose were Sinovac, the second dose of Sinovac and the Moderna for booster dose

Table 1. Respondent demographics

Characteristics	Total (n=400)	Percentage (%)
Gender		
Man	155	38.8
Woman	245	61.2
Age		
<20 years	6	1.5
20-29 years	155	38.8
30-39 years	70	17.5
40-49 years	67	16.7
50-59 years	59	14.7
>60 years	43	10.8
Level of education		
No school	2	0.5
Elementary School	2	0.5
Junior High School	9	2.25
Senior High School	78	19.5
Diploma	58	14.5
Bachelor	230	57.5
Postgraduate-master degree	19	4.75
Postgraduate-doctoral degree	2	0.5
Work		
Health workers	138	34.5
Not a health worker	262	65.5
History of suffering from COVID-19 before the vaccine		
Once	100	25.0
Never	300	75.0
Comorbid		
Food/medication allergies	72	18.0
Smoke	59	14.8
Regular drug consumption	91	22.7
History of chronic disease	132	33.0
Diabetes Mellitus	29	7.2
Hypertension	55	13.8
Heart disease	9	2.25
Chronic respiratory disease	5	1.2
Obesity	13	3.3
Arthritis	11	2.7
Osteoporosis	3	0.8
Thyroid disease	2	0.5
Cancer	4	1.0
Bleeding disorders	1	0.3
Received vaccine dose		
Dose 1	400	100.0
Dose 2	400	100.0
Boosters	342	85.5
Type of vaccine dose 1		
Sinovac	306	76.5
AstraZeneca	81	20.3
Moderna	7	1.7
Pfizer	6	1.5
Type of vaccine dose 2		
Sinovac	300	75.0

AstraZaneca	83	20.8
Moderna	15	3.7
Pfizer	6	1.5
Booster dose vaccine type		
Sinovac	17	4.9
AstraZaneca	113	33.1
Moderna	137	40.0
Pfizer	72	21.0
Sinoparm	3	1.0

In this study, the most significant side effects were felt in the booster vaccine, namely as many as 245 people or 71.6%, while side effects were felt at first dose 230 people or 57.5%, and second dose as many as 179 people or 44.8%. Clinical manifestations that were felt as follow-up events after the vaccine can be seen in Table 2. Table 2 showed the side effects that are felt in the first, second, and booster doses of the vaccine. Based on the number of patients who experienced side effects at each dose, the first dose most felt drowsiness at 87.9%, swelling and pain at the injection site at 77.9%, and weakness at 60.4%. At dose two, most of the complaints were the same as in the first dose, drowsiness at 79.3%, swelling and pain at the injection site at 64.8% and feeling of weakness and weakness at 49.7%. However, the side effects experienced at dose two were fewer than those experienced at the first dose, most receiving the Sinovac vaccine. In the booster vaccine, the most common side effects were felt, local swelling and pain at the injection site, which was 76.3%, fever was 63.3%, and drowsiness was 59.2%.

Table 2. Adverse event following vaccination of COVID-19

Complaint	Vaccine 1		Vaccine 2		Booster vaccine	
	n	%	n	%	n	%
Side effects	230	57.5	179	44.8	245	71.6
Weak and limp	139	60.4	89	49.7	128	52.2
drowsiness	202	44.3	142	79.3	145	59.2
Sleep disorders	36	15.6	22	12.3	36	14.7
Impaired vision	9	3.9	4	2.2	8	3.3
Swollen eyes	3	1.3	3	1.7	1	0.4
Fever	120	52.2	80	44.7	155	63.3
Headache	82	35.6	44	24.6	104	42.4
Local swelling and pain	179	77.8	116	64.8	187	76.3
Joint pain	88	38.2	50	27.9	91	37.1
Swelling of hands and feet	18	7.8	14	7.8	20	8.2
Muscle ache	117	50.9	58	32.4	123	50.2
Nauseous	20	8.7	13	7.3	34	13.9
Vomit	3	1.3	1	0.5	9	3.7
Diarrhea	9	3.9	4	2.2	4	1.6
Abdominal pain	13	5.6	13	7,3	10	4.1
Red skin rash	12	5.2	5	2.8	10	4.1

The onset and duration of post-vaccine adverse events 1, 2, and boosters could be seen in Table 3. The onset was divided into 4, 5-8, 9-12,13-16, 17-20, and 21-24 hours and the duration were divided into < 1, 1-3, 4-7, > seven days. In this study, most respondents experienced symptoms (onset) at 13-16 hours after vaccine 1, around 48.7%, with symptoms lasting for (duration) 1-3 days 60.4%. The second vaccine's, the most common symptom onset was 4 hours, at 35.2%, with 1-3 days duration at 58.1%. At the booster dose, symptoms are felt 5-8 hours after injection at 35.1% and the duration is 1-3 days at 64.1%.

Table 3. Onset and duration of symptoms Post-immunization adverse events

Time	Vaccine 1		Vaccine 2		Booster vaccine	
	n	%	n	%	n	%
Onset						
4 hours	75	32.6	63	35.2	60	24.5
5-8 hours	86	37.4	60	33.5	86	35.1
9-12 hours	37	16.1	34	19.0	61	24.9
13-16 hours	112	48.7	8	4.5	16	6.5
17-20 hours	4	1.7	6	3.4	12	4.9
21-24 hours	16	6.9	8	4.5	10	4.1
Duration						
<1 day	79	34.3	70	39.1	69	28.2
1-3 days	139	60.4	104	58.1	157	64.1
4-7 days	8	3.5	5	2.8	18	7.3
>7 days	4	1.7	0	0.0	1	0.4

DISCUSSION

The vaccine needed approximately 10-14 years to be released. This pandemic forced many COVID-19 vaccines to develop in high-speed clinical development. It doesn't mean that the vaccine skipped the safety elements. Nevertheless, the vaccines might not be free from adverse effects that remain undetectable in clinical trials, so evaluation, monitoring, and surveillance of adverse effects following immunization (AEFI) are vital. AEFI's related to many aspect such as Vaccine product-related, Vaccine quality-related, Immunization error-related where the reaction is due to inappropriate handling, prescription, or administration of the vaccine, Immunization stress-related where the reaction is due to inappropriate handling, prescription, or administration of the vaccine, Immunization stress-related where the adverse event is because of the fear of being injected, and coincidental where an adverse event has no direct relationship with the vaccine or any of the above, but it occurs soon after vaccination and hence may be attributed to it nonetheless.[7]

This research was conducted on 400 respondents who received various types of vaccines and several doses. Most of them had reached the booster dose. These respondents reported AEFI both at doses 1, 2 and, booster. Most vaccines received at doses 1 and 2 are the Sinovac vaccine. Symptoms experienced during AEFI vary and can be felt by more than one symptom in 1 patient, including drowsiness, swelling and local pain at the injection area, weakness and weakness, fever, visual disturbances, sleep disturbances, rashes on the skin, diarrhea, vomiting, nausea, muscle aches, joint pains, headaches, stomach pains, and swollen eyes.[8]

A study in China found that the incidence of overall adverse reactions post-vaccination Sinovac was 15.6% for the first injection, and 14.6% for the second injection. The most common adverse reactions were localized pain or itching at the injection site, with an incidence of 9.6% after the first dose and 10.7% after the second dose. Fatigue, muscle pain, headache and dizziness were the most commonly reported systemic adverse events.[9]

Among all the symptoms reported after injection of Moderna are sore arm or localized pain, generalized weakness or fatigue, headache, myalgia or muscle pain, chills, fever, nausea, joint pain, sweating, localized swelling at the injection site, dizziness, itching, rash, decreased appetite, muscle stiffness or spasm, decreased sleep quality, and brain fogging are the most

commonly reported symptoms, followed by flushing, heat or cold intolerance, palpitations, diarrhea, nasal stuffiness, sore throat as other predominant symptoms.[4,10]
The most common events after the first dose of Pfizer were injection-site pain (71–83%), fatigue (34–47%), headache (25–42%), and AstraZeneca most frequently reported adverse effects in mild to moderate symptoms were bony aches (69.3%), fever (51.6%), localized arm pain (11.3%), and GIT disorder in the form of diarrhea (3.2%).[11–13]
Individuals with evidence of past SARS-CoV-2 infection were also more likely to have adverse effects than those without evidence of past infection with both vaccines. Although it remains to be tested, it is possible that this increased reactogenicity relates to increased immunogenicity. It has been shown that vaccines have increased immunogenicity in individuals with past infection, and these people have higher antibody titers than those without previous infection. In children, the proportion of children with a reported AEFI trended upward with age. The prevalence of fever was lowest in children aged 5–11 years, 2.9% after dose 1 and 4.9% after dose 2, and was higher in older adolescents.[10–12,14–17]

At doses 1 and 2, most of them received the Sinovac vaccine. The most common symptoms felt were drowsiness, local swelling and pain, and a feeling of weakness and weakness. However, the respondents experienced an effect on dose one more than dose two, namely 230 and 179. The most common side effects were obtained after the Sinovac vaccine based on *the Food and Health Bureau* in Hong Kong with ≥10% pain at the injection site, headaches, and fatigue, and systemic symptoms may include nausea, fever/chills, joint pain, and rarely a skin rash. The results of this study were almost the same as in vaccine 1, showing symptoms of local pain (77.8%), weakness and weakness (60.4%), drowsiness (44.3%), headache around (35.6%), and the least vomiting (1.3%) and swollen eyes (1.3%). Another study by Abanoub et al. in Turkey showed common symptoms found in injection site pain (41.5%), fatigue (23.6%), headaches (18.7%), muscle pain (11.2%), pain joints (5.9%), and nausea (5.3%).[9,11,12,18,19]

Phase 1 and phase 2 clinical studies of the Sinovac vaccine showed a decrease in vaccine side effects up to day 28, mild to moderate side effects related to dose, and no serious side effects related to vaccination. Clinical research on the BNT162b1 vaccine from Pfizer showed mild to moderate local and systemic side effects at lower vaccine doses and severe side effects in the form of grade 3 fever and sleep disturbances at higher vaccine doses, no disturbances in laboratory values greater than grade 1. In phase 1 clinical research of the mRNA vaccine from Moderna, side effects occurred in more than 50% of vaccination participants in the form of fatigue, chills, headache, myalgia, and pain at the injection site, especially at higher doses. Vaccination side effects are more common in the second dose of vaccine, especially at higher doses, and severe side effects occur. Another study by Mennni et al. in the United Kingdom showed adverse events were significantly more common in women than men, in people aged 55 years or younger than those older than 55 years, and after the second vaccine than after the first dose, and among those who previously had COVID-19. Post-vaccination symptoms (both systemic and local) often last 1-2 days after injection. Similar to this study, which found symptoms lasting 1-3 days but did not analyzed further regarding the relationship between gender, age, history of COVID-19 infection and the appearance of AEFI symptoms.[11,12,18,20]
In the booster vaccine, most of them received AstraZeneca and Moderna. In vaccines with Moderna, local reactions to vaccinations were mild; however, moderate to severe systemic side effects, such as fatigue, myalgia, arthralgia, and headache, were noted in approximately 50%. These side effects were transient, starting about 15 hours after vaccination and disappearing on day 2, with no sequelae. Late injection site reactions/onset more than eight days after injection were rare. In the study by Mitiku et al. It was found that 217 (74.1%) vaccine recipients had side effects after the first dose, while 162 (55.3%) had side effects after the second dose with the AstraZeneca vaccine. Common side effects are pain at the injection site, fever, headache, diarrhea, and

joint pain. Most people tolerate these side effect and don't take any medication.[12,19,21]
A study from Rahmat et al. found that the highest prevalence of symptoms < 24 hours after booster vaccination with Moderna was pain at the injection site (85.2%). Followed by fever (38%), shoulder pain (36.1%), and headache (4.2%). While Kadali et al. stated that the common complaints after administration of the mRNA vaccine to health workers were shoulder pain (94.21%), fatigue/weakness (65.74%), headache (59.26%), muscle pain (54.17%), shivering (52.78%), and fever (35.65%). The headaches occur because the mRNA vaccine produces spike proteins that can cross the blood-brain barrier, causing intracranial inflammation.[10,22,23]
The limitations of this study were not knowing the effect and relationship between age, comorbidities, gender, and history of COVID-19 infection with post-immunization adverse events that appear in each type of vaccine.

CONCLUSION

Symptoms experienced during AEFI were varied and could be felt more than one symptom in one patient. The first and second doses that mostly received Sinovac have drowsiness, swelling, and local pain in the injection area weakness; however, the adverse effects experienced at dose two were fewer than those experienced at the first dose. In the booster vaccine, which mostly receives Moderna, the most common side effects were local swelling and pain at the injection site, fever, and drowsiness. The onset was felt 13-16 hours after the first vaccine, 9-10 hours faster in the second dose, and 5-8 hours after injection, and the duration is 1-3 days. This event also varied without looking at the patient's characteristics before, whether with comorbidities or not. This research requires further research to determine the effect and association of age, comorbidities, gender, and history of COVID-19 infection with post-immunization adverse events that appear in each type of vaccine.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare. All co-authors have seen and agree with the contents of the manuscript and there is no financial interest to report. We certify that the submission is original work and is not under review at any other publication.

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