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Factors associated with adverse events following immunization of COVID-19 vaccination

Hoirun Nisa[1]*, Putri Kurniawati[1], Rifka Qatrunnida[1], Dadang Mulyono[1]
[1]Department of Public Health, Faculty of Health Sciences, Syarif Hidayatullah State Islamic University (UIN) Jakarta, 15412, Indonesia

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***Corresponding author:**
hoirun.nisa@uinjkt.ac.id

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ABSTRACT

Background: Evidence indicates that COVID-19 vaccines are effective at helping to prevent serious infection and risks of hospitalization due to COVID-19. Seven types of vaccines have been used in Indonesia. Adverse events following immunization (AEFI) may occur after the COVID-19 vaccination.
Objective: This study aimed to determine factors associated with AEFI of the COVID-19 vaccination.
Methods: This cross-sectional study included 160 respondents who had been vaccinated against COVID-19. Data were collected by using google form distributed through social media from October 12-20, 2021. Multivariate analysis was performed by using a logistic regression test.
Result: The incidence of AEFI of the COVID-19 vaccination was 69.4%, and the AEFI symptoms were lower in the second dose of COVID-19 vaccine than the first dose. Poor dietary habits were associated with higher risks of the AEFI (OR=2.34 CI 95% 1.14-4.80). The second vaccine dose was related to decreased risks of the AEFI (OR=0.35 CI 95% 0.13-0.92).
Conclusion: The incidence of AEFI of the COVID-19 vaccination was quite high, and the common AEFI was systemic symptoms. Dietary habits and vaccine doses were associated with the AEFI of the COVID-19 vaccination. These findings suggest that poor dietary habits may increase the risks of the AEFI, and decreased risks of the AEFI may be experienced in the second dose of COVID-19 vaccine. Further studies are warranted to explore the effects of both doses of COVID-19 vaccines on the AEFI.

Latar Belakang: *Banyak bukti menunjukkan vaksin COVID-19 mencegah infeksi serius dan risiko untuk rawat inap. Tujuh jenis vaksin telah digunakan di Indonesia. Efek samping atau kejadian ikutan pasca imunisasi (KIPI) dapat muncul setelah vaksinasi.*
Tujuan: *Penelitian ini bertujuan untuk mengetahui faktor-faktor yang berhubungan dengan KIPI COVID-19.*
Metode: *Penelitian ini menggunakan desain cross-sectional dengan melibatkan 160 responden yang telah divaksinasi COVID-19. Data dikumpulkan menggunakan google form yang didistribusikan melalui media sosial pada 12 – 20 Oktober 2021. Analisis multivariat dilakukan dengan menggunakan uji regresi logistik.*
Hasil: *Insiden KIPI COVID-19 adalah 69,4%, dan KIPI pada dosis kedua lebih rendah daripada dosis pertama. Kebiasaan makan yang buruk berhubungan dengan resiko KIPI yang lebih tinggi (OR=2,34 CI 95% 1,14-4,80). Dosis vaksin kedua berhubungan dengan penurunan resiko KIPI (OR=0,35 CI 95% 0,13-0,92).*
Kesimpulan: *Kejadian KIPI COVID-19 relatif tinggi dengan gejala yang paling umum dikeluhkan adalah gejala sistemik. Kebiasaan diet dan dosis vaksin berhubungan dengan KIPI COVID-19. Penelitian menunjukkan bahwa kebiasaan makan yang buruk dapat meningkatkan risiko KIPI, dan penurunan risiko KIPI dapat dialami pada dosis kedua vaksin COVID-19. Penelitian lebih lanjut diperlukan untuk mengeksplorasi efek samping pada kedua dosis vaksin COVID-19.*

INTRODUCTION

Vaccination against COVID-19 is a significant milestone in controlling the spread of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the causal agent of the corona virus disease 2019 (COVID-19) pandemic. Vaccination

can reduce viral transmission and disease severity, especially in groups who are at risks for complications.[1] Some vaccination programs have been initiated globally to prevent the spread of COVID-19. Indonesia, like other countries, has issued regulations regarding the COVID-19 vaccination program.[2] Decree of the Minister of Health of the Republic of Indonesia, HK.01.07/MENKES/12758/2020 regarding vaccine types for the COVID-19 vaccination, mentions that there are 7 types of vaccines used in Indonesia: Sinovac® by Sinovac Biotech, Moderna® by Moderna and the National Institutes of Allergy and Infectious Diseases (NIAID), AstraZeneca® by AstraZeneca in collaboration with the University of Oxford, Sinopharm® by the Beijing Institute of Biological Products in collaboration with the Chinese state-owned company Sinopharm, Novavax® by Novavax, and Pfizer® by the German biotechnology company BioNTech in collaboration with the US pharmaceutical company Pfizer.[3] According to the 2021 Food and Drug Administration's report, the effectiveness of Pfizer® (BNT162b2) and Moderna® as COVID-19 vaccines in preventing COVID-19 infection was 95% and 94%, respectively.[4] Furthermore, Sinovac® vaccine had an effectiveness of 83% based on a survey in Indonesia[5], and AstraZeneca® vaccine had an effectiveness of 90%.[6] In fact, adverse events following immunization (AEFI) may occur after the COVID-19 vaccination. For example, there was 0.2% (4,393) of 1,893,360 individuals experiencing the AEFI after the administration of the first dose of the Pfizer® vaccine in the United States.[7]

AEFI of COVID-19 vaccination is generally divided into local, systemic, and other reactions including allergies. Local reactions consist of pain, redness, swelling at the injection site, and cellulitis; meanwhile, systemic reactions consist of fever, muscle aches throughout the body (myalgia), joint pain (arthralgia), weakness, and headache; and other reactions may include urticaria, edema, anaphylactic reactions, and syncope (fainting).[8] Results from a systematic review on AEFI of COVID-19 vaccine trials reported that most of the reactions were mild to moderate, and a few reactions were with severe intensity; however, all reactions resolved within 3-4 days.[9]

Previous studies demonstrated that AEFI occurred higher in young individuals, in females, and in individuals with certain diseases.[10] Lifestyle behaviours may have direct associations with vaccine responses, thereby impacting the incidence of AEFI. A recent systematic review of epidemiological studies revealed that active smoking negatively affected humoral responses to COVID-19 vaccines, although it was uncertain whether the effect was related to duration of smoking or number of cigarettes smoked per day.[11] Sufficient sleep was also shown to improve immune responses after vaccination, whereas individuals who slept shorter in the days before and after vaccination had lower immune responses after COVID-19 vaccination.[12] Furthermore, physical activities can promote strong immune systems and better vaccine responses. A previous review highlighted that physically active older individuals often had greater immunity after vaccination than their less-active peers.[13] An effective immune response is formed in an individual with a good nutritional status. Vitamins and minerals are needed to create a good immunity. Nutrient deficiencies are known to have negative effects on the immune system and lead to poor vaccine responses.[14] A recent review based on studies on previous vaccines indicated that low-quality food or poor diet might affect the responses after the vaccination.[14]

Recently, COVID-19 vaccines have been launched in many countries. Although their protective efficacies are frequently discussed, information regarding the AEFI is important to educate the public, dispel misinformation, and reduce vaccine hesitancy. In addition, knowledge about factors associated with the AEFI is important for an appropriate prevention or treatment of the AEFI. Thus, this study aimed to determine factors associated with the AEFI of the COVID-19 vaccination.

METHODS

Research design and participants

This study applied a cross-sectional study design. Its respondents were individuals aged >12 years who had received the COVID-19 vaccination before October 20, 2021. The sample size was calculated by using AEFI of COVID-19 proportion of 10.5%, power level of 80%, and confidence level of 95%.[15] Based on this calculation, the required minimum sample was 145 respondents. Its inclusion criteria were individuals aged >12

years who had received at least one dose of the COVID-19 vaccination. The respondents were selected by a purposive sampling method. A total of 163 respondents participated in this survey; however, 3 respondents were excluded because of their incomplete data on studied variables. Thus, 160 respondents were included in the final analysis. This study was approved by the Research Ethics Committee of Faculty of Health Sciences, UIN Syarif Hidayatullah Jakarta with a letter No. Un.01/F.10/kp.01.1/KE.SP/10.08.02/202. All the respondents provided informed consent before participating in this study.

Data collection and measurements

Data of this study were collected by using google form from October 12 to 20, 2021. The survey was disseminated through social media such as WhatsApp group, Facebook, and Instagram. The structured questionnaire included information about respondent's characteristics (age, gender, residence, sleep duration, smoking behaviour, physical activities, dietary habits, nutritional status, and history of chronic diseases), types of COVID-19 vaccines received, vaccine doses, and AEFI of COVID-19 vaccination.

The AEFI symptoms were categorized into local, systemic, and other reactions. Local reactions consisted of pain, redness, swelling at the injection site, and cellulitis. Systemic reactions consisted of fever, muscle aches throughout the body (myalgia), joint pain (arthralgia), weakness, and headache. Other reactions were allergies such as urticaria, edema, anaphylactic reactions, and syncope (fainting).[16] The vaccine doses were categorized into the first dose if the COVID-19 vaccine received was only the first dose and the second dose if the COVID-19 vaccine received was up to the second dose.

The respondents' residence was categorized into district and city according to the official landmark of administration. After that, their nutritional status was defined by body mass index (BMI). The BMI was estimated by dividing body weight (kg) and height (m^2) for individuals aged ≥18 years; the BMI was grouped into undernutrition if the BMI was <18.5 kg/m^2, normal nutrition if the BMI was 18.5-25.0 kg/m^2, and overnutrition if the BMI was >25.0 kg/m^2.[17] BMI according to age (BMI/age) was used for individuals aged <18 years; the BMI was categorized into undernutrition if the BMI/age was <-2SD), normal nutrition if the BMI/age was -2SD - 1SD), and overnutrition if the BMI/age was >1SD.[18] For final analysis, the BMI was then categorized into normal if the BMI was in normal range, and it was abnormal nutrition if the BMI was undernutrition or overnutrition. History of chronic diseases was a self-reported of any chronic diseases.

Sleep duration was divided into <7 hours/day, 7-8 hours/day, and >8 hours/day.[19] Smoking behaviour was defined by smoking behaviour within 7 days before vaccinated against COVID-19. Physical activities were assessed by using an International Physical Activity Questionnaire (IPAQ). The physical activities were categorized into low, moderate, and high based on the total score of Metabolic Equivalent (MET)-minutes/week. The physical activities were low if the total score was <600 MET minutes/week, moderate if the total score was 600-1499 MET minutes/week, and high if the total score was ≥1500 MET minutes/week.[20] Furthermore, Food Frequency Questionnaire (FFQ) was used to acquire information about consumption frequency of 67 foods, including staple foods, animal-based side dishes, plant-based side dishes, vegetables, and fruits. The respondents' food consumption was scored 0 if never eating, 10 if eating 1-2 times/week, 15 if eating 3-6 times/week, 25 if eating 1 time/day, and 50 if eating >3 times/day. Thus, their dietary habits were categorized into good and poor based on the mean value (201.5) of the total score of the food frequency.[21]

Statistical analysis

Descriptive data were presented by using mean or frequency. Comparisons between AEFI (yes/no) were conducted by the χ^2 test for categorical data and by an independent t-test for continuous data (age). Variables with p-value <0.250 on the bivariate analysis were entered to multivariate logistic regression model to identify their independent effects. Variables of residence, history of chronic diseases, types of vaccine, and smoking behaviour were not further analysed because of the homogeneity of their data. Odds Ratio (OR) values and 95% Confidence Interval (CI) were used to evaluate the risks of AEFI at a significance level of <0.05. The statistical analyses were calculated by using SPSS software (SPSS, Inc., version 25.0).

RESULTS

Most of the respondents reported the AEFI of COVID-19 vaccination (69.4%), received the Sinovac® vaccine (79.9%), and had been vaccinated with the second dose of COVID-19 vaccination (77.5%). Majority of the respondents were female (82.5%), and the average of their age was 21 years with age range of 14.0 to 55.0 years old. More than half of the respondents resided in the city (60.6%), had poor dietary habits (67.5%), had a normal nutritional status (57.5%), and slept <7 hours/day (61.9%). Almost all the respondents were non-smokers (99.4%) and without history of chronic diseases (96.9%). A few of the respondents had moderate (40.6%) and high (30.0%) physical activities (Table 1).

The AEFI symptoms are presented in Figure 1. Some respondents reported more than one of AEFI symptoms. Of the 111 respondents with the AEFI of COVID-19 vaccination, there were 106 (95.5%) respondents experiencing systemic symptoms, 24 (21.6%) respondents experiencing local symptoms, and 4 (5.4%) experiencing other symptoms (Figure 1A). The frequency of AEFI symptoms according to COVID-19 vaccine doses is demonstrated in Figure 1B. The AEFI symptoms were reported lower in the second dose than the first dose. The systemic effects were more commonly found among the respondents (80.6%) who received the first dose of COVID-19 vaccine.

Table 1. The respondents' characteristics

Characteristics		n=160	%
AEFI	No	49	30.6
	Yes	111	69.4
Age (years)		21.02 (14.0-55.0)*	
Gender	Male	28	17.5
	Female	132	82.5
Residence	District	63	39.4
	City	97	60.6
Types of Vaccine	Sinopharm®	1	0.6
	Sinovac®	127	79.9
	AstraZeneca®	22	13.8
	Moderna®	6	3.8
	Pfizer®	4	2.5
Vaccine Doses	First	36	22.5
	Second	124	77.5
Dietary Habits	Good	52	32.5
	Poor	108	67.5
Smoking Behaviour	Yes	1	0.6
	No	159	99.4
History of chronic diseases	Yes	5	3.1
	No	155	96.9
Nutritional Status	Normal	92	57.5
	Abnormal	68	42.5
Sleep Duration (hour/day)	<7	99	61.9
	7-8	56	35.0
	>8	5	3.1
Physical Activities	Low	47	29.4
	Moderate	65	40.6
	High	48	30.0

*Data are presented as mean (range) values

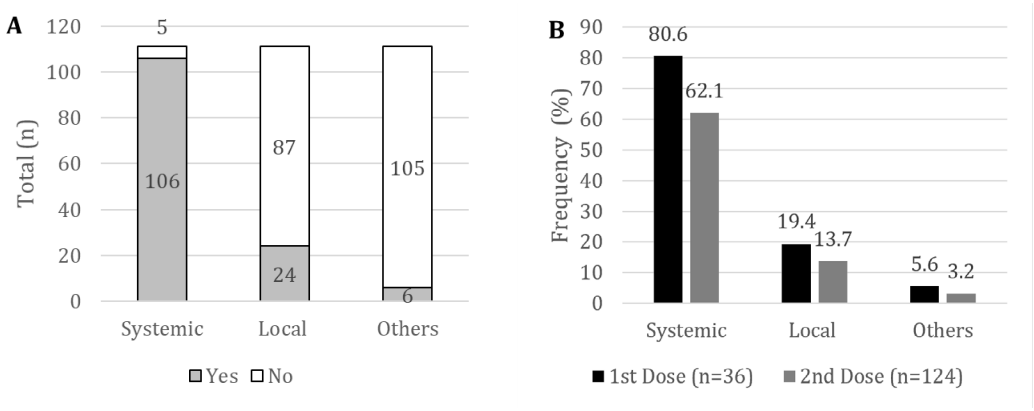

Figure 1. AEFI symptoms by categories (A) and vaccine doses (B)

Table 2 illustrates the respondents' characteristics according to the AEFI of COVID-19 vaccination. The respondents with the AEFI were more likely female than male. Meanwhile, mean (±SD) age of the respondents reporting AEFI and without AEFI were 20.8 (±2.6) years and 21.5 (±7.3) years, respectively. The AEFI was higher in the respondents who resided in city (58.6%), higher in the respondents with normal nutritional status (58.6%), higher in the respondents with poor dietary habits (73.0%), higher in the respondents with <7 hours/day of sleeping (61.3%), higher in the respondents with moderate physical activities (44.1%), and higher in the respondents with the second dose of COVID-19 vaccine (73.0%). The associations of dietary habits and the vaccine doses with the AEFI were statistically significant. There were no significant associations of age, gender, nutritional status, physical activities, and sleep duration with the AEFI (Table 2).

Table 2. Bivariate analysis of the AEFI of COVID-19 vaccines with covariates

Variable		AEFI of COVID-19		p-value*
		No, n=49	Yes, n=111	
		n (%)	n (%)	
Age (years)**		21.5±7.3	20.8±2.6	0.554
Gender	Male	8 (16.3)	20 (18.0)	0.795
	Female	41 (83.7)	91 (82.0)	
Residence	District	17 (34.7)	46 (42.4)	0.421
	City	32 (65.3)	65 (58.6)	
Nutritional status	Normal	27 (55.1)	65 (58.6)	0.815
	Abnormal	22 (44.9)	46 (41.4)	
Physical activities	Low	17 (34.7)	30 (27.0)	
	Moderate	16 (32.7)	49 (44.1)	0.377
	High	16 (32.7)	32 (28.8)	
Dietary Habits	Good	22 (44.9)	30 (27.0)	0.026
	Poor	27 (55.1)	81 (73.0)	
Sleep Duration (hours/day)	<7	31 (63.3)	68 (61.3)	
	7-8	18 (36.7)	28 (34.2)	0.318
	>8	0 (0.0)	5 (4.5)	
Vaccine Doses	First	6 (12.2)	30 (27.0)	
	Second	43 (87.8)	81 (73.0)	0.039

*p-values were calculated by independent t-test for continuous variable and by the Pearson's chi-square test for categorical variables.
** Data are presented as mean ± standard deviation.

Table 3. Multivariate analysis of the associations of dietary habits and vaccine doses with the AEFI of COVID-19 vaccination

Variable	AOR*	95% CI	p-value
Dietary Habits			
Good	1.00	Reference	-
Poor	2.34	1.14-4.80	0.020
Vaccine Doses			
First	1.00	Reference	-
Second	0.35	0.13-0.92	0.034

*Adjusted Odds Ratio

Table 3 demonstrates the multivariate analysis results on the factors associated with the AEFI of COVID-19 vaccination. The dietary habits and the vaccine doses were significantly associated with the AEFI. The respondents with poor dietary habits had a 2.34-fold higher risk of the AEFI than the respondents with good dietary habits. The respondents who had been vaccinated with the second dose of COVID-19 vaccine showed a moderate decrease in ORs of the AEFI.

DISCUSSION

The results of this study indicated that most (69.4%) of the respondents reported AEFI of COVID-19 vaccination; the majority (95.5%) were systematic symptoms. The AEFI symptoms were lower in the second dose than the first dose, and the systemic symptoms were more commonly reported. The AEFI was higher in this study than that in a previous study (10,5%).[15] In addition, this finding was similar to results of a previous study reporting higher systematic symptoms than other symptoms.[22]

This study found that the AEFI was significantly associated with dietary habits and vaccine doses. In this study, respondents who had poor dietary habits were 2.34 times more likely to experience the AEFI than those who had good dietary habits. Poor dietary habits may affect immune dysfunction,[23,24] making an individual susceptible to diseases. Consumption of a balanced diet and rich nutrition such as green vegetables, turmeric, garlic, and fruits containing vitamin C, may be beneficial to strengthen immunity and prevent the incidence of the AEFI.[24] Although there is no evidence that hydration will lessen the side effects of the AEFI, hydration may support the body for different systems to work properly thereby preventing effects of dehydration.[25] Dehydration can cause the body to tire quickly, to weaken the immune system, and to easily get infected.[26] The Centre for Disease Control and Prevention recommends those who get the vaccines to stay well hydrated after vaccination if they experience a fever as a side effect.[27]

This study revealed that the respondents with the second dose of COVID-19 vaccine were less likely to experience the AEFI than those in the first dose. Similarly, results from a previous study reported that AEFI such as redness or swelling at the injection site was much lower after the second dose than that in the first dose.[4] In addition, after administration of the first and second doses of vaccines, the most common side effects were fatigue, headache, myalgia, and pain at the injection site.[28] The systemic side effects were more common in respondents who received the first dose than those in the second dose. Lower reactogenicity after the second dose of vaccine and an increase in the immune response to the virus might increase geometric mean antibody titter by 2.6 to 2.9. The local effect of Pfizer® vaccine occurred lower in the second dose (68.5%) than that in the first dose (71.9%).[29]

This study did not demonstrate an association between nutritional status and the AEFI. Results from a previous study found that the lower BMI was associated with the AEFI.[30] The risks of the AEFI, such as fever, vomiting, diarrhoea and chills, were higher in individuals who were undernutrition and normal nutrition than those who were overnutrition.[31] Although there was no significant effect of the BMI on the AEFI, individuals with abnormal nutritional status experienced more vaccine reactions than those with normal nutritional status.[32]

This finding is similar with a finding of a previous study showing no association between

age and the AEFI.[33] This is likely because the respondents were young adults, with the average age of 21 years. This study did not identify an association between physical activities and the AEFI. This finding is similar with results from a previous study reporting that physical activities before COVID-19 vaccination were not associated with the AEFI and that physical activities of healthy individuals before COVID-19 vaccination did not impact the physiological endpoints in blood and during exhalation.[34]

Furthermore, in this study sleep duration was not associated with the AEFI, although a previous study reported effects of sleep duration on the AEFI.[35] Sleep is related to immunity. During sleep, especially in the late stages, certain information about the target antigen from immune cells is transferred and encrypted to produce better immunology against the antigen.[36] Thus, lack of sleep duration can cause the AEFI.[37]

The strength of this study is the data collection process conducted during the COVID-19 vaccination program; therefore, it minimizes information bias regarding the AEFI of COVID-19 vaccination experienced by the respondents. In addition, the results of this study can be one of evidence in the decision-making steps to determine the appropriate intervention for AEFI of COVID-19 vaccination. This study, however, has some limitations. First, the results of this study could not be generalized because the sampling technique used was non-probability sampling. Second, the data of this study were collected online; only people with internet access could participate. Finally, this study did not inquire whether the respondents had the AEFI at both doses of the vaccines even though the AEFI could occur at both doses, which might be specific to different types of vaccines.

CONCLUSION

The incidence of the AEFI of COVID-19 vaccination was relatively high, and the common AEFI was systemic symptoms. Dietary habits and vaccine doses were associated with the AEFI. These findings suggested that poor dietary habits might increase the risks of the AEFI, and decreased risks of the AEFI might be experienced in the second dose of COVID-19 vaccine. Further studies are warranted to explore the effects of both doses of COVID-19 vaccines on the AEFI.

CONFLICT OF INTEREST

There was no conflict of interest in this study.

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