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Factors associated with side effects of COVID-19 vaccine in Indonesia

Purpose: As coronavirus disease 2019 (COVID-19) continues to spread rapidly causing approximately 186 million confirmed cases around the world, the urgency to reach herd immunity through vaccination is increasing. However, vaccine safety is a top priority to limit the occurrence of adverse events. Henceforth, this study aims to recognize and perceive COVID-19 vaccine safety in Indonesia during the pandemic.

Materials and Methods: This is a cross-sectional study and was conducted in Indonesia during the COVID-19 pandemic using an online survey of demographic information and a qualitative questionnaire. Responses were recorded and the association between demographic characteristics from survey questions was tested using chi-square with a risk estimate and 95% confidence interval.

Results: A total of 311 participants from 33 out of 34 provinces in Indonesia participated in this study. Recorded responses showed multiple side effects of the COVID-19 vaccine both short- and long-term experienced by the participants. Significant associations were found between demographic factors and COVID-19 vaccine side effects such as female gender with short-term puncture site (odds ratio [OR], 0.463; 95% confidence interval [CI], 0.263–0.816) and short-term other reactions (OR, 0.463; 95% CI, 0.263–0.816), domicile outside Java island with long-term puncture site (OR, 4.219; 95% CI, 1.401–12.701) and immune reactions (OR, 3.375; 95% CI, 1.356–8.398), also between married marital status and long-term vagal reaction (OR, 4.655; 95% CI, 1.321–16.409).

Conclusion: Gender, domicile and marital status factors were associated with COVID-19 vaccine side effects in Indonesian people.

Keywords: COVID-19, Vaccination, Vaccines, Side effect

Introduction

Coronavirus disease 2019 (COVID-19) is an infectious and highly contagious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), targeting the respiratory system of the human body [1]. Globally, as of 13 July 2021, there have been approximately 186 million confirmed cases of people infected by COVID-19 with more than 4 million deaths since the first identified case of COVID-19 in Wuhan, China in December 2019 [2,3]. Among Southeast Asia countries, Indonesia has been reported the highest confirmed cases of COVID-19 and the second highest in mortality rate following the Philippines [4]. As of now, the COVID-19 pandemic continues to af-

fect Indonesia with more than 20,000 daily confirmed cases to this day [5]. As chaos rises due to deaths caused by COVID-19 and no certain definitive treatment yet to be discovered, the importance of herd immunity through an effective and secured vaccination is crucial to break the virus transmission and improve social and economic burdens caused by COVID-19 [6].

As of now, about 3.4 billion doses of the COVID-19 vaccine have been administered globally with approximately 29 million doses being administered each day [7]. With the benefits of the vaccine, which is to help protect from the virus, vaccines may also have some side effects which is a normal sign for the human body of building immune protection [8]. The World Health Organization (WHO) reported COVID-19 vaccines can cause mild, short-term side effects, for instance, low-grade fever, pain on the body, redness at the injection site, and other rare side effects [9]. Alongside the various amount of vaccine side effects, vaccine safety is a top priority to ensure the efficacy and effectiveness of the vaccine [10]. Although COVID-19 vaccine side effects are quite common, COVID-19 vaccines are continually monitored for as long as they are in use to detect adverse events and apply approaches to ensure their occurrence limitation [9].

Several studies reported adverse events caused by the COVID-19 vaccine to establish the safety of the vaccine, yet there are very few studies regarding the investigation of COVID-19 side effects in Indonesia [11]. Henceforth, this study was conducted to recognize and perceive the COVID-19 vaccine safety in Indonesia during the pandemic.

Materials and Methods

Study sampling and procedure

This cross-sectional study was conducted from early February to May in Indonesia during the COVID-19 pandemic. The survey made with Google Forms was distributed through online platforms and social media. Particularly all Indonesian citizens across the country who already get vaccinated with COVID-19 vaccines were eligible to participate in this study.

Screening instruments

Sociodemographic information such as age, gender (male or female), domicile (within or outside Java Island), marital status (single or married), education levels, occupation (healthcare workers or non-healthcare workers), and previous vaccination status (unvaccinated, unsure, partial, or completed)

were asked in this survey. Questions about the COVID-19 vaccine including dosage (first or second) and type of COVID-19 vaccine that were administered (*Sinovac* or other than *Sinovac*) were also in this survey. COVID-19 vaccine side effects (short-term and long-term) questions were put together with multiple choice answers in this study. Other questions made up of COVID-19 screening, comorbidity, disease history, treatment of symptoms appearance, and health protocol after getting vaccinated were also compiled in this survey.

Data analysis

Recorded data were analyzed using IBM SPSS ver. 25.0 (IBM Corp., Armonk, NY, USA). The sociodemographic data were presented descriptively and variables were tested using chi-square with a risk estimate and 95% confidence interval.

Ethical consideration

The Ethics Committee of the Faculty of Medicine, Pelita Harapan University has approved the protocol for this study. The approval letter was issued with the number 085/K-LJK/ETIK/II/2021. This study was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. All of the informed consent were obtained from the participants of this study.

Results

A total of 311 participants from 33 out of 34 provinces in Indonesia were included in this study. Table 1 shows the demographic characteristics of all the participants who have filled the questionnaire. The median age was 25 years (participant age between 19–71 years) and 69.7% were ≤ 24 years old. The majority of the participants were female (67.5%), marital status was single (89.4%), educational level as undergraduates (94.9%), previously fully vaccinated (84%), work as health workers (89.4%), and live within Java Island (92.0%).

Participants' responses showed mostly have been administered with *Sinovac* (98.7%) as their COVID-19 vaccine with the majority having received the first dose (60.8%). Responses were shown with particularly few who had disease history (4.2%) and comorbidity (2.9%); moreover, participants were mostly got vaccinated in hospitals (84.2%). Healthcare workers who participated were taking rapid and swab COVID-19 antigen test (54.7%) as their usual screening test, and merely a few had a positive result (1.3%).

Table 1. Demographic characteristics of participants

Characteristic	No. of participants (%)
Age (yr)	
≤24	211 (67.8)
>24	100 (32.2)
Domicile	
Within Java Island	286 (92.0)
Outside Java Island	25 (8.0)
Gender	
Male	101 (32.5)
Female	210 (67.5)
Marital status	
Single	278 (89.4)
Married	33 (10.6)
Occupation	
Healthcare	278 (89.4)
Non-healthcare	33 (10.6)
Vaccination status	
Unvaccinated, partially vaccinated, unsure	49 (15.8)
Fully vaccinated	262 (84.2)
Education level	
Less than university, college	16 (5.1)
University, college graduates	295 (94.9)

Survey results showed participants experienced the short-term side effects of the COVID-19 vaccine (42.4%) more than the long-term (29.3%). The short-term side effects of the vaccine were furthermore categorized, 15.4% showed puncture site reaction (pain, redness, and swelling), 17.0% gave immune reaction (mild fever and pain on the muscles and joints), about 3.2% showed vagal reaction (confusion, shortness of breath, and syncope) and as much as 29.9% felt otherwise (drowsiness, headache, polyphagia, numbness, and nausea). Additionally, the long-term side effects were also further categorized and the results showed 6.8% experienced puncture site reaction, 13.8% felt immune reaction, 3.9% showed a vagal reaction, and about 18.0% for the other reactions. There were no data results regarding the allergic reaction to the vaccine as there were no participants who experienced both short-term and long-term side effects. Data results regarding the side effects of the COVID-19 vaccine are shown in Fig. 1.

Bivariate analysis of the short-term COVID-19 vaccine side effects was done with the demographic characteristics of the participants (Table 2). There were significant relationships between gender factor with both puncture site reaction (odds ratio [OR], 0.366; 95% confidence interval [CI], 0.164–0.814)

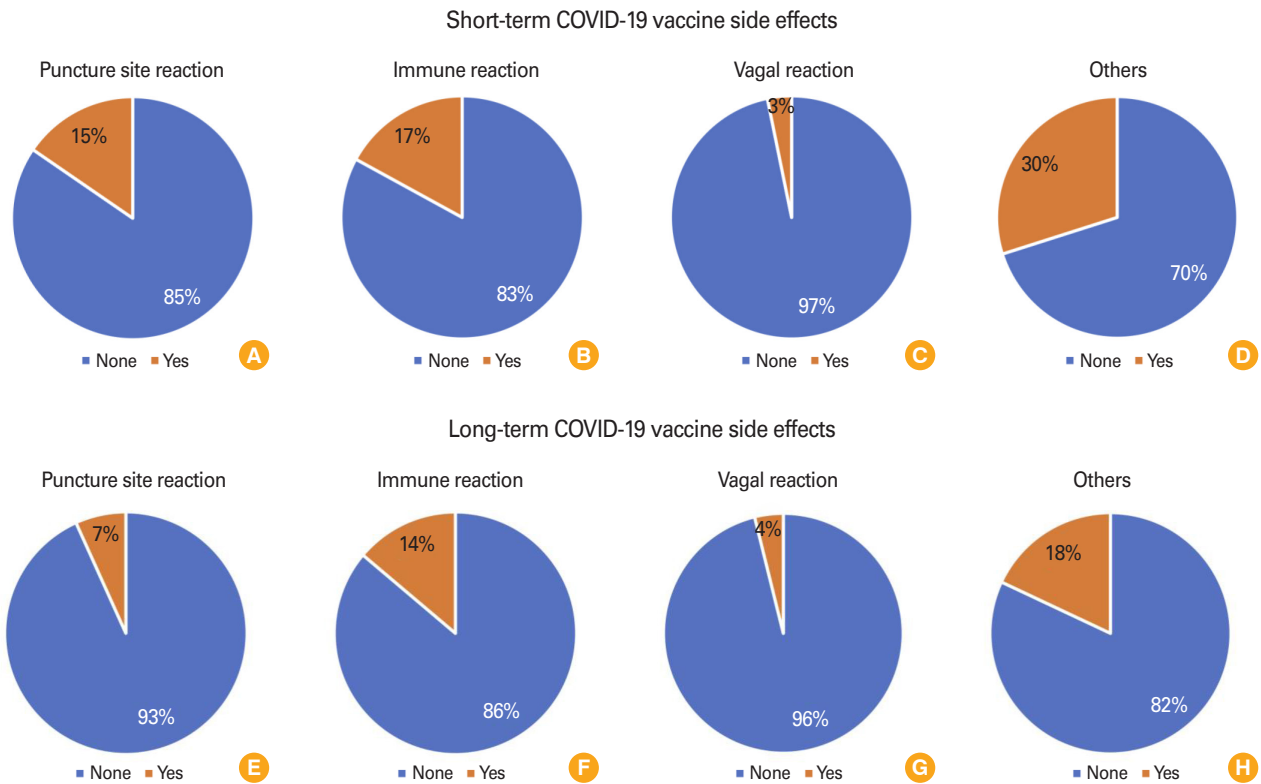


Fig. 1. Sample answers of experiencing coronavirus disease 2019 (COVID-19) side effects: short-term (A–D) and long-term (E–H) COVID-19 vaccine side effects.

Table 2. Bivariate analysis between sociodemographic characteristics of participants and short-term coronavirus disease 2019 vaccine side effects

Variable	Puncture site reaction		OR (95% CI)	p-value	Immune reaction		OR (95% CI)	p-value	Vagal reaction		OR (95% CI)	p-value	Other reaction		OR (95% CI)	p-value
	None	Yes			None	Yes			None	Yes			None	Yes		
Age group (yr)																
≤24	183 (86.7)	28 (13.3)	1.634 (0.869–3.071)	0.172	170 (80.6)	41 (19.4)	0.568 (0.283–1.131)	0.143	202 (95.7)	9 (4.3)	0.227 (0.028–1.815)	0.238	148 (70.1)	63 (29.9)	1.007 (0.599–1.693)	1.000
>24	80 (80.0)	20 (20.0)			88 (88.0)	12 (12.0)			99 (99.0)	1 (1.0)			70 (70.0)	30 (30.0)		
Domicile																
Within Java Island	244 (85.3)	42 (14.7)	1.835 (0.692–4.861)	0.343	240 (83.9)	46 (16.1)	2.029 (0.802–5.134)	0.214	277 (96.9)	9 (3.1)	1.282 (0.156–10.553)	1.000	204 (71.3)	82 (28.7)	1.955 (0.852–4.484)	0.168
Outside Java Island	19 (76.0)	6 (24.0)			18 (72.0)	7 (28.0)			24 (96.0)	1 (4.0)			14 (56.0)	11 (44.0)		
Gender																
Male	93 (92.1)	8 (7.9)	0.366 (0.164–0.814)	0.018	90 (89.1)	11 (10.9)	0.489 (0.240–0.996)	0.066	99 (96.0)	2 (2.0)	0.510 (0.106–2.447)	0.608	81 (80.2)	20 (19.8)	0.463 (0.263–0.816)	0.010
Female	170 (81.0)	40 (19.0)			168 (80.0)	42 (20.0)			202 (96.2)	8 (3.8)			137 (65.2)	73 (34.8)		
Marital status																
Single	233 (83.8)	45 (16.2)	0.518 (0.151–1.770)	0.417	228 (82.0)	50 (18.0)	0.456 (0.134–1.553)	0.298	269 (96.8)	9 (3.2)	0.934 (0.115–7.614)	1.000	192 (69.1)	86 (30.9)	0.601 (0.251–1.438)	0.341
Married	30 (90.9)	3 (9.1)			30 (90.9)	3 (9.1)			32 (97.0)	1 (3.0)			26 (78.8)	7 (21.2)		
Occupation																
Healthcare	238 (85.6)	40 (14.4)	1.904 (0.803–4.516)	0.220	228 (82.0)	50 (18.0)	0.456 (0.134–1.553)	0.298	268 (96.4)	10 (3.6)	0.964 (0.942–0.986)	0.558	192 (69.1)	86 (30.9)	0.601 (0.251–1.438)	0.341
Non-healthcare	25 (75.8)	8 (24.2)			30 (90.9)	3 (9.1)			33 (100.0)	0			26 (78.8)	7 (21.2)		
Vaccination status																
Unvaccinated, partially vaccinated, unsure	42 (85.7)	7 (14.3)	0.898 (0.378–2.137)	0.978	44 (89.8)	5 (10.2)	0.507 (0.191–1.345)	0.238	47 (95.9)	2 (4.1)	1.351 (0.278–6.562)	1.000	39 (79.6)	10 (20.4)	0.553 (0.263–1.161)	0.158
Fully vaccinated	221 (84.4)	41 (15.6)			214 (81.7)	48 (18.3)			254 (96.9)	8 (3.1)			179 (68.3)	83 (31.7)		
Education level																
Less than university, college	12 (75.0)	4 (25.0)	1.902 (0.587–6.164)	0.464	15 (93.8)	1 (6.3)	0.312 (0.040–2.411)	0.402	16 (100.0)	0	0.966 (0.946–0.987)	0.983	13 (81.3)	3 (18.8)	0.526 (0.146–1.890)	0.471
University, college graduates	251 (85.1)	44 (14.9)			243 (82.4)	52 (17.6)			285 (96.6)	10 (3.4)			205 (69.5)	90 (30.5)		

Values are presented as mean±standard deviation or number (%) or OR (95% CI), unless otherwise stated. Statistically significant results are marked in bold. OR, odds ratio; CI, confidence interval.

Table 3. Bivariate analysis between sociodemographic characteristics of participants and long-term coronavirus disease 2019 vaccine side effects

Variable	Puncture site reaction		OR (95% CI)	p-value	Immune reaction		OR (95% CI)	p-value	Vaginal reaction		OR (95% CI)	p-value	Other reaction		OR (95% CI)	p-value
	None	Yes			None	Yes			None	Yes			None	Yes		
Age group (yr)																
≤24	198 (93.8)	13 (6.2)	1.324 (0.531–3.306)	0.718	179 (84.8)	32 (15.2)	0.691 (0.333–1.436)	0.413	206 (97.6)	5 (2.4)	3.101 (0.959–10.026)	0.096	171 (81.0)	40 (19.0)	0.814 (0.431–1.538)	0.634
>24	92 (92.0)	8 (8.0)			89 (89.0)	11 (11.0)			93 (93.0)	7 (7.0)			84 (84.0)	16 (16.0)		
Domicile																
Within Java Island	270 (94.4)	16 (5.6)	4.219 (1.401–12.701)	0.019	251 (87.8)	35 (12.2)	3.375 (1.356–8.398)	0.015	277 (96.9)	9 (3.1)	4.197 (1.059–16.631)	0.096	235 (82.2)	51 (17.8)	1.152 (0.413–3.213)	1.000
Outside Java Island	20 (80.0)	5 (20.0)			17 (68.0)	8 (32.0)			22 (88.0)	3 (12.0)			20 (80.0)	5 (20.0)		
Gender																
Male	92 (91.1)	9 (8.9)	1.614 (0.657–3.966)	0.418	89 (88.1)	12 (11.9)	0.779 (0.382–1.589)	0.607	100 (99.0)	1 (1.0)	0.181 (0.023–1.421)	0.132	83 (82.2)	18 (17.8)	0.982 (0.529–1.823)	1.000
Female	198 (94.3)	12 (5.7)			179 (85.2)	31 (14.8)			199 (94.8)	11 (5.2)			172 (81.9)	38 (18.1)		
Marital status																
Single	261 (93.9)	17 (6.1)	2.118 (0.667–6.720)	0.351	240 (86.3)	38 (13.7)	1.128 (0.410–3.100)	1.000	270 (97.1)	8 (2.9)	4.655 (1.321–16.409)	0.033	229 (82.4)	49 (17.6)	1.258 (0.517–3.063)	0.789
Married	29 (87.9)	4 (12.1)			28 (84.8)	5 (15.2)			29 (87.9)	4 (12.1)			26 (78.8)	7 (21.2)		
Occupation																
Healthcare	260 (93.5)	18 (6.5)	1.444 (0.402–5.192)	0.842	237 (85.3)	41 (14.7)	0.373 (0.086–1.618)	0.271	266 (95.7)	12 (4.3)	0.957 (0.933–0.981)	0.460	229 (82.4)	49 (17.6)	1.258 (0.517–3.063)	0.789
Non-healthcare	30 (90.9)	3 (9.1)			31 (93.9)	2 (6.1)			33 (100.0)	0			26 (78.8)	7 (21.2)		
Vaccination status																
Unvaccinated, partially vaccinated, unsure	48 (98.0)	1 (2.0)	0.252 (0.033–1.923)	0.262	45 (91.8)	4 (8.2)	0.508 (0.173–1.493)	0.305	48 (98.0)	1 (2.0)	0.475 (0.060–3.768)	0.752	42 (85.7)	7 (14.3)	0.724 (0.307–1.709)	0.592
Fully vaccinated	242 (92.4)	20 (7.6)			223 (85.1)	39 (14.9)			251 (95.8)	11 (4.2)			213 (81.3)	49 (18.7)		
Education level																
Less than university, college	15 (93.8)	1 (6.3)	0.917 (0.115–7.297)	1.000	15 (93.8)	1 (6.3)	0.402 (0.052–3.121)	0.596	16 (100.0)	0	0.959 (0.937–0.982)	0.876	15 (93.8)	1 (6.3)	0.291 (0.038–2.249)	0.356
University, college graduates	275 (93.2)	20 (6.8)			253 (85.8)	42 (14.2)			283 (95.9)	12 (4.1)			240 (81.4)	55 (18.6)		

Values are presented as mean±standard deviation or number (%) or OR (95% CI), unless otherwise stated. Statistically significant results are marked in bold. OR, odds ratio; CI, confidence interval.

and other reaction (OR, 0.463; 95% CI, 0.263–0.816) of COVID-19 side effects. Furthermore, bivariate analysis of the long-term COVID-19 vaccine side effects was also done (Table 3). Association was found between domicile factor with puncture site reaction (OR, 4.219; 95% CI, 1.401–12.701) and immune reaction (OR, 3.375; 95% CI, 1.356–8.398) of COVID-19 vaccine adverse effects. Additionally, there was also an association between marital status and vagal reaction (OR, 4.655; 95% CI, 1.321–16.409) side effects. There were no results regarding allergic reactions from COVID-19 vaccine side effects as there were no samples of it in the population.

Further results of the survey showed that approximately 18.0% of participants who experienced side effects have taken action (went to healthcare workers or bought drugs) while the rest have done nothing to take care of the side effects. Most participants (94.5%) continued to do a complete health protocol (keep distance, wear a mask, and hand hygiene) after getting vaccinated. Additionally, there were no participants diagnosed COVID-19 positive after being vaccinated.

Discussion

The core of this study is to determine factors associated with COVID-19 vaccine side effects among Indonesian people.

The result data obtained from this study indicated several factors regarding COVID-19 vaccine side effects such as gender, domicile, and marital status. The female gender was more likely to experience short-term side effects of the COVID-19 vaccine, such as puncture site reaction (19.0%) and other reactions (34.8%). Results also showed that Indonesian who lived outside Java Island were more likely to get puncture site reaction (20.0%) and immune reaction (32.0%) as their COVID-19 vaccine side effects after getting vaccinated. Additionally, married marital status was also associated with vagal reaction (12.1%) side effects.

In addition to factors affecting COVID-19 vaccine side effects, data results showed most participants experienced other reaction side effects (drowsiness, headache, polyphagia, numbness, and nausea) more commonly than others. In contrast, the vagal reaction was the least type of side effect of the COVID-19 vaccine that has been experienced by the participants in both the short- and long-term. Furthermore, the results showed short-term COVID-19 vaccine side effects were more common than long-term side effects.

Based on the data samples, many healthcare workers were still taking rapid and swab COVID-19 antigen test as their

screening test after getting vaccinated; however, WHO still recommends polymerase chain reaction (PCR) as the gold standard test for SARS-CoV-2. This finding may explain the complementation and acceleration of overall testing capacity, although it is preferred to use PCR rather than rapid tests [12].

Adella Halim et al. [13] found that young people of Indonesia are aware of the COVID-19 pandemic yet have inadequate knowledge about preventive measures. However, the opposite was found in this study where it is shown that overall the participants continued to follow a complete health protocol despite after getting vaccinated (94.5%) where it is also consistently what the federal government requires [14]. These contrast findings may be due to the majority of healthcare workers as an occupation in the population sample. This finding was also supported by a study conducted by Rizki et al. [15] where it is stated that most Indonesian healthcare workers have a good understanding of preventing COVID-19 transmission.

The strength of this study is that it was conducted in early February 2021 when the initial phase of COVID-19 vaccination was administered on priority groups such as healthcare workers and government officers. Throughout the time, there were minimal studies discussing factors associated with COVID-19 vaccine side effects. However, we acknowledge several limitations in this study, such as potential selection bias caused by online surveys resulting in failure to round up extensive data on the various social level and populations in the rural area. Furthermore, the population in this study tends to be greater for the female sex, ≤ 24 years old age group, education of university or college graduates, domicile in Java Island, single marital status, healthcare workers as occupation, and complete previous vaccination status. Small population samples were also a lack of this study where it is not sufficient to represent the Indonesian population adequately. However, there are minimum studies discussing COVID-19 vaccine side effects especially in Indonesia; therefore, this study may benefit in monitoring and understanding further COVID-19 vaccine safety.

In conclusion, there were demographic factors associated with COVID-19 vaccine side effects such as gender, domicile, and marital status in the population of Indonesian people. Further research is needed to continue monitoring COVID-19 vaccine side effects to ensure its safety.

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