Original Article

Exploring Adverse Events Following COVID-19 Vaccination and Community Anxiety in Banda Aceh, Indonesia

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ABSTRACT

OBJECTIVE: This study aimed to explore the relationship between Adverse events following immunization (AEFI) reaction and community anxiety levels related to the COVID-19 vaccine.
METHODOLOGY: A retrospective correlational study was conducted. The study sample comprised 344 individuals who received two doses of the COVID-19 vaccine and resided in the Syiah Kuala sub-district of Banda Aceh. Data collection was facilitated through the administration of "Post-Immunization Adverse Events" and "Beck Anxiety Inventory (BAI)" questionnaires were utilized. Spearman's rank test analyzed the data.
RESULTS: The findings of this study demonstrated a significant relationship between AEFI the COVID-19 vaccine dose 1 (p = 0.025), dose 2 (p = 0.000), AEFI local reactions dose 1 (p = 0.004), and dose 2 (p = 0.016), AEFI systemic reaction dose 1 (p = 0.000), and dose 2 (p = 0.002), with the community' anxiety levels.
CONCLUSION: AEFI refers to medical events related to the vaccination effect consisting of local and systemic reactions. AEFI reactions may potentially elevate the community's anxiety. The study noted an increase in severe symptoms in AEFI local reactions and a decrease in AEFI systemic reaction during the second dose of the COVID-19 vaccine, possibly attributed to variations in antibody titers of the community. It is recommended that patients pay attention to AEFI reactions and seek immediate support from the hospital if excessive local and systemic reactions appear, for healthcare workers could provide educational programs to the community regarding the risks of AEFI local and systemic reactions and efforts to look for treatment.

KEYWORDS: Adverse event, immunization, vaccine, COVID-19, anxiety, community

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)[1]. As of December 2022, COVID-19 had affected 657 million individuals across 233 countries, resulting in 6.6 million fatalities worldwide[2]. In the context of Indonesia, the country reported 6.7 million COVID-19 cases and 160,000 confirmed deaths[3]. Various preventive measures have been implemented to mitigate the further spread of COVID-19, with vaccination programs emerging as a pivotal tool to combat the pandemic[4]. Globally, by December 2022, approximately 5 billion people have their first or second doses of the COVID-19 vaccine[5]. Within Indonesia, 203 million individuals had received their first dose, 1.174 million had completed their second dose, and 67 million had received a third dose[6].

Vaccination may cause side effects, commonly called adverse events following immunization (AEFI) or *kejadian ikutan pasca immunisasi* (KIPI). AEFI is a medical problem that occurs after immunization[7]. Symptoms of AEFI consisted of local and systemic reactions. Local reactions are shown with redness, itching, swelling, and pain in the arm area at the injection site. Systemic reactions include headaches, muscle and joint pain, fever, chills, nausea, vomiting, fatigue, diarrhea, chest pain, sore throat, blocked nose, hot flashes, shortness of breath, stomach aches, and cough[8].

A similar study related to the AEFI reactions of the Sinovac vaccine showed the most common reactions were pain at the injection site (42.5%), followed by fatigue (11.4%), muscle or joint pain (4.9%), and redness at the injection site (4.9%)[9]. According to the Centers for Disease Control and Prevention (CDC), the most common AEFI reactions at the second dose of the Moderna vaccine were pain (90.1%), fatigue (67.6%), headache (62.8%), chills (48.3%), pain joints (45.2%), nausea and vomiting (21.3%)[10]. Meanwhile, AEFI reactions reported from the Pfizer vaccine were headache, dizziness, pain at the injection site, lethargy, fever, flu, lymphadenopathy, shortness of breath, and nausea[11].

The emergence of AEFI symptoms after COVID-19

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vaccination may impact community anxiety levels[12]. In this context, anxiety is characterized as a state of fear accompanied by uncertainty, helplessness, isolation, and insecurity[13]. A prior study observed that 23% of respondents reported experiencing mild anxiety, 74% reported moderate anxiety, and 3% reported severe anxiety due to COVID-19 vaccination. The anxiety symptoms were manifested through increased pulse rate, hyperventilation, muscle weakness, and other related manifestations[14]. Additionally, other studies showed individuals who experience AEFI are more prone to heightened anxiety levels [15].

According to population data, Banda Aceh is home to 257,635 residents, and the Syiah Kuala sub-district, covering an area of 1,424 km, has a population of 33,545. Data in Banda Aceh reported that 244,947 people have received their first dose of the COVID-19 vaccine, 184,723 individuals have completed their second dose, and 61,091 people have received a third dose. Syiah Kuala sub-district, consisting of ten villages, vaccination data as of July 2022 revealed that 12,431 residents had been vaccinated with the first, second, and third doses[16].

METHODOLOGY

Study Design

The study conducted was a quantitative study with a retrospective design to explore the relationship between the AEFI reaction and community anxiety levels related to the COVID-19 vaccine.

Population and Sample

The entire community resides in the Syiah Kuala sub-district, constituting 9,897 households, with 2,474 individuals undergoing COVID-19 vaccination. To identify the sample size using the Slovin formula (margin of error 5%) and resulting in 344 selected respondents were conducted in ten villages (an average of 34 respondents per village). The sampling approach employed a purposive sampling technique, guided by the following inclusion criteria: 1) individuals residing in Syiah Kuala sub-district, Banda Aceh, 2) aged 18 years or older, 3) recipients of both doses (1 and 2) of the COVID-19 vaccination, and 4) a willingness to participate in the study as indicated by their informed consent.

Instruments

The instruments used in this study were:

Respondents' Demographic data consisted of age, gender, religion, highest level of education, occupation, marital status, type and dose of COVID-19 vaccine received, and address.

The AEFI questionnaire measures local and systemic reactions using the Guttman scale with the option "yes" (1) or "no" (0). This instrument was validity tested, and the results showed that 28 of the 32 questions were valid with a correlation value of $r \geq 0.388$, and the reliability test with *Cronbach's alpha* score was 0.902.

The Beck Anxiety Inventory (BAI) questionnaire was used to measure the respondents' anxiety levels. This questionnaire consists of 21 statements using a 4-point Likert scale with the option "not at all" (0), "doesn't really bother me" (1), "sometimes bothers me" (2), and "very much bothers me" (3). Each question item was given a value of 0-3 according to the answer chosen. The interpretation of this instrument: if the total score of 0-21 was categorized as mild anxiety, the total score of 22-35 was moderate anxiety, and ≥36 score was severe anxiety[17]. The reliability test for BAI showed Cronbach's alpha score was 0.944.

Data collection

Data was collected by researchers and assisted by five research assistants who were given explanations regarding research procedures to find similarities in perceptions between researchers. The data collection technique was carried out through direct screening of respondents who met the inclusion criteria and sought treatment at two Community Health Centers in the Syiah Kuala sub-district area, Banda Aceh and also carried out door-to-door to meet the number of respondents required. Data collection was also supported by the availability of data and addresses of respondents from the two Community Health Centers in the sub-district (data on a community who had been vaccinated was available at both Community Health Centers).

Data Analysis

The assessment of data normality through the Kolmogorov-Smirnov normality test revealed a non-normal distribution ($p<0.05$). Consequently, the Spearman's rank correlation coefficient test was employed for further analysis.

Ethical permission: This study has been approved by the Faculty of Nursing Ethics Committee, Universitas Syiah Kuala (approval number: 111101041022).

RESULTS

The results of this study, involving 344 respondents who received both doses (1-2) of the COVID-19 vaccination, are presented in this section.

Table I shows that the average age of the respondents was 29.92 years, with a predominant representation of women (53.2%). Furthermore, 48.5% of the respondents had intermediate-level education, while 39% of the participants identified as students. Most respondents were unmarried (53.2%), and a significant proportion had received the Sinovac vaccine (78.5%).

Table II shows that the predominant local symptoms reactions to the AEFI COVID-19 vaccine at doses 1 and 2 were pain at the injection site (56.4% and 66%, respectively). Conversely, respondents' least reported local reaction symptoms at doses 1 and 2 were swelling at the injection site (12.8% and 31.4%, respectively).

Table I:
Demographic Data of Respondents (n=344)

Demographic Data	Frequency	Percentage
Age (M ± SD)	29.92 ± 11.839	
Gender		
Male	161	46.8
Female	183	53.2
Educational History		
Basic	24	7.0
Intermediate	167	48.5
High	153	44.5
Working		
Student	134	39.0
Government employee	67	19.5
Self-employed	66	19.2
Farmer/Fisherman	13	3.8
Not working	64	18.6
Marital Status		
Married	161	46.8
Not married yet	183	53.2
Type of vaccine		
Sinovac	270	78.5
Moderna	63	18.3
Pfizer	11	3.2

Table III showed the most systemic reaction symptoms to the AEFI COVID-19 vaccine at doses 1 and 2: the desire to sleep (63.1% and 64.8%, respectively). In contrast, the most minor symptom of a systemic reaction was a pain in the lymph nodes (0.6% at dose 1).

Table IV shows that among the respondents who experienced mild AEFI following the COVID-19 vaccine at dose 1, 87.9% reported mild anxiety.

Table II: Distribution of Symptoms of Local Reactions of the Community to AEFI COVID-19 Vaccine Doses 1 and 2 in Syiah Kuala Sub-district (n=344)

Vaccine dose	Classification	Local reaction	Frequency	Percentage
1	Severe	Pain at the injection site	194	56.4
	Mild	Swelling at the injection site	44	12.8
2	Severe	Pain at the injection site	227	66.0
	Mild	Swelling at the injection site	108	31.4

Table III: Distribution of Systemic Reactions Symptoms of AEFI to COVID-19 Vaccine Doses 1 and 2 among the Community at Syiah Kuala Sub-district (n=344)

Vaccine dose	Classification	Systemic reaction	Frequency	Percentage
1	Severe	Desire to sleep	217	63.1
	Mild	Pain in the lymph nodes	2.0	0.6
2	Severe	Desire to sleep	223	64.8
	Mild	Pain in the lymph nodes	0	0

Similarly, among those who experienced mild AEFI after receiving the COVID-19 vaccine at dose 2, 88.4% reported experiencing mild anxiety.

Table V shows that among the respondents experiencing mild local AEFI reactions at dose 1, 91.8% had mild anxiety. Among those experiencing

Table IV: Relationship of AEFI COVID-19 Vaccine Doses 1 and 2 with Community Anxiety Levels (n=344)

Vaccine Dosage	AEFI	Anxiety						Total		α	*p-value*
		Mild		Moderate		Severe					
		f	%	f	%	f	%	f	%		
1	Mild	297	87.9	32	9.5	9	2.7	338	100	0.05	0.025
	Severe	5	83.3	0	0	1	16.7	6	100		
2	Mild	297	88.4	30	8.9	9	2.7	336	100	0.01	0.000
	Severe	5	62.5	2	25	1	12.5	8	100		

Table V: Relationship of AEFI Local Reaction to the COVID-19 Vaccine Doses 1 and 2 with Community Anxiety Levels (n=344)

Vaccine Dosage	Local Reaction	Anxiety						Total		α	*p-value*
		Mild		Moderate		Severe					
		f	%	f	%	f	%	f	%		
1	Mild	270	91.8	18	6.1	6	2	294	100	0.01	0.004
	Severe	32	64	14	28	4	8	50	100		
2	Mild	132	93	7	4.9	3	2.1	142	100	0.05	0.016
	Severe	170	84.2	25	12.4	7	3.5	202	100		

Table VI: Relationship of AEFI Systemic Reaction to the COVID-19 Vaccine Doses 1 and 2 with Anxiety Levels (n=344)

Vaccine Dosage	Systemic Reaction	Anxiety						Total		α	*p-value*
		Mild		Moderate		Severe					
		f	%	f	%	f	%	f	%		
1	Mild	297	87.9	32	9.5	9	2.7	338	100	0.01	0.000
	Severe	5	83.3	0	0	1	16.7	6	100		
2	Mild	298	88.4	30	8.9	9	2.7	337	100	0.01	0.002
	Severe	4	57.1	2	28.6	1	14.3	7	100		

severe local AEFI reactions at dose 2, 84.2% had severe anxiety.

Table VI presents data indicating that among respondents who experienced mild systemic reactions to AEFI at dose 1, 87.9% reported mild anxiety, while at dose 2, 88.4% reported experiencing mild anxiety.

DISCUSSION

Adverse events following immunization (AEFI) with the COVID-19 vaccine are medical events related to immunization[18]. These AEFI reactions can be categorized into two types: local reactions characterized by pain and swelling at the injection site and systemic reactions marked by symptoms of a desire to sleep, nausea, vomiting, headache, dizziness, and pain in the lymph nodes. Typically, AEFI manifests within 2-3 days post-vaccination[19]. Some side effects, such as headaches, have been reported in response to the COVID-19 vaccine. This observation is supported by a study that indicated that 33% of individuals experienced headaches after receiving the second dose of the Pfizer vaccine. Hence, providing information regarding positive side effects becomes imperative in enhancing the community's willingness to receive the COVID-19 vaccine[20]. Additionally, symptoms of AEFI, including fever, fatigue, headache, nausea, chills, joint pain, muscle pain, and injection site reactions, may be associated with individual characteristics such as age, gender, lifestyle, and medical history[21].

The statistical analyses conducted in this study examined AEFI reactions at doses 1 and 2, revealing significant findings for doses 1 (p=0.025) and 2 (p=0.000). The results of the study showed a substantial relationship between AEFI following COVID-19 vaccination and the community anxiety level, particularly in doses 1 and 2 of the vaccine. These findings align with a previous study that has reported associations between AEFI reactions and anxiety levels[14]; this is also supported by an earlier study that has identified an increased incidence of AEFI alongside heightened anxiety responses following COVID-19 vaccination [15]. Anxiety is an emotional state characterized by tension, apprehension, and physiological changes[13]; This is in line with a study reporting that 48.1% of respondents felt anxious about side effects following immunization[22].

The emergence of anxiety related to vaccination can be attributed to internal and external factors. Internal factors include personality type, history of anxiety or other psychological illnesses, phobia of needles, and a history of drug use leading to psychiatric issues. Meanwhile, external factors include misinformation spread in the media regarding vaccination, poor previous immunization experience, and lack of trust in health services[14]. Another study reported that anxiety or depression is associated with a high risk of neurological problems. Factors such as a lack of confidence in healthcare providers, residing in high-income countries, younger age, female gender, and political ideology have played pivotal roles in vaccine hesitancy[23]. Therefore, public health campaigns delivered via mass media channels are essential to increase community willingness to undergo vaccination[24]. Furthermore, it is imperative to disseminate information regarding COVID-19 vaccination through social media platforms, as this can enhance public awareness and mitigate anxiety stemming from negative information about vaccine side effects[25].

According to the data presented in **Table IV**, it is evident that a significant majority of respondents reported experiencing mild anxiety (87.9% and 88.4% for doses 1 and 2, respectively), aligning closely with mild AEFI complaints. These findings align with the study's reported side effects of COVID-19 vaccines, which were mild to moderate. The most commonly reported side effects include myalgia and pain or redness at the injection site[4]. Such side effects typically manifest within 1-3 days following vaccination, with the highest incidence observed among recipients of the Pfizer-BioNTech and Moderna vaccines and the lowest among those who received the Sinopharm and Sinovac vaccines[26]. Moreover, a related study has suggested that the level of anxiety experienced by respondents concerning AEFI reactions falls within the average to mild range[27]. Mild anxiety is a natural reaction of the individual to anticipate potential threats. Furthermore, another

study also reported that anxiety generally appears within 20 minutes following vaccination related to AEFI, experienced mental distress, and need to comprehend the psychology of individuals[28,29].

According to the data in **Table V**, this study indicates the inverse relationship between the severity of AEFI reactions experienced by individuals and the intensity of anxiety they report. This finding is in line with the study stated severe AEFI experiences may increase symptoms of anxiety and depression levels in affected individuals[15]. Another study reported that 91.9% of individuals experienced mild AEFI reactions, with 59% of them reporting mild anxiety, further highlighting the link between the nature of AEFI and anxiety levels[30]. Multiple factors contribute to the emergence of AEFI reactions, including age, gender, and the types of vaccines administered[31]. Based on demographic data, respondents had an average age of 29.92 years old and showed mild AEFI at doses 1-2. This trend is consistent with prior research, showing that 82.2% of young adults and adults tended to experience only a few AEFI symptoms[32]. Another study showed that individuals aged 45 years and older were less likely to report AEFI reactions than those under 30[32].

Demographic data in **Table I** showed that most respondents were female (53.2%). Females tend to experience more AEFI symptoms than males[33]. However, gender cannot be the only risk factor for AEFI symptoms because each individual's immune system is different. A subsequent study reported that the side effects were significantly more frequent among females with a history of comorbidities, such as diabetes mellitus, hypertension, asthma, and other chronic diseases, than those without comorbidities[4].

Most respondents in this study received the Sinovac vaccine (78.5%), known for its relatively mild side effects. A previous study indicated that respondents who received the Sinovac tended to exhibit milder AEFI symptoms, including local and less severe systemic reactions[31]. In contrast, a previous study reported the Pfizer and Moderna vaccines ranked first and third in causing the highest incidence of AEFI symptoms[33]. This observation is consistent with reports that pain and redness at the injection site, myalgia, headache, fever, and fatigue were the most frequent side effects after administering the booster dose of the Pfizer-BioNTech vaccine[4]. It is important to note that AEFI local reactions do not necessarily stem from an individual's allergic condition but can be attributed to high antibody titers or direct effects of the vaccine injection[34]. These local reactions are categorized as mild if the respondent only experiences at least one symptom and severe reactions if the respondent experiences two or more symptoms.

Table VI showed that 85.4% of respondents experienced mild AEFI systemic reactions at dose 1, whereas 58.7% reported severe systemic reactions at dose 2, with 78.4% and 49.4% experiencing mild anxiety reactions, respectively. The increase in symptoms may be attributed to higher vaccine antibody titers than at dose 1. This finding aligns with the study that reported a rise in AEFI after receiving dose 2 of the vaccine[35]. Additionally, another study revealed a rise in AEFI symptoms for local reactions, increasing from 71.1% at dose 1 to 76.6% at dose 2 [36]. The most prevalent local reaction AEFI symptom was pain at the injection site (91%)[37]. Furthermore, a separate study also reported that 27.2% of AEFI symptoms were pain at the injection site[38]. Gender plays a role in these reactions, as women tend to have a lower pain threshold than men[39].

AEFI symptoms interfere with the daily activities of individuals. Pain, redness, and swelling at the injection site were reported to impede daily activities from 1.1% to 9.5% [35]. As indicated in **Table V**, respondents who experience AEFI mild local reactions tend to experience mild anxiety; this aligns with the supported study, which showed that respondents with local reaction symptoms felt anxiety in the mild range (8.4%-18.8%)[31]. To alleviate the discomfort associated with pain and swelling in the injection area, the individual can apply a cold compress to the painful area or take a medicine (paracetamol)[40].

Table VI indicates that at doses 1 and 2, 98.2% and 97.9% of respondents who experienced mild AEFI systemic reactions also reported mild anxiety (87.9% and 88.4% at doses 1 and 2, respectively). Notably, there was a decrease in the frequency of systemic reactions at doses 1 and 2. This finding aligns with previous research, which reported a significant reduction in the frequency of all systemic reaction symptoms following dose 2 [36]. Another study also supported the result of this study, reporting a decrease in the percentage of symptoms of headaches, fever, and fatigue following the administration of dose 2 of the COVID-19 vaccine [35].

The predominant systemic reaction symptoms of AEFI observed in this study were feelings of drowsiness or a desire to sleep, with percentages of 63.1% and 64.8% at doses 1 and 2, respectively. These findings agree with a previous study reporting that drowsiness is a symptom of a significant systemic reaction[38]. Drowsiness is related to activating the immune system, requiring more energy, and leading to a drowsy effect[41]. Skin irritation was a rare symptom of systemic reactions after the second dose, in line with a previous study that reported only 11 out of 2,050 respondents experiencing skin irritation following their second COVID-19 vaccination[36]. Conversely, the lowest occurrence of systemic reactions in AEFI vaccination doses 1 and 2 is pain in the lymph nodes; this is supported by a previous study that reported the incidence of symptoms of pain or swelling in the lymph nodes was only 0.9% [15].

CONCLUSION

AEFI reactions of the COVID-19 vaccine may include local and systemic reactions. The emergence of various local and systemic reactions could be related to the acceptance of vaccination and the emergence of community anxiety. This study found that the most common AEFI local reactions were pain and swelling at the injection site, and AEFI systemic reactions were desire to sleep and pain in the lymph nodes. The findings of this study provide evidence that AEFI reactions arising from the COVID-19 vaccine are associated with community anxiety levels. This study revealed an increase in the severity of AEFI local reactions and a simultaneous decrease in AEFI systemic reaction following the second dose of the COVID-19 vaccine, which can be attributed to variations in antibody titers among the community.

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AUTHORS CONTRIBUTION

Putri N: Conducted the data collection and contributed in the data analysis.
Kasih LC: Wrote the protocol and monitored the data collection.
Husna C: Performed the data analysis and wrote the initial manuscript and critical review of the manuscript.
Tahlil T: Performed the data analysis and wrote the initial manuscript and critical review of the manuscript.
All authors have approved the final version of the article.

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