

Severity of Immunisation Adverse (KIPI) Based on Allergic History and Vaccine Stages

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Abstract: Covid-19 prevention has also entered a new era with the availability of the Covid-19 vaccine, which has undergone clinical trials and has been mass-produced to enhance immunity. However, the administration of vaccinations has resulted in unexpected reactions known as Adverse Events Following Immunization (KIPI). This phenomenon suggests that low vaccination rates may be associated with perceived dangerous KIPI reactions, which can be attributed to doubts and misinformation about vaccines. This study used a correlation analytical research design with a retrospective method. The population of this study consisted of all individuals who had received vaccination and experienced KIPI reactions in the working area of Teja Health Center, totaling 30 people. The characteristics of the respondents, as seen from their allergic history and vaccine stages, showed a significant correlation ($p = 0.027 < 0.05$). The p-value for vaccine stages was 0.000, indicating a significant relationship with the severity of KIPI reactions in Covid-19 vaccine recipients. However, age and gender were not significantly associated with the severity of KIPI reactions. The severity of KIPI reactions in Covid-19 vaccine recipients has a significant correlation with the characteristics of the respondents, as seen from their allergic history and vaccine stages.

Keywords: Allergic; Immunisation adverse; KIPI Reactions; Vaccination.

Introduction

Prevention of Covid-19 has also entered a new era with the availability of the Covid-19 vaccine, which has undergone clinical trials and has been mass-produced to increase the immunity of the population at risk of exposure to the Covid-19 virus (Hotez, 2021; Plichta et al., 2022). In January, one of the government's strategies was a gradual and free vaccination program, in accordance with the Regulation of the Minister of Health of the Republic of Indonesia No. 10 of 2021 concerning the implementation of Vaccination in the context of the Covid-19 pandemic (Fahmi et al., 2023). However, the administration of the vaccine has resulted in unexpected reactions called adverse events following immunization (KIPI). Each person may show different side effects after vaccination. Some may experience little

or no side effects at all (Harryandi et al., 2021; Lestari et al., 2023).

As of October 31, 2021, the vaccination target in East Java has reached 31.8 million doses, with 19.6 million (61.7%) of the population having received the first dose, and 11.5 million (36.1%) doses for those who have completed the second dose or full vaccination (Daulay, 2021). Meanwhile, data from the Teja Community Health Center in Pamekasan Regency, the area of the study, based on the initial data collection conducted by the researchers in November 2021, the achievement rate of the vaccination program in the working area of the Teja Community Health Center for the first dose was only 56.9%, and the second phase of vaccination was only 43.6%, and it was reported that 30 people experienced KIPI after vaccination, both from the first and second doses (Fauziah, 2023; Kurniawati et al., 2022; Santoso et al., 2022).

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The above phenomenon, that low vaccination coverage may be related to perceived post-vaccination KIPi reactions as something dangerous (Ernawati & Nurhayati, 2023). Doubts and misinformation about vaccines can be major obstacles to achieving coverage and community immunity. However, the Ministry of Health targets a good immunization coverage of at least 80% (Astuti et al., 2021; Febriyanti et al., 2021). This can also be caused by the lack of information obtained by the public about the benefits of vaccines in increasing the body's immune system. In addition, the spread of hoaxes received by the public makes them hesitant to visit available vaccination centers. There is a lot of information circulating, especially about the side effects after vaccination, such as pain at the injection site, fever, fatigue, headache, body aches, and chills (Andrzejczak-Grządko et al., 2021; Mohammed et al., 2022; Wu et al., 2023).

Based on the above phenomenon, to support the education process for the public about vaccination and KIPi reactions as something common that can be managed and anticipated, it is deemed necessary to conduct research related to KIPi reactions to support the government's program in maximizing vaccination coverage. The aim of this study is to determine the correlation between the status of KIPi reactions after vaccination and the characteristics of gender, age, vaccination stage, and allergy history of vaccine recipients in the Teja Community Health Center area, Pamekasan Regency.

Method

The research design used in this research is correlation analytical research with a retrospective method. The places for this research were all villages within the working area of the Teja Community Health Center, Pamekasan district. Population is all subjects studied in a study (Nursalam, 2019). The population in this study were all targets who had undergone vaccination and experienced KIPi reactions in the Teja Community Health Center working area, totaling 30 people. In this research, the sampling used was saturated non-propability sampling, namely a sampling technique by taking all members of the population as samples. Data collection in this study was through interviews using a questionnaire which was cross-checked with initial data on KIPi complaint reports from health center medical records after 1 week post-vaccination.

Data processing uses Statistical Product for Service Solutions (SPSS) 17. The independent variable data in this study is categorical data. After carrying out the chi square test, because the 2 independent and dependent

variables have a correlated categorical data scale, so it can be seen that the large p value is considered significant is $P < 0.05$ and the confidence interval (CI) is 95%. This research protocol has received a certificate of ethical suitability from the health research ethics commission of RSUD Dr. Slamet Martodirjo Pamekasan with number: 070/079 /432.603 / KEPK/2022.

Result and Discussion

Result

This research was carried out by collecting data in the working area of the Teja Pamekasan Community Health Center in September - October 2022. The total population recorded as experiencing KIPi reactions after Covid 19 vaccination during 2020 - 2022 was 30 people.

Univariate Analysis

Table 1. Frequency Distribution of Respondents Based on Vaccine Type

Category	Frequency (f)	Percentage (%)
Sinovac	24	80
Astrazeneca	4	13
Moderna	2	7
Total	30	100 percent

Based on the Table 1, the characteristics of respondents based on the type of vaccine obtained show that the majority of respondents received Sinovac vaccine, with 24 people (80%), while 4 people (13%) received AstraZeneca and 2 people (7%) received Moderna.

Table 2. Results of statistical tests on the effect of gender on post-COVID-19 vaccination side effects in Teja Village, Pamekasan

Gender	KIPI reaction				Total		<i>p</i>
	Lightweight		Weight				
	N	%	N	%	N	%	
Male	9	29.7%	1	3.3%	10	33.3%.	0.068
Female	17	56%	3	10%	20	66.7%.	
Total	26	86.7%.	4	13.3%	30	100%	

*Chi-square test with a significance level of < 0.05

Based on the crosstab results from table 2, it can be seen that the majority of respondents are female, with a total of 20 people (67.7%), with a distribution of 17 people (56.0%) classified as mild and 3 people (10.0%) classified as severe. The analysis using correlation test yielded a p-value of 0.068, which means that there is no relationship between age factors and the clinical symptoms of post-vaccination KIPi in the working area of Teja Pamekasan Health Center in 2022.

Table 3. Results of statistical test on age factor and the status of KIPi post COVID-19 vaccination in Teja Village, Pamekasan

Age factor	KIPI Reaction					Total	<i>p</i>
	Lightweight		Weight				
	NN	%	N	%	N		
Teenagers	6	20	1	3	7	23	0.273
Adults	13	43	1	3	14	45	
Elderly	7	23	2	8.6	9	32	
Total	26	86	4	14	30	100	

*Chi-square test with a significance level of <0.05

Based on the crosstab results from table 3, it can be seen that the majority of respondents are adults, with a total of 14 people (45.0%), with a distribution of 13 people (4.0%) classified as mild and 1 person (3.0%) classified as severe. The analysis using correlation test

yielded a p-value of 0.273, which means that there is no relationship between gender factors and the clinical symptoms of post-vaccination KIPi in the working area of Teja Pamekasan Health Center in 2022.

Table 4. Results of statistical tests on the Vaccine Stage factor on the status of post-vaccination adverse events following COVID-19 vaccination in Desa Teja, Pamekasan

Vaccination Stage Factor	KIPI Reaction				Total	p	
	Lightweight		Weight				
	N	%	N	%			N
Vaccine 1	13	43.7	3	10	16	53.7	0.027
Vaccine 2	10	33	0	0	10	33	
Vaccine 3	3	10	1	3.3	4	13.3	
Total	26	86.7	4	13.3	30	100	

*Chi-square test with a significance level of <0.05

Based on the cross-table results from table 4, it can be seen that the majority of respondents are those who received the vaccine in stage 1, with a total of 16 people (53.7%), with a distribution of 13 people (43.0%) classified as mild and 3 people (10.0%) classified as severe. The analysis using correlation test yielded a p-

value of 0.027, indicating that there is a relationship between the vaccine stage factor and the clinical symptom status of post-vaccination adverse events in the working area of Puskesmas Teja Pamekasan in 2022.

Table 5. Results of statistical tests on the Allergy History factor on the status of post-vaccination adverse events following COVID-19 vaccination in Desa Teja, Pamekasan

Allergy History	Adverse Events				Total	<i>p</i>	
	Lightweight		Weight				
	N	%	N	%			N
None	24	76.7	3	10	27	86.7	0.000
Have	2	10	1	3.3	3	13.3	
Total	26	86.7	4	13.3	30	100	

*Chi-square test with a significance level of <0.05

Based on the cross-table results from table 5, it can be seen that the majority of respondents are those who do not have a history of allergies, with a total of 27 people (86.7%), with a distribution of 24 people (76.7%) classified as mild and 3 people (10.0%) classified as severe. The analysis using correlation test yielded a p-value of 0.000, indicating that there is a relationship between the allergy history factor and the clinical symptom status of post-vaccination adverse events in the working area of Puskesmas Teja Pamekasan in 2022.

Discussion

To determine the relationship between the characteristics of vaccine recipients and the status of adverse events following Covid-19 vaccination in the Teja Community Health Center working area, it can be seen from the analysis of the reported questionnaire answers, which are then summarized and matched with theories in existing journals, so that they can be classified into 2 groups of severity levels of adverse events, either mild or severe. To determine the relationship between the characteristics of vaccine recipients and the status of

adverse events following Covid-19 vaccination in the Teja Community Health Center working area, it can be seen from the analysis of the reported questionnaire answers, which are then summarized and matched with theories in existing journals, so that they can be classified into 2 groups of severity levels of adverse events, either mild or severe. Meanwhile, based on the severity level of adverse events associated with gender, because the use of this vaccine may increase cases in females. However, in this study, gender showed no association with the severity level of adverse events following vaccination ($P=0.068$). The results of this study are consistent with a previous study on 100 healthcare workers who received the Moderna vaccine, which found that gender was not related to the degree of KIPi complaints that affected activities for 48 hours post-vaccination ($p=0.999$) (Hidayat et al., 2021).

Based on the characteristics of Covid-19 vaccine recipients in the Teja Community Health Center working area, it was found that the samples with adult and elderly age categories were more numerous, with percentages of 47% and 30% compared to the teenage age group, which was 23%. This means that the average KIPi patients after Covid-19 vaccination in the Teja Community Health Center working area belong to the adult and older age groups. Several existing studies have stated that the severity level of KIPi symptoms is influenced by several factors, one of which is age. In this study, however, age did not show an association with the severity level of adverse events following vaccination ($P=0.273$). This fact differs from previous studies, which found a significant difference in the proportion of side effects after the first dose between the age groups ≤ 34 years and >34 years. Another study also found a significant difference in the proportion of side effects between the age groups ≤ 43 years and >43 years (Simanjorang et al., 2021). The difference in results from previous studies is due to the fact that in this study, age is associated with the severity level of adverse events, not with the occurrence of post-vaccination adverse reactions.

An interesting phenomenon in this study is that the characteristics of respondents based on the vaccination stage show a significant relationship between the vaccination stage of vaccine recipients and the severity level of their adverse reactions ($p=0.027 < 0.05$), as evidenced by the higher occurrence of mild KIPi reactions in both the first, second, and third stages of vaccination. This study further clarifies and complements previous studies that explain that a history of previous adverse events significantly affects the occurrence of KIPi, such as headache and fever, in subjects receiving the Moderna booster vaccine, as well as the severity level of KIPi ($P<0.05$). Regular medication

use reduces the likelihood of experiencing KIPi in patients, although not significantly. The severity level of KIPi can also be influenced by BMI and regular medication use ($P<0.05$). Although there is no study on the influence of previous vaccines on Moderna vaccination, a trial conducted by Hause et al. using the CDC showed that in the mRNA Pfizer vaccine, subjects who experienced KIPi in the first dose will experience the same KIPi in the second and third doses of the vaccine. Therefore, the resulting KIPi reactions vary, both locally and systemically. This means that the absence of previous KIPi in the first and second doses of the vaccine affects the absence of headache and fever reactions in subsequent doses, even though the previous vaccination used a different type of vaccine (Harismayanti et al., 2021; Lukas et al., 2024).

However, on the contrary, there is a difference in the proportion of side effects between the group with a history of allergies and the group without a history of allergies. This study also reveals a significant relationship ($P=0.000$) between a history of allergies and the severity of KIPi reactions, as evidenced by a higher proportion of severe symptoms in vaccinated individuals with a history of allergies, accounting for 13.3%, while mild symptoms only accounted for 3.3%. This complements and strengthens previous research with different samples on healthcare workers, which stated that there is a significant difference in the proportion of vaccine side effects between the group with a history of allergies and the group without a history of allergies ($P=0.001$). Participants with a history of allergies have a higher proportion of experiencing KIPi reactions compared to those without any side effects (Nisa et al., 2023).

The added value of this research is the latest study on the proportion and characteristics of KIPi that has never been done before in the general population receiving the Sinovac COVID-19 vaccine (Nurfaizi et al., 2023). The selection of respondents who meet the research sample criteria, as well as the monitoring and observation based on reports for 3-7 days post-immunization, were conducted. Based on the research conducted on a sample of 30 people, it was found that respondents who received the Sinovac vaccine reported experiencing mild KIPi symptoms, accounting for 26 people (86.7%), while 4 people (13.3%) reported experiencing severe KIPi symptoms. The proportion of KIPi from the entire sample of the Sinovac COVID-19 vaccine recipients in the Teja Pamekasan Health Center working area is 80%. This indicates that the majority of those who received the Sinovac vaccine experienced KIPi after vaccination, whether mild or severe. The research was conducted on the entire sample of KIPi cases in the community in the Teja Pamekasan Health

Center working area, and none of them were healthcare workers. This fact is different from the research conducted by Hanung et al. (2022) on healthcare workers in Surakarta, which found that the majority of the samples did not experience KIPi after the COVID-19 vaccination, accounting for 85 respondents (89.5%). There are many factors that can cause KIPi in consumers, such as immune system and body condition, co-incidence, and other factors that cannot be determined with certainty (Elsadibah et al., 2023; Tanjaya et al., 2022). With the high vaccination coverage, the frequency of vaccine use also increases, thus increasing the potential for unexpected vaccine reactions.

The difference in results may be due to the fact that KIPi does not always have a causal relationship with varying host-individual characteristics, but can be influenced by procedural errors, co-incidence, anxiety reactions, the number of respondents, or cause-and-effect relationships that cannot be determined. According to the researchers, it is common for KIPi reactions to occur due to multifactor triggers, and this is a new type of vaccine that requires further monitoring and evaluation to analyze the potential side effects that may occur after vaccination, both in terms of safety and vaccine effectiveness in providing protection against COVID-19 infection (Fan et al., 2021; Hulu et al., 2022; Polack et al., 2020).

Conclusion

The characteristics of respondents, as seen from a history of allergies and a history of vaccine stages, have a significant relationship with the severity of AEFI reactions in COVID-19 vaccine recipients, while age and gender do not have a significant relationship with the severity of KIPi reactions. Further studies are needed to expand the population coverage of the research and compare it with other types of vaccines to determine the overall side effects in the general population, thus increasing public confidence, as indicated by an increased awareness to visit vaccination centers provided by the government. In addition, further studies on drug specifications that can affect or inhibit the occurrence of KIPi reactions should also be conducted.

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Conflicts of Interest

In writing this article, the authors do not have any conflict of interest.

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