

Evaluation of AEFI (Adverse Events Following Immunization) Efficacy of Sinovac Vaccination Among Children Aged 6-11 Years in Indonesia

Nuril Islami and Diana Laila Rahmatillah

Faculty of Pharmacy, Universitas 17 Agustus 1945 Jakarta, Indonesia

Keywords: COVID-19, Sinovac, AEFI (Adverse Events Following Immunization), Efficacy, Children Aged 6-11 Years.

Abstract: Although children are rarely diagnosed in the early days of COVID-19, vaccination of children is still carried out to achieve herd immunity status in the world. The Indonesian government urges the use of the Sinovac vaccine for children aged 6-11 years. This study was conducted to evaluate AEFI and the efficacy of the Sinovac vaccination among children aged 6-11 years in Indonesia and other factors that influence these things. 456 participants who fulfilled the inclusion criteria were involved. This study uses the prospective cross-sectional method. A valid questionnaire was used in this study with Cronbach alpha 0,8. Those participants filled out the google form which was shared through social media. It was found that males 194 and females 262. A significant correlation was found between AEFI and Efficacy with gender, comorbidities, age, and BMI (p value $<0,05$). 63,04% of participants had pain in the injection area and 44,88% of them had pain in the upper arm after vaccination. Around 1,8% of participants were infected by Covid-19. From this study, it can be concluded that Sinovac vaccination has high efficacy and most of them had pain in the injection area event following immunization as adverse.

1 INTRODUCTION

Coronavirus is part of family Coronaviridae. They spread amongst many hosts. Clinically, it provides a diffusion of signs of breathing infections, from the commonplace bloodless to severe and often even fatal. The brand-new virus chargeable for this outbreak turned into originally named "2019-ncov" or "SARS-cov-2". Sars-cov-2 has recently been carefully related to SARS-CoV, which has 80% identification in the RNA sequence (Ramatillah & Isnaini, 2021). The virus spreads through the air, could be very easily transmitted between human beings with a long and threatening incubation duration, and spreads quickly.

Severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2), a new coronavirus, was first detected in the city of Wuhan, China in December 2019 (Dhar et al., 2020). The virus spread to the sector from China, prompting the sector fitness agency (WHO) to claim an endemic on March 11, 2020. The national index case was introduced on March 2nd, traced from a restaurant in South Jakarta. Nine months later, extra than 7,000 new

cases and more than one hundred fifty each day deaths had been stated as a seven-day moving average in Indonesia, without signs and symptoms of slowing or bending the curve (Ophinni et al., 2020).

As for children, they are diagnosed exceptionally not often at the start of the presence of Covid-19 inside the global. To start with, children have been considered less prone to Covid-19. In a report through Wu and mcgoogan2, which recorded instances from December eight to February 20, 2020, 1% of youngsters and 1% of kids under 10 years of age in China had been affected. Other researchers said that the hazard of serious illness and death from Covid-19 turned higher inside the older age institution. However, more and more young human beings are being identified because of the sickness pandemic's progress and the fast Development of Covid-19 checking out techniques. These days we recognize that younger humans can also be critically affected by SARS-cov-2 (Levy et al., 2021). Based totally on the analysis of Covid-19 statistics on April 10, 2022, the wide variety of Covid-19 sufferers who died at the age of 3-6 years is said to have been 131

sufferers (0.16%) at the same time as they were aged elderly 7-12 years had been 246 sufferers (0.14%) (Per, 2022).

To grow the immunity of kids elderly 6-11 towards publicity to the Covid-19 virus, the Indonesian government is vaccinating kids of that age (Kementerian Pendidikan Dan Kebudayaan » Republik Indonesia, n.d.). The vaccine presently in use is of the Sinovac type and already has an Emergency Use Authorization (EUA) (Vaksinasi COVID-19 Untuk Anak Usia 6-11 Tahun Dimulai 14 Desember – Sehat Negeriku, n.d.). Similarly, the Indonesian Technical Advisory Group on Immunization (ITAGI) has also made hints for implementing the Covid-19 vaccination for youngsters aged 6-eleven.

The Corona Vac vaccine from Sinovac Biotech in China is an inactivated SARS cov-2 virus and uses aluminum hydroxide as an excipient. The maximum common AEFI from the Covid-19 vaccination is nearby pain on injection, followed with the aid of malaise. There is no association between the occurrence of AEFI symptoms and gender. Both ladies and men have the same chance of experiencing symptoms of AEFI. We observed some rare symptoms which have been suggested, including drowsiness and dysphagia. The immune response may additionally play a function in the signs and symptoms of dysphagia after vaccination (Supangat et al., 2021).

Although the third clinical trial for the Sinovac vaccine has been conducted using numerous international locations thus far in Brazil, Turkey, Indonesia, and Chile, there are nonetheless minimum facts on AEFI (Adverse Events After Immunization) and the efficacy related to the Sinovac vaccine for children aged 6-11 years (Empat Negara Berbagi Pengalaman Uji Klinis Tahap-3 Vaksin Sinovac, n.d.). Based on these matters, further clinical research to evaluate AEFI (Adverse Events After Immunization) and the efficacy of the Sinovac vaccination among children aged 6-11 years in Indonesia is enormously wished. This takes a look at becoming conducted with the aid of searching at diverse elements along with sociodemography that may link AEFI (Adverse Events Following Immunization) and the efficacy of the Sinovac vaccine in youngsters elderly 6-11 years in Indonesia.

On December 31, 2019, the WHO China country workplace received records of approximately a case of pneumonia of unknown etiology detected in Wuhan (Hubei Province of China), which would later be considered the center of the spread of SARS-

cov-2. The emergence of Covid-19 is presently already the third excessive epidemic resulting from -cov in people during the last many years, after excessive Acute respiration Syndrome (SARS) and center East Respiratory Syndrome (MERS), in 2002 and 2012.

The pathogenesis of Covid-19 is complex. However, it could be defined conceptually using traditional models for three predominant pathological methods associated with irritation of the local manifestations of classical (canonical) general irritation, acute systemic inflammation, and continual systemic infection of low depth (Matsuzawa et al., 2022).

The destructive impact of Covid-19 during the last year has led to a worldwide attempt to build herd or network immunity, starting with immunity on the individual degree to boost the population stage. Viral immunity is mediated by immunological memory, which develops after the number one immune response is generated to viral antigens. The natural immunity of SARS-cov-2 can increase from previous infections; this could result in a speedy and powerful immune response, accordingly, defending the devotee. However, the presence and length of SARS-cov-2- precise immune memory cells that offer dependable protecting immunity in individuals with beyond infections is still poorly understood. Statistics concerning these responses can be useful in figuring out whether received immunity will successfully contribute to the Development of herd immunity (Mistry et al., 2019).

As of August 29, 2020, it was expected that about 15.8 in keeping with 100,000 children ages 0-4 and 9.2 consistent with 100,000 in those elderly 5- 17 years were hospitalized within the U.S. due to Covid-19 virus infection. From these records, it is regarded that there are fewer youngsters hospitalized because of Covid-19 virus infection, but this still exceeds the pre-vaccine technology hospitalization burden from different viruses that can currently be averted via vaccination. About a third of the kids hospitalized with Covid-19 positive, 80% of them have the multisystem inflammatory syndrome in kids (MIS-C) and are admitted to extensive care devices (ICU). Further, the deaths of youngsters from Covid-19 had been no longer expected to be close to 110-188 deaths (Qona et al., 2022).

Some of the corona viruses can cause respiratory infections in humans ranging from mild symptoms such as coughs and colds to more serious symptoms. Symptoms of COVID-19 are usually mild and appear gradually. some infected individuals may be asymptomatic and still feel well (Ramatillah et al.,

2021). People who get infected may also experience asymptomatic viral shedding or fever, fatigue, myalgia, arthralgia, rhinorrhea, sore throat, and/or conjunctivitis at one point of the spectrum. But it can also progress to fever, cough, hemoptysis, silent hypoxia, chest pain or tenderness, respiratory failure, or even multiorgan failure. Olfactory (hyposmia, anosmia, and parosmia) or taste (dysgeusia) problems have been identified as important chemosensory problems in Covid-19. Non-conductive olfactory disorder (OD) may be the only manifestation. Different extrapulmonary manifestations consist of diarrhea, lymphopenia, thrombocytopenia, impaired liver and kidney function, rhabdomyolysis, meningoencephalitis, stroke, seizures, Guillain-Barré syndrome, cardiac arrhythmias or heart block, pancreatitis, multisystem vasculitis including Kawasaki disease, rash or lesions including have a cold. chills, thromboembolism, and acute thyroiditis.

Six months after the onset of symptoms of Covid-19, more than 60% of the patients were observed to have persistent symptoms of fatigue or muscle weakness. Sleep problems (26%), anxiety, or melancholy (23%) are also not uncommon. Other symptoms namely disturbances in smell or taste, palpitations, joint pain, dizziness, diarrhea, vomiting, and chest pain, a series of signs known as "Covid-19 acute-delivery syndrome". Those with severe diseases need assisted breathing to overcome impaired diffusion from the lungs.

In general, children have shorter and milder illnesses than adults. However, at some point in the healing phase of the disorder, an extraordinary but life-threatening Kawasaki-like disease is seen, called early life multisystem inflammatory syndrome (MIS-C) or pediatric inflammatory syndrome transiently associated with SARS-cov-2. Children with MIS-C tend to be older, have fewer lymphocytes and platelets, and have higher CRP and ferritin levels than children with Kawasaki disease (Kai-Wang To et al., 2021).

Research for the expansion of a robust vaccine for SARS-cov-2 began early in the Covid-19 pandemic (Rashedi et al., 2022). Several vaccines have been developed to reduce the morbidity and mortality associated with Covid-19 and prevent transmission of the virus (Eid et al., 2021). More than 70 SARS-cov-2 vaccines developed from the unique vaccine platform, including inactivated whole manufacture virions, live attenuated viruses, nucleic acid viruses, viral vectors, and recombinant S proteins, are already in clinical trials (Kai-Wang To et al., 2021).

Active immunization can produce herd immunity and expanding the newly formulated and approved Covid-19 vaccine using the US Food and Drug Administration (FDA) is being rolled out. Covid-19 vaccines, such as messenger RNA (mRNA; Pfizer-BioNTech Comirnaty - BNT162b2 & Moderna - mrna-1273), protein-based (Novavax - NVX-cov2373), and viral vector-based (Johnson & Johnson Janssen - Ad26.COV2. S , Oxford-AstraZeneca - AZD1222/chadox1, Sputnik V vaccine - gamcovid-Vac- rad26/rad5), mainly goal spike protein (S), while inactivated conventional vaccines (Sinopharm-BBIBP-cov, Sinovac-coronacov, Covaxin - BBV152) targets the complete virus (Mistry et al., 2019).

Nine standard options can help guide whether a Covid-19 vaccine for children should be mandated. The criteria can be divided into three classes: four criteria related to vaccines, 2 related to disease, and 3 related to implementation. Typically, each of these criteria will be considered in determining whether a vaccine should be mandated for children, although those given for each criterion may be exceptional. At a time of great demand for public wellness, together with the current pandemic, it is proposed that every criterion remains in vaccine policymaking. However, five criteria should be prioritized. The criteria that should be prioritized over relaxation are paramount: there must be evidence that the Covid-19 vaccine is safe for children at an acceptable stage of risk. Assembly of these standards usually requires a pre-licensed safety process and data from license-issuing studies to reveal facet results after the vaccine has been administered to more than one human. 4 different standards want to be prioritized in considering whether the Covid-19 vaccine is mandatory for young people. First, the severity of the Covid-19 disorder must be large and sufficient, at least for a portion of the population (the fifth criterion). Second, vaccinating children must reduce the threat of disease transmission (criterion 6). The basis of a necessary vaccine policy regarding children is that a higher proportion of those who are immune saves you from harming others.

This criterion, rather than the role of children in the transmission of SARS-cov-2 characters to individuals, is still lacking. 1/3, the Covid-19 vaccine must also be effective in protecting children from disease (second criterion). It doesn't need to be 100% strong, similar to other vaccines we currently order for children. Fourth, because the benefits of the Covid-19 vaccine will mostly be felt by adults who are too threatened, not children, they should not feel lazy for children; or, in place of, the parent or mother

or father of the child, to comply with the vaccine mandate (criterion 9). This means that mandated vaccines must be widely available, easy on the hands, and inexpensive to anyone (Medical Association, 2020).

Protein-based vaccines or inactivated vaccines are currently used repeatedly in children in general with added aluminum salts. Picovacc, also called coronavac, is an alum-adsorbed inactivated virus vaccine (SARS-cov-2 pressure CN2) that produces neutralizing antibodies extensively in rodents and non-human primates and demonstrates safety in established doses in demanding situations (Gao et al., 2020).

AEFI can be classified as Serious Adverse Events (SAE), which are events that require hospitalization, endanger the patient (cause a risk of death and require immediate clinical intervention to prevent death), and cause significant and/or permanent dysfunction. Disability, resulting in congenital abnormalities or causing death; or Non-Serious Adverse Events (NSAE), i.e., all events that do not meet the SAE criteria. Any serious, undesirable, or unexpected signs or symptoms that manifest in individuals who have received any type of immunobiological are considered AEFI and can be caused by several factors related to the immunobiological component, the vaccination process, or people who have been vaccinated (da Silva et al., 2021).

Clinical trials of vaccines before distribution permission received crucial information approximately AEFI and due to the fact Covid-19 vaccines were advanced the usage of new technology, publish-advertising surveillance has become critical to detecting uncommon or lengthy-time period side consequences (Kant et al., 2022; Tan et al., 2022). Most of the discovered AEFI had been expected and associated with local reactions at the site of vaccine administration (Živanović et al., 2021). AEFI, which was recorded right away after the injection of the vaccine, couldn't expressly display a causal dating c (Gianfredi et al., 2021). Non-allergic AEFI that is regularly related to the covid-19 vaccine usually appears to be the same as other existing vaccines (Kim et al., 2021). Mechanically, most AEFI is caused by using organ hypersensitive reactions or immune responses to vaccines (Fu et al., 2021). Participants who had Covid-19 (confirmed with a positive test) experienced one or more of the well-known systemic extra frequently after the primary dose than after the second dose (Kant et al., 2022). Primarily based on previous research conducted in Indonesia, it is said

that side outcomes skilled by way of recipients of the overall dose of the Sinovac vaccine are expected, which include ache on the injection website online, fever, drowsiness, and pain in the upper limbs (Kezia & Ramatillah, 2022).

2 MATERIALS AND METHODS

2.1 Design

This is a prospective cross-sectional study. The method was carried out to evaluate AEFI (Adverse Events Following Immunization) and the efficacy of the Sinovac vaccination among children aged 6-11 years in Indonesia using a questionnaire. This research was conducted for three months, starting from March to June 2022. The data collection technique carried out in this study is convenience sampling. Sampling takes all the items that make up the research inclusion criteria. The inclusion criteria in this study include all children aged 6-11 years in the country who received a full dose of the Sinovac vaccine and provided informed consent to be included in this study. Then the exclusion criteria are children aged 6-11 years who have not been vaccinated with a full dose, suffering from cancer, HIV/AIDS, tuberculosis (TBC), and autoimmune patients.

2.2 Participants

Participants in this study were all children in Indonesia aged 6 to 11 years that have been conducting a full dose of vaccination with the vaccine Sinovac. The total of participants in the study was 456 respondents.

2.3 Instruments

This study uses a questionnaire distributed through social media, such as WhatsApp, Twitter, Facebook, Instagram, and Telegram. The total of questions in the questionnaire in this study were 85 questions consisting of questions about identity, efficacy of Sinovac vaccine after the first and second vaccinations, AEFI (Adverse Event Following Immunization) vaccines obtained after the first and second doses of vaccination in a short time. and long-term vaccines and combine efficacy and AEFI for 3 months after vaccination.

2.4 Statistical Analysis

AEFI of the vaccine. The value of $p < 0.05$ is considered significant.

2.5 Ethical Consent

This research has received ethical approval from the ethics committee of health research at the University of August 17 1945 Jakarta, with approval letter No.35/KEPK-UTA45JKT/EC/FB/07/2022.

3 RESULTS AND DISCUSSION

In this study, the number of respondents obtained was 456 respondents. All these respondents were children aged 6-11 years who had done a full dose of Covid-19 vaccination with Sinovac which was the inclusion criterion in this study.

It is known that in this study there were more female respondents with a percentage of 57.5% compared to male respondents (42.5%). (Figure 1)

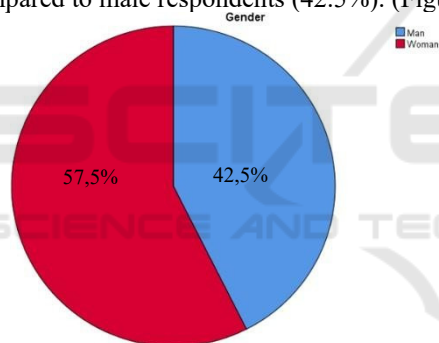


Figure 1. The percentage of gender among vaccinated children with Sinovac (6-11 years)

Respondents in this study were spread almost all over Indonesia. The percentage of respondents' domicile is 83.1% for the island of Java. This shows that in this study most of the respondents live on the island of Java such as West Java, Banten, DKI Jakarta, Central Java, DI Yogyakarta, and East Java. Then Sumatra Island 12.5%, Kalimantan Island 2.4%, and the least proportion is Nusa Tenggara Island and Bali at 2.0%. In this study, the researcher did not find respondents who live in Sulawesi Island and Maluku & Papua Island (Lemhannas RI, 2020). This may be due to the lack of power in social media that researchers have. (Figure 2)

Of 456 respondents, only 3 respondents had comorbidities, namely one respondent with comorbidity of sinusitis and 2 respondents with

comorbidities asthma. The percentage of those

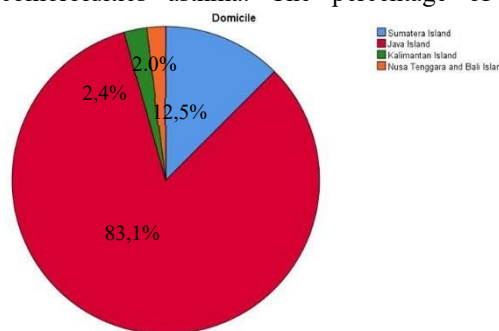


Figure 2. The percentage of domicile among vaccinated children with Sinovac (6-11 years) comorbidities can be seen in figure 3.

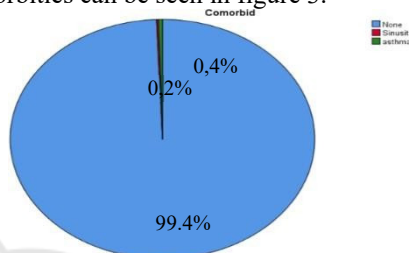


Figure 3. The percentage of comorbidities among vaccinated children with Sinovac (6-11 years)

3.1 AEFI (Adverse Events Following Immunization) Vaccine

Based on kipi.covid-19.go.id, the AEFI of the Covid-19 vaccine is usually mild and only temporary. These mild AEFI reactions include arm pain in the injection area, headache, muscle pain, joint pain, chills, nausea, vomiting, fatigue, fever, and also flu (*Informasi Tentang KIPi Atau Reaksi Setelah Vaksinasi COVID-19*, n.d.). Regarding monitoring, although there has been no official research related to AEFI menstrual cycle disorders, in some studies it is known that the Covid-19 vaccine can affect changes in the menstrual cycle in reproductive women (Mahasing et al., 2022). In this study, it was found that there were many relationships between sociodemographics and the AEFI of vaccines.

3.1.1 Relationship Between Gender with AEFI Vaccine

After data analysis using fisher and chi-square tests, it was found that there was a relationship between gender and vaccine AEFI. (Table 1).

Table 1: Relationship of gender with AEFI vaccine.

Variable	Male (n=194)		Female (n=262)		p-value
	Frequency	Percentage	Frequency	Percentage	
AEFI after the first vaccination					
Thirst or dehydration	29	14,95%	60	22,90%	0,034*
Diarrhea	1	0,52%	9	3,44%	0,035*
Cough	14	7,22%	35	13,36%	0,036*
AEFI vaccine after the second vaccination					
Cough	20	10,31%	12	4,58%	0,018*
Fever	46	23,71%	39	14,89%	0,017*
Monitoring after 1 month of vaccination					
Menstrual cycle problems	-	-	2	0,76%	0,000 #
Monitoring after 2 months of vaccination					
Menstrual cycle problems	-	-	1	0,38%	0,000 #
Monitoring after 3 months of vaccination					
Menstrual cycle problems	-	-	1	0,38%	0,000 #

Chi-Square test #Fisher test

It is known that vaccine recipients with a female gender experience AEFI more than male vaccine recipients. After the first vaccination, 22.90% of female respondents experienced thirsty AEFI or dehydration ($p=0.034$) after doing the first dose of vaccination, while for male respondents, only 14.95% experienced AEFI. After the second vaccination, it was found that there was a difference that male respondents who received the vaccine experienced more AEFI than female respondents. Likewise, with AEFI diarrhea ($p=0.035$) and cough ($p=0.018$), female respondents who experienced AEFI diarrhea were 3.44%, and for AEFI, the cough was 13.36% while male respondents were 0.52% for AEFI diarrhea and 7.22% for AEFI cough. (Table 1)

After the chi-square test was carried out to see if there was a relationship between gender and vaccines on monitoring 1-3 months after vaccination, it was found that there was a relationship between gender and the AEFI vaccine, namely, female respondents experienced menstrual cycle problems with a p-

value <0.05 . The above is by research that has been carried out previously in Thailand. The study stated that the AEFI of the Covid-19 vaccine was more experienced by women. AEFI is usually spelled out at the time of introducing a new vaccine. Similarly, in this study, the Sinovac-CoronaVac vaccine is the first Covid-19 vaccine and has only been introduced to the Indonesian people since the beginning of the vaccination recommendation for Covid-19. The study also mentioned that the Covid-19 vaccination can affect the menstruation cycle in reproductive women which may be caused by the stress experienced in these women (Mahasing et al., 2022). (Table 1)

3.1.2 Relationship Between Comorbidities with AEFI Vaccine

After data analysis using Fisher and chi-square tests, it was found that there was a relationship between comorbidities and vaccine AEFI. (Table 2)

Table 2: Relationship between comorbidities with AEFI vaccine.

Variable	Sinusitis (n=1)		Asthma (n=2)		p-value
	Frequency	Percentage	Frequency	Percentage	
AEFI after the first vaccination					
Nauseous	-	-	2	100%	0,000*
Heart attack	1	100%	-	-	0,000*
AEFI vaccine after the second vaccination					
Cough	1	100%	-	-	0,001*
Thirst or dehydration	1	100%	1	50%	0,005*
Monitoring 1 month after vaccination					
Menstrual cycle problems	1	100%	-	-	0,000 #
Thirst or dehydration	1	100%	1	50%	0,014 #
Monitoring 2 months after vaccination					
Menstrual cycle problems	1	100%	-	-	0,000 #
Thirst or dehydration	1	100%	-	-	0,000 #
Tired	1	100%	-	-	0,003 #

Chi-Square test #Fisher test

It is known that respondents who have sinusitis disease experience more AEFI than respondents who have asthma-borne diseases. Just like the Relationship of comorbidities with a vaccine after the first and second vaccinations, in monitoring after 1-3 months after vaccination, respondents with concomitant diseases, and sinusitis experienced more AEFI than respondents with asthma comorbidities. On monitoring 3 months after vaccination, no relationship was found between comorbidities and AEFI vaccines. The above can occur because sinusitis patients are susceptible to the virus (Marin et al., 2023). Another possibility is due to the presence of invasive fungal infections in respondents receiving the vaccine. Based on invasive fungal infection sinusitis case reports seen in the literature, the fungal infection is very influential on the severity of Covid-19 (Borrelli et al., 2022). More research is needed on the Relationship between comorbidities and AEFI covid-19 vaccines, especially Sinovac. (Table 2)

3.1.3 Relationship Between Age and AEFI Vaccine

Table 3. Relationship between age with AEFI vaccine.

Variable	Age (n=456)		p-value
	Frequency	Percentage	
AEFI after the first vaccination			
Nauseous	46	10,09%	0,014*
Upper arm pain	232	50,88%	0,041*
AEFI after the second vaccination			
Fever	85	18,64%	0,020*
Dizzy	76	16,67%	0,004 #
Easy to get sleepy	150	32,89%	0,007 #
Thirst or dehydration	52	11,40%	0,044 #
Upper arm pain	179	39,25%	0,005 #
Monitoring 1 month after vaccination			
Menstrual cycle problems	2	0,44%	0,009 #
Monitoring 2 months after vaccination			
Menstrual cycle problems	1	0,22%	0,036 #

* Mann-Whitney test #Kruskal Wallis test

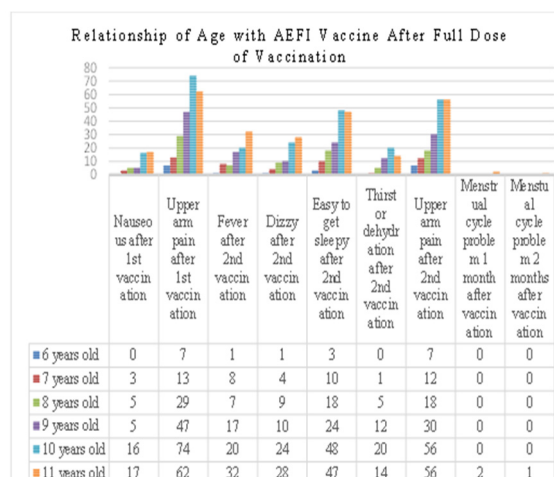


Figure 4. Diagram of the relationship between age with AEFI Vaccine

After data analysis using the Mann-Whitney Test for questions related to the AEFI vaccine and the Kruskal Wallis test for monitoring questions 1-3 months after vaccination, it was found that there was a relationship between age and AEFI vaccine. This is indicated with a p-value of less than 0.05. The most experienced AEFI of respondents was upper arm pain after the first vaccination (p=0.041) with a percentage of 50.88% and the least was at the time of AEFI monitoring until 3 months after vaccination, namely changes in the menstrual cycle after 2 months of vaccine acceptance (p=0.036) with 0.21%. (Table 3)

It is known that younger children have less AEFI. This can happen because the immune systems of younger people are Stronger and more efficient than those of older people. Another possibility that can occur is the clinical symptoms of the inflammatory response to the lung injury of the younger children are milder than those older children (Qona et al., 2022). (Figure 4)

3.1.4 Relationship between BMI and AEFI Vaccine

Table 4: Relationship of gender with vaccine efficacy.

Variable	BMI (n=456)		p-value
	Frequency	Percentage	
AEFI after the first vaccination			
Fever	203	42,38%	0,021*
Pain in the injection area	338	70,56%	0,00*
Nauseous	48	10,02%	0,036*
Dizzy	145	30,27%	0,003*
Easy to get sleepy	228	47,60%	0,000*
Upper arm pain	242	50,52%	0,036*
AEFI after the second vaccination			
Pain in the injection area	266	55,53%	0,050*
Flu	26	5,43%	0,039*
Easy to get sleepy	162	33,82%	0,026*
Upper arm pain	188	39,25%	0,004*
Monitoring 2 months after vaccination			
Menstrual cycle problems	1	0,21%	0,007 #
Easily Tired	30	6,26%	0,000 #
Upper arm pain	31	6,47%	0,000 #
Thirst or dehydration	20	4,18%	0,000 #
Bleeding	3	0,63%	0,000 #
Monitoring 3 months after vaccination			
Easily Tired	6	1,25%	0,016 #
Upper arm pain	6	1,25%	0,016 #

*Mann-Whitney test #Kruskal Wallis test

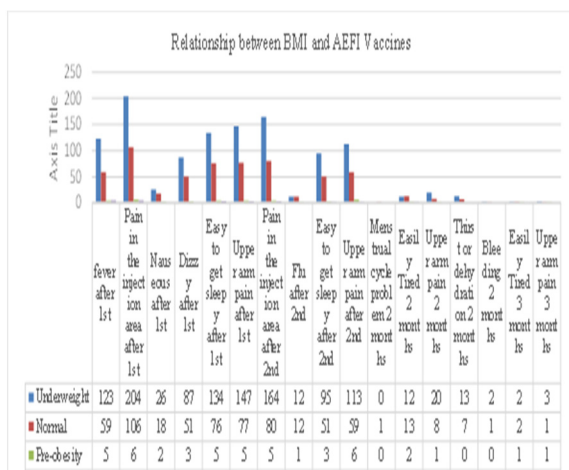


Figure 5: Relationship between BMI and AEFI vaccine.

After analyzing the data using Mann-Whitney for questions related to the vaccine AEFI and the Kruskal Wallis test to find out 3 months after vaccination it was found that there was a relationship between BMI and vaccine AEFI with a p-value of 0.05, which can be seen in table 1. the data that can be used in the graph in Figure 2, it is known that the respondents who received the vaccine the most experiencing AEFI were children aged 6-11 years who had low body weight. (Table 4)

The results obtained in this study are following previous studies related to the side effects of Sinovac in adolescents aged 12-18 years that have been carried out by Qona et al. In this study, it was found that respondents who received vaccines with BMI <18.5 (less body weight) had the majority of AEFI vaccines (Qona et al., 2022). The results obtained in this study may be caused by the respondents obtained by the researchers having a BMI of less than 18.5 (less body weight). (Figure 5)

3.2 Vaccine Efficacy

The efficacy of the Sinovac vaccine was 98.46% after all respondents had the first vaccination and 99.34% in the second vaccination. Based on this, it can be known that the efficacy of the Sinovac vaccine after all respondents have been vaccinated in the first and second doses or the full dose is 98.2%. (Figure 6)

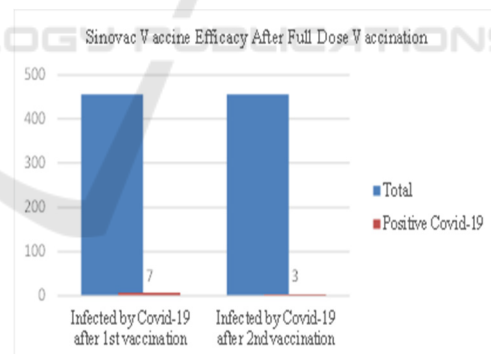


Figure 6: Diagram of vaccine efficacy.

3.2.1 Relationship Between Gender and Vaccine Efficacy

After data analysis using fisher tests, it was found that there was a relationship between comorbidities and vaccine efficacy. (Table 5)

Table 5: Relationship of gender with vaccine efficacy.

Variable	Male (n=194)		Female (n=262)		p-value
	Frequency	Percentage	Frequency	Percentage	
Infected with Covid-19 after vaccination					
Second vaccination	3	1,55%	-	-	0,043*
Self-isolation	3	1,55%	-	-	0,043#
Mild symptoms	3	1,55%	-	-	0,043#

*Fisher Test #Chi-Square Test

It is known that in this study, only a relationship was found between gender and vaccine efficacy after vaccination respondents carried out the second dose of vaccination. Likewise, it can also be seen that only respondents of the male gender were infected with covid-19 after receiving the second dose of vaccination. Based on the data above, it can be concluded that in female respondents the Sinovac vaccine works more effectively against Covid-19. The possibility that can happen because in general, women practice more preventive behaviors and avoid behaviors at risk of contracting Covid-19 (Khubchandani et al., 2021). (Table 5).

3.2.2 Relationship Between Comorbidities and Vaccine Efficacy

After data analysis using fisher tests, it was found that there was a relationship between comorbidities and vaccine efficacy. (Table 6).

Table 6: Relationship between comorbidities and vaccine efficacy.

Variable	Sinusitis (n=1)		Asthma (n=2)		p-value
	Frequency	Percentage	Frequency	Percentage	
After the first vaccination					
Loss of sense of disengagement and taste	1	100%	-	-	0,000*
Respiratory distress	1	100%	1	50%	0,000*
Cough and sore throat	-	-	2	100%	0,002*
Diarrhea	1	100%	-	-	0,000*
Skin rash	1	100%	-	-	0,000*
After the second vaccination					

Loss of sense of disengagement and taste	1	100%	-	-	0,000*
Respiratory distress	1	100%	-	-	0,000*
Headache	1	100%	-	-	0,019*

*Fisher test

It is known that respondents who have congenital sinusitis ailment reveal in extra symptoms of being inflamed with Covid-19. That is inconsistent with preceding research on continual Rhinosinusitis and Covid-19. Inside the observation, it became said that, although CRS patients are vulnerable to exacerbation of viral infections, CRS has now not been said chief comorbidity and isn't a dangerous aspect for Covid-19, there can also be a defensive role towards SARS-cov-2 infection, and CRS is not related to severe Covid-19. Even though the observation also referred to that in CRS sufferers who were unresponsive to medical remedies and carried out surgical processes, the treatment could affect the danger of SARS-Cov-2 infection with the aid of modulating the host's immune response to viral infections, ACE2 expression in airway epithelial cells, and pre-present syntonin irritation resulting from CRS (Marin et al., 2023). (Table 6)

3.2.3 Relationship Between Age and Vaccine Efficacy

After data analysis using the Mann-Whitney test, it was found that there was a relationship between age and vaccine efficacy. (Table 7)

Table 7: Relationship between age with vaccine efficacy.

Variable	Age (n=456)		p-value
	Frequency	Percentage	
After the first vaccination			
Respiratory distress	21	4,61%	0,000*
After the second vaccination			
Cough and sore throat	32	7,02%	0,010*
Fever	64	14,04%	0,032*
Headache	53	11,62%	0,015*

*Mann-Whitney test

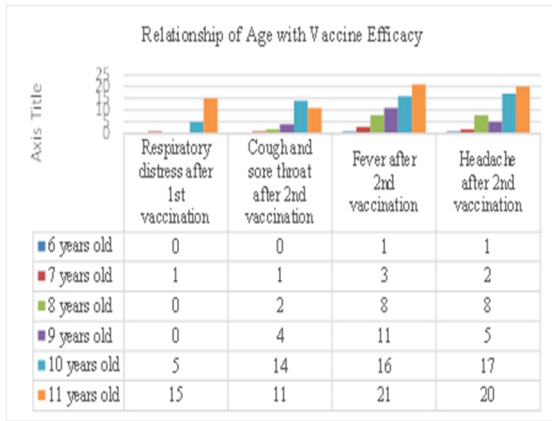


Figure 7. Diagram of Relationship between age and vaccine efficacy

It can be concluded that there is a relationship between age and vaccine efficacy. The most common symptoms of Covid-19 experienced by respondents receiving the Sinovac vaccine were fever with 14.04% ($p = 0.032$). The aforementioned are supported with a p-value of less than 0.05. There was no relationship between age and vaccine efficacy on monitoring for 3 months after vaccination. (Table 7)

It is known that respondents receiving vaccines with older age experience more symptoms of Covid-19 than younger vaccine respondents. This is not much different from previous studies preliminary reports show that only a small percentage of Covid-19 cases occur in children and adolescents (aged 0–18 years), with the incidence increasing with age (European Centre for Disease Prevention and Control, 2020). (Figure 7)

3.2.4 Relationship Between BMI and Vaccine Efficacy

Table 8: Relationship of BMI with vaccine efficacy.

Variable	BMI (n=456)		p-value
	Frequency	Percentage	
After the first vaccination			
Cough and sore throat	67	14,69%	0,007*
Diarrhea	19	4,17%	0,047*
AEFI after the second vaccination			
Loss of sense of disengagement and taste	7	1,54%	0,033*
Cough and sore throat	32	7,02%	0,005*
Diarrhea	9	1,97%	0,049*

*Mann-Whitney test

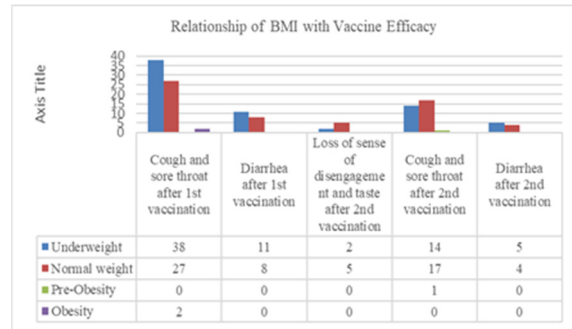


Figure 8: Diagram of Relationship BMI with vaccine efficacy.

After data analysis using the Mann-Whitney test, it was found that there was a relationship between BMI and vaccine efficacy with a p-value of less than 0.05 (Table 8). In the data that has been described in the graph, it is known ones who experience the most symptoms of Covid-19 are children who have low body weight. (Figure 8)

A cohort study conducted by previous researchers stated that people with very low BMI risk of being hospitalized or dying from Covid-19 than people with normal weight (Wilder-smith & Frahsa, 2022).

4 CONCLUSIONS

The efficacy of the Sinovac vaccine among children aged 6-11 years is very high at 98.2%. The sociodemography that results in the most severe AEFI is comorbidities. The vaccine AEFI that most respondents felt was upper arm pain and pain in the injection area after the first vaccination. Meanwhile, the vaccine AEFI that most respondents felt at 3 months of monitoring was upper arm pain after 2 months after vaccination.

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