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Adverse reactions following COVID-19 immunization in children of elementary school age

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Abstract

Purpose: Due to the low rate of parent acceptance of vaccines, this study was conducted to evaluate post-vaccination adverse events among elementary school students. **Methods:** This survey took place in the Manggala Subdistrict of Makassar City. The study was conducted from September to October 2022 by distributing a paper-based questionnaire regarding the COVID-19 vaccines. **Results:** Of 129 respondents, the age range was 7-12 years. Sixty-five percent of respondents received the first vaccine shot in January or February, with a 4-week interval of the second dose among 46.5% of children. The vaccine administered was CoronaVac from Sinovac. The most common adverse events were injection pain (45-48%) and fever (15-17%). The other side effects were itching, swelling, fever, and shortness of breath. Around 17-18 % of respondents did not have any adverse reactions. There is no increase in the risk for younger children (years 1-3) compared with older children (years 4-6). **Conclusion:** The children reported only mild adverse events such as injection pain, weakness, and fever. The CoronaVac has minimal side effects among elementary school children.

Keywords: CoronaVac; COVID-19; elementary school children; vaccine adverse effects

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is caused by the SARS-CoV-2 virus, which originated in Wuhan, China, at the end of 2019 [1,2]. It manifests primarily in the respiratory tract and often causes severe pneumonia and death [3,4]. Other symptoms can include fever, cough, fatigue, loss of taste or smell, sore throat, and shortness of breath [1,5].

The SARS-CoV-2 virus is highly transmissible through the air when someone coughs, sneezes, laughs, or talks [1]. Therefore, COVID-19 has spread globally and caused many deaths. By the end of November 2022, two years since the emergence of COVID-19, the number of cases worldwide had reached 636,440,663, with a mortality rate of 6,606,624 (1.04%) [6]. There were 6,634,648 confirmed cases in Indonesia, with a mortality rate of 2.4% [7]. Due to the rapid transmission, world health protocols have been implemented, such as wearing face masks, maintaining distance, washing hands, and vaccinations [8]. Before the discovery of a vaccine, there were restrictions on crowds, travel, domestic and international, public places, and office work.

The COVID-19 pandemic has now changed to endemic status, meaning that the virus does not completely disappear and will continue to infect humans, especially in environments where herd immunity is still low [9]. Until the end of 2022, the transmission rate was relatively high, and new variants emerged due to mutations [10]. Highly efficacious vaccines should be distributed to achieve herd

immunity, with a 70-90% coverage [11]. Fortunately, vaccine development research centers responded quickly to the pandemic and produced a COVID-19 vaccine on various platforms approved for emergency use within a year. This was supported by successful findings on the virus entry mechanism, where its spike protein binds to the angiotensin-converting enzyme 2 (ACE2) receptor found in human body cells [12,13]. Various platforms are used in developing this vaccine, such as adenovirus vector [14], RNA-based [15-17], and virus inactivation [18], targeting the spike protein on the surface of the virus.

Since January 2021, Indonesia has also started a COVID-19 vaccine campaign with the initial target of health workers using the SARS-CoV-2 virus developed by Sinovac from China, known as CoronaVac [19]. In a phase 3 clinical trial for this vaccine in Turkey, it was reported that vaccine efficacy was 83% with minimal side effects [18]. Besides CoronaVac, widely used in Indonesia, the AstraZeneca vaccine based on adenovirus developed by Oxford University is also used [14]. Meanwhile, RNA-based vaccines known as Pfizer and Moderna are widely used, especially as boosters, because they are reported to be highly productive, reaching 95% [15,17]. As of the end of November 2022, WHO reported that the number of complete vaccine recipients in Indonesia was 62 per 100 population [7]. Child vaccination in Indonesia only started at the end of 2021 [20].

The Central Statistics Agency reported that population of Indonesia aged 5-9 years is 23,973,800 out of a total population of 268,074,600 with the number in the 10-14 age group being 23,057,100 [21]. The number of children aged 5-14 is 47 million, or 17.5% of the total population. Because the proportion of children in Indonesia's population is very high, vaccination coverage for children is essential to achieving herd immunity. However, it is reported that immunization coverage of COVID-19 vaccines in children is still relatively low because many parents do not approve it for their children [22,23]. As a result, this study aimed to gather information on the vaccination rates among kids in one of the Makassar Municipality's sub-districts and to track any adverse reactions that COVID-19 vaccine recipients experienced. There is limited studies on the vaccine side effects in Indonesia.

METHODS

We surveyed schools since community health centers collaborate with elementary schools to facilitate child vaccinations. We visited the elementary schools located at Manggala SubDistrict, Makassar, South Sulawesi Province, from September to October 2022. The subjects of this research were elementary school-age children who had received at least one dose of the COVID-19 vaccine. Data was obtained by distributing questionnaires to be filled out by parents. In addition, we interviewed teachers regarding the vaccination coverage at the school. We excluded the incomplete questionnaire.

Initially, we distributed the questionnaires to parents through the students' teachers. After the questionnaires were filled out and returned, we implemented data verification and quality control by conducting a subsequent cross-check on the questionnaire responses by contacting parents through the provided contact number written in the questionnaire. During the cross-check process, we also sought confirmation of the questionnaire responses by aligning them with the "PeduliLindungi" data related to the date of receiving the COVID-19 vaccination. Furthermore, we also inquired about adverse events following COVID-19 vaccination symptoms experienced by the children to the parents via a telephone call or a mobile chat application. We excluded the incomplete questionnaire and those with unreachable parents to keep the data reliable.

Data analysis evaluates whether there is an increased risk of a side effect in younger class children (classes 1-3) compared to older class children (classes 4-6), data was analyzed by calculating the odds ratio and confidence interval (CI) for each side effect that occurred. Based on interviews with teachers and principals from four elementary schools, we found vaccination coverage to be low, ranging only between 20–30%. This is primarily because vaccinations are not mandatory, and a majority of parents do not consent to them. From the study, we had data for 129 students that were analyzable. However, we had to exclude some questionnaires due to reasons such as discrepancies between the written data and parental confirmations, difficulties in contacting parents, and missing contact information on the questionnaire sheets. This study was funded by the Hasanuddin University Research and Community Service Institute in 2022.

RESULTS

Table 1 shows that students aged 7-12, with an even mix of females and males, participated in the study. About 4.7% had COVID-19 before, and 8.5% had family members who were infected. Of those who had COVID-19, most (83.3%) also had a family history of the virus.

Table 2 presents the vaccination schedule and dose interval. Around thirty-seven percent and 27.9% of students received the first vaccine in January and Feb-

Table 1. Characteristics of participants (N=129)

Characteristic	n	%
Age (median/range)	11 (7-12 years)	
Gender		
Female	69	53.55
Male	60	46.5
Elementary school		
SD Inpres Perumnas Antang 1	50	38.6
SD Inpres Antang 2	42	32.6
SD Inpres Perumnas Antang 2/1	30	23.3
SD Inpres Perumnas Antang 1/1	7	5.4
History of COVID-19	6	4.7
Family history of COVID-19	11	8.5

ruary, respectively. This follows the schedule for the commencement of the national vaccination campaign for children. However, three children received their first dose in 2021. Around 46.5% of children followed the 4-week dose interval according to the schedule, while 4.7% who received two doses in two consecutive months. The percentage of children receiving the second dose after more than six weeks from the first dose (8-12 weeks) was 6.2%. There were 9.3% of respondents with a 2-month absence. They did not remember the exact date, so we could not determine how many weeks the dose interval was. Nine of the 129 children had not received the second dose. Regarding the vaccine name, only 68% of respondents knew the vaccine name they received in the first vaccination and 65% in the second vaccination. All respondents who knew the name of the vaccine were informed that they had received the Sinovac vaccine.

The respondents reported several adverse events after receiving the first and second doses of vaccines. The majority was injection pain (**Figure 1**).

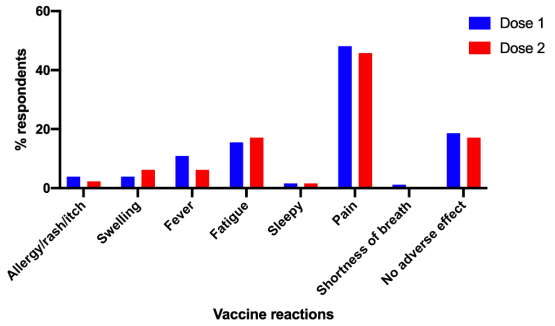

Figure 1. Vaccine adverse events following administration of dose 1 and dose 2

Fatigue also commonly occurs after the first and second doses, as reported by 15-17 % of respondents. Fever occurred in around 10% of children after the first vaccination but was reduced to 6% after the second vaccination. Two children reported experiencing shortness of breath after the first vaccination but did not experience similar symptoms after the second dose. Of the 129 people, 17–18% did not experience any complaints after the first or second vaccine.

Table 2. Vaccination schedule & dose interval (N=129)

Variable	n	%
Dose 1		
January 2022	48	37.2
February 2022	36	27.9
March 2022	10	7.8
April 2022	4	3.1
July/August 2022	4	3.1
March 2021	1	0.8
August 2021	1	0.8
November 2021	1	0.8
Forgotten	24	18.6
Interval of doses (weeks)		
1	1	0.8
3	2	1.6
4	60	46.5
5	3	2.3
6	6	4.7
8	4	3.1
9	3	2.3
12	1	0.8
1 month*	6	4.7
2 months*	12	9.3
Forgotten	21	16.3
Only 1 dose	9	7.0

*The subject only remembered the month, not the exact date

Next, we evaluated the increased risk of side effects in the younger class (grades 1-3) compared with the older class (grades 4-6). Analysis of the odds ratio of each adverse event showed no significant increase risk of side effects among younger children compared to older children (p>0.05; **Table 3**). After the first dose administration, the fever had an OR of 2.13; however, the confidence interval (CI) is 0.63-6.63.

DISCUSSION

In this study, we found that most students received vaccinations at the beginning of the vaccination campaign. However, only half received the vaccine at the recommended interval of four weeks or one month. A longer dose interval may affect vaccine effectiveness and, ultimately, the development of immune responses. Since the children only received the Sinovac vaccine, we could not compare its side effects to those of the other COVID-19 vaccines. There is no difference in adherence to vaccination based on the child's gender.

We also found that there should be an improvement in the data collection system on COVID-19 vaccination in schools and community health centers because the data obtained from community health centers was ex-

Table 3. Adverse events among the younger-class children and older-class children

Adverse events	Vaccine 1				Vaccine 2			
	6-9 y.o[a]	10-12 y.o[b]	OR (95% CI)	p value	6-9 y.o[c]	10-12 y.o[d]	OR (95% CI)	p value
Pain	16/36	47/93	0.78 (0.36 - 1.7)	0.26	16/34	43/86	0.89 (0.4 - 1.97)	0.38
Allergy/itchy	1/36	3/93	0.86 (0.09 - 8.52)	0.44	1/34	2/86	1.27 (0.11-14.51)	0.42
Fatigue	0/36	0/93	~	-	1/34	2/86	1.27 (0.11- 14.51)	0.42
Fever	6/36	8/93	2.13 (0.68 - 6.63)	0.01	1/34	8/86	0.3 (0.04 - 2.46)	0.12
Swelling	2/36	3/93	1.76 (0.28 -11.02)	0.27	2/34	5/86	1.01 (0.19 - 5.49)	0.49
Sleepy	0/36	2/93	0		0/34	2/86	0	
Shortness of breath	0/36	2/93	0		0/34	2/86	0	

[a] the number of younger-class children (1-3) who experienced adverse events (AE) after 1st dose/the number of all younger-class children receiving 1st dose
[b] the number of older-class children (4-6) who experienced AE after 1st dose/the number of all older-class children receiving 1st dose
[c] the number of younger-class children (1-3) who experienced AE after 2nd dose/the number of all younger-class children receiving 2nd dose
[d] the number of older-class children (4-6) who experienced AE after 2nd dose/the number of all older-class children receiving 2nd dose

tracted from the "PeduliLindungi" application, with no recorded data from schools. Due to this problem, it was impossible to cross-check the data of several respondents who had forgotten their vaccination schedule or did not know the name of the vaccine given. It would be better for community health centers to have specific data for each school.

On the other hand, the school staff should also have a record of their students' vaccinations, including the date and type of vaccine received. This recording is vital because there are other vaccinations at school, such as BIAN (National Child Immunization Month). Apart from that, information for parents also needs to be improved so that they have records of their children's vaccinations. To address such an issue, the government might need to distribute individual vaccination books.

Our result also demonstrated no serious side effects from the COVID-19 vaccination. The most common complaint is pain during injections, similar to the report of a systematic review on the side effects of Coronavac in adults, although with a smaller percentage [24]. In another study on the adverse events following the administration of the Pfizer vaccine in children in the United States, it was reported that the side effects were injection pain, fatigue, and fever, which occurred in 55%, 26%, and 13%, respectively [25]. Around 17-18% of children had no complaints after receiving the vaccine shot. Based on the data, we may persuade the public, especially parents, to take the COVID-19 vaccine. There were reports of shortness of breath after the first vaccine, but this symptom did not occur again after the second dose. However, we did not look into the length and severity of the respondents' shortness of breath further.

The limitation of this study is that it depends on the recall regarding the side effects experienced by the children, which has occurred in more than half a year so it might be incomplete, including the duration of these side effects. To minimize recall bias, especially on the side effects, we confirmed the answer by contacting the parents. Due to challenges in communication with some students' parents, such as inactive contacts, rejected calls, and unclear contact information, we excluded several respondents from the study to keep the data reliable. The implication of the recall bias is the incomplete data on the time of vaccination and the inability to explore further information on the side effects, such as the duration of the side effects.

However, despite the limitations, this study can provide an overview of COVID-19 vaccination in children, which is essential for planning vaccine campaigns on children, especially for parents who are still reluctant to allow their children to be vaccinated. Moreover, we also suggest better vaccination records in schools and community health centers in Manggala District.

CONCLUSION

Several children received two doses of the CoronaVac vaccine at a longer dose interval. The children reported only mild adverse events such as

injection pain, weakness, and fever. The younger children had a similar risk as the older children in experiencing any side effects. Since the COVID-19 pandemic has not ended yet and the number of new cases in Indonesia has risen again recently, these results support urgent advocacy for the local government on the need to promote children's vaccination and improve its record management.

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