The Evaluation of Adverse Effects of Sinovac® COVID-19 Vaccine After Receiving the First Dose - Maros Health Center, December 2021

An Nisaa Nurzak[1], Muhammad Iqbal[2], Syafruddin[3], Arifuddin Yunus[4], Dwi Fitrah Wahyuni[*5]

[1,4]Farmakologi, Program DIII Farmasi, STIKes Salewangang Maros, South Sulawesi, Indonesia Farmasi Klinik, Program DIII Farmasi, STIKes
[2,5]Salewangang Maros, South Sulawesi, Indonesia

[3]Prodi DIII Kebidanan, STIKes Salewangang Maros, South Sulawesi, Indonesia

Email: annisaanurzak.pharm@gmail.com

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Abstract

One of the Indonesian government's efforts to reduce COVID-19 disease is holding vaccinations for all people in Indonesia. The effect of administering the first dose of Sinovac® COVID-19 Vaccine occurs after injection, as a result of deep penetration and different needle directions, as well as Unexpected Events (KTD), which are generally mild and temporary. This research aimed to determine attitudes, perceptions, and the effects of the first Sinovac® vaccine. The research used an observational study by taking a sample of 130 people who met the inclusion criteria through the purposive sampling technique. The study showed that the most common adverse effects of local injections were itching and pain, as much as 54%, followed by fatigue (tiredness) at 46%, muscle pain at 41%, and a small proportion of joint pain, nausea, and changes in body temperature. Patients who experience symptoms both locally at the injection site and other mild side effects are more likely to be female by up to 60%. General symptoms of negative effects in local injection with ages 18-40 years (54.4%) and 41-50 years (54.9%). The common symptom effects are in the form of fatigue, joint pain, muscle pain, and nausea, with a vulnerable age of 41–50 years (56.9%) predominating. Patients with general symptom effects in the form of fatigue, joint pain, muscle aches, and nausea, with an age range of 41–50 years (56.9%), predominated. Based on the results of the research, it was found that the most effective Sinovac® vaccine caused bad effects by local injection. This can be solved by giving an antipathy to reduce the symptoms of the bad effects of local injection that can occur.

Keywords: effects, local, injection, vaccine.

INTRODUCTION

At the beginning of 2020, the world was shocked by the outbreak of a new virus, namely the new type of coronavirus (SARS-CoV-2) and the disease called Coronavirus Disease (COVID-19). It is known that the origin of this virus originated in Wuhan, China. It was discovered at the end of December 2019. So far, it has been confirmed that hundreds of countries have been infected with this virus (Syauqi, 2020). 7,805,148 cases were recorded worldwide. Starting from the animal-to-human transmission, followed by human-to-human spread (Levani et al., 2021). The number of confirmed COVID-19 cases in Indonesia in early 2021 reached 1,174,779 with the addition of positive cases in the last 24 hours reaching 8,700 people. Various efforts to stop the increase in cases are needed both from the government and from society itself. Indonesia is still trying to get rid of the pandemic, and the government is still trying to help.

Vaccination is accompanied by 3M disciplines (wearing masks, washing hands, and maintaining distance) and strengthening 3Ts (Testing, Tracing, and Treatment). Prevention that has been proclaimed to stop the increase in COVID-19 cases has not been able to stop the journey of COVID-19 cases in Indonesia.

In order to accelerate efforts to contain COVID-19 in Indonesia, the government has launched a program to provide COVID-19 vaccinations to all Indonesian people. The first stage of 3 million Covid-19 vaccines produced by Sinovac®, which was the producer of the Covid-19 vaccine, has been imported by the Indonesian government in two stages, the first in early 2021 and the second time in the middle of 2021 to 2022.

The implementation of the COVID-19 vaccination in Indonesia has experienced many obstacles in the community. Some people support this COVID-19 vaccination program, but not a few doubt the effectiveness and efficacy of the Covid-19 vaccine. Some

of them even refuse to be vaccinated. The Sinovac® vaccine, which is used for the COVID-19 vaccination, has been clinically tested in several stages and received a distribution permit from the Food and Drug Administration (BPOM) as well as from the Indonesian Ulema Council (MUI). Even so, there were still some arguments from those who refused to be vaccinated against COVID-19. Those who refuse to feel doubtful and afraid if there were adverse effects after administering the vaccine, therefore the need for mentoring education and clinical evidence that has been published to the public in order to increase the participation of all Indonesian citizens to assist government programs in reducing the risk of transmission of COVID-19.

Vaccines are biological products that contain antigens like microorganisms or their parts or substances that have been processed in such a way that they are safe and which, when given to a person, cause active specific immunity against certain diseases (Ministry of Health of the Republic of Indonesia, 2021). One of the COVID-19 vaccines, Coronavac (Sinovac® Life Science, Beijing, China), is an inactivated virus vaccine that was one of the earliest to join the COVID-19 vaccine trial line In April 2020 (Riad et al., 2021). In general, the bad effects that arise can vary, are generally mild and temporary and do not always exist depending on the condition of the human body. The bad effects such as fever and muscle aches or rashes at the injection site are normal but still need to be monitored (Ministry of Health of the Republic of Indonesia, 2021).

The results of the research conducted by Simanjorang et al., 2022) explain that the injection and systemic bad effects experienced include pain at the injection site, swelling at the injection site, headache, fatigue/lethargy, and not feeling well. Based on the description above, the researchers conducted the research to know the bad effects of giving the first dose of the Sinovac® vaccine in the Health Center of Maros Regency.

RESEARCH METHODS

The type of research used is observational research by taking data in a prospective cohort study (Teng et al., 2020). The instrument, or tool, in this research, used the questionnaire for data collection. A questionnaire is a data collection technique that is done by giving a set of questions or written statements to respondents to answer. This research has obtained permission from the ethical committee of the Faculty of Medicine, Muslim University of Indonesia, Number: 057/A.1/KEPK-UMI/II/2022.

Research Design

The data used in this study is primary data. The primary data in this study is the respondents' answers to the questions contained in the questionnaire data distributed to the respondents. The questionnaire discusses the side effects of the COVID-19 vaccine.

All of the patients received a briefing on the procedure in accordance with the study protocol and written informed consent was obtained. All patients having the required laboratory evaluation parameters, including negative Antigen Covid 19 test findings, were given a thorough general physical examination before vaccination to meet our inclusion and exclusion criteria. Before vaccination, the candidate's name, age, and contact information were recorded in the record in the immunization room with emergency resuscitation equipment. Vital signs and a recent history of respiratory tract illnesses were also noted. 0.5 mL of inactivated coronavirus per dosage. Each applicant received a vaccination, followed by a 30-minute observation period. After that, candidates received a paper-based proforma designed to measure unfavourable impacts. Then, candidates received a paper-based adverse effects proforma created by pertinent papers on this topic. The questionnaire also asked about comorbid conditions, history of coronavirus sickness, and readiness to receive vaccinations. The section on results lists the negative effects that were asked about in the questionnaire. These effects were tracked for seven days after the vaccination was given.

IBM SPSS was used to statistically evaluate the data (version 22.0). For categorical data, frequencies and percentages were employed, and mean and standard deviation were reported for continuous variables. The Chi-Square test was used to evaluate post-vaccination adverse effects between categorical groups, such as gender, comorbidities, and history of COVID-19 infection, while the independent samples T-test was used to compare post-vaccination side effects with age. A 0.05 p-value indicated statistical significance.

RESULTS

The bad effect incidence was after the first dose of the Sinovac® vaccine, based on the results of the interview. Interviews were conducted after the vaccine to determine the effect of the injection and continued one to two days after the administration of the vaccine to determine the systemic effect. The results were obtained through interviews with all respondents after giving the first dose of Sinovac® vaccine, which experienced the most frequent side effects, namely: injection of itching pain in as many as 71 people (54.6%); fatigue in 61 people (46.9%); muscle pain in 54 people (41.5%); and a small proportion experienced nausea in 3 people (2.3%) (Figure 1.)

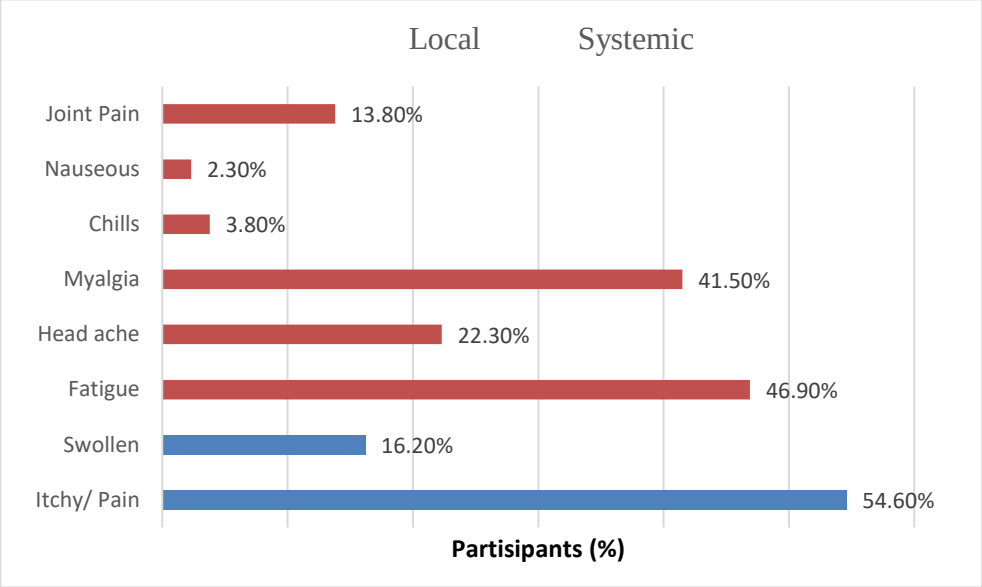

Figure 1: The Local and Systemic Effects after given First Dose of Sinovac® Vaccine

Based on Figure 2. The most common local effects of the first dose of Sinovac® vaccine are itching and pain; namely, male respondents were 26 (46.4%), while female respondents were 45 (60.8%). However, the bad effect of local pain at the injection site did not cause swelling in all respondents; only under 20% experienced it. This is evidenced by research (Leonardi Hasan, 2021), that the most common adverse local is pain at the injection site, followed by swelling at the injection site.

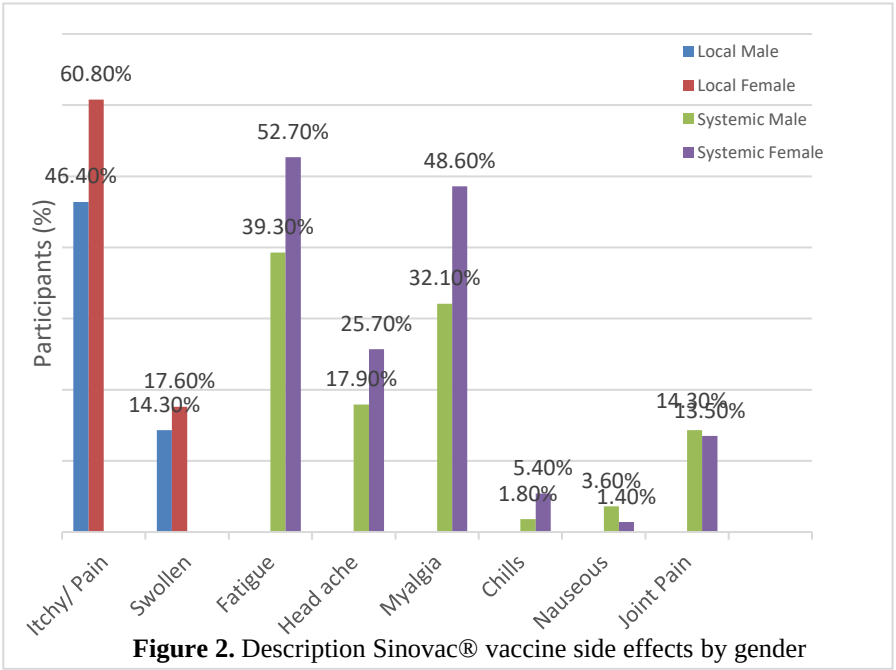

Figure 2. Description Sinovac® vaccine side effects by gender

The systemic incidence of bad effects in the first dose of the Sinovac® vaccine was 22 people (39.3%), and women were 39 people (52.7%), followed by complaints of muscle pain in more than 32% of male and female respondents. Headaches, chills, and nausea only occurred in a small proportion of participants who had received the vaccine injection. According to research (Bati et al., 2021), the most common systemic side effects after vaccine administration are fatigue, headache, and muscle aches.

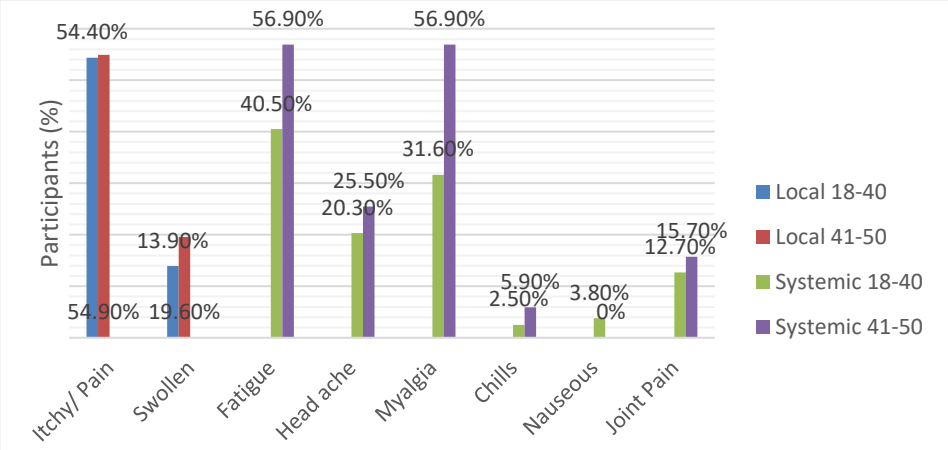

Figure 3. Description of Sinovac® vaccine side effects by age

The results of the research are based on Figure 3. The description of the bad effects of vaccines by age 18–40 years. Itching and pain are the most common adverse effects of the first dose of Sinovac® vaccine injection, affecting more than half of all age groups. Furthermore, the most prominent negative effects are muscle pain and fatigue, which generally occur in those aged 41–50 years.

DISCUSSION

Vaccination, or immunization, aims to make a person's immune system able to recognize and quickly fight bacteria or viruses that cause infection. The goal to be achieved by giving the COVID-19 vaccine is to reduce the death rate and the death rate due to this virus. So far today, the coronavirus has not ended. To suppress the increasing number of cases, the COVID-19 vaccine has been administered. The government also ensures that everyone gets it. It is important to provide safe and effective COVID-19 vaccinations and anticipate the effects that may occur in the community. Vaccines, in general, did not cause a reaction in the human body, or if they did, it was only a mild one. Vaccination triggers immunity by causing the immune system to react to the antigens contained in the vaccine. Local and systemic reactions such as pain at the site of a charge or fever may occur as part of the immune response. The other vaccine components (e.g., adjuvants, stabilizers, and preservatives) may also trigger reactions. A quality vaccine causes a mild reaction but still triggers the best immune response.

In this study, the Sinovac® vaccine was well received in all age groups (18–50 years) without severe adverse effects. The most common post-vaccination bad effects were itching and pain in 71 people (54.6%), followed by systemic bad effects, namely fatigue/malaise in 61 people (46.9%) and muscle pain/myalgia in 41.5%. A similar vaccine, Sino-pharm, was tested in China and did not report fatigue, headache, fever, and muscle aches but reported 14.3% local pain and 2.4% dem. 10 Variation in side effects may be due to context and population differences. Vaccination trials are underway in limited countries, including Europe, the United States, Australia, and China, so further evaluation should be carried out in other contexts and different age groups. Clinical trials were conducted in the UK with AstraZeneca® and side effects were analyzed; 70% of participants reported fatigue, 68% of headaches, 60% of muscle aches, and 51% reported feeling feverish. Another study conducted in the United States with BioNTech-Pfizer found that 83.3% of participants reported post-vaccination fatigue and all participants experienced localized headaches and pain. This finding supports some of the side effects that the Sino-pharm and Sinovac® vaccinations can cause, and it is supported by the fact that none of the participants experienced symptoms of SARS-CoV-2 infection during the trial. Therefore, the inactivated Sinovac® vaccine in the current study exhibits a relatively better safety profile compared to other available vaccines. However, this comparison should be concluded with more caution because some studies still use respondents under 1000 people, and there are still some studies reporting serious side effects. Some bad effects are common with most vaccines and usually mimic the symptoms of the coronavirus. The literature shows a fairly low incidence of bad effects with Sino-pharm and Sinovac® vaccines (Tanriover et al., 2021). This study has many exclusion criteria; therefore, the effect of this vaccine on the wider population needs to be considered.

Researchers around the world have invested enormous resources in the development of effective vaccines. There are very positive reports of phase III clinical trials in efficacy and safety conditions. But approved vaccines will face challenges in that the general public will be skeptical of more widespread adoption of the vaccine because of its novelty. As per initial reports, 82% of the population in certain regions must be vaccinated to develop herd immunity, but experts acknowledge that there is

widespread doubt about the vaccine's effectiveness. There have been no serious effects reported. This study would help reduce vaccine doubt. Many countries around the world have reported high levels of vaccine doubt in early studies. The findings of this study will help researchers, health specialists, and the general public to get a safe COVID-19 vaccination without anxiety because it contains minimal bad effects (Abbas et al., 2021).

The limitation of this study is the very small sample size. Based on the small sample size, it was difficult to infer a bad effect profile from the COVID-19 vaccination. In addition, the results of this study were carried out only in patients inoculated with the Sinovac® vaccination. Therefore, analyses of other available vaccinations could not be evaluated.

The incidence of systemic bad effects in the first dose of Sinovac® vaccine was common among male respondents (39.3%), while women were 39 people (52.7%), followed by headaches in the male gender. Muscle pain with male gender 18 people (32.1%), female 36 people (48.6%), fever with type 1 person (1.8%), 4 women (5.4%), nausea with 2 male sex (3.6%), 1 female (1.4%), and joint pain with sex 8 people (14.3%), women 10 people (13.5%).According to research (Bati et al., 2021), the most common systemic side effects are fatigue, headaches, and muscle aches. There were 95 respondents of the male sex who experienced bad effects, while there were 167 respondents of the female sex. The Centers for Disease Control (CDC) says women tend to have stronger side effects from the COVID-19 vaccine than men. This is common with vaccinations because the estrogen in a woman's body is designed to elicit a stronger immune response. A report released by the CDC found that of the first 13.8 million doses of the COVID-19 vaccine given to Americans, On the other hand, women have more reports of side effects than men. Experts suspect that in women, especially postmenopausal women, estrogen levels help activate the immune response to disease and therefore, to vaccines. On the other hand, men have more testosterone, a hormone that can dampen or slow down the vaccine response, simply put. Women generally have a stronger response in terms of activating what the vaccine introduces into the body (CDC, 2021).

Based on the age interval of the respondents with the age of the second group, namely the early elderly age of 41–50 years, the most susceptible to symptoms from several injections and systemic side effects. Likewise, research (Rengganis, 2017) stated the aging process of the body's immune system involves many types of cells, starting from lymphoid cell progenitors in the bone marrow and thymus, thymus gland, and non-specific immunity. This process contributes to age-related susceptibility to infectious diseases so that the symptoms become more severe, the duration of illness is longer, and the protective effect of vaccination can be decreased. The decrease in immune response at an older age makes the effect of a vaccine not as good as in younger individuals.

CONCLUSION

Based on the research, it was found that most of the bad effects caused were local effects after giving the first dose of Sinovac® vaccine, namely itching pain in as many as 71 people (54.6%), fatigue in 61 people (46.9%), muscle pain in 54 people (41.5%), and a small proportion experienced nausea. The incidence of systemic bad effects was generally experienced by female participants, with a range of 41–50 years of age. This can be solved with adequate rest, nutritional intake, and the administration of antipyretics if the patients have fever and pain to reduce the symptoms of local and systemic bad effects that occur.

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