

INTENSIVE MONITROING OF SINOVAC VACCINE FOR SAFETY AND EFFICACY AMONG INDONESIAN POPULATION

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ABSTRACT

Objective: To Evaluate intensively patients taking Sinovac-CoronaVac vaccine for the side effects and effectiveness in preventing COVID infection.

Methods: This is a prospective crosssectional study using convenience sampling for all Indonesian populations who received full dose of Sinovac-CoronaVac vaccine.

Results: The efficacy and safety of the Sinovac-CoronaVac vaccine is 96.8%. factors that influence efficacy and safety are side effects with Age, BMI and Gender with p -value<0.05.

Conclusion: There is correlation between side effects of Sinovac-CoronaVac with Age, BMI and Gender for safety and efficacy.

Keywords: Efficacy and safety, Sinovac-corona vac vaccine, Monitoring

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INTRODUCTION

Virus is the smallest living things that cannot see by the eye. A virus named *Sars-Cov-2*, otherwise known as COVID-19 coming from Wuhan, China and hit the world at the end of December 2019. From December 2019 to January 2020 there was a rapid increase cases in Asian countries [1]. According to WHO, they declared on March 11, 2020 COVID 19 as a pandemic. As of October 12, 2021, in Indonesia there were 1,262 new cases, bringing the number of confirmed COVID-19 cases to 4,229,813 and an increase of 47 deaths, bringing the death cases to 142,763 [2]. According to WHO, this virus can spread through liquid particles or droplets that come out when someone coughs, sneezes, talks or breathes [3]. The symptoms of COVID 19 are usually mild and appear gradually even for some individuals when infected are still in good health [4]. The effects of this virus range from mild respiratory distress to directional pneumonia, which then leads to organ failure to death [5]. Due to its increasingly rapid spread, this virus continues to mutate. The variants include Alpha (B.1.1.7), Beta (1.351), Gamma (P.1), Epsilon (B.1.427), Kappa (B.1.617.1), Delta B.1.617.2 variants. and Mu (B.1.621, B.1.621.1) [6] As a preventive measure, the government takes concrete steps to limit all community mobility. Such as social distancing to prevent the spread of the virus. In addition, world researchers are also developing vaccines which are expected to be the right step to control the pandemic and prevent the occurrence of COVID-19 infection.

Vaccine is a biological product that contains antigens which, if given to humans, will trigger the formation of antibodies and cause active immunity in certain diseases. One example is the COVID-19 vaccine that we use. One of the COVID-19 vaccines that we use is the Sinovac

CoronaVac vaccine. CoronaVac is an inactivated whole-virus that developed by Sinovac Life Science and already passed 3 phase of clinical trials in Brazil, Indonesia and Turkey [7]. On June 1, 2021, WHO declared the use of coronavac vaccine as emergency use. WHO's EUL (emergency use listing) provides an opportunity for countries to make agreements to import and manage the COVID 19 vaccine [8]. According to an article, that two shots of sinovac-coronavac vaccine give 94% effectiveness to preventing Covid-19 [9]. Vaccines are expected to increase herd immunity. Herd immunity is when enough people have been vaccinated against the disease and have developed protective antibodies against future infections [10]. The purpose of this research is to evaluate the intensively efficacy and safety of sinovac-coronavac vaccine among Indonesian population.

MATERIALS AND METHODS

This study is an observational study using mixed methods and a prospective cross-sectional study, collecting primary data from Indonesian people who have received the Sinovac-CoronaVac vaccine. The quisionnaire includes personal data, including side effects and the efficacy of the Sinovac-CoronaVac vaccine. This research was conducted within a period of 3 mo (Oct-Dec). For the inclusion criteria were all Indonesian population aged 18 y and above, already received Sinovac-CoronaVac vaccine for full dose, and were willing to be respondents in this research. For the exclusion criteria were Indonesian population who have final stage cancer (stage 3 and 4), HIV/AIDS patients, TB patient, Lupus patient, Pregnant and Breastfeeding patients, under 18 y old will be excluded in this research. Total respondents in this study is 406 respondents.

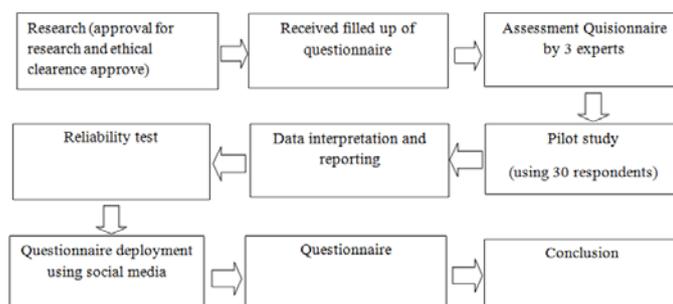


Fig. 1: Framework

Ethical approval

As seen in fig. 1, this research was approved by 17 august 1945 university Jakarta ethics committee with reference number: No.6/KEPK-UTA45]KT/EC/EXP/11/2021.

RESULTS AND DISCUSSION

The number of respondents from this study were 406 respondents who had received 2 (two) doses of the Sinovac-coronavac vaccine and were included in the inclusion criteria. Respondents in this study received questionnaires through social media such as Facebook, WhatsApp, Telegram and Instagram.

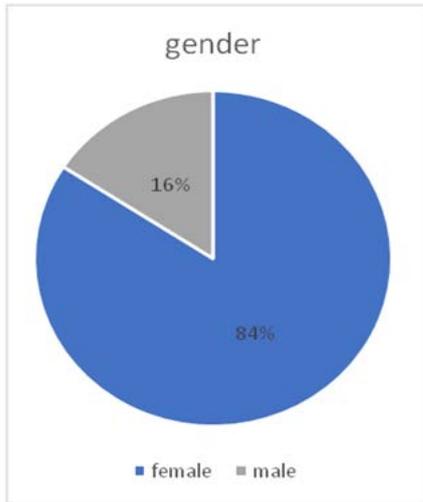


Fig. 2: Participants based on gender

Based on fig. 2 of 406 respondents, 84% (342 respondents) are women and 16% (64 respondents) are men. based on research in Bangladesh 697 respondents who have completed the questionnaire, 53.4% of respondents are male and 46.6% of respondents are female [11].

This research was conducted thoroughly throughout Indonesia. With the following presentation

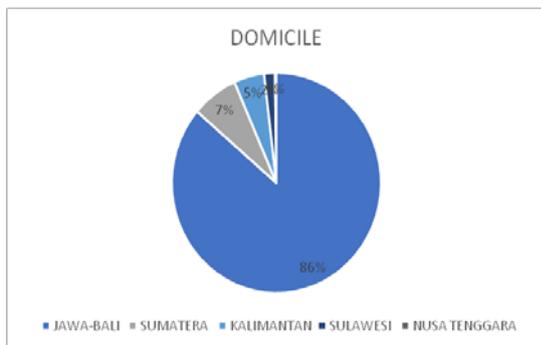


Fig. 3: Participants domicile

Based on fig. 3, there are 86% of respondents from Java-Bali (DKI Jakarta, Banten, Depok, West Java, East Java, Central Java, DI Jogjakarta, Bali), 7% from Sumatra Island (North Sumatra, South Sumatra, West Sumatra, Bengkulu, Riau, Riau Island, Riau, Bandar Lampung, Aceh, Jambi), 5% Kalimantan Island (South Kalimantan, Central Kalimantan, East Kalimantan, West Kalimantan), 1.7% Sulawesi Island (South Sulawesi, North Sulawesi), 0.2% from from nusa southeast (west nusa southeast).

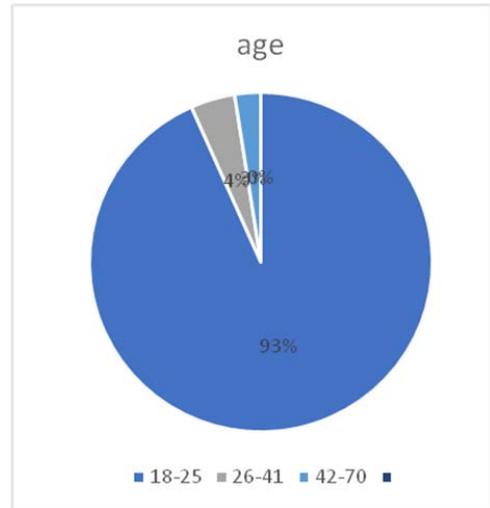


Fig. 4: Participant based on age

Based on fig. 4, 406 respondents were aged 18-70 y with a percentage of 93% for those aged 18-25 y, 4% for those aged 26-41 y and 3% for those aged 42-70 y. Based on research in Malaysia, the age of participants ranging from 18 y-60 y and over [12].

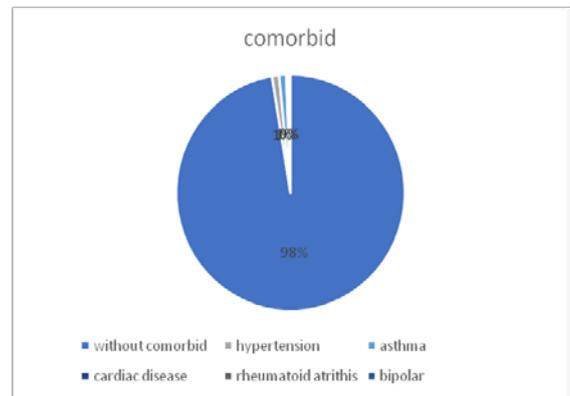


Fig. 5: Based on fig. 5, of the 406 respondents, 98% stated that they did not suffer from any comorbid disease, and the rest of the respondents had been diagnosed by doctors as having hypertension, asthma, cardiac disease, rheumatoid arthritis and bipolar. In one study, 66.6% had no comorbid disease, 25.8% had at least one comorbid disease and 7.6% had at least two or more comorbid diseases [13]

Side effects

Based on table 1 and 2, In this study, the common side effects felt by respondents on the first dose of Sinovac-Coronavac were fever 14.3%, pain at the injection site 79.6%, cough 4.4%, flu 4.7%, nausea 7.4%, diarrhea 2%, dizziness 28.6%, sleepiness 69.5%, pain in the upper arm 70.7%. while at the second dose, the side effects were fever 14.8%, pain at the injection site 77.8%, cough 3.4%, flu 4.7%, nausea 3.9%, diarrhea 1.7%, sleepiness 59.1%, pain in the upper arm 63.3%. other side effects such as an increase in cholesterol 1%, bleeding 0.5% and heart problems 1.5%. From this study found a slight difference with the study on Healthcare workers in Turkey, it was found that 62.5% of them experienced the most common side effects such as pain at the injection site (41.5%), fatigue (23.6%), muscle aches (11.2%), and pain. joints (5.9%) [14] while in a study in Indonesia, 181 people experienced side effects of drowsiness, 144 people experienced side effects of pain in the arms and 66 people experienced side effects of fever [15].

Table 1: Side effects after 1st dose of vaccination

| Variables | Frequency (n=406) | Percentage % |
|--|-------------------|--------------|
| Side effect 1 st dose vaccination | | |
| Fever | 58 | 14.3 |
| Pain in injection site | 323 | 79.6 |
| Cough | 18 | 4.4 |
| Flu | 19 | 4.7 |
| Nausea | 30 | 7.4 |
| Diarrhea | 8 | 2 |
| Dizziness | 116 | 28.6 |
| Sleepiness | 282 | 69.5 |
| Increase in cholesterol level | 2 | 0.5 |
| Hemorrhage | 0 | 0 |
| Cardiovascular events | 0 | 0 |
| Upperlimb pain | 287 | 70.7 |

Table 2: Side effects after 2nd dose of vaccination

| Variables | Frequency (n=406) | Percentage % |
|--|-------------------|--------------|
| Side effect 2 nd dose vaccination | | |
| Fever | 60 | 14.8 |
| Pain in injection site | 316 | 77.8 |
| Cough | 14 | 3.4 |
| Flu | 19 | 4.7 |
| Nausea | 16 | 3.9 |
| Diarrhea | 7 | 1.7 |
| Dizziness | 94 | 23.2 |
| Sleepiness | 240 | 59.1 |
| Increase in cholesterol level | 4 | 1.0 |
| Hemorrhage | 2 | 0.5 |
| Cardiovascular events | 6 | 1.5 |
| Upperlimb pain | 257 | 63.3 |

Table 3: Variables correlation with age

| Variables | Frequency Age (n = 406 Mean = 21.80) | p-value |
|---|---|---------|
| Efficacy 1 st dose vaccination | | |
| Rash | 2 (0.5%) | 0.023 |
| Monitoring 1-6 after vaccination | | |
| Smooth Period 1-3 mo after vaccination | 273 (79.8%) | 0.002 |
| Smooth Period 4-6 mo after vaccination | 294 (85.9%) | 0.001 |

Table 4: Correlation variables with gender

| Variables | Frequency | | p-value |
|--|-------------|----------------|---------|
| | male (n=64) | Female (n=342) | |
| side effects 1 st vaccination | | | |
| Pain at the injection site | 36 | 287 | 0.000 |
| Dizziness | 10 | 106 | 0.015 |
| Pain in upperlimb | 35 | 252 | 0.004 |
| Efficacy 1 st vaccination | | | |
| Headache | 6 | 71 | 0.036 |
| Side effects 2 nd vaccination | | | |
| Pain at the injection site | 41 | 275 | 0.008 |
| Dizziness | 8 | 86 | 0.035 |
| Sleepiness | 30 | 210 | 0.037 |
| Hemorrhage | 0 | 2 | 0.026 |
| Cardiovascular events | 4 | 2 | 0.007 |
| Pain in upperlimb | 24 | 233 | 0.000 |
| Monitoring 1-6 mo after vaccination | | | |
| COVID event 4-6 mo after vaccination | 3 | 2 | 0.030 |
| Smooth period 1-3 mo | 0 | 273 | 0.000 |
| Smooth Period 4-6 mo | 0 | 294 | 0.000 |

Age and side effects

In this study, side effects were also influenced by gender and age. In accordance with the research that has been done, many side effects are felt by those who are in the age range of 21-22 y. See table 3. more side effects were felt by young people compared to the elderly

due to aging of immune cells combined with depletion of T cells through thymic atrophy worsening age-related loss of immunity against new pathogens or vaccines [16] perceived side effects such as rash on the skin 0.5% (p-value 0.023), Based on the study before the results of the 3rd clinical trial, the skin rash reaction felt by the respondent could occur due to hypersensitivity to either the active

vaccine component or one of the other components [17] As for monitoring 1-6 mo after the vaccine was found, the women who had a smooth menstrual cycle at 1-3 mo after the vaccine were 79.8% (p-value 0.002) and also had a smooth menstrual cycle at 4-6 mo after the vaccine was 85.9% (p-value 0.001) the rest were those who answered "don't know (male)" and answered "no" because their menstrual cycles were not smooth after vaccination. In one study, it was not found that the COVID-19 vaccination caused changes in the menstrual cycle, in the study, it was stated that the menstrual cycle returned to normal after vaccination [18].

Gender and side effects of corona vac

Based on table 4, another risk factor is gender. In this study, it appears that female feel more side effects than male. From 406

respondents reported that female had significantly feel of side effects 1st dose such as pain at the injection site (4.8%; p-value 0.000), dizziness (30.99%; p-value 0.015), pain in upperlimb (73.68; p-value 0.004), significantly feel efficacy after 1st dose which is headache (20.76%; p-value 0.036). female had significantly feel side effects after 2nd dose such as pain at injection (80.40%; p-value 0.008), dizziness (25.24%; p-value 0.035), sleepiness (61.40%; p-value 0.037), hemorrhage (0.05%; p-value 0.026), pain upperlimb (68.12%; p-value 0.000) This proves that in a study in Saudi Arabia, women were more experience side effects compared to men due to psychosocial and biological factors such as hormones [19] In a 2019 study, women experienced more side effects from vaccination because women had higher cytokine and antibody responses than men after get flu vaccine [20].

Table 5: Side effects 1st dose vaccination and monitoring 1-6 mo after vaccination

| Variables | Frequency BMI (n= 406 Mean =21.87) | p-value |
|---|---------------------------------------|---------|
| Side effects 1 st dose vaccination | | |
| Pain at injection site | 323 (79.55%) | 0.017* |
| Monitoring 1-6 mo after vaccination | | |
| Smooth Period 1-3 mo after vaccination | 273(67.2%) | 0.028** |
| Smooth Period 4-6 mo after vaccination | 294 (72.41%) | 0.014** |

In addition to gender and age, there is also BMI (Body Mass Index) which can affect side effects. See table 5. From this study, individuals who experienced side effects of pain in the injection area were 79.55% (p-value 0.017), and at monitoring 1-6 mo after the vaccine, there were 67.2% (p-value 0.028) female respondents who experienced smooth menstruation 1-3 mo after the vaccine and 72.41% (p-value 0.014) of respondents Women who felt smooth menstruation 4-6 mo after the vaccine. to date there are no studies that prove BMI affects the side effects of the COVID-19 vaccination. In one study, it was stated that BMI affects the menstrual cycle. The results were 75.51% of women with a BMI of 14-24.9 had smooth menstrual cycles, while 16 women with a BMI of 25-29.9 had irregular menstrual cycles [21].

CONCLUSION

The side effects experienced by respondents who received the full dose of Sinovac vaccine were common side effects such as pain at the injection site, fever, drowsiness and pain in the upper limbs. and the efficacy and safety of the Sinovac-CoronaVac vaccine was 96.8% seen from those exposed to covid at dose 1 as many as 13 people from 406 respondents (96.8%) and those exposed to covid at dose 2 as many as 13 people from 406 respondents (96.8%).

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Nil

AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICT OF INTERESTS

Declared none

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