Evaluation the Effectiveness of AstraZeneca's COVID-19 Vaccine After 6 Months of the Second Dose

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Abstract: Growing efforts are being made to socialize the vaccination program in order to establish a global herd immunity. In clinical trials of strategy and development, the astrazeneca vaccine's efficacy is a crucial concern. The purpose of this study was to evaluated the effectiveness of Astrazeneca's Covid-19 vaccine after 6 months of the second dose. This study was conducted to evaluate the effectiveness of the Astrazeneca vaccine after 6 months of the second dose in Indonesian people. This type of research is observational with a cross sectional design. This method is done by direct observation of the survey data. This research requires ethical approval No.40/KEPK-UTA45JKT/EC/EXP/07/2022. The results of this study showed that there was a significant relationship between sociodemography and the incidence of COVID-19 infection after administration of the AstraZeneca vaccine such as gender, age, and BMI. The most common side effect of receiving AstraZeneca is pain at the injection site. The effectiveness of the astrazeneca vaccine can be seen from the average not exposed to covid-19, which is 95% where the Covid-19 vaccine in this study is safe for gender and age > 18 years.

1 INTRODUCTION

The respiratory condition known as Coronavirus 2019 (covid-19) is brought on by the pandemic-causing severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (Vesselaldo & Ramatillah, 2022). Chinese health officials alerted the WHO towards the end of 2019 about unidentified pneumonic cases in Wuhan, Hubei Province, China. At early January, throat swab sample from a patient led to the discovery of a novel coronavirus (ncov-2019). The pathogen is then given the names coronavirus disease 2019 (Covid-19) by WHO and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by coronavirus study group. (Harapan et al., 2020).

The incubation period for COVID-19 is between 1-14 days, ranging from 3 to 7 days. The most common symptoms in mild to moderate patients are fever, fatique, and a dry cough accompanied by other symptoms such as headache, nasal congestion, sore throat, muscle aches, and joint pain (Yang et al., 2020). Until January 2022 SARS-CoV 2, virus that started the COVID-19 pandemic, had already killed more than 5.5 million people. One of the current vaccine which is one of the most popular treatments available for the Covid-19 pandemic is an adenoviral vector based vaccine (Barin et al., 2022).

The astrazeneca vaccine was created by the University of Oxford and clinical trials were conducted in the UK, Brazil and South Africa (Voysey et al., 2021). A vaccine called Astrazeneca was created using a genetically altered virus (viral vector). This type of vaccine functions by encouraging or inducing the body to develop antibodies that fight infection with the SARS-CoV-2 virus (Pane, 2021). The decline of serum SARS-CoV-2 antibodies has been brought up questionable long-term immunity, which have been linked to breakthrough infections and led to the consideration of extra booster doses of the vaccine (Padoan et al., 2022).

Study conducted by scientists at King's College London showed that protection from a full-dose Astrazeneca Covid-19 vaccine dropped within 6

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months. Protection 1 month after the second dose of Astrazeneca vaccine drops from 77% to 67% after 4 to 5 months (Sorongan, 2021).

According to research by The BMJ Covid-19 booster vaccines: What we know and who's doing what that immunity is indeed reduced, especially against the delta variant (Mahase, 2021). Researchers found that a single dose of the Oxford-Astrazeneca vaccine was only about 30% effective against delta, although two doses were more effective: 67% for Astrazeneca (Mahase, 2021b). In an experimental study, antibody responses to a single dose of Astrazeneca (AZ) (ChAdOx1 nCoV-19) vaccine (Astrazeneca, Lund, Sweden) using five SARS-CoV-2 antibody tests showed that seroconversion rates after the first vaccination ranged from 66.2% up to 92.5%, which is consistent with previous studies (Jeong et al., 2021).

Although data relating to the effectiveness of the astrazeneca vaccine already exist. Further clinical research is needed on the Evaluation of the Effectiveness of the Astrazeneca Covid-19 Vaccine after 6 months of the second dose, by looking at various other aspects such as sociodemography that allows for an association with the efficacy and side effects of the astrazeneca vaccine.

2 METHOD

2.1 Design

This study used mixed methods and a prospective cross-sectional study by collecting primary data from Indonesian people who had received the complete dose of Astrazeneca vaccine. This research was conducted over a period of 4 months (April-July). For inclusion criteria, all Indonesian people aged >18 years who have received the second dose of AstraZeneca vaccine for more than 6 months and are willing to be respondents in this study. The exclusion criteria for all Indonesian people with cancer, HIV/AIDS patients, TB patients, autoimmune patients (lupus patients) and less than 6 months of the second dose will be excluded in this study.

2.2 Participant

Participants in this study were Indonesian people >18 years old who had received the complete dose of AstraZeneca vaccine with a total of 310 respondents.

2.3 Instrument

This study used questionnaires distributed through social media (WhatsApp, Facebook, Instagram, Telegram and Twitter). The total number of questionnaires in this study were 62 of identity questions and comorbidities. 62 of these questions were about side effects received after the first and second doses of vaccination short-term and long-term and monitoring of side effects from the vaccine for 1-6 months after being vaccinated.

2.4 Statistic Analysis

The collected results were analyzed using SPSS version 25 application. Fisher, Chi-Square, Mann-Whitney, and Kruskal Wallis tests were used to find associations between risk factors (gender, age, BMI) and side effects. A p-value of 0.05 was considered significant.

2.5 Ethical Approval

This study was reviewed and approved by the University Ethics Committee 17 August 1945 on 26 July 2022 (No.40/KEPK-UTA45JKT/EC/EXP/07/2022).

3 RESULT

3.1 Demographic Characteristic

This study was conducted based on demographic status, namely gender as many as 310 respondents in this study consisted of 73 men (23.5%), and 237 women (76.5%) with an age range of 18-25 years 225 (72.5 %), 26-40 years 76 (24.3%), 41-50 years 5 (1.5%) and 51-57 years 4 (1.2%). Respondents are also spread across several parts of Indonesia, around 10.0% from Sumatra, 85.2% from Java, 3.9% from Kalimantan, 0.3% from Papua, and 0.6% from Sulawesi. Based on comorbid diseases, most of the respondents in this study 289 people (93.2%) did not have comorbid diseases, 5 people (1.6%) with comorbid diabetes, 2 people (0.6%) hypertension and the last 14 people (4.5%) Asthma. (Table 1).

Table 1. Demographic characteristic (N=310).

Variables	Frequency	Percentage (%)
Gender		
Male	73	23,5%
Female	237	76,5%
Age		
18-25	225	72,5%
26-40	76	24,3%
41-50	5	1,5%
51-57	4	1,2%
Domicile		
Sumatera	31	10,0%
Jawa	264	85,2%
Kalimantan	12	3,9%
Papua	1	0,3%
Sulawesi	2	0,6%
Comorbidity		
Diabetes	5	1,6%
Hypertension	2	0,6%
Asthma	14	4,5%

3.2 Side Effect after Vaccination

Table 2: Side Effect after Vaccination.

Variables	Frequency / Persentage (%) 1st dose (n=310)	Frequency / Persentage (%) 2nd dose (n=310)
Side effect 1st dose vaccination		
Fever	182 (58,7%)	109 (35,2%)
Pain in the injection area	233 (75,2%)	188 (60,6%)
Cough	39 (12,6%)	28 (9%)
Flu	60 (19,4%)	37 (11,9%)
Nausea	56 (18,1%)	28 (9%)
Diarrhea	17 (5,5%)	18 (5,8%)
Dizziness	140 (45,2%)	96 (31%)
Sleepiness	156 (50,3%)	130 (41,9%)
Dehydrated	72 (23,2%)	49 (15,8%)
Bleeding	3 (1%)	2 (0,6%)
Pain in the upper arm	200 (64,5%)	136 (43,9%)
Cardiovascular events	10 (3,2%)	7 (2,3%)

Based on table 2, it is known that the common side effects felt by respondents in this study at the first dose of AstraZeneca were fever 58.7%, pain at the injection site 75.2%, cough 12.6%, flu 19.4%, nausea 18,1%, diarrhea 5.5%, dizziness 45.2%, feeling sleepy 50.3%, thirst or dehydration 23.2%, bleeding 1.0%, upper arm pain 64.5%, and cardiovascular 3.2 %. In the second dose, the side effects were fever 35.2%, pain at the injection site 60.6%, cough 9.0%, flu 11.9%, nausea 9.0%, diarrhea 5.8%, dizziness 31%, feeling sick. drowsiness 41.9%, thirst or dehydration 15.8%, bleeding 0.6%, upper arm pain 43.9%, and cardiovascular 2.3%.

3.3 Between Gender and Side Effects

Table 3: Correlation between gender and side effects

Variables	Frequency / Percentage (%) Male (n=73)	Female (n=237)	p-value
Side effects 1st vaccination			
Sleepiness	29 (39,7%)	127 (53,5%)	0,045*
Monitoring 1-3 months after vaccination			
Menstrual problems	0	23 (9,7%)	0,000#
Monitoring 4-6 months after vaccination			
Menstrual problems	0	16 (6,7%)	0,000#

*Fisher test, #Chi-square test

In this study, the variable that had a significant correlation with the side effects that appeared was gender. From a total of 310 respondents, 23.5% of respondents were male and 76.5% were female. The details of the data are presented in table 3. For questions about side effects of fisher's test results and chi-square test results for follow-up 1-3 months and 4-6 months after vaccination.

3.4 Between Age and Side Effects

Another variable that has a significant relationship is age and vaccine side effects. In this study, the overall age of the respondents was 18-57 years. Most of the side effects are felt by those who are at the age of 23 years. Detailed data are presented in table 4. from the results of the Mann-Whitney test for questions about side effects after receiving the vaccine and the results of the Kruskal Wallis test for questions about monitoring side effects after 1-3 months and 4-6 months after vaccination. In accordance with research that has been done, many side effects are felt by those who are at the age (median: 23 years).

3.5 Between BMI and Side Effects

The last variable that correlates is BMI. In this study, individuals who experienced side effects of fever (p = 0.035) and loss of smell (p = 0.013) with an average BMI (Body Mass Index) of 21.

Table 4: Correlation between age and side effects.

Variables	**Frequency**	**p-value**
	Age (n:310 median: 23)	
Side effects 1st vaccination		
Nauseous	56 (18,1%)	0,040*
Covid-19 infection after 1st dose		
Cough and Sore Throat	63 (20,3%)	0,001*
Headache	104 (33,5%)	0,029*
Covid-19 infection after 2nd dose		
Cough and Sore Throat	44 (14,1%)	0,011*
Monitoring 1-3 months after vaccination		
Infected with Covid-19	11 (3,5%)	0,039#
Menstrual problems	24 (7,7%)	0,001#
Heart problems	6 (1,9%)	0,011#
Monitoring 4-6 months after vaccination		
Menstrual problems	16 (5,1%)	0,001#

*Mann-whitney test, #Kruskal wallis test

Table 5: Correlation between BMI and side effects.

	Frequency / Persentage (%)	
Variables	**BMI (n:310 median 21)**	**p-value**
Side effects 1st vaccination		
Fever	21 (6,7%)	0,035*
Side effects 2nd vaccination		
Loss of smell	13 (4,1%)	0,013*

*Mann-whitney test

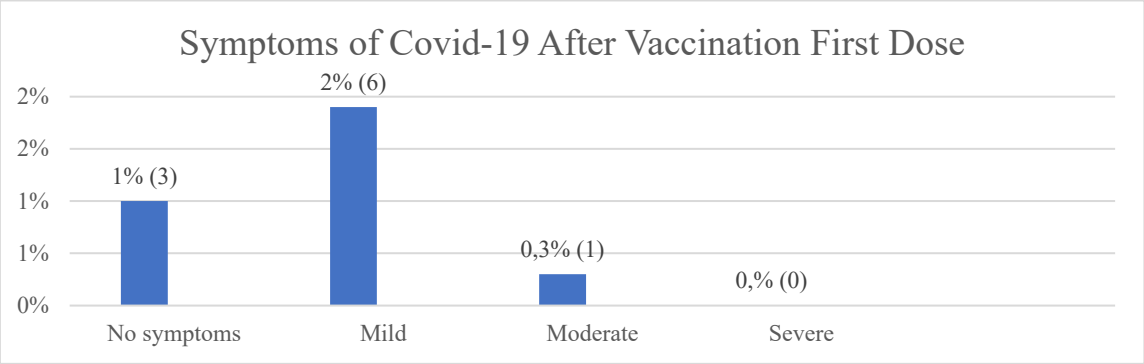

Figure 1: Symptoms of Exposure to Covid-19 1st Dose.

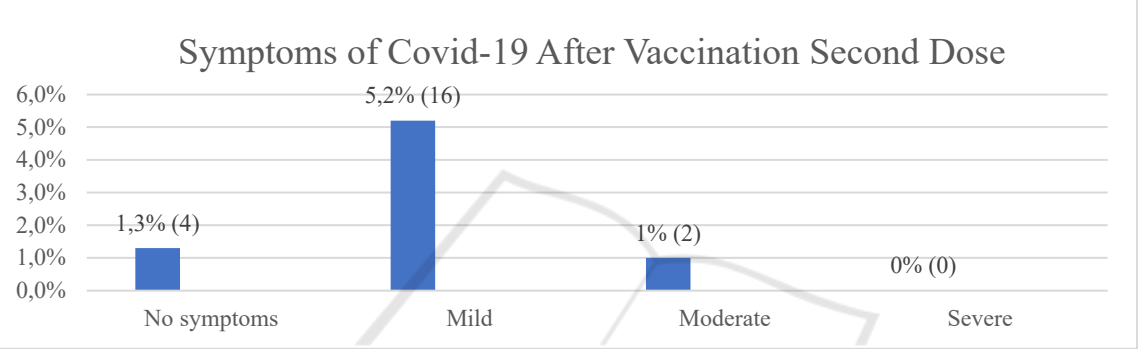

Figure 2: Symptoms of Exposure to Covid-19 2nd Dose.

3.6 The Wffectiveness of the AstraZeneca Vaccine Based on the Symptoms of Exposure to Covid-19

Based on Fig 1 and 2. above, it can be seen that most of the respondents in this study were not exposed to COVID-19 after the first dose of AstraZeneca vaccination as much as 97%, asymptomatic 1%, mild symptoms 1.9%, moderate symptoms 0.3%, and 0% respondents with severe symptoms. 93% were not exposed to covid-19 after the second dose of AstraZeneca vaccination, 1.3% asymptomatic, 5.2% mild symptoms, 1% moderate symptoms, and 0% of respondents with severe symptom.

4 DISCUSSION

4.1 Vaccine Side Effects

This study involved 310 people who were fully vaccinated, participants received a questionnaire that they experienced the side effects of the vaccine. As shown in Table 2 of this study found a slight difference with the study in Vietnam, it was found that the most common side effects were fever (69.4%), muscle aches (68.6%), fatigue/drowsiness (62, 5%), body aches (59.4%), headache (58.3%) and chills (45.7%) (Tran et al., 2020). Whereas in another study from Saudi Arabia reported some side effects such as fatigue (90%), injection site pain (85%), fever (66%), and headache (62%) (Alhazmi et al., 2021). The side effect that is most commonly felt is pain in the injection area, this is in accordance with previous research conducted in Ethiopia which described that the most common local effect was pain at the injection site (65.48%) (Solomon et al., 2021).

4.2 Correlation Between Gender and Vaccine Side Effects

There was a significant difference between the side effects felt by the patients and gender. As it was found that female vaccine recipients had more side effects than male vaccine recipients. 53.3% of female respondents experienced side effects of feeling drowsy after receiving the first dose of vaccine, while 39.7% for males. For monitoring 1-3 months after vaccination it was found that 9.7% of women who received the vaccine experienced a change in their menstrual cycle, while for monitoring 4-6 months

after vaccination it was found that 6.7%. See table 3. Females experience side effects more than males. Out of 310 respondents reported that women experienced significant side effects of the first dose such as feeling drowsy (53.5% ; p-value 0.045) this proves that women generally have a greater level of antibody response to viruses, infections and vaccinations (Scully et al., 2020).

4.3 Correlation Between Age and Vaccine Side Effects

As the data in table 4 shows, age has an impact on vaccine side effects. The findings of this study are in accordance with research that has been done, many side effects are felt by those who are at the age (median: 23 years). These results are in agreement with a study conducted on Bangladeshi population that reported side effects were much greater in young adults than in older adults (p = 0.02) (Jahan et al., 2021). In Hamed Zare's study on health workers in Iran the frequency of side effects such as injection site pain, fatigue, headache and fever was higher in those under 40 years of age (Zare et al., 2021). This phenomenon is interpreted using the concept of immunosenescence which refers to the decline in the function of the immune system with increasing age (Ramasamy et al., 2020).

4.4 Correlation Between BMI and Vaccine Side Effects

The last variable that correlates with side effects and vaccine efficacy is BMI. In this study, individuals who experienced side effects of fever (p= 0.035) and loss of smell (p=0.013) with an average BMI (Body Mass Index) of 21. Vaccine recipients with a BMI <25 had a higher risk of experiencing side effects from the vaccine Covid-19 (Sutardi & Ramatillah, 2022).

4.5 The Effectiveness of the AstraZeneca Vaccine based on the Symptoms of Exposure to Covid-19

In Figures 1 and 2 of this study, the average 310 respondents who were exposed to COVID-19 after the first dose of vaccination were 3.3%, and 7.5% exposed to Covid-19 after the second dose of vaccination. The results of this study prove that the effectiveness of the complete dose of AstraZeneca vaccine can reduce the risk and prevent COVID-19 by up to 94%. A study conducted in the United States in a phase III trial found that the vaccine produced by the University of Oxford (AstraZeneca) was 79% effective in preventing symptoms of COVID-19 and 100% effective in preventing serious illness and hospitalization (Boytchev, 2021).

5 CONCLUSIONS

The most common side effects is pain in the injection after the first and second doses. The variables that affect the side effects and effectiveness of the vaccine are gender, age and BMI. For gender, female vaccine recipients experienced significantly more side effects than males. The age of the vaccine recipients was dominated by the age of 23 years who experienced side effects after vaccination. As for BMI, it was found that vaccine recipients who have BMI < 25 had a higher risk of experiencing side effects. The effectiveness of the astrazeneca vaccine can be seen from the average not exposed to COVID-19, which is 95%. Overall, based on this study the Covid-19 vaccine was safe for gender and age >18 years, in this study no severe side effects or fatal allergic reactions were found in AstraZeneca vaccine recipients.

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