Comparative Evaluation of AEFI (Adverse Event Following Immunization) and Effectiveness of Astrazeneca and Pfizer Booster Vaccines among Indonesia Citizen

Ayu Novita Sari, Liandhajani and Diana Laila Ramatillah Faculty Pharmacy, Universitas 17 Agustus 1945 Jakarta, Indonesia

Keywords: Covid-19, Booster Vaccine, Astrazeneca, Pfizer, AEFI.

Abstract: The booster vaccine was launched amid concerns about the spread of omicron. The booster is effective against the Omicron variant according to the pseudovirus neutralization test. Complete vaccine plus booster can provide up to 91% protection from death or other worst risks from Covid-19. This study was conducted to evaluate the comparison of the effectiveness of the AstraZeneca and Pfizer booster vaccines in the community in Indonesia. This type of research is observational with cross-sectional. This method is done by direct observation of the survey data. The most common side effects of receiving the AstraZeneca and Pfizer booster vaccines are pain at the injection site and pain in the upper arm. This research was conducted using a validated questionnaire with Cronbach alpha = 0,8. The number of respondents in this study was 600 people, 300 recipients of the AstraZeneca booster vaccine and 300 recipients of the Pfizer booster vaccine. Respondents in this study were > 18 years. This research requires ethical approval No. 36/KEPK-UTA45JKT/EC/EXP/07/2022. There is a significant relationsip between socio-demography and AEFI of the AstraZeneca and Pfizer booster vaccine with p-value <0,05. The effectiveness of the Pfizer booster vaccine is 98,3% and the AstraZeneca booster vaccine is 97%.

1 INTRODUCTION

At the end of 2019, an infectious disease emerged which was designated by WHO as "coronavirus disease (Covid-19)" which originated from the city of Wuhan, China. The cause of Covid-19 is the SARS-CoV-2 virus (SanJuan-Reyes et al., 2021). The chronology of the Covid-19 infection, the first case occurred in December 2019. On January 2, 2020, there were 41 confirmed Covid-19 patients. On January 22, 2020 there were 571 cases of Covid-19.

The Chinese National Committee reported the first 17 deaths on January 22, 2020 (Ramatillah et al., 2021). Furthermore, on January 30, 2020, as many as 7734 confirmed Covid-19 in China and 90 other cases have also been reported from all countries, namely Taiwan, Thailand, Republic of Korea, UAE, United States, Philippines, India, Australia, Canada, Finland and Germany (Ramatillah et al., 2021). The high death rate is a problem especially in China. On January 22, 2020, China's National Health Commission reported 17 deaths (Ramatillah et al., 2021).

In Indonesia, there were recorded cases of Covid-19 as of February 17, 2022, namely 63,956 confirmed cases of Covid-19 including 24,678 active cases, 39,072 confirmed cases recovered and 206 cases died (Indonesian covid task force, 2022). The fact is that Indonesian people still do not apply health protocols. Indonesia launches booster vaccine amid concerns about the spread of the Omicron variant (Kompas.com, 2022). Several studies have shown that antibodies to SARS-CoV-2 gradually decrease after the second vaccination. Even at 6 months after vaccination, two-dose mRNA induces long-term immune memory against the variant SARS-CoV-2 (Seki et al., 2022). Complete vaccination plus booster can provide protection up to 91% death or other worst risks from Covid-19 (Kemenkes, 2022). Booster vaccines are safe for healthy adults aged 18 - 59 years. Vaccines are a way to control outbreaks of infectious diseases and a way to reduce the risk of pandemics and epidemics (Seki et al., 2022).

Until 22 February 2022, the number of active Covid-19 cases was 549,431 people with a total of 37,638 COVID-19 patients being hospitalized,

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Comparative Evaluation of AEFI (Adverse Event Following Immunization) and Effectiveness of Astrazeneca and Pfizer Booster Vaccines Among Indonesia Citizen. DOI: 10.5220/0011978400003582

In Proceedings of the 3rd International Seminar and Call for Paper (ISCP) UTA âĂŹ45 Jakarta (ISCP UTA'45 Jakarta 2022), pages 186-192 ISBN: 978-989-758-654-5: ISSN: 2828-853X

consisting of 813 in serious condition and 185 in critical condition (Kemenkes, 2022). Based on an analysis of the number of 17,871 patients who were hospitalized in the period from January 21 to February 22, 2022, the death toll reached 2,489. Most of the patients who died were not fully vaccinated. The risk of death of non-comorbid elderly who received a booster was 0.49%, while the risk of death of non-comorbid elderly who received two full doses of the vaccine was 2.9%, while the risk of death in the elderly without comorbidities who received the full dose of the vaccine was 22.8% (Kemenkes, 2022). The number of deaths in the comorbid group that did not get the complete vaccine was 739 deaths compared to those who received the booster only 20 deaths (Kemenkes, 2022).

Vaccines are a way to control outbreaks of infectious diseases and a way to reduce the risk of pandemics and epidemics (Excler et al., 2021). The occurrence of an adverse reaction to the vaccine indicates that the vaccine is effective and the recognition of the disease increases (Francis et al., 2021). According to the Centers for Disease Control and Prevention (CDC) and other studies, there are several reactions that occur after vaccination, namely injection site symptoms (backache, fatigue, headache, joint pain, body aches, chills, fever and nausea) (Francis et al., 2021).

Symptoms of patients infected with SARS-CoV-2 range from minimal symptoms to heavy breathing with multiple organ failure. On computerized tomography (CT) scans, characteristic opacities of the lung base glass can be seen even in asymptomatic patients. Symptoms of Covid-19 start from 2-14 days of exposure, symptoms include dry cough, fever, and fatigue. In some cases, the symptoms of Covid-19 patients may include pain, nasal congestion, diarrhea, loss of smell and chills (Al-Awwal et al., 2022).

Vaccines are a way to control outbreaks of infectious diseases and a way to reduce the risk of pandemics and epidemics (Excler et al., 2021). The Pfizer vaccine uses RNA or genetic code to make body cells produce specific spikes for the coronavirus (Health AGD, 2022). Astrazeneca-Oxford is an adenovirus viral vector vaccine (Francis et al., 2021). The viral vector vaccine uses an adenovirus-based safe vector that does not cause disease, but can function as a vector to deliver the genetic material of the Covid virus to host cells. The host cell creates a copy of the corona virus protein (spike protein) making an immune response, producing Tlymphocytes and antibodies against viral antigens (spike protein) (Shekhar et al., 2021).

After the first and second doses, the immune

response slowly decreases. The second dose causes a second, larger immune response, which gradually declines over time. However, a large number of memory B cell pools (with higher affinity for antigen affinity maturation) are left behind, favoring a broader and faster stage of the immune process against the same pathogen in the future (Shekhar et al., 2021).

A third or subsequent dose of the Covid-19 vaccine has the potential to increase titers of neutralizing antibodies against SARS-CoV-2 and its variants, particularly in immunocompromised individuals or individuals with underlying comorbidities or who are at increased risk of COVID-19 exposure and transmission. However, it is imperative to apply appropriate use criteria for the third or subsequent doses of the Covid-19 vaccine without jeopardizing global vaccination efforts and further exacerbating global vaccine inequities (Shekhar et al., 2021).

2 MATERIALS AND METHODS

2.1 Design

This research uses mixed methods and prospective cross-sectional study. This research was conducted 3 months (May July). The data for collection technique was carried out using a survey method using google form which will later be distributed through social media to all Indonesian people who have carried out booster vaccinations with the Astrazeneca and Pfizer booster vaccines using the convenience sampling method. The method is carried out by direct observation of the survey data. The purpose of this survey method is to measure the output value and to find out how the AEFI and the effectiveness of the Astrazeneca and Pfizer booster vaccines in people aged >18 years. The instrument used in this study was a questionnaire used to collect research data and was made based on existing references.

2.2 Instrument

This research was conducted using a validated questionnaire with Cronbach alpa = 0,8 and it distributed through social media (WhatsApp, Facebook, Instagram, Telegram, and Twitter). Data collection was carried out from May to July 2022. The data collected were 600 respondents during the study. Only 600 respondents fulfilled the criteria inclution.

Reserch (approval of Conclusion research and ethical approval) Ouestionnare deployment using Questionnare social media Questionnare Assement of deployment using questionnaire by social media expert Questionnare valid Pilot Study (30 and reliable with respondens cronbach alpha 0,8 Received up of Validity and questionnare reliability test Figure 1. Research Framework.

2.3 Statistical Analysis

3 RESULT AND DISCUSSION

3.1 Result

Based on table 1. It shows that most of the respondents in this study were female with a percentage of Astrazeneca vaccine booster recipients 65,3% while men with a percentage of 34,6%. while women recipients of Pfizer booster vaccine with a percentage of 68.3% and men with a percentage of 31.6%. The same as the research of Araminda et al. that reported women were predominant than men it was found that the majority of respondents were women than men (Araminda & Ramatillah, 2022).

Table 1: Gender.

Variab	Astrazenec	Pfizer
el	a n=300	n=300
Male	104/34,	95/31,6
	6	
Female	196/65,	205/68,3
	3	

As many as 600 respondents who filled out the questionnaire, the age of 18-25 years old recipients of the Astrazeneca booster vaccine was 161 people with a percentage of 53,6%, and 181 people who received the Pfizer booster vaccine with a percentage of 60,3%. There were 118 people aged 26-40 years who received the Astrazeneca booster vaccine with a percentage of 39,3% and 109 people who received the Pfizer booster vaccine, with a percentage of 36,3%. Ages 41-50 years were recipients of the Astrazeneca booster vaccine with a percentage of 4,6% and the recipients of the Pfizer booster vaccine were 1,3%. Ages 51 - 67 years are recipients of the Astrazeneca booster vaccine with a percentage of 3% while the Pfizer booster vaccine recipients are 2%. the age between 26-40 years is a productive society. Their work requires vaccination before they come to the office. we can see people who have been vaccinated are around 18-40 years old. Booster vaccine recipients in Indonesia are over 18 years of age and over (kemenkes, 2022a). The priority target recipients of the booster vaccine are the elderly (kemenkes, 2022a).

Table 2. Age.

Age	Astrazeneca n=300	Pfizer n=300
18 – 25 years	161/53,6%	181/60,3 %
26 – 40 years	118/39,3%	109/36,3 %
41 – 50 years	14/4,6%	4/1,3 %
51 – 67 years	9/3%	6/2%

This research was conducted throughout Indonesia, namely Java with a percentage of 88.33%, Sumatera at 7.67%, Kalimantan at 3.00%, Bali at 0.67%, and Sulawesi at 0.33%. The Covid-19 booster vaccination on August 3, 2022 for the category of people and the elderly, namely Java 30,062,042 with a percentage of 31.76%, Bali as much as 1,467,027 with a percentage of 55.72%, Kalimantan 2,152,076 with a percentage of 22.66%, Sulawesi 1,317,983 with a percentage of 12.25%, and Sumatra 7,752,729 with a percentage of 23.83% (kemenkes, 2022b). Comparative Evaluation of AEFI (Adverse Event Following Immunization) and Effectiveness of Astrazeneca and Pfizer Booster Vaccines Among Indonesia Citizen



Figure 2. Prevalence Domicile.

3.1.1 Adverse Event Following Immunization

Table 3: Adverse Event Following Immunization.

Variable	Frekuensi/Persentage (n=600)
Fever	266/44,3%
Pain at the injection	401/66,8%
site	
Cough	64/10,6%
Flu	95/15,8%
Nauseous	50/8,3%
Diarrhea	37/6,1%
Dizzy	214/35,6%
Drowsiness	287/47,3%
Thirst or	96/16%
dehydration	
Bleeding	4/0,6%
Pain in the upper	292/48,6%
arm	
Heart problems	10/1,6%

Based on table 3. the common AEFIs felt by respondents after the Astrazeneca and Pfizer booster vaccines were fever 44.3%, pain in the injection area 66.8%, cough 10.6%, flu 15.8%, nausea 8.3%, diarrhea 6 .1%, dizziness 35%, drowsiness 47.3%, thirst or dehydration 16%, bleeding 0.6%, pain in the upper arm 48.6% and heart problems 1.6%.

Table 4.	Correlation	between	gender	and AEFI.
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	Male		Fen	nale	p-value
Variable	(n=19	9)	(n=4	401)	
	Astrazene	Pfizer	Astra	Pfizer	
	ca		zenec		
			а		
Fever after	40/20,1%	34/17	96/23	98/24	0,015*
booster		,0%	,9%	,4%	
vaccine					
Sleepy after	14/7,0%	25/12	58/14	60/14	0,010*
booster		,5%	,4%	,9%	
vaccine					
Diarrhea	4/2,0%	3/1,5	13/3,	22/5,	0,017*

after		%	2%	4%	
booster					
vaccine					
Headache	11/5,5%	22/11	44/10	56/13	0,022*
after		,0%	,9%	,9%	
booster					
vaccine					
Monitoring	0	0	19/4,	11/2,	0,000#
after 1			7%	7%	
month of					
booster					
vaccine for					
menstrual					
problems					

*Fisher Test #Chi Square Test

Table 4. shows that there are more women than men. AEFI in women is more dominant than men. Such as fever after booster vaccine in women with Astrazeneca booster vaccine by 23,9% and Pfizer recipients by 24,4%, while men with astrazeneca booster vaccine by 20,1% and Pfizer booster recipients by 17,0%. women experienced fever after the Astrazeneca booster vaccine with a percentage of 14,4% and 14,9% of the recipients of Pfizer booster, while men recipients of Astrazeneca booster with percentage 7,0% and recipients of Pfizer vaccine 12,5%. 3,2% of female respondents who received Astrazeneca booster vaccine and 5,4% of the respondents who received the Pfizer booster vaccine recipients had diarrhea. While on male recipents are 2,0 of Astrazeneca booster vaccine and 1,5% of Pfizer booster vaccine recipents. Female respondents who experienced headache are 10,0% of Astrazeneca vaccine booster recipents and 13,9% of Pfizer vaccine booster recipents. While on male recipents the percentage are 5,5% of Astrazeneca booster vaccine recipents and 11,0% of Pfizer booster vaccine recipents. Female respondents who experienced a change in their menstrual cycle are 4,7% of Astrazeneca vaccine booster recipents and 2,7% of Pfizer vaccine booster recipents.

3.1.2 Correlation Between Age and Vaccine AEFI

Variable	Astrazeneca n=300 (median=	Pfizer n=300	p- value
		//	
Cough and	113/37,6%	101/33,6%	0,025
sore throat			*
after booster			
vaccine			
Fever after	155/51,6%	132/44%	0,041
booster			*
vaccine			

Table 5. Correlation Between Age and Vaccine AEFI.

Monitoring after 1 month of booster vaccine				
Menstrual	19/6,3%	11/3,6%	0,000 #	
problems				
Tired easily	35/11,6%	31/10,3%	0,009 #	
Pain in the	40/13,3%	41/13,6%	0,003 #	
arm				
Thirst or	28/9,3%	31/10,3%	0,037 #	
dehydration				
Heart	5/1,6%	5/1,6%	0,002 #	
problems				

*Mann-whitney, #Kruskal Wallis Test

Table 5. shows that the perceived AEFIs include cough, sore throat, and fever. The average age in this study was 26.4. From the results of the study, the AEFI of old age is felt to be less than that of yaoung age. Meanwhile, the AEFI felt by Astrazeneca booster vaccine recipients such as cough and sore throat was 37,6% and fever was 51,6%. while 33,6% of Pfizer booster vaccines received had cough and sore throat and 44% had fever.

3.1.3 Correlation Between BMI and Vaccine AEFI

Table 6. Correlation Between BMI and Vaccine AEFI.

Variable	Astrazeneca	Pfizer	P-value
	n=300	n=300	
	Median	= 21	
Cough	36/12%	28/9,3%	-0,017*
after		-	
booster			
vaccine	NCE A		
Diarrhea	27/9%	10/3,3%	0,027*
after			
booster			
vaccine			
Covid-19	9/3%	5/1,6%%	0,024*
infection			
after 1			
month of			
booster			
vaccine			
Monitoring	19/6,3%	11/3,6%	0,000#
after 1			
month of			
booster			
vaccine for			
menstrual			
problems			

*Mann-whitney Test, #Kruskal Wallis Test

Based on table 6. BMI (Body Mass Index) also affects AEFI with p-value <0.05. Respondents who received the Astrazeneca booster vaccine experienced AEFI cough and diarrhea with a percentage of 12% and 9% respectively. while the recipients of the pfizer booster vaccine who experienced cough and diarrhea with a

percentage of 9,3% and 3,3%. Covid-19 infection after 1 month of Astrazeneca booster vaccine was 3% and menstrual problem by 6,3%. While 9,3% of the recipents of Pfizer booster vaccine experienced AEFI of cough and 3,3% experienced diarrhea.

3.1.4 Relationship between Vaccine Types and AEFI

Variable	Astrazeneca	Pfizer	P-value
	n=300	n=300	
Flu after	57/19%	38/12%	0,044*

Table 7. Relationship between vaccine types and AEFI.

variable	n=300	n=300	P-value
Flu after booster vaccine	57/19%	38/12%	0,044*
Diarrhea after booster vaccine	25/8,3%	12/4%	0,040*
Skin rash after booster vaccine	46/15,3%	27/9%	0,024*

*Mann-whitney

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Table 7. show that the AEFI of Astrazeneca booster vaccine such as fluwhit percentage of 19%, diarrhea 8,3%, and skin rashes 15,3%. Meanwhile AEFI of Pfizer booster vaccine such as flu whit a percentage of 12%, diarrhea 4%, and skin rashes 4,5%.

3.1.5 Effectiveness of Astrazeneca and Pfizer Booster Vaccines Based on **Exposure to Covid-19 After Booster** Vaccination



Figure 3. Exposure to covid-19.

From the results of the study, it is known that the effectiveness of the vaccine is seen from the number of people exposed to Covid. Among total 600 respondent, 300 respondents recipients booster vaccine and 300 recipients of Pfizer booster vaccine. After the Astrazeneca booster vaccine, 9 respondent were exposed to Covid-19 and 5 respondents who received the Pfizer booster vaccine were exposed to Covi-19 after vaccination.



Figure 4. Effectiveness vaccine.

From the results of this study, the effectiveness of the Pfizer booster vaccine was 98,3% and the Astrazeneca booster vaccine was 97%.

3.2 Discussion

Based on the results of this study, similar to that of David Hillus et al., it was found that the most frequently felt AEFIs were pain at the injection site and tenderness. Local reactions are usually mild to moderate. No major differences were observed in the frequency or severity of local reactions after the primary or booster vaccine, except of a slightly higher frequency of local reactions after the heterologous Astrazeneca – Pfizer booster vaccination compared with the homologous Pfizer booster vaccine. The frequency of local reactions was lower after homologous Astrazeneca booster vaccination than after heterologous Astrazeneca– Pfizer vaccination (Hillus et al., 2021).

AEFI and vaccine effectiveness were not related because there was no significance between the two variables. In other studies, there is no evidence that AEFIs affect the effectiveness of vaccines.

Gender has a p-value <0.05 which means it has a significant relationship with AEFI. According to research, because of psychological factors, AEFI in women in the form of pain is higher than in men (Alghamdi et al., 2021). According to another study, women produce antibody titers after vaccination and have a stronger immune system so they experience higher AEFI (Iguacel et al., 2021). Monitoring after 1 month after the booster vaccine found menstrual cycle problems in women with a percentage of 7.4%. According to research conducted by Muhaid, after 1 week of vaccination, symptoms of changes in the menstrual cycle appear, then menstruation returns to normal after 2 months of vaccination (Muhaidat et al., 2022).

This is in accordance with previous research where the AEFI of the elderly is less pronounced than the younger age. Elderly AEFI is less pronounced than younger people because immune cells are aging combined with T cell depletion as atrophy exacerbates the loss of new pathogens or vaccines and age-related immunity (Kezia & Ramatillah, 2022).

According to research by Zare et al, AEFI is highest in people with a BMI above 25 (Zare et al., 2020). From the results of the study, it was found that BMI and AEFI were significant in the form of coughing and diarrhea, this might occur because most of the respondents had a BMI less than 25.

The results showed that the AEFI of the Astrazeneca booster vaccine was more dominant than the Pfizer booster vaccine. Respondents felt that their skin rash was due to hypersensitivity to vaccine ingredients or the active ingredients of a vaccine (Cebeci & Kartal, 2021).

From the results of this study, the effectiveness of the Pfizer booster vaccine was 98,3% and the Astrazeneca booster vaccine was 97%. Another study reported that ChAdox1-S COVID-19 booster vaccination againt the Omicron and Delta variants in Englandhad the effectivity 82,3% (64,2 to 91,3%) (Kirsebom et al., 2022).

4 CONCLUSIONS

From the result of this study it can be observed that the effectiveness of the Pfizer booster vaccine is 98,3% and the Astrazeneca booster vaccine is 97%. The AEFI in the Astrazeneca booster vaccine was higher than the pfizer booster vaccine. Most of those participants are from Java and this study female more predominant than male. The AEFI felt by the respondents were fever, pain at the ijection site, diarrhea, dizzinezz, drowsiness and pain above the arm. AEFI in female more than male such as fever, drowsiness, diarrhea, headaches, and menstrual problems. AEFI on BMI such as cough and diarrhea. Astrazeneca booster vaccine AEFI are more felt than Pfizer booster vaccine recipients.

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