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Adverse Events Occurred within 30 Minutes Following COVID-19 Vaccination at Bang Sue Central Vaccination Center, Bangkok, Thailand, July to December 2021

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Abstract

COVID-19, with a case fatality rate of 0.98%, requires treatment based on severity of illness. Vaccination is crucial for preventing virus spread and decreasing severity of illness, yet it may lead to side effects. This study explored the 30-minute adverse events following immunization (AEFI) after receiving COVID-19 vaccination at Bang Sue Central Vaccination Center (BSCVC). Data (demographic profile of vaccines, type of vaccines administered for the first and second doses and occurrence of AEFI within 30 minutes) from 871,446 vaccine administrations from July to December 2021 at BSCVC were analyzed. There were 386 occurrences (44.29 per 100,000 doses of vaccine administered) of 30-minute AEFI, with females experiencing AEFI twice as often as males. The highest AEFI rate was with the ChAdOx1 nCoV-19 vaccine (62.68 cases per 100,000 vaccinations). First doses resulted in nearly four times more AEFI than second doses. When considering the second dose, the heterologous regimens had more AEFI than the homologous regimens. Common AEFI symptoms included dizziness/lightheadedness (34%), palpitations/chest tightness (16%), and numbness (11%). No serious AEFI was observed. Further monitoring of AEFI across all vaccination centers in the country should be done including causality assessments for any serious AEFI reported.

Keywords: Adverse events following immunization, COVID-19, COVID-19 vaccine, Immunization, Thailand

Introduction

Coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), typically presents with mild or no symptoms in 80% of cases. In some individuals, symptoms resemble those of upper respiratory tract infections, while around 15% may experience coughing and fever. Elderly individuals are more prone to severe symptoms, including fever, and respiratory issues. In approximately five percent of cases, this can progress to critical illness leading to respiratory failure and shock.[1] The mortality rate in Thailand increased from 0.50% in March 2021 to 0.98% by December 2021.[1,2] Preventive measures recommended by the Ministry of Public Health (MOPH) included wearing masks, frequent hand washing, social distancing, and quarantine.[3,4]

Additionally, efforts have been made to develop COVID-19 vaccines to bolster the body's defenses against the virus, reducing its severity upon entry into the body. This also aids in the establishment of herd immunity, where a significant portion of the global population develops immunity to COVID-19, either through natural infection or vaccination, thereby limiting its spread. COVID-19 vaccines utilize various manufacturing technologies, classified into four main processes: 1) Genetic vaccines (e.g., Pfizer-BioNTech and Moderna); 2) Viral vector vaccines (e.g., Oxford-AstraZeneca, CanSino Biologics, Johnson & Johnson, and Gamaleya); 3) Protein subunit vaccines (e.g., Novavax); and 4) Inactivated virus vaccines (e.g., Sinovac and Sinopharm).[4]

In Thailand, four COVID-19 vaccines were being deployed in 2021: the CoronaVac vaccine from Sinovac (SV), ChAdOx1 nCoV-19 vaccine from AstraZeneca (AZ), BNT162b2 vaccine from Pfizer (PZ, Comirnaty, BioNTech), and mRNA-1273 vaccine from Moderna (MD). These vaccines were administered at the Bang Sue Central Vaccination Center (BSCVC) in Bangkok from May 2021 and March 2022, which provided over

five million vaccine doses to Thai individuals aged 18 and above, in line with the MOPH guidelines. The BSCVC served as a large and centralized facility, providing various vaccines allocated by the MOPH during the vaccination campaign aimed at building immunity.

Adverse events following immunization (AEFI) have been generally observed, with most reactions being mild or not severe. These adverse events might result from vaccine administration, but can also stem from other factors unrelated to the vaccine. The Department of Disease Control, MOPH, categorizes AEFI into two types primary types: 1) Allergic reactions and severe allergies, which can be further subdivided into two groups.[4] The first group consists of side effects, which are predictable reactions such as pain, swelling, and warmth at the injection site, and systemic symptoms (e.g., fever, body aches, fatigue, nausea, vomiting, dizziness, and headache). The second group involves hypersensitivity reactions, which occur when the body has allergic reactions to the vaccine or its components. These reactions can range in severity, with the most severe form being anaphylaxis. 2) Stress-related reactions, which are physical responses to stress during vaccination, accompanied by typical post-vaccination side effects. These reactions can occur with all types and batches of vaccines although the mechanism of disease development is not yet clear. Symptoms of stress-related reactions vary and may include lightheadedness, abdominal cramps, nausea, dizziness, high blood pressure, rapid heartbeat, and dissociative neurological symptoms such as weakness, tingling, abnormal body movements, speech difficulties, brain-like symptoms, or seizures. Most often, symptoms occur within 30 minutes after vaccination, but in some cases, they may occur hours or days later. Typically, individuals in this group tend to recover within 1–3 days, although some may experience symptoms for longer periods. Nonetheless, individuals in this group can return to their daily activities as usual.

This study focused on investigating the 30-minute AEFI of COVID-19 vaccination at the BSCVC, specifically in Thai individuals aged 18 and above. The study period, from May 2021 to March 2022, coincided with the MOPH's vaccination efforts aimed at establishing immunity. The BSCVC adhered clinical practice guidelines for anaphylaxis from July to December 2021, ensuring the safe administration of COVID-19 vaccines.[5]

Methods

This was a retrospective descriptive study that investigated AEFI among individuals who received the COVID-19 vaccine and had a history of completing either homologous or heterologous vaccinations. The homologous vaccination group was the vaccine group in which the first and second doses were the same type, e.g., SV-SV, AZ-AZ, PZ-PZ, and MD-MD, and the heterologous vaccination group was the vaccine group in which the first and second doses were different types, e.g., SV-AZ, AZ-PZ, and PZ-MD. The study included only individuals who received two doses of the vaccine at the BSCVC between July and December 2021, encompassing a total of 871,446 vaccine doses administered.

Data collection involved gathering information from reports of AEFI from the BSCVC electronic database during a 30-minute observation period after vaccination. The process included several steps. First, evaluation of AEFI by trained medical personnel or volunteer rescue workers, who were assigned to observe and report symptoms every 15 minutes after vaccination. Second, if necessary, individuals exhibiting symptoms were referred to the primary care unit for further assessment and care by medical personnel or volunteer rescue workers. Finally, documentation of personal information, vaccine type received, and details of the adverse events categorized by vaccine type and injection sequence were documented on patient report forms.

The data were analyzed descriptively, presenting results as percentages of AEFI and focusing on its primary signs or symptoms, i.e., chief complaint. To explore the differences in AEFI within the 30-minute observation period after COVID-19 vaccination, subgroup analysis on different injection sequences was conducted to examine various variables within each subgroup. Additionally, the study assessed acute adverse events occurrence during the observation period among individuals who received various homologous heterologous vaccination strategies.

Ethics

This research was approved by the Research Ethics Committee of the Faculty of Medicine, Chulalongkorn University (IRB No. 0507/65, approval date 21 Jul 2023, expiration date 20 Jul 2024), and received project extension approval from the Research Ethics Committee for Human Research for fiscal year 2024 (IRB/IEC No. 017/2565, approval date 13 Sep 2023).

Results

A total of 871,446 vaccine doses were administered during the study period. There were 386 occurrences of 30-minute AEFI after receiving the COVID-19 vaccine in the study sample (44.29 per 100,000 doses of vaccine administered). It was found that AEFI

occurred more frequently in females, approximately twice as often as in males. Primarily, AEFI occurred in the age group of 18 to less than 20 years, with a rate of 134.51 per 100,000 doses. The highest occurrence of AEFI was associated with the ChAdOx1 nCoV-19 vaccine, at a rate of 62.68 per 100,000 doses. Additionally, individuals who received their first doses experienced AEFI almost four times more frequently than those who received their second doses (Table 1).

Table 1. Demographic and vaccination data at Bang Sue Central Vaccination Center, July to December 2021

Variables	Number of vaccine doses administered (n=871,446)		Number of AEFI reports (n=386)	
	Number	Percent	Number	Rate per 100,000 doses*
Gender	**871,446**	**100.00**	**386**	**44.29**
Male	410,314	47.08	105	25.59
Female	461,132	52.92	281	60.94
Age group (years)	**871,446**	**100.00**	**386**	**44.29**
18–<20	15,612	1.79	21	134.51
20–29	263,370	30.22	98	37.21
30–39	197,772	22.69	89	45.00
40–49	159,784	18.34	70	43.81
50–59	118,918	13.65	37	31.11
60–69	52,486	6.02	30	57.16
70–79	33,126	3.80	20	60.38
≥80	29,118	3.34	21	72.12
Unknown	1,260	0.14	0	0.00
Type of vaccine	**118,918**	**13.65**	**386**	**44.29**
CoronaVac (Sinovac)	15,612	1.79	23	21.22
ChAdOx1 nCoV-19 (AstraZeneca)	263,370	30.22	294	62.68
BNT162b2 (Pfizer)	197,772	22.69	59	24.37
mRNA-1273 (Moderna)	159,784	18.34	10	19.26
Injection sequence	**871,446**	**100.00**	**386**	**44.29**
First dose	435,723	50.00	305	70.00
Second dose	435,723	50.00	81	18.59
Vaccine regimen†	**871,446**	**100.00**	**386**	**44.29**
Homologous	381,016	43.72	259	67.98
Heterologous	490,430	56.28	127	25.90

**Proportion of AEFI occurrence per 100,000 doses of vaccine administered. †Combining numbers of AEFI occurrence of the first and the second doses. AEFI: adverse events following immunization.*

The analysis of AEFI stratified by age group also found that AEFI occurred more frequently when receiving the first dose than the second dose in all age groups. When considering the second dose, AEFI occurred more frequently in those receiving heterologous regimens than in those receiving homologous regimens in the under-20 age group and the 20–59 age group, except for the age group over 60 years, where the opposite trend was observed. However, for overall, the second dose of heterologous regimens had a higher AEFI occurrence compared to that of the homologous regimens, with rates of 22.03 per 100,000 doses and 14.21 per 100,000 doses, respectively (Table 2).

Additionally, the reporting rate of primary signs and symptoms of AEFI across all age groups were dizziness/lightheadedness, palpitations/chest tightness, and numbness, ranked as the first, second, and third most common symptoms, respectively (Table 3).

Table 2. Number and rate of 30-minute adverse events following immunization (AEFI) by vaccine regimen, dosage, and age group at Bang Sue Central Vaccination Center, July to December 2021

Vaccine regimen and dosage	Age group (years)							
	18–<20		20–59		≥60		Total	
	No. of AEFI (No. of vaccine injection)	Rate per 100,000 doses*	No. of AEFI (No. of vaccine injection)	Rate per 100,000 doses*	No. of AEFI (No. of vaccine injection)	Rate per 100,000 doses*	No. of AEFI (No. of vaccine injection†)	Rate per 100,000 doses*
Overall	**21 (15,612)**	**134.51**	**294 (739,844)**	**39.74**	**71 (114,730)**	**61.88**	**386 (870,186)**	**44.36**
First dose	**14 (7,806)**	**179.35**	**232 (369,922)**	**62.72**	**59 (57,365)**	**102.85**	**305 (435,093)**	**70.10**
Second dose	**7 (7,806)**	**89.67**	**62 (369,922)**	**16.76**	**12 (57,365)**	**20.92**	**81 (435,093)**	**18.62**
Homologous	2 (7,796)	25.65	15 (137,953)	10.87	10 (44,257)	22.60	27 (190,006)	14.21
Heterologous	5 (10)	50,000.00	47 (231,969)	20.26	2 (13,108)	15.26	54 (245,087)	22.03

**Proportion of AEFI occurrence per 100,000 doses of vaccine administered. †Excluding the records whose variables age were missing (1,260 doses).*

Table 3. Number and rate of signs and symptoms of 30-minute adverse events following immunization (AEFI) by age group at Bang Sue Central Vaccination Center, July to December 2021

Signs and symptoms	Age group (years)							
	18–<20		20–59		≥60		Total	
	Number of vaccine injections (n=15,612)		Number of vaccine injections (n=739,844)		Number of vaccine injections (n=114, 730)		Number of vaccine injections (n=870,186†)	
	No. of AEFI	Rate per 100,000 doses*	No. of AEFI	Rate per 100,000 doses*	No. of AEFI	Rate per 100,000 doses*	No. of AEFI	Rate per 100,000 doses*
Dizziness/lightheadedness	6	38.43	101	13.65	27	23.53	134	15.40
Palpitations/chest tightness	3	19.22	50	6.76	10	8.72	63	7.24
Numbness	2	12.81	36	4.87	6	5.23	44	5.06
Headache	1	6.41	23	3.11	5	4.36	29	3.33
Fainting	3	19.22	21	2.84	4	3.49	28	3.22
Nausea	2	12.81	19	2.57	3	2.61	24	2.76
Vomiting	0	0.00	9	1.22	5	4.36	14	1.61
Rash	0	0.00	13	1.76	0	0.00	13	1.49
Pain, swelling, redness, and warmth at the injection site	1	6.41	8	1.08	1	0.87	10	1.15
Fatigue, weakness, lack of energy	2	12.81	3	0.41	3	2.61	8	0.92
Muscle pain	1	6.41	3	0.41	2	1.74	6	0.69
Diarrhea	0	0.00	0	0.00	0	0.00	0	0.00
Other symptoms	0	0.00	8	1.08	5	4.36	13	1.49
Total	**21**	**134.51**	**294**	**39.74**	**71**	**61.88**	**386**	**44.36**

**Proportion of primary signs or symptoms reported per 100,000 doses of vaccine administered. †Excluding the records whose variables age were missing (1,260 doses).*

Among 386 AEFI found, majority of individuals experiencing adverse events reported primary symptoms such as dizziness, palpitations/chest tightness, numbness, and headache (Table 4).

The analysis results of AEFI occurrence among various types of homologous and heterologous vaccination strategies were shown in detail in Table 5–7. When combining the AEFI numbers of both doses, the AZ-AZ regimen (ChAdOx1 nCoV-19 (AZ) vaccine for the first and second doses) had the highest occurrence (99.63 per 100,000 doses) among homologous vaccination regimens, while the AZ-PZ regimen (ChAdOx1 nCoV-19 (AZ) vaccine for the first dose and BNT162b2 (PZ) vaccine for the second dose) had the highest occurrence (30.31 per 100,000 doses) among heterologous vaccination regimens (Table 5).

Table 4. Number and proportion of primary signs and symptoms associated with 30-minute adverse events following immunization (AEFI) of COVID-19 vaccine at Bang Sue Central Vaccination Center, July to December 2021 (n=386)

Signs and symptoms	Number of occurrences	Percentage among reported event
Dizziness/lightheadedness	134	34.72
Palpitations/chest tightness	63	16.32
Numbness	44	11.40
Headache	29	7.51
Fainting	28	7.25
Nausea	24	6.22
Vomiting	14	3.63
Rash	13	3.37
Pain, swelling, redness, and warmth at the injection site	10	2.59
Fatigue, weakness, lack of energy	8	2.07
Muscle pain	6	1.55
Diarrhea	0	0.00
Other symptoms	13	3.37

Table 5. Number of 30-minute adverse events following immunization (AEFI) by vaccine regimen and type

Vaccine type and vaccination regimen*	Number of vaccine administrations (n=871,446)		Number of AEFI (n=386)	
	Number	Percentage	Number	Rate per 100,000 doses†
Homologous type*	**381,016**	**43.72**	**259**	**67.98**
SV-SV	104	0.01	0	0.00
AZ-AZ	223,832	25.69	223	99.63
PZ-PZ	105,182	12.07	26	24.72
MD-MD	51,898	5.96	10	19.27
Heterologous type*	**490,430**	**56.28**	**127**	**25.90**
SV-AZ	216,564	24.85	44	20.32
SV-PZ	22	<0.01	0	0.00
SV-MD	0	0.00	0	0.00
AZ-SV	0	0.00	0	0.00
AZ-PZ	273,802	31.42	83	30.31
AZ-MD	26	<0.01	0	0.00
PZ-AZ	4	<0.01	0	0.00
PZ-MD	6	<0.01	0	0.00
MD-PZ	6	<0.01	0	0.00
Total	**871,446**	**100.00**	**386**	**44.29**

**Vaccine regimens are listed in chronological order before and after according to the vaccination policy. †Proportion of AEFI occurrence per 100,000 doses of vaccine administered. SV is the CoronaVac vaccine from Sinovac, AZ is the ChAdOx1 nCoV-19 vaccine from AstraZeneca, PZ is the BNT162b2 vaccine from Pfizer (PZ, Comirnaty, BioNTech), and MD is the mRNA-1273 vaccine from Moderna.*

The most common AEFI symptoms in the homologous group were dizziness/lightheadedness, followed by numbness, palpitations/chest tightness and headache (Table 6). Similarly, in individuals receiving heterologous vaccination, the most frequent AEFI symptoms in the heterologous group were dizziness/lightheadedness followed by palpitations/chest tightness, fainting and nausea (Table 7).

Furthermore, the analysis of 30-minute AEFI in individuals receiving homologous vaccination (Table 6), categorized by dose sequence and vaccine type, revealed that the ChAdOx1 nCoV-19 vaccine had the highest incidence, with 99.63 events per 100,000 doses. The most common AEFI symptoms associated with the ChAdOx1 nCoV-19 vaccine were dizziness/ lightheadedness, followed by numbness, palpitations/ chest tightness and headache, predominantly occurring after the first dose. Similarly, in individuals receiving heterologous vaccination (Table 7), the ChAdOx1 nCoV-19 vaccine had the highest incidence, with 28.96 events per 100,000 injections. The most common AEFI symptoms associated with the ChAdOx1 nCoV-19 vaccine were dizziness/lightheadedness, followed by palpitations/chest tightness, fainting, nausea and rash, predominantly occurring after the first dose.

Table 6. 30-minute adverse events following immunization (AEFI) in individuals receiving homologous vaccination, stratified by dose sequence and vaccine type (n=381,016)

Signs and symptoms	All AEFI	Rate per 100,000 doses *	CoronaVac vaccine (SV)						ChAdOx1 nCoV-19 vaccine (AZ)						BNT162b2 vaccine (PZ)						mRNA-1273 vaccine (MD)					
			Number of vaccine injections						Number of vaccine injections						Number of vaccine injections						Number of vaccine injections					
			n=104		n=52		n=52		n=223,832		n=111,916		n=111,916		n=105,182		n=52,591		n=52,591		n=51,898		n=25,949		n=25,949	
			All dose AEFI	Rate per 100,000 doses *	1st dose AEFI	Rate per 100,000 doses *	2nd dose AEFI	Rate per 100,000 doses *	All dose AEFI	Rate per 100,000 doses *	1st dose AEFI	Rate per 100,000 doses *	2nd dose AEFI	Rate per 100,000 doses *	All dose AEFI	Rate per 100,000 doses *	1st dose AEFI	Rate per 100,000 doses *	2nd dose AEFI	Rate per 100,000 doses *	All dose AEFI	Rate per 100,000 doses *	1st dose AEFI	Rate per 100,000 doses *	2nd dose AEFI	Rate per 100,000 doses *
Dizziness/ lightheadedness	86	22.57	0	0.00	0	0.00	0	0.00	72	32.17	64	57.19	8	7.15	11	10.46	10	19.01	1	1.90	3	5.78	1	3.85	2	7.71
Numbness	40	10.50	0	0.00	0	0.00	0	0.00	40	17.87	38	33.95	2	1.79	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Palpitations/ chest tightness	35	9.19	0	0.00	0	0.00	0	0.00	26	11.62	23	20.55	3	2.68	4	3.80	4	7.61	0	0.00	5	9.63	4	15.41	1	3.85
Headache	25	6.56	0	0.00	0	0.00	0	0.00	24	10.72	23	20.55	1	0.89	1	0.95	1	1.90	0	0.00	0	0.00	0	0.00	0	0.00
Fainting	13	3.41	0	0.00	0	0.00	0	0.00	8	3.57	6	5.36	2	1.79	5	4.75	4	7.61	1	1.90	0	0.00	0	0.00	0	0.00
Nausea	12	3.15	0	0.00	0	0.00	0	0.00	11	4.91	9	8.04	2	1.79	1	0.95	1	1.90	0	0.00	0	0.00	0	0.00	0	0.00
Vomiting	10	2.62	0	0.00	0	0.00	0	0.00	9	4.02	9	8.04	0	0.00	1	0.95	1	1.90	0	0.00	0	0.00	0	0.00	0	0.00
Fatigue, weakness, lack of energy	7	1.84	0	0.00	0	0.00	0	0.00	5	2.23	4	3.57	1	0.89	1	0.95	0	0.00	1	1.90	1	1.93	1	3.85	0	0.00
Pain, swelling, redness, and warmth at the injection site	7	1.84	0	0.00	0	0.00	0	0.00	7	3.13	7	6.25	0	0.00	0	0.00	0		0	0.00	0	0.00	0	0.00	0	0.00
Rash	7	1.84	0	0.00	0	0.00	0	0.00	6	2.68	5	4.47	1	0.89	0	0.00	0	0.00	0	0.00	1	1.93	1	3.85	0	0.00
Muscle pain	5	1.31	0	0.00	0	0.00	0	0.00	5	2.23	5	4.47	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Diarrhea	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Other symptoms	12	3.15	0	0.00	0	0.00	0	0.00	10	4.47	10	8.94	0	0.00	2	1.90	1	1.90	1	1.90	0	0.00	0	0.00	0	0.00
Total	**259**	**67.98**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**223**	**99.63**	**203**	**181.39**	**20**	**17.87**	**26**	**24.72**	**22**	**41.83**	**4**	**7.61**	**10**	**19.27**	**7**	**26.98**	**3**	**11.56**

**Proportion of primary signs or symptoms reported per 100, 000doses of vaccine administered. SV: Sinovac. AZ: AstraZeneca. PZ: Pfizer. MD: Moderna.*

Table 7. 30-minute adverse events following immunization (AEFI) in individuals receiving heterologous vaccination, stratified by dose and vaccine type (n=490,430)

Signs and symptoms	All AEFI	Rate per 100,000 doses *	CoronaVac vaccine (SV)						ChAdOx1 nCoV-19 vaccine (AZ)						BNT162b2 vaccine (PZ)						mRNA-1273 vaccine (MD)					
			Number of vaccine injections						Number of vaccine injections						Number of vaccine injections						Number of vaccine injections					
			n=108,293		n=108,293		n=0		n=245,198		n=136,914		n=108,284		n=136,920		n=5		n=136,915		n=19		n=3		n=16	
			All dose AEFI	Rate per 100,000 doses *	1st dose AEFI	Rate per 100,000 doses *	2nd dose AEFI	Rate per 100,000 doses *	All dose AEFI	Rate per 100,000 doses *	1st dose AEFI	Rate per 100,000 doses *	2nd dose AEFI	Rate per 100,000 doses *	All dose AEFI	Rate per 100,000 doses *	1st dose AEFI	Rate per 100,000 doses *	2nd dose AEFI	Rate per 100,000 doses *	All dose AEFI	Rate per 100,000 doses *	1st dose AEFI	Rate per 100,000 doses *	2nd dose AEFI	Rate per 100,000 doses *
Dizziness/ lightheadedness	48	9.79	10	9.23	10	9.23	0	0.00	27	11.01	19	13.88	8	7.39	11	8.03	0	0.00	11	8.03	0	0.00	0	0.00	0	0.00
Palpitations/ chest tightness	28	5.71	3	2.77	3	2.77	0	0.00	12	4.89	8	5.84	4	3.69	13	9.49	0	0.00	13	9.49	0	0.00	0	0.00	0	0.00
Fainting	15	3.06	4	3.69	4	3.69	0	0.00	10	4.08	10	7.30	0	0.00	1	0.73	0	0.00	1	0.73	0	0.00	0	0.00	0	0.00
Nausea	12	2.45	4	3.69	4	3.69	0	0.00	6	2.45	3	2.19	3	2.77	2	1.46	0	0.00	2	1.46	0	0.00	0	0.00	0	0.00
Rash	6	1.22	0	0.00	0	0.00	0	0.00	6	2.45	3	2.19	3	2.77	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Headache	4	0.82	1	0.92	1	0.92	0	0.00	1	0.41	1	0.73	0	0.00	2	1.46	0	0.00	2	1.46	0	0.00	0	0.00	0	0.00
Numbness	4	0.82	0	0.00	0	0.00	0	0.00	2	0.82	1	0.73	1	0.92	2	1.46	0	0.00	2	1.46	0	0.00	0	0.00	0	0.00
Vomiting	4	0.82	0	0.00	0	0.00	0	0.00	3	1.22	2	1.46	1	0.92	1	0.73	0	0.00	1	0.73	0	0.00	0	0.00	0	0.00
Pain, swelling, redness, and warmth at the injection site	3	0.61	1	0.92	1	0.92	0	0.00	1	0.41	0	0.00	1	0.92	1	0.73	0	0.00	1	0.73	0	0.00	0	0.00	0	0.00
Fatigue, weakness, lack of energy	1	0.20	0	0.00	0	0.00	0	0.00	1	0.41	1	0.73	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Muscle pain	1	0.20	0	0.00	0	0.00	0	0.00	1	0.41	1	0.73	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Diarrhea	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Other symptoms	1	0.20	0	0.00	0	0.00	0	0.00	1	0.41	1	0.73	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Total	**127**	**25.90**	**23**	**21.24**	**23**	**21.24**	**0**	**0.00**	**71**	**28.96**	**50**	**36.52**	**21**	**19.39**	**33**	**24.10**	**0**	**0.00**	**33**	**24.10**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

**Proportion of primary signs or symptoms reported per 100, 000doses of vaccine administered. SV: Sinovac. AZ: AstraZeneca. PZ: Pfizer. MD: Moderna.*

Discussion

This study revealed that 30-minute AEFI predominantly occurred in females compared to males, approximately twice as often, which aligned with previous studies such as Zahid MN's study in Bahrain in 2021.[6] Females experience a higher incidence of AEFI than males, possibly due to stronger immune responses influenced by hormonal factors, such as estrogen, which enhances immune activity.[7,8] Females are also more likely to report symptoms, leading to higher recorded AEFI rates.[9] Additionally, standard vaccine doses, not adjusted for body weight, may cause proportionally stronger effects in females.[10] Genetic differences also contribute to varying immune responses by gender.[11] Additionally, AEFI incidence was higher in the younger age group, particularly in those aged 18 to less than 20 years, with 134.51 cases per 100,000 vaccine doses. Several studies have reported an increased incidence of AEFI in younger populations. For instance, a study by Joshi et al in 2021 noted a higher rate of AEFI in individuals aged 16–29 years, with rates of 128 cases per 100,000 doses.[12] Similarly, an analysis by Jeon et al in 2021 found that individuals aged 18–24 experienced the most frequent AEFI.[13] Younger individuals tend to experience more AEFI due to their more robust immune responses, which can result in stronger inflammatory reactions.[14] Additionally, younger populations may report symptoms more frequently, leading to higher incidence.[15] Hormonal fluctuations and higher metabolic rates in younger people may also contribute to increased vaccine reactions.[8,16] Psychological factors, such as anxiety, could amplify the perception of AEFI.[17]

This study found immediate AEFI occurred higher among the first dose than the second dose. This might be partially explained by the fact that the vaccine type injected the most and with the highest AEFI rate in this study was ChAdOx1 nCoV-19 vaccine. This was consistent with several previous studies that reported higher AEFI occurrence after receiving the first dose than the subsequent doses among ChAdOx1 nCoV-19 vaccine recipients.[18,19] Another possible reason could be higher concern of both recipients and healthcare personnel at the center for the adverse effects after receiving the first dose than the second one.

When considering both the first and second doses together, there was a noticeable difference in AEFI occurrence between the two vaccination strategies, with higher AEFI incidence in homologous vaccination compared to heterologous vaccination. But the difference could be explained by multiple factors or mechanisms such as vaccine type, host response, or boosting immunity. When focusing on the second vaccine dose, however, it was found that heterologous regimens had AEFI more than the homologous regimens which might be mainly resulted from boosting immunity, which is consistent with the study of Polack et al. in 2020.[20] As demonstrated in study, stratifying AEFI occurrences of various vaccination strategies and sequences by age can help revealing significant insights into demographic influences on vaccine safety.[13] These findings highlight the need for tailored vaccination strategies that consider both efficacy and safety across different populations.

The most common AEFI symptoms observed included dizziness/lightheadedness, palpitations/chest tightness, numbness and headache, most of which were not serious. These findings differ from other studies such as Alhazmi A's study in Saudi Arabia in 2021, where fatigue and local pain were the most common AEFI.[21] No serious side effects or AEFI were noted, at least immediately following vaccination.

This study has several important strengths. First, it was a large population-based study, which provided a greater opportunity to detect rare AEFI, compared to a small study. Second, the study was able to estimate the incidence of immediate AEFI, which is of critical importance for public health policy makers in planning immunization service delivery and resource allocation, particularly in terms of manpower and budget.

Limitations

A limitation of the study is that the data was only collected from a specific vaccination center. Therefore, the results of this study cannot be used as a proxy for the incidence of AEFI in different contexts of other vaccinations. Additionally, this study focused on the primary signs or symptoms of the AEFI occurring within 30 minutes. These might not include other less concerned symptoms occurred during the period or AEFI that may occur in the following hours or days after vaccination. Hence, these findings do not give a comprehensive assessment of COVID-19 vaccine safety.

Conclusion

Overall, the study highlights the importance of ongoing AEFI surveillance and monitoring, particularly concerning different vaccination strategies and vaccine types. The research findings indicate that the occurrence of AEFI varies among different vaccine formulations, with a higher incidence in heterologous vaccination compared to homologous vaccination. AEFI is more common after

the first dose than after the second dose. However, there should be a comprehensive study of AEFI occurrence from all vaccination centers nationwide in the future with extended monitoring period, e.g., asking individuals and healthcare personnel to report any serious signs/symptoms or illness requiring hospitalization within a month post-vaccination, and followed by a causality assessment for any serious AEFI found.

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Conflicts of Interests

The authors declare that there is no conflict of interest.

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