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Adverse events following COVID-19 vaccination in South Korea between February 28 and August 21, 2021: A nationwide observational study

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ABSTRACT

Objectives: To investigate the clinical characteristics of adverse events (AEs) after COVID-19 vaccination in patients in South Korea.

Design: Data from the Korean Disease Control and Prevention Agency on AEs from 4 COVID-19 vaccines, including AZD1222, BNT162b2, JNJ-78436735, and mRNA-1273, from February 26, 2021, to August 21, 2021, were assessed. The epidemiological characteristics, clinical symptoms, severity, complications, and mortality were descriptively analyzed.

Results: Overall, 36.3 million individuals who completed the COVID-19 vaccination doses during the study period were included, and 153,183 AEs were reported. Most AEs occurred after the first dose (80.6%) and within a day (63.2%) after vaccination. Of the AEs, 95.5% were nonsevere cases; however, 4.5% were severe. Most mild AEs showed a similar frequency across all age groups, but major severe AEs and mortality events increased with age.

Conclusions: Although there were differences in the frequency of occurrence, various adverse reactions were confirmed in using all 4 COVID-19 vaccines, even with the BNT162b2 (Pfizer-BioNTech) vaccine. Caution is needed, and further research should be continuously conducted.

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Introduction

The World Health Organization (WHO) declared COVID-19 as a global pandemic in March 2020. Presently, 6 COVID-19 vaccines have been approved by the WHO and administered to control transmission, achieve herd immunity, and reduce disease severity and mortality (Swan et al., 2021). These vaccines are effective in preventing COVID-19 and generally safe to use with a low incidence of adverse reactions and side effects (Baden et al., 2021) (Klein et al., 2021) (Oliver et al., 2021; Polack et al., 2020) (Folegatti et al., 2020). Adverse reactions after COVID-19 vaccines are primarily mild and short-lasting, including headache, muscle pain, chills, diarrhea, and pain at the inoculation site. However, serious complications such as neurological events (Cari et al., 2021a) (Goss et al., 2021), myocarditis (Das et al., 2021), anaphylaxis (Shimabukuro et al., 2021), vesiculobullous skin (Coto-Segura et al., 2021), acute kidney injury (Lebedev et al., 2021), intravascular thrombosis, and thrombocytopenia (Lebedev et al., 2021) (Cari et al., 2021b) (Pottegård et al., 2021) may rarely occur. Most mild adverse reactions can be managed through rest, intake of nonalcoholic liquids, and acetaminophen (Prevention).

Four COVID-19 vaccines are being used in South Korea: AZD1222 (AstraZeneca), BNT162b2 (Pfizer-BioNTech), JNJ-78436735 (Janssen), and mRNA-1273 (Moderna). In the early vaccination stages, AZD1222 was commonly used. However, the BNT162b2 vaccine became more commonly used after serious side effects were reported in the AZD1222 vaccine recipients. Regardless, several adverse reactions and complications are still reported to be associated with the 4 COVID-19 vaccines, which led to vaccine hesitancy (Turner et al., 2021). From February 26, 2021, to August 21, 2021, a total of 153,183 (0.46%) reported individuals experienced adverse reactions from COVID-19 vaccines in South Korea (Agency).

Therefore, this study aimed to investigate the clinical characteristics of the adverse reactions experienced by patients after the 4 COVID-19 vaccinations in South Korea.

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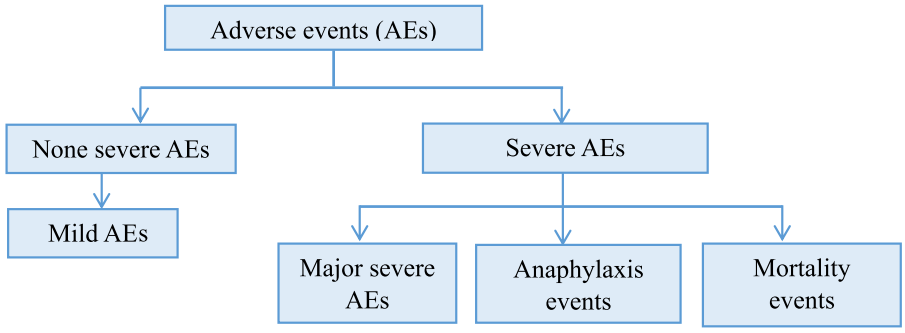

Figure 1. Adverse events subgrouping.

Methods

Study Design

This was a retrospective observational study during the COVID-19 pandemic in South Korea. Data were collected from February 28, 2021, to August 21, 2021. The study protocol was approved by the institutional review board of the Boramae Medical Center in Seoul, Korea (approval number 07-2021-36). Informed consent was waived because of the retrospective nature of the study design.

Study Setting and Population

Adverse events (AEs) were reported as suspected adverse reactions after vaccination against COVID-19 and were calculated based on the reports by medical institutions in South Korea. Data regarding the number of people vaccinated with COVID-19 vaccines and the adverse reactions that followed were collected from the Korea Centers for Disease Control and Prevention on August 25, 2021 (Agency). Four COVID-19 vaccines (AZD1222 [AstraZeneca], BNT162b2 [Pfizer-BioNTech], JNJ-78436735 [Janssen], mRNA-1273 [Moderna]) were administered, in which AZD1222, BNT162b2, and mRNA-1273 had a 2-dose regimen, whereas JNJ-78436735 had a 1-dose regimen.

All information on AE cases was updated weekly and available at https://ncv.kdca.go.kr/eng/. Vaccination data, including vaccine type, epidemiological data, symptom onset dates, symptoms, and complications from the Korea Centers for Disease Control and Prevention, were collected. Only patients who experienced adverse reactions were included in this study. Patients who did not experience adverse reactions were excluded from the evaluation. The severity of adverse reactions after vaccination was assessed based on the guidelines prepared by the Korea Food & Drug Administration (Administration KFD 2013). The guidelines, written in Korean, describe local and systemic reactions, hematology, electrolytes, and so forth. The severity is divided into grades 1, 2, 3, and 4. Grade 1 severity occurs within 48 hours, does not require treatment, and does not affect daily activities. Grade 2 severity includes cases in which normal daily activities can still be performed at more than 50% capacity and minimal medical treatment is required. Grade 3 severity includes cases where daily activities are limited to less than 50% capacity, and hospitalization is required for treatment. Grade 4 is a life-threatening severity and requires hospitalization because of severe activity limitation. Cases with grades 1 and 2 severities correspond to nonsevere AEs. Grades 3 and 4 correspond to severe AEs.

Outcomes

First, enrolled AE cases were divided into 4 groups based on severity as follows: (1) mild AE, (2) major severe AE, (3) anaphylactic event, and (4) mortality event. Disease severity was classified based on the guidelines developed by the Korean Food & Drug Administration (Administration KFD 2013). Nonsevere AEs such as dizziness, myalgia, headache, fever, nausea, and indigestion were considered mild AEs. Most severe AEs were critical complications, such as thrombocytopenic purpura, acute paralysis, and acute cardiovascular injury, and were considered major severe AEs. Anaphylaxis and mortality events were separately classified (Figure 1 and Table 1). Patients whose deaths were confirmed after the COVID-19

Table 1
Baseline characteristics of South Korean patients who completed the COVID-19 vaccination doses (N = 36,299,704) stratified by severity of adverse effects.

	Vaccinated people (N = 36,299,704)	Nonsevere AE	Severe AE			Total
		Mild AE, 146,215	Major severe AE, 5,776	Anaphylaxis event, 703	Mortality event, 489	153,183
Vaccine brand						
AZD1222	14,659,668	78,337	3,318	290	201	82,146
BNT162b2	18,166,856	52,574	2,059	342	278	55,253
JNJ-78436735	1,129,784	7,314	279	45	8	7,646
mRNA-1273	2,343,396	7990	120	26	2	8,138
Sex						
Male	17,061,753	47,536	2,517	202	281	50,536
AZD1222	6,820,877	24,610	1,366	69	120	26,165
BNT162b2	8,129,342	16,620	885	91	151	17,747
JNJ-78436735	978,890	5,824	219	36	8	6,087
mRNA-1273	1,132,644	2,037	47	6	2	2,092
Female	19,237,951	98679	3,259	501	208	102,647
AZD1222	7,838,791	55,282	1,952	221	81	57,536
BNT162b2	10,037,514	35,954	1,174	251	127	37,506
JNJ-78436735	150,894	1,490	60	9	0	1,559
mRNA-1273	1,210,752	5,953	73	20	0	6,046

Table 2
Adverse events stratified by age.

Age range in years		Vaccinated people	Nonsevere AE		Severe AE		Total
			Mild AE	Major severe AE	Anaphylaxis event	Mortality event	
12–17		27,869	95	1	1	0	97
	AZD1222						
	BNT162b2	27,869	95	1	1		97
	JNJ-78436735						
	mRNA-1273						
18–29		3,961,740	19,821	296	157	3	20,277
	AZD1222	271,314	4,982	45	29	1	
	BNT162b2	3,441,417	12,725	223	119	2	
	JNJ-78436735	19					
	mRNA-1273	248,990	2,114	28	9		
30–39		3,023,379	18,931	508	152	11	19,602
	AZD1222	694,722	6,979	188	60		
	BNT162b2	1,421,562	6,015	119	54	5	
	JNJ-78436735	802,987	5,334	192	36	6	
	mRNA-1273	104,108	603	9	2		
40–49		3,602,176	15,472	442	116	11	16,041
	AZD1222	1,087,039	7,269	258	55	9	
	BNT162b2	2,171,330	6,565	120	49	1	
	JNJ-78436735	197,549	1,180	53	6	1	
	mRNA-1273	146,258	458	11	6	0	
50–59		7,492,119	19,869	591	115	28	20,603
	AZD1222	1,484,816	6,631	273	44	16	
	BNT162b2	4,175,139	8,536	239	59	10	
	JNJ-78436735	60,396	278	9	3	1	
	mRNA-1273	1,771,768	4,424	70	9	1	
60–69		8,459,348	43,072	1,838	90	76	45,076
	AZD1222	7,668,251	39,797	1,739	83	73	
	BNT162b2	671,862	2,504	78	7	2	
	JNJ-78436735	60,234	450	21			
	mRNA-1273	59,001	321			1	
70–79		6,121,989	20,302	1,289	32	129	21,752
	AZD1222	3,088,323	12,332	744	16	53	
	BNT162b2	3,012,446	7,828	539	16	76	
	JNJ-78436735	8,278	72	4			
	mRNA-1273	12,942	70	2			
≥80		3,611,084	8,653		40	231	9,735
	AZD1222	365,203	347		3	49	
	BNT162b2	3,245,231	8,306		37	182	
	JNJ-78436735	321				0	
	mRNA-1273	329				1	

Table 3
Adverse events stratified by the order of administered dose.

Dose series		Vaccinated people	Nonsevere AE		Severe AE		Total
			Mild AE	Major severe AE	Anaphylaxis event	Mortality event	
Total	Dose 1	25,866,970	117,820	4,739	622	343	123,524
	Dose 2	10,432,734	28,395	1,037	81	146	29,659
AZD1222	Dose 1	10,836,390	73,870	3,130	270	180	77,450
	Dose 2	3,823,278	4467	188	20	21	4,696
BNT162b2	Dose 1	11,620,319	29,894	1,217	282	153	31,546
	Dose 2	6,546,537	22,680	842	60	125	23,707
JNJ-78436735		1,129,784	7,314	279	45	8	7,646
mRNA-1273	Dose 1	2280477	6,742	113	25	2	6,882
	Dose 2	62,919	1,248	7	1	0	1,256

vaccination were assigned to the mortality group. Second, enrolled AE cases were grouped according to the vaccine administered and age ranges (12–17 years, 18–29 years, 30–39 years, 40–49 years, 50–59 years, 60-69 years, 70-79 years, ≥80 years) (Table 2).

Data normalization using the total number of vaccinated people

The rate of AE after COVID-19 vaccination in each of the 4 groups was calculated using the following formula (Cari et al., 2021b):

$$Rate = (number\ of\ adverse\ events / number\ of\ vaccinated\ people) \times 1,000,000$$

Statistical Analysis

Descriptive variables are reported as median (range) and categorical variables as frequencies. Statistical analyses were performed using IBM SPSS Statistics for Windows Version 20.0 (Armonk, New York).

Table 4
Symptom onset period of each adverse event group.

	Mild AE	Major severe AE	Anaphylaxis event	Mortality event
Symptom onset, day, median (min–max)	1 (0–106)	4 (0–95)	0	4 (0–69)
0	47,105	713	703	42
1	47,226	892		80
2	12,191	615		54
3	9,967	566		51
4	5,769	363		31
5	3,648	255		24
6	2,968	237		25
≥7	17,349	2,135		182

Mild AE includes dizziness, myalgia, headache, fever, and nausea.

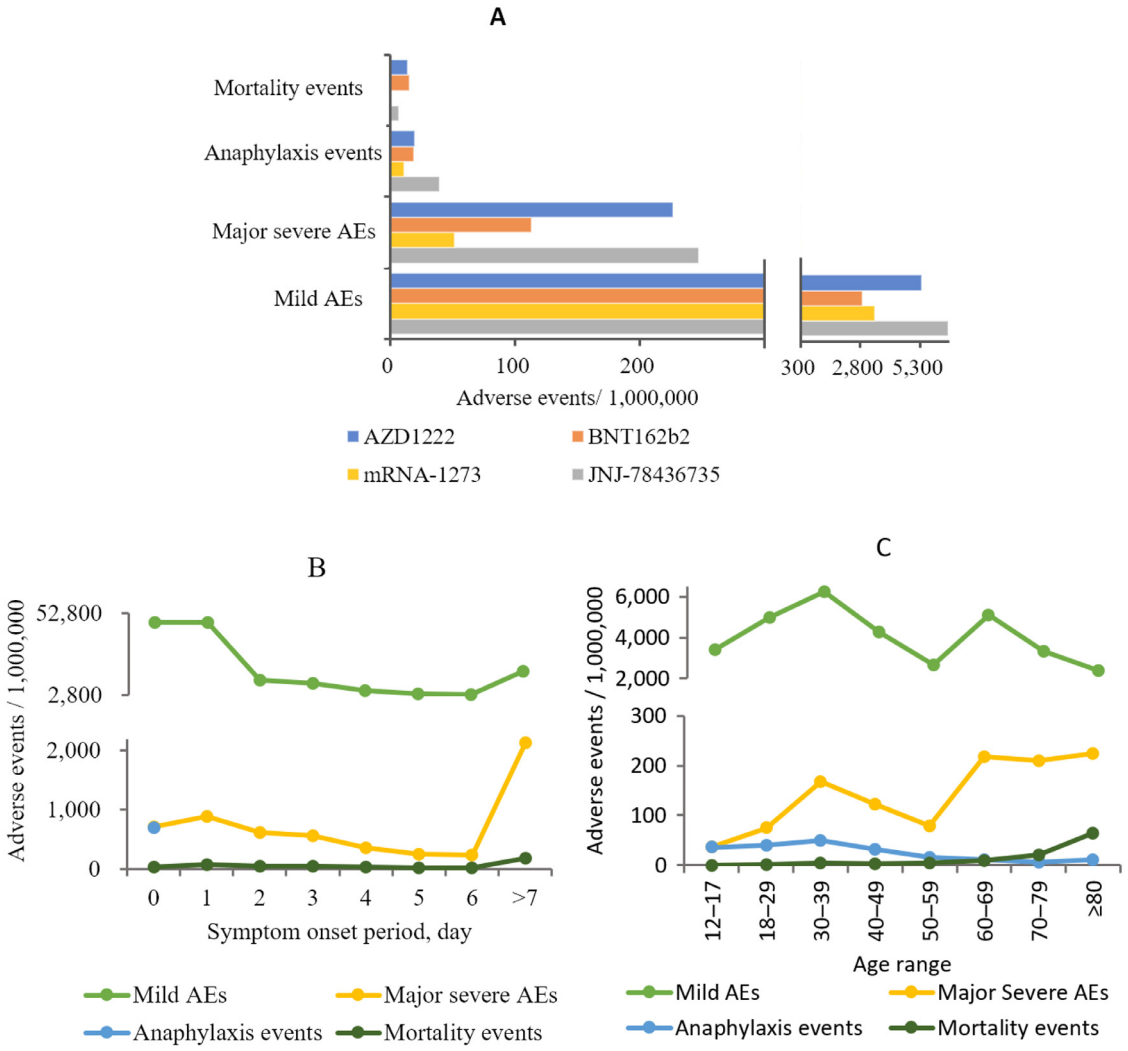

Figure 2. Frequency of AEs after vaccination. The number of AEs was divided by the number of vaccinated people. (A) AEs according to vaccine type and severity. (B) AEs by onset. (C) AEs by age range.
Abbreviations: AEs = adverse events.

Results

Characteristics of the Study Population

A total of 36.3 million individuals completed their COVID-19 vaccine doses during the study period. Four COVID-19 vaccines were administered. The number of vaccinated people and the occurrence of AEs were highest in the AZD1222 and BNT162b2 groups. The frequency of AEs was proportional to the frequency of vaccination (Table 1). The AEs classified into the following 4 groups according to severity had these accumulated number of reports: 146,215 mild AEs (95.5%), 5,776 major severe AEs (3.8%), 703 anaphylactic events (0.5%), and 489 mortality events (0.3%) (Table 1).

For accurate interpretation, we performed data normalization by dividing the number of AEs by the number of vaccinations. The data correction method is described below each figure. Figures were constructed based on new data.

Stratification of AE by sex

The incidence of mild AE, major severe AE, anaphylactic events, and mortality events was higher in women than in men (Table 1, Figure 5).

Onset of AE

Most AEs (80.6%) occurred after the first dose of vaccination. Mild AEs and anaphylactic events were mostly seen within 1 day. However, for severe AEs and mortality events, the onset of symptoms varied (Table 3 and 4, Figure 2 and 6).

The frequency of AEs according to the number of administrations

Adverse reactions with AZD1222 administration were more common with the first dose than with the second dose (Figure 6). However, adverse reactions in BNT162b2 were more common at the second dose than at the first dose, except for anaphylactic reactions.

The frequency of mild AEs

The primary presenting symptoms were pain-related symptoms (63.5%), myalgia (32.2%), headache (29.4%), gastrointestinal symptoms (25.3%), skin-related symptoms (22.4%), neurologic symptoms (17.6%), and arthritis (1.9%). Most presenting symptoms occurred within a day after vaccine administration (63.2%) (Figure 3, Table 5).

In mild AEs, the frequency of allergic reaction, headache, arthritis, fever, local skin response, and cellulitis was higher with AZD1222 than BNT162b2 (Figure 3, Table 5).

The frequency of severe AEs

In severe AEs, the frequency of anosmia, acute kidney injury, acute liver damage, thrombocytopenic purpura, thrombocytopenia, neurological complications, and severe skin reactions was higher in AZD1222 than BNT162b2 (Figure 3, Table 5).

Stratification of AE by age range

The frequency of AEs according to age is shown in Figures 2 and 4, and Table 2. Overall, mild AEs showed a similar frequency across all age groups, but major severe AEs and mortality events increased with age. Anaphylactic events were more frequent in the group aged 18-39 years. The incidence of mild AEs was high in the group aged 18-29 years receiving AZD1222, those aged 30-39 years receiving BNT162b2 and mRNA-1273, and those aged 70-79 years

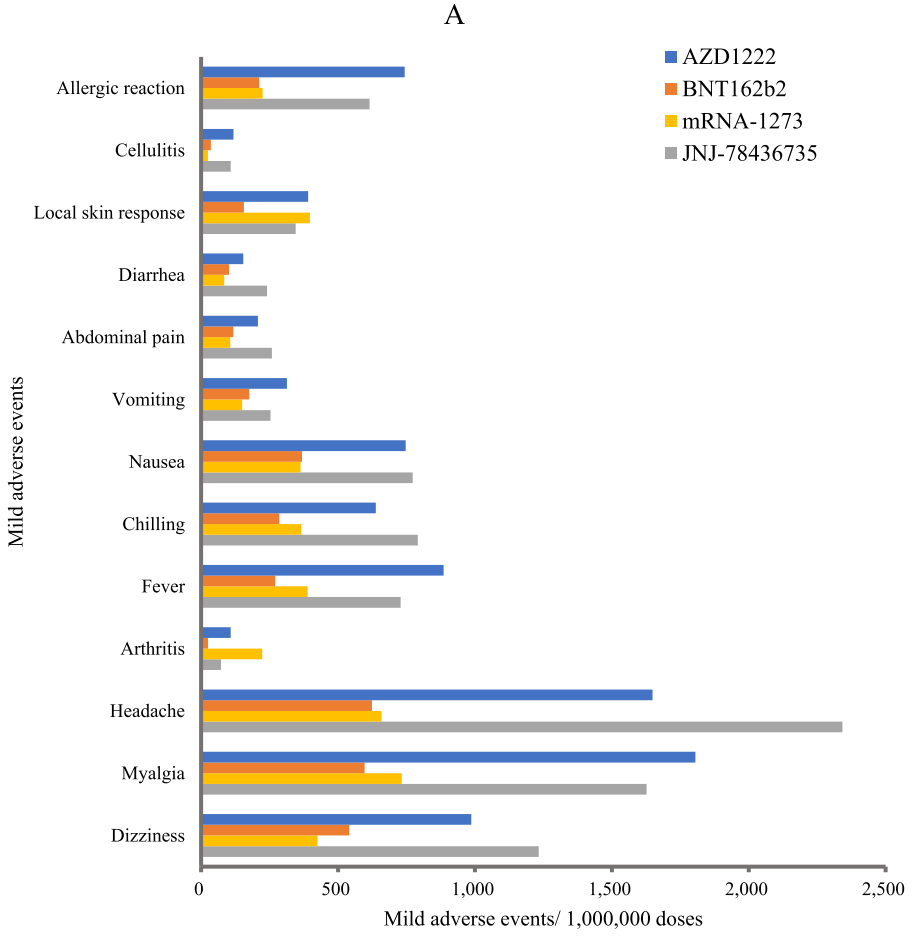

Figure 3. Individual cases of AEs after vaccination. The number of AE was divided by the number of vaccinated people. (A) Frequency of mild AEs according to vaccine type. (B) Frequency of major severe AEs and anaphylactic events according to vaccine type.
Abbreviations: AEs = adverse events.

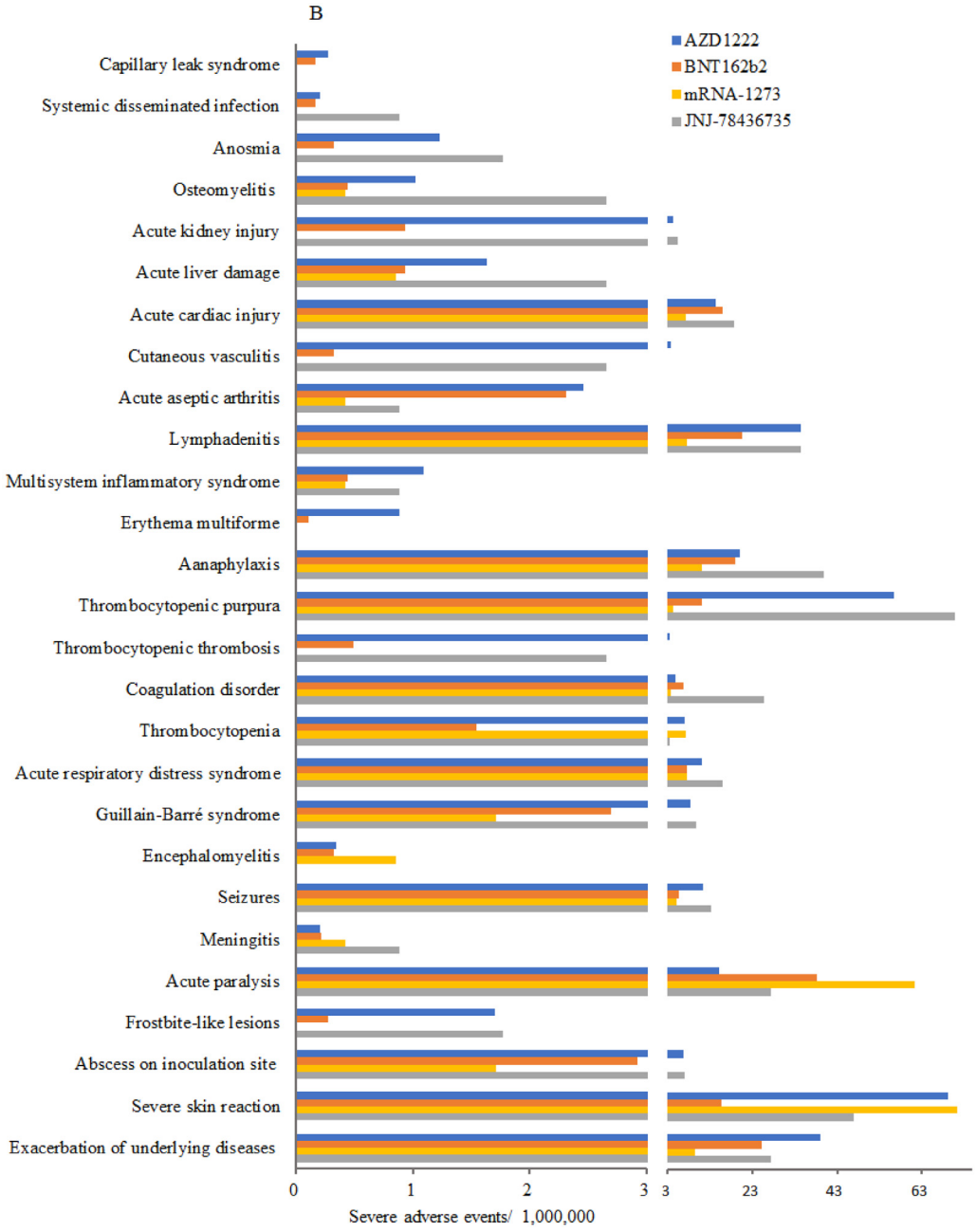

Figure 3. Continued

receiving JNJ-78436735. The incidence of major severe AEs was the highest in the group aged ≥80 years receiving AZD1222 and those aged ≥70 years receiving BNT162b2. For anaphylactic events, a high incidence was observed in the group aged 18-29 years receiving AZD1222, those aged 30-39 years receiving BNT162b2 and mRNA-1273, and those aged 50-59 years receiving JNJ-78436735. For mortality events, the incidence was high in the group aged 40-49 years receiving AZD1222, those aged 30-39 years receiving BNT162b2 and mRNA-1273, and those aged 70-79 years receiving JNJ-78436735.

Discussion

Comparative studies on BNT162b2 and AZD1222 have been conducted, and various vaccine adverse reactions have been revealed. However, these studies are still limited to Saudi Arabia and Europe (Cari et al., 2021b) (Alghamdi et al., 2021). Studies conducted in Asian countries are rare. This study on adverse reactions after COVID-19 immunization conducted in South Korea has the advantage of comparing 4 different brands of COVID-19 vaccines in large-scale research.

In this study, as in recently published papers (Shimabukuro et al., 2021; Coto-Segura et al., 2021; Lebedev et al., 2021; Lebedev et al., 2021; Cari et al., 2021b), various adverse reactions were identified. These adverse reactions were classified into 4 groups according to severity, age, sex, and inoculation frequency.

In interpreting results, vaccine comparison of adverse reactions was mainly performed between AZD1222 and BNT162b2. The frequency of AEs was higher in women than in men. In BNT162b2 and mRNA-1273, the occurrence of AEs was higher in the second dose than in the first dose. These findings were similar to other studies

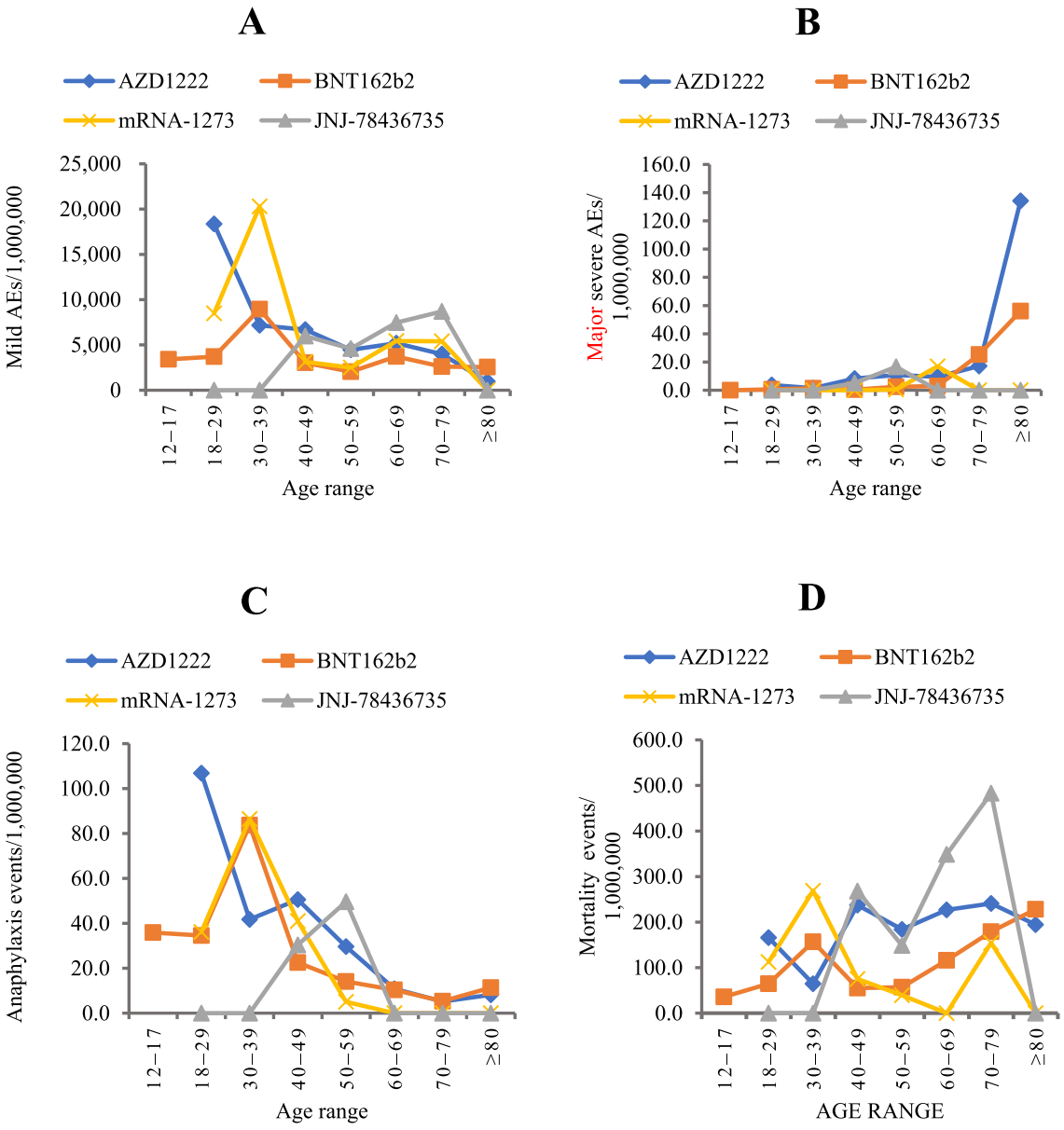

Figure 4. Frequency of AEs according to age range and severity. (A) Mild AEs. (B) Major severe AEs. (C) Anaphylactic events. (D) Mortality events. Abbreviations: AEs = adverse events.

(Alhazmi et al., 2021) (Polack et al., 2020). Overall, mild AEs, such as gastrointestinal symptoms, allergic reactions, fever, headache, and myalgia, were less frequent in those receiving BNT162b2 and mRNA-1273 than those receiving AZD1222.

Overall, major severe AEs were also less frequent in those receiving BNT162b2 than in those receiving AZD1222. Thrombocytopenic thrombosis occurred with all 4 vaccines; however, the incidence was lower in those receiving BNT162b2 than in those receiving AZD1222 (Table 5). An acute cardiac injury such as myocarditis was also less in those receiving BNT162b2 than AZD1222 (Patone M. et al., 2021) (Cari et al., 2021a). Neurologic AEs such as Guillain-Barré syndrome had a high incidence in those who received AZD1222 than BNT162b2 (Patone Martina et al., 2021), (García-Grimshaw et al., 2021a), (García-Grimshaw et al., 2021b). Our findings were similar to previous studies (Pottegård et al., 2021) (Das et al., 2021) (Lau and Galea, 2021). However, because these AEs may be related to patient factors such as the patient's age, drug susceptibility, genetics, ethnicity, and underlying disease, further investigations are needed to confirm the association.

Exacerbation of underlying diseases is often observed in vaccinated individuals (Table 5). The mortality events after vaccination may be attributed to the exacerbation of underlying diseases, particularly in the case of the older population. Because of this, we believe that the mortality incidence in older age is higher in vaccinated people than in the general population.

Adverse reactions observed in vaccinated individuals were very similar to complications in COVID-19 patients. These complications have been described as "Vaccine-Induced COVID-19 Mimicry" Syndrome, a condition caused by COVID-19 vaccines (Kowarz et al., 2021). However, compared with patients with COVID-19 (Stokes et al., 2020), vaccinated individuals had a faster onset of symptoms, a higher rate of asymptomatic infections, and lower severity and mortality (Swan et al., 2021).

This study had several strengths. First, all adverse reactions in South Korea were objectively collected and processed through an adverse reaction reporting system established by medical and government institutions. Second, data were accumulated weekly for 25

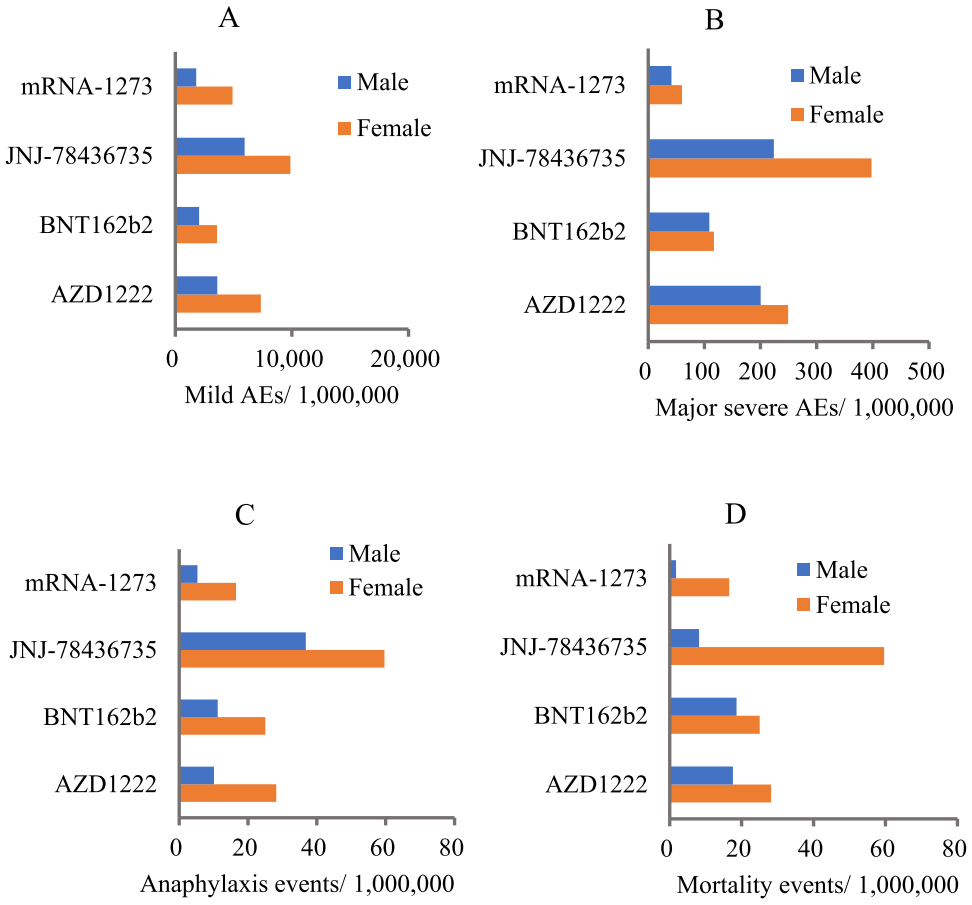

Figure 5. Frequency of AEs according to sex. (A) Mild AEs. (B) Major severe AEs. (C) Anaphylactic events. (D) Mortality events.
Abbreviations: AEs = adverse events.

Table 5
Clinical symptoms of patients with adverse events.

	AZD1222	BNT162b2	JNJ-78436735	mRNA-1273	Total
Nonsevere AE (Mild AE)					
Dizziness	14,468	9,820	1,393	995	26,676
Myalgia	26,461	10,843	1,838	1,717	40,859
Headache	24,166	11,337	2,646	1,544	39,693
Arthritis	1,584	459	82	523	2,648
Fever	12,983	4,912	823	911	19,629
Chills	9,352	5,181	894	857	16,284
Nausea	10,953	6,690	873	850	19,366
Vomiting	4,592	3,182	286	351	8,411
Abdominal pain	3,039	2,126	292	249	5,706
Diarrhea	2,256	1,846	272	197	4,571
Local skin response	5,725	2,838	390	931	9,884
Cellulitis	1,729	645	122	58	2,554
Allergic reaction	10,898	3,853	695	526	15,972
Severe AE					
Exacerbation of underlying diseases	572	459	31	22	1,084
Skin reaction					
Severe skin reaction	1,014	286	53	167	1,520
Abscess on Inoculation site	100	53	8	4	165
Frostbite-like lesions	25	5	2	0	32
Erythema multiforme	13	2	0	0	15
Aanaphylaxis	290	342	45	26	703

(*continued on next page*)

Table 5 (*continued*)

	AZD1222	BNT162b2	JNJ-78436735	mRNA-1273	Total
Neurological complications					
Acute paralysis	224	693	31	144	1,092
Encephalopathy	238	174	19	4	435
Meningitis	3	4	1	1	9
Seizures	167	102	15	12	296
Encephalomyelitis	5	6	0	2	13
Guillain-Barré syndrome	122	49	11	4	186
Acute respiratory distress syndrome	161	137	18	18	334
Coagulation disorders					
Thrombocytopenia	104	28	4	17	153
Coagulation disorder	72	120	29	9	230
Thrombocytopenic thrombosis	50	9	3	0	62
Thrombocytopenic purpura	826	203	80	10	1,119
Inflammation disorders					
Multisystem inflammatory syndrome	16	8	1	1	26
Lymphadenitis	503	372	39	18	932
Acute aseptic arthritis	36	42	1	1	80
Cutaneous vasculitis	54	6	3	0	63
Osteomyelitis	15	8	3	1	27
Acute cardiac injury	212	289	21	17	539
Acute liver damage	24	17	3	2	46
Acute kidney injury	62	17	6	0	85
Anosmia	18	6	2	0	26
Systemic disseminated infection	3	3	1	0	7
Capillary leak syndrome	4	3	0	0	7
Mortality	201	278	8	2	489

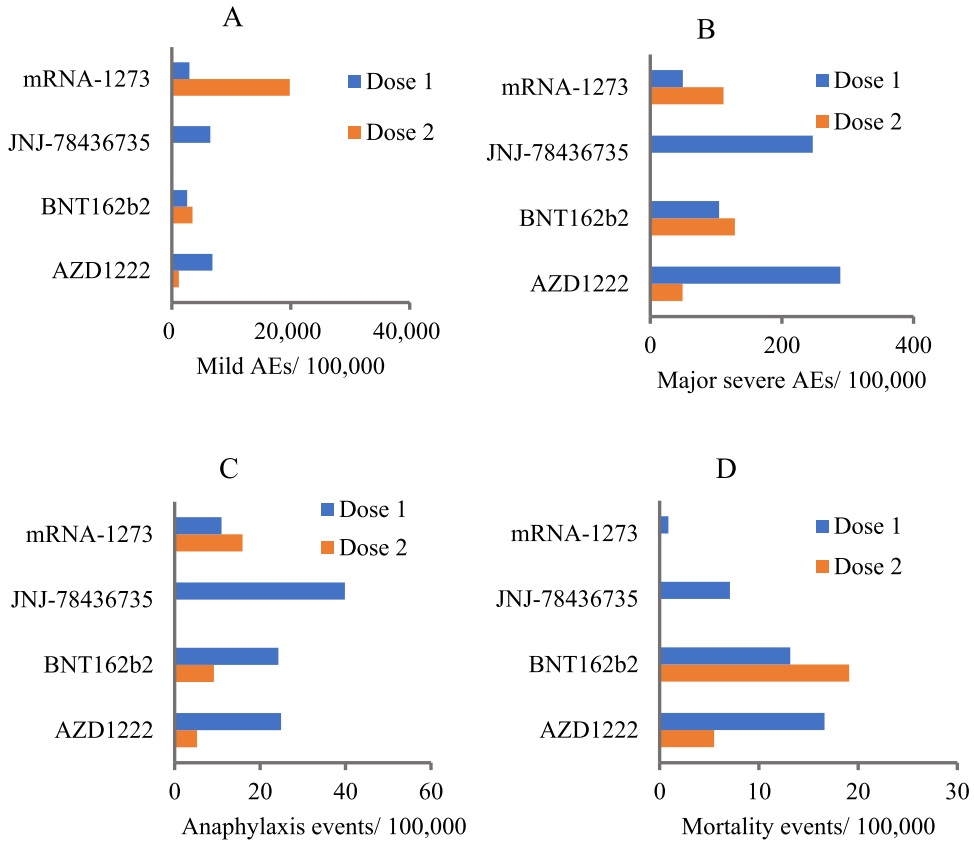

Figure 6. Frequency of AEs according to the dose order of the administered vaccine. (A) Mild AEs. (B) Major severe AEs. (C) Anaphylactic events. (D) Mortality events. Abbreviations: AEs = adverse events.

weeks. This large-scale study data helped improve the reliability of the interpretation of the results.

This study had some limitations. First, AEs were reported as suspected adverse reactions after vaccination against COVID-19 and were calculated based on the reports by medical institutions. Patients who did not report AEs were inadvertently excluded from the evaluation. Therefore, actual AEs may have a higher incidence. Second, because blood test data, which could help predict the severity of AEs, were not available, we could not assess whether vaccinated individuals had elevated levels of inflammation, coagulation, lymphopenia, neutropenia, and troponin, which are hallmark events involved in disease severity. Third, complete causal-

ity between the vaccine and the adverse reaction was not secured, and the classification of notification status may change when new information is added.

Conclusion

In this study, adverse reactions ranging from mild, to severe, and even death were shown in all 4 COVID-19 vaccines in South Korea. Adverse reactions varied with severity, age, sex, and dose order. Overall, AEs were less frequent in those receiving BNT162b2 than in those receiving AZD1222. Caution is needed regarding adverse reactions after COVID-19 vaccination, and further research should be continuously conducted.

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Ethical Approval Statement

Ethics approval was received from the Boramae Medical Center in Seoul, Korea (approval number 07-2021-36).

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ijid.2022.03.007.

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