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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.
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 Borame Medical Center in Seoul, Korea (approval number 07-2021-38). 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 90% 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 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              | AZD1222/ BNT162b2/JNJ-78436735/mRNA-1273 | 27,869       | 95         | 1      | 1     | 0 | 97 |
|                    |                   | 27,869       | 95         | 1      | 1     | 0 | 97 |
| 18–29              | AZD1222/ BNT162b2/JNJ-78436735/mRNA-1273 | 3,961,740   | 19,821     | 296    | 157   | 3 | 20,277 |
|                    |                   | 271,314      | 4,982      | 45     | 29    | 1 |  |
|                    |                   | 3,441,417    | 12,725     | 223    | 119   | 2 |  |
| 30–39              | AZD1222/ BNT162b2/JNJ-78436735/mRNA-1273 | 3,023,379   | 18,931     | 508    | 152   | 11 | 19,602 |
|                    |                   | 694,722      | 6,879      | 188    | 60    |  |  |
|                    |                   | 1,421,562    | 6,015      | 119    | 54    | 5 |  |
| 40–49              | AZD1222/ BNT162b2/JNJ-78436735/mRNA-1273 | 802,987     | 5,334      | 192    | 36    | 6 |  |
|                    |                   | 104,108      | 603        | 9      | 2     |  |
| 50–59              | AZD1222/ BNT162b2/JNJ-78436735/mRNA-1273 | 3,602,176   | 15,472     | 442    | 116   | 11 | 16,041 |
|                    |                   | 1,087,039    | 7,269      | 258    | 55    | 9 |  |
|                    |                   | 197,549      | 1,180      | 53     | 6     | 1 |  |
| 60–69              | AZD1222/ BNT162b2/JNJ-78436735/mRNA-1273 | 146,258     | 458        | 11     | 6     | 0 |  |
|                    |                   | 1,484,816    | 6,631      | 273    | 44    | 16 |  |
|                    |                   | 4,175,139    | 8,536      | 239    | 59    | 10 |  |
| 70–79              | AZD1222/ BNT162b2/JNJ-78436735/mRNA-1273 | 60,396      | 278        | 9      | 3     | 1 |  |
|                    |                   | 1,771,768    | 4,424      | 70     | 9     | 1 |  |
| ≥80                | AZD1222/ BNT162b2/JNJ-78436735/mRNA-1273 | 7,668,251   | 39,797     | 1,739  | 83    | 73 |  |
|                    |                   | 671,862      | 2,504      | 78     | 7     | 2 |  |
|                    |                   | 60,234       | 450        | 21     |  |  |
|                    |                   | 59,001       | 321        |  |  |  |

### 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 | 29,639 |
|             |                   | 10,836,390   | 73,870     | 3,130  | 270   | 180 | 77,450 |
| AZD1222     | Dose 1            | 3,883,278    | 4467       | 188    | 20    | 21  | 4,696 |
|             | Dose 2            | 11,620,319   | 29,894     | 1,217  | 282   | 153 | 31,546 |
| BNT162b2    | Dose 1            | 6,546,537    | 22,680     | 842    | 60    | 125 | 23,707 |
|             | Dose 2            | 1,129,784    | 7,314      | 279    | 45    | 8   | 7,646 |
| JNJ-78436735/mRNA-1273 | Dose 1 | 1,228,477    | 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):

\[
\text{Rate} = \frac{\text{number of adverse events} \times \text{number of vaccinated people}}{1,000,000}
\]

#### 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).

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**Note:** The provided text includes some missing or incomplete entries in the tables, which are not accurately represented in the natural text. Ensure complete data are included for an accurate transcription.
Table 4
Symptom onset period of each adverse event group.

| Symptom onset, day, median (min–max) | Mild AE | Major severe AE | Anaphylaxis event | Mortality event |
|--------------------------------------|---------|-----------------|-------------------|----------------|
| 0                                    | 1 (0–106) | 4 (0–95)        | 0                 | 4 (0–69)       |
| 1                                    | 47,105               | 713             | 703               | 42             |
| 2                                    | 47,226               | 892             | 54                | 80             |
| 3                                    | 12,191               | 615             | 51                | 51             |
| 4                                    | 9,967                | 566             | 31                | 31             |
| 5                                    | 5,769                | 363             | 24                | 24             |
| 6                                    | 3,648                | 255             | 25                | 25             |
| ≥7                                   | 17,349               | 2,135           | 182               | 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 (19%). Most presenting symptoms occurred within a day after vaccine administration (63.2%) (Figure 3, Table 5).

In mild AEs, the frequency of anaphylactic 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, thrombotic 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.
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.
Further age, these 2021 (received as occurring carditis receiving incidence topenic mRNA-1273 and as receiving AZD1222 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 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.](image-url)
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       | 5,471   |
| 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      |
| Anaphylaxis         | 290     | 342      | 45           | 26        | 703     |

(continued on next page)
Table 5 (continued)

| Neurological complications                     | AZD1222 | BNT162b2 | JNJ-78436735 | mRNA-1273 | Total  |
|------------------------------------------------|---------|----------|--------------|-----------|--------|
| 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    |
| Thrombotic thrombosis                         | 50      | 9        | 3            | 0         | 62     |
| Thrombotic 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 inadvertantly 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 Boramea 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.jiid.2022.03.007.

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