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Original article

Risk of Bell's palsy following SARS-CoV-2 infection: a nationwide cohort study

Hye Jun Kim [1], Seogsong Jeong [2], Jihun Song [1], Sun Jae Park [1], Yun Hwan Oh [3], Jaehun Jung [4], Nam-Kyong Choi [5], Sang Min Park [1, 6, *]

[1] Department of Biomedical Sciences, Seoul National University College of Medicine, Seoul, South Korea
[2] Department of Biomedical Informatics, CHA University School of Medicine, Seongnam, South Korea
[3] Department of Family Medicine, Chung-Ang University Gwangmyeong Hospital, Chung-Ang University College of Medicine, Gwangmyeong, South Korea
[4] Department of Preventive Medicine, Gachon University College of Medicine, Incheon, South Korea
[5] Department of Health Convergence College of Science and Industry Convergence, Ewha Womans University, Seoul, South Korea
[6] Department of Family Medicine, Seoul National University Hospital, Seoul, South Korea

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ABSTRACT

Objectives: Despite some evidence of an increased risk of neurologic symptoms following viral vector COVID-19 vaccine administration, it is unclear whether SARS-CoV-2 infection is associated with Bell's palsy (BP), especially over a long enough follow-up period.

Methods: The study population of this nationwide population-based study was derived from the South Korean population, including 11 593 365 and 36 565 099 participants with and without COVID-19, respectively. The Fine and Gray's regression model was utilized to calculate the adjusted sub-distribution hazard ratio (aSHR), considering death as a competing risk, to assess the association between SARS-CoV-2 infection and the risk of BP. All participants were followed up from 1 December 2021, until the incident BP, SARS-CoV-2 infection, death, or 31 March 2022. Subgroup analyses were conducted based on participants' vaccination status (completion of the primary series vs. unvaccinated).

Results: COVID-19 was associated with an increased risk of BP in all participants (aSHR, 1.24; CI, 1.19−1.29). However, the size of the COVID-19−related BP risk was significantly lower among those who completed the primary series of the COVID-19 vaccine (aSHR, 1.20; 95% CI, 1.15−1.25) compared to those who were unvaccinated (aSHR, 1.84; 95% CI, 1.59−2.12; p for interaction: <0.001). The severity of COVID-19 exhibited a gradual escalation in BP risk for both vaccinated and unvaccinated individuals.

Discussion: While both unvaccinated individuals and those who completed the primary series of the COVID-19 vaccine may be at an increased risk of developing BP due to COVID-19, the risk appears to be lower among those who completed the vaccination. **Hye Jun Kim, Clin Microbiol Infect 2023;▪:1**

Introduction

Bell's palsy (BP), typically manifesting as acute paralysis of the idiopathic cranial nerve VII on one side, is a common occurrence in emergency departments [1]. While the underlying etiologies of BP remain unknown, viral infections, particularly those caused by the herpes simplex virus, are often considered a contributing factor [2].

In the very early phase of the COVID-19 epidemic in China, an increasing number of reports suggested that COVID-19 patients were experiencing neurologic symptoms, including central, peripheral, and skeletal muscular injuries [3]. A patient with SARS-CoV-2 demonstrated left facial weakness, with an MRI showing an enhancement of the left facial nerve on the sixth day of illness in early March 2020 [4]. Following the announcement of the COVID-19 pandemic, several case series reported BP with nerve damages, but SARS-CoV-2 was not detected in cerebrospinal fluid by PCR [5]. The United States Food and Drug Administration then suggested enhanced surveillance for safety monitoring of BP after Moderna vaccination, and some case series reported BP after the second dose

* Corresponding author. Sang Min Park, Department of Biomedical Sciences and Family Medicine, Seoul National University Hospital, Seoul National University College of Medicine, 101 Daehak-ro, Jongno-gu, Seoul, South Korea.
E-mail address: smpark.snuh@gmail.com (S.M. Park).

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of Moderna and Pfizer COVID-19 vaccines [6–9]. More recently, Xu et al. [10] reported that delayed-onset neurologic sequelae of COVID-19, such as Guillain–Barré syndrome, mental health disorders, peripheral neuropathy, and memory problems, may develop even at 12 months after the infection. However, the association of COVID-19 with BP, including delayed-onset BP, is yet unclear.

Although a few population-based studies have examined the association between the COVID-19 vaccine and BP, most of these studies have only looked at the very short-term side effects and have not evaluated the risk of BP linked with SARS-CoV-2 infection [11].[1] This suggests that further investigation with a certain period of follow-up period is required to fully comprehend the COVID-19–related BP risk. Herein, we explored the association between COVID-19 and BP in the South Korean population.

Methods

Study population

This study is based on a nationally representative cohort database provided by the Korea Disease Control and Prevention Agency (KDCA) and the Korea National Health Insurance Service (NHIS). The KDCA has been monitoring and collecting data on SARS-CoV-2 infection and COVID-19 vaccination for Korean citizens since 1 January 2020, and provides information on the infection and vaccination dates, doses, and vaccine types for each individual. NHIS offers mandatory insurance services that cover all aspects of medical healthcare for all Korean citizens, including sociodemographic characteristics, drug prescriptions, medical treatments, and health screening examination results, as well as questionnaires on lifestyle behaviours, serological characteristics, and anthropometric measurements [12].

In the current study, we merged the two separate databases provided by KDCA and NHIS and that incorporates 52 883 804 individuals with and without COVID-19 diagnosis between 1 January 2021 and 31 March 2022. Given that the mean onset day of BP in the Korean population with COVID-19 was 109.8 days, the index date for this study was set as 1 December 2021 to ensure the inclusion of a majority of BP cases during the follow-up period. Among 52 883 804 individuals, individuals who died (n = 3218) before the index date, had a history of BP before the index date (n = 239 217), and those who have had a history of BP-related conditions in the last 3 years (n = 4 482 905) were excluded. Finally, the main cohort included 11 593 365 participants with COVID-19 and 36 565 099 participants without COVID-19 before the index date (Fig. 1).

Those who received the health screening at least once between 2018 and 2020 were chosen for the adjusted analyses for health screening outcomes. After excluding missing covariates, this health screening cohort included 4 001 332 participants with COVID-19 and 12 972 906 participants without COVID-19 (Fig. S1).

Follow-up and outcome

All participants were followed up until incident BP, COVID-19 diagnosis, death, or 31 March 2022 from the index date. We identified patients diagnosed with BP in outpatient and inpatient settings using the International Classification of Diseases 10th revision (ICD-10) code of G51.0 (BP) and prescribed glucocorticoids (Table S1). This study was approved by the Institutional Review Board of Seoul National University Hospital (No.: 2204-126-1319). The requirement for informed consent was waived due to the database's anonymization by strict confidentiality guidelines.

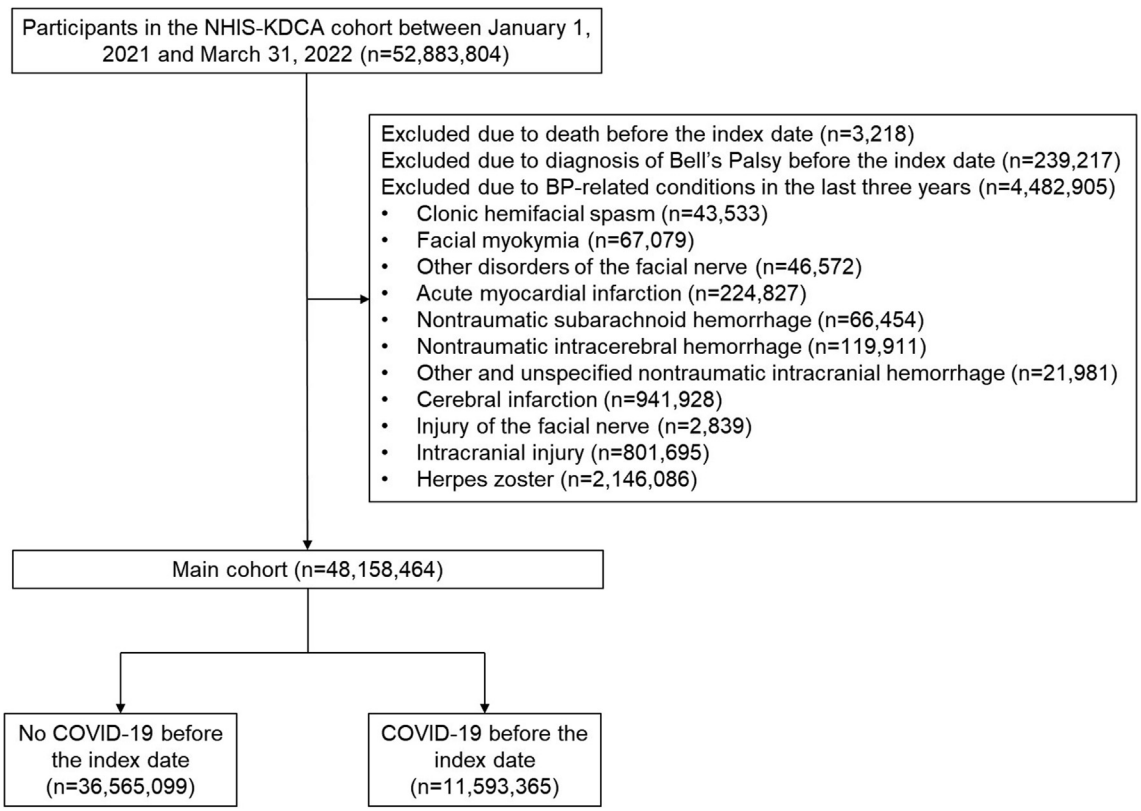

Fig. 1. Flow diagram for the inclusion of study participants in the main cohort.

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Key variables

In the main cohort, the following variables were considered as potential confounding factors for the adjusted analyses: age (continuous; years), sex (categorical; men and women), insurance premium as a proxy for household income (categorical; first (lowest), second, third, and fourth (highest) quartiles), and the Charlson comorbidity index (CCI; categorical; 0, 1, and ≥2). The CCI was calculated as described in a previous study [13].

In the health screening cohort, body mass index (BMI; continuous; kg/m^2), total cholesterol (continuous; mg/dL), hypertension (categorical; yes and no), type 2 diabetes mellitus (categorical; yes and no), dyslipidemia (categorical; yes and no), smoking (categorical; never, past, and current), alcohol consumption (categorical; yes and no), and moderate-to-vigorous physical activity (categorical; 0, 1–2, 3–4, and ≥5 times/week) were further considered as covariates for the adjusted analyses. The presence of the ICD-10 codes and prescription records for antihypertensive, antidiabetic, and antidyslipidemic drugs indicated the presence of hypertension (ICD-10 codes, I10), diabetes mellitus (ICD-10 codes, E10-E14), and dyslipidemia (ICD-10 codes, E78), respectively.

The COVID-19 vaccination status was determined based on completing the primary series of COVID-19 vaccinations prior to the index date, encompassing BNT162b2, mRNA-1273, ChAdOx1 nCoV-19, NVX-CoV2373, and Ad26.COV2.S vaccines using both homologous and heterologous schedules. If a patient had received a single Ad26.COV2.S vaccine, it was considered a complete primary series as this vaccine is not approved for a second dose. On the other hand, completing two doses or more of the other vaccines indicated primary series completion, whereas the others were classified as unvaccinated.

Individuals who were younger than 60 years old and had no comorbidities (i.e. hypertension, type 2 diabetes, liver disease, cancer, cardiovascular diseases, sickle-cell disorders, chronic obstructive pulmonary disease) and no immune suppression prescription were classified as the mild-low risk group. Individuals aged 60 or older, those with any of the aforementioned comorbidities, or those prescribed with COVID-19 medications (i.e. redanvimab, ritonavir, molnupiraviar, remdesivir), but without hyperbaric oxygen therapy, artificial ventilation, and extracorporeal circulation, were considered the mild-high-risk group. Individuals who were prescribed COVID-19–specific medications, tocilizumab, or baricitinib, and did not require oxygen therapy, artificial ventilation, or extracorporeal circulation were considered the serious group. Individuals who were hospitalized in intensive care units or isolation rooms, or prescribed COVID-19–specific medications, tocilizumab, or baricitinib, and underwent oxygen therapy, artificial ventilation, or extracorporeal circulation were classified as the severely serious group.

Statistical analysis

Competing risk analyses with death as a competing outcome were performed using the Fine and Gray's regression model to evaluate the subdistribution hazard ratio (SHR) for BP. We estimated the risk of SARS-CoV-2 infection on BP with or without adjustment for covariates such as COVID-19 vaccination status (completion of the primary series vs. unvaccinated), age, sex, household income, and CCI. To discern the effect of SARS-CoV-2 infection and COVID-19 vaccination on the risk of BP, subgroup analyses were performed based on each participant's vaccination status. One crude and two adjustment models were estimated for these subgroup analyses. The proportionality assumption of the Fine and Gray's regression model was tested using the supremum test, and the proportional hazards assumptions were not violated. In the minimally adjusted model, the adjusted subdistribution hazard ratio (aSHR) and 95% CI were estimated after age and sex were adjusted. The second adjustment model considered age, sex, household income, and CCI as covariates. Participants who were not infected with SARS-CoV-2 were used as a reference group in all the above analyses.

The risk of BP following SARS-CoV-2 infection was estimated for the health screening cohort in the same manner. We started by analysing the risk of SARS-CoV-2 infection on BP, considering covariates including COVID-19 vaccination status. Subsequently, subgroup analyses were conducted based on the vaccination status of each participant. Each crude and adjusted model were estimated, and the adjusted model included age, sex, household income, CCI, BMI, underlying diseases such as hypertension, diabetes mellitus, dyslipidemia, smoking, alcohol consumption, and moderate-to-vigorous physical activity as covariates. Stratified analyses were carried out after stratification according to age, sex, CCI, and obesity. Furthermore, additional analyses were conducted to examine whether the severity of COVID-19 and a history of BP prior to SARS-CoV-2 infection influence the risk of BP after COVID-19. The significance level was considered as a two-tailed p value of less than 0.05. SAS version 9.4 (SAS Institute Inc) was used to perform all data mining and statistical analyses.

Results

Table 1 shows the descriptive characteristics of the main cohort study participants. In the main cohort, there were 11 593 365 participants with COVID-19 and 36 565 099 participants without COVID-19 out of a total of 48 158 464 participants. Participants with COVID-19 were more likely to be younger, women, have lower household income, and were less likely to have completed the primary series of the COVID-19 vaccine. Table S2 explains the descriptive characteristics of the study population in the health screening cohort. Among the total 16 974 238 participants in the health screening cohort, which included 12 972 906 without COVID-19 and 4 001 332 with COVID-19, those with COVID-19 were more likely to be younger, women, have lower household income, and were less likely to be vaccinated against COVID-19.

In the main cohort, a total of 715 661 participants died during the follow-up period. COVID-19 was found to be associated with an increased risk of incident BP after adjusting for the covariates (aSHR, 1.24 95% CI, 1.19–1.29; Table S3). In the subgroup analyses based on vaccination status, COVID-19 was also associated with a higher risk of incident BP among both participants who completed the primary series of the COVID-19 vaccine (aSHR, 1.20; 95% CI, 1.15–1.25), and participants who were unvaccinated (aSHR, 1.84; 95% CI, 1.59–2.12). However, unvaccinated participants had a significantly higher risk of developing BP after SARS-CoV-2 infection compared to those who completed the primary series of the COVID-19 vaccine (p for interaction: <0.001; Table 2). These trends were further supported in the health screening cohort. While COVID-19 was found to be associated with the development of BP among both participants who completed the primary series of the COVID-19 vaccine and unvaccinated participants, those who were unvaccinated had a significantly higher risk of incident BP after SARS-CoV-2 infection (aSHR, 1.47; 95% CI, 1.11–1.94; p for interaction: 0.015; Table S4–5).

Stratified analyses based on age, sex, CCI, and obesity were also conducted after adjusting for covariates. No significant interactions were found in these analyses (Table 3).

When patients were stratified based on the severity of COVID-19, the risk of incident BP appeared to be highest in unvaccinated patients with serious-severely serious COVID-19 (aSHR, 2.40; 95% CI, 1.37–4.21). Additionally, there was a significant trend of

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Table 1
Descriptive characteristics of the study population in the main cohort

	No COVID-19 (n = 36 565 099)	COVID-19 (n = 11 593 365)	p value
Age, y	43.3 (20.8)	33.8 (20.9)	<0.001
Sex, n (%)			<0.001
Men	18 757 895 (51.3)	5 499 268 (47.4)	
Women	17 807 204 (48.7)	6 094 097 (52.6)	
Household income[a], n (%)			<0.001
1st quartile (lowest)	11 799 861 (32.2)	3 916 700 (33.8)	
2nd quartile	9 176 151 (25.1)	3 077 488 (26.5)	
3rd quartile	7 336 652 (20.1)	2 259 747 (19.5)	
4th quartile (highest)	8 252 435 (22.6)	2 339 430 (20.2)	
Charlson comorbidity index, n (%)			<0.001
0	14 304 414 (39.1)	4 364 493 (37.7)	
1	15 730 496 (43.0)	5 671 060 (48.9)	
≥2	6 530 189 (17.9)	1 557 812 (13.4)	
COVID-19 vaccination, n (%)			<0.001
Completion of the primary series	30 317 541 (82.9)	8 751 776 (75.5)	
Unvaccinated	6 247 558 (17.1)	2 841 589 (24.5)	

Data are mean (standard deviation) unless indicated otherwise.
[a] Proxy for socioeconomic status.

Table 2
Analyses of the association of COVID-19 with the risk of Bell's palsy in the main cohort

	No COVID-19	COVID-19	p value	p for interaction
Unvaccinated				
Study population, N	6 247 558	2841 589		
Event, N (%)	803 (0.01)	375 (0.01)		
Person-years	2 042 576	777 076		
SHR (95% CI)	1.00 (reference)	1.23 (1.09–1.40)	0.001	0.026
aSHR (95% CI)[a]	1.00 (reference)	1.87 (1.62–2.15)	<0.001	<0.001
aSHR (95% CI)[b]	1.00 (reference)	1.84 (1.59–2.12)	<0.001	<0.001
Completion of the primary series				
Study population, N	30 317 541	8 751 776		
Event, N (%)	11 514 (0.04)	2936 (0.03)		
Person-years	9 897 777	2378 269		
SHR (95% CI)	1.00 (reference)	1.07 (1.02–1.11)	0.002	
aSHR (95% CI)[a]	1.00 (reference)	1.22 (1.17–1.27)	<0.001	
aSHR (95% CI)[b]	1.00 (reference)	1.20 (1.15–1.25)	<0.001	

aSHR, adjusted subdistribution hazard ratio; SHR, subdistribution hazard ratio.
SHRs were estimated using the Fine and Gray's regression model.
[a] Adjusted for age and sex.
[b] Adjusted for age, sex, household income, and Charlson comorbidity index.

Table 3
Stratified analysis on the association of COVID-19 with the risk of Bell's palsy in the main cohort

	No COVID-19	COVID-19	p value	p for interaction
Age				0.333
<65 y	1.00 (reference)	1.28 (1.22–1.34)	<0.001	
≥65 y	1.00 (reference)	1.16 (1.06–1.27)	0.002	
Sex				0.996
Men	1.00 (reference)	1.24 (1.18–1.32)	<0.001	
Women	1.00 (reference)	1.24 (1.17–1.31)	<0.001	
Charlson comorbidity index				0.551
0	1.00 (reference)	1.29 (1.19–1.40)	<0.001	
≥1	1.00 (reference)	1.23 (1.17–1.28)	<0.001	
Obesity				0.443
Yes, ≥25 kg/m^2	1.00 (reference)	1.17 (1.08–1.27)	<0.001	
No, <25 kg/m^2	1.00 (reference)	1.26 (1.15–1.38)	<0.001	

Data are adjusted subdistribution hazard ratio estimated using the Fine and Gray's regression model after adjustments for age, sex, household income, Charlson comorbidity index, and COVID-19 vaccination.

increasing risk of COVID-19–related BP as the severity of COVID-19 worsened (p for trend: 0.001). Similarly, among patients who had completed the COVID-19 vaccine primary series, a significant difference was found between the no COVID-19, mild COVID-19, and serious-severely serious COVID-19 groups. Patients with serious-severely serious COVID-19 exhibited the highest risk of incident BP (aSHR, 2.25; 95% CI, 1.40–3.61), with a clear trend of increasing risk as COVID-19 symptoms worsened (p for trend: <0.001; Table S6).

Furthermore, when analysing the relationship between COVID-19 and incident BP among participants with a history of BP prior to the index date, a significant COVID-19–related BP risk was found

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among unvaccinated participants (aSHR, 1.39; 95% CI, 1.11–1.74; p for interaction: 0.002) but not among participants who had completed the COVID-19 vaccine primary series (Table S7).

Discussion

During the COVID-19 pandemic in South Korea, SARS-CoV-2 infection was associated with a higher risk of incident BP among both participants who completed the primary series of the COVID-19 vaccine and those who had not. Notably, the COVID-19–related BP risk was more pronounced in unvaccinated participants compared to those who completed the primary series of the COVID-19 vaccine. Among both vaccinated and unvaccinated patients, those with serious-severely serious COVID-19 exhibited more than two-fold higher risk of BP, while patients with mild COVID-19 were associated with a 36% (unvaccinated) and a 21% (completion of the primary series of the COVID-19 vaccine) higher risk of BP compared to participants without COVID-19. SARS-CoV-2 infection may be a risk factor for the onset of BP, especially for those who remain unvaccinated against COVID-19.

In this study, the risk of BP after SARS-CoV-2 infection was higher compared to non-COVID-19 participants. There have been a few hypotheses elucidating the neurologic damage by COVID-19. The first one is the central nervous system dissemination by trans-neuronal or hematogenous spread by cranial nerves that cause direct damage from viral neurotropism [5]. Another potential mechanism is that the abnormal immune-mediated response may cause neuronal damage, which may give rise to the development of dysimmune neuropathy, such as Guillain–Barré Syndrome [14,15]. We suppose that the first potential mechanism may be the cause of BP after COVID-19 in most cases, considering the common clinical manifestations of COVID-19 BP cases [16,17]. Another potential mechanism is that BP is associated with an autoimmune phenomenon that occurs through the mimicry of host molecules by activation of reactive dormant T cells or the antigens [18]. Other potential mechanisms include the reactivation of latent herpes virus infection and immune-mediated segmental demyelination [19–21].

Recently, studies from Israel and Finland suggested a decline in the incidence of BP during the early stages of the COVID-19 pandemic in 2020, a period marked by the implementation of SARS-CoV-2 restrictions aimed at curbing the spread of infections [22,23]. In South Korea, the annual incidence of BP was 25.9 per 100 000 persons between 2006 and 2015 [24]. In the present study, the incidence of BP was 32.5 per 100 000 persons during a 4-month period, specifically from December 2021 to March 2022 (103.5 events per 100 000 person-years), suggesting that the incidence of BP may have increased during the COVID-19 pandemic in South Korea.

This study has some underlying limitations that need to be considered before direct interpretation. Firstly, the recorded date of COVID-19 diagnosis may be delayed because the announcement of PCR test results was usually made the next day in South Korea. Therefore, the diagnosis date may be delayed up to three days considering the weekend. Secondly, this study excluded participants with BP-related conditions, such as cerebral infarction and herpes zoster, to better determine the association of COVID-19 with BP. Therefore, our data may represent the general population but not the high-risk population for BP. Thirdly, the phases of COVID-19 dominant variants, types of COVID-19 vaccinations, and the incidence of BP vary in different regions [25–27]. Studies from other regions are needed before generalization. Lastly, the enrolment and follow-up periods were before the large omicron BA.2 dominant phase. Our data may represent pre-omicron variant COVID-19 phases, mostly the delta variant COVID-19 phase.

In conclusion, COVID-19 was independently associated with a higher risk of BP in both participants who completed the primary series of the COVID-19 vaccine and those who did not. Notably, the COVID-19–related BP risk was higher among participants who had not completed their COVID-19 vaccination compared to those who had completed. Future biological experiments are needed to elucidate the underlying mechanisms and provide a comprehensive understanding of the relationship between COVID-19 and BP.

Author contributions

HJK and SJ contributed equally to this work. HJK, SJ, and SMP conceptualized and designed the study. SMP had full access to all the data in the study and took responsibility for the integrity of the data and the accuracy of the data analysis. HJK and SJ conducted the statistical analysis. All authors engaged in the analysis and interpretation of data. HJK and SJ wrote the draft of the manuscript. All authors critically revised the manuscript to express important intellectual content in a clearer manner. SMP provided administrative, technical, or material support.

Transparency declaration

Sang Min Park is a member of the vaccination committee of the Korea Disease Control and Prevention Agency. This study was supported by the Korea National Institute of Infectious Diseases, Korea National Institute of Health, and Korea Disease Control and Prevention Agency (2021-ER1902–00), the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the National Institute of Infectious Diseases, National Institute of Health Republic of Korea (grant number: HD22C2045), and the Research Program of the Korea Medical Institute.

Access to data

Since the database contained national clinical and medical records, access to the data used in this study was restricted to authorized researchers for a predetermined period of time. Therefore, the raw data cannot be made public.

Acknowledgements

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cmi.2023.08.014.

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