INCIDENCE OF COVID-19 REINFECTION: AN ANALYSIS OF OUTPATIENT-BASED DATA IN THE UNITED STATES OF AMERICA

Mahalul Azam[1], Feddy Setio Pribadi[2], Arief Rahadian[1], Muhammad Zakki Saefurrohim[1], Yudhy Dharmawan[3,4], Arulita Ika Fibriana[1], Ima Arum Lestarini[5], Syed Mohamed Aljunid[6] and Martha Irene Kartasurya[7]

[1]Department of Public Health, Faculty of Sports Science, [2]Department of Informatics and Computer Engineering Education, Faculty of Technics, Universitas Negeri Semarang, Semarang, Indonesia; [3]Department of Public Health, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands; [4]Department of Biostatistics and Population Studies, Faculty of Public Health, Diponegoro University, Semarang, Indonesia; [5]Department of Clinical Pathology, Faculty of Medicine, Mataram University, Mataram, Indonesia; [6]Department of Health Policy and Management, Faculty of Public Health, Kuwait University, Kuwait City, Kuwait; [7]Department of Public Health Nutrition, Faculty of Public Health, Diponegoro University, Semarang, Indonesia

Abstract. COVID-19 reinfection cases are evidence of antibody waning in recovered individuals. Previous studies had reported cases of COVID-19 reinfection both in hospital-based and community-based settings. However, open access data on COVID-19 reinfection in large community-based are limited. The present study aimed to provide the incidence of COVID-19 reinfection based on secondary data in the United States since these were the only available comprehensive data on COVID-19 reinfection in the general population. A cross-sectional study on COVID-19 reinfection was conducted using the secondary data provided by Healthjump from COVID-19 Research Database Consortium. Reinfection was defined as diagnosed with COVID-19 twice with ≥90 days intervals between diagnoses. Age, gender, and region data were also explored. A Chi-square test continued by a binary logistic regression was conducted to determine the association between parameters. Data collecting and processing were done in the Amazon workspace. The study revealed 3,778 reinfection cases of 116,932 COVID-19 infected cases (3.23%). Reinfection cases

were more common in females (3.35%) than males (3.23%). Elderly subjects were the highest incidence (5.13%), followed by adults (4.14%), young adults (2.35%), and children (1.09%). Proportion in the region of living Northeast was the highest (3.68%), compared to the South (3.49%), West (2.59%), and Midwest (2.48%). The study concluded that the incidence of COVID-19 reinfection was 3.23%, suggesting our concern with COVID-19 management and future research to understand COVID-19 reinfection better. The incident is more likely to occur in female and elderly patients.

Keywords: COVID-19 reinfection, COVID-19 research database consortium, elderly, incidence, recurrence

Correspondence: Mahalul Azam, Department of Public Health, Faculty of Sports Science, Universitas Negeri Semarang, F Building, UNNES Campus, Sekaran, Gunungpati, Semarang 50299, Indonesia
Tel: +62 8122853982 E-mail: mahalul.azam@mail.unnes.ac.id

INTRODUCTION

As of 31 August 2021, coronavirus diseases-19 (COVID-19) has infected more than 216 million people and almost 4.5 million people died since first found in Wuhan (WHO, 2021). Individuals who have recovered from COVID-19 are protected from future severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection by the specific antibodies produced during COVID-19 infection (Hall *et al*, 2021). Some reports suggested that primary infection can provide better protection against reinfection in the healthcare population and the general population (Gazit *et al*, 2021; Hall *et al*, 2021). Previous study reported naive infection to provide better protection from reinfection compared to naive vaccination (Gazit *et al*, 2021) but some other studies reported on the contrary (Cavanaugh *et al*, 2021a; Deng *et al*, 2021; Stamatatos *et al*, 2021).

On the other hand, some studies recently reported cases of COVID-19 reinfection both in hospital-based and community-based settings (Azam *et*

al, 2020; Breathnach *et al*, 2021; Cavanaugh *et al*, 2021b; Hansen *et al*, 2021; Husain *et al*, 2021; Pilz *et al*, 2021; Vitale *et al*, 2021). Reinfection cases are the evidence of antibody waning or loss of recovered individuals (To *et al*, 2021a). It is crucial to understand more about reinfection incidence and its characteristics to mitigate the COVID-19 pandemic better. For future health policy guidelines, it is important to acknowledge that SARS-CoV-2 can mutate into distinct RNA virus strains and investigate its potential to reinfect (Wang *et al*,2021). Limited studies provide evidence of COVID-19 reinfection in extensive community-based data. COVID-19 Research Database (https://covid19researchdatabase.org/) is a consortium that consists of a representative from all contributing data sources and institutions committed to making data freely available for understanding and combating the current pandemic in the interest of patients and the public health in the United States. The present study aimed to provide the incidence of COVID-19 reinfection based on secondary data in the US since these the only available comprehensive data on COVID-19 reinfection in the general population.

MATERIALS AND METHODS

A cross-sectional study was conducted to explore the incidence of COVID-19 reinfection in outpatient recorded secondary data. The primary endpoint to be observed is the occurrence of COVID-19 reinfection. We also observed determinant factors of COVID-19 reinfection, such as a patient's characteristics and demography.

Variable determination

COVID-19 reinfection was determined as the second positive result of reverse transcription-polymerase chain reaction (RT-PCR) after the

first positive result that was diagnosed more or equal to 90 days (CDC, 2020; Yahav *et al*, 2021). A positive result of RT-PCR data was provided in the diagnosis data as confirmed COVID-19 code U07.1 (WHO, 2019). To determine COVID-19 reinfection at different times; the encounter data of outpatients are. We determined the interval between the first and second diagnosis COVID-19 for more or equal to 90 days based on the Centers for Disease Control and Prevention (CDC)'s protocol for suspected reinfection cases (CDC, 2021). The patient's characteristics consist of age, gender, and region. Age was categorized as child for subjects with 0-14 years old, young for subjects aged 15-47 years old, adult for 48-63 years old, and elderly for 64 years old or above. The region was categorized into four main regions in the US, *ie*, Northeast, Midwest, South, and West as published by U.S. Census Bureau at https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf.

Data collection

We used secondary data provided by COVID-19 Research Database (https://covid19researchdatabase.org/). A detailed explanation of the data availability, database selection, data description, data requests, data collection, data extraction and data analysis as well as all related issues can be accessed at https://covid19researchdatabase.org/#works. The Healthjump application exports data for the electronic health records (EHR) and practice management system (PMS), providing all data that was changed from the last time the application ran. It is up to the receiving application to append these data to the data previously received. The data involved all regions and states in the US.

Identification of variables and parameters

This study's population was all subjects in outpatients diagnosed

as COVID-19 since 2019; we then determined the COVID-19 reinfection incidence in the study population by being diagnosed with COVID-19 twice in a ≥90 days period from the first diagnosis. The dates of first and the second diagnoses with infections were used to determine the time interval of re-infection.

Data utilized in this study are as follows:

a. Subjects with COVID-19 were determined by the ICD-10 diagnosis code U07.1 (confirmed virus identified).

b. Data of COVID-19 reinfection cases, *ie*, those who were diagnosed with COVID-19 twice within 90 days period, were extracted.

c. Data of age (calculated from date of birth and encounter date), gender, and regions that converted from the States of residency provided in the out-patients' addresses were also accessed.

d. After all needed data was extracted, we then selected only the complete data for the analysis.

Statistical analysis

The clean and firm data had been analyzed and presented in proportion since the type of data were nominal. Analysis to determine the association between parameters and primary outcomes was conducted. Binary logistic regression has been conducted to conclude the regression model related to the occurrence of COVID-19 reinfection. Before building a binary logistic regression model, the confounding analysis, the interaction effect of the determinants, the nonlinear data effect, and the goodness of fit were considered. We developed a regression model of the particular parameters to be visualized. Statistical analysis as well as general data analysis was performed using STATA Release 17 (StataCorp, College Station, TX).

Working in the workspace environment

We conducted our study on Snowflake (https://www.snowflake.com/en/) using Python programming language version, 2.7 (Python Software Foundation, Bozeman, MT) to process data from the provided COVID-19 Research Database. We chose Python because it was integrated to the Snowflake. The display in Python also helped us to do data analysis because Python can display the program output in one frame.

Ethical approval

The COVID-19 Research Database was established with institutional review board/ patients advocacy and ethics approval (https://covid19researchdatabase.org/) and exemption from patient consent due to the use of Health Insurance Portability and Accountability Act (HIPAA) de-identified data, HIPAA limited data, or non-HIPAA covered data, along with strong governance measures in place to control access to all data. This exemption covers all research performed within the COVID-19 Research Database. COVID-19 Research Database Statement of Ethics and Intent provided at https://covid19researchdatabase.org/statement-of-ethics/.

RESULTS

Our study acquired 195,911 COVID-19 confirmed cases with the diagnosis code U07.1. Of them, 78,979 had incomplete data, and finally, 116,932 were included in the analysis. (Fig 1). The present study revealed that the incidence of COVID-19 reinfection cases was 3.23 % (3,778) from 116,932 infected people in our data (Table 1). Table 1 also shows that COVID-19 infection in female was significantly more common than male (56.88 % *vs* 43.12%, p=0.001) and so did the COVID-19 reinfection (2,225

(3.35%) *vs* 1,553 (3.23%), *p*=0.001) (Table 2). In the age category, the young adult (15-47 years) was the most common age group getting COVID-19 infection (55.12%) while COVID-19 reinfection occurred more commonly in the elderly aged 64 years or above (5.13%). Southern United States, which have 17 states in 3 divisions, namely South Atlantic, East South Central, and West South Central, had the highest number of COVID-19 infections at 67,670 cases or 57.87%; however, the highest percentage of COVID-19 reinfections was in the Northeast region (496 cases or 3.68%) and the south region placed in the second highest at 2,363 cases or 3.49%.

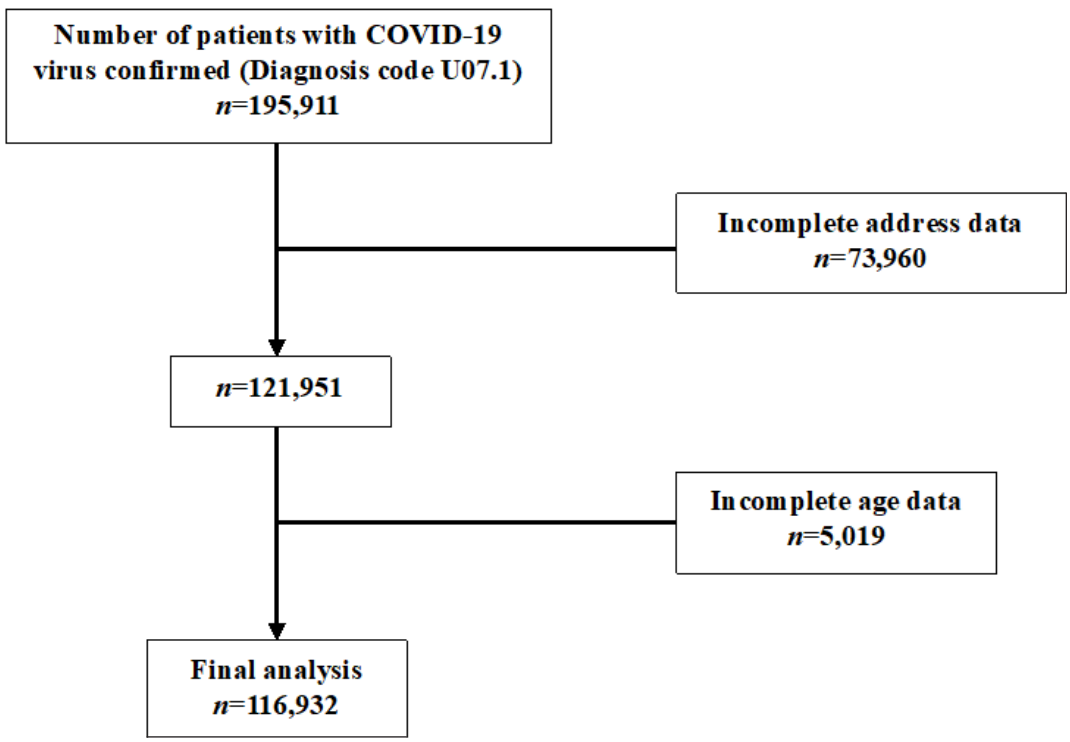

Fig 1 - Subject selection chart

Note: Diagnosis code follows the criteria of WHO ICD-10 (WHO, 2019).

COVID-19: Coronavirus disease

Table 1
Subjects' characteristics (N = 116,932)

Characteristic	Frequency *n* (%)
Reinfection	
Yes	3,778 (3.23)
No	113,154 (96.77)
Sex	
Female	66,511 (56.88)
Male	50,421 (43.12)
Age*	
Child	5,601 (4.79)
Young adult	64,449 (55.12)
Adult	20,447 (17.49)
Elderly	26,435 (22.61)
Region†	
Northeast	13,461 (11.51)
Midwest	7,267 (6.21)
South	67,670 (57.87)
West	28,534 (24.40)

*Age categories are defined as follow: Child (0-14 years old), Young adult (15-47 years old), Adult (48-63 years old) and Elderly (≥64 years old).

†The region was categorized into four main regions in the US, *ie*, Northeast, Midwest, South, and West as published by US Census Bureau at https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf

Table 2
Subjects' characteristics based on reinfection status

Characteristic	COVID-19 reinfection		Total number	*p*-value
	Yes, *n* (%)	No, *n* (%)		
Sex				0.0001
Female	2,225 (3.35)	64,286 (96.65)	66,511	
Male	1,553 (3.23)	48,868 (96.92)	50,421	
Age*				0.0001
Child	61 (1.09)	5,540 (98.91)	5,601	
Young adult	1,515 (2.35)	62,934 (97.65)	64,449	
Adult	847 (4.14)	19,600 (95.86)	20,447	
Elderly	1,355 (5.13)	25,080 (94.87)	26,435	
Region†				0.0001
Northeast	496 (3.68)	12,965 (96.32)	13,461	
Midwest	180 (2.48)	7,087 (97.52)	7,267	
South	2,363 (3.49)	65,307 (96.51)	67,670	
West	739 (2.59)	27,795 (97.41)	28,534	

*Age categories are defined as follow: Child (0-14 years old), Young adult (15-47 years old), Adult (48-63 years old) and Elderly (≥64 years old).

†The region was categorized into four main regions in the US, *ie,* Northeast, Midwest, South, and West as published by US Census Bureau at https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf

COVID-19: Coronavirus disease 2019

A binary logistic regression was then conducted and found that females, the elderly, and those living in the south region had a significantly higher risk of getting COVID-19 reinfection cases (Table 3). The coefficient estimate was -0.099 for males, which means the event of COVID-19 reinfection is a factor exponential of (-0.099) = 0.91 or 9% lower in males than females when the group of age and region is equal. This binary logistic regression also showed us that the elderly group living in the south region had a higher risk than others.

DISCUSSION

The present study reported the incidence of COVID-19 reinfection, *ie*, 3.23% of total 116,932 infected cases, based on the US community-based data acquired from outpatients' secondary data recorded on the COVID-19 Research Database Consortium. This finding adds the evidence of COVID-19 reinfection based on large community data, which is limited studies have been reported. Compared with previous reports, the incidence of COVID-19 reinfection in this study was higher. The previous community-based study was also conducted in Austria and revealed that reinfection incidence was 0.27% of 14,840 cases (Pilz *et al*, 2021). Previous study used total national records of COVID-19 infection data from the Austrian epidemiological reporting system. Reinfection was considered for patients who had a positive polymerase chain reaction (PCR) test during the first and second infection wave. The first wave was from February to April 2020, while the second wave was from September to November 2020, which means that the reinfection interval ranged from 5 months to 9 months.

Our study determined that the interval period was equal or more than 90 days (3 months). Another study by Slezak *et al* (2021), reported a COVID-19 reinfection incidence rate of 0.8% from 75,149 total cases.

Table 3
Binary logistic regression of subjects' characteristics for COVID-19 reinfection

Variable	Correlation coefficient	Standard error	Z	95% CI	*p*-value
Being Male	-0.099	0.033	-2.96	-0.165 to -0.033	0.003
Being young adult	0.766	1.131	5.83	0.509 to 1.024	<0.001
Being adult	1.339	0.133	10.03	1.078 to 1.601	<0.001
Being elderly	1.557	0.131	11.81	1.298 to 1.815	<0.001
Living in Midwest US	-0.396	0.088	-4.49	-0.570 to -0.223	<0.001
Living in South US	-0.066	0.050	-1.33	-0.165 to 0.031	0.185
Living in West US	-0.263	0.059	-4.44	-0.379 to -0.147	<0.001
Constant	-4.324	0.137	-31.41	-4.593 to -4.054	<0.001

Age categories are defined as follow: Young adult (15-47 years old), Adult (48-63 years old) and Elderly (≥64 years old).

Region of residence was categorized into four main regions in the US, *ie*, Northeast, Midwest, South, and West as published by US Census Bureau at https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf

CI: confidence interval; COVID-19: Coronavirus disease 2019

They defined the term of reinfection as same as the current study, *ie* a positive PCR test for SARS-CoV-2 was ≥90 days after the first positive test. In addition, Slezak *et al* (2021) conducted a sensitivity analysis using a suspected reinfection definition of ≥120 days to anticipate a potential late viral shedding that might influence the result. Previous study in Qatar, determining the suspected reinfection as the patients had interval period of ≥45 days between the infections, revealed the incidence of COVID-19 reinfection was 0.18% from 133,266 cases (Abu-Raddad *et al*, 2021). It also showed a classification of COVID-19 based on the strength of supporting evidence. For examples, having positive PCR cycle threshold (Ct) value of <30 at least 45 days after the first positive, having good control at the first infection, being ≥70 years old, performing several PCR measurements on hospitalized patients, and meeting the criteria of severe WHO disease classifications were all the strong evidence of COVID-19 reinfection risk factors (Abu-Raddad *et al*, 2021). A systematic review and meta-analysis also reported that the pooled estimated incidence of COVID-19 reinfection was 0.3% even though the determinations of reinfection in each study under the systematic review were varying based on interval period only or viral genome sequencing confirmation (Sotoodeh Ghorbani *et al*, 2022).

Determination of the interval period between the first and second infection is related to the proportion of COVID-19 reinfection incidence. Previous study which did not consider a recurrence positivity period equal to or more than 90 days reported a higher incidence rate (Sotoodeh Ghorbani *et al*, 2022). Our previous systematic review study revealed that 14.8% of recovered COVID-19 patients acquired re-positivity after negative test results (Azam *et al*, 2020). Our previous review did not consider the interval period between both infections. Another previous review conducted by Dao *et al* (2021) revealed that re-positivity proportions were varied from 2.4% to 69.2%. The potential cause of re-positivity in this study varied, such as false positive in the first or second diagnosis, false negatives in determining recovery, reactivation or reinfection with

another SARS-CoV-2 strain (Dao *et al*, 2021; Wulandari *et al*, 2021).

In the general term, reinfection was determined that a person was infected with an agent, recovered, and became infected again (Sotoodeh Ghorbani *et al*, 2022). Present study determined COVID-19 reinfection as persons with at least one detection of SARS-Cov-2 RNA test, equal or more than 90 days after the first detection of SARS-Cov-2 RNA, whether or not symptoms were present (CDC, 2020; Sotoodeh Ghorbani *et al*, 2022; Yahav *et al*, 2021). Yahav *et al* (2021) described reinfection can be any positive RT-PCR after more than 90 days since the first episode. However, Yahav *et al* (2021) also explained the need to know whether CT value was <35 to conclude COVID-19 infection, yet explaining any suspect of reinfection needs to be considered in isolation. Persons with COVID-19-like symptoms and SARS-Cov-2 RNA detection between 45 and 89 days since first SARS-CoV-2 infection is considered COVID-19 reinfection. This condition is supported by the evidence of close-contacts and without evidence of another cause of infections (Sotoodeh Ghorbani *et al*, 2022). In the present study, data regarding close contacts were not provided in the database.

For epidemiological confirmation, viral genotype assays of the first and second specimens are needed to conclude two different phylogenetic strains by high-throughput sequencing, corresponding to local epidemiology (proof of two episodes with two distinct virus variants with any sequence variation) (Sotoodeh Ghorbani *et al*, 2022; To *et al*, 2021b; Torres *et al*, 2021; Yahav *et al*, 2021). For clinical practice, reinfection may be defined as clinical recurrence of symptoms compatible with COVID-19; accompanied by positive PCR test (Ct <35); more than 90 days after the onset of the primary infection; supported by close-contact exposure or outbreak settings; and no evidence of another cause of infection. In the presence of epidemiological risk factors (*ie*, significant exposure), reinfection should be considered during the first 90 days if

clinical symptoms of the first episode resolved and two PCR tests were negative before the new episode. Viral culture, if collected, is expected to be positive (Sotoodeh Ghorbani *et al*, 2022; To *et al*, 2021b; Torres *et al*, 2021; Yahav *et al*, 2021). Likewise, epidemiological and clinical practice data were also not provided in the COVID-19 Research Database Consortium.

The present study adds COVID-19 reinfection evidence defined as cases that are twice diagnosis COVID-19 (ICD-10 coded this as U07.1), with the interval between diagnosis ≥90 days. Although prior infection protects against reinfection (Hanrath *et al*, 2021), reinfection cases were revealed in this study. Indeed, other studies also concluded that reinfection occurred with mild symptoms and faster recovery (Fitriani *et al*, 2021; West *et al*, 2021; Zheng *et al*, 2020). Previous study also reported that the estimated antibody levels associated with protection against reinfection likely last 1.5-2 years on average, with levels related to protection from severe infection present for several years (Wei *et al*, 2021). Another study reported that rapid waning of COVID-19 antibody responses attenuated after 90 days (Alter and Seder, 2020), however, a recent longer follow-up study showed that antibody titers remained stable over four months (Huang *et al*, 2020). This presence of antibodies actually was not equal to the protective immunity (Alter and Seder, 2020).

The current study also concluded that several factors affect the occurrence of reinfection and revealed that sex was a significant factor affecting reinfection where reinfection in females are more commonly than in males. The association between gender and risk of reinfection is still a contradiction. A recent systematic review stated that males have a higher reinfection rate than females (Sotoodeh Ghorbani *et al*, 2022). However, other studies (Slezak *et al*, 2021; Vitale *et al*, 2021) concluded in line with the current study that females were more common to be re-infected than males. Another study (Hansen *et al*, 2021) concluded no difference between sex and the occurrence of COVID-19 reinfection. This present study also

deduced that reinfection was more common in the elderly (>64 years old) compared to the other age categories. A recent systematic review stated that reinfection occurred in patients aged 15 to 99 years old (Sotoodeh Ghorbani *et al*, 2022) while another study stated that the average age of the reinfection cases was 50 years old (Breathnach *et al*, 2021). Study in Southern California concluded that COVID-19 reinfections were common in the elderly, and also concluded that reinfections were related to immunocompromised patients (Slezak *et al*, 2021).

The present study also revealed that the highest COVID-19 reinfection cases proportion was in the northeast region (3.68%), followed by the south region (3.49%), west region (2.59%), and midwest region (2.48%). This proportion was not in line with the proportion of infection cases, which the highest was the south region (67.67%), west region (28.53%), northeast (13.46%), and midwest region (7.27%). The reinfection proportion was also not in line with the proportion of the population within the regions, *ie*, northeast region (49.29%), midwest region (31.81%), south region (17.13%), and west region (1.77%) (CDC, 2021). The regional condition of the COVID-19 reinfection was directly proportional to the no-intention to be vaccinated (Fisher *et al*, 2020). Attitudes to SARS-CoV-2 vaccination were related to younger age, Black race, and lower educational attainment (Fisher *et al*, 2020). However, this present study did not observe more parameters due to the data availability access.

The next important step for future mitigation of COVID-19 is whether reinfection will represent a serious problem or not. The case of reinfection in COVID-19 is still elusive. Many cases of reinfection have been reported from all over the world. The limitation of our study is that our data did not include genome sequencing data of the virus so that we could not differentiate between reinfection or reactivation of the virus. Nevertheless, the three months difference between each PCR test provided in the diagnosis data has been accepted as a period that is possible for reinfection because

of the reduction of antibodies, yet the least possible for reactivation.

In summary, the present study concluded that the 3.23% incidence of COVID-19 reinfection is higher than in previous studies suggesting our concern about COVID-19 management and future research to understand COVID-19 reinfection better.

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CONFLICT OF INTEREST DISCLOSURE

The authors declared that there are no competing interests.

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