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Original Article

A matched case-control study on the attributable risk of CES-D positivity to the incidence of COVID-19 breakthrough infections

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Abstract

Objectives: To investigate whether the Center for Epidemiologic Studies Depression Scale (CES-D) positivity (16 and above) is a risk factor for breakthrough infections of coronavirus disease 2019 (COVID-19), a matched case-control study was conducted among hospital employees. **Methods:** Participants were matched based on known risk factors, including serum SARS-CoV-2 anti-S antibodies. A multivariate logistic regression analysis was conducted with CES-D score measured at baseline as the explanatory variable and the presence of breakthrough infection after a specified period as the outcome variable, and gender, age, and other covariates were included. **Results:** Logistic regression analysis showed that CES-D positivity was significantly associated with the breakthrough COVID-19 infections (odds ratio 4.393; 95% confidence interval, 1.318–14.642, P = 0.016). **Conclusions:** An increase in the number of hospital employees with CES-D positivity during the pandemic might contribute to a rise in breakthrough infections. It is considered necessary to alleviate people's stress levels through the enhancement of mental health care interventions, complementing infection control measures.

Keywords: breakthrough infections, COVID-19, mental health

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Introduction

As infection control measures against pandemics caused by emerging infectious diseases, two primary strategies are implemented: behavioral restrictions and vaccination. However, during the coronavirus disease 2019 (COVID-19) pandemic, limitations were observed in both approaches. In regions where the implementation of strict infection control measures has led, the prevalence of major depressive disorder (MDD) has increased in the general population, as reported in various countries, such as Italy[1)] and Japan[2)]. These findings highlight a secondary issue that adversely affects public health. Regarding vaccination, in Japan, 61.8% of the population had completed their vaccination by October 2021[3)]. However, post-vaccination breakthrough infections have been reported[4)], so vaccination alone had limited effectiveness as an infection control measures. Furthermore, it has been reported that a history of MDD is a risk factor for common viral infections[5)]. Therefore, MDD induced by behavioral restrictions may potentially trigger breakthrough infections post-vaccination. If there is

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a correlation between MDD and breakthrough infections, it will be necessary to integrate mental health care for the affected population with infection control measures. This approach will enable the enhancement of containment strategies during the initial phases of future pandemics caused by novel infectious diseases and will help alleviate the psychological burden on the general public.

Risk factors for COVID-19 breakthrough infections has been reported, including a decrease in serum SARS-CoV-2 anti-S antibodies[6], poverty in the residential area[7], reinfection in COVID-19 patients[8], and close contact with confirmed cases[9]. However, there is limited research on the impact of MDD as a risk factor for breakthrough infections. The Center for Epidemiologic Studies Depression Scale (CES-D) is a self-administered tool that facilitates the investigation of depressive states. Clarifying the relationship between CES-D positivity and breakthrough infections could enable the development of effective infection control measures. Notably, it has been reported that CES-D positive group includes a significant number of individuals with MDD[10]. Behavioral changes, such as alterations in immunity[11], may contribute to the acquisition of infections.

Therefore, this study aimed to investigate whether CES-D positivity is a risk factor for breakthrough infections by conducting a matched case-control study among hospital staff.

Methods

Study design

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Juntendo University ethical review board (E21-0344). Consent for participation in this study was obtained through an opt-out manner by publicly posting the research plan on the university's clinical research announcement website. All patient information was de-identified to ensure the confidentiality of personal data.

Juntendo University Hospital, one of the largest university hospitals in Japan, conducted a matched-pair case-control study of full-time employees who worked at the hospital from April 2020 to November 2021. Serum SARS-CoV-2 anti-S antibody titers determined during periodic health screenings were used to match case-control pairs. However, employees were excluded from participation if they (1) were fully vaccinated (second vaccination) less than 2 weeks before the June 2021 health screenings, (2) had a history of COVID-19 infection prior to being fully vaccinated, or (3) had a history of being serum anti-SARS-CoV-2 nucleocapsid antibody positive, and (4) had missing periodic health screenings data.

Cases of COVID-19 infections among hospital staff were identified from the staff list of novel coronavirus-infected patients collected by Department of Safety and Health Promotion. Confirmed cases were defined as individuals whose respiratory samples tested positive for SARS-CoV-2 in clinical tests (such as Polymerase Chain Reaction test or Nicking Enzyme Amplification Reaction test) or individuals with a clinical diagnosis based on the presence of symptoms like fever and respiratory difficulties in conjunction with a history of close contact[12]. This method excluded cases of breakthrough infection that developed prior to the periodic health screenings in 2021. It was possible to assess whether attributes observed at the periodic health screenings were factors in subsequent breakthrough infections.

The selection of clinical features as explanatory variables was guided by recommendations from clinical psychiatrists. Demographic variables, encompassing age, gender, body mass index (BMI), medical history, and physical symptoms, alongside assessments of mental well-being using CES-D, were incorporated. Moreover, lifestyle factors, including living alone, potentially conducive to stress, and behaviors, such as alcohol consumption and stress-induced snacking, were identified. These clinical features were obtained at the same health screenings in 2021. Mandatory stress checks are conducted annually in Japanese workplaces[13] and are used for detection of workers' mental health problems. In addition to the mandatory check items, our clinic survey CES-D, a screening tool for depressive state; CES-D is a self-rated checklist of 20 items, each scored 0 to 3 points, with a higher total score indicating depressive state[14]. In this study, CES-D was used to assess depressive state, which was regarded as a binary variable with a cutoff value of 16. To enable multivariate analysis even with a small sample size, some variables, including discrete variables, were transformed using the binning method (Table 1). While detailed symptom names and medical diagnoses were recorded during the health examination, it was assumed that the study population predominantly consisted of healthy individuals, and that the number of staff members with symptoms

Table 1. Variable conversion using the binning method

Binary variable	Negative	Positive
Smoking habit	Never smoker / ex-smoker	Current smoker
Live in solitude	Living with family / others	Dormitory / alone / solo assignment
Frequent alcohol consumption	Rare / occasional	Chronic
Heavy alcohol intake	Social drinker / light drinker	Moderate drinker / heavy drinker
Frequent snacking	Rare / Occasional	Chronic

or medical conditions would be limited. Therefore, individuals with any reported symptoms were classified as having symptoms, and those with any underlying conditions were classified as having underlying conditions. Reported symptoms included stiff shoulders, back pain, headaches, and eyestrain. Reported underlying conditions included lifestyle-related diseases and allergic diseases requiring chronic treatment. Four levels of alcohol intake (the amount of pure alcohol consumed) were used to categorize participants; social drinker (alcohol intake of ≥ 0 g and < 22 g), light drinker (≥ 22 g and < 44 g), moderate drinker (≥ 44 g and < 66 g), heavy drinker (≥ 66 g).

A periodic health screenings was conducted twice during the study period: in June 2020, after the first pandemic of COVID-19 had reduced, and in 2021, after the fourth pandemic of COVID-19 had abated. The 2021 health examinations were conducted after the fourth COVID-19 pandemic was waning and after the COVID-19 vaccination was completed (from March to April in 2021). To investigate the association with post-vaccination breakthrough infections, statistical analyses were performed using the dataset from the 2021 health examination. Additionally, a sub-analysis was conducted using the 2020 health examination dataset to assess changes in lifestyle and their relationship with breakthrough infections.

Statistical analysis

For the matched pairs, the case group consisted of confirmed COVID-19 cases that met the aforementioned criteria, and the control group consisted of employees with serum SARS-CoV-2 anti-S antibody titers similar to the titers in the case group determined at the periodic health screenings in 2021. The matching ratio was 1:5, and Nearest Neighbor Matching was performed.

In order to investigate the distribution of clinical characteristics, numbers and proportions were calculated for binary variables and means and variances were calculated for continuous variables.

To assess the impact of each clinical characteristic on breakthrough infections, univariate logistic regression analysis was performed and odds ratios were calculated. In addition, considering that clinical characteristics can be confounding factors, adjusted odds ratios were calculated using multivariate logistic regression analysis. To account for the similarity of the matched pairs, we performed conditional logistic regression analysis stratified by the matched pairs. Because of the small sample size, there was a risk of overfitting if too many explanatory variables in the multivariate analysis were used. Therefore, among the binary variables, those that were not significantly different in the univariate analysis and had three or fewer positives were excluded from the explanatory variables in the multivariate analysis. A significance level of 5% was set.

In addition, the longitudinal changes in lifestyle were also investigated. To assess the impact of lifestyle changes on breakthrough infections, univariate logistic regression analysis was performed, and odds ratios were calculated. Lifestyle changes were observed in the health examination results from 2020 to 2021, for example, in smoking habits, expressed as "no smoking ⇒ no smoking", "no smoking ⇒ smoking", "smoking ⇒ no smoking", and "smoking ⇒ smoking".

Statistical analysis was performed using R version 4.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Figure 1 presents the results of the sample selection. The target population consisted of 2,752 employees. Exclusion of 278 individuals who did not develop an antibody response by the time of the health examination, 26

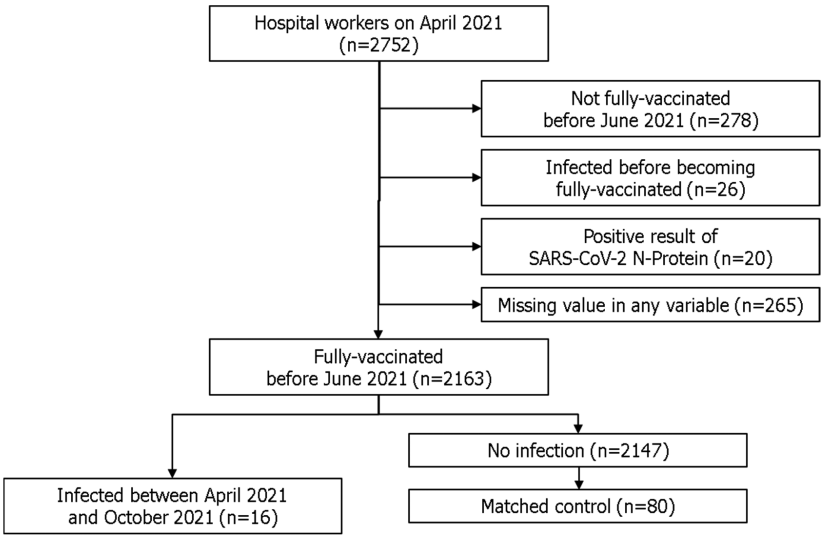

Fig 1. Inclusion criteria for research participation

individuals who experienced infections before developing an antibody response, 20 individuals with serum SARS-CoV-2 anti-N antibodies detected during the periodic health screenings, and 265 individuals with missing variables for analysis resulted in a sample of 2,163 employees with an established antibody response. Breakthrough infections with the novel coronavirus were identified by October 2021 in 16 individuals in the sample. These 16 cases were classified as the case group, and through nearest neighbor matching, a control group of 80 individuals was identified.

Table 2 shows the statistics of the clinical characteristics of the study population: the percentage of employees with high CES-D was 34.2%.

Table 2. Clinical characteristics of the study population (n = 2,163)

Characteristic	Statistics
Age	36.7 ± 11.3
BMI	22.0 ± 3.4
SARS-CoV-2 spike antibody	1179.1 ± 797.9
History of chronic disease	354 (16.4%)
Stress	510 (23.6%)
Symptom	598 (27.6%)
Live in solitude	776 (35.9%)
Breakthrough infection	16 (0.7%)
Frequent alcohol consumption	332 (15.3%)
Heavy alcohol intake	182 (8.4%)
CES-D positivity (≧16)	739 (34.2%)
Gender (male)	747 (34.5%)
Smoking habit	105 (4.9%)
Frequent snacking	442 (20.4%)

BMI, body mass index; CES-D, Center for Epidemiologic Studies Depression Scale.
Values are reported as mean ± standard deviation or n (%).

Table 3 presents the statistical analysis of the clinical characteristics of the matched cases and controls. Using S antibody titers to match case-control pairs, we found no significant differences in age, gender, or S antibody titers between the case and control groups, indicating a balanced distribution. Regarding clinical characteristics, no significant differences were observed, except for CES-D positivity.

Table 4 displays the results of the regression analysis. Both univariate and multivariate analyses revealed significant differences only for CES-D positivity, with an odds ratio of 4.393 in the multivariate analysis. The 95% confidence interval for the odds ratio was wide, ranging from 1.318 to 14.642. The results of both univariate and multivariate analyses showed no significant difference in age, BMI, symptoms, and live in solitude status. Additionally, because variables such as gender, smoking, symptoms, high-frequency drinking, heavy drinking, and high-frequency snacking did not exhibit significant differences in univariate analysis and had fewer than three positive cases, they were excluded as explanatory variables in multivariate analysis.

Table 5 present the results of the analysis of lifestyle changes. It corresponds to a specific variable, displaying the number and proportion for each label separately for the case and control groups. For labels that were only present in either the case or control group, the number of persons is indicated as N/A (not available) and no test was performed. There was a significant change in the pattern of alcohol consumption in some staff members from "Social Drinker => Light Drinker," with an odds ratio of 3.76. Staff members in the case group were confirmed to have increased their alcohol intake. No significant differences were found for smoking, drinking frequency, or snacking frequency.

Table 3. Statistical analysis of clinical characteristics in case-control study

Characteristic	Case (n = 16)	Control (n = 80)	P-value
Age	34.9 ± 10.3	36.7 ± 12.0	0.531
Gender (male)	3 (18.8%)	25 (31.3%)	0.482
SARS-CoV-2 spike antibody	1294.8 ± 1060.5	1291.6 ± 1026.9	0.991
BMI	23.1 ± 3.6	22.2 ± 3.7	0.353
History of chronic disease	1 (6.3%)	13 (16.3%)	0.518
Stress	8 (50.0%)	20 (25.0%)	0.088
Symptom	5 (31.3%)	19 (23.8%)	0.752
Live in solitude	9 (56.3%)	33 (41.3%)	0.408
Frequent alcohol consumption	2 (12.5%)	9 (11.3%)	1.000
Heavy alcohol intake	3 (18.8%)	4 (5.0%)	0.160
CES-D positivity	11 (68.8%)	26 (32.5%)	0.015
Smoking habit	3 (18.8%)	5 (6.3%)	0.248
Frequent snacking	3 (18.8%)	14 (17.5%)	1.000

BMI, body mass index.
Values are reported as mean ± standard deviation or n (%).

Table 4. Results of regression analysis of breakthrough infection

Variable	Univariate analysis			Multivariate analysis		
	Odds ratio	95% CI	P-value	Odds ratio	95% CI	P-value
Age	0.983	0.931–1.037	0.528	0.972	0.906–1.044	0.442
BMI	1.061	0.934–1.206	0.363	1.086	0.932–1.266	0.291
Symptom	1.445	0.454–4.597	0.533	1.097	0.274–4.397	0.896
Live in solitude	1.806	0.621–5.255	0.278	1.120	0.350–3.589	0.848
CES-D positivity	4.401	1.416–13.678	0.010*	4.393	1.318–14.642	0.016*
Gender (male)	0.490	0.122–1.964	0.314			
Smoking habit	3.702	0.720–19.028	0.117			
History of chronic disease	0.319	0.037–2.745	0.298			
Frequent alcohol consumption	1.164	0.182–7.444	0.873			
Heavy alcohol intake	3.750	0.839–16.755	0.084			
Frequent snacking	1.087	0.276–4.283	0.906			

BMI, body mass index; CES-D, Center for Epidemiologic Studies Depression Scale; CI, confidence interval.

Table 5. Results of univariate regression analysis of change in alcohol intake

Change pattern (2020 => 2021)	Case	Control	Odds ratio	95% CI	P-value
Social => social drinker	6 (37.5%)	38 (47.5%)	0.66	0.22–2	0.47
Light => social drinker	1 (6.3%)	14 (17.5%)	0.31	0.04–2.58	0.28
Social => light drinker	6 (37.5%)	11 (13.8%)	3.76	1.14–12.44	0.03*
Social => moderate drinker	2 (12.5%)	2 (2.5%)	5.57	0.72–42.88	0.1
Light => moderate drinker	1 (6.3%)	N/A	N/A	N/A	N/A
Light => light drinker	N/A	5 (6.3%)	N/A	N/A	N/A
Social => heavy drinker	N/A	1 (1.3%)	N/A	N/A	N/A
Moderate => light Drinker	N/A	3 (3.8%)	N/A	N/A	N/A
Moderate => social drinker	N/A	5 (6.3%)	N/A	N/A	N/A
Moderate => moderate drinker	N/A	1 (1.3%)	N/A	N/A	N/A

N/A, not applicable.

Discussion

The aim of this study is to investigate whether a high level of CES-D positivity is a risk factor for breakthrough infections. In the analysis of the association between breakthrough infection and CES-D positivity and lifestyle, a case-control study was conducted using serum SARS-CoV-2 anti-S antibodies as a known risk factor to match case-control pairs. The results showed that the percentage of employees with CES-D positivity was significantly greater in the breakthrough infection group than in the control group by 4.393 times. Thus, it was suggested that CES-D positivity is a risk factor for breakthrough infection of COVID-19. In addition, in the analysis of the association between lifestyle changes and breakthrough infection, alcohol consumption was increased (Social Drinker => Light Drinker) significantly more often in the case group, suggesting that changes in behavioral characteristics are associated with breakthrough infections.

CES-D positivity was found in 34.2% of staff in the study population. The percentage of our staff with CES-D positivity increased from 27.5% to 31.3% between 2019 and 2020 after the COVID-19 pandemic[15], indicating that the rate continued to increase during the period of this study. Using a cutoff value of 16, CES-D has a sensitivity and specificity for MDD of 0.87 and 0.70[10]. In this study, the staff members with a CES-D positivity were considered to be affected by mental stress during the COVID-19 pandemic and prone to MDD.

A possible reason why CES-D positivity increases the risk of infection may have involved alterations in immunity. A history of MDD has been reported as a risk factor for common viral infections[5] and is associated with diminished natural killer (NK) cell activity[11], reflecting compromised immune function. Moreover, a correlation between decreased NK cell activity and CES-D positivity group has been observed[16], potentially indicating an increased risk of infection. Another possibility is that changes in behavioral characteristics may have contributed to breakthrough infections. MDD is known to induce various behavioral changes and has been found to worsen medication adherence in patients with epilepsy[17]. Additionally, it is associated with increased health risk behaviors, including alcohol consumption[18] and overeat-

ing[19]. In the target population of this study, these behavioral changes may have worsened adherence to infection control behaviors.

Regarding the mental health care provided at the hospital, during normal times, the results of CES-D are returned to employees to assist them in self-care and to make recommendations for medical examinations. In addition, during the COVID-19 pandemic, interviews were conducted by industrial physicians in high-stress departments. In order to provide more individualized interventions, providing mental health care according to the type of stress coping is considered effective. On the other hand, high-stress individuals respond to high stress in various ways. Three types of responses to high stress have been proposed: active-cognitive coping, active-behavioral coping, and avoidance coping[20]. One of these, active-behavioral coping, involves seeking advice from experts or discussing the issue with family and friends, and engaging in actions that address the problem collectively. On the other hand, avoidance coping is characterized by avoiding the problem and taking evasive action to reduce tension[20]. Regarding mental health care for nurses during the COVID-19 pandemic, it was shown that cognitive behavioral therapy is effective in developing coping skills and that online cognitive behavioral therapy is effective in reducing stress levels among nurses[21]. These findings suggest that individualized interventions, such as focused mental health care for staff members who tend to use avoidance coping, may be effective in reducing stress.

Limitations of this study include the small number of cases, inability to identify the route of infection, the homogeneity of the hospital employee population, and limited evaluation of psychological factors. The small number of cases resulted in a wide confidence interval for the odds ratio (1.318–14.642), highlighting the need for further investigation with a larger number of cases. And since a quantitative assessment of the routes of infection could not be made, it is not possible to suggest infection control measures. Additionally, since the study population consisted of hospital employees with a relatively homogeneous socio-economic status, it is necessary to verify whether similar findings can be obtained in other populations exposed to various background factors in the general society. In addition, psychological factors were assessed solely using CES-D, and diagnosis of MDD according to DSM-5 by psychiatrists was not conducted. Besides, one item that could not be observed was the characteristics of individual stress coping, and we were not able to examine whether differences in the incidence of infection depend on the type of coping.

This study found that the number of staff members with CES-D positivity increased after the pandemic. Furthermore, CES-D positivity was a risk factor for breakthrough infections. In conclusion, to minimize breakthrough infections during a pandemic, improving mental health care to reduce stress levels may be a useful component of infection control measures.

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Author contributions

Study design: Y.S., S.H., H.F., N.K., M. Saita, and T.N. Data acquisition and analysis: Y.S., H.F., N.K., M. Saita, M.O., Masaya S., and Mari S. Drafting the manuscript: Y.S. and S.H. Critical revision: H.F., N.K., M. Saita, and T.N. All authors approved the final manuscript.

Conflict of interest statement

The authors have no conflicts of interest to declare.

Data availability statement

The data underlying this article cannot be shared publicly due to participants of this study did not agree for their data to be shared publicly.

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