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Post–acute Sequelae of COVID-19 Among Solid Organ Transplant Recipients: Insights From the Omicron Period

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Background. In solid organ transplant recipients (SOTRs), studies investigating post–acute sequelae of SARS-CoV-2 infection (PASC) are limited, and risk factors for their development require further investigation. **Methods.** In this cross-sectional study, we evaluated PASC symptoms among SOTRs followed at our institutions who had COVID-19 during the Omicron period from December 28, 2021, to November 4, 2022. Participants were surveyed using a newly published PASC score containing 13 symptoms experienced for ≥30 d. PASC was defined as a score of ≥12. **Results.** Of 299 SOTRs invited, 93 completed the survey and were analyzed. The mean age was 58 y and 43% were women. Forty-six individuals (49%) reported experiencing ≥1 PASC symptom for ≥30 d, of whom 13 (14%) met the PASC definition. Multivariable analysis showed that female sex (adjusted odds ratio [aOR] = 0.32; 95% confidence interval [CI], 0.12-0.83), years from transplantation (aOR = 0.90 per additional year; 95% CI, 0.81-0.99), and tixagevimab-cilgavimab preexposure prophylaxis (aOR = 0.33; 95% CI, 0.12-0.84) were associated with significantly lower odds of developing ≥1 PASC symptom. **Conclusions.** PASC symptoms are common in SOTRs infected during the Omicron period. PASC symptoms are less frequent in those with a longer time since transplant and in those who received tixagevimab-cilgavimab. New SARS-CoV-2 prevention and treatment strategies should also evaluate PASC symptoms as outcomes.

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Long-term consequences of SARS-CoV-2, often referred to as post–acute sequelae of SARS-CoV-2 infection (PASC), are now increasingly recognized, given their significant impact on quality of life.[1,2] Consequently, efforts have been made to describe and identify the long-term effects of SARS-CoV-2 infection in the general population.[1,3] Although these studies have identified a constellation of symptoms, including respiratory, neurocognitive, mental health, metabolic, and gastrointestinal disorders,[4,5] universally recognized standards for diagnosing PASC have yet to be established.[4,6-8] This is likely due in part to the lack of defined biological biomarkers for the condition. Recently, a new definition of PASC was developed by Thaweethai et al[1] using a scoring system based on the prevalence of symptoms after SARS-CoV-2 infection compared with controls (**Table S1, SDC,** http://links.lww.com/TXD/A687).

SARS-CoV-2 infection is associated with higher mortality in solid organ transplant recipients (SOTRs) compared with

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Data to support the findings in the study are available from the corresponding author on request.

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immunocompetent individuals.[9] In SOTRs, studies investigating PASC are limited, and risk factors for their development in this group require further investigation. The prevalence of PASC in SOTRs using this new definition has not been investigated.

This study aims to describe the prevalence of symptoms of PASC in SOTRs during the Omicron period using the new definition and to evaluate the association of clinical characteristics with the development of PASC.[1]

MATERIALS AND METHODS

Study Design

This is a cross-sectional study evaluating PASC symptoms among SOTRs who had SARS-CoV-2 infection during the Omicron period from December 28, 2021, to November 4, 2022, and who were followed at our institutions (Massachusetts General Hospital and Brigham and Women's Hospital). During this period, the BA.1, BA.1.1, BA.2, BA.2.12.1, BA.2.3, BA.3, BA.4, BA.4.6, BA.5, BQ.1, and BQ.1.1 sublineages were most prevalent in the United States.[10,11] The individuals were identified using our prior study,[12] and all had a positive SARS-CoV-2 antigen or polymerase chain reaction test. Clinical characteristics were collected from each individual by manual chart review. SOTRs were contacted between September 29, 2023, and December 1, 2023, to complete a survey assessing symptoms of PASC. The individuals were initially contacted through the electronic health record with a link to electronically complete the survey. Individuals who did not respond to the electronic health record message were then contacted by phone to complete the survey. Individuals who had symptoms included in the survey (eg, fatigue, shortness of breath) that had started before their SARS-CoV-2 infection were excluded from the analysis.

The definition of PASC and the survey used (**Table S1, SDC,** http://links.lww.com/TXD/A687) were based on the recent definition by Thaweethai et al in which a score of ≥12 is required to meet the criteria for PASC.[1] Symptoms must have started or worsened after SARS-CoV-2 infection and must have lasted for at least 30 d to be included as a PASC symptom. The association between clinical characteristics and the development of symptoms of PASC was then evaluated. This study was approved by the Mass General Brigham institutional review board (protocol No. 2023P002198). Informed consent was obtained from all participants. Data are reported in compliance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.

Statistical Analysis

Continuous variables are reported as either means (±SDs) or medians (interquartile ranges, IQR) depending on the distribution. Categorical variables are described in frequencies and percentages. Univariable logistic regression was used to assess the association between clinical characteristics and the odds of developing the symptoms of PASC. Multivariable logistic regression was used to adjust for covariates if there were sufficient events for the analysis and if the covariates included did not meet the criteria for multicollinearity (ie, variance inflation factor <2.5). The number of covariates in the multivariable model was limited to prevent model overfitting, given the limited number of events. The associations between clinical characteristics and outcomes are reported as unadjusted odds ratios (uORs) and adjusted odds ratios (aORs) for univariable and multivariable models, respectively, with 95% confidence intervals (CIs). Prism version 9.5.1 and SPSS version 24 were used for figure creation and statistical analysis, respectively.

RESULTS

Cohort Characteristics

A total of 299 SOTRs were contacted, of whom 101 completed the survey (20 electronically and 81 by phone). From the 101 individuals who completed the survey, 8 individuals were excluded from the analysis because of their symptoms beginning before the time of their SARS-CoV-2 infection and, therefore, 93 were included in the analysis (Table 1). These 93

TABLE 1.

Clinical characteristics of the cohort

Characteristic	Participants (N = 93)
Age, y, mean (± SD)	58 (±13)
Female sex, n (%)	40 (43)
Race, n (%)	
White	75 (81)
Black/African American	7 (8)
Asian	5 (5)
Unknown/decline to report	6 (6)
Ethnicity, n (%)	
Non-Hispanic	80 (86)
Hispanic	7 (8)
Unknown/decline to report	6 (6)
Years from transplantation, median (IQR)	4.1 (2.1–7.7)
Type of transplant, n (%)	
Kidney	41 (44)
Lung	26 (28)
Heart	14 (15)
Liver	7 (8)
Kidney/heart	4 (4)
Kidney/liver	1 (1)
Prior SARS-CoV-2 infection before the Omicron period, n (%)	24 (26)
No. of vaccines received, n (%)	
None	1 (1)
Two	3 (3)
Three	33 (35)
Four	33 (35)
Five	20 (22)
Six	3 (3)
Months between last vaccine and infection, median (IQR)	4.2 (2.5–8.0)
Tixagevimab-cilgavimab preexposure prophylaxis, n (%)	46 (49)
Hospitalizations for SARS-CoV-2 infection, n (%)	11 (12)
Underwent reduction in immunosuppression during SARS-CoV-2 infection, n (%)	28 (30)
SARS-CoV-2 treatment, n (%)	
None	22 (24)
Monoclonal antibody	50 (54)
Remdesivir[a]	16 (17)
Molnupiravir[a]	6 (6)

IQR, interquartile range.

individuals completed the survey at a median of 15 mo (IQR, 13–17) after their SARS-CoV-2 infection.

The mean age at infection was 58 y (±13) and 43% were women. The most common type of organ transplant was kidney (n = 41; 44%), and the median time since transplantation was 4.1 y (IQR, 2.1–7.7). Twenty-four individuals (26%) had also had a SARS-CoV-2 infection before the Omicron period. At the time of infection during the Omicron period, 92 individuals (99%) had received at least 1 vaccine dose with a median number of 4 vaccines (IQR, 3–4) and a median of 4.2 mo since the last vaccination (IQR, 2.5–8.0). Forty-six individuals (49%) had received tixagevimab-cilgavimab preexposure prophylaxis. Twenty-eight individuals (30%) had their immunosuppression reduced during infection, 71 (76%) received antiviral treatment (outlined in Table 1), and 11 (12%) required hospitalization for infection.

PASC Symptom Prevalence

Forty-six individuals (49%) reported experiencing ≥1 of the 13 symptoms assessed by the PASC score for a duration of ≥30 d (Figure 1A). Eighteen patients (19%) reported having symptoms at the time of the survey. The most frequent symptoms were fatigue (65%), post-exertional malaise (57%), and brain fog (43%). The median duration of each type of symptom in symptomatic individuals is shown in Figure 1B. In symptomatic individuals, each individual experienced, on average, 3.0 symptoms at 2 mo postinfection, gradually decreasing to 1.6 symptoms at 12 mo postinfection (Figure 1C). Using the PASC score, 13 individuals (14%) met the PASC definition.[1]

Association Between Clinical Characteristics and Development of Any PASC Symptoms

We evaluated the association between clinical characteristics and the development of any (≥1) PASC symptom, whether they met the full definition of PASC (ie, a score of ≥12 on the PASC survey). Univariable analysis (Figure 2A) showed that female sex (uOR = 0.29; 95% CI, 0.12-0.68; $P = 0.005$) and years from transplantation (uOR = 0.91 for each additional year, 95% CI, 0.83-0.99; $P = 0.038$) were associated with significantly lower odds of developing ≥1 PASC symptoms. Age at infection, solid organ type, a history of infection before the Omicron period, the number of vaccine doses, time since last vaccine dose, tixagevimab-cilgavimab preexposure prophylaxis, hospitalization for infection, immunosuppression reduction, and antiviral treatment were not associated with the odds of developing ≥1 PASC symptoms ($P > 0.05$ for all). Multivariable analysis (Figure 2B) showed that female sex (aOR = 0.32; 95% CI, 0.12-0.83; $P = 0.022$), years from transplantation (aOR = 0.90 for each additional year; 95% CI, 0.81-0.99; $P = 0.042$), and tixagevimab-cilgavimab preexposure prophylaxis (aOR = 0.33; 95% CI, 0.12-0.84; $P = 0.024$) were associated with significantly lower odds of developing ≥1 PASC symptoms. Age at infection and the number of vaccine doses were not associated with the odds of developing ≥1 PASC symptoms in multivariable analysis ($P > 0.05$ for both).

Association Between Clinical Characteristics and Development of PASC

We evaluated the association of clinical characteristics with the development of PASC, defined as a score of ≥12 on the PASC survey. Univariable analysis (**Figure S1, SDC,** http://links.lww.com/TXD/A687) showed that years from transplantation (uOR = 0.73 for each additional year, 95% CI 0.53-0.92, $P = 0.025$) was the only factor associated with significantly lower odds of developing PASC. Although there was no significant association between receiving any antiviral treatment and the development of PASC ($P = 0.454$), we noted that none of the individuals who received remdesivir (n = 16) developed PASC. Multivariable analysis could not be performed because of the limited number of events.

DISCUSSION

In this study, we aimed to describe PASC in SOTRs infected during the Omicron period using a new robust definition and to evaluate the association between clinical characteristics and the development of PASC symptoms.[1] Our main findings were that (1) PASC symptoms are common in SOTRs infected during the Omicron period and take months to improve; (2) female sex, longer time since transplantation at the time of infection, and tixagevimab-cilgavimab preexposure prophylaxis were associated with lower odds of developing ≥1 PASC symptoms in SOTRs

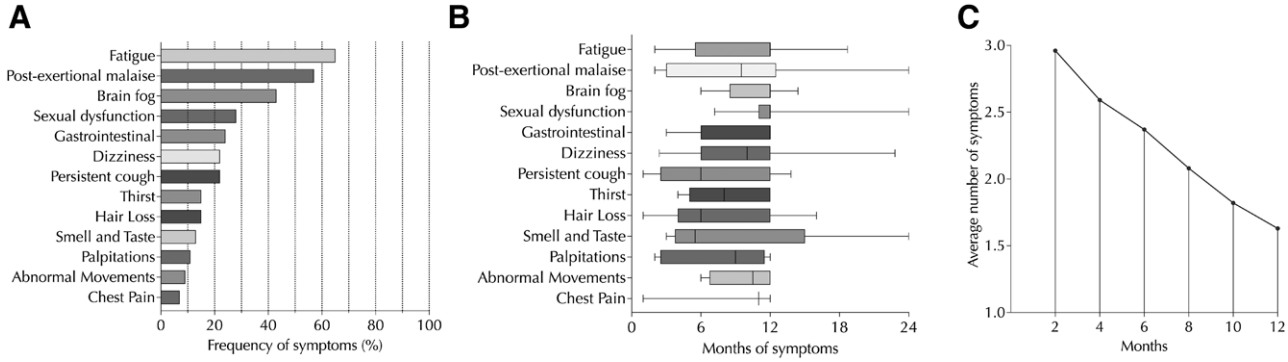

FIGURE 1. Symptoms of PASC in solid organ transplant recipients infected during the Omicron period. A, Frequency of PASC symptoms in the cohort (n = 93). B, Duration of each PASC symptom. The boxplot shows 10th, 25th, 50th, 75th, and 90th percentiles. C, Average number of PASC symptoms per symptomatic individual in the cohort (n = 46). PASC, post–acute sequelae of SARS-CoV-2 infection.

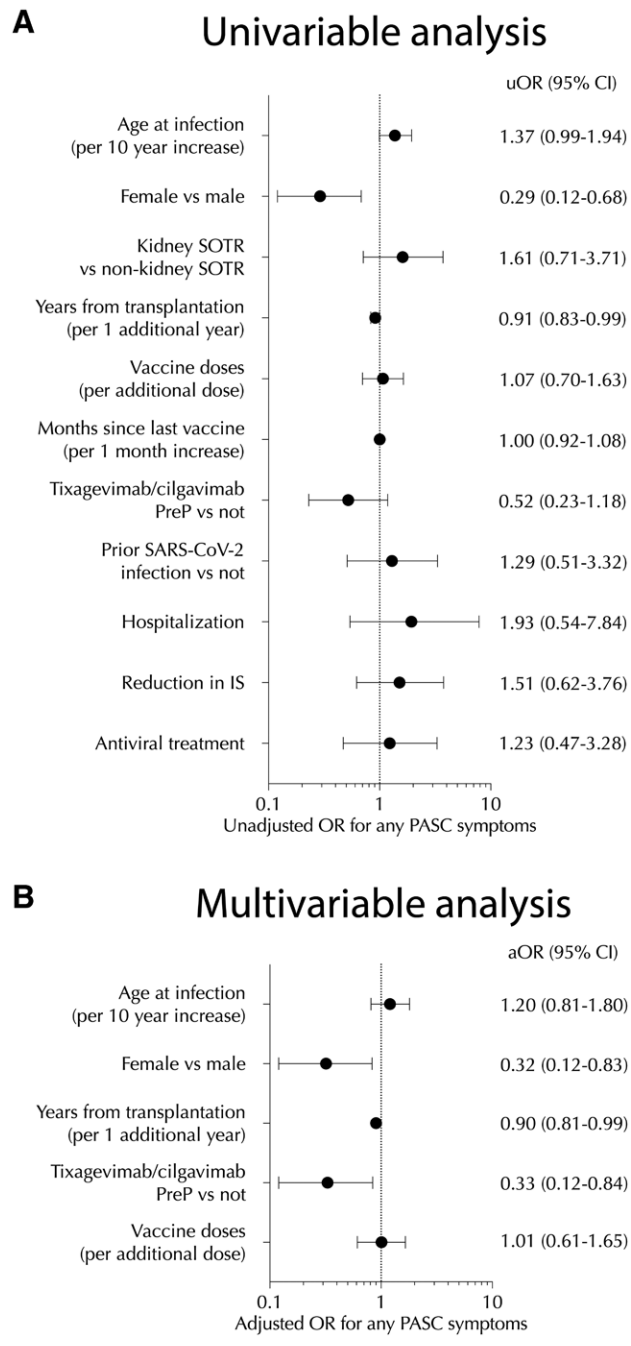

FIGURE 2. The association between clinical characteristics and the development of symptoms PASC in solid organ transplant recipients infected during the Omicron period. Statistics by univariable (A) and multivariable (B) logistic regression. aOR, adjusted odds ratio; IS, immunosuppression; PASC, post–acute sequelae of SARS-CoV-2 infection; PreP, preexposure prophylaxis; SOTR, solid organ transplant recipient; uOR, unadjusted odds ratio.

infected during the Omicron period; and (3) a longer time since transplantation at the time of infection was associated with lower odds of developing a PASC symptom score of ≥12 that defines PASC.

The definition of PASC used in our article was derived from a study of 9764 patients where symptoms had a prevalence of ≥2.5% and an adjusted odds ratio of ≥1.5 in the exposed versus control groups to be included. Also, the overall score of ≥12, which was used to define PASC was used to minimize the number of uninfected individuals who were able to meet the criteria for PASC.[1] Although the methodology used to define PASC was sound, it is important to note a few points: (1) rare symptoms that did not meet the ≥2.5% prevalence criteria may still be part of PASC and (2) PASC may include a spectrum and, therefore, people with fewer symptoms may not meet the full definition of PASC proposed (score of ≥12). However, these symptoms may still have an impact on quality of life. Because of that, we decided to analyze the development of both (1) any PASC symptom and (2) PASC symptoms meeting the proposed definition of PASC.

PASC is more common in immunocompromised individuals and has a significant effect on physical health, cognition, and quality of life of individuals, and therefore, it is important to investigate this.[4,6,13] We found that 49% of SOTRs had at least 1 symptom associated with PASC and 14% met the definition of PASC.[1] The most common symptoms were fatigue, post-exertional malaise, and brain fog, which lasted for several months with a median duration of 5.5 to 12.0 mo, depending on the symptom. Prior studies in non-transplant patients have demonstrated that 32% to 56.9% have ≥1 PASC symptom at varying intervals after a COVID infection.[2,3] The incidence of PASC symptoms in SOTRs also varies, with studies reporting rates between 27% and 70.1%.[14-19] Because these studies had different populations and used other definitions of PASC, comparisons are difficult to make. However, these studies consistently show that PASC symptoms are common.

When we evaluated clinical characteristics, we found that a longer time since transplantation at the time of infection was associated with lower odds of developing (1) any PASC symptoms and (2) a PASC symptom score ≥12 meeting the definition of PASC. This finding may be because of SOTRs requiring a lower amount of immunosuppression farther out from transplantation, but this requires confirmation because the immunosuppression regimen at the time of infection was not captured in our collected data. This finding has not been consistent in previous studies. In 2 studies of kidney transplant recipients, there was no association between time since transplantation and the development of PASC symptoms.[14,15] These studies differed from ours in that they included only kidney transplant recipients, included SOTRs who were on average 6–8 y out from transplantation (as opposed to 4.1 in our study), were conducted in the pre-Omicron era, and used a different definition of PASC.

&&Prior studies have yielded inconsistent findings regarding the association between hospitalization for SARS-CoV-2 infection and the risk of PASC in kidney transplant recipients.[14–16,18] When we evaluated the characteristics of SARS-CoV-2 infection and its treatment, we found no significant association between hospitalization, antiviral treatment, or reduction in immunosuppression at the time of infection with the development of PASC symptoms. One notable finding was that no individuals who received remdesivir treatment developed PASC symptoms that met the criteria for PASC. Because our study was underpowered to evaluate these associations, we cannot conclude that they do not exist, and larger studies looking at the association between specific antiviral treatments and reduction in immunosuppression with PASC outcomes, not just mortality or hospitalization, are needed.

Vaccination has been associated with reduced mortality from SARS-CoV-2 infection in SOTRs.[20–22] The association between vaccination and PASC in SOTRs has not been studied thoroughly. Within our cohort, we compared the association between additional vaccine doses and months since the last vaccination with the odds of developing PASC symptoms but did not find associations between them. In our study, we were not able to compare vaccinated to unvaccinated individuals because our cohort was 99% vaccinated, and the number of PASC events made our study underpowered to find differences based on the number of vaccines. In one study that included both immunocompetent and immunocompromised individuals infected before the Omicron era, prior vaccination was associated with a 15% reduction in the risk of developing PASC symptoms.[6] In a recent study of 208 SOTRs, pretransplant SARS-CoV-2 vaccination was associated with lower odds of developing PASC, possibly because of improved vaccine-induced immune responses generated before transplantation.[18]

We also evaluated the association between tixagevimab-cilgavimab preexposure prophylaxis and the odds of developing PASC symptoms. Tixagevimab-cilgavimab preexposure prophylaxis is associated with a lower risk of SARS-CoV-2 infection during the early Omicron period in vaccinated SOTRs,[12,23] but its association with PASC symptoms has not been examined. Multivariable analysis showed that tixagevimab-cilgavimab preexposure prophylaxis was associated with lower odds of developing PASC symptoms. Although tixagevimab-cilgavimab is no longer used because of its reduced efficacy against newer SARS-CoV-2 lineages, this finding highlights the point that newer preventive and treatment strategies for SARS-CoV-2 need to evaluate their impact on PASC as an outcome and not only mortality or hospitalization.

The strengths of our study include the granular clinical data collected by manual chart review, the evaluation of the associations between previously unevaluated characteristics with the development of PASC symptoms, and the utilization of the new PASC definition. The limitations of our study include (1) its cross-sectional design, which only captures a snapshot of symptoms, and the long duration between SARS-CoV-2 infection and survey administration, which makes the participants susceptible to recall bias, (2) the small sample size, which may have underpowered our study to find certain associations and limited our ability to adjust our analyses for additional covariates that may confound the associations we found, (3) selection bias as individuals who responded to the survey may differ from those who did not, (4) the lack of availability of certain clinical information such as immunosuppression regimens at the time of infection, which may influence PASC outcomes, and (5) the underrepresentation of certain subgroups such as unvaccinated SOTRs and liver transplant recipients to whom our findings may not be generalizable.

In summary, we described PASC symptoms in SOTRs infected during the Omicron period and evaluated the association between clinical characteristics and the development of PASC symptoms. These findings need to be validated in larger prospective studies and need to be combined with studies to identify biological biomarkers of PASC.[24] We propose that PASC symptoms be included in future studies evaluating preventive and treatment strategies for SARS-CoV-2 infection in SOTRs.

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