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TRANSPLANT INFECTIOUS DISEASE

BRIEF COMMUNICATION

Clinical characteristics of COVID-19 in solid organ transplant recipients following COVID-19 vaccination: A multicenter case series

Kapil K. Saharia[1] | Shweta Anjan[2] | Judy Streit[3] | Susan E. Beekmann[3] | Philip M. Polgreen[3] | Matthew Kuehnert[4] | Dorry L. Segev[5] | John W. Baddley[1] | Rachel A. Miller[6] | the EIN COVID-19 Study Team

[1] Institute of Human Virology, Division of Infectious Diseases, University of Maryland School of Medicine, Baltimore, Maryland, USA

[2] Department of Medicine, Division of Infectious Diseases, University of Miami Miller School of Medicine, Miami, Florida, USA

[3] Department of Medicine, Division of Infectious Diseases, University of Iowa Carver College of Medicine, Iowa City, Iowa, USA

[4] Department of Medicine, Hackensack Meridian School of Medicine, Hackensack, New Jersey, USA

[5] Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA

[6] Department of Medicine, Division of Infectious Diseases, Duke University School of Medicine, Durham, North Carolina, USA

Correspondence
Kapil K. Saharia, Institute of Human Virology, Division of Infectious Diseases, University of Maryland School of Medicine, 725 W. Lombard Street, Rm N354, Baltimore, MD 21201, USA.
Email: ksaharia@ihv.umaryland.edu

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Background: Solid organ transplant recipients (SOTR) have diminished humoral immune responses to COVID-19 vaccination and higher rates of COVID-19 vaccine breakthrough infection than the general population. Little is known about COVID-19 disease severity in SOTR with COVID-19 vaccine breakthrough infections.

Methods: Between 4/7/21 and 6/21/21, we requested case reports via the Emerging Infections Network (EIN) listserv of SARS-CoV-2 infection following COVID-19 vaccination in SOTR. Online data collection included patient demographics, dates of COVID-19 vaccine administration, and clinical data related to COVID-19. We performed a descriptive analysis of patient factors and evaluated variables contributing to critical disease or need for hospitalization.

Results: Sixty-six cases of SARS-CoV-2 infection after vaccination in SOTR were collected. COVID-19 occurred after the second vaccine dose in 52 (78.8%) cases, of which 43 (82.7%) occurred ≥14 days post-vaccination. There were six deaths, three occurring in fully vaccinated individuals (7.0%, $n = 3/43$). There was no difference in the percentage of patients who recovered from COVID-19 (70.7% vs. 72.2%, $p = .90$) among fully and partially vaccinated individuals. We did not identify any differences in hospitalization (60.5% vs. 55.6%, $p = .72$) or critical disease (20.9% vs. 33.3%, $p = .30$) among those who were fully versus partially vaccinated.

Conclusions: SOTR vaccinated against COVID-19 can still develop severe, and even critical, COVID-19 disease. Two doses of mRNA COVID-19 vaccine may be insufficient to protect against severe disease and mortality in SOTR. Future studies to define correlates of protection in SOTR are needed.

KEYWORDS
breakthrough infection, COVID-19 vaccine, mRNA vaccines, severe COVID-19, solid organ transplantation

Abbreviations: CNI, calcineurin inhibitor; EIN, Emerging Infections Network; FDA, Food and Drug Administration; IQR, interquartile range; mRNA, messenger ribonucleic acid; PCR, polymerase chain reaction; SOTR, solid organ transplant recipient

1 | INTRODUCTION

During the early phase of the COVID-19 pandemic, SARS-CoV-2 infection in solid organ transplant recipients (SOTR) resulted in increased morbidity and mortality when compared with the general population. In the United States, approximately 75% of SOTR with COVID-19 required hospitalization, and of these 35%–40% required intensive care. Mortality from COVID-19 infection in SOTR ranged from 18%–24%.[1,2]

The US Food and Drug Administration (FDA) approved three COVID-19 vaccines under emergency use authorization: BNT162b2 (Pfizer) and mRNA-1273 (Moderna), both messenger RNA (mRNA) vaccines, and Ad26.COV2.S (Johnson and Johnson), an adenovirus vector-based vaccine. Clinical trial data demonstrate vaccine efficacy of 95% for the mRNA vaccines and 66% for Ad26.COV2.S among healthy volunteers.[3–5] However, the efficacy of these vaccines in SOTR is less clear as these patients were excluded from clinical trials.

Antibody responses to COVID-19 vaccine in SOTR are diminished when compared to immunocompetent controls.[6–8] This is consistent with the reports of reduced antibody responses to influenza, pneumococcal, and hepatitis B vaccination in SOTR.[9–12] Despite concerns about diminished humoral immune responses, rates of COVID-19 vaccine breakthrough infection in SOTR are low, estimated at 0.23%–2.5%.[13–16] However, these rates are higher than those reported in the general population (0.01%).[17] Presently, data in SOTR with COVID-19 vaccine breakthrough infection are limited to small case series.[13–15] In this large, multicenter case series acquired by an Emerging Infections Network (EIN) survey, we describe characteristics of COVID-19 infection following vaccination among SOTR and show that fully vaccinated SOTRs with COVID-19 vaccine breakthrough infection remain at risk for severe and critical COVID-19 and have mortality estimates that remain greater than the general population.

2 | MATERIALS AND METHODS

The Infectious Diseases Society of America's EIN is comprised of approximately 2800 members, primarily US-based infectious disease (ID) physicians, some international ID physicians, and federal, state, and local public health officials, who are linked via a moderated listserv.[18] On 4/7/21, we requested case report submissions via the EIN listserv of SARS-CoV-2 infection following COVID-19 vaccination in immunocompromised individuals. Four emailed reminders with the link to the case report form were sent; case reports were collected until 6/21/21. Online data collection included patient demographics, COVID-19 vaccine administration dates, and relevant COVID-19 clinical data. Vaccine breakthrough infection was defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory sample from an individual ≥14 days after completing all recommended doses of an FDA-authorized COVID-19 vaccine.[17] Individuals who developed COVID-19 <14 days after completing all recommended doses or after the first dose of a two-dose series were considered partially vaccinated. Patients diagnosed with COVID-19 who did not require hospitalization were classified as having mild disease, those requiring hospitalization but not ICU level care were classified as having severe disease, and those requiring ICU level care were categorized as having critical disease. We performed a descriptive analysis of patient factors and evaluated variables associated with critical disease or need for hospitalization using chi-square or Fisher's exact testing. Two-sided p-values <.05 were considered statistically significant.

This study was reviewed by the University of Iowa IRB which determined it did not meet the regulatory definition of human subjects' research and approved this study as a public health surveillance activity.

3 | RESULTS

Eighteen physicians contributed 66 adult cases of COVID-19 after vaccination in SOTR. All COVID-19 cases were diagnosed by polymerase chain reaction (PCR) testing, none by antigen testing. Of the 66 cases, 37 (56.1%) occurred in males, and 52 (78.8%) occurred in individuals between 45 and 74 years of age. Renal transplant recipients accounted for 30 (45.5%) cases. The most common maintenance immunosuppressive regimens in this cohort included calcineurin inhibitor (CNI) + mycophenolate (N = 17, 25.8%) and steroids + CNI + mycophenolate or azathioprine (N = 38, 57.8%) (Table 1).

COVID-19 occurred after the first vaccine dose in nine (13.6%) cases at a median of 9 (IQR 5–16) days from initial vaccination. COVID-19 occurred after the second vaccine dose in 52 (78.8%) cases, of which 43 (82.7%) occurred ≥14 days postvaccination. The median time to symptom onset from last vaccination among individuals with vaccine breakthrough infection was 34 (IQR 26–60) days. Vaccine administration dates were unknown for five cases, and two cases occurred in fully vaccinated, asymptomatic individuals identified through contact investigation.

Monoclonal antibodies were administered to 15 (53.5%, n = 28) SOTR with mild COVID-19, of which casirivimab/imdevimab was given to 14 individuals. Remdesivir was administered to 13 (61.9%, n = 21) patients with severe disease and five (29.4%, n = 17) individuals with critical disease. Convalescent plasma was administered to three patients with critical disease.

Thirty-eight SOTR (57.6%) with COVID-19 after vaccination required hospitalization, 17 (25.8%) individuals developed critical illness, and 10 (15.2%) individuals required mechanical ventilation (Table 2). At the time of reporting, six (9.1%) individuals died. All six deaths occurred in individuals aged 45 years or older, who were transplanted 2 or more years prior to symptom onset. Three of the six deaths occurred in individuals with vaccine breakthrough infection (3/43, 7.0%). Forty-five individuals (68.2%) recovered or were improving following COVID-19 infection, with similar percentages in fully vaccinated and partially vaccinated groups (70.7% [29/41] vs. 72.2% [13/18], p = .90).

When comparing individuals who received BNT162b2 or mRNA-1273 COVID-19 vaccines, there were no statistically significant differences in hospitalization frequency (55.1% [27/49] vs. 64.3% [9/14],

TABLE 1 Patient demographics and clinical characteristics

	Number (%)
Gender	
Male	37 (56.1%)
Female	28 (42.4%)
Unknown	1
Age	
18–44	7 (10.6%)
45–64	28 (42.4%)
65–74	24 (36.4%)
75-84	7 (10.6%)
Organ transplanted	
Lung	14 (21.2%)
Heart	10 (15.2%)
Kidney	30 (45.5%)
Liver	5 (7.6%)
Dual[†]	7 (10.6%)
Time from organ transplant	
<1 year	9 (13.6%)
1–2 years	9 (13.6%)
2–5 years	20 (30.3%)
>5 years	24 (36.4%)
Unknown	4 (6.1%)
Vaccine administered	
BNT162b2 (Pfizer)	49 (74.2%)
mRNA-1273 (Moderna)	14 (21.2%)
Ad26.COV2.S (Johnson & Johnson)	1 (1.5%)
Unknown	1 (1.5%)
Symptom onset[¶]	
After 1st vaccine dose	9 (13.6%)
After completing vaccine series	
<14 days after completing all recommended doses	9 (13.6%)
14 or more days after completing all recommended doses[‡]	41 (62.1%)
Maintenance immunosuppression	
Calcineurin inhibitor + Mycophenolate	17 (25.8%)
Steroids + calcineurin inhibitor + mycophenolate or azathioprine	38 (57.6%)
Other[¶¶]	10 (9.1%)

[†]Five kidney/pancreas, two liver/kidney.

[¶]Seven individuals excluded; date of vaccine administration not known for five individuals, and two individuals were asymptomatic.

[¶¶]Steroids/Tacrolimus/Sirolimus (n = 1), steroids/mycophenolate/everolimus/belatacept (n = 1), steroids/mycophenolate/belatacept (n = 1), steroids/belatacept (n = 1), sirolimus/belatacept (n = 1), steroids/calcineurin inhibitor (n = 2), tacrolimus (n = 1), steroids/tacrolimus/rituximab (n = 1), tacrolimus/mycophenolate/azathioprine (n = 1), mycophenolate/sirolimus (n = 1).

TABLE 2 Outcomes of COVID-19 following SARS-CoV-2 vaccination in solid organ transplant recipients

	Number (%)
Disease severity	
Mild	28 (42.4%)
Severe	21 (31.8%)
Critical[†]	17 (25.8%)
Outcomes	
Recovered/Improving	45 (68.2%)
Deteriorating/Sequelae	11 (16.7%)
Died	6 (9.1%)
Unchanged	2 (3%)
Unknown	2 (3%)

[†]Ten patients with critical illness required mechanical ventilation.

TABLE 3 Outcomes of COVID-19 among fully and partially vaccinated solid organ transplant recipients[†]

	Fully vaccinated[¶] N = 43 (%)	Partially vaccinated N = 18 (%)	p-value
Hospitalized	26 (60.5%)	10 (55.6%)	p = .72
Not hospitalized	17 (39.5%)	8 (44.4%)	
Critical disease	9 (20.9%)	6 (33.3%)	p = .30
Not critical disease	34 (79.1%)	12 (66.7%)	
Recovered/Improving	29 (70.7%)	13 (72.2%)	p = .90
Not improving[‡]	12 (29.3%)	5 (27.8%)	

[†]The date of vaccine administration was not known for five cases. These five cases were excluded from analysis.

[‡]Not improving includes the following complications: died, deteriorating, sequelae, and unchanged clinical status.

[¶]Final outcome for two individuals who were fully vaccinated was reported as unknown.

p = .76) or critical COVID-19 (20.4% [10/49] vs. 42.9% [6/14], p = .16). Similarly, there were no significant differences in hospitalization frequency (60.5% [26/43] vs. 55.6% [10/18], p = .72) or critical disease (20.9% [9/43] vs. 33.3% [6/18], p = .30) when comparing fully vaccinated and partially vaccinated groups (Table 3). Finally, maintenance immunosuppressive therapy at the time of SARS-CoV-2 infection (CNI + mycophenolate vs. steroids + CNI + mycophenolate or azathioprine) did not impact the frequency of critical disease (23.5% [4/17] vs. 23.7% [9/38], p = .99) or need for hospitalization (58.8% [10/17] vs. 57.9% [22/38], p = .95).

One case of acute rejection occurred after COVID-19 in a lung transplant recipient with critical COVID-19 diagnosed 9 days after receiving the second dose of mRNA-1273 COVID-19 vaccine; acute rejection was presumptive as it was not biopsy confirmed. No cases of putative or confirmed acute rejection attributable to COVID-19 vaccination were reported. A single case of allograft loss was reported in a kidney transplant recipient with critical COVID-19.

4 | DISCUSSION

This multicenter case series provides a detailed description of COVID-19 in SOTR following SARS-CoV-2 vaccination. Most COVID-19 cases met the Centers for Disease Control definition of vaccine breakthrough infection (43/66, 65.1%) and occurred a median of 34 days after completing the COVID-19 vaccine series. Key findings of our study are the high frequency of hospitalization (60.5%) and critical COVID-19 (20.9%) among fully vaccinated SOTR with breakthrough infection and increased mortality in SOTR with COVID-19 vaccine breakthrough infection (7.0%) when compared to reports in the general population (2%).[17] This suggests that for a sizable proportion of SOTR, two doses of mRNA COVID-19 vaccine may be insufficient to protect against severe disease and mortality.

The mortality in SOTR with COVID-19 vaccine breakthrough infection in our study is consistent with the reports from the UK Transplant Registry (7.7% mortality) and a multicenter evaluation of COVID-19 vaccine breakthrough infections in SOTR (9.3%).[16,19] While these mortality rates are higher than the general population, the UK transplant registry study found that fully-vaccinated SOTRs have a lower mortality than unvaccinated SOTR (7.7% vs. 12.6%).[19] Additionally, mortality from COVID-19 vaccine breakthrough infection in SOTR appears to be lower than mortality estimates among SOTR hospitalized for COVID-19 from June 2020 to December 2020,[20] a period prior to COVID-19 vaccination and characterized by improvements in COVID-19 supportive and therapeutic management.

Although most COVID-19 breakthrough infection cases in our series required hospitalization and one-fifth had critical COVID-19, the frequency of critical COVID-19 in fully vaccinated SOTR is lower compared to unvaccinated SOTR in the later stage of the COVID-19 pandemic (39.2%).[20] This is consistent with the data from the general population which also found a lower frequency of critical COVID-19 in fully vaccinated individuals with breakthrough COVID-19 infection in comparison to unvaccinated cases (20% vs. 33.6%).[21]

Unlike other groups that found a lower frequency of hospitalization in fully vaccinated individuals with COVID-19 than partially vaccinated individuals[22,23] we did not observe significant differences between our fully and partially vaccinated groups. This likely reflects insufficient power to detect differences due to our small sample size. Another explanation could be the inclusion of individuals who completed the COVID-19 vaccine series but developed COVID-19 infection <14 days after completing the vaccine series ($N = 9$) in our partially vaccinated group. It is possible the second vaccine dose could have conferred enhanced protection, reducing their risk of critical COVID-19 and need for hospitalization. Alternatively, additional doses of COVID-19 vaccine may be needed in SOTR to improve protection against infection and severe disease. To support this, several recent publications have demonstrated improved antibody responses following additional doses of COVID-19 mRNA vaccine,[24–26] prompting an FDA- recommendation for a third dose of mRNA vaccine in SOTR.

Reduced immunogenicity to COVID-19 vaccines has been associated with mycophenolate use and use of triple immunosuppression.[6–8] We were unable to evaluate the impact of anti-metabolite use on COVID-19 disease outcomes in our cohort as nearly all patients were receiving anti-metabolites as part of their immunosuppressive regimen (89.4%, $n = 59/66$) at the time of COVID-19 diagnosis. We did not appreciate any differences in the frequency of hospitalization (58.8% vs. 57.9%) when comparing individuals receiving triple immunosuppression to those receiving CNI + mycophenolate, nor in the frequency of critical COVID-19 disease (23.7% vs. 23.5%).

Despite a theoretical concern that COVID-19 vaccination may trigger organ rejection, we did not identify any cases of biopsy-proven organ rejection attributable to COVID-19 vaccination in our case series. The single putative case of organ rejection occurred in a partially vaccinated individual following COVID-19 diagnosis, and this case was not biopsy-proven. Our findings are consistent with other reports describing safety of COVID-19 vaccination among SOTR.[6–8]

Our study has several limitations. First, only 18 physicians contributed cases for this multicenter case series. Cases were submitted retrospectively and represent a convenience sample raising concerns about selection bias. It is likely that the cases reported were skewed toward hospitalized patients, overestimating disease severity and mortality. One-quarter of our study patients (17/66, 25.7%) remained hospitalized at the time of data reporting which could impact mortality estimates. Data collection was not complete for all cases. For example, the dates of vaccination and outcomes were unknown for a subset of cases.

To expedite survey completion, we did not collect data on chest imaging, oxygen saturation, or need for supplemental oxygen. We could not differentiate hospitalized patients with moderate disease from those with severe disease using established definitions[27,28] and, therefore, categorized all hospitalized patients with COVID-19 as having severe disease.

Importantly, serologic data were available for only a subset of cases and only at the time of or after PCR confirmation of SARS-CoV-2 infection. We were unable to correlate humoral immunity with disease severity. The absence of serological data was not unexpected as both the FDA and professional societies (American Society for Transplantation, Infectious Diseases Society of America) recommended against routine use of commercially available antibody tests to assess vaccine-induced immunity.

Finally, we did not capture viral sequencing data and do not know if breakthrough infections were caused by viral variants, such as the delta variant (B.1.617.2), which is associated with increased transmissibility and disease severity.[22]

In summary, this large, multicenter case series provides detailed characteristics of SARS-CoV-2 infection following COVID-19 vaccination among SOTR. Our data confirm that vaccinated SOTR can develop severe and even critical COVID-19 after vaccination. However, our findings suggest that fully vaccinated SOTR may have lower rates of critical COVID-19 and lower mortality from COVID-19 when compared to data from unvaccinated SOTR during the later stages of the COVID-19 pandemic. These data should provide some reassurance to vaccinated SOTR and used to encourage vaccine uptake among unvaccinated SOTR. However, it remains important for SOTR to continue to follow strict COVID-19 precautions to lessen risk. Further studies are

needed to determine the long-term effectiveness of COVID-19 vaccination in SOTR, the impact of viral variants on outcomes of vaccinated SOTR, and whether additional vaccine doses of mRNA vaccine will provide enhanced protection against COVID-19.

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CONFLICT OF INTEREST

All the authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Kapil Saharia contributed cases, performed data analysis, data interpretation, and wrote the manuscript. Shweta Anjan contributed cases, performed data interpretation, critical revision of the manuscript. Judy Streit, Susan Beekmann, and Phil Polgreen performed study design, data collection, data interpretation, and critical revision of the manuscript. John Baddley, Matthew Kuehnert, and Dorry Segev performed data interpretation and critical revision of the manuscript. Rachel Miller contributed cases, performed study design, data interpretation, and wrote manuscript.

ETHICS STATEMENT

This study was reviewed by the University of Iowa IRB which determined it did not meet the regulatory definition of human subjects' research and approved this study as a public health surveillance activity.

ORCID

Kapil K. Saharia https://orcid.org/0000-0002-5116-0042
Shweta Anjan https://orcid.org/0000-0002-7761-1163
Judy Streit https://orcid.org/0000-0001-8629-3622
Susan E. Beekmann https://orcid.org/0000-0003-0278-506X
John W. Baddley https://orcid.org/0000-0001-9111-625X

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