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MAJOR ARTICLE

Monoclonal Antibody Therapy for COVID-19 in Solid Organ Transplant Recipients

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Background. Bamlanivimab and casirivimab-imdevimab are authorized for emergency use treatment of mild to moderate coronavirus disease 2019 (COVID-19) in patients at high risk for developing severe disease or hospitalization. Their safety and efficacy have not been specifically evaluated in solid organ transplant recipients.

Methods. We retrospectively reviewed solid organ transplant recipients who received monoclonal antibody infusion for COVID-19 at Mayo Clinic sites through January 23, 2021. Outcomes included emergency department visit, hospitalization, mortality, and allograft rejection.

Results. Seventy-three patients were treated, most commonly with bamlanivimab (75.3%). The median age was 59 years, 63% were male, and the median Charlson comorbidity index was 5. Transplant type included 41 kidney (56.2%), 13 liver (17.8%), 11 heart (15.1%), 4 kidney-pancreas (5.5%), 2 lung (2.7%), 1 heart-liver, and 1 pancreas. Eleven (15.1%) patients had an emergency department visit within 28 days of infusion, including 9 (12.3%) who were hospitalized for a median of 4 days. One patient required intensive care unit admission for a nonrespiratory complication. No patients required mechanical ventilation, died, or experienced rejection. Ten adverse events occurred, with 1 seeking medical evaluation. Hypertension was associated with hospital admission ($P < .05$), while other baseline characteristics were similar. The median time from symptom onset to antibody administration was 4 days in nonhospitalized patients compared with 6 days among hospitalized patients ($P < .05$).

Conclusions. Monoclonal antibody treatment has favorable outcomes with minimal adverse effects in solid organ transplant recipients with mild to moderate COVID-19. Earlier administration of monoclonal antibody therapy appears to be more efficacious.

Keywords. bamlanivimab; casirivimab-imdevimab; COVID-19; SARS-CoV-2; transplant.

As of March 9, 2021, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has affected over 116 million people and is responsible for >2.5 million deaths worldwide [1]. Morbidity and mortality from coronavirus disease 2019 (COVID-19) are higher in patients with medical conditions, including solid organ transplantation [2–4]. Data from a large, multicenter registry showed that transplant recipients with COVID-19 had poor outcomes, including a hospitalization rate of 78%, mechanical ventilation rate of 31%, and 28-day mortality of 20.5% [5]. Other studies have shown similarly poor outcomes in this immunocompromised population [6–10].

Several therapies have been approved or authorized for the treatment of COVID-19, often directed at later stages of illness when patients need hospitalization [11]. Monoclonal antibodies targeting the SARS-CoV-2 spike protein, such as bamlanivimab and casirivimab-imdevimab, have specifically been evaluated as an early outpatient treatment to prevent the clinical progression of mild to moderate COVID-19. In an interim analysis of the BLAZE-1 trial, there were fewer hospitalizations and emergency department (ED) visits in patients who received bamlanivimab, particularly among older populations and those with a body mass index (BMI) of 35 or higher [12]. The REGN-COV2 trial of casirivimab and imdevimab showed a similar reduction in medically attended visits [13]. On the basis of these trials, bamlanivimab and casirivimab-imdevimab received separate emergency use authorizations (EUA) in the United States in November 2020 for the treatment of mild to moderate COVID-19 in patients at high risk for progression to severe disease or hospitalization [14, 15]. Patients receiving immunosuppressive drug treatment, such as solid organ transplant recipients, are included in the high-risk criteria for emergency use, although they were not specifically analyzed as part of the BLAZE-1 or REGN-COV2 trials.

There is very limited experience with monoclonal antibodies in transplant recipients [16]. Furthermore, there are no data regarding adverse effects or risk of allograft rejection after

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monoclonal antibody therapy in the transplant population. In this report, we aim to describe our early experience with the use of monoclonal antibody therapy for the treatment of solid organ transplant recipients with mild to moderate COVID-19.

METHODS

Monoclonal Antibody Allocation Process

The Mayo Clinic monoclonal antibody treatment (MATRx) program was established on November 7, 2020, with the creation of COVID-19 dedicated outpatient infusion units and multidisciplinary teams in anticipation of the EUA of monoclonal antibody therapies for COVID-19 by the US Food and Drug Administration [17].

The MATRx team developed the Monoclonal Antibody Selection Score, which automatically and rapidly identifies all eligible patients, including transplant recipients, from the electronic health record system. Under the EUA, patients are eligible for monoclonal antibodies if they have a positive SARS-CoV-2 polymerase chain reaction (PCR) or antigen test, have mild to moderate COVID-19, are within 10 days of symptom onset, and have at least 1 of the following criteria: age ≥65 years, BMI ≥35, diabetes mellitus, chronic kidney disease, immunosuppressive medication use, or an immunocompromising condition, including solid organ transplant recipients. Patients 55 years and older also qualify if they have hypertension, cardiovascular disease, or chronic lung disease.

A multidisciplinary MATRx team reviewed all patients identified from this registry of patients with positive SARS-CoV-2 PCR tests and self- and provider-referred patients. All eligible patients were proactively approached for education about monoclonal antibodies and discussion about their potential benefits and adverse reactions. During the first 45 days of the MATRx program, a total of 2820 patients were deemed eligible and were approached for monoclonal antibody therapy. However, only 60% of them consented to monoclonal antibody infusion. All patients who agreed to treatment were immediately scheduled for infusion in 1 of 9 COVID-19 infusion therapy units at any Mayo Clinic site. Patients who were initially undecided were referred to their transplant providers, who supported the treatment and encouraged transplant patients to consent for the monoclonal antibody infusion. Accordingly, during the time of this study, all eligible solid organ transplant recipients consented to and received an infusion of either bamlanivimab monotherapy or casirivimab-imdevimab.

Monoclonal antibody was infused over an hour without premedication followed by another hour of monitoring for adverse effects. Patients were subsequently followed by a remote monitoring program and/or were provided a phone number to call back to report any untoward reactions [18]. All transplant patients were included in the Monoclonal Antibody Treatment Registry.

Patient Data

After approval by the Mayo Clinic Institutional Review Board, we retrospectively reviewed and collected data from recipients of bamlanivimab or casirivimab-imdevimab who had a history of solid organ transplantation. Patients were included if treated between the first infusion date of November 19, 2020, and January 23, 2021. Patients were followed up to 28 days. Abstracted data included demographics, comorbid conditions, type and date of transplantation, and dates of symptom onset, positive COVID-19 testing, and monoclonal antibody administration. Chronic lung disease included chronic obstructive pulmonary disease, asthma, and interstitial lung disease. Chronic liver disease included cirrhosis, nonalcoholic steatohepatitis, and nonalcoholic fatty liver disease. Recent acute rejection included those occurring within 6 months of COVID-19 diagnosis. We included details surrounding ED visits, hospital admission, intensive care unit (ICU) admission, mortality, adverse events, and allograft rejection.

Outcome Definitions

Outcomes included ED visit, hospital admission, ICU admission, mortality, and allograft rejection at 28 days after monoclonal antibody administration. All-cause ED visits, hospital admission, and death were included. Short-term outcomes were also analyzed at 14 and 21 days. Adverse events were defined as new or worsened symptomatology following monoclonal antibody administration. Episodes of allograft rejection were based on pathologic findings or empiric antirejection treatment for acute changes in organ function.

Statistical Analysis

Continuous variables were summarized as their median and interquartile range (IQR). Other variables were reported as total number with associated percentage. The hospitalized and nonhospitalized groups were analyzed using the Fisher exact test for categorical variables and the *t* test for continuous variables.

RESULTS

Patient Characteristics

We identified 73 patients meeting inclusion criteria. These patients were majority male, with a median age of 59 years (Table 1). Most patients received bamlanivimab (75.3%). The most common types of transplanted organs were kidney (56.2%), liver (17.8%), and heart (15.1%). The median time from transplantation to COVID-19 diagnosis (IQR) was 4.9 (2.0–9.8) years. The median Charlson comorbidity index (CCI) score was 5 (Supplementary Table 1). Three patients experienced acute allograft rejection within 6 months of COVID-19 diagnosis. However, these episodes were mild, and no one required augmented immunosuppression for rejection. Patients received monoclonal antibody at a median (IQR) of 4 (3–7) days

Table 1. Patient Characteristics

	Total (n = 73)	Hospitalized (n = 9)	Nonhospitalized (n = 64)	*P* Value[a]
Age, median (IQR), y	59 (49–67)	62 (60–74)	57 (49–67)	.16
Male gender, No. (%)	46 (63.0)	7 (77.8)	39 (60.9)	.47
Bamlanivimab, No. (%)	55 (75.3)	8 (88.9)	47 (73.4)	.44[b]
Casirivimab-imdevimab, No. (%)	18 (24.7)	1 (11.1)	17 (26.6)	
Time from symptom onset to antibody administration, median (IQR), d	4 (3–7)	6 (4–7)	4 (2–6.25)	**.03**
Time from positive COVID-19 testing to antibody administration, median (IQR), d	2 (1–2)	2 (2–2)	1 (1–2.25)	.24
BMI, median (IQR), kg/m^2	29.17 (25.78–33.01)	31.91 (27.53–32.9)	28.75 (25.37–33.08)	.22
Kidney, No. (%)	41 (56.2)	7 (77.8)	34 (53.1)	.28[c]
Kidney-pancreas, No. (%)	4 (5.5)	0	4 (6.3)	
Liver, No. (%)	13 (17.8)	0	13 (20.3)	
Heart, No. (%)	11 (15.1)	2 (22.2)	9 (14.1)	
Heart-liver, No. (%)	1 (1.4)	0	1 (1.6)	
Lung, No. (%)	2 (2.7)	0	2 (3.1)	
Pancreas, No. (%)	1 (1.4)	0	1 (1.6)	
Prednisone, No. (%)	45 (61.6)	8 (88.9)	37 (57.8)	.14
Tacrolimus, No. (%)	64 (87.7)	8 (88.9)	56 (87.5)	1
Cyclosporine, No. (%)	2 (2.7)	0	2 (3.1)	1
Sirolimus, No. (%)	6 (8.2)	0	6 (9.4)	1
Mycophenolate, No. (%)	57 (78.1)	7 (77.8)	50 (78.1)	1
Azathioprine, No. (%)	2 (2.7)	0	2 (3.1)	1
Belatacept, No. (%)	3 (4.1)	1 (11.1)	2 (3.1)	.33
Recent rejection, No. (%)	3 (4.1)	0	3 (4.7)	1
Time from transplant, median (IQR), d	1777 (729–3582)	1503 (366–1829)	1890 (801.75–3821.25)	.22
CAD, No. (%)	13 (17.8)	3 (33.3)	10 (15.6)	.19
CHF, No. (%)	7 (9.6)	2 (22.2)	5 (7.8)	.20
Hypertension, No. (%)	48 (65.8)	9 (100)	39 (60.9)	**.023**
Diabetes mellitus, No. (%)	31 (42.5)	3 (33.3)	28 (43.8)	.72
CKD, No. (%)	40 (54.8)	6 (66.7)	34 (53.1)	.50
Malignancy, No. (%)	16 (21.9)	3 (33.3)	13 (20.3)	.40
Chronic lung disease, No. (%)	8 (11.0)	1 (11.1)	7 (10.9)	1
Chronic liver disease, No. (%)	9 (12.3)	0	9 (14.1)	.59
Current tobacco use, No. (%)	2 (2.7)	0	2 (3.1)	1
Previous tobacco use, No. (%)	26 (35.6)	4 (44.4)	22 (34.4)	.71
CCI, median (IQR)	5 (3–7)	6 (4–8)	5 (3–7)	.30

Bold indicates *P* value that reach statistical significance.

Abbreviations: BMI, body mass index; CAD, coronary artery disease; CCI, Charlson comorbidity index; CHF, congestive heart failure; CKD, chronic kidney disease; IQR, interquartile range.

[a]Comparison of hospitalized and nonhospitalized groups.

[b]Comparing risk of hospitalization for bamlanivimab and casirivimab-imdevimab.

[c]Comparing risk of hospitalization for kidney transplant and non–kidney transplant.

from symptom onset and 2 (1–2) days from positive COVID-19 testing. All patients completed the full 28-day follow-up. Characteristics of the cohort are detailed in Table 1.

Outcomes

The majority of ED visits (8 of 11) occurred within 14 days after monoclonal antibody infusions. Eleven patients (15.1%) presented to the ED within 28 days of monoclonal antibody infusion. The median time from symptom onset to ED visit (IQR) was 5 (3.5–6.5) days, and the median time from antibody administration to ED visit (IQR) was 2 (1.5–2) days. The most common reason for an ED visit was respiratory symptoms (7 patients, 63.6%). Other presenting complaints or conditions were hypertension, chest pain, headache with fever, and fever alone.

Most hospital admissions (7 of 9) occurred within 14 days of monoclonal antibody infusion. Nine patients were hospitalized within 28 days. All were admitted after an ED evaluation. Hospitalization was attributed to COVID-19 in 7 patients (77.8%). The other 2 patients were admitted for acute pyelonephritis and septic arthritis, respectively. The median time from symptom onset to hospitalization (IQR) was 11 (6–16) days, and the median time from antibody infusion (IQR) was 1 (0–9) day. Hospitalized patients had a median (IQR) of 6 (4–7) days from symptom onset to antibody administration, compared with 4 (2–6.25) days in the nonhospitalized cohort (Table 2). The median time from positive COVID-19 testing to monoclonal infusion (IQR) was longer for the hospitalized group, at 2 (2–2) days, compared with 1 (1–2.25) day in those not requiring hospitalization.

Table 2. Characteristics of Hospitalizations

	Hospitalized Patients (n = 9)
Admission attributable to COVID-19, No. (%)	7 (77.8)
Time from symptom onset to hospital admission, median (IQR), d	11 (6–16)
Time from antibody administration to hospital admission, median (IQR), d	1 (0–9)
Admission oxygen saturation, median (IQR), %	96 (93–96)
Maximum administered oxygen, median (IQR), L/min	1 (0–2)
Mechanical ventilation, No.	0
Remdesivir administration, No. (%)	7 (77.8)
Corticosteroid administration, No. (%)	2 (22.2)
Pre-COVID-19 lymphocyte count, median (IQR), 10^9/L	1.5 (0.94–1.96)
Admission lymphocyte count, median (IQR), 10^9/L	0.79 (0.66–0.96)
Hospital length of stay, median (IQR), d	4 (2–5)
ICU admission, No. (%)	1 (11.1)
Mortality, No.	0

Abbreviations: ICU, intensive care unit; IQR, interquartile range.

One heart transplant patient required ICU admission for dopamine infusion, not related to COVID-19 progression. Patients tended to be normoxic or mildly hypoxic, with a median admission oxygen saturation of 96% and highest recorded supplemental oxygen rate of 3 L/min. No patients required high-flow oxygen therapy, noninvasive positive pressure ventilation, or mechanical ventilation. No death was recorded during follow-up (Table 2). Rates of ED visit, hospitalization, and ICU admission at 14, 21, and 28 days are presented in Table 3.

Comorbidities and time from symptom onset or positive COVID-19 testing to monoclonal antibody administration were analyzed for association with hospitalization (Table 1). Hypertension was significantly associated with hospitalization ($P = .023$). Longer time from symptom onset to monoclonal antibody administration was associated with hospitalization ($P = .03$). There was not a significant difference in outcomes between the 2 monoclonal antibody therapies.

Adverse Events

Ten adverse events potentially attributable to monoclonal antibody therapy were noted. These included 4 patients with fever, 2 patients with vomiting, and 1 patient each with nausea, rash, rigors, and acutely worsened sinus congestion. One patient with vomiting presented to the ED and was subsequently admitted. There were no cases of anaphylaxis. No patients experienced allograft rejection (including 3 patients who had routine allograft biopsy, 1 who had biopsy for evaluation of worsened forced expiratory volume in 1 second, and 1 with newly diagnosed proteinuria).

Table 3. Outcomes at Differing Time Points From Monoclonal Antibody Administration in 73 Transplant Recipients With Mild to Moderate Coronavirus Disease 2019

	14 Days	21 Days	28 Days
ED visit, No. (%)	8 (11.0)	10 (13.7)	11 (15.1)
Hospital admission, No. (%)[a]	7 (9.6)	8 (11.0)	9 (12.3)
ICU admission, No. (%)	1 (1.4)	1 (1.4)	1 (1.4)

Abbreviations: ED, emergency department; ICU, intensive care unit.

[a]Includes ICU admission.

DISCUSSION

We report our initial experience with COVID-19-directed monoclonal antibody therapy in 73 solid organ transplant recipients. Compared with historical data showing high morbidity and mortality [5, 10], the outcomes appear favorable in our cohort of transplant recipients who received monoclonal antibodies for mild to moderate COVID-19. While historical studies do not provide optimal comparison given the difference in availability of COVID-19 therapies and improvement in practices over time, our cohort had no deaths, and only 1 patient required ICU admission for a nonrespiratory condition. Respiratory complications were uncommon in those patients who required hospitalization, with little to no oxygen support and no requirement for advanced respiratory support. Hospital length of stay was relatively short, compared with a median length of stay (IQR) of 6 (4–12) days for all patients admitted for COVID-19 at the Mayo Clinic (unpublished data).

Hospitalizations and ED visits occur most commonly within 14 days of COVID-19 diagnosis. In this cohort of transplant patients, hypertension was significantly associated with hospitalization. This is consistent with prior reports of risks for severe COVID-19 [19]. While hospitalized patients tended to be older, to be male, to have a higher BMI, to have undergone more recent transplant, and to have more comorbid conditions, these observations were not statistically significant, probably due to the small size of our cohort [3, 20, 21]. We further observed that the hospitalized patients had a longer time from symptom onset to monoclonal antibody infusion, which highlights the time-sensitive nature of these experimental therapies [12]. Accordingly, earlier treatment appears to be important to maximize therapeutic benefit.

We did observe a small but nonsignificant difference in hospitalizations between those who received bamlanivimab and casirivimab-imdevimab. Whether this relates to escape mutant variants of concern is difficult to prove, as we did not perform gene sequencing analysis. However, the current data suggest that the SARS-CoV-2 variant of concern B.1.1.7 is predominant in our communities at the present time. B.1.1.7 was first identified in Minnesota on January 9, 2021, near the end of our study period, and the data suggest that it remains susceptible to bamlanivimab and casirivimab-imdevimab [22]. Another resistant variant of concern, P.1, was identified in Minnesota on January 25, 2021, and was travel related, with no documented local transmission [23]. The P.1

variant, along with other subsequently identified variants, has reduced susceptibility to bamlanivimab, but casirivimab-imdevimab remains active. It is possible that these variants were present in our study; however, without systematic testing, their prevalence in our study population is not established. As the predominant SARS-CoV-2 strains in our regions are currently wild-type and B.1.1.7, which retains susceptibility to bamlanivimab, we believe that the difference in hospital admission rates between the 2 monoclonal antibodies may be related to our small sample size. Regardless, we encourage surveillance of circulating SARS-CoV-2 variants as it is essential in determining optimal monoclonal antibody therapy.

The safety data presented here are encouraging. Adverse effects were mild, with only 1 event leading to an ED visit or hospital admission. Many of the reported adverse events could have been due to COVID-19 infection rather than the monoclonal antibody treatment. No cases of anaphylaxis were observed. There have been concerns regarding allograft rejection related to prior antibody therapies [24], and it is unclear if bamlanivimab or casirivimab-imdevimab carry this risk. Our patient cohort did not experience allograft rejection, including 5 patients who were evaluated by allograft biopsy.

This study has several limitations. First, this is a retrospective review, which is subject to biases intrinsic to such studies. Second, we did not include a control arm of untreated patients in this report, as all transplant patients who were eligible for monoclonal antibody therapies during the study period consented to the infusion. Due to the strong partnership with transplant providers who have advocated the treatment for their compromised patients, we did not have any untreated cohort of transplant patients during the period of this study. This prevented comparison to a contemporary cohort of untreated transplant patients who would have otherwise been provided similar care. Similarly, while the outcomes are better than prior studies, there has also been further improvement in the medical care of patients in recent months with the use of remdesivir and corticosteroids, leading to potentially better outcomes. Most patients were closely followed by our remote monitoring program. However, it is possible that some who declined remote monitoring sought ED evaluation or hospitalization at another center. Finally, the sample size was relatively small, which limited robust analysis of outcomes, although this is the largest cohort of transplant patients treated with monoclonal antibodies to date.

In conclusion, this single-center experience on monoclonal antibody therapy for COVID-19 in solid organ transplant recipients demonstrates favorable efficacy and safety outcomes. While ED visits and hospitalizations remain common, there were no deaths, COVID-19-related ICU admissions, or requirement for advanced respiratory support. While a randomized controlled trial is preferred to assess the efficacy in transplant patients, this is difficult to perform after EUA has been issued for these products. Thus, the encouraging data that we report here may help guide and encourage the transplant community in recommending monoclonal antibody therapy for mild to moderate COVID-19 in the transplant population.

Supplementary Data

Supplementary materials are available at Open Forum Infectious Diseases online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

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Patient consent. The design of this work was approved by our local institutional review board (IRB). Written patient consent was obtained when necessary; however, this study was deemed exempt by our local IRB.

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