

BRIEF COMMUNICATION

Use of anti-spike monoclonal antibodies in kidney transplant recipients with COVID-19: Efficacy, ethnic and racial disparities

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Organ transplant recipients may not mount an adequate immune response to COVID-19 infection and therefore may benefit greatly from passive immunization with anti-spike monoclonal antibodies (mAbs), which have been shown to decrease hospitalization rates in the general outpatient population. We evaluated the efficacy of mAb therapy in decreasing hospitalizations or emergency room (ER) visits among kidney transplant recipients (KTR) with COVID-19. We identified KTR with COVID-19 between March 1, 2020 and April 30, 2021. Patients were excluded if they had multi-organ transplant or hospital-acquired COVID-19. We studied 95 KTR; 20 received mAb. mAb administration was associated with a significant decrease in hospitalizations or ER visits (15% vs. 76%, $p < 0.001$). This association remained significant after adjustment for potential confounders, and analysis of mAb administration as a time-dependent variable, with day of symptom onset as day 1 (adjusted HR 0.216, $p = 0.04$). Black or Hispanic patients were less likely to receive mAb and more likely to be admitted to the hospital or visit the ER. In our KTR population, mAb therapy for COVID-19 may have helped decrease hospitalizations and ER visits. Healthcare inequities, including access to investigational treatments, have been exacerbated by the COVID-19 pandemic. Antiviral mAbs are a promising therapeutic modality, especially for immunocompromised patients.

KEYWORDS

health services and outcomes research, infection and infectious agents—viral, infectious disease, kidney transplantation/nephrology, patient survival

1 | INTRODUCTION

Since December 2019, coronavirus disease 2019 (COVID-19) has had devastating effects on the global population and contributed to more than 4.3 million deaths as of August 2021.¹ Organ transplant recipients (OTR) may be at increased risk for complications or death from COVID-19 because of immunosuppression and comorbidities.² Some investigators showed worse clinical outcomes in OTR compared to matched nontransplant patients,³ whereas others did

not.⁴ OTR may be unable to mount a sufficient immune response to respiratory viruses, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, several studies to date report the detection of SARS-CoV-2-specific antibodies within 15 days of symptom onset and up to 6 months postinfection in OTR, similar to the nontransplant population.⁵ Nonetheless, these findings are primarily from case reports or small case series.

It is therefore possible that OTR with COVID-19 may benefit greatly from passive immunization with anti-spike monoclonal

Abbreviations: BMI, body mass index; CHF, congestive heart failure; CKD, chronic kidney disease; COVID-19, coronavirus disease 2019; DM, diabetes mellitus; ER, emergency room; EUA, emergency use authorization; KTR, kidney transplant recipients; mAb, monoclonal antibody; OTR, organ transplant recipients; PS, propensity score; PSM, propensity score matching; RI, Rhode Island; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; VOC, variant(s) of concern; VOI, variant(s) of interest.

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antibody (mAb) therapy, but this hypothesis warrants further investigation. Bamlanivimab and casirivimab/imdevimab were granted emergency use authorization (EUA) status for the treatment of mild to moderate COVID-19 in November 2020. Bamlanivimab/etesevimab received EUA status for the same indication in February 2021.⁶ These mAbs have been shown to decrease the rates of hospitalization in the general outpatient population.⁷⁻¹⁰ Small case series of OTR with COVID-19 have also reported good efficacy and tolerability with¹¹ or without¹²⁻¹⁷ comparator groups.

In this study, we retrospectively evaluated the efficacy and tolerability of anti-spike mAb therapy in our cohort of kidney transplant recipients (KTR) with COVID-19, and compared clinical outcomes between KTR who received mAbs and those who did not, adjusting for potential confounders.

2 | METHODS

We identified KTR diagnosed with COVID-19 at Brown University-affiliated hospitals between March 1, 2020 and April 30, 2021. Details of our transplant population and protocols were previously described.¹⁸

OTR diagnosed with COVID-19 after the EUA for bamlanivimab (November 9, 2020) were eligible for anti-spike mAb administration if they: (1) were not hospitalized due to COVID-19, (2) did not require oxygen therapy (or increased oxygen flow rate if already receiving oxygen for a different indication) due to COVID-19, and (3) had symptoms for <10 days, given that mAbs are most effective when given early in the course of COVID-19.

The primary endpoint was hospitalization or emergency room (ER) visit after COVID-19 symptom onset. Secondary endpoints were mechanical (invasive or noninvasive) ventilation and all-cause in-hospital mortality or discharge to hospice. The study was approved by the Lifespan Institutional Review Board.

Patients were excluded if they contracted COVID-19 while in the hospital, thereby conflicting with the primary endpoint. We also excluded multi-organ transplant recipients to achieve a homogeneous population—such patients often have more comorbidities and require higher levels of immunosuppression. We performed sensitivity analyses for the primary endpoint after exclusion of patients who had COVID-19 when mAbs were not available and those who were admitted at the time of first evaluation, due to hypoxia or other reasons <10 days of symptom onset.

Data are presented as median (interquartile range [IQR]) for continuous variables and number (%) for categorical variables, which were compared with the Mann-Whitney *U* test and Fisher's exact test, respectively. To adjust for possible confounders and "immortal bias,"^{19,20} we performed univariate and multivariate Cox regression analyses with the day of symptom onset as baseline (day 1) and mAb administration as time-dependent variable. Factors with a *p*-value of <.2 on univariate analyses were entered in the multivariate models.

Immortal bias occurs when cohort members cannot experience an outcome until the time of cohort entry. In our study, patients

could not have the primary outcome (hospitalization or ER visit) until the time of mAb administration (up to 10 days). This can lead to a spurious benefit from mAb administration, if mAb administration is analyzed as a time-fixed variable. Therefore, we analyzed mAb administration as a time-dependent variable, that is, patients who received mAb were considered "controls" up to the time point of mAb administration.^{19,20}

To further adjust for residual confounding, we estimated a propensity score (PS) as the logistic regression-based probability for mAb administration, including age, sex, race, ethnicity, BMI, time from transplantation, and comorbidities. We built Cox regression models using the PS as covariate, either alone or added to other significant covariates ("double robust" model). We used 1:1 nearest neighbor matching without replacement and caliper distance of 0.2x the pooled standard deviation of the PS. Patients who did not have a match were excluded, and a matched-pair analysis was conducted.

All analyses were performed with SPSS statistical software, version 24.0 (IBM Corporation). Statistical significance was set at a two-tailed *p*-value of .05.

3 | RESULTS

We studied 95 KTR. Demographic and clinical characteristics are summarized in Table 1. Twenty patients received mAb as outpatients—15 received bamlanivimab, 1 received bamlanivimab/etesevimab, and 3 received casirivimab/imdevimab. One patient received anti-spike mAb at an outside center with no additional information available to us other than the date of administration. All patients tolerated the infusion well; three patients experienced worse fever and fatigue the night of mAb infusion. One patient reported these symptoms persisted and was admitted to the hospital, where he was found to be afebrile, without significant symptoms or signs, and was discharged after 2 days.

Of the 75 patients who did not receive mAb, 27 had COVID-19 before mAbs became available under EUA. Of the remaining 48 patients: 19 were admitted to the hospital for COVID-19 due to hypoxia or other reasons <10 days of symptom onset, 6 refused mAb, 6 had symptoms for >10 days, and for 17 patients the reasons were unclear without documented offer of mAb treatment.

More patients in the group who did not receive mAb had chronic kidney disease (CKD). Patients who received mAb therapy were more frequently men and had higher body mass index (BMI), although these differences did not reach statistical significance at the 0.05 level (Table 1).

Black or Hispanic patients were less likely to receive mAbs, constituting 5% and 15% of the group who received mAb therapy, as opposed to 19% and 33% of those who did not, respectively. Being Black or Hispanic was significantly associated with lower likelihood of mAb administration (4/20 [20%] vs. 39/75 [52%], *p* = 0.01) (Table 1).

Hispanics constituted 48% (13/27) and 22% (15/68) of all patients before and after mAb (bamlanivimab) EUA, respectively (*p* = 0.02). The respective proportion for Black patients did not

TABLE 1 Comparison of baseline characteristics and outcomes between KTR with COVID-19 who received anti-spike monoclonal antibody treatment as outpatients and those who did not

Parameter	Unmatched cohort			Propensity score-matched cohort		
	mAb, n = 20	No mAb, n = 75	p-value	mAb, n = 18	No mAb, n = 18	p-value
Demographics						
Age (years)	55.0 (31–79)	58 (38–78)	.691	56.0 (43–67.5)	55.5 (40.5–62.5)	0.501
Men	15 (75.0)	45 (60.0)	.299	13 (72.2)	14 (77.8)	>0.999
Black	1 (5.0)	14 (18.7)	.181	1 (5.6)	3 (16.7)	0.603
Hispanic	3 (15.0)	25 (33.3)	.167	3 (16.7)	1 (5.6)	0.603
Black or Hispanic	4 (20.0)	39 (52.0)	.010	4 (22.2)	4 (22.2)	>0.999
BMI, kg/m ²	30.4 (26.5–35.3)	28.2 (24.4–33.9)	.333	29.0 (25.9–34.3)	26.7 (23.6–32.9)	0.339
Time after transplant (months)	44.5 (16.8–176.3)	50.0 (26.0–132.0)	.635	44.5 (18.3–148.0)	42.5 (22.0–89.0)	0.650
Comorbidities						
Hypertension	19 (95.0)	65 (86.7)	.448	17 (94.4)	16 (88.9)	>0.999
CKD	11 (55.0)	59 (78.7)	.046	10 (55.6)	11 (61.1)	>0.999
CHF	1 (5.0)	9 (12.0)	.683	1 (5.6)	1 (5.6)	>0.999
Diabetes	7 (35.0)	32 (42.7)	.615	6 (33.3)	5 (27.8)	>0.999
Lung disease	4 (20.0)	15 (20.0)	>.999	3 (16.7)	3 (16.7)	>0.999
Baseline immunosuppression						
3-drug regimen	18 (90.0)	60 (80.0)	.512	16 (88.9)	17 (94.4)	>0.999
2-drug regimen	2 (10.0)	13 (17.3)	.730	2 (11.1)	1 (5.6)	>0.999
1-drug regimen	0 (0.0)	2 (2.7)	>.999	0 (0.0)	0 (0.0)	>0.999
Calcineurin/mTOR inhibitor	19 (95.0)	73 (97.3)	.512	17 (94.4)	17 (94.4)	>0.999
Tacrolimus	15 (75.0)	60 (80.0)	.758	13 (72.2)	15 (83.3)	0.691
Sirolimus	2 (10.0)	8 (10.7)	>.999	2 (11.1)	1 (5.6)	>0.999
Cyclosporine	2 (10.0)	3 (4.0)	.282	2 (11.1)	1 (5.6)	>0.999
Antimetabolite	18 (90.0)	60 (80.0)	.512	16 (88.9)	18 (100.0)	>0.999
Mycophenolate	15 (75.0)	53 (70.7)	.787	13 (72.2)	16 (88.9)	0.402
Azathioprine	3 (15.0)	7 (9.3)	.434	3 (16.7)	2 (11.1)	>0.999
Held or decreased ^a	8 (44.4)	43 (71.6)	.047	7 (43.8)	10 (58.8)	0.505
Prednisone	20 (100.0)	73 (97.3)	>.999	17 (94.4)	18 (100.0)	>0.999
Outcomes						
Hospitalization or ER visit	3 (15.0)	57 (76.0)	<.001	3 (16.7)	10 (55.6)	0.035
Mechanical ventilation	0 (0.0)	13 (17.3)	.063	0 (0.0)	1 (5.6)	>0.999
In-hospital death or hospice	0 (0.0)	8 (10.7)	.197	0 (0.0)	0 (0.0)	>0.999

Note: Data are presented as mean median (interquartile range [IQR]) for continuous variables and number (%) for categorical variables. Two-sided p-values <.05 are bold.

Abbreviations: BMI, body mass index; CHF, congestive heart failure; CKD, chronic kidney disease; ER, emergency room; KTR, kidney transplant recipients; mAb, mammalian target of rapamycin.

^aPercentage refers to the number of KTR who were taking an antimetabolite at baseline.

change significantly (3/27 [11%] vs. 12/68 [18%]; Table S1). Black and Hispanic patients lived closer to the infusion clinic, which is located in an urban setting, near underserved communities ($p < 0.005$ compared to KTR who were not Black or Hispanic). Black KTR had comorbid conditions more frequently, with the difference being statistically significant for diabetes (Table S1). The reasons why KTR did not receive mAbs by race and ethnicity are summarized in Table S2. Six of 11 (54.5%) Black and seven of 12 (58.5%) Hispanic KTR were not given mAbs when they were available, because they

had symptoms >10 days or required hospital admission, compared to 12 of 25 (48%) non-Black, non-Hispanic KTR.

There were no significant differences in baseline immunosuppression between KTR who received mAbs and those who did not. Among patients on an antimetabolite, more patients who did not receive mAbs eventually had it discontinued or the dose decreased (43/60 [72%]), compared to those who did (8/18 [44%], $p = 0.047$).

On univariate analysis, mAb administration was associated with a marked decrease in hospitalizations or ER visits (3/20 [15%] vs.

TABLE 2 Factors significantly associated with hospitalization or ER visit

	Univariate analysis			Multivariate analysis		
	HR	95% CI	p-value	HR	95% CI	p-value
Age (years)	1.022	1.004–1.041	.019	1.023	1.003–1.044	.024
mAb administration	0.115	0.036–0.368	.009	0.216	0.050–0.929	.040
CKD	2.456	1.243–4.855	.010	2.087	1.043–4.176	.038
Black race	2.168	1.186–3.964	.012	1.881	0.959–3.689	.066
Hispanic ethnicity	1.701	1.003–2.883	.049	2.029	1.111–3.703	.021

Note: mAb administration was analyzed as a time-dependent variable. *p*-values <.05 are bold.

Abbreviations: CKD, chronic kidney disease.

57/75 [76%], $p < 0.001$; univariate HR [time-dependent] 0.115, $p = 0.009$). The difference remained significant after limiting the analysis to KTR who had COVID-19 when mAbs were available (3/20 [15%] vs. 36/48 [75%], $p < 0.001$), and after exclusion of 19 patients who were admitted at the time of evaluation but <10 days of symptom onset (3/20 [15%] vs. 17/29 [59%], $p = 0.003$).

Age, CKD, Black race, and Hispanic ethnicity were significantly associated with hospitalization or ER visit (Table 2). The protective effect of mAb administration was retained after adjustment for these factors (adjusted HR [time-dependent] for mAb [aHR] 0.216, $p = 0.04$; Table 2), after using the PS as a covariate (aHR 0.232, $p = 0.049$) or in a “double robust” model (aHR 0.236, $p = 0.053$) (Table S3), and after PS matching (PSM) (3/18 [17%] vs. 10/18 [56%], $p = 0.035$; Table 1, Figure S1).

None of the patients who received mAbs died or required mechanical ventilation. Of the patients who did not receive mAb, 13 (17%) required mechanical ventilation ($p = .06$ compared to KTR treated with mAbs), seven (9%) died, and one was discharged to hospice (11% mortality or discharge to hospice among patients who were not treated as outpatients with mAbs, 8% overall; Table 1).

Regarding variants of interest (VOI) or concern (VOC), the weekly frequencies of VOI/VOC during the study period were recently reported in a large sample of specimens from Rhode Island (RI).²¹ The most frequent VOI with the potential to be nonsusceptible to bamlanivimab during the study period was the Iota (New York origin) variant B.1.526, but not all isolates of this lineage are nonsusceptible to bamlanivimab.²² The two next most frequent nonsusceptible VOI were the Epsilon variants B.1.427 and B.1.429 (California origin). The only nonsusceptible VOC during the study period was the Gamma (Brazil origin) variant, P.1, which was detected in a small number of specimens, beginning in late March 2021. Overall, VOI/VOC with reduced susceptibility to bamlanivimab were detected in <10% of RI specimens until mid-February 2021. Five patients from our study received bamlanivimab between that time point and April 15, 2021, when the EUA was revoked due to the emergence of nonsusceptible variants nationwide.²² None of these five patients were admitted to the hospital nor had an ER visit.

4 | DISCUSSION

There is conflicting evidence regarding clinical outcomes^{3,4} and appropriate immune response among OTR with COVID-19 compared

to immunocompetent individuals, further confounded by the lack of an established threshold for protective immunity.²³ In our patient population, mAb therapy was well-tolerated and associated with less hospitalizations or ER visits in KTR with COVID-19. This association remained significant after adjustment for potential confounders.

Our findings are in agreement with two randomized controlled trials^{7,9} and three retrospective studies.^{8,10,11} However, efficacy in transplant recipients was not explicitly analyzed in the clinical trials^{7,9} and one retrospective report.¹⁰ Kumar et al.⁸ included 109 immunocompromised patients in their study but did not specify how many were OTR. Del Bello et al. recently reported improved outcomes in 16 OTR who were treated with mAbs compared to 32 historical controls without multivariate or time-to-event analyses.¹¹ To our knowledge, our study is one of the first to compare OTR who received anti-spike mAbs with those who did not, adjusting for demographics and comorbidities.

Notably, among KTR treated with mAbs, in addition to significantly better clinical outcomes, we captured less frequent discontinuation or decrease in the dose of the antimetabolite (Table 1). Therefore, another benefit of outpatient management of COVID-19 with mAbs in OTR may be less needed to adjust immunosuppression for severe disease, risking subsequent organ rejection.

Importantly, our results highlight the health inequities exacerbated by the COVID-19 pandemic. Black race and Hispanic ethnicity were strongly associated with hospitalization or ER visit and these patients were the minority in the group receiving mAbs. The latter finding agrees with a recent large-scale report, which, nevertheless, included mostly White non-Hispanic patients.²⁴ It is possible that novel therapeutics for COVID-19 are less accessible to patients who identify as minorities.²⁵

To this end, we explored potential determinants of ethnic and racial disparities. Our Hispanic or Black KTR were not hesitant to consent to mAb treatment, as the numbers of Hispanic or Black patients who declined mAbs were extremely low, and the proportions numerically lower, compared to non-Black, non-Hispanic KTR (Table S2). Black or Hispanic patients were closer to the infusion center, compared to non-Black, non-Hispanic KTR (Table S1); therefore, access to care probably did not play a major role either, although we did not assess means of transportation. Likewise, different insurance plans are also unlikely to have contributed to our results. Most OTR

have good insurance coverage, and mAbs were available to eligible patients through the State.

Clearly, our Hispanic community was overrepresented earlier in the pandemic, when mAbs were not available (Tables S1 and S2).²⁶ The proportion of Hispanic, but not Black, KTR in our study decreased significantly over time. This was likely the result of a coordinated outreach to the Hispanic population of RI,²⁶ speaking to the power of community efforts and patient education.

We noted a trend for more frequent comorbidities in Black patients (Table S1). Higher complexity favors the acceptance of investigational treatments.²⁴ However, because of a higher degree of medical complexity, Black or Hispanic patients can present frequently with severe disease, which may have prompted a lower threshold for hospital admission over outpatient management with mAbs. More than half of Black (54.5%) or Hispanic (58.5%) patients who were not given mAbs when mAbs were available had symptoms for >10 days or required hospital admission (Table S2). Thus, it is possible that Black or Hispanic patients with multiple comorbid conditions may benefit even more from early diagnosis and timely administration of mAbs and should be target groups for education about available treatments for high-risk outpatients with COVID-19.

As a result of the above findings and institutional experience with COVID-19, our team is now sending all KTR a letter in English, Spanish, and Portuguese with key reminders and updates about COVID-19, including the phrase: "It is very important that you let the transplant clinic know immediately if you have symptoms that could be suspicious for COVID-19, or close contact with someone diagnosed with COVID-19, as we now have effective treatments that you may be able to get."

This brief report has limitations, which should be taken into consideration in the design of future studies. First, the FDA revoked the EUA for bamlanivimab monotherapy²² and recently paused shipment of bamlanivimab/etesevimab, due to increasing circulation of nonsusceptible variants.²⁷ Nevertheless, in our study, none of the five patients who received bamlanivimab around the time that the rates of nonsusceptible VOI/VOC increased significantly in RI²¹ required hospital admission. Even though we did not collect patient-level data regarding variants with decreased susceptibility to bamlanivimab, it is unlikely that more detailed information about VOI/VOC could have affected our study conclusions, which can be extended to mAbs with activity against circulating variants at different time points.

Second, this was a single-center retrospective study, and the number of KTR who received mAb was relatively small, but within range of what has been reported by other investigators.^{11,13,14,16,17} Fourth, we did not assess the autologous antibody response prior to mAb, neither the virological response, due to lack of standardized assays.

Last, our institutional policy was to offer immunocompromised patients diagnosed with mild to moderate COVID-19 mAb therapy as outpatients, which was strongly encouraged by the transplant team. Therefore, the number of candidates who refused or were not offered mAb therapy was too small to allow comparison between

concurrent groups of adequate size. Also, the transplant team and patients may have had more confidence in opting against ER visit or direct hospital admission due to previous mAb administration.

For these reasons, and given the overall better outcomes in later stages of the pandemic,^{28,29} residual confounding is possible. However, the two groups of KTR had similar baseline characteristics and the results remained significant after adjustment for potential confounders and immortal bias.^{19,20} Moreover, the benefit associated with mAb administration was significant after PSM, after exclusion of KTR from the pre-mAb EUA stage of the pandemic, and after exclusion of those who were not eligible for outpatient mAb administration because they required hospital admission due to hypoxia or other reasons. It should also be noted that none of the patients who received mAbs died or required mechanical ventilation. Therefore, despite study limitations, our conclusions are well-aligned with those of two randomized, double-blinded, placebo-controlled clinical trials,^{7,9} and two large retrospective studies with concurrent controls.^{8,10}

In summary, we found a strong signal for less hospitalizations or ER visits in KTR who received anti-spike mAbs, compared to those who did not. Based on our results and those of multiple other studies,^{11-14,16} mAbs are an important addition to the antiviral therapeutic armamentarium for immunocompromised patients. Such agents could help improve clinical outcomes and significantly decrease the burden of ER visits and hospital admissions during the ongoing and potential future pandemics. Healthcare inequities, including knowledge of and access to investigational treatments, have been exacerbated by the COVID-19 pandemic, and call for better patient education and outreach to underserved communities.

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DISCLOSURE

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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