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5-28-2022

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SARS-CoV-2 neutralizing antibodies for COVID-19: Outcomes for bamlanivimab versus bamlanivimab-etesevimab combination in a racially diverse cohort of patients with significant comorbidities

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Abstract

What Is Known and Objective: Anti-spike monoclonal antibodies (MAB) including bamlanivimab (BAM) and bamlanivimab/etesevimab (BAM/E) have shown reduced hospitalization rates for non-severe coronavirus disease 2019 (COVID-19) in clinical trials. Recent data have provided real-world hospitalization rates for high-risk patients treated with BAM, however, data on a similar cohort treated with BAM/E are lacking.

Methods: This retrospective cohort study evaluated outpatients ≥ 18 years with laboratory-confirmed mild/moderate COVID-19 who received MAB from 1 December 2020 to 19 April 2021. Use of BAM monotherapy changed to BAM/E combination on 27 March 2021. Primary outcome was overall rate of COVID-19 related-hospitalization, including comparison of hospitalization rates between MAB-formulation groups. Secondary outcomes were 30-day mortality and length of stay (LOS).

Results and Discussion: The population included 643 patients (BAM and BAM/E); median age was 58 years, 43% were male, median BMI was 33 kg/m², and 24% self-identified as Black. Patients in the BAM/E combination group were significantly younger with higher median BMI and a longer time from symptom onset to infusion. The incidence of 30-day COVID-19 related hospitalization was similar between patients receiving either BAM or BAM/E combination (7.8% and 7.2%, respectively).

What Is New and Conclusion: This study represents the first such publication of real-world BAM/E hospitalization outcomes. Hospitalization rates utilizing BAM/E were comparable to BAM in our real-world study.

KEYWORDS

bamlanivimab, etesevimab, SARS-CoV-2 neutralizing antibody

1 | WHAT IS KNOWN AND OBJECTIVE

Persons infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have disease severity ranging from asymptomatic to respiratory failure and death. Some patients with mild-to-moderate

infection progress to severe disease (requiring hospitalization) while others do not. Reducing the proportion of patients who progress to severe disease is a crucial strategy to reduce the burden of Coronavirus disease 2019 (COVID-19) on hospitals. Clinical trials of neutralizing monoclonal antibody (MAB) have reported overall reduced

hospitalization rates in patients with mild-to-moderate COVID-19.¹⁻³ Post hoc analysis of COVID-19 patients at high risk for progression to severe disease (those aged ≥ 65 or with body mass index [BMI] ≥ 35) who received bamlanivimab (BAM) showed reduced rates of hospitalizations or emergency department (ED) visits compared to placebo (4.2% versus 14.6%).¹ As of December 2021, five MABs have been granted Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for the treatment of mild-to-moderate COVID-19 in patients at high risk of progressing to severe disease; bamlanivimab (BAM), bamlanivimab in combination with estesevimab (BAM/E), casirivimab and imdevimab combination, and sotrovimab.⁴⁻⁶ The effect of BAM monotherapy on hospitalization rates in real-world high-risk patients in the United States (US) with mild-to-moderate COVID-19 have been recently reported.⁷⁻¹⁰ The FDA has subsequently revoked the EUA for BAM monotherapy due to increased prevalence of variants with reduced susceptibility to BAM.¹¹ There is limited real-world data with BAM/E combination therapy use in Europe, however, there are no data on a high-risk US cohort treated with BAM/E.¹² Additionally, an observational comparison of BAM monotherapy and BAM/E combination has not been performed. BAM was administered to outpatients with mild-to-moderate COVID-19 per EUA guidance at our institution from December 2020 and was replaced with BAM/E in March 2021. Michigan experienced a surge of COVID-19, allowing for a large cohort of patients that were treated with BAM and BAM/E.¹³ We sought to quantify the impact of BAM monotherapy versus BAM/E on hospitalization and mortality among a real-world high-risk cohort of outpatients with COVID-19.

2 | METHODS

2.1 | Setting for the study and subjects

This retrospective cohort study included outpatients, ≥ 18 years old, with laboratory-confirmed SARS-CoV-2 and mild-to-moderate COVID-19 who received MAB (either BAM 700 mg as a single infusion or BAM/E 700 mg/1400 mg combination as a single infusion) at Henry Ford Health System (HFHS) between 1 December 2020 and 19 April 2021. HFHS is large multicentre health-system based in Southeast Michigan, including a large 900-bed quaternary referral centre in urban Detroit and three other hospitals in the surrounding metropolitan suburbs. Institutional formulary change from BAM to BAM/E combination occurred on 27 March 2021. Mild-to-moderate disease was defined by World Health Organization criteria as mild or moderate symptoms with an oxygen saturation $\geq 94\%$ on room air. Patients were eligible for infusion if they had at least one additional pre-defined risk factor for progression to severe disease as defined by the EUA: age ≥ 65 years, BMI ≥ 35 kg/m², age 55-64 years with ≥ 1 comorbidity risk factor, or age 18-54 years with ≥ 2 comorbidity risk factors. Comorbidity risk factors included cardiovascular disease, hypertension, chronic obstructive pulmonary disease, other chronic respiratory disease, chronic kidney disease (CKD), diabetes mellitus (DM), or immunosuppressive disease or medication. Patients were

identified by providers during outpatient clinic or ED visits and referred to one of four infectious diseases (ID) infusion clinics for eligibility assessment by an ID physician. Patients who had severe disease, required hospitalization, or were beyond 10 days from symptom onset were excluded.

2.2 | Outcomes

Primary outcome was COVID-19 related hospitalization through day 30 post-infusion, defined as hospital admission due to signs or symptoms consistent with severe COVID-19 or its sequelae, including non-respiratory complications such as diarrhoea, dehydration, kidney injury or laboratory abnormalities necessitating inpatient care. Secondary outcomes included COVID-19 related ED visit, 30-day all-cause mortality and length of stay (LOS).

2.3 | Statistical analysis

Characteristics and comorbidities were compared between patients who received BAM versus BAM/E using Chi-square and Mann-Whitney *U* test as appropriate. A power calculation was performed for a dichotomous endpoint compared between two independent samples. Sample size required was 432 subjects, assuming alpha 0.05, beta 0.2, and using incidence rates for hospitalization observed in other retrospective real-world MAB studies.⁷⁻¹⁰ The Institutional Review Board approved the study (IRB No. 14630).

3 | RESULTS AND DISCUSSION

MAB was administered to 643 patients during the study period (294 received BAM and 349 BAM/E). The characteristics and outcomes of the two groups are shown in Table 1. Patients in the BAM/E cohort were younger, more morbidly obese and had lower rates of diabetes. Other characteristics between groups were similar (Table 1). BAM/E patients had longer median time from symptom onset to infusion (median 6 vs. 4 days, $p < 0.001$). This was driven by a longer time between symptom onset (date patient first noted any symptoms) to referral (date the patient saw a physician who requested MAB infusion) with a median of 3 days for BAM versus 5 days for BAM/E ($p < 0.001$). Time from symptom onset to test date were similar between groups (median 2 [1-3] days, $p = 0.837$). Time from referral to infusion was similar between groups (median 1 day for both, 0.782). Thirty-day hospitalization rates did not differ between groups (7.8% vs. 7.2%, $p = 0.751$). LOS and 30-day mortality (1% vs. 0.3%, $p = 0.238$) were also similar.

In this single-centre study, 643 patients received either BAM or BAM/E and had similar rates of 30-day COVID-19-related hospitalization. It is plausible that the BAM/E did not outperform BAM monotherapy due to higher rates of morbid obesity or a longer time from symptom onset to infusion in the combination group. Groups had similar times from onset of symptoms to test date, and from referral to

**TABLE 1** Characteristics and outcomes of COVID-19 patients receiving monoclonal antibody

| Characteristics | Total (n = 643) | Bamlanivimab (n = 294) | Bamlanivimab /etesevimab (n = 349) | p-value |
|---|-----------------|------------------------|------------------------------------|---------|
| Age | | | | |
| Median (IQR) | 58 (47–66) | 61 (50–69) | 55 (45–65) | <0.001 |
| ≥65 years (%) | 206 (32.0) | 112 (38.1) | 94 (26.9) | 0.003 |
| Male | 275 (42.8) | 137 (46.9) | 138 (39.5) | 0.086 |
| Self-identified race/ethnicity (%) | | | | |
| White | 411 (63.8) | 185 (62.9) | 226 (64.8) | 0.630 |
| Black | 153 (23.8) | 68 (23.1) | 85 (24.4) | 0.716 |
| Middle Eastern | 30 (4.7) | 17 (5.8) | 13 (3.7) | 0.218 |
| Hispanic/Latinx | 24 (3.7) | 14 (4.8) | 10 (2.9) | 0.206 |
| Other | 15 (2.3) | 5 (1.7) | 10 (2.9) | 0.636 |
| Declined | 10 (1.6) | 5 (1.7) | 5 (1.4) | 0.784 |
| Comorbidities (%) | | | | |
| BMI ^a median (IQR) | 32.9 (27.6–39) | 32.2 (27.2–37.2) | 33.6 (28.3–40.1) | 0.007 |
| BMI ≥35 (%) | 261 (41.2) | 99 (34.6) | 162 (46.7) | 0.002 |
| BMI 30–40 (%) | 260 (41.1) | 120 (42.0) | 140 (40.3) | 0.682 |
| BMI ≥40 (%) | 141 (22.3) | 49 (17.1) | 92 (26.5) | 0.005 |
| Cardiovascular disease ^b | 468 (72.8) | 213 (72.4) | 255 (73.1) | 0.861 |
| Pulmonary disease ^c | 189 (29.4) | 94 (32.0) | 95 (27.2) | 0.188 |
| Immunosuppressed ^d | 136 (21.2) | 72 (24.5) | 64 (18.3) | 0.059 |
| Diabetes | 215 (33.4) | 110 (37.4) | 105 (30.1) | 0.050 |
| Chronic kidney disease | 65 (10.1) | 30 (10.2) | 35 (10.0) | 0.941 |
| Disease parameters | | | | |
| Mild (%) | 505 (78.5) | 221 (75.2) | 284 (81.4) | 0.067 |
| Moderate (%) | 138 (21.5) | 73 (24.8) | 65 (18.6) | 0.056 |
| Timing parameters, median (IQR) | | | | |
| Test positivity to infusion, days | 3 (2–4) | 2 (1–4) | 3 (2–5) | < 0.001 |
| Symptom onset to infusion, days | 5 (4–7) | 4 (3–7) | 6 (5–8) | <0.001 |
| Outcomes (30-days) | | | | |
| COVID-related hospitalization (%) | 48 (7.5) | 23 (7.8) | 25 (7.2) | 0.751 |
| COVID-related ED visit (%) | 21 (3.3) | 7 (2.4) | 14 (4.0) | 0.247 |
| Length of stay, median days (IQR) | 4 (2–6.5) | 4 (2–7.5) | 4 (2–6) | 0.794 |
| All-cause mortality (%) | 4 (0.6) | 3 (1.02) | 1 (0.29) | 0.238 |

Abbreviations: BMI, body mass index (defined as weight in kilograms divided by height in metres squared); COVID-19, coronavirus Disease 2019; IQR, interquartile range.

^aBMI data not available for 10 of 643 patients.

^bDefined as any cardiovascular comorbidity including coronary artery disease, myocardial infarction, congestive heart failure or hypertension.

^cDefined as any pulmonary comorbidity including obstructive sleep apnea, chronic obstructive pulmonary disease or asthma.

^dDefined as active malignancy, prior solid organ or stem cell transplantation, living with HIV (regardless of CD4 count) or autoimmune disease requiring immunosuppressive therapy.

infusion. Therefore, the delay in receiving infusion in the BAM/E appears to be driven by waiting longer to seek care. We hypothesize that this delay in seeking care may have been due to the younger age in the BAM/E cohort. Compared with patients in clinical trials evaluating MAB, our study population had more advanced age, higher median BMI (33 kg/m²), more patients who self-identified as Black race (24%), and longer median duration of symptoms prior to infusion (5 days).^{1–3} All patients in our study at had least one pre-defined risk

factor for progression to severe COVID-19 per EUA criteria, compared with only 70% of patients in the BAM and BAM/E trials, and 65% of patients in the casirivimab and imdevimab combination trial.^{1–3} These differences reflect a higher risk population and may explain the rate of 30-day hospitalization of 7.5% compared with 0.9% to 3% in the clinical trials.^{1–3}

A comparison of our study of 643 patients that received BAM and BAM/E to other real-world cohorts that received BAM outside of

TABLE 2 Patient characteristics and outcomes in monoclonal antibody studies for coronavirus disease 2019

| First author | Kumar ⁷ | Bariola ⁸ | Ganesh ⁹ | Ganesh ¹⁰ | Current Study |
|---|----------------------------------|-------------------------------|----------------------------------|-----------------------------------|--------------------------------|
| Study group | Chicago | Pittsburgh | Four states | Five states | Detroit |
| Study period | 20 November 2020–19 January 2021 | 9 December 2020–13 March 2021 | 12 November 2020–17 January 2021 | 19 November 2020–11 February 2021 | 12 December 2020–19 April 2021 |
| Treatment arm, (n) | BAM (218) | BAM (232) | BAM (2335) | BAM (2747) | BAM (294) BAM/E (349) |
| Characteristics^a | | | | | |
| Median age, years | 66 | 67 | 63 | 62 | 61 |
| Age ≥ 65 years (%) | 54 | 47 | 48 | 51 | 38 |
| Male (%) | 53 | 47 | 51 | 51 | 47 |
| Median BMI kg/m ² | 30.5 | | | | 32.2 |
| BMI ^b > 35 kg/m ² (%) | 30 | | 34 | 39 | 35 |
| BMI ^b > 40 kg/m ² (%) | | 26 | 18 | | 17 |
| Black race (%) | 6 | 5 | 2 | | 23 |
| Symptom onset to infusion, median days | 5 | | | | 4 |
| Test positivity to infusion, median days | | | 2 | 2 | 2 |
| Outcomes^a | | | | | |
| Hospitalization (%) | 7.3 | 6.5 | 2.5 | 4.3 | 7.8 |
| Mortality (%) | 0.5 | 1.7 | 0.1 | 0.002 | 1.0 |
| ED visit (%) | | 6.9 | | 7.8 | 2.4 |
| ICU admission (%) | 0.9 | | 0.6 | 0.8 | 0.3 |
| LOS, median days | 4 | | | | 4 |

Abbreviations: BAM, bamlanivimab; BAM/E, bamlanivimab etesevimab combination; BMI, body mass index.

^aCharacteristics and outcomes provided are for treatment groups only, and outcomes are provided at 28 or 30 days.

^bCalculated as weight in kilograms divided by height in metres squared.



clinical trials is shown in Table 2. Kumar et al. compared 218 patients that received BAM to 185 patients that were referred for BAM but did not receive it.⁷ Bariola et al. evaluated 232 patients that received BAM to a propensity-matched comparator group of 1160 patients who were eligible for BAM but were not treated.⁸ Ganesh and colleagues have published two observational studies; one comparing 2335 patients that received BAM to propensity matched controls, and another comparing 2747 patients that received BAM to those who received casirivimab-imdevimab combination.^{9,10} The rates of comorbidities were comparable to our study as only patients that met EUA criteria for high risk of progression to severe COVID-19 were included in these real-world studies. However, our patients were younger, with higher median BMI, and more self-reported their race as Black.⁷⁻¹⁰ The differences in age and weight may be due to the changing demographics of COVID-19 over time. By early May 2021, cases and hospitalizations in obese adults under age 50 years were on the rise, while hospitalizations among those over age 65 years had fallen significantly.¹⁴ The rates of hospitalization at 28 days in the Mayo Clinic studies were lower than those reported in other real world studies including ours (2.5%–4.3% vs. 6.5%–7.8%).⁷⁻¹⁰ Those patients had similarly high BMI and test positivity to infusion time (2 days) as our BAM group, but were less racially diverse (93% white), which may have contributed to lower rates of progression to severe disease. In the Mayo Clinic study, hospitalization rates were higher in the BAM group than the combination group (4.3% vs. 2.8%, respectively), however, this was not significantly different after adjusting for medical comorbidities.¹⁰ Our cohort included more Black patients (24% as compared with 2%–6% in the other studies), this difference may be reflective of the community demographics.⁷⁻¹⁰ Despite differences in age, weight, and race, our patients were hospitalized at rates similar to those in two other real-world studies (7.5% vs. 6.5% and 7.3%, respectively).^{7,8} Notably, the untreated groups in two of these real-world studies were hospitalized at rates of 14.8% and 20% which is similar to the 14.6% rate in high-risk subgroup of patients in the BAM clinical trial.^{1,7-8} It should be noted that our study included both BAM and BAM/E cohorts while these included BAM alone.⁷⁻⁸ Although our study lacked an untreated control group, the rates of hospitalization as well as ED visit (3.2%), ICU admission (0.45%), LOS (4 days) and 30-day all-cause mortality (0.65%) compared favourably with the other real-world cohorts.^{7,8} Taken together, these real-world studies suggest that BAM and BAM/E were effective in preventing progression to severe disease and hospitalization in high-risk patients including a high percentage of Blacks in current study cohort.

3.1 | Strengths and limitations

Strengths of this study include its power to detect a difference in hospitalization rates and a patient population more racially diverse compared with other published MAB studies. This study also has limitations. One of the challenges facing use of MAB for COVID-19 has

been the emergence of SARS-CoV-2 variants over time. At the time of our study conclusion (Late April 2021), the primary variants in Southeast Michigan were the B.1.1.7 (Alpha) and B.1.526 (Iota).¹⁵ The P.1 and B.1.351 variants were circulating in low numbers (<3%) during the time of our study and the B.1.617 (Delta) variant had not yet emerged.¹⁵ Presence of these variants with low binding affinity to BAM/E should not have affected outcomes based on the timeline, however, the unknown true prevalence of variants circulating at any given remain a limitation of all MAB studies. On June 25, 2021, the FDA paused distribution of BAM/E due to rising proportion of the P.1 (Gamma) and B.1.351 (Beta) variants that displayed poor in vitro susceptibility to both bamlanivimab and etesevimab. Later on 21 October 2021, BAM/E distribution was officially resumed as the combined frequency of variants resistant to BAM/E was less than 5% in all US states, territories and jurisdictions.¹⁶ The B.1.1.529 (Omicron) emerged in late 2021 and was not present at the time of this study. Given the global differences in available antibody formulations and geographical variant distribution, this study adds value as the first to describe BAM/E combination outside of clinical trials especially in high-risk populations.

4 | WHAT IS NEW AND CONCLUSIONS

Our study of a cohort of over 600 patients adds to the reported favourable experience of BAM and BAM/E therapy in preventing disease progression of COVID-19 and resulting hospitalizations for susceptible variants. Outcomes did not differ in patients receiving BAM monotherapy and BAM/E, possibly due to more obesity or longer time from symptom onset to infusion in the BAM/E group. Given the high proportion of Black patients in this study, our results are important for clinicians caring for racially diverse patients that have thus far been underrepresented in clinical and real-world studies of MABs.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the Henry Ford Hospital Department of Pharmacy and members of the pharmacy and therapeutics committee for their time and effort in procuring and facilitating timely administration of monoclonal antibody at our institution.

CONFLICT OF INTEREST

The authors report no conflicts of interest.

PATIENT CONSENT STATEMENT

The institutional review board granted a waiver of informed consent due to retrospective data collection.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon request.

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How to cite this article: Monday LM, Brar I, Alangaden G, Ramesh MS. SARS-CoV-2 neutralizing antibodies for COVID-19: Outcomes for bamlanivimab versus bamlanivimab-etesevimab combination in a racially diverse cohort of patients with significant comorbidities. *J Clin Pharm Ther.* 2022;1-6. doi:10.1111/jcpt.13694