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Abstract—Background: Bamlanivimab and casirivimab/imdevimab are recombinant neutralizing monoclonal antibodies that decrease viral load in patients with coronavirus disease 2019 (COVID-19) and can decrease hospitalizations. Few data exist comparing these two therapies. Objective: Our aim was to compare the efficacy and safety of bamlanivimab and casirivimab/imdevimab in emergency department (ED) patients with COVID-19 who met criteria for monoclonal antibody therapy. Methods: We performed a single-center, open-label, prospective study in adult ED patients with confirmed COVID-19 and high-risk features for hospitalization. Enrolled patients received bamlanivimab or casirivimab/imdevimab, depending on the day of the week that they arrived. We observed patients for post–infusion-related reactions and contacted them on days 5, 10, and 30. The primary outcome was the number of hospitalizations through day 30. In addition, we compared groups with regard to return visits to the ED, symptom improvement, antibody-induced adverse events, and deaths. Results: Between December 17, 2020 and January 17, 2021, 321 patients completed the study. We found no statistically significant difference in the rate of subsequent hospitalization between groups (bamlanivimab: n = 18 of 201 [8.9%] and casirivimab/imdevimab: n = 13 of 120 [10.8%]; p = 0.57). In addition, we found no statistically significant differences between groups regarding return visits to the ED or symptom improvement. One patient had a possible adverse reaction to the treatment, and 1 patient died. Both of these events occurred in the bamlanivimab group. Conclusions: We found no statistically significant differences in rates of subsequent hospitalization or other outcomes for ED patients with COVID-19 when they received bamlanivimab as opposed to casirivimab/imdevimab. Adverse events were rare in both groups. © 2021 Elsevier Inc. All rights reserved.

Keywords—COVID-19; monoclonal antibodies; bamlanivimab, casirivimab/imdevimab, REGN-CoV-2; LY-CoV555

1. Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causing coronavirus disease 2019 (COVID-19) has created a global pandemic since its emergence in January 2020. During the course of the last year, multiple therapies were investigated as potential treatments for patients with COVID-19 (1–7). Many of these studies focused on patients with severe COVID-19 requiring hospitalization, for which dexamethasone has shown a mortality benefit (8).

For mild to moderate COVID-19, two recombinant neutralizing monoclonal antibody therapies that target the virus spike protein and subsequent attach-
ment to human ACE-2 receptors—bamlanivimab (LY-CoV555) and casirivimab/imdevimab (REGN-COV2)—have shown promise (9,10). The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for these therapies for use in patients with mild to moderate COVID-19 within 10 days of symptom onset, who are at high risk for progressing to severe COVID-19 or hospitalization, and the use of these therapies is already widespread (11,12). Although bamlanivimab and casirivimab/imdevimab have shown efficacy in lessening viral load and decreasing hospitalization and emergency department (ED) visits, no prospective studies have compared these therapies to each other (9,10).

We now report the findings of a prospective study that compared the efficacy and safety of bamlanivimab to casirivimab/imdevimab for ED patients with mild to moderate COVID-19 who met current criteria for monoclonal antibody therapy.

2. Materials and Methods

2.1. Study Design and Setting

We performed an open-label, prospective, single-center, parallel trial, in a cohort of symptomatic (i.e., fever, cough, sore throat, malaise, headache, muscle pain, gastrointestinal symptoms, or shortness of breath on exertion) adult ED patients with COVID-19. The study took place at an academic, tertiary care hospital in Miami Beach, FL, with an annual ED volume of approximately 80,000 visits. The study was reviewed and approved by our local Institutional Review Board. All patients provided written informed consent before participating in the study.

2.2. Patients

Potential study participants were identified by emergency physicians at the study site or referred for eligibility by physicians affiliated with the institution. To be eligible for participation, patients must have been diagnosed with COVID-19 by polymerase chain reaction or a direct antigen test (from our facility or an outside testing facility) and have had one or more mild to moderate symptoms; presented to our hospital within 10 days of symptom onset; and had high-risk features for progressive disease or hospitalization. The following were considered high-risk features: age 65 years or older, body mass index (BMI) ≥ 35 kg/m² (using patient reported height and weight), diabetes mellitus, chronic kidney disease (glomerular filtration rate < 60 mL/min per 1.73 m²), and any condition or use of medication that weakens the immune system (such as corticosteroids and immunomodulators). In addition, patients aged 55 or older with heart disease, high blood pressure, or long-term lung disease were considered to have high-risk features. Patient inclusion started on December 17, 2020 and ended on January 17, 2021. The date of final follow-up was February 16, 2021.

2.3. Intervention

Enrollment took place from 8 AM to 8 PM on assigned days. Enrolled patients received either bamlanivimab or casirivimab/imdevimab. The monoclonal antibodies were administered as a single, 1-h intravenous infusion. Casirivimab and imdevimab were given at 1.2 g each. The bamlanivimab dose was 700 mg. For practicality, selection of therapy received depended on the day of the week the infusion took place. Bamlanivimab was given on Tuesday, Thursday, Saturday, and Sunday, and casirivimab/imdevimab was given on Monday, Wednesday, and Friday. Prior to receiving the monoclonal antibody infusion, all patients received 25 mg of diphenhydramine and 20 mg of famotidine intravenously (allergy prophylaxis). A patient care area in our 50-bed ED was designated for infusion administrations. Infusions were administered from 8 AM to 8 PM. All patients were observed for 1 additional hour for potential medication-related reactions.

2.4. Data Collection

Principal and co-investigators collected the following information at the time of infusion: patient demographics, date of symptom onset, date of positive COVID-19 test results, date of the infusion, symptoms, vital signs, and associated comorbidities. A comorbidity score was generated, with a score of 1 indicating one comorbidity, a score of 2 indicating presence of two comorbidities and so on. On days 5 and 10, progression of symptoms was assessed via phone calls by bilingual research assistants or co-investigators. If the patient did not answer the initial call, a text message in English or Spanish was sent (see Appendix 1). We employed a 1–5 ordinal scale to gather the patients’ self-assessment of their well-being at day 5 and 10 post infusion (see Appendix 1). On day 30, a return to ED or hospitalization was gathered via phone call and or text messages, as well as medical record review. Two co-investigators were responsible for data extraction.

2.5. Outcomes

The primary outcome of the study was the percentage of patients requiring hospitalization within 30 days of the monoclonal antibody treatment in each treatment group. We analyzed these hospitalizations and determined which
A COMPARISON OF SARS-COV-2 NEUTRALIZING ANTIBODY THERAPIES IN HIGH-RISK PATIENTS

Figure 1. Flowchart. AMA = against medical advice; ED = emergency department.

of these hospitalizations were COVID-19–related (i.e., worsening symptoms: fever, cough, sore throat, malaise, headache, muscle pain, gastrointestinal symptoms, or shorten of breath on exertion). We also compared the bamlanivimab and casirivimab/imdevimab groups with respect to the total number of return visits to the ED within 30 days, patient-reported symptoms (measured on a scale of 1 to 5) on days 5 and 10 post infusion, frequency of monoclonal antibody–induced adverse events, and deaths within 30 days.

2.6. Statistical Analyses

Results were presented as means ± standard deviation (SD), median (interquartile range [IQR]), or number of observations (percentage). The Mann-Whitney U test was employed to test for differences between medians for ordinal variables, and unpaired Welch’s t-test was used to assess for differences in mean values of continuous variables. Fisher exact test and relative risk (95% confidence interval [CI]) were used to assess for comparison of binary variables across treatment groups. CIs in this report were not adjusted for multiplicity. Adjustments for multiple testing were not conducted. Statistical analyses were performed with SPSS software (IBM Corp.).

Using an α of .05, we calculated that we would need to enroll 140 patients in each group to have 80% power to detect a difference in hospitalization rate of 10% between the two groups. We anticipated an approximately 15% loss to follow-up rate, so we planned to enroll at least 322 patients.
Table 1. Patient Demographics, Comorbidities, and Baseline Vital Signs

| Variable                              | All Patients (n = 321) | Bamlanivimab (n = 201) | Casirivimab/Imdevimab (n = 120) |
|---------------------------------------|------------------------|------------------------|---------------------------------|
| Age, y, mean ± SD                     | 65.0 ± 12.5            | 64.2 ± 12              | 66.3 ± 13.2                     |
| Sex, female (n = 321), n/N (%)        | 128/321 (39.8)         | 83/201 (41.2)          | 45/120 (37.5)                   |
| Ethnicity,† Hispanic (n = 321), n/N (%) | 160/321 (49.8)     | 104/201 (57.7)         | 56/120 (46.7)                   |
| Race,† White (n = 320), n/N (%)       | 298/321 (92.8)         | 189/201 (94)           | 109/120 (90.8)                  |
| BMI, kg/m² (n = 314), median (IQR)    | 29.9 (29.3–30.6)      | 30.2 (29.3–31.0)       | 29.6 (28.5–30.7)                |
| No. of days from symptom onset to infusion (n = 321), median (IQR) | 5 (3–7) | 5 (3–7) | 4 (3–6.75) |
| Comorbidities (n = 321), n (%)        |                        |                        |                                |
| Age ≥ 65 y                            | 183 (57.0)             | 113 (56.2)             | 70 (58.3)                       |
| BMI ≥ 35 kg/m²                        | 61 (19.0)              | 40 (19.9)              | 21 (17.5)                       |
| History of CKD                        | 8 (2.5)                | 6 (2.9)                | 2 (1.7)                         |
| History of DM                         | 74 (23.0)              | 51 (25.4)              | 23 (19.2)                       |
| History of immune suppression/treatment† | 37 (11.5)            | 21 (10.4)              | 16 (13.3)                       |
| HTN                                   | 37 (11.5)              | 21 (10.4)              | 16 (13.3)                       |
| CAD                                   | 20 (6.2)               | 10 (4.9)               | 10 (8.3)                        |
| COPD                                  |                        |                        |                                |
| Comorbidities score‡ (n = 321), median (IQR) | 1 (1–2)            | 1 (1–2)               | 1 (1–2)                         |
| HR, mean ± SD                         | 79.4 ± 14.8            | 79.0 ± 14.4            | 80.0 ± 15.4                     |
| RR, mean ± SD                         | 17.4 ± 1.5             | 17.6 ± 1.6             | 17.0 ± 1.3                      |
| SBP, mean ± SD                        | 137 ± 19.5             | 137 ± 19.6             | 137 ± 19.4                      |
| DBP, mean ± SD                        | 80.6 ± 12.1            | 81.2 ± 12.3            | 79.5 ± 11.7                     |
| SpO₂, mean ± SD                       | 97.1 ± 1.8             | 97.2 ± 1.8             | 97.1 ± 1.8                      |
| Temperature°C, mean ± SD              | 36.8 ± 3.1             | 36.8 ± 3.2             | 36.7 ± 3.2                      |

BMI = body mass index; CAD = coronary artery disease; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; DBP = diastolic blood pressure; DM = diabetes mellitus; HTN = hypertension; IQR = interquartile range; RR = respiratory rate; SBP = systolic blood pressure; SD = standard deviation.

† Race and ethnicity were reported by the patients.

‡ History of immune suppressive disease or treatment with immune-suppressant drugs.

§ Comorbidities score indicates the median (IQR) number of comorbidities present (age ≥ 65 y, BMI ≥ 35 kg/m², CKD, DM, immune suppression, HTN, CAD, and COPD).

3. Results

Between December 17, 2020 and January 17, 2021, we enrolled 327 patients, but 5 were lost to follow-up and 1 left against medical advice before data completion. Three hundred and twenty-one patients were included for analysis (Figure 1). Among these patients, 39.8% self-identified as female and 92.8% self-identified as White. Nearly one-half of the patients (49.8%) identified their ethnicity as Hispanic. Mean ± SD age was 65.0 ± 12.5 years. Mean BMI was 29.9 ± 6.1 kg/m². Median number of comorbidities present at baseline was 1 (IQR 1–2; range 1–5). Median number of days from symptom onset to infusion was 5 (IQR 3–7).

Bamlanivimab was administered to 62.6% (n = 201 of 321) and casirivimab/imdevimab to 37.4% (n = 120 of 321) of the study patients. The two treatment groups were well balanced regarding demographic characteristics, risk factors, onset of symptoms, symptom severity, and time from diagnosis to infusion therapy (Table 1).
Table 2. Outcomes for Prespecified Endpoints: Emergency Department Visits, Hospitalizations, Medication Reactions, and Deaths for Patients with COVID-19 Treated with Monoclonal Antibodies

| Outcomes                                      | All Patients (n = 321) | Bamlanivimab (n = 201) | Casirivimab/Imdevimab (n = 120) | Relative Risk Ratio (95% CI), p Value |
|-----------------------------------------------|------------------------|-------------------------|----------------------------------|-------------------------------------|
| All ED visits in 30 d, n (%)                  | 46 (14.3)              | 28 (13.9)               | 18 (15.0)                        | 0.96 (0.73–1.21), 0.87              |
| No. of COVID-19–related ED visits in 30 d; % (95% CI) | 33; 10.3 (7.2–14.3)    | 21; 10.4 (6.6–15.5)     | 12; 10.0 (5.3–16.8)              | 1.02 (0.74–1.23), > 0.99           |
| All hospitalizations in 30 d, n (%)           | 31 (9.7)               | 18 (8.9)                | 13 (10.8)                        | 0.92 (0.64–1.19), 0.57             |
| No. of COVID-19–related hospitalizations in 30 d; % (95% CI) | 20; 6.2 (3.8–9.5)      | 13; 6.5 (3.5–10.8)      | 7; 5.8 (2.4–13.5)                | 1.04 (0.74–1.45), 1.00             |
| Possible medication reactions, n (%)          | 1 (0.8)                | 1 (0.8)                 | 0 (0)                            | —                                  |
| Hospitalizations due to medication reactions, n (%) | 1 (0.3)                | 1 (0.5)                 | 0 (0)                            | —                                  |
| Deceased, n (%)                               | 1 (0.6)                | 1 (0.96)                | 0 (0)                            | —                                  |

CI = confidence interval; COVID-19 = coronavirus disease 2019; ED = emergency department.

With regard to the primary outcome, there was no statistically significant difference in the percentage of patients who were subsequently hospitalized within 30 days of monoclonal antibody treatment. In particular, 18 of 201 patients (8.9%) who received bamlanivimab and 13 of 120 patients (10.8%) who received casirivimab/imdevimab were subsequently hospitalized (p = 0.57). There were no differences in the baseline values for BMI, comorbidities scores, heart rate, respiratory rate, blood pressure, SpO2, and body temperature between hospitalized and nonhospitalized patients. There was no difference in number of days that elapsed from symptom onset to infusion administration for hospitalized (median 6 days; IQR 3–7 days) and nonhospitalized (median 4.5 days; IQR 3–7 days) patients (p = 0.61).

Of the 18 hospitalizations in the bamlanivimab group, 13 (72.2%) were considered to be COVID-19–related, and 7 of the 13 hospitalizations (53.8%) in the casirivimab/imdevimab group were considered to be COVID-19–related (Table 2). There were no statistically significant differences between the COVID-19–related hospitalization rates between the two groups: bamlanivimab 6.5% and casirivimab/imdevimab 5.8% (p = 1.00).

There were 46 return visits to the ED (14.3% of all enrolled patients) during the 30 days of the study period, of which 33 (10.3% of study patients) were considered as COVID-19–related ED visits (worsening symptoms: fever, cough, sore throat, malaise, headache, muscle pain, gastrointestinal symptoms, or shortness of breath on exertion). COVID-19–related ED visits occurred in 10.4% (n = 21 of 201) of the patients that received bamlanivimab and in 10.0% (n = 12 of 120) of the patients that received casirivimab/imdevimab (p > 0.99) (Table 2).

Improvements in symptoms and overall general health were assessed on days 5 and 10 after monoclonal antibody administration (Table 3). There were no significant differences in the self-reported symptoms and health scores between the bamlanivimab arm and the casirivimab/imdevimab arm. Return to pre–COVID-19 health 5 days after infusion was reported in 30.7% and 32.2% of patients treated with bamlanivimab and casirivimab/imdevimab, respectively. Return to pre–COVID-19 health at 10 days after the infusion was reported in 58.3% and 54.7% of patients who received bamlanivimab and casirivimab/imdevimab, respectively (p = 0.56) (Table 3).
Table 3. Outcomes for Prespecified Endpoints: Symptoms Resolution for Patients with COVID-19 Treated with Monoclonal Antibodies

| Variable                        | All Patients (n = 321) | Bamlanivimab (n = 201) | Casirivimab/Imdevimab (n = 120) | Relative Risk Ratio (95% CI), p Value |
|---------------------------------|------------------------|-------------------------|----------------------------------|-------------------------------------|
| Day 5 after infusion            |                        |                         |                                  |                                     |
| How bad are your symptoms today?| 4 (4–5)                | 4 (4–5)                 | 4 (4–5)                          | —                                   |
| Patients that reported no symptoms, n (%) | 92/306 (30.1)       | 51/188 (27.1)          | 41/118 (34.7)                    | 0.87 (0.69–1.05), p = 0.16          |
| How is your general health today?|                        |                         |                                  |                                     |
| Patients that reported excellent health (score 5), n (%) | 4 (3–4)               | 4 (3–4)                 | 4 (3–5)                          | —                                   |
| Have you returned to your usual (pre-COVID) health today? Yes, n (%) | 76/307 (24.8)         | 46/189 (24.3)          | 30/118 (25.4)                    | —                                   |
| Day 10 after infusion           |                        |                         |                                  |                                     |
| How bad are your symptoms today?| 5 (4–5)                | 5 (4–5)                 | 5 (4–5)                          | —                                   |
| Patients that reported no symptoms (score 5), n (%) | 180/316 (56.9)        | 114/199 (57.3)         | 66/117 (56.4)                    | 1.01 (0.86–1.21), p < 0.001         |
| How is your general health today?|                        |                         |                                  |                                     |
| Patients that reported excellent health, n (%) | 4 (4–5)               | 4 (4–5)                 | 4 (4–5)                          | —                                   |
| Have you returned to your usual (pre-COVID) health today? Yes, n (%) | 144/316 (45.6)        | 91/199 (45.7)          | 53/117 (45.2)                    | —                                   |

CI = confidence interval; COVID-19 = coronavirus disease 2019.

Patient self-assessment of symptoms improvement was evaluated at day 5 and day 10 after antibody administration. The following three questions were employed: “Overall, how bad your symptoms were today?” Answers: 1 very severe, 2 severe, 3 moderate, 4 mild, 5 no symptoms, “Overall, how is your general health today?” Answers: 1 poor, 2 fair, 3 good, 4 very good, 5 excellent. “Have you returned to your usual (pre-COVID) health today?” Answers: yes or no.

Of the 31 patients hospitalized, 30 patients were discharged. One death occurred in a patient who received bamlanivimab (see Appendix 2 for details). A possible infusion-related reaction was reported in 1 patient who received bamlanivimab (see Appendix 2 for details). No deaths or adverse reactions from the infusion occurred in the casirivimab/imdevimab group.

4. Discussion

Previously published data suggest that bamlanivimab and casirivimab/imdevimab provide benefits in reducing viral load and can reduce COVID-19–related hospitalizations and medical visits (9,10). Although the use of bamlanivimab and casirivimab/imdevimab is already widespread, until now, no prospective study has compared the efficacy and safety of bamlanivimab and casirivimab/imdevimab.

In our study, we found no statistically significant differences between the bamlanivimab and casirivimab/imdevimab groups in the number of visits to the ED, need for hospitalization, or symptom improvement. These data suggest comparable outcomes with both antibody treatments. However, further studies in larger number of
patients, preferably with a randomized trial are needed to confirm our observations.

Regarding monoclonal antibody safety, we observed only one possible medication reaction related to the treatments in this study—this occurred in a patient who received bamlanivimab. Consistent with prior studies, this low rate of adverse events indicates that the treatment can be administered outside of a traditional infusion center (12,13).

Of note, due to increasing SARS-CoV-2 viral variants and their resistance to bamlanivimab, the FDA recently revoked the EUA for bamlanivimab alone, and it is now given in combination with etesevimab. Therefore, the specific treatment (bamlanivimab alone) evaluated in this study is no longer a viable option. It is unclear how the results of this study would have changed had etesevimab been given with bamlanivimab. However, it seems unlikely that the combination of bamlanivimab and etesevimab would be less efficacious than bamlanivimab alone and, in addition, our data suggest that adverse events from casirivimab/imdevimab are rare. Therefore, in the absence of better data, either bamlanivimab/etesevimab or casirivimab/imdevimab seem like reasonable options for patients with COVID-19 who meet criteria for monoclonal antibody therapy (14).

4.1. Limitations

This study has several limitations. First, this study was not randomized. Patients were administered either bamlanivimab or casirivimab/imdevimab based on the day of the week. Although the measured baseline characteristics of the groups were similar, the method of treatment assignment we used might have created unrecognized differences between groups. In addition, this study did not include a placebo or control group, and the results of this study cannot be used to prove the efficacy of monoclonal antibody treatment compared to placebo. Although monoclonal antibody therapies have been shown to decrease viral load, the data suggesting benefits for patient-oriented outcomes are less robust.

Next, we did not assess for pre-existing immune response and viral load at baseline and after monoclonal antibody infusion therapy. Theoretically, exogenous antibody therapy will have the most benefit in patients whose natural immune response has not been initiated (8). However, pre-infusion immune response screening seems unsuitable for daily practice.

Finally, the sample size of this study was too small to detect small differences between groups or to assess for rare adverse events related to monoclonal antibody infusions for COVID-19. We can, however, state that adverse events are rare, and there do not appear to be any large differences in outcomes when using bamlanivimab as opposed to casirivimab/imdevimab.

5. Conclusions

In this prospective study, we found no statistically significant differences in the rate of subsequent hospitalization or other outcomes for patients who received bamlanivimab compared to casirivimab/imdevimab for mild to moderate COVID-19. Adverse events related to the infusion of the monoclonal antibody medications were rare.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jemermed.2021.07.025.

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ARTICLE SUMMARY

1. Why is this topic important?
   The use of monoclonal antibody therapies for COVID-19 is now commonplace, but few data exist comparing the two frequently used options of bamlanivimab and casirivimab/imdevimab.

2. What does this study attempt to show?
   This study attempts to compare the efficacy and safety of bamlanivimab and casirivimab/imdevimab in ED patients with mild to moderate COVID-19 and high-risk features for hospitalization.

3. What are the key findings?
   No statistically significant differences were found between groups with regard to return visits to the ED, hospitalizations, or deaths within 30 days. Adverse events related to monoclonal antibody infusions were rare in both groups.

4. How is patient care impacted?
   For patients with COVID-19 who meet criteria for monoclonal antibody therapy, both bamlanivimab and casirivimab/imdevimab seem to be reasonable options.