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Rates of Severe Outcomes After Bamlanivimab-Etesevimab and Casirivimab-Imdevimab Treatment of High-Risk Patients With Mild to Moderate Coronavirus Disease 2019



John O'Horo, MD, MPH; Douglas W. Challener, MD; Ryan J. Anderson, PharmD, RPh; Richard F. Arndt, PharmD, RPh; Sara E. Ausman, PharmD, RPh; Scott T. Hall, PharmD; Alexander Heyliger, PharmD, RPh; Brian D. Kennedy, RPh; Perry W. Sweeten, PharmD; Ravindra Ganesh, MBBS, MD; and Raymund R. Razonable, MD

Abstract

Bamlanivimab-etesevimab and casirivimab-imdevimab are authorized by the US Food and Drug Administration for emergency treatment of mild to moderate coronavirus disease 2019 (COVID-19) in high-risk persons. There has been no study comparing their clinical efficacy. In this retrospective study of 681 patients with mild to moderate COVID-19 during a period dominated by severe acute respiratory syndrome coronavirus 2 wild-type and alpha variants, 25 patients (3.7%) had progression to a severe outcome requiring hospitalization and oxygen supplementation within 30 days after monoclonal antibody infusion. Severe outcome was significantly higher among the 181 patients who were treated with casirivimab-imdevimab when compared with the 500 patients who received bamlanivimab-etesevimab (21 [6.6%] vs 13 [2.6%]; $P=.01$). Patients treated with casirivimab-imdevimab had higher odds of severe outcomes compared with those who received bamlanivimab-etesevimab (odds ratio, 2.67; 95% CI, 1.17 to 6.06). The demographic and clinical characteristics, and the time to monoclonal antibody infusion, of the 2 treatment cohorts were not significantly different. The reason behind this significant difference in the clinical outcomes is unclear, but our observations emphasize potential efficacy differences among antispikes monoclonal antibodies against COVID-19. Further clinical studies using larger cohorts of patients are needed to confirm or refute these observations.

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Monoclonal antibodies directed against the receptor-binding domain of the spike protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have received emergency use authorization (EUA) from the US Food and Drug Administration (FDA) for treatment of high-risk patients with mild to moderate coronavirus disease 2019

(COVID-19).^{1,2} Randomized clinical trials have found that these antispikes monoclonal antibody therapies were associated with a more rapid decline in viral load as well as a reduction in rates of medically attended visits and hospitalizations.³⁻⁵

Bamlanivimab (Lilly) monotherapy was the first to receive EUA in November 2020.¹ Although real-world experience with the use



From the Division of Infectious Diseases (J.O., D.W.C., R.R.R.), Division of Pulmonary and Critical Care Medicine (J.O.), Department of Pharmacy (R.J.A., A.H.), and Division

Affiliations continued at the end of this article.

of bamlanivimab monotherapy was favorable, with substantial reductions in hospitalization, intensive care unit admission, and mortality among bamlanivimab-treated patients,⁶ the emergence of SARS-CoV-2 variants of concern (mainly SARS-CoV-2 B.1.351 [beta] and P.1 [gamma] variants) led to the revocation of its EUA as monotherapy in February 2021.⁷ At that time, the FDA authorized the use of bamlanivimab only if it was given in combination with etesevimab (Lilly).^{4,7} In a randomized controlled trial, the bamlanivimab-etesevimab combination resulted in a marked reduction in hospitalization compared with bamlanivimab monotherapy.⁴

Casirivimab-imdevimab (Regeneron Pharmaceuticals Inc), another antispikes monoclonal antibody combination, received EUA in November 2020.² In a randomized trial, casirivimab-imdevimab was significantly associated with a more rapid decline in viral load when compared with placebo.² A retrospective study reported a significant reduction in hospitalization rates among patients who received casirivimab-imdevimab compared with propensity-matched untreated patients with mild to moderate COVID-19.⁸

There are no studies comparing the clinical efficacy of bamlanivimab-etesevimab and casirivimab-imdevimab. In this study, we sought to assess differences in clinical efficacy by comparing the rates of severe outcomes among high-risk patients treated with bamlanivimab-etesevimab or casirivimab-imdevimab for mild to moderate COVID-19 during the period prior to the surge of SARS-CoV-2 delta and omicron variants of concern.

PATIENTS AND METHODS

Study Setting

Mayo Clinic is an integrated health care delivery network serving over 1 million patients each year across southern Minnesota, northeastern Iowa, western Wisconsin, and the metropolitan areas of Jacksonville, Florida, and Phoenix, Arizona. On November 7, 2020, Mayo Clinic established its Monoclonal Antibody Treatment (MATRx)

program to administer antispikes monoclonal antibodies to patients at high risk of severe disease in an attempt to mitigate the risk of disease progression and hospitalization. The MATRx program, protocols, and procedures have been described previously.⁹

For this study, only patients treated in Minnesota and Wisconsin were included. By limiting the geographic area, we could directly compare the efficacy of these 2 monoclonal antibody products given similar circulating variants in the community. At the time of this study, the predominant circulating variants were SARS-CoV-2 wild-type and alpha (B.1.1.7 lineage) variants, while the proportions of SARS-CoV-2 beta (B.1.351 lineage) and gamma (P.1 lineage) variants were low, allowing the use of both monoclonal antibody products interchangeably without concerns for viral resistance. In contrast, the proportion of the resistant viral variants circulating in our clinic sites in Florida and Arizona was above 5%, which prevented the use of bamlanivimab-etesevimab in those sites.

Study Population and Design

This was a retrospective study among adult patients (≥ 18 years) who were identified from Mayo Clinic electronic health records during the period when bamlanivimab-etesevimab or casirivimab-imdevimab were simultaneously authorized for use (February 9, 2021, to June 25, 2021). Bamlanivimab-etesevimab was authorized for emergency use on February 9, 2021, but its distribution was paused on June 25, 2021, due to the emergence of resistant variants of concern. Casirivimab-imdevimab, on the other hand, has been authorized for use continuously since it was first authorized for emergency use in November 2020, as it has retained activity against all known variants of concern.² All patients with mild to moderate COVID-19 treated with antispikes monoclonal antibodies during the study period were included in this study. The population was divided into 2 cohorts based on the specific monoclonal antibody received.

Antispike Monoclonal Antibodies

Antispike monoclonal antibodies were distributed to infusion facilities on behalf of the US government. The specific monoclonal antibody administered to any eligible patient was based solely on the product available at the infusion facility during the date of treatment. There were no clinical criteria to favor one product over another. The products available during this study were bamlanivimab-etesevimab (700-mg/1400-mg dose, as a one-time infusion) and casirivimab-imdevimab (1200-mg/1200-mg dose until June 4, 2021, when the authorized dose was reduced to a 600-mg/600-mg dose, as a one-time infusion).^{4,5} Both monoclonal antibodies were available in all infusion facilities.

Clinical Eligibility Criteria and Risk Factor Scores

Patients were eligible to receive antispike monoclonal antibodies if they had mild to moderate COVID-19, confirmed by a positive SARS-CoV-2 polymerase chain reaction or antigen test results, and were within 10 days of symptom onset. In addition, patients had to have at least one of the following criteria: age 65 years or older, body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) of 35 kg/m² or greater, diabetes mellitus, chronic kidney disease, immunosuppressive drug use, or an immunocompromising condition. Patients 55 years and older qualified if they had hypertension, cardiovascular disease, or chronic lung disease.¹⁰

Based on the FDA EUA criteria, the Monoclonal Antibody Screening Score (MASS) was developed. The MASS assigned points to each of the eligibility criteria, as follows: age 65 years or older, 2 points; BMI of 35 kg/m² or greater, 1 point; diabetes mellitus, 2 points; chronic kidney disease, 3 points; cardiovascular disease in a patient 55 years or older, 2 points; chronic respiratory disease in a patient 55 years or older, 3 points; hypertension in a patient 55 years or older, 1 point; and immunocompromised status, 3 points.¹⁰ In an initial analysis during the first 6 weeks of the MATRx program, the rate of all-cause

hospitalization among untreated high-risk patients correlated directly with the MASS; higher hospitalization rates were observed among patients with a higher MASS.^{10,11} On May 14, 2021, the FDA expanded the eligibility criteria for monoclonal antibody infusion. The expansion included the removal of age restriction for hypertension, cardiac disease, and lung disease and the inclusion of all adults with a BMI of 25 kg/m² or greater, sickle cell disease, neurodevelopmental disorders, and medicotechnological dependence. COVID-19 vaccination status was not part of the criteria for allocation of monoclonal antibody treatment.

For the purpose of this study, we used the MASS as the measure of high-risk characteristics because it was the comorbidity measure used for the majority of the study period. In addition, we correlated the outcomes with the Charlson comorbidity index as another measure of medical complexity.

Outcome

The primary outcome of interest was the proportion of patients with severe outcomes by day 30 after antispike monoclonal antibody infusion.¹² We defined severe outcomes in this study according to the World Health Organization Ordinal Scale score of 4 (hospitalized and oxygen supplementation by mask or nasal prongs) or greater.¹²

Ethical Considerations

This study was conducted in accordance with the aim of the Strengthening of Reporting of Observational Studies in Epidemiology (STROBE).¹³ The Mayo Clinic Institutional Review Board approved this study. Informed consent was waived. Only patients with research authorization were included.

Statistical Analyses

The baseline characteristics and outcomes of patients who received infusions with bamlanivimab-etesevimab or casirivimab-imdevimab were compared using standard descriptive statistics. Outcomes were compared across groups using a Kruskal-Wallis test. Unadjusted and adjusted logistic regression models were created to estimate

TABLE 1. Demographic and Clinical Characteristics of Patients With Mild to Moderate Coronavirus Disease 2019 Treated With Bamlanivimab-Etesevimab and Casirivimab-Imdevimab^{a,b}

Characteristic	Bamlanivimab-etesevimab (n=500)	Casirivimab-imdevimab (n=181)	All patients (N=681)	P value
Age (y)	55.8 (41.6-64.8)	58.4 (40.8-67.1)	56.7 (41.2-65.5)	.39
Female	222 (44.2)	89 (49.7)	311 (45.7)	.20
Body mass index (kg/m ²)	31.0 (26.9-37.1)	32.4 (27.5-38.3)	31.2 (27.2-37.8)	.17
Race				.30
White	466 (93.2)	166 (91.7)	632 (92.8)	
Asian	11 (2.2)	1 (0.6)	12 (1.8)	
Black/African American	7 (1.4)	5 (2.8)	12 (1.8)	
American Indian/Pacific Islander	3 (0.6)	1(0.6)	4 (0.6)	
Unknown	13 (2.6)	8 (4.4)	21 (3.1)	
Ethnicity				.79
Hispanic/Latino	27 (5.4)	8 (4.4)	35 (5.1)	
Cardiovascular disease	84 (16.8)	26 (14.4)	110 (16.2)	.45
Diabetes mellitus	126 (25.2)	42 (23.2)	168 (24.7)	.59
Hypertension	177 (35.4)	68 (37.6)	245 (36.0)	.60
Lung disease	53 (10.6)	18 (9.9)	71 (10.4)	.80
Renal disease	12 (2.4)	5 (2.8)	17 (2.5)	.79
Immunocompromised status	69 (13.8)	28 (15.5)	97 (14.2)	.58
Completed vaccination	70/331 (21.1)	40/104 (38.5)	110/435 (25.2)	.01
Charlson comorbidity index score	90.2 (53.4-95.9)	90.2 (53.4-95.9)	90.2 (53.4-95.9)	.56
Risk factors for severe infection with COVID-19	2.0 (1.0-3.0)	2.0 (1.0-4.0)	2.0 (1.0-3.0)	.29
Monoclonal Antibody Screening Score	2.0 (1.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	.73
Time to monoclonal antibody infusion (d)	2.0 (2.0-3.0)	2.0 (2.0-3.0)	2.0 (2.0-3.0)	.21

^aCOVID-19, coronavirus disease 2019.

^bData are presented as No. (percentage) of patients or median (IQR).

the odds ratio (OR) of severe outcome with infusion of casirivimab-imdevimab compared with bamlanivimab-etesevimab. The adjusted OR was calculated by adding Charlson comorbidity index to the regression. This adjustment was performed as a sensitivity analysis to assess the possibility of this index impacting the findings (and was not an exercise in model derivation). Analyses were performed using RStudio version 1.4.1106 (PBC) and the packages `dplyr`,¹⁴ `epitools`,¹⁵ `sjplot`,¹⁶ and `ggplot2`.¹⁷ In addition, we conducted a sensitivity analysis calculating adjusted odds to adjust risk of severe outcome for comorbidities.

RESULTS

The study population included 681 patients with mild to moderate COVID-19 who received treatment with bamlanivimab-

etesevimab (n=500) or casirivimab-imdevimab (n=181) between February 9, 2021, and June 25, 2021 (a period prior to the SARS-CoV-2 delta surge in our communities). The median patient age was 56.7 years (interquartile range, 41.2 to 65.5 years), 311 (45.7%) were female, and 632 (92.8%) were White. The demographic and clinical characteristics are listed in Table 1.

The 2 treatment cohorts were comparable in terms of age, sex, BMI, race, and ethnicity. Risk factors for severe COVID-19 were comparable between the 2 cohorts, as assessed by several measures including the Charlson comorbidity index. The FDA EUA eligibility criteria, as measured by the MASS, was also comparable between the 2 treatment cohorts. There were no significant differences in the individual components of the MASS ($P=.73$); the proportion of

patients with cardiovascular disease ($P=.45$), chronic kidney disease ($P=.79$), diabetes mellitus ($P=.59$), hypertension ($P=.60$), and pulmonary disease ($P=.80$) was not significantly different between the 2 cohorts. Likewise, the proportion of patients with immunocompromised status was not significantly different between the two cohorts ($P=.58$) (Table 1). However, COVID-19 vaccination was significantly higher among patients who received casirivimab-imdevimab ($P<.01$). The median time to antispike monoclonal antibody infusion was similar between the 2 cohorts (median of 2 days; range, 1 to 9 days from the time of positive SARS-CoV-2 polymerase chain reaction). All patients were infused within the 10-day period since the onset of symptoms.

Of the 681 patients, 25 (3.7%) experienced the primary outcome (had a score of 4 or higher on the World Health Organization ordinal scale for clinical improvement)¹² by day 30 after the monoclonal antibody infusion (Table 2). The primary outcome was significantly higher among the 181 patients treated with casirivimab-imdevimab compared with the 500 patients who received bamlanivimab-etesevimab (21 [6.6%] vs 13 [2.6%]; $P=.01$). Casirivimab-imdevimab was associated with higher odds of severe outcomes than bamlanivimab-etesevimab (OR, 2.67; 95% CI, 1.17 to 6.06).

To further investigate the difference in the overall outcomes between the 2 cohorts, a subgroup analysis was performed on 172 patients residing in Olmsted and Blue Earth counties served predominantly by Mayo Clinic in Minnesota. The 172 patients were selected in this subgroup analysis because they would be less likely to seek care outside hospital system. The demographic and clinical characteristics were comparable for the 117 patients treated with bamlanivimab-etesevimab and 55 patients treated with casirivimab-imdevimab (Supplemental Table, available online at <http://www.mayoclinicproceedings.org>). By day 30 after monoclonal antibody infusion, severe outcome was observed in 2 patients (1.7%) treated with bamlanivimab-etesevimab and

TABLE 2. Outcomes of Monoclonal Antibody Treatment by Day 30 After Infusion According to the NIH Outcome Classification Score^{a,b,c}

Outcome Classification Score	Bamlanivimab-etesevimab (n=500)	Casirivimab-imdevimab (n=181)	All patients (N=681)
1	36 (7.2)	21 (11.6)	57 (8.4)
2	442 (88.4)	145 (80.1)	587 (86.2)
3	9 (1.8)	3 (1.7)	12 (1.8)
4	12 (2.4)	11 (6.1)	23 (3.4)
6	1 (0.2)	1 (0.6)	2 (0.3)

^aNIH, National Institutes of Health.
^bData are presented as No. (percentage) of patients.
^c $P=.04$ (calculated using Kruskal-Wallis test).

5 patients (9.1%) treated with casirivimab-imdevimab ($P=.02$; Supplemental Figure A). The temporal trends of severe outcomes over time in this subgroup are depicted in Supplementary Figure B (available online at <http://www.mayoclinicproceedings.org>).

DISCUSSION

SARS-CoV-2 B.1.1.7 (alpha) was the predominant circulating variant in Minnesota and Wisconsin, in addition to the wild-type virus, during the time of this study. Bamlanivimab-etesevimab and casirivimab-imdevimab were considered similarly effective for treatment of these variants.^{2,4} However, a head-to-head comparison between bamlanivimab-etesevimab and casirivimab-imdevimab has not been performed. Because both antibody products were available for use without clinical criteria that would favor one product over another, comparing the outcomes of the treated patients during the study period could provide insights into their clinical efficacy.⁹

In this retrospective study, the overall rate of severe outcomes was 3.7%, and this overall rate is comparable to our previous observations.¹⁰ However, the rate of severe outcome was considerably higher among patients who received casirivimab-imdevimab when compared with bamlanivimab-etesevimab. This marked difference in outcome between the 2 products was a surprising finding because pseudovirus experiments have suggested that they should be

similarly effective against variants that were circulating in our communities during the study period.¹⁸ This major difference is unexpected considering that the cohort of patients who received casirivimab-imdevimab had higher COVID-19 vaccination rates. Although the reason behind this substantial difference in clinical outcomes between bamlanivimab-etesevimab and casirivimab-imdevimab is not clearly apparent, it emphasizes the importance of comparing their efficacy in real-world practice in order to guide their clinical use.

In a prior study, we observed that the risk of hospitalization after monoclonal antibody therapy is influenced by the number of medical comorbidities.¹⁰ Hospitalizations were higher among those with multiple medical comorbidities. However, this factor could not account for the difference in the outcomes in this study. There was no apparent imbalance in the risk factor profiles between the 2 treatment cohorts. The 2 groups were not markedly different in terms of age, BMI, sex, Charlson comorbidity index score, and MASS. The individual components of the MASS such as diabetes, obesity, cardiovascular disease, and lung diseases were also not remarkably different between the 2 cohorts.

Despite the differences in clinical outcomes, we believe that casirivimab-imdevimab remains effective in reducing the risk of severe outcomes and hospitalization. In a prior study, casirivimab-imdevimab reduced the rate of hospitalization compared with a propensity-matched untreated cohort.⁸ Another retrospective study observed that the 28-day hospitalization rate was not substantially different between patients treated with casirivimab-imdevimab and those who received bamlanivimab monotherapy.¹⁰ Thus, the underlying reason behind this notable difference in clinical outcomes between casirivimab-imdevimab and bamlanivimab-etesevimab therapies in the current study deserves further investigation.

The limitation of this study is its retrospective study design, and some clinical outcomes may not have been fully captured.

This limitation is counterbalanced by the close follow-up of our high-risk patients using the remote monitoring program.¹⁹ In addition, subgroup analysis of patients who resided in Olmsted and Blue Earth counties (who are more likely to seek subsequent care in Mayo Clinic hospitals) reflected the overall outcomes of the full cohort. Second, our program did not randomly allocate the 2 monoclonal antibody products because we were dependent on available supply allocated from the US government. Moreover, bamlanivimab-etesevimab was only available and infused during a part of the study period (as its distribution was affected by federal allocation), while casirivimab-imdevimab was available throughout the study period. Despite this lack of randomization, however, the EUA criteria allowed for highly comparable demographic and clinical characteristics between the 2 treatment groups. Third, this study is limited by the imbalance in the total number of patients between the 2 treatment cohorts, with only 181 patients treated with casirivimab-imdevimab. Because of the small denominator of patients treated with casirivimab-imdevimab, the proportion of severe outcomes may have been considerably skewed by even a few events. Indeed, this limitation could potentially account for the notable difference in the study outcomes between the 2 cohorts. It is therefore suggested that larger patient cohorts be included in future studies to either confirm or refute our observations. Future studies should also include a more diverse cohort, especially underrepresented populations who have been reported to have higher rates of severe outcomes. Finally, our findings reflect only the period dominated by the SARS-CoV-2 wild-type and alpha variants and may not represent the efficacy of these antibodies against the SARS-CoV-2 delta (B.1.617 lineage), which has emerged as the predominant variant circulating in our communities, when the analysis for this study was conducted in October 2021.²⁰ Casirivimab-imdevimab and bamlanivimab-etesevimab are reported to be similarly effective against the delta variant in experimental studies. Whether bamlanivimab-etesevimab

also outperforms casirivimab-imdevimab in the era of delta remains to be seen in the clinical setting.

CONCLUSION

Antispike monoclonal antibodies have emerged as highly effective treatment of mild to moderate COVID-19 among high-risk patients. Our retrospective study revealed that while both treatments are associated with low rates of severe disease progression, balmanivimab-etesevimab was significantly associated with better clinical outcome compared with casirivimab-imdevimab. At the time of this report, SARS-CoV-2 omicron variant has replaced delta as the circulating variant of concern in our communities. Balmanivimab-etesevimab and casirivimab-imdevimab are not active against omicron. Although both antibody products are not currently used in clinical practice, infusion facilities were advised to retain their allocated supplies in case a susceptible variant emerges during this pandemic. Our observations emphasize the need to perform real-world analyses that are intended to guide clinical use. Real-time assessment of clinical outcomes should continue to guide health care and public health professionals in deciding what monoclonal antibody to use to prevent severe outcomes among high-risk patients with mild to moderate COVID-19.

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SUPPLEMENTAL ONLINE MATERIAL

Supplemental material can be found online at <http://www.mayoclinicproceedings.org>. Supplemental material attached to journal articles has not been edited, and the authors take responsibility for the accuracy of all data.

Abbreviations and Acronyms: BMI, body mass index; COVID-19, coronavirus disease 2019; EUA, emergency use authorization; FDA, Food and Drug Administration; MASS, Monoclonal Antibody Screening Score; MATRx, Monoclonal Antibody Treatment; OR, odds ratio; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2

Affiliations (Continued from the first page of this article.): of General Internal Medicine (R.G.), Mayo Clinic, Rochester, MN; Department of Pharmacy, Mayo Clinic Health System, Eau Claire, WI (R.F.A., S.E.A.); Department of Pharmacy, Mayo Clinic Health System—Franciscan Healthcare, La Crosse, WI (S.T.H.); Department of Pharmacy, Mayo Clinic Health System, Lake City, MN (B.D.K.); and Department of Pharmacy, Mayo Clinic Health System, Mankato, MN (P.W.S.).

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Correspondence: Address to Raymund R. Razonable, MD, Division of Infectious Diseases, Mayo Clinic, 200 First St SW, Rochester, MN 55905 (Razonable.raymund@mayo.edu).

ORCID

John O'Horo: <https://orcid.org/0000-0002-0880-4498>; Richard F. Amdt: <https://orcid.org/0000-0003-4723-689X>; Brian D. Kennedy: <https://orcid.org/0000-0003-3347-917X>; Ravindra Ganesh: <https://orcid.org/0000-0002-6877-1712>

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