

Efficacy of Bamlanivimab in Cancer Patients with COVID-19

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ABSTRACT

OBJECTIVE

Bamlanivimab was the first monoclonal antibody available for patients at high risk for progressing to severe COVID-19. We evaluated the efficacy of bamlanivimab in cancer patients with COVID-19.

METHODS

This retrospective case-controlled chart review examines outcomes in cancer patients with mild to moderate COVID-19, before and after institutional implementation of bamlanivimab therapy for eligible patients beginning December 15, 2021. Patients were matched by age and underlying malignancy. All patients had a baseline oxygen saturation $\geq 94\%$ and an absolute neutrophil count $>500/\text{ml}$. Categorical variables and continuous variables were compared separately. Logistic regression analysis was used to evaluate independent impact of bamlanivimab treatment.

RESULTS

We evaluated 108 patients, 54 in each cohort. Patients who received bamlanivimab were less likely to be admitted to the hospital (24% vs. 91%; $P < 0.0001$), experience oxygen desaturation $<94\%$ during follow-up (11% vs. 44%; $P = 0.0001$), require supplemental oxygen (7% vs. 44%; $P < 0.0001$), or be admitted to the ICU (4% vs. 15%; $P = 0.046$). The groups' 30 days all-cause mortality rates did not differ significantly with no deaths in the bamlanivimab group.

CONCLUSION

Bamlanivimab was associated with decreased hospital admissions and oxygen desaturation rates in cancer patients.

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KEYWORDS

COVID-19; Bamlanivimab; Monoclonal antibodies; Cancer; Efficacy

INTRODUCTION

Cancer patients are particularly susceptible to developing severe coronavirus disease 2019 (COVID-19), the disease caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) [1-4]. Initially, validation of treatments such as remdesivir and steroids was focused on COVID-19 patients who were severely ill or hospitalized [5,6]. Following early promising results with convalescent plasma therapy, research turned to development of passive immune therapy with neutralizing monoclonal antibodies [7]. Monoclonal antibody therapy offered the advantage of outpatient administration earlier in the disease course with an emphasis on prevention of severe COVID-19 requiring hospitalization.

In November 2020, the U.S. Food and Drug Administration granted an emergency use authorization for bamlanivimab (LY-CoV555, Lilly, Indianapolis, IN) for the treatment of patients with mild to moderate COVID-19 at risk of progressing to severe disease [8,9]. Bamlanivimab was the first recombinant, fully humanized, anti-spike monoclonal antibody authorized for prevention of severe disease among the many now approved or in the pipeline [7]. Used in the outpatient setting, bamlanivimab has shown beneficial results, decreasing immunocompetent patients' rates of hospitalization and return emergency department visits [9,10]. Limiting bamlanivimab's more general use is the fact that the antibody must be administered intravenously, and, per the EUA, the patient must be monitored in a setting where emergency medical services are available to treat potential infusion reactions. Being an Acute Cancer Care Center (ACCC) dedicated to the management of emergencies within MD Anderson comprehensive care center, we were able to quickly establish a program that made

bamlanivimab infusions readily accessible to our cancer patients with COVID-19.

Cancer patients are often immunocompromised and bamlanivimab's efficacy in this vulnerable population remains unclear. In the original BLAZE (Blocking Viral Attachment and Cell Entry with SARS-CoV-2 Neutralizing Antibodies) trial, immunocompromised patients, including cancer patients, were part of the group considered at risk for severe COVID and qualified for bamlanivimab treatment, but cancer patients were not studied as a unique cohort [10]. Since that trial's completion in October 2020, single monoclonal antibody therapy has been found to have diminished effectiveness against disease caused by SARS-CoV-2 variants, and many new combination monoclonal antibody therapies have been approved or are under investigation for the treatment of COVID-19. Because bamlanivimab was the first monoclonal antibody therapy available at our institution for out-patient therapy, investigation of our experience may provide valuable data for evaluating the efficacy of future generations of monoclonal antibodies in cancer patients. The importance of this type of therapy continues to grow, as monoclonal antibody therapy is now being proposed for post-exposure prophylaxis and in hospital use [11,12].

Using a before and after case control model, our purpose was to determine the impact of bamlanivimab in cancer patients with COVID-19.

METHODS

Study Design, Participants, and Setting

This retrospective matched cohort before and after study included all cancer patients diagnosed with mild to moderate COVID-19 and received bamlanivimab in the

ACCC between December 15, 2020, and March 21, 2021. We compared these patients with a control group of patients with mild to moderate COVID-19 presenting to the ACCC between March and November 2020 before the introduction of bamlanivimab and that met the following inclusion criteria: 1) Positive COVID-19 history; 2) ACCC visit; and 3) History of cancer or active cancer diagnosis. Controls were matched by age and underlying malignancy. All patients had a baseline oxygen saturation of $\geq 94\%$ and an absolute neutrophil count $\geq 500/\text{ml}$. Positive COVID-19 status was determined by reverse-transcriptase polymerase chain reaction (PCR) analysis of a nasopharyngeal specimen performed in our laboratory within 1 week of the encounter or by an outside facility's report of a positive COVID-19 PCR test.

Patients in the bamlanivimab group received a single 700 mg dose of the monoclonal antibody after providing verbal consent per emergency use authorization criteria. The eligibility criteria for bamlanivimab infusion were based on the manufacturer's recommendations in addition to conditions set forth by MD Anderson's COVID algorithm work group (Table 1). All patients either self-referred to the ACCC or were referred by their primary physician for treatment.

This study was approved by MD Anderson's Institutional Review Board with a waiver for informed consent.

<ul style="list-style-type: none"> • COVID-19-positive with moderate symptoms (changed on 1/6/2021 to include mild symptoms) that will NOT be admitted <ul style="list-style-type: none"> ○ Moderate COVID-19 symptoms & within 10 days of symptom onset <ul style="list-style-type: none"> ▪ Oxygen saturation $>93\%$ and not requiring supplemental oxygen or an increase from baseline oxygen flow rate ▪ Respiratory rate <30 bpm ▪ Heart rate <125 bpm ○ Weight ≥ 40 kg • AND meet one or more of the following criteria <ul style="list-style-type: none"> ○ Age ≥ 65 years ○ Body mass index ≥ 35 ○ Diabetes ○ Chronic kidney disease ○ Immunosuppressive therapy ○ Immunosuppressive disease ○ Age ≥ 55 years AND <ul style="list-style-type: none"> ▪ Cardiovascular disease OR ▪ Hypertension OR ▪ Chronic obstructive pulmonary disease/other chronic respiratory disease ○ Age 12 years - 17 years AND <ul style="list-style-type: none"> ▪ Body mass index $\geq 85^{\text{th}}$ percentile for age and gender OR ▪ Sickle cell disease OR ▪ Congenital heart disease/acquired heart disease OR ▪ Neurodevelopmental disorder OR ▪ Medical-related technological dependence OR ▪ Asthma, reactive airway, or other chronic respiratory disease • Additional MD Anderson criteria <ul style="list-style-type: none"> ○ Absolute neutrophil count $>500/\text{mL}$ ○ Not on investigational protocol(s); if on protocol, explicit communication needed with the protocol principal investigator prior to ordering medication ○ Non-medical criteria <ul style="list-style-type: none"> ▪ Capable of taking a follow-up phone call

Table 1: Eligibility criteria for bamlanivimab infusion.

Data Collection

Patients' demographic and clinical characteristics, including age, sex, ethnicity, type of underlying malignancy, oncological therapy status, associated

comorbidities, and presenting signs and symptoms, were obtained from the patient's electronic health records. Adverse events to bamlanivimab infusion were ascertained by direct observation during the infusion and by follow up

calls to the patients 3 days - 5 days later. All patient-level data were aggregated in the Syntropy platform, Palantir Foundry, as part of the Data-Driven Determinants of COVID-19 Oncology Discovery Effort protocol at MD Anderson. The laboratory tests and vital signs we analyzed were those recorded upon patients' arrival to the ACCC. Patients were followed for 1 month from the time of their presentation to the ACCC.

Statistical Analysis

Patient characteristics and outcomes (hospital admissions related to COVID-19, oxygen desaturation, requirement for supplemental oxygen, intensive care unit [ICU] admission, and 30 days mortality) were compared between COVID-19 patients who received bamlanivimab and those who did not. Categorical variables were compared using chi-square or Fisher's exact test as appropriate, and continuous variables were compared using Wilcoxon rank-sum test. Logistic regression analysis was used to identify independent predictors (risk factors and protectors) of each outcome, except mortality, and to evaluate the independent impact of bamlanivimab treatment on those outcomes. Multivariable analysis for mortality was not performed due to only 2 patient deaths. All statistical tests were two-sided with a significance level of 0.05. The analyses were performed using SAS version 9.3 (SAS Institute Inc., Cary, NC).

RESULTS

Patient Characteristics

Of the 108 patients (54 bamlanivimab, 54 controls) shown in Table 2, most were male (67% and 52% in the bamlanivimab and control groups, respectively). In both groups, 33% were ≥ 65 years of age, and 59% had hematologic malignancies. The most common presenting symptoms in both groups were fever, dyspnea, and cough. Hypertension, diabetes mellitus, and chronic kidney disease were among the most common comorbidities in both groups; however, patients in the bamlanivimab group

were less likely to be obese and had fewer comorbidities (chronic obstructive pulmonary disease, congestive heart failure, and coronary artery disease).

Patients who received bamlanivimab were more likely to be undergoing active therapy for their underlying malignancy (74% vs. 56%; $P = 0.044$) but less likely to be admitted to the hospital (24% vs. 91%; $P < 0.0001$), experience oxygen desaturation $< 94\%$ during follow-up (11% vs. 44%; $P = 0.0001$), require oxygen supplementation (7% vs. 44%; $P < 0.0001$), or be admitted to the ICU (4% vs. 15%; $P = 0.046$).

Mortality

Overall, there were only 2 deaths (both controls) within 30 days of presentation, with no significant difference between cohorts ($P = 0.50$). The two patients who died after being made DNR were both older than 75 years and died from acute hypoxemic respiratory failure and multiple organ failure, potentially associated with COVID-19.

Risk Factors and Protectors of Severe Disease; Effects of Bamlanivimab Therapy

The independent impact of bamlanivimab treatment on each outcome of interest as evaluated by multivariable logistic regression analysis is shown in Table 3. We identified two independent predictors associated with COVID-19 related hospitalization: 1) Diabetes mellitus as a risk factor (odds ratio [OR] = 3.33, $P = 0.037$) and 2) Bamlanivimab treatment as a protector (OR = 0.027, $P < 0.0001$); thus, bamlanivimab treatment reduced the odds of hospitalization for COVID-19 by as much as 97%. Bamlanivimab treatment was also independently associated with a reduced risk of requiring supplemental oxygen by 94% (OR = 0.06, $P < 0.0001$), whereas dyspnea (OR = 8.91, $P < 0.001$) and an absolute lymphocyte count ≤ 0.5 K/ μ L at baseline (OR = 3.29, $P = 0.039$) were independent risk factors for requiring supplemental oxygen. Similarly, bamlanivimab therapy was an

independent protector against oxygen desaturation <94% (OR = 0.11, P = 0.0001), such that bamlanivimab treatment reduced the odds of oxygen desaturation by 89%, whereas dyspnea was an independent risk factor for oxygen desaturation <94% (OR = 7.18, P <.001). Congestive heart failure (OR = 9.36, P = 0.02) and an absolute lymphocyte

count ≤ 0.5 K/ μ L (OR = 10.09, P = 0.007) were the independent predictors of ICU admission we identified by multivariable logistic regression analysis. After adjusting for them, bamlanivimab treatment showed no significant impact on ICU admission in the analysis (P = 0.23).

Variable	BAM	Control	P-value
	(N = 54)	(N = 54)	
Age (Years), Median (Range)	61 (17-85)	58 (21-84)	0.84
Age ≥ 65	18 (33)	18 (33)	>.99
Sex, Male	36 (67)	28 (52)	0.12
Race			0.001
Asian	2/53 (4)	1 (2)	
Black	2/53 (4)	15 (28)	
Hispanic	13/53 (25)	16 (30)	
White	36/53 (68)	22 (41)	
Unknown	1		
Type of Cancer			>.99
Haematological Malignancy	32 (59)	32 (59)	
Solid Tumor	22 (41)	22 (41)	
Active Therapy within 30 Days	40 (74)	30 (56)	0.044
Comorbidities			
Smoker			0.1
Former	14 (26)	22 (41)	
No	40 (74)	32 (59)	
Chronic Kidney Disease	13 (24)	21 (39)	0.1
Asthma	5 (9)	5 (9)	>.99
COPD	2 (4)	13 (24)	0.002
Congestive Heart Failure	2 (4)	10 (19)	0.014
Diabetes Mellitus	21 (39)	22 (41)	0.84
Coronary Artery Disease	0 (0)	10 (19)	0.001
Hypertension	33 (61)	39 (72)	0.22
Venous Thromboembolism	8 (15)	12 (22)	0.32
Obesity	7 (13)	28 (52)	<.0001
Symptoms at the Time of Infusion			
Obstructive Sleep Apnea	5 (9)	9 (17)	0.25
GI Symptom	11 (20)	14 (26)	0.49
Ageusia	3 (6)	4 (7)	>.99
Anosmia	4 (7)	4 (7)	>.99
Fever	31 (57)	34 (63)	0.56
Dyspnea	25 (46)	21 (39)	0.44
Cough	41 (76)	36 (67)	0.29
Duration of COVID Positivity	1 (0-9)	0 (0-6)	<.0001
(Days), Median (Range)			
WBC (K/ μ L), Median (Range)	4.2 (1.0-24.7)	4.8 (1.6-16.4)	0.44
ANC (K/ μ L), Median (Range)	2.54 (0.61-15.57)	2.95 (0.91-10.94)	0.2
ALC (K/ μ L), Median (Range)	0.92 (0.08-17.29)	0.64 (0.13-2.75)	0.32
ALC ≤ 0.5 K/mL	14 (26)	20 (37)	0.21
Hospitalization for COVID-19	13 (24)	49 (91)	<0.0001
O ₂ Saturation <94%	6 (11%)	24 (44%)	0.0001
O ₂ Supplement	4 (7%)	24 (44%)	<0.0001
ICU Admission	2 (4)	8 (15)	0.046
Death within 30 days of Discharge	0 (0)	2 (4)	0.5

Table 2: Characteristics of the bamlanivimab and control groups. Data are presented as no. (%) unless otherwise indicated.

Abbreviations: N: Number; COPD: Chronic Obstructive Pulmonary Disease; GI: Gastrointestinal; WBC: White Blood Cell Count; ANC: Absolute Neutrophil Count; ALC: Absolute Lymphocyte Count; O₂: Oxygen; ICU: Intensive care unit.

Outcome	Independent Predictor	OR	95% CI	p-value
Hospitalization for COVID-19				
	Diabetes Mellitus	3.33	1.08 to 10.32	0.037
	Bamlanivimab	0.027	0.008 to 0.088	<.0001
Oxygen supplement requirement				
	Dyspnea at baseline	8.91	2.71 to 29.33	<.001
	ALC \leq 0.5 K/ μ L	3.29	1.06 to 10.18	0.039
	Bamlanivimab	0.06	0.02 to 0.23	<.0001
Oxygen saturation <94%				
	Dyspnea at baseline	7.18	2.41 to 21.38	<.001
	ALC \leq 1.0 K/ μ L	2.76	0.91 to 8.34	0.072*
	Bamlanivimab	0.11	0.03 to 0.33	0.0001
ICU admission				
	Congestive heart failure	9.36	1.42 to 61.8	0.02
	ALC \leq 0.5 K/ μ L	10.09	1.88 to 54.23	0.007

Table 3: Independent predictors of each outcome by multivariable logistic regression analysis.

Abbreviations: OR: Odds Ratio; 95% CI: 95% Confidence interval; ALC: Absolute Lymphocyte Count; ICU: Intensive Care Unit

Note* In order to maintain a good model fit, ALC was forced to be included in the final model despite its non-statistical significance.

Adverse Events

Bamlanivimab was well tolerated. Only two adverse events related to the infusion were reported during the 54 infusions and on a follow up call: 1 patient had fever and chills occurring 1 hour after infusion, and a second patient developed a rash 3 days after infusion.

DISCUSSION

To our knowledge, our study is the first to investigate the performance of bamlanivimab in cancer patients specifically, a population whose immunosuppression and general frailty may limit the efficacy of treatments and vaccines, making it particularly vulnerable to the effects of COVID-19 infection. We showed that bamlanivimab was effective in preventing hospitalization (by 97%) and oxygen requirement (by 94%) compared to a matched cohort of cancer patients who were treated prior to the availability of monoclonal antibody therapy. Although there was no association with reduced ICU admissions after adjusted analysis, by virtue of its reducing the risks of hospitalization and oxygen desaturation, bamlanivimab does effectively alter the progression to severe disease. The reduction in hospitalization and progression to severe COVID-19 disease in cancer patient was similar to that

found in the general population or those with well-established risk factors for severe disease such as obesity, diabetes and hypertension [13-18]. In an observational propensity-matched cohort study over the same chronological period as ours, patients receiving bamlanivimab had 60% lower risk-adjusted odds of hospitalization or mortality but were not matched for cancer or its treatment [18].

Bamlanivimab was the first monoclonal antibody to receive emergency authorization for the treatment of high-risk patients with COVID-19 in the ambulatory setting. The use of monoclonal antibodies has since been expanded to hospitalized patients, and a recent trial showed promising results for monoclonal antibody therapy as post-exposure prophylaxis [11,19,20]. Unfortunately, as its indications have widened, bamlanivimab's efficacy has been limited by the emergence of virulent new SARS-CoV-2 variants such as delta. On April 16, 2021, its emergency use authorization as monotherapy was revoked, and single bamlanivimab has since been eliminated as a treatment option owing to the resistance of the beta and gamma variants [21]. Nevertheless, investigations into bamlanivimab's efficacy and safety are essential as limited clinical data are available on monoclonal antibody therapy

in cancer patients and because it can be used in combination with other drugs. In September 2021 emergency use authorization was reinstated for bamlanivimab when administered together with etesevimab [10,22]. As the first available monoclonal antibody there is a larger body of data on the efficacy of bamlanivimab, and it can model the potential uses of this therapeutic class in COVID-19.

A recent study from the Mayo Clinic that included cancer patients with COVID-19 directly compared bamlanivimab therapy to usual care. This study showed that patients who received bamlanivimab had lower rates of all-cause hospitalization, ICU admission, and all-cause mortality at 14 days [16]. Although the study included cancer patients (15.4% with localized disease and 3% with metastatic disease), these patients' outcomes were not reported separately. Our study validates the Mayo Clinic study's findings, showing a strong association between bamlanivimab treatment and reduced rates of hospitalization, oxygen desaturation, and the need for oxygen supplementation. The 30 day hospitalization rate of our bamlanivimab-treated cancer patients (24%) was much higher than the 28 day hospitalization rate reported in the Mayo study (2.5%), even though we investigated only COVID-19 related hospitalization, whereas the Mayo study investigated all-cause hospitalization. Likewise, our bamlanivimab-treated cancer patients had a higher rate of ICU admission (4% vs. 0.56%). However, both studies reported extremely small rates of all-cause 30 day mortality (2 out of 1789 treated patients for the Mayo study and none in our group), which reflects the efficacy of bamlanivimab in preventing severe disease [16]. Rather than stemming from a decreased efficacy of bamlanivimab, the higher hospitalization and ICU admission rate of our bamlanivimab-treated cancer patients may have been due to institutional practice, and/or the sicker patient population found in a tertiary cancer hospital. Moreover, 74% of our patients were on active cancer therapy when

they received bamlanivimab, which may have dampened their response to the infection until obtaining passive immunity from the monoclonal antibody infusion [23].

Several studies have shown that cancer patients have a high risk of contracting COVID-19 and dying from the complications of severe disease, but direct comparisons of cancer and non-cancer patients are limited [1-3,24-26]. One observational study conducted at our institution early in the pandemic showed that admitted cancer patients with COVID-19 had discharge rates similar to those reported in the literature for non-cancer patients [27]. However, another early review of more than 1000 patients from a multi-national cancer consortium showed that cancer patients with COVID-19 had a high rate of severe clinical events such as ICU admission, invasive ventilation, and death. The review also showed that, in addition to the comorbidities known to increase the risk for severe COVID, progressive malignancy, poor Eastern Cooperative Oncology Group performance status, and active therapy also increased the odds of 30-day mortality [28]. A cohort study conducted at another tertiary cancer hospital similar to ours showed that hematologic malignancy, lung cancer and lymphopenia increased adverse outcomes (defined as hypoxemia, invasive ventilation and all-cause mortality) but the administration of chemotherapy within the past 35 days did not [4]. Finally, a recent meta-analysis of multiple cohort studies showed that cancer patients with COVID-19 have a composite mortality risk of 14.1%, which is five times higher than that of the general population [29]. Severe disease requiring intensive care or invasive ventilation was also increased in patients with cancer compared to those without by a hazard ratio of 3.5 in some of the initial reports from China [30]. Given these data, it is not surprising that the cancer patients in our study had a higher rate of hospitalization and ICU admission after receiving bamlanivimab than the broader population in the Mayo

Clinic study, even though that study also included cancer patients and used similar eligibility criteria.

Among the comorbidities we reviewed (congestive heart failure, coronary artery disease, chronic obstructive pulmonary disease, diabetes, lymphocytopenia, and obesity), only diabetes was an independent risk factor for hospitalization, whereas congestive heart failure and lymphocytopenia were risk factors for ICU admission. Both the bamlanivimab and control groups had such low mortality rates that a comparison was not statistically feasible. Larger studies are likely needed to detect salient differences that could confidently prognosticate admission among patients treated with monoclonal antibodies. As in previous studies [2,4], our patients tended to be Caucasian, hypertensive, and diabetic, but fewer had established risk factors for severe COVID-19, such as obesity, chronic kidney disease, coronary artery disease, and chronic respiratory disease, likely reflecting the unique characteristics of our cancer population.

Our study had several limitations. First, it had the limitations inherent to a retrospective chart review. Second, its relatively small sample size and single-center setting limit the generalizability of its results. Likewise, data was drawn from a specific time period and may not be applicable in the future as the virus evolves and develops resistance. Finally, although we assessed outcomes at our institution 30 days after patients presented with confirmed COVID-19, we were unable to determine whether patients sought subsequent care elsewhere; thus, the study may

have underestimated the rates of hospitalization and death following bamlanivimab administration. However, we believe this cohort highlights a population necessitating study due its unique vulnerability to severe COVID-19 disease and potential for limited response to therapies. Continued investigation of the efficacy of monoclonal antibodies to emerging variants in cancer patients is necessary.

CONCLUSION

Diabetes, congestive heart failure, active cancer treatment and lymphocytopenia were identified as risk factors for moderate to severe COVID-19. Bamlanivimab was well tolerated in cancer patients and prevented progression to severe COVID-19, reducing the risks of hospitalization and respiratory compromise by nearly 100% and 90%, respectively.

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CONFLICT OF INTEREST

None.

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