


BRIEF REPORT**Clinical outcomes of monoclonal antibody therapy during a COVID-19 outbreak in a skilled nursing facility—Arizona, 2021**

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Abstract

Background: Adult residents of skilled nursing facilities (SNF) have experienced high morbidity and mortality from SARS-CoV-2 infection and are at increased risk for severe COVID-19 disease. Use of monoclonal antibody (mAb) treatment improves clinical outcomes among high-risk outpatients with mild-to-moderate COVID-19, but information on mAb effectiveness in SNF residents with COVID-19 is limited. We assessed outcomes in SNF residents with mild-to-moderate COVID-19 associated with an outbreak in Arizona during January–February 2021 that did and did not receive a mAb.

Methods: Medical records were reviewed to describe the effect of bamlanivimab therapy on COVID-19 mortality. Secondary outcomes included referral to an acute care setting and escalation of medical therapies at the SNF (e.g., new oxygen requirements). Residents treated with bamlanivimab were compared to residents who were eligible for treatment under the FDA's Emergency Use Authorization (EUA) but were not treated. Multivariable logistic regression was used to determine association between outcomes and treatment status.

Results: Seventy-five residents identified with COVID-19 during this outbreak met eligibility for mAb treatment, of whom 56 received bamlanivimab. Treated and untreated groups were similar in age and comorbidities associated with increased risk of severe COVID-19 disease. Treatment with bamlanivimab was associated with reduced 21-day mortality (adjusted OR = 0.06; 95% CI: 0.01, 0.39) and lower odds of initiating oxygen therapy (adjusted OR = 0.07; 95% CI:

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0.02, 0.34). Referrals to acute care were not significantly different between treated and untreated residents.

Conclusions: mAb therapy was successfully administered to SNF residents with COVID-19 in a large outbreak setting. Treatment with bamlanivimab reduced 21-day mortality and reduced initiation of oxygen therapy. As the COVID-19 pandemic evolves and newer immunotherapies gain FDA authorization, more studies of the effectiveness of mAb therapies for treating emerging SARS-CoV-2 variants of concern in high-risk congregate settings are needed.

KEYWORDS

COVID-19, monoclonal antibody therapy, outbreak, skilled nursing facilities

INTRODUCTION

The ongoing coronavirus 19 (COVID-19) pandemic has resulted in unprecedented morbidity and mortality worldwide, with a disproportionate number of illnesses and deaths occurring among residents of skilled nursing and long term care facilities (LTCFs).¹⁻³ Since November 2020, the Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for multiple monoclonal antibody (mAb) therapies for the treatment of mild-to-moderate COVID-19 in non-hospitalized persons at high risk of severe disease.⁴ Limited data from clinical trials and real-world effectiveness studies suggest that use of mAbs reduces emergency department visits and hospitalization rates among those treated.⁵ However, mAb use has largely been reported in outpatient, non-congregate settings; and the effectiveness and feasibility of mAb therapies among older and medically vulnerable populations during COVID-19 outbreaks in LTCFs is limited.⁶ We describe the use of the mAb bamlanivimab for treatment of mild-to-moderate COVID-19 during an outbreak in residents of a large SNF in Arizona from January to February 2021.

METHODS

Setting and case identification

Facility A is a skilled nursing facility (SNF) licensed for 270 beds with approximately 282 employees. On January 14, the SNF performed facility-wide SARS-CoV-2 antigen testing after a symptomatic staff member tested positive for SARS-CoV-2 infection. The facility then implemented twice weekly SARS-CoV-2 testing of all staff and once weekly testing of all residents via antigen test and/or reverse transcription-polymerase chain reaction (RT-PCR). Residents identified as close contacts of SARS-

Key points

- Receipt of monoclonal antibody therapy significantly reduced odds of mortality and need for supplemental oxygen in skilled nursing facility residents with mild-to-moderate COVID-19.
- Use of monoclonal antibody therapy in skilled nursing facilities requires close partnership with local health departments and healthcare entities.

Why does this paper matter?

This paper describes the use of monoclonal antibody therapy in the setting of a COVID-19 outbreak at a skilled nursing facility. Additionally, this paper reaffirms that use of monoclonal antibody therapies in persons with mild-to-moderate COVID-19 prevents severe outcomes such as death.

CoV-2 cases had antigen testing performed daily, and any residents demonstrating symptoms of COVID-19 were likewise tested immediately and subsequently as clinical presentation warranted. For this investigation, an outbreak case was defined as SARS-CoV-2 detection in a resident of Facility A between January 1, 2021 (within a week of the index COVID-19 case's onset) and February 9, 2021 (the last day on which a case was identified).

Bamlanivimab administration

Bamlanivimab was offered to any resident with mild-to-moderate COVID-19 illness who was within 10 days of symptom onset and deemed by facility providers as being

at high risk for severe disease per FDA's EUA at the time of the study for bamlanivimab.⁴ Residents were ineligible for bamlanivimab therapy if they met any EUA criteria for severe COVID-19 at the time of treatment consideration: hospitalization due to COVID-19, new oxygen therapy requirement due to COVID-19, or an increase in baseline oxygen requirement due to COVID-19. Facility A and the local health department administered bamlanivimab to residents within 72 hours of positive SARS-CoV-2 test, which is previously described.⁶

Study design

We investigated the impact of bamlanivimab therapy on clinical outcomes in residents with SARS-CoV-2 at Facility A. We compared characteristics of residents who received mAb treatment versus untreated residents among those eligible for mAb treatment. Medical records were reviewed for residents with laboratory-confirmed COVID-19 to collect demographic information, pre-existing comorbidities, eligibility to receive bamlanivimab, testing and SARS-CoV-2 vaccination data, and clinical course.⁷ In those receiving bamlanivimab, information on potential side effects or adverse reactions was also collected. All medical records were also reviewed at 21 days following initial COVID-19 diagnosis to allow for more complete clinical outcome information. This activity was reviewed by CDC and was conducted consistent with

applicable federal law and CDC policy, see for example, 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.

Outcomes of interest among eligible persons

The primary outcome of interest was all-cause mortality within 21-days of a positive SARS-CoV-2 test. Secondary outcomes of interest included other clinical outcomes suggestive of escalated disease severity such as initiation of new oxygen therapy, increase in baseline oxygen requirement, referral to an acute care setting (defined as referral to an emergency department visit or hospital admission), clinically or radiographically diagnosed pneumonia, initiation of intravenous fluids within the facility, and treatment with a COVID-19-directed course of systemic corticosteroids within the facility.

Analysis and statistical methods

Resident data were abstracted from medical records in the electronic health record (EHR) system (MatrixCare, ResMed, San Diego, CA). Data were collected and managed in the Research Electronic Data Capture (REDCap) system hosted by CDC, without personal identifying information.^{8,9} Statistical analyses were conducted using SAS

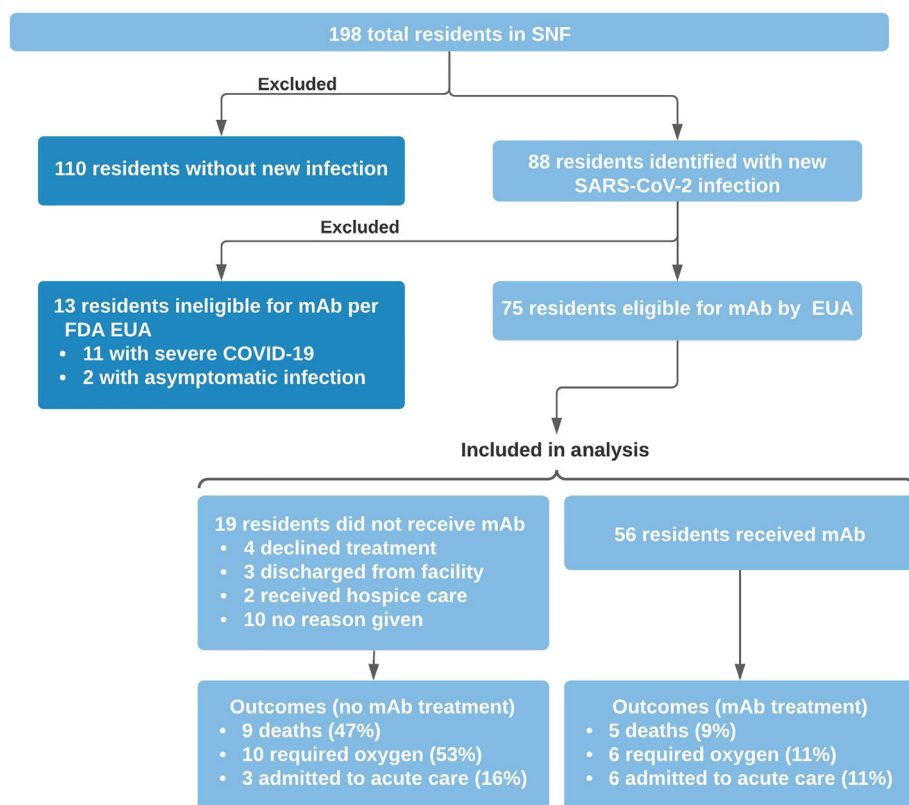


FIGURE 1 Flow diagram of inclusion and exclusion residents of a skilled nursing facility during a SARS-CoV-2 outbreak in an analysis of outcomes following receipt of monoclonal antibody treatment—Arizona, January–February 2021. FDA-EUA, United States Food and Drug Administration emergency use authorization; mAb, monoclonal antibodies; SNF, skilled nursing facility

TABLE 1 Demographics of SARS-CoV-2 positive residents of skilled nursing facility by receipt of bamlanivimab therapy—Arizona, January–February 2021

	Received bamlanivimab (n = 56) N (%) or median (IQR)	Did not receive bamlanivimab (n = 19) N (%) or median (IQR)	p value
Age	73.5 (54–95)	76 (37–98)	0.48 ^a
Sex			
Female	36 (64.3%)	6 (31.6%)	0.01
Male	20 (35.7%)	13 (68.4%)	
Race			0.94 ^b
White (reference)	42 (75.0%)	15 (78.9%)	
Black or African American	2 (3.6%)	0	
Asian, Native Hawaiian, or Pacific Islander	0	0	
American Indian or Native American	3 (5.4%)	0	
Unknown race	11 (19.6%)	4 (21.1%)	
Ethnicity			0.66
Hispanic or Latino	12 (21.4%)	5 (26.3%)	
Non-Hispanic or Latino	44 (78.6%)	14 (73.7%)	
Test type (positive result)			0.45
PCR	20 (35.7%)	5 (26.3%)	
Antigen (BinaxNOW)	36 (64.3%)	14 (73.7%)	
Pre-existing conditions			
Obesity	18 (32.1%)	3 (15.8%)	0.24 ^b
Diabetes	31 (55.4%)	9 (47.4%)	0.55
Chronic kidney disease	19 (33.9%)	4 (21.1%)	0.39 ^b
End stage renal disease	1 (1.8%)	0	1.0 ^b
Cancer (not in remission)	3 (5.4%)	2 (10.5%)	0.60 ^b
Autoimmune conditions	7 (12.5%)	1 (5.3%)	0.67 ^b
Cardiovascular disease	30 (53.6%)	10 (52.6%)	0.94
Hypertension	43 (76.8%)	14 (73.7%)	0.78
COPD	10 (17.9%)	6 (31.6%)	0.21
Total number of chronic conditions	3 (0–7)	2 (1–5)	–
Pre-existing neurological conditions			
Dementia/Alzheimer’s	25 (44.6%)	10 (52.6%)	0.55
History of stroke	7 (12.5%)	2 (10.5%)	1.0 ^b
Traumatic brain injury	2 (3.6%)	1 (5.3%)	1.0 ^b
Epilepsy	3 (5.4%)	2 (10.5%)	0.60 ^b
Chronic Encephalopathy	2 (3.6%)	0	1.0 ^b
Any neurological conditions	43 (76.8%)	14 (73.7%)	0.78
Chronic medications			
Systemic steroids	3 (5.4%)	0	0.57 ^b
Antibiotics	3 (5.4%)	1 (5.3%)	1.0 ^b
Inhaled medications	9 (16.1%)	3 (15.8%)	1.0 ^b
Other immunosuppressing medications	2 (3.6%)	0	1.0 ^b
None of the medications of interest	41 (73.2%)	16 (84.2%)	0.33

(Continues)

TABLE 1 (Continued)

	Received bamlanivimab (<i>n</i> = 56)		Did not receive bamlanivimab (<i>n</i> = 19)		<i>p</i> value
	<i>N</i> (%) or median (IQR)		<i>N</i> (%) or median (IQR)		
Partial completion of COVID-19 vaccine series ^c	22 (39.2%)		7 (36.8%)		0.31
Time to	<i>N</i>	Median days (range)	<i>N</i>	Median days (range)	<i>p</i> value
Symptom resolution	43	10 (0–22)	7	7 (3–25)	0.30 ^a
Length of stay (hospitalization)	2	4.5 (3–6)	1	12	N/A
Bamlanivimab administration from test positive	56	1 (0–3)	0	–	–
Bamlanivimab administration from symptom onset	50	2 (–3 to 7)	0	–	–

Notes: N/A cannot be calculated due too few of observations.

^aTwo sample *t*-testing used to quantify significance.

^bFischer's exact test used to quantify significance. Unless otherwise indicated, comparisons via chi-square testing were performed.

^cHave received at least one dose of COVID-19 mRNA vaccine greater than or equal to 14 days before testing positive for SARS-CoV-2.

9.4 software (SAS Institute, Cary, NC). Eligible resident characteristics were compared using chi-square, two sample, or Fischer's exact tests. Logistic regression was used for univariate and multivariable analysis to assess three outcomes of interest: all-cause 21-day mortality, initiation of new oxygen therapy, and referral to an acute care setting. Multivariable analyses included the following variables that have been previously associated with poorer outcomes from COVID-19: age, African American or Black race, male sex, Hispanic ethnicity, the presence of any neurological conditions of interest including dementia or Alzheimer's, and total number of chronic, high-risk medical conditions.⁵ Total number of chronic conditions was a sum of the following variables for a range of zero to seven: obesity (BMI >30 kg/m²), diabetes, chronic kidney disease, end stage renal disease, cancer (not in remission), autoimmune conditions, cardiovascular disease, hypertension, and chronic obstructive pulmonary disease.^{5,10–12} Hosmer–Lemeshow tests were used to assess goodness of fit for each model.¹³

RESULTS

Among 198 residents, 89 residents were identified to have SARS-CoV-2 infection during the outbreak; six residents were hospitalized and 18 died. A decision tree regarding inclusion of 89 in this study is described by Figure 1. One resident tested positive within 90 days of a previous COVID-19 infection and was excluded from this analysis. Among 88 residents with identified SARS-CoV-2 infection, median age was 73.5 years (range: 37–98 years) (Table 1). A total of 75 residents were ultimately included for analysis in this study (Figure 1), of whom 56 received bamlanivimab (Table 1).

Residents who did not receive bamlanivimab tended to be male (68% vs. 36%, *p* = 0.01); treated and untreated

residents were otherwise similar in age, pre-existing comorbidities, and neurologic comorbidities associated with adverse outcomes from COVID-19 (Table 1). Time from positive SARS-CoV-2 test to bamlanivimab treatment was a median of 1 day (range: 0–3 days), and persons who received treatment had a longer median duration of symptoms (7 days vs. 10 days). Additionally, 27 (22 received mAb, 5 did not) tested positive for SARS-CoV-2 greater than 14 days after receiving their first dose of COVID-19 vaccine. No residents were considered fully vaccinated by the time of test positive. While fever, shortness of breath, cough, and fatigue were the most common signs and symptoms in both groups, bamlanivimab recipients were significantly less likely to have reported respiratory symptoms of cough and shortness of breath (41% vs. 68%, *p* = 0.04; 23% vs. 53%, *p* = 0.02, respectively). Bamlanivimab treatments were well tolerated, with one episode of nausea reported and no serious adverse events.

Clinical outcomes of all residents were assessed; 14 residents died within 21-days of SARS-CoV-2 positive test (5 treated, 9 untreated), 16 required new oxygen therapy (6 treated, 10 untreated), and 9 required either an emergency department visit or hospitalization (6 treated, 3 untreated). In univariate analysis, treatment with bamlanivimab significantly reduced the odds of death within 21 days of a SARS-CoV-2 positive test result (OR = 0.11; 95% CI: 0.03, 0.39). Monoclonal antibody therapy also significantly reduced the odds of requiring new oxygen therapy (OR = 0.11; 95% CI: 0.03, 0.37) during COVID-19 illness. No significant differences were seen in odds of referral to an acute care setting (OR = 0.64; 95% CI: 0.14, 2.86) or other secondary clinical outcomes.

On multivariable analysis, treatment with bamlanivimab was associated with a 94% reduction in odds of death relative to the non-treatment group (OR = 0.06; 95% CI: 0.01, 0.39; Table 2). Adjustment for “African American

TABLE 2 Multivariable predictors for death in skilled nursing facility residents—Arizona, January–February 2021

Outcome: 21-Day mortality ($\chi^2 = 12.5, p = 0.09$)				
Risk factor	β	p value	OR	95% CI
mAb therapy	-2.82	<0.01	0.06	(0.01, 0.39)
Age	0.10	<0.01	1.10	(1.03, 1.19)
Sex (male)	-0.01	0.98	0.98	(0.19, 5.15)
Hispanic ethnicity	1.69	0.05	5.40	(1.02, 28.5)
Total number of chronic conditions	0.34	0.31	1.40	(0.73, 2.71)
Any neurological conditions	0.70	0.46	2.02	(0.31, 13.1)
Intercept	-9.31	<0.01	-	-
Outcome: Oxygen therapy initiation ($\chi^2 = 7.93, p = 0.34$)				
Risk factor	β	p value	OR	95% CI
mAb therapy	-2.63	<0.01	0.07	(0.02, 0.34)
Age	0.04	0.20	1.04	(0.98, 1.10)
Sex (male)	-0.06	0.88	0.89	(0.22, 3.77)
Hispanic ethnicity	1.18	0.11	3.26	(0.76, 14.03)
Total number of chronic conditions	0.42	0.14	1.51	(0.87, 2.62)
Any neurological conditions	1.08	0.23	2.94	(0.51, 16.9)
Intercept	-4.83	0.07	-	-
Outcome: Emergency department visit or hospital admission ($\chi^2 = 12.6, p = 0.08$)				
Risk factor	β	p value	OR	95% CI
mAb therapy	-0.88	0.33	0.42	(0.07, 2.40)
Age	-0.05	0.14	0.95	(0.89, 1.02)
Sex (male)	-0.49	0.27	0.38	(0.07, 2.18)
Hispanic ethnicity	0.13	0.90	1.14	(0.17, 7.81)
Total number of chronic conditions	0.49	0.09	1.64	(0.92, 2.90)
Any neurological conditions	1.08	0.31	2.95	(0.37, 23.6)
Intercept	-0.72	0.80	-	-

or Black Race” was not included in modeling due to only two persons identifying as African American or Black and both receiving mAb therapy. Receiving bamlanivimab was associated with a 93% reduction in requiring new supplemental oxygen over the course of illness (OR = 0.07; 95% CI: 0.02, 0.34 $p < 0.01$; Table 2). Treatment with bamlanivimab was not associated with meaningful reductions in the odds of referral for evaluation to an acute care setting (OR = 0.42; 95% CI: 0.07, 2.40; Table 2). Addition of partial vaccination status ($n = 27$) did not change models significantly. All models met goodness-of-fit assumptions using a Hosmer-Lemeshow statistic.

DISCUSSION

In this analysis, we describe the use of bamlanivimab during a large SARS-CoV-2 outbreak in a 270-bed SNF in

Arizona and examine the associations of such use in the long-term care facility setting. Treatment of mild-to-moderate COVID-19 with bamlanivimab was well-tolerated and associated with a significantly lower odds of all-cause 21-day mortality compared to not receiving treatment, an association reported previously among adults outside of congregate settings.¹⁴ Bamlanivimab was also associated with a reduction in lower respiratory symptoms and oxygen requirement during COVID-19 illness. Although we did not find reductions in acute care admissions among those treated with monoclonal antibodies as has been reported by other effectiveness studies,^{14,15} this finding may be secondary to the small sample size of the study population and low numbers of hospitalization overall. Taken together with previous reports,¹⁶ these findings support the continued use of monoclonal antibody therapies in long-term care facilities and in persons at higher risk for severe COVID-19.

This study is subject to several limitations. First, the retrospective, observational design and the small size of the population studied may result in certain biases of the data analyzed. Residents with goals of care that minimize medical intervention (due to advanced age or underlying comorbidities) may have been less likely to be considered for bamlanivimab therapy by healthcare personnel. Further, the prevalence of comorbidities did not differ among treatments groups, nor did the scope of advanced directives (e.g., do not resuscitate orders or not) among the residents with COVID-19, and multivariable models were used to adjust for the number of high-risk medical and neurological comorbidities known to be associated with severe COVID-19. However, goals of care, including hospice status, and changes in goals of care that occurred after COVID-19 diagnosis were also often not documented in detail in the EHR, and such changes may have impacted the decision to obtain acute care evaluation or other medical interventions, particularly among those not treated with bamlanivimab. An additional limitation is that the data relied heavily on chart abstraction; available documentation in the EHR could have been limited due to the overwhelming nature of COVID-19 outbreak response on SNF staff.

The current study should also be interpreted in the context of the changing landscape of COVID-19 immunotherapies as new SARS-CoV-2 variants emerge. For example, bamlanivimab monotherapy demonstrates greatly reduced in vitro neutralizing activity against the B.1.351 (Beta), P.1 (Gamma), and B.1.617.2 (Delta) variants of concern.^{17,18} While available sequencing data ($n = 2$) obtained from residents within this outbreak did not detect infection with these variants, the lack of sequencing information on remaining cases is a potential limitation to results of this investigation. However, these variants of concern were not widely circulating at the time of this outbreak in Arizona according to available sequencing data.¹⁹ Due to sustained increases in such resistant variants of concern, the FDA revoked the EUA for bamlanivimab monotherapy on April 16, 2021²⁰ and, on June 25, 2021 paused distribution of combination bamlanivimab/estevimab for the treatment of COVID-19.²¹ After prophylactic use of bamlanivimab was found to reduce the incidence of COVID-19 in those with high-risk exposures, including among skilled nursing facility residents, the FDA authorized bamlanivimab/estevimab for post-exposure prophylaxis for COVID-19 for adults and pediatrics patients on September 16, 2021.^{22,23} Other monoclonal antibody therapies have also been made available under FDA EUA for prophylaxis and treatment of COVID-19 in non-hospitalized priority populations.²¹ Monoclonal antibody therapies remain relevant even as SARS-CoV-2 vaccination coverage increases, as breakthrough SARS-CoV-2 infections are expected to occur.

While the feasibility of administering mAb therapies in SNFs via the use of a specialized mobile infusion unit has been recently described, this report describes successful early implementation and use of facility-administered mAb in a large cohort of SNF residents during a large COVID-19 outbreak.²² Treatment with bamlanivimab reduced 21-day mortality and the clinical respiratory burden of COVID-19. Given the potential for reduced mortality and morbidity in residential settings, logistical considerations for administering mAb on site warrant public health consideration.

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CONFLICT OF INTEREST

All authors report no actual or potential conflicts of interest upon consideration of the following categories: employment or affiliation, grants or funding, honoraria, speaker forum membership, consultant, stock ownership or options, royalties, expert testimony, advisory board, patents (pending, filed, or received), family or personal relationships.

AUTHOR CONTRIBUTIONS

All authors contributed to conception of this manuscript, and from that start point, shared in writing and revision process.

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