Control of inflammatory markers and cytokines following infliximab therapy

Values from individuals are connected with solid lines, with deceased individuals indicated in red. Statistics: n=18, paired ratio t-test compared to baseline; *: P<0.05, **: P<0.01, ***: P<0.001, ****: P<0.0001, n.s.: not significant.

Conclusion. Consistent with a central role of TNFα, the clinical and cytokine data indicate that infliximab-abda may rapidly abrogate pathological inflammatory signaling to facilitate clinical recovery in severe and critical COVID-19. Randomized studies are formally evaluating infliximab therapy in this context. Funding: National Center for Advancing Translational Sciences.

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500. A Real-World Cohort Study of Bamlanivimab Versus Bamlanivimab-Etesevimab for Non-severe COVID-19
Lea Monday, PharmD, MD¹; George J. Alangaden, MD²; Indira Brar, MD²; Ramesh Mayur, MD²; ¹Henry Ford Health System, Detroit, Michigan; ²Henry Ford Hospital, Detroit, Michigan

Session: P-24. COVID-19 Treatment

Background. Anti-spike monoclonal antibodies (mAb) including Bamlanivimab (BAM) and Bamlanivimab-Etesevimab (BAM/E) have shown reduced hospitalization rates for non-severe coronavirus disease 2019 (COVID-19) in clinical trials. Recent studies provided real-world hospitalization rates for BAM. But, similar data on those who received BAM/E are lacking. In spring 2021, Michigan experienced a surge of COVID-19 with more cases per capita than any other state. We sought to quantify the impact of BAM monotherapy versus BAM/E combination on hospitalization and mortality among a real-world high-risk cohort of outpatients with COVID-19.

Methods. This retrospective cohort study evaluated outpatients ≥18 years with laboratory-confirmed mild/moderate COVID-19 who received mAb in a Detroit health system based on emergency use authorization criteria. Inclusion began on December 3rd 2020 with BAM monotherapy, changed to BAM/E combination on March 27, 2021, and included patients until April 19th 2021 (Figure 1). Demographics, comorbidities, and clinical characteristics were compared between patients who received BAM versus BAM/E using Chi-square and Mann-Whitney U test. Primary outcome was 30-day COVID-19 related hospitalization. Secondary outcomes were 30-day mortality and length of stay (LOS).

Results. 643 patients received mAb (294 in BAM group and 349 in BAM/E group). Patients in the BAM/E cohort were younger and more obese with lower rates of diabetes, myocardial infarction, and cancer. Other characteristics were similar (Table 1). BAM/E patients had longer time from symptom onset to infusion (6 vs 4 days, p<0.001). COVID-19 related 30-day hospitalization rates did not differ between groups (7.8 vs 7.2%, p=0.751). LOS and 30 day mortality (1% vs 0.3%, p=0.238) were also similar (Table 2).

Conclusion. Rates of hospitalization in our study were higher than in clinical trials of mAb and may reflect differences in study populations (Table 3). Compared to other real-world studies, our cohort of young, obese, and Black patients, had similar hospitalization rates of 7.5%. The lack of difference in outcomes noted among the mAb formulations in our study may be related to longer time from symptom onset to infusion in the BAM/E combination group.

Table 1: Baseline Characteristics in Outpatients Receiving Monoclonal Antibody

| Characteristics | Total (n=643) | Bamlanivimab (n=294) | Bamlanivimab-Etesevimab (n=349) | p-value |
|-----------------|--------------|----------------------|---------------------------------|--------|
| Age Median (IQR) | 58 (47.65) | 61 (50.09) | 55 (45.65) | <0.001 |
| <65 years (%) | 206 (32.0) | 112 (38.1) | 94 (26.9) | 0.003 |
| Male n (%) | 275 (42.8) | 137 (46.9) | 138 (39.5) | 0.176 |
| Race/Ethnicity n (%) | 182 (55.6) | 106 (54.1) | 76 (41.8) | 0.218 |
| White | 411 (63.3) | 189 (62.9) | 222 (63.6) | 0.630 |
| Black | 153 (23.5) | 66 (23.1) | 87 (24.8) | 0.716 |
| Hispanic | 30 (4.7) | 17 (5.8) | 13 (7.7) | 0.218 |
| Asian | 24 (3.7) | 14 (4.8) | 10 (7.9) | 0.206 |
| Native American | 3 (0.5) | 0 (0.0) | 3 (0.9) | 0.911 |
| Other | 10 (1.6) | 5 (1.7) | 5 (1.8) | 0.784 |

Table 2: Clinical Characteristics and Outcomes in Patients Receiving Monoclonal Antibody

| Disease Severity (%) | Total (n=643) | Bamlanivimab (n=294) | Bamlanivimab-Etesevimab (n=349) | p-value |
|---------------------|--------------|----------------------|---------------------------------|--------|
| Mild | 51 (79.0) | 221 (75.2) | 289 (82.1) | 0.067 |
| Moderate | 138 (21.5) | 74 (24.8) | 64 (17.9) | 0.228 |
| Severe | 51 (79.0) | 221 (75.2) | 289 (82.1) | 0.067 |

Table 3: COVID-19-Related 30-Day Admission, n (%)

| COVID-19-Related 30-Day Admission, n (%) | Total (n=643) | Bamlanivimab (n=294) | Bamlanivimab-Etesevimab (n=349) | p-value |
|-----------------------------------------|--------------|----------------------|---------------------------------|--------|
| None | 24 (3.7) | 9 (3.1) | 15 (4.3) | 0.656 |
| Acute 30-Day Death, n (%) | 2 (0.3) | 2 (0.7) | 0 (0.0) | 0.418 |

BAM/E patients had longer time from symptom onset to infusion (6 vs 4 days, p<0.001). COVID-19 related 30-day hospitalization rates did not differ between groups. Length of stay and 30-day mortality were also similar.

Conclusion. Rates of hospitalization in our study were higher than in clinical trials of mAb and may reflect differences in study populations (Table 3). Compared to other real-world studies, our cohort of young, obese, and Black patients, had similar hospitalization rates of 7.5%. The lack of difference in outcomes noted among the mAb formulations in our study may be related to longer time from symptom onset to infusion in the BAM/E combination group.

Abbreviations: Interquartile Range (IQR), Body Mass Index (BMI), Coronavirus Disease (COVID), Comorbid Heart Failure (CHF), Chronic Obstructive Pulmonary Disease (COPD), Obstructive Sleep Apnea (OSA)
Our patients were older with higher rates of obesity and other comorbidities than those in clinical trials (shown in orange). Compared to other real-world studies (in blue), our cohort of younger, more obese Black patients had similar hospitalization rates of 7.5%.

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501. Implementation and Outcomes of a Program to Coordinate and Administer Monoclonal Antibody Therapy to Long-Term Care Facility Residents with COVID-19

Andrew B. Watkins, PharmD; Lisa M. Brand, BS; Michelle Schwedhelm, MSN, RN, NEA BC; Heather L. Jensen, RN, BSN; Brandon Scott, PharmD; Dan K. German, MBA; Kyle P. Strand, BS; Ishrat Kamal-Ahmed, PhD; James Lawler, MD, MPH, FIDSA; M. Salman Ashraf, MBBS; Nebraska Medicine, Omaha, Nebraska; UNMC, Yutan, Nebraska; Region VII Disaster Health Response Ecosystem (R7DHRE), Nebraska Medicine/University of Nebraska Medical Center, Omaha, Nebraska; Great Plains Health, North Platte, Nebraska; Community Pharmacy Services, Gretna, Nebraska; Nebraska Department of Health and Human Services, Lincoln, Nebraska; Division of Public Health, Nebraska Department of Health and Human Services, Lincoln, Nebraska; University of Nebraska Medical Center, Omaha, Nebraska

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Background. Long-term care facility (LTCF) residents are at increased risk of severe COVID-19, with CMS data indicating >20% mortality. BLZE-1 trial noted lower hospitalization rates in high-risk patients receiving monoclonal antibody (mAb) vs placebo (4.2% vs 14.6%) for mild to moderate infections, making it a treatment option for LTCF residents; however, many LTCF lack staff to prepare and administer mAb therapy. To address this need, Region VII Disaster Health Response Ecosystem (R7DHRE) coordinated via NE Medical Emergency Operations Center (NEMEOC) an ASPR pilot project to facilitate infusion of COVID-19 mAb therapeutics for LTCF residents in the state.

Methods. R7DHRE partnered with Great Plains Health, Nebraska DHHS, Nebraska Antimicrobial Stewardship Assessment and Promotion Program (ASAP) and Infection Control Assessment and Promotion Program (ICAP) to survel cases in the state, establish administration/infusion protocols, and educate providers on mAb therapeutics. A multi-hub-and-spoke model was created to allow LTSC to work with regional hospitals or pharmacy services to administer drug in their facilities, reducing time to therapy and transmission risk associated with patient transport.

A centralized request process was created using a REDCap platform and verification ties, reducing time to therapy and transmission risk associated with patient transport. The study met the pre-defined primary efficacy endpoint in a preplanned interim analysis: the risk of COVID-19 progression was significantly reduced by 85% compared to placebo (4.2% vs 14.6%).

Results. Through this program, 513 doses were administered to LTCF residents. Average time from symptom onset to infusion was 2.6 days. COVID-related hospitalization and mortality rates were lower than previously reported for LTCF residents (Table 1).