Anti-SARS-CoV-2 Monoclonal Antibodies in Pediatrics: Statewide Experience in Rhode Island

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ABSTRACT

BACKGROUND: The pediatric population has suffered COVID-19 infections with measurable morbidity and mortality. Without oral options in those less than 12 years of age, practical treatment in this rapidly evolving disease is necessary. One treatment modality is monoclonal antibodies. Limited information describes the efficacy and safety of anti-SARS-CoV-2 monoclonal antibodies in pediatrics. This is the largest case series addressing efficacy and safety of monoclonal antibodies in this population.

OBJECTIVE: To report patient characteristics, side effects encountered, and hospital admissions or emergency department visits within 30 days following treatment.

DESIGN: This retrospective case series includes high-risk pediatric COVID-19 patients who received monoclonal antibody infusions in a tertiary care center as outpatients between January 2021 and January 2022.

OUTCOMES: There were 108 patients included with seven patients (6.5%) having infusion-related reactions with no other adverse events reported. Following the monoclonal treatment, three patients presented to the emergency department for worsening symptoms, and one patient was admitted to the pediatric ICU for worsening respiratory status. No other admissions or emergency department visits were reported in the one month following the infusion.

CONCLUSIONS: In this case series study, monoclonal antibody infusions were well tolerated.

KEYWORDS: COVID-19, monoclonal antibodies, pediatrics

INTRODUCTION

COVID-19 infection can manifest as a serious disease with severe consequences in pediatrics, especially those with certain high-risk medical conditions. Thirty percent of hospitalized unvaccinated children with COVID-19 require intensive care unit admission.[1,2,3] Of those who were hospitalized, more than 80% had at least one underlying medical condition.[2] A large portion of children and youth are not vaccinated against COVID-19 in the United States.[4] Furthermore, immunosuppressed patients remain vulnerable to severe disease due to lower vaccine efficacy in this group.[5] This leaves a significant percentage of the pediatric population vulnerable to severe COVID-19 infections and subsequent multisystem inflammatory syndrome (MIS-C), thus the necessity for effective treatment measures, particularly as more transmissible strains of COVID-19 emerge. One such promising therapeutic agent to prevent severe illness and death has been the development of anti-SARS-CoV-2 monoclonal antibody therapies (mAbs). They target the receptor binding domain on the spike protein of the SARS-CoV-2 virus neutralizing the virus and minimizing the progression to the hyperinflammatory stage of COVID-19.[6]

The US Food and Drug Administration (FDA) reviewed and approved multiple Emergency Use Authorizations (EUA) for mAbs used in mild-to-moderate Covid-19 illness or as post-exposure prophylaxis in children with risk factors for progression to severe disease. These indicated risk factors included the following: BMI above 85th percentile, immunosuppressive disease or treatment, cardiovascular disease or hypertension, chronic lung diseases, sickle cell disease or thalassemia, neurodevelopmental disorders, having a dependence on medical technology, diabetes mellitus, chronic kidney disease, or pregnancy. However, due to the prevalence of the Omicron sub-variants, casirivimab/imdevimab, bamlanivimab/etesevimab, sotrovimab, bebtelovimab, tixagevimab/cilgavimab are no longer authorized in the United States.

Clinical trials have demonstrated decreasing viral loads and reductions in hospitalization and death in these high-risk COVID-19 patients after mAbs administration.[7,8] However, there were few pediatric patients in these trials, and there remains insufficient literature examining the effectiveness and tolerability of mAbs in clinical practice among the broader pediatric population. Available literature includes multiple case series of variable sizes and the largest study included 94 patients.[9,10,11,12] Overall, the administration was safe with a variable rate of side effects in adolescents and young adults. A recent European case series reported good tolerance in children younger than 12 years with no significant adverse events.[13]

This study reports a statewide experience with mAbs administration in eligible children of all age groups with

risk factors for severe COVID-19 disease, including transdisciplinary discussion of referral, administration, and clinical outcomes in Rhode Island, which has the highest documented rate of pediatric COVID-19 infection (38%) during the pandemic within the United States.[14]

METHODS

Patients with mild-to-moderate COVID-19 infection who had risk factors for developing severe disease and received monoclonal antibody infusion in the Tomorrow Fund Clinic at Hasbro Children's Hospital, the only tertiary pediatric hospital in RI, from January 2021 to January 2022 were included in the study. All patients had at least one underlying risk factor as per the FDA EUA. Patients were referred by community pediatricians and all of them were outpatients. Communications with referring pediatricians were by phone utilizing a standardized referral form. Communication between teams was done via HIPAA-compliant electronic methods. Pediatric Infectious Diseases specialists determined mAb eligibility. Patients were considered high risk if they had at least one of the following comorbidities: age less than one year, BMI above 85th percentile, immunosuppression, cardiovascular disease or hypertension, chronic lung diseases, sickle cell disease, neurodevelopmental disorders, liver disease, diabetes mellitus, chronic kidney disease, having a dependence on medical technology. All patients received one of the following: (1) bamlanivimab 700 mg, (2) casirivimab 600 mg and imdevimab 600 mg, (3) bamlanivimab 700 mg and etesevimab 1400 mg or (4) sotrovimab 500 mg over 30 minutes and all were observed for one hour afterward. After obtaining Lifespan's Institutional Review Board approval, relevant demographic and clinical data including sex, ethnicity, age, symptomatology, underlying disease, side effects, and outcome were abstracted retrospectively from the electronic health record. Quality checks were applied to the data to remove duplicates and errors. Descriptive statistics were reported using Microsoft Excel (2016).

RESULTS

Overall, 108 patients received mAb infusions for COVID-19, with 97 (89.8%) for treatment needs and 11 (10.2%) as post-exposure prophylaxis (**Table 1**). Of these, nine patients (8.3%) received bamlanivimab, 62 patients (57.4%) received bamlanivimab/etesevimab, 36 patients (33.3%) received casirivimab/imdevimab, and one patient (0.9%) received sotrovimab. Of the high-risk conditions, 65 patients (60.2%) had one comorbidity and 43 patients (39.8%) had two or more comorbidities. The most common comorbidities were obesity, chronic lung diseases, and immunosuppression. Patients ranged in age from 3 months to 26 years and the average age was 14.5 years. Fifty-one percent were females and 49% were males.

Table 1. Characteristics of patients – N 108 (%)

Age in years	Below 1: 6 (5.6) 1–11: 28 (25.9) 12–18: 66 (61.1) Above 18: 8 (7.4)
Gender	Male 53 (49) Female 55 (51)
Ethnicity	Hispanic 21 (19.4) Non-Hispanic 81 (75) Unknown 6 (5.6)
Comorbidities Age<1 Obesity CKD DM Immunosuppression CHD/HTN Chronic lung diseases SCD Neurodevelopmental Liver disease Dependence on medical technology	168 6 48 1 5 33 13 37 4 15 3 3
Number of comorbidities per patient	One comorbidity: 65 (60.2) Two comorbidities: 29 (26.8) Three comorbidities:11 (10.2) Four comorbidities: 3 (2.8)
PCR timing in days	2 (median) 1–3 (25th and 75th quartiles)
Duration of symptoms in days	4 (median) 2–6 (25th and 75th quartiles)
Vaccination	Not vaccinated: 80 (74.1) Received 1 dose: 5 (4.6) Received 2 doses: 17 (15.7) Received 3 doses: 4 (3.7) Unknown: 2 (1.8)
BMI	Below 85th percentile: 60 (55.6) Above 85th percentile: 48 (44.4)
County	Providence: 61 (56.5) Newport: 6 (5.6) Washington: 7 (6.5) Kent: 13 (12) Bristol: 9 (8.3) Outside RI: 12 (11.1)
Clinical outcomes	Infusion reactions: 7 (6.5) 30-d ED visit: 4 (3.7) 30-d admission: 3 (2.8)

Nearly all patients tolerated the infusion. There were seven cases (6.5%) of infusion-related reactions that resolved in the observation area with the infusion discontinued in four patients (3.7%)(**Table 2**). Of the cohort, 101 patients (93.5%) completed their recovery at home without emergency department visits or escalation of care (**Table 3**).

Table 2. Documentation of adverse events that occurred during infusion

Patient number	Side effect	Comorbidities	agent	Infusion completion
Patient 1	Chest tightness and desaturation down to 86%	B-ALL	Bamlanivimab/etesevimab	No
Patient 2	Dyspnea with desaturation to 70%, perioral cyanosis	Obesity	Bamlanivimab/etesevimab	No
Patient 3	Abdominal discomfort	Obesity	Casirivimab/imdevimab	Yes
Patient 4	Tingling lips and throat, cough, SOB, received solumedrol	HLH, obesity, HTN	Casirivimab/imdevimab	No
Patient 5	"Felt throat closing", fever, given solumedrol, acetaminophen, diphenhydramine	Obesity	Bamlanivimab/etesevimab	Yes
Patient 6	self-resolving itchiness, pain	DM, Asthma, Obesity	Casirivimab/imdevimab	Yes
Patient 7	Pain in legs and back, tightness	SCD, Asthma	Bamlanivimab/etesevimab	No

Table 3. Characteristics of patients with ED visits or hospital admissions

Patient number	Comorbidities	Initial symptoms	infusion	Duration of symptoms before infusion in days	Vaccination	Type of revisit
COVID related						
Patient 1	Asthma, obesity	Rhinorrhea	Bamlanivimab/ etesevimab	8	Not vaccinated	PICU admission
Patient 2	Asthma, obesity	Fever, rhinorrhea, cough	Bamlanivimab/ etesevimab	6	Not vaccinated	ED visit
Patient 3	Obesity	Fever, cough, vomiting, diarrhea	Bamlanivimab/ etesevimab	8	Not vaccinated	ED visit
Patient 4	Asthma, obesity, chronic liver disease, cardiovascular disease	Cough, dyspnea, aches, nausea/vomiting	Casirivimab/ imdevimab	8	2 doses	ED visit
Non-Covid related						
Patient 1	Sickle cell disease, asthma	Post-exposure prophylaxis	Bamlanivimab/ etesevimab	NA	Not vaccinated	ED visit for SCD pain crisis
Patient 2	Sickle cell disease	Fever, cough, dehydration/vomiting/myalgia	Casirivimab/ imdevimab	2	2 doses	Floor admission for SCD pain crisis
Patient 3	B cell ALL	Cough, diarrhea	Bamlanivimab	2	Not vaccinated	Floor admission for ALL relapse and sepsis

Only one patient (0.9%) with obesity and asthma was admitted to the pediatric intensive care unit (PICU) 4 days after the infusion due to COVID-19 progression resulting in respiratory distress. The patient required continuous positive airway pressure and steroids and was discharged home after four days. Two patients (1.8%) were admitted to the hospital within 30 days due to other conditions, and of those, one patient with sickle cell disease was admitted for bilateral lower limb pain ischemic-occlusive crisis, while the other patient was admitted with leukemia relapse. Four total patients (3.7%) presented to the emergency department, three with worsening symptoms and one other with sickle cell-induced pain crisis, with all four treated symptomatically and discharged home. No cases with MIS-C were reported within two months post-infusion.

DISCUSSION

To date, there are few case series addressing the safety and tolerability of mAbs in pediatrics. In these studies, patients received different agents with good tolerability.[9-12,15,16] The clinical trials and adult data showed that side effects are usually mild. However, there remains a paucity of evidence for the safety, tolerability, efficacy, and indications for the usage of mAbs in the pediatric population. There is evidence in adults that early administration of mAbs decreases the burden on health systems by decreasing hospital admissions, emergency department visits, hospitalization, and duration of hospitalizations.[17,18] Data from one adult study assessing casirivimab/ imdevimab, showed decreased rates of hospital admissions in patients above 65 years of age, but the infusion was conversely associated with longer stays in the ED due to the mAb infusion process.[19] For this reason,

we gave the infusions in an outpatient center to prevent the overwhelming of emergency department resources.

There were four different regimens in our cohort. Bamlanivimab alone was infused in nine patients, and all of them recovered. While bamlanivimab demonstrated promising outcomes among high-risk populations including solid organ transplant recipients, it is no longer authorized due to emerging resistance among the SARS-CoV-2 variants.[20,21] Ninety-eight patients received bamlanivimab/etesevimab and casirivimab/imdevimab with good tolerance and promising efficacy but as the omicron variant became predominant, the FDA suspended authorization due to decreased activity and inability to neutralize the predominant subvariants.

The emergence of resistant variants that decrease the efficacy of vaccines and therapeutics is a major obstacle that needs collaborative efforts from governments, scientists, hospitals, and companies. Future surges of COVID-19 are a distinct threat, and physicians must be nimble to respond to emerging variants by streamlining supply chains for new treatments.

The route of parenteral administration can be a challenge, especially with overwhelmed health systems. A recent study showed that subcutaneous casirivimab and imdevimab had good efficacy compared with intravenous infusion.[22] Other obstacles to widespread mAb use among pediatric patients include cost, feasibility in community settings, and equity in delivery.[23] Multiple studies had shown Black and Hispanic patients with COVID-19 infection were less likely to receive mAbs.[24,25] This could be attributed to multiple factors including decreased awareness in some ethnic groups, inadequate insurance coverage, lack of health system access, and lack of transportation. The Rhode Island Department of Health did work with a home ambulance agency to administer mAbs in the community to those over 12 years of age. We were not able to report race in our study as our chart review process was able to identify ethnicity but not race.

There was an up-trending number of infusions per week in the last few months of the infusion period. This can be attributed to expanding EUA for bamlanivimab/etesevimab to include children of all ages but could also be attributed to improved community awareness and clinicians' understanding of mAbs safety and efficacy that supplanted the general lack of data and formal guidance among high-risk pediatric patients. Initially, some clinicians were not aware of the availability of mAbs for children, few were hesitant due to the absence of endorsement of routine use by the Pediatric Infectious Diseases Society during the study period.[26] As we are a large referring center, our pediatric infectious diseases fellows and faculty received phone calls from community physicians requesting guidance in managing children with comorbidities which helped to increase awareness. Our referral information, along with other community infusion resources were available on the state's Department of Health website.

Data regarding risk factors for severe COVID-19 in pediatrics is emerging; a case series of COVID-19 decedents showed that 86% of patients had at least one underlying comorbid condition including obesity (42%) and asthma (29%).[27] The evidence that conditions like obesity, immunosuppression, respiratory technology dependence, and chronic respiratory diseases can be independent risk factors for severe COVID-19 disease led the Pediatric Infectious Diseases Society to update its guidance on the use of mAbs.[28] However, there is a knowledge gap regarding how severe underlying conditions contribute to increased risk for COVID-19 severe disease. This can be important to ensure equity of treatment given the interruptions in supply. Data are still emerging regarding the other comorbidities listed in the FDA EUA. Most mAbs trials insufficiently enrolled pediatric populations inclusive of comorbidities like genetic disorders which can be absent in adult populations. As data emerge, indications for mAbs will continue to be modified. Partnering with our adult colleagues on clinical trials helped create the scaffolding to operationalize infusions once EUA approval occurred. In addition, key collaboration with pharmacy, information technology, and our infusion teams created the seamlessness necessary in our pathways to respond to changing environments concerning new/revoked authorizations, eligibility criteria, and emerging variants with resistance to mAbs.

Our 108-patient case series revealed that mAb infusions were well tolerated. The infusion was discontinued in 3.7 % of patients with all having complete resolutions of symptoms before leaving the infusion center. All patients recovered at home except for one patient who required PICU admission. He required respiratory support by BiPAP for 4 days before recovering completely, and three other patients presented to the emergency department. Another three patients required emergency department visits or admission for other reasons. It is worth mentioning that all the patients who represented to the hospital received the infusion between days 6 and 8 of symptoms. This, suggesting early infusion of mAbs, may indeed be more effective in preventing severe COVID-19 infection, death, and lower hospital services utilization among the high-risk pediatric population during COVID-19 surges. While we do not know the number needed to treat, we offer the largest pediatric mAbs case series to date during this pandemic. Ideally, a prospective study would provide strong evidence regarding the overall efficacy and tolerability of these treatments; however, this is not feasible due to inherent ethical concerns of withholding such a treatment to high-risk patients.

This study has several limitations as it is vulnerable to bias intrinsic to retrospective studies. There is no control arm to compare the mAbs cohort to an untreated population with the same characteristics to understand efficacy. The heterogeneity of the underlying comorbid conditions and mAb infusions is also a limitation that would prevent the generalizability of the results to the greater population,

especially among patients who do not have risk factors for severe COVID-19 infection. Another limitation is the convenience of the sample, as there was also limited availability for community infusions in those 12 years and older and whose outcomes we do not know. We can report there were no fatalities due to COVID-19 in children within the state during the study period.

CONCLUSION

In conclusion, we present the experience of a tertiary pediatric care facility with multiple regimens of monoclonal antibody infusion for COVID-19 in the high-risk pediatric population which demonstrates good tolerability and efficacy in preventing severe COVID-19 infection. The pediatric population cannot remain an afterthought with respect to therapeutics as this pandemic continues and further research is needed to support their therapeutics.

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The authors have no conflicts of interest to disclose.

Disclaimer

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