Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Pregnancy outcomes after administration of monoclonal antibody therapy for COVID-19

OBJECTIVE: SARS-CoV-2 was initially identified in Wuhan, China, and was discovered to be the causative agent of COVID-19. Since then, it has spread throughout the world and was declared a pandemic in March 2020.

Novel treatments have been used in an attempt to reduce the severity, morbidity, and mortality of the disease. It has been shown that pregnant patients are at significantly higher risk of requiring hospital admission, mortality, and presenting perinatal complications because of COVID-19.[1,2] An update from the Centers for Disease Control and Prevention found that pregnant patients were 4 times more likely to require invasive ventilation than nonpregnant patients of the same age. In addition, they uncovered significant health disparities. Pregnant Asian and Native Hawaiian or Pacific Islander women had higher intensive care unit admissions. Hispanics and African Americans also had disproportionate rates of SARS-CoV-2 infection and a higher risk of hospitalization.[1,3]

Based on results from randomized controlled trials, several antispike monoclonal antibodies (mAbs) received Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) in 2021.[4–6] However, pregnant patients were not included in the clinical trials, and the effects on pregnancy outcomes are unknown. In this case series, we described the outcomes of 47 pregnant patients who had confirmed COVID-19 and who received antispike mAb therapy. To the best of our knowledge, our study is the second largest report of this kind and includes the use of sotrovimab in 10 pregnant patients.

STUDY DESIGN: After institutional review board approval, we performed a retrospective cohort study of 47 pregnant patients aged ≥18 years who received mAb infusion for the treatment of mild-to-moderate COVID-19 between April 2021 to January 2022. We extracted the data from St. Luke's University Health Network electronic medical record system. Mild disease was characterized by fever, change of taste or smell, and cough. Moderate disease was characterized by dyspnea, evidence of disease on imaging, or oxygen saturation of ≥94%. Severe disease was characterized by viral symptoms (mentioned in the definitions of mild and moderate diseases) with additional shortness of breath, and very severe disease was characterized by respiratory failure or shock. All patients had a confirmed positive result of direct SARS-CoV-2 testing. Patients were selected for mAb therapy if they met the eligibility criteria based on EUA guidelines released by the FDA and additional criteria defined by our institutional protocol (Figure). Pregnant patients were monitored for adverse reactions at the injection site, headache, dizziness, fever, weakness, nausea, vomiting, pruritus, rashes, anaphylaxis, diarrhea, and low blood pressure. We defined tolerability as a low rate of side effects and low admission rates. Data analysis was completed using SPSS (version 28; International Business Machines Corporation, Armonk, NY).

RESULTS: A total of 47 pregnant patients were included in the study. The characteristics of the patient population are displayed in Table 1. The patients' mean age was 30 years with most patients being White (85.1%). Most patients were obese (63.8%) and in their third trimester of pregnancy (57.4%). Most patients (46.8%) received bamlanivimab and etesevimab treatment, and 10 patients (21.3%) received sotrovimab.

Of note, 76% of the study population was unvaccinated. Moreover, 3 patients visited the emergency department (ED) after the infusion. Of the 3 patients, 2 had continuous COVID-19 symptoms, for which 1 patient was hospitalized because of COVID-19 pneumonia. The patient was unvaccinated and had obesity as a risk factor. Moreover, 1 patient presented to the ED because of decreased fetal movement, but this resolved during the admission as there was good feal movement on ultrasound and reassuring fetal heart tones. The nonstress test was reactive, and the amniotic fluid index was 8.28 cm. Of note, 1 pregnant patient received the infusion during early labor. The patient developed a fever during labor, but it was unclear whether this was related to the mAb infusion. Another patient received treatment after delivery without any adverse reactions or complications. There was no report of adverse effects 1 hour after the infusion or in follow-up (see other maternal clinical care outcomes in Table 3).

As of January 2022, no miscarriage or intrauterine demise has been reported (more pregnancy outcomes in Table 2). Of note, 46 patients have thus far delivered, with 2 patients (4.3%) requiring a vacuum-assisted delivery and 18 patients (39.1%) requiring cesarean delivery. Moreover, 1 patient was lost to follow-up. Lastly, 3 neonates developed infections in the first 2 months of life (yeast dermatitis, neonatal conjunctivitis, and fever), but none of the infections were deemed attributable to the treatment.

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FIGURE

UsePer Journal style, as there is only 1 figure, Figure 1 label and callout have been changed to "Figure." of monoclonal antibodies during limited supply divided by tiers

OF MONOCLONAL ANTIBODIES DURING LIMITED SUPPLY DIVIDED BY TIERS

The risk factor tier division included pregnant patients in tier 1 or 3.

EUA, Emergency Use Authorization.

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TABLE 1

Characteristics of study patient population

Variable	Numeric value
Age range (y), mean±SD	18–45: 30.19±5.269
Race, n (%)	
White	40 (85.1)
Black or African American	4 (8.5)
American Indian or Alaska Native	1 (2.1)
Other race	2 (4.3)
Ethnicity, n (%)	
Not Hispanic or Latino or Spanish	39 (83.0)
Hispanic or Latino	7 (14.9)
Not reported or declined to answer	1 (2.1)
Language, n (%)	
English	47 (100.0)
Marital status, frequency (%)	
Single	23 (48.9)
Married or civil union	24 (51.1)
Comorbidities, n (%)	
BMI≥30	30 (63.8)
Hypertension	9 (19.1)
Anxiety	14 (29.8)
Depression	15 (31.9)
Asthma	10 (21.3)
Migraine	11 (23.4)
Anemia during pregnancy	8 (17.0)
Diabetes mellitus	8 (17.0)
Vitamin D deficiency	4 (8.5)

(continued)

TABLE 1

Characteristics of study patient population *(continued)*

Variable	Numeric value
Smoking history, n (%)	
Smoker	4 (8.5)
Former smoker	13 (27.7)
Nonsmoker	30 (63.8)
Obstetrical history, median (IQR)	
Gravida	3 (1–8)
Para	1 (0–5)
Abortions	0 (0–4)
Gestational age at infusion, n (%)	
First trimester	1 (1.1)
Second trimester	19 (40.4)
Third trimester	27 (57.4)
Singleton pregnancies, n (%)	46 (96.0)
Twin pregnancies, n (%)	2 (4.0)
Delivered, n (%)	46 (97.8): one patient lost to follow-up
Type of delivery, n (%)	
Cesarean delivery	18 (39.0)
Spontaneous vaginal delivery	26 (57.0)
Vacuum assisted vaginal delivery	2 (4.0)

BMI, body mass index; *IQR*, interquartile range; *SD*, standard deviation.

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TABLE 2
Pregnancy outcomes

Outcomes	n (%)
Miscarriage	0 (0)
Retained placenta	1 (2.1)
Preeclampsia	6 (13.0)
Hemorrhage requiring transfusion	0 (0)
NICU admission	1 (2.2)
Birthweight<2500 g	5 (10.4)[a]
Gestational age at delivery (wk)	
≤36.6	4 (8.7)
37.0–40.0	41 (89.1)
>40.6	1 (2.2)

NICU, neonatal intensive care unit.

[a] These data include 2 sets of twins and a neonate born at 38 weeks of gestation with low birthweight but had no other complication.

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TABLE 3
Other maternal clinical care outcomes

Criteria	n (%)
ED visits within 1 mo of infusion	7 (15.2)
ED visits related to infusion	0 (0)
ED visits in the postpartum period	9 (19.6)
ED visits related to infusion	0 (0)
Patients undergoing DVT workup or diagnosed with DVT	4 (8.7): one-fourth of patients positive for DVT
Respiratory distress requiring imaging	4 (8.7)

DVT, deep vein thrombosis; *ED*, emergency department.

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CONCLUSION: We described the use of antispike mAbs to treat mild to moderate COVID-19 in 47 pregnant patients. We found no conclusive evidence of maternal or fetal complications because of the treatment. Only 2 patients had progression of the disease, and only 1 patient required hospitalization.

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The authors report no conflict of interest.

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