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Research Letter

Anti-Spike Monoclonal Antibody Therapy in Pregnant Women With Mild-to-Moderate Coronavirus Disease 2019 (COVID-19)

Bright P. Thilagar, MD, Aditya K. Ghosh, MD, Jerome Nguyen, BS, Regan N. Theiler, MD, PhD, Myra J. Wick, MD, PhD, Ryan T. Hurt, MD, PhD, Raymund R. Razonable, MD, and Ravindra Ganesh, MBBS, MD

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is associated with increased risk of hospitalization and death, particularly in certain patients with underlying conditions, including pregnancy.[1–6] Anti-spike monoclonal antibodies have received emergency use authorizations from the U.S. Food and Drug Administration for the outpatient treatment of mild-to-moderate COVID-19 in patients at increased risk of severe outcomes.[7–10] On May 14, 2021, the U.S. Food and Drug Administration expanded the emergency use authorization to include pregnancy as a qualifying condition for monoclonal antibodies. Guidelines from the National Institutes of Health, the American College of Obstetricians and Gynecologists, and the Society for Maternal-Fetal Medicine suggest that pregnant women should be considered candidates for monoclonal antibody therapy.[11–13] However, the adoption of these recommendations has been limited by the lack of clinical data on its use in pregnant women.[14,15] Here we present a case series of 51 pregnant women who received anti-spike monoclonal antibody therapy for mild-to-moderate COVID-19.

METHODS

This was a retrospective cohort study of pregnant patients who received monoclonal antibody therapy at a single institution from November 6, 2020, through October 30, 2021, who were identified from an institutional COVID-19 treatment registry. Patients diagnosed with mild-to-moderate COVID-19 at our institution were automatically evaluated for eligibility and contacted for education and consent and enrolled in a treatment registry as previously described.[16] Patients were considered to have mild-to-moderate COVID-19 if they were symptomatic, had an oxygen saturation higher than 94%, and otherwise did not need admission for COVID-19, for example, due to hemodynamic instability. After approval by the Mayo Clinic Institutional Review Board, the monoclonal antibody treatment registry was queried for pregnant patients,[16] and 86 were identified. The medical records of all patients were reviewed, and the data are presented using descriptive methods (Fig. 1).

RESULTS

After excluding patients who had false-positive pregnancy test results and those who received monoclonal antibodies after delivery, 51 pregnant women who received monoclonal antibodies for mild-to-moderate COVID-19 during pregnancy were included (Fig. 1). Demographic characteristics of the cohort are displayed in Table 1.

From the Division of General Internal Medicine, the Department of Nursing, the Department of Obstetrics and Gynecology, and the Division of Infectious Diseases, Mayo Clinic, Rochester, Minnesota.

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Corresponding author: Ravindra Ganesh, MBBS, MD, Division of Infectious Diseases, Mayo Clinic, Rochester, MN; email: Ganesh.ravindra@mayo.edu.

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Ryan T. Hurt is a consultant for Nestle Nutrition. Raymund R. Razonable is principal investigator of clinical trials on COVID-19 treatment funded by Gilead (remdesivir), Regeneron (sarilumab, casirivimab-imdevimab), Roche (tocilizumab), and research on Monoclonal Antibody Therapy funded by the Mayo Clinic. They have been on the data safety monitoring board for a Novartis clinical trial. They disclosed that bamlanivimab, bamlanivimab-etesevimab, casirivimab-imdevimab, and sotrovimab are all investigational products authorized for emergency use EUA by the U.S. FDA. The other authors did not report any potential conflicts of interest.

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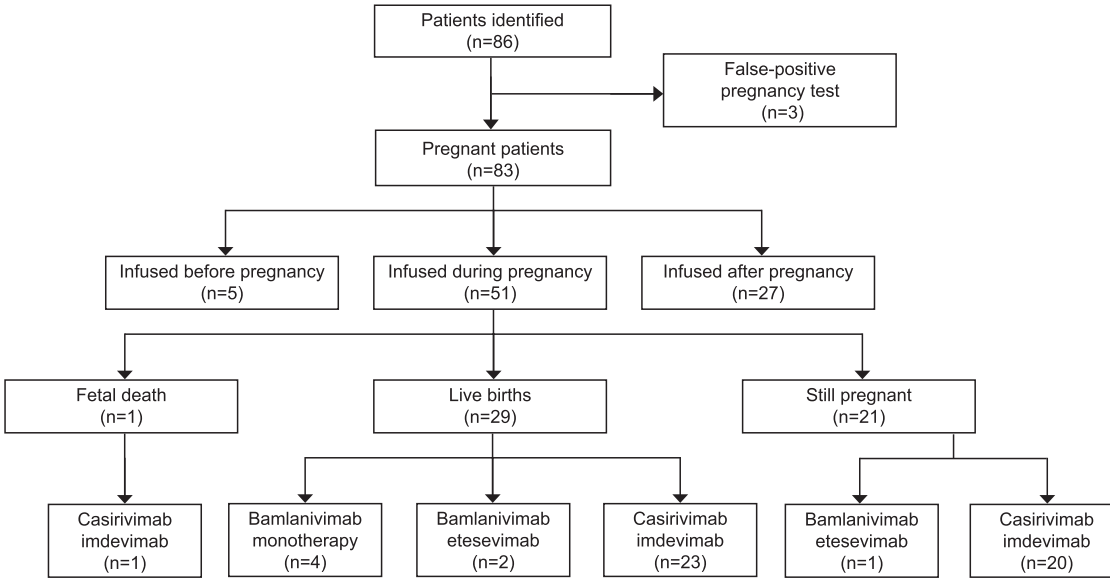

Fig. 1. Patient inclusion and characteristics.

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Monoclonal antibody treatment was performed in an outpatient area for individuals who had tested positive for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and patients were monitored for 1 hour afterward for immediate adverse effects, with none observed in our cohort. Patients were then evaluated by in the obstetrics department within the next week for any further complications. During the 28-day period after infusion, 10 patients sought care in the emergency department, but only one was related to COVID-19 (dyspnea), with the remainder being related to the pregnancy or underlying conditions. No patients required any additional COVID-19–directed therapy. Four patients were admitted to the hospital while pregnant for reasons unrelated to COVID-19 or monoclonal antibody infusion. At the time of manuscript submission, no patients had pregnancy complications or fetal distress, 21 patients were still pregnant, and 29 had delivered healthy neonates (mean birth weight 3,110 g, mean gestational age 38.6 weeks) now aged 5–310 days (mean age 86 days).

DISCUSSION

This retrospective cohort study of 51 pregnant women who received monoclonal antibody therapy for mild-to-moderate COVID-19 demonstrates no immediate adverse effects, and no patient had COVID-19 progression. Despite these reassuring findings, we suggest continued research with larger populations of diverse patients, longer maternal and infant follow-up, and the examination of efficacy of monoclonal antibodies as SARS-CoV-2 variants of concern emerge.

Table 1. Characteristics of Patients at Time of Monoclonal Antibody Infusion (N=51)

Patient Factors	Value
Age (y)	30.5 [7.5]
Gravidity	3 [2]
Parity	1 [1]
Race	
Black	1 (2)
American Indian	1 (2)
Pacific Islander	1 (2)
White	46 (90)
None of the above	2 (4)
Ethnicity	
Hispanic	4 (8)
Not Hispanic	47 (92)
Language	
Arabic	1 (2)
English	49 (96)
Spanish	1 (2)
Comorbidities	
Anxiety	5 (10)
Asthma	8 (16)
BMI higher than 30 (kg/m^2)	11 (22)
Depression	21 (41)
Migraines	17 (33)
Preeclampsia without severe features	2 (4)
Infusion	
Time to infusion (d)	2.9±1.6
Gestational age at infusion (wk)	25.7±10.1
Monoclonal antibody	
Bamlanivimab	4 (14)
Bamlanivimab–etesevimab	2 (7)
Casirivimab–imdevimab	23 (79)

BMI, body mass index.
Data are median [interquartile range], n (%), or mean±SD.

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