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.

3. Castorino K, Polsky S, O'Malley G, et al. Performance of the Dexcom G6 continuous glucose monitoring system in pregnant women with diabetes. Diabetes Technol Ther 2020;22:943–7.
4. Ross KM, Leahey TM, Kiernan M. Validation of the Stanford Leisure-Time Activity Categorical Item (L-Cat) using armband activity monitor data. Obes Sci Pract 2018;4:276–82.
5. JMP Statistical Discovery. Predictive and specialized modeling, functional data explorer. 2021. Available at: https://www.jmp.com/support/help/en/16.2/index.shtml#page/jmp/functional-data-explorer.shtml. Accessed September 12, 2021.
6. Law GR, Alnaji A, Alrefaii L, et al. Suboptimal nocturnal glucose control is associated with large for gestational age in treated gestational diabetes mellitus. Diabetes Care 2019;42:810–5.

 https://doi.org/10.1016/j.ajog.2022.09.004

Effectiveness of REGEN-COV combination monoclonal antibody infusion to reduce the risk of COVID-19 hospitalization in pregnancy: a retrospective cohort study

Check for updates

OBJECTIVE: Pregnancy is a risk factor for severe COVID-19.[1] The REGEN-COV combination monoclonal antibody infusion, efficaciously reduced COVID-19 hospitalization in nonpregnant patients who were at risk of severe disease but did not meet the admission criteria.[2] When REGEN-COV was issued emergency use authorization in the summer of 2021, national organizations endorsed the use of antispike monoclonal antibodies in pregnant patients, despite their exclusion from efficacy trials.[3] We hypothesized that REGEN-COV infusion reduces the risk of COVID-19 hospitalization among pregnant patients diagnosed during alpha- and delta-predominant COVID-19 waves.

STUDY DESIGN: This is a retrospective cohort study in a large regional hospital system including unvaccinated pregnant patients with polymerase chain reaction-confirmed symptomatic SARS-COV-2 infection who did not meet admission criteria at the time of diagnosis from March 2020 through December 2021. Patients with higher-order multiple gestations and symptom onset at >10 days before presentation were excluded, as were those who received inpatient care at the time of diagnosis—either for COVID-19 or for delivery. REGEN-COV administration was compared against no administration; the decision for administration was made by the treating clinician and the patient concerned, based on a shared decision-making model. The primary outcome was subsequent COVID-19 hospitalization. The secondary outcomes included National Institutes of Health-defined critical or severe COVID-19, preterm delivery, and perinatal outcomes. Adverse events included an infusion reaction or re-presentation to care secondary to suspected complications from REGEN-COV infusion. A subanalysis was planned to

TABLE
Outcomes among pregnant patients with COVID-19 meeting the criteria for antispike monoclonal antibody infusion by administration status

	No antibodies N=676		REGEN-COV N=88			
Outcome	N	%	N	%	OR	95% CI
COVID-19 hospitalization	8	1.2	1	1.1	0.86[a]	0.10–7.11
Critical or severe COVID-19	7	1.0	1	1.1	1.01	0.12–8.64
Supplemental oxygen	6	0.9	1	1.1	1.21	0.14–10.71
Cesarean delivery	128	35.6	14	29.2	0.75	0.39–1.44
Preterm delivery	47	13.1	1	2.1	0.65	0.22–1.91
Neonatal intensive care admission	54	15.0	3	6.2	0.87	0.35–2.14
Small for gestational age	12	3.3	0	0.0	0.73	0.09–5.81

CI, confidence interval; *OR*, odds ratio.

[a] Adjusted for maternal age, pregravid body mass index, and third trimester COVID-19 diagnosis.

Williams. REGEN-COV effectiveness against COVID-19 hospitalization in pregnancy. Am J Obstet Gynecol 2023.

assess outcomes in patients at the highest risk of admission, defined as having COVID-19 Risk of Complications Score ≥3.[4] The demographic and clinical characteristics were compared by Student *t* test, chi-square, or Fisher exact test where appropriate. Outcome odds ratios (OR) including 95% confidence intervals (CIs) were generated via logistic regression, with prespecified adjustments made for maternal age, body mass index, and third trimester diagnosis based on previously reported risk factors for admission.[5] $P<.05$ or confidence interval not including 1 were considered significant. Data analysis was performed using R (R Core Team, Vienna, Austria).

RESULTS: Among 1186 patients testing positive for SARS-CoV-2, 141 previously immunized patients and 281 admitted at diagnosis were excluded from analysis. Of the 764 included patients, 88 (12%) patients received REGEN-COV infusion compared with 676 unexposed patients. No baseline differences were observed between the groups, including age, obesity, third trimester diagnosis, or COVID-19 Risk of Complications Score. The primary outcome was similar, with 1.2% of untreated and 1.1% of REGEN-COV patients being subsequently hospitalized for COVID-19 (adjusted OR, 0.86; 95% CI, 0.10−7.11; Table). The secondary outcomes were likewise similar, with no adverse events reported for REGEN-COV administration. Analysis limited to high-risk patients was precluded by low numbers, although of the untreated patients, 2 of 54 (3.7%) ultimately required admission owing to COVID-19, whereas none of the 8 treated patients required subsequent admission.

CONCLUSION: In a retrospective cohort of unvaccinated pregnant patients with symptomatic COVID-19, administration of REGEN-COV combination monoclonal antibody infusion did not reduce subsequent COVID-19−related admission. The findings were primarily related to infrequent admission in the untreated group (1.2%)—well below the 3% to 5% reported in nonpregnant efficacy trials. As novel therapies are developed for both new and existing diseases affecting pregnant women, ensuring their inclusion in clinical trials is essential. ■

Frank B. Williams, MD/MPH
John A. Morgan, MD
Ardem Elmayan, MPH
Jane K. Martin, MD
Naiha Mussarat, MD
Joseph R. Biggio, MD
Department of Women's Services
Ochsner Clinic Foundation
Ochsner Health System
2700 Napoleon Ave.
4th Floor Maternal Fetal Medicine
New Orleans, LA 70119
frank.williams2@ochsner.org

The authors report no conflict of interest.

F.B.W. ORCID ID: 0000-0001-7507-4870.

REFERENCES

1. Jamieson DJ, Rasmussen SA. An update on COVID-19 and pregnancy. Am J Obstet Gynecol 2022;226:177–86.
2. Weinreich DM, Sivapalasingam S, Norton T, et al. REGEN-COV antibody combination and outcomes in outpatients with Covid-19. N Engl J Med 2021;385:e81.
3. American College of Obstetricians and Gynecologists. COVID-19 FAQs for obstetrician-gynecologists, obstetrics. Available at: https://www.acog.org/clinical-information/physician-faqs/covid-19-faqs-for-ob-gyns-obstetrics. Accessed May 26, 2022.
4. Halalau A, Imam Z, Karabon P, et al. External validation of a clinical risk score to predict hospital admission and in-hospital mortality in COVID-19 patients. Ann Med 2021;53:78–86.
5. Kalafat E, Prasad S, Birol P, et al. An internally validated prediction model for critical COVID-19 infection and intensive care unit admission in symptomatic pregnant women. Am J Obstet Gynecol 2022;226:403.e1−13.

 https://doi.org/10.1016/j.ajog.2022.09.017