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

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 antispikes 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 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

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

Outcome	No antibodies N = 676		REGEN-COV N = 88		OR	95% CI
	N	%	N	%		
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* 2022.

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. ■

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