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 and birth outcomes after SARS-CoV-2 vaccination in pregnancy

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BACKGROUND: SARS-CoV-2 infection during pregnancy is associated with significant maternal morbidity and increased rates of preterm birth. For this reason, COVID-19 vaccination in pregnancy has been endorsed by multiple professional societies, including the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine, despite the exclusion of pregnant women from initial clinical trials of vaccine safety and efficacy. However, to date, little data exist regarding the outcomes of pregnant patients after COVID-19 vaccination.

OBJECTIVE: To assess the safety and efficacy of COVID-19 vaccines in pregnant patients.

STUDY DESIGN: A comprehensive vaccine registry was combined with a delivery database for an integrated healthcare system to create a delivery cohort that included vaccinated patients. Maternal sociodemographic data were examined to identify factors associated with COVID-19 vaccination. Pregnancy and birth outcomes were analyzed, including a composite measure of maternal and neonatal pregnancy complications, the Adverse Outcome Index.

RESULTS: Of 2002 patients in the delivery cohort, 140 (7.0%) received a COVID-19 vaccine during pregnancy, and 212 (10.6%) experienced a COVID-19 infection during pregnancy. The median gestational age at first vaccination was 32 weeks (range, 13 6/7–40 4/7 weeks), and patients vaccinated during pregnancy were less likely than unvaccinated patients to experience COVID-19 infection before delivery (2/140 [1.4%] vs 210/1862 [11.3%]; $P<.001$). No maternal COVID-19 infection occurred after the vaccination of pregnant patients. Factors significantly associated with increased likelihood of vaccination in a multivariable logistic regression model included older age, higher level of maternal education, being a nonsmoker, use of infertility treatment for the current pregnancy, and lower gravidity. Compared with unvaccinated patients, no significant difference in the composite adverse outcome (7/140 [5.0%] vs 91/1862 [4.9%]; $P=.95$) or other maternal or neonatal complications, including thromboembolic events and preterm birth, was observed in vaccinated patients.

CONCLUSION: In this birth cohort, vaccinated pregnant women were less likely than unvaccinated pregnant patients to experience COVID-19 infection, and COVID-19 vaccination during pregnancy was not associated with increased pregnancy or delivery complications. The cohort was skewed toward late pregnancy vaccination, and thus, findings may not be generalizable to vaccination during early pregnancy.

Key words: Adverse Outcomes Index, birth, COVID-19, gestation, immunity, mRNA vaccine, pregnancy, SARS-CoV-2, teratogenicity, vaccination

In late 2020, the US Food and Drug Administration (FDA) approved 2 messenger RNA (mRNA) vaccines, manufactured by Pfizer-BioNTech (BNT162b2) (Pfizer Inc, Philadelphia, PA) and Moderna (mRNA-1273) (Moderna, Inc, Cambridge, MA), for emergency use to prevent COVID-19. Both vaccines were studied with large numbers of subjects during phase 3 randomized controlled trials, and both vaccines were shown to be highly effective at preventing COVID-19 infection in nonpregnant participants.[1,2] Because none of the trials undertaken to gain FDA approval included pregnant or lactating women, use of the vaccines during pregnancy and lactation has been controversial.[3] During phase 1A of the vaccine rollout in the United States, healthcare workers were the first population with access to vaccination, and thus, many pregnant healthcare workers received the vaccine. During phase 1B, teachers and other essential workers were vaccinated, adding to the population of reproductive-age individuals who were eligible for vaccination. Starting in December 2020, the American College of Obstetricians and Gynecologists, the Society for Maternal-Fetal Medicine, and the World Health Organization endorsed the availability of COVID-19 vaccines for pregnant women using a shared decision making model with healthcare providers.[3,4]

EDITOR'S CHOICE

COVID-19 during pregnancy is known to have severe manifestations in pregnant women compared with nonpregnant controls, with increased risk of maternal hospitalization, intensive care unit (ICU) admission, invasive ventilation, and death.[5–7] Other adverse outcomes observed with SARS-CoV-2 infection during pregnancy include increased rates of preterm birth and preeclampsia, which have been linked to inflammatory mechanisms.[5] Because of the known increased maternal risk of adverse outcomes with COVID-19 infection and the lack of proven harm from the available vaccines, many patients have opted for vaccination despite limited safety and efficacy data of the vaccines for pregnant patients.[8] The vaccines are thought to be effective when administered during pregnancy, as antibody production occurs rapidly after administration. However, immune alterations that occur in pregnancy may theoretically decrease the vigor of cell-mediated

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AJOG MFM at a Glance

Why was this study conducted?

Limited data exist supporting the safety and efficacy of COVID-19 vaccination during pregnancy.

Key findings

Sociodemographic differences in COVID-19 vaccine uptake were observed among pregnant patients. Vaccinated patients did not experience more adverse pregnancy outcomes than nonvaccinated patients, but they were less likely to experience COVID-19 infection during pregnancy.

What does this add to what is known?

The study demonstrated both the safety and efficacy of COVID-19 vaccination during pregnancy.

immune responses to infection.[2,9] Neutralizing antibody response is highly reassuring and suggests robust efficacy during pregnancy with possible benefits to the neonate.

Recently published COVID-19 vaccine surveillance data from the Centers for Disease Control and Prevention's voluntary V-safe registry that included 3958 subjects vaccinated during pregnancy suggest that pregnant women do not have increased rates of adverse vaccine reactions compared with control patients and that patients do not report increases in adverse pregnancy outcomes compared with nonpregnant women.[10] However, the V-safe data are limited to patient-reported vaccine reactions and pregnancy events; thus, conclusions are subject to selection bias and lack of validated primary data supporting conclusions. For this reason, vaccine efficacy should be demonstrated in pregnancy using infectious outcomes as well. Adding to the available data, we presented pregnancy outcomes from a Mayo Clinic Health System delivery cohort delivering during the first 4 months of vaccine availability.

Methods

A comprehensive vaccine registry was created that captured COVID-19 vaccine administrations, manufacturers, and patients, identifying information from Mayo Clinic vaccination sites and other sites across the states of Minnesota and Wisconsin. Moreover, the vaccination registry was linked to the Mayo Clinic delivery registry, which contains detailed maternal and neonatal outcomes from all births within the Mayo Clinic Health System. The delivery registry data are derived directly from elements in the electronic medical record, and all fields have been validated manually during development. The creation of the registries and subsequent analysis was performed under the human subjects regulations under approval by the Mayo Clinic Institutional Review Board. These data sources were combined to form a retrospective cohort of all births during the study time frame.

Criteria for study inclusion included all patients aged 16 to 55 years with a delivery event between December 10, 2020, and April 19, 2021, at a hospital within the Mayo Clinic Health System. Patients who opted out to use their medical records for research were excluded from the study if their delivery occurred in Minnesota. COVID infection during pregnancy, regardless of temporal relationship to the vaccine, was defined as a positive SARS-CoV-2 result via a reverse transcription–polymerase chain reaction test documented in the medical record between the dates of conception and delivery, stratified by first-trimester (2 0/6–13 6/7 weeks' gestation), second-trimester (14 0/7 –27 6/7 weeks' gestation), and third-trimester (≥28 weeks' gestation) infections.

For purposes of assessing vaccine side effects and pregnancy outcomes, vaccinated individuals are defined as those receiving any dosage of vaccine during pregnancy. For purposes of assessing vaccine effectiveness, fully vaccinated was defined as >14 days after the final dosage of vaccine.

The composite outcome, the Adverse Outcome Index (AOI), was calculated as a composite of any of the following events during the delivery hospitalization: (1) maternal death during hospitalization; (2) intrapartum neonatal death within 7 days of birth with a birthweight of ≥2500 g and ≥37 weeks' gestation; (3) hypoxic-ischemic encephalopathy; (4) uterine rupture; (5) unplanned maternal ICU admission; (6) return to the operating room within 72 hours of delivery; (7) postpartum hemorrhage with blood transfusion; (8) third- or fourth-degree laceration; (9) 5-minute Apgar score of <7 with a birthweight of ≥2500 g and ≥37 weeks' gestation; (10) admission to the neonatal ICU within 1 day of birth for >1 day with a birthweight of ≥2500 g and ≥37 weeks' gestation; or (11) neonatal birth trauma. All qualifying events were verified by medical record review. The AOI for a group of patients was calculated as the number of patients with one or more identified adverse events divided by the total number of deliveries, multiped by 100. A woman with multiple gestation was counted as a single delivery. Moreover, a modified AOI was calculated by not considering third- and fourth-degree perineal lacerations as adverse events. Additional outcomes measured included thromboembolism or stroke within 4 weeks before or after delivery, gestational hypertensive disorders diagnosed up to 72 hours after delivery, low and very low birthweight, preterm birth (<37 weeks' gestation), length of postpartum maternal stay after delivery, and stillbirth.

Here, the primary outcome was AOI.[11–13] The AOI was 4.9% within the Mayo Clinic Health System for the calendar year 2019. This study was designed with 80% power, using a 2-sided chi-square test with a type I error rate of 0.05, to detect a difference in AOI of 4.9% vs 11.5% between patients with and without COVID-19

vaccination during pregnancy, based on 1862 and 140 patients in the 2 groups.

Data management and statistical analysis were performed using SAS (version 9.4; SAS Institute Inc, Cary, NC). Comparisons between the groups were evaluated using the chi-square test or Fisher exact test for nonordered categorical variables, the Wilcoxon rank-sum test for ordinal variables, and the 2-sample *t* test for continuous variables. A multivariable logistic regression model was fit to identify a set of characteristics independently associated with having received a COVID-19 vaccine during pregnancy, by including all of the factors identified with $P<.20$ based on univariate analysis. Before fitting the multivariable model, an additional category was created for each variable with missing data. A 95% confidence interval (CI) for the difference in the AOI between the 2 groups was calculated based on exact methods for a binomial parameter. All calculated *P* values were 2-sided, and *P* values of <.05 were considered statistically significant.

Results

Of 2002 patients, 140 (7.0%) received at least 1 dose of a COVID-19 vaccine before delivery, and 212 (10.6%) experienced a COVID-19 infection during pregnancy. Among the vaccinated patients, 1 received the Janssen (Ad.26.COV2.S) COVID-19 vaccine (Janssen Biotech, Inc, Pharmaceutical Companies of Johnson & Johnson, New Brunswick, NJ), 12 received the Moderna vaccine, and 127 received the Pfizer-BioNTech vaccine (Supplemental Table 1 provided in the Appendix). The median estimated gestational age (EGA) at the initiation of the vaccination series was 32 (range, 13 6/7–40 4/7) weeks' gestation. Completed vaccination was documented at a median EGA of 35 2/7 (range, 17 1/7–44 1/7) weeks' gestation, with 73.6% of the 140 patients completing vaccination before delivery.

Sociodemographic factors (Table 1) positively associated $P<.05$ with maternal vaccination based on univariate analysis included older maternal age at delivery, higher level of maternal education, and use of infertility treatment for

TABLE 1
Sociodemographics in unvaccinated and vaccinated patients

Characteristic	COVID vaccination during pregnancy		Total (N=2002)	*P* value[a]
	No (n=1862)	Yes (n=140)		
Maternal age at delivery (y)	30.5 (5.2)	31.8 (3.7)	30.1 (5.2)	<.001
Race				.019
Asian	89 (4.8)	6 (4.3)	95 (4.8)	
Black or African American	99 (5.4)	3 (2.2)	102 (5.1)	
Others combined	128 (6.9)	2 (1.4)	130 (6.6)	
White	1528 (82.9)	128 (92.1)	1656 (83.5)	
Unknown or not disclosed	18	1	19	
Ethnicity				.022
Hispanic or Latino	173 (9.5)	5 (3.6)	178 (9.1)	
Not Hispanic or Latino	1651 (90.5)	132 (96.4)	1783 (90.9)	
Unknown or not disclosed	38	3	41	
Education (y)				<.001
<12	70 (4.7)	0 (0.0)	70 (4.3)	
12–16	1218 (81.9)	70 (53.4)	1288 (79.6)	
>16	199 (13.4)	61 (46.6)	260 (16.1)	
Not documented	375	9	384	
Current smoker	196 (10.5)	0 (0.0)	196 (9.8)	<.001
Illicit drug use	56 (3.0)	0 (0.0)	56 (2.8)	.030
Gravidity				.007
1	546 (29.3)	56 (40.0)	602 (30.1)	
2	519 (27.9)	34 (24.3)	553 (27.6)	
3	350 (18.8)	29 (20.7)	379 (18.9)	
≥4	447 (24.0)	21 (15.0)	468 (23.4)	
Prepregnancy BMI				.004
<25	573 (39.6)	70 (56.5)	643 (41.0)	
25–30	409 (28.3)	21 (16.9)	430 (27.4)	
30–35	226 (15.6)	15 (12.1)	241 (15.4)	
35–40	139 (9.6)	14 (11.3)	153 (9.7)	
≥40	99 (6.8)	4 (3.2)	103 (6.6)	
Not documented	416	16	432	
Pregestational diabetes mellitus	11 (0.6)	2 (1.4)	13 (0.6)	.23
Pregestational hypertension	64 (3.4)	6 (4.3)	70 (3.5)	.63
Asthma	206 (11.1)	15 (10.7)	221 (11.0)	.90
Infertility treatment	14 (0.8)	6 (4.3)	20 (1.0)	.002
Multiple gestation				.68
Singleton	1840 (98.8)	138 (98.6)	1978 (98.8)	
Twins	22 (1.2)	2 (1.4)	24 (1.2)	
GBS test result				.51

(continued)

TABLE 1
Sociodemographics in unvaccinated and vaccinated patients *(continued)*

Characteristic	COVID vaccination during pregnancy		Total (N=2002)	*P* value[a]
	No (n=1862)	Yes (n=140)		
Negative	1283 (80.8)	94 (78.3)	1377 (80.6)	
Positive	305 (19.2)	26 (21.7)	331 (19.4)	
Not tested	274	20	294	

Data are presented as mean (standard deviation) or number (percentage), unless otherwise indicated.

BMI, body mass index; *GBS*, group B streptococcus.

[a] Comparisons between the groups were evaluated using the 2-sample *t* test for maternal age, the Wilcoxon rank-sum test for maternal education, gravida, and parity, and the chi-square test or Fisher exact test for the remaining categories.

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the current pregnancy. Factors negatively associated ($P<.05$) with vaccination included non-White race, Hispanic ethnicity, current smoking status, current illicit drug use, higher gravidity, and higher prepregnancy body mass index. The presence of comorbid conditions, including pregestational diabetes mellitus, chronic hypertension, and asthma, was not significantly associated with vaccination status. The following factors retained statistical significance in the multivariable logistic regression analysis: older age, higher level of maternal education, being a nonsmoker, use of infertility treatment for the current pregnancy, and lower gravidity.

Patients vaccinated during pregnancy were less likely than unvaccinated patients to experience COVID-19 infection before delivery (2/140 [1.4%] vs 210/1861 [11.3%]; $P<.001$), with 2 of the infections occurring in the vaccinated group before vaccination. In the unvaccinated group, COVID-19 infections occurred during each trimester of pregnancy, with 26 infections in the first trimester of pregnancy, 84 during the second trimester of pregnancy, and 100 in the third trimester of pregnancy (Table 2). The composite pregnancy outcome, AOI, did not differ by maternal vaccination status, with rates of 5.0% (7/140) vs 4.9% (91/1862) in the vaccinated and unvaccinated groups (95% CI for the difference in proportions, −3.6% to 3.6%). No maternal or early neonatal death occurred in the cohort. Moreover, mode of delivery, gestational age at delivery, neonatal birthweight, thromboembolic events, and rates of gestational hypertension and preeclampsia did not significantly differ between the groups. Additional comparison between nonvaccinated patients with COVID-19 (n=210) and vaccinated patients without a history of COVID-19 (n=138) did not show any difference among the pregnancy outcomes examined in the cohort, but the study was not sufficiently powered to detect a difference in these outcomes (Supplemental Table 2 provided in the Appendix). Among the unvaccinated patients, pregnancy and birth outcomes did not significantly differ between those with (n=210) and without (n=1652) COVID-19 during pregnancy (Supplemental Table 2 provided in the Appendix).

Discussion

Principal findings

COVID-19 vaccination in pregnant patients was associated with fewer COVID-19 infections during pregnancy and did not result in a detectable increase in adverse outcomes during pregnancy, delivery, or delivery hospitalization.

Results

Sociodemographic factors associated with increased vaccination rates in pregnancy included older age, higher level of maternal education, being a nonsmoker, use of infertility treatment for the current pregnancy, and lower gravidity. No pattern of adverse maternal or neonatal outcomes was observed in this cohort of 140 pregnant patients who were vaccinated under the FDA Emergency Use Authorization for SARS-CoV-2 vaccines, and significantly fewer vaccinated women experienced COVID-19 infection during the pregnancy than unvaccinated women.

Clinical implications

Given the danger of COVID-19 during pregnancy and early studies supporting the safety and effectiveness of vaccination in pregnant patients, specific efforts should be targeted toward the least vaccinated populations to enhance uptake, moving forward. This study revealed sociodemographic factors associated with vaccine access and uptake in the pregnant population. Vaccination eligibility during the time frame analyzed was limited to healthcare workers, the elderly, and teachers or other essential workers. For this reason, we cannot discern whether sociodemographic differences in vaccination status are because of vaccine hesitancy or differences in eligibility for vaccination, but we have observed socioeconomic disparity between those who received vaccination during gestation and those who did not.

Research implications

This study largely represents outcomes after third-trimester vaccination, but patients who received the vaccine during the late first trimester through second trimester of pregnancy and delivered preterm are represented in this data set. The absence of an increase in preterm births in the cohort suggested that vaccination is unlikely to increase preterm birth rates, but analysis of outcomes from currently ongoing pregnancies will be needed to confirm this finding. Additional studies will be needed to examine differences in rare adverse birth outcomes and outcomes following vaccination during early pregnancy.

Strengths and limitations

The strengths of this study included the inclusion of comprehensive population-level vaccine registry data in combination with a validated, all-inclusive

TABLE 2
Pregnancy and birth outcomes in unvaccinated and vaccinated patients

Outcome	COVID-19 vaccination during pregnancy		Total (N=2002)	*P* value[a]
	No (n=1862)	Yes (n=140)		
SARS-CoV-2 infection during pregnancy				.003
None	1652 (88.7)	138 (98.6)	1790 (89.4)	
First trimester	26 (1.4)	0 (0.0)	26 (1.3)	
Second trimester	84 (4.5)	2 (1.4)	86 (4.3)	
Third trimester	100 (5.4)	0 (0.0)	100 (5.0)	
AOI	91 (4.9)	7 (5.0)	98 (4.9)	.95
AOI, excluding laceration	55 (3.0)	5 (3.6)	60 (3.0)	.61
AOI components				
Maternal death during hospitalization	0 (0.0)	0 (0.0)	0 (0.0)	—
Intrapartum neonatal death within 7 d of birth, ≥2500 g, ≥37 wk	0 (0.0)	0 (0.0)	0 (0.0)	—
Hypoxic-ischemic encephalopathy	1 (0.1)	0 (0.0)	1 (0.0)	1.00
Uterine rupture	1 (0.1)	0 (0.0)	1 (0.0)	1.00
Unplanned maternal ICU admission	2 (0.1)	1 (0.7)	3 (0.1)	.20
Birth trauma	11 (0.6)	0 (0.0)	11 (0.5)	1.00
Return to the operating room	6 (0.3)	1 (0.7)	7 (0.3)	.40
Neonatal ICU admission within 1 d of birth, for >1 d, ≥2500 g, ≥37 wk	11 (0.6)	1 (0.7)	12 (0.6)	.58
5-min Apgar score of <7, ≥2500 g, ≥37 wk	38 (2.0)	3 (2.1)	41 (2.0)	.76
Postpartum hemorrhage with transfusion	5 (0.3)	1 (0.7)	6 (0.3)	.35
Third- or fourth-degree laceration	37 (2.0)	2 (1.4)	39 (1.9)	1.00
Mode of delivery				.65
Spontaneous vaginal	1238 (66.5)	89 (63.6)	1327 (66.3)	
Operative vaginal	69 (3.7)	7 (5.0)	76 (3.8)	
Cesarean delivery	555 (29.8)	44 (31.4)	599 (29.9)	
Gestational age at delivery (wk)				.70281
≥37 0/7	1703 (91.5)	127 (90.7)	1830 (91.4)	
32 0/7–36 6/7	134 (7.2)	10 (7.1)	144 (7.2)	
24 0/7–31 6/7	21 (1.1)	2 (1.4)	23 (1.1)	
<24 0/7	4 (0.2)	1 (0.7)	5 (0.2)	
Length of stay (d)[b]	2 (1–2)	2 (1–2)	2 (1–2)	.27
Quantitative blood loss>1000 mL	57 (3.1)	6 (4.3)	63 (3.1)	.45
Transfusion	241 (12.9)	25 (17.9)	266 (13.3)	.12
Thromboembolism[c]	2/1580 (0.1)	0/129 (0)	2 (0.1)	1.00
Stroke[c]	2/1581 (0.1)	0/129 (0.0)	2 (0.0)	1.00
Eclampsia or preeclampsia up to 72 h from delivery	23 (1.2)	1 (0.7)	24 (1.2)	1.00
Gestational hypertension	225 (12.1)	19 (13.6)	244 (12.2)	.60
Low birthweight (<2500 g)	121 (6.5)	11 (7.9)	132 (6.6)	.53
Very low birthweight (<1500 g)	21 (1.1)	3 (2.1)	24 (1.2)	.23
Stillbirth	6 (0.3)	0 (0.0)	6 (0.3)	1.00

Data are presented number (percentage) or median (interquartile range [25th and 75th percentiles]), unless otherwise indicated.

AOI, Adverse Outcome Index; *ICU*, intensive care unit.

[a] Comparisons between the groups were evaluated using the Wilcoxon rank-sum test for gestation age and length of stay and the chi-square test or Fisher exact test for the categorical variables; [b] Length of stay from time of delivery to discharge from the hospital; [c] Thromboembolism and stroke were assessed within 4 weeks before or after delivery. Crude percentages are reported among the subset who either had the outcome or had sufficient follow-up.

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delivery database, including births at multiple community and teaching hospitals across 2 states. Because the data were extracted from the primary medical record, it is not subject to recall bias. Given the absence of infection in any vaccinated patient after the first dose administration (incidence rate ratio of 0 and vaccine efficacy of 1) with a short observation period, our ability to estimate vaccine efficacy was limited for this cohort. Other limitations of this analysis included the small percentage of non-White subjects in this geographic region, the potential for confounding because of the observational nature of the study, and the data currently available being biased toward those vaccinated later in gestation and skewed toward the population in the US healthcare workforce. Finally, only 2 COVID-19 infections occurred in the vaccinated group early in pregnancy, so they may be a group who had lower baseline exposure than the unvaccinated group. Prepregnancy COVID-19 infection history was not available, so previously existing antibody status was unknown and limited the efficacy conclusions.

Conclusions

Although COVID-19 infection in pregnancy has been associated with significant adverse maternal and neonatal outcomes in multiple studies, the current findings should give clinicians confidence that COVID-19 vaccination during pregnancy is protective against maternal SARS-CoV-2 infection and that no pattern of adverse maternal or birth outcomes is evident after vaccination during pregnancy. Outreach to underrepresented populations of pregnant patients should be a focus of future education and vaccination efforts. ■

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.ajogmf.2021.100467.

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