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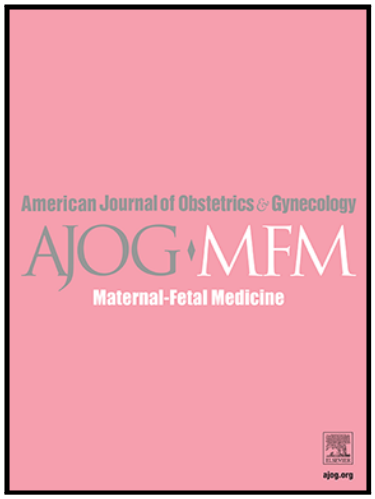

COVID-19 vaccination in pregnancy: early experience from a single institution

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COVID-19 vaccination in pregnancy: early experience from a single institution

Short title: COVID-19 vaccination in pregnancy

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Objective

Pregnant women are at increased risk for morbidity due to infection with COVID-19[1]. Vaccination presents an important strategy to mitigate illness in this population. However, there is a paucity of data on vaccine safety and pregnancy outcomes as pregnant women were excluded from initial Phase 3 clinical trials. Our objective was to describe maternal, neonatal, and obstetrical outcomes of women who received an mRNA COVID-19 vaccine during pregnancy during the first four months of vaccine availability.

Study Design

This was an IRB-approved descriptive study of pregnant women at NYU Langone Health who received at least one dose of an mRNA COVID-19 vaccine approved by the Food and Drug Administration (Pfizer/BioNTech or Moderna) from time of FDA Emergency Use Authorization to April 22, 2021. Eligible women were identified via search of the electronic medical record (EMR). Vaccine administration was ascertained via immunization records from the New York State Department of Health. Women were excluded if they were vaccinated prior to conception or during the postpartum period. Charts were reviewed for maternal demographics and pregnancy outcomes. Descriptive analyses were performed using R Version 4.0.2 (Boston, MA).

Results

We identified 424 pregnant women who received an mRNA vaccination. 348 (82.1%) received both doses and 76 (17.9%) received only one dose. Maternal characteristics and

vaccination information are shown in Table 1. 4.9% of women had a history of confirmed COVID-19 infection prior to vaccination. After vaccination, no patient in our cohort was diagnosed with COVID-19 infection. In terms of pregnancy outcomes, 9 had spontaneous abortions, 3 terminated their pregnancies, and 327 have ongoing pregnancies. 85 delivered liveborn infants. There were no stillbirths in our population.

Eight of the nine spontaneous abortions occurred in the first trimester at a range of 6-13 weeks gestation. There was one second trimester loss. The rate of spontaneous abortion among women vaccinated in the first trimester was 6.5%.

The 327 women with ongoing pregnancies have been followed for a median of 4.6 weeks (range 0-17) following their most recent dose. 113 (34.6%) initiated vaccination in the first trimester, 178 (54.4%) in the second trimester, and 36 (11.0%) in the third trimester. Following vaccination, two fetuses (0.6%) developed growth restriction while five (1.5%) were diagnosed with anomalies.

Outcomes for the 85 women who delivered are shown in Table 2. 18.8% of women were diagnosed with a hypertensive disorder of pregnancy. The rate of preterm birth was 5.9%. One preterm delivery was medically indicated while the remaining three were spontaneous. 15.3% of neonates required admission to the neonatal intensive care unit (NICU). 61.5% of NICU admissions were due to hypoglycemia or evaluation for sepsis. Other reasons for admission included prematurity, hypothermia, and transient tachypnea of the newborn. 12.2% of neonates were small for gestational age (SGA) per World Health Organization standards.

Conclusion

This series describes our experience with women who received an mRNA COVID-19 vaccination while pregnant. In line with other published findings[2], we observed no concerning

trends. There were no stillbirths. Our 6.5% rate of spontaneous abortion is within the expected rate of 10%[3] and our preterm birth rate of 5.9% is below the national average of 9.5%.[4] Our rate of pregnancy-related hypertensive disorders is higher than our baseline institutional rate of 9.5%, though this may be due to underlying characteristics of our study population or skewed by small sample size. Our 12.2% rate of SGA neonates is near the expected value as well, given by definition 10% of neonates will be SGA at birth. The NICU admission rate is on par with our institutional rate of 12%. To date, most women in this series have had uncomplicated pregnancies and have delivered at term.

Strengths of this study include using the EMR to identify subjects and gather data. We did not rely on self-enrollment and self-report, reducing selection and recall bias. By performing manual chart review, we obtained detailed and reliable information about individual patients. One limitation of this study is lack of a matched control group consisting of unvaccinated pregnant women, so direct conclusions are unable to be drawn about relative risk of complications. In addition, our cohort is small and may not be generalizable. Finally, many women included are healthcare workers who had early access to the vaccine.

As more pregnant women become eligible for the COVID-19 vaccine, there is an urgent need to report on maternal, neonatal, and obstetrical outcomes with COVID-19 vaccine in pregnancy. The results of this study can be used to counsel and reassure pregnant patients facing this decision.

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Table 1: Study population demographics and vaccination characteristics

Study variable	Total study population N=424
Age (years)	35 (6)
Age ≥35 years	220 (51.9)
Race/ethnicity	
White	262 (61.8)
Black	22 (5.2)
Asian	57 (13.4)
Hispanic/Latino	37 (8.7)
Other/not recorded	46 (10.8)
Pre-pregnancy body mass index (kg/m^2)	23.2 (5.2)[a]
Body mass index ≥30 kg/m^2	42 (11.3)[a]
Pre-pregnancy comorbidities	
Chronic hypertension	28 (6.6)
Pregestational diabetes	5 (1.2)
Cardiac disease	10 (2.4)
Respiratory disease	38 (9.0)
Autoimmune disease	19 (4.5)
Malignancy (past or present)	10 (2.4)
Nulliparous	267 (63.0)
Insurance	
Private	407 (96.0)

Public	16 (3.8)
Unknown/uninsured	1 (0.2)
History of COVID infection	21 (4.9)
Vaccine type	
Pfizer/BioNTech	332 (78.3)
Moderna	92 (21.7)
Gestational age at first dose (weeks)	21.0 (16.4)
Gestational age at second dose (weeks)	23.9 (17.6)
Trimester at vaccine initiation	
First (<14 weeks)	124 (29.2)
Second (14-27 weeks)	193 (45.5)
Third (>28 weeks)	107 (25.2)

Data reported as n (%) or median (IQR)

a. Missing values, n=371

Table 2: Characteristics and outcomes of delivered women

Study variable	Total delivered population N=85
Vaccine type	
Pfizer/BioNTech	65 (86.5)
Moderna	20 (23.5)
Trimester at vaccine initiation	
First (<14 weeks)	0
Second (14-27 weeks)	14 (16.5)
Third (>28 weeks)	71 (83.5)
Time from vaccination until delivery (weeks)	2.86 (0.29 - 12.7)
Both vaccine doses completed prior to delivery	68 (80)
Fetal or neonatal demise	0
Gestational age at delivery (weeks)	39.3 (33.0 - 41.7)
Preterm delivery <37 weeks	5 (5.9)
Mode of delivery	
Vaginal birth	55 (64.7)
Cesarean birth	30 (35.3)
Obstetrical complications	
Pregnancy-related hypertensive disorders	16 (18.8)
Preterm labor	0
Preterm prelabor rupture of membranes	2 (2.4)
Abruption	1 (1.2)

Placenta previa	1 (1.2)
Neonatal intensive care unit admission	13 (15.3)
Birthweight (grams)	3374 (1910 - 4360)
Small for gestational age	10 (12.2)
Congenital anomalies	2 (1.2)

Data reported as n (%) or median (range)