

COVID-19 Vaccine During Pregnancy and Perinatal Outcomes

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Abstract

Initially, there was little data on the safety of immunization against COVID-19 infection in pregnant women. However, previous studies revealed no safety concerns for pregnant women or newborns who received an mRNA COVID-19 vaccine during pregnancy. Therefore, this study aimed to investigate the effects of COVID-19 vaccination on perinatal outcomes. Methods: This cross-sectional study. It started from January 2022 to June 2022. The questionnaire was developed and validated by experts. This study included all women admitted to the postpartum ward who were more than 18 years old and had received the COVID-19 vaccine. The study excluded women without proof of their vaccination status or who could not complete the questionnaire. The primary outcome was the effect of COVID-19 vaccination on gestational age and birth weight. Results: A total of 365 participants. The mean gestational age of the unvaccinated women was 38.83 ± 1.62 weeks ($p < 0.001$), higher than that of vaccinated women (37.69 ± 2.9 weeks). However, the average birth weight for the unvaccinated women was 2.96 ± 0.4 kg ($p = 0.89$) and for vaccinated women (2.97 ± 0.66 kg). Conclusion: COVID-19 vaccination, regardless of the type of vaccine received before, during, or after pregnancy, is not associated with any unfavorable perinatal outcomes.

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Abstract

Introduction:

When COVID-19 vaccination started, there was little data on the safety of immunization against COVID-19 infection in pregnant women. previous studies revealed no safety concerns for pregnant women or newborns who received an mRNA COVID-19 vaccine during pregnancy. This study aimed to investigate the effects of COVID-19 vaccination on pregnant women and perinatal outcomes.

Methods:

This cross-sectional study was conducted in a maternity hospital in King Saud Medical City. It started from January 2022 to June 2022. The questionnaire was developed and validated by experts. This study included all women admitted to the postpartum ward who were more than 18 years old and had received the COVID-19 vaccine. The study excluded women who had no proof of their vaccination status or could not complete the questionnaire. The primary outcome was the effect of COVID-19 vaccination on gestational age and birth weight. The secondary outcomes included the development of polyhydramnios, oligohydramnios, mode of delivery, Apgar score, postpartum hemorrhage, and neonatal intensive care unit admission.

Results:

A total of 365 pregnant women participated in this study. The mean gestational age of the unvaccinated women was 38.83 ± 1.62 weeks, which was significantly ($p < 0.001$) higher than that of vaccinated women (37.69 ± 2.9 weeks). In addition, the average birth weight for the unvaccinated women was 2.96 ± 0.4 kg, and it did not differ significantly ($p = 0.89$) from that of vaccinated women (2.97 ± 0.66 kg).

Conclusion :

COVID-19 vaccination, regardless of the type of vaccine received before, during, or after pregnancy, is not associated with any unfavorable perinatal outcomes for pregnant women or neonates.

Keywords: COVID-19 vaccine, COVID-19 infection, pregnant women, birth weight, perinatal outcomes

Introduction:

COVID-19 was considered a devastating worldwide pandemic after it caused the deaths of millions of people worldwide⁽¹⁾. Many types of research have studied the effects of COVID-19 on physical and mental health during pregnancy⁽²⁻⁴⁾. Compared to nonpregnant women of the same reproductive age, pregnant women are at higher risk of severe illness and mortality from COVID-19, besides also being at increased risk of unfavorable pregnancy outcomes such as preterm birth⁽⁵⁻⁷⁾. At the onset of vaccination during this pandemic, there was a paucity of safety data on COVID-19 immunization in pregnant women. However, later, the available evidence documented no harmful maternal or neonatal consequences of the administration of COVID-19 vaccines to pregnant women, and there is also a growing body of evidence that supports the safety of such vaccination⁽⁸⁻¹²⁾. Findings from three safety monitoring systems revealed no safety concerns for pregnant women who received an mRNA COVID-19 vaccine in their late pregnancy, or for newborns⁽¹³⁾. The acceptance among pregnant women varies, even with the increasing evidence. However, the immunization rate is still low among pregnant women⁽¹⁴⁾. Pfizer and Moderna vaccines are the preferred vaccines for eligible pregnant women of any age because of their more extensive experience of their use in pregnancy⁽¹⁵⁾. Therefore, this study was conducted to investigate the effect of different COVID-19 vaccines approved in saudia arabia on perinatal outcomes.

Methods:

This cross-sectional study was conducted in a maternity hospital in King Saud Medical City (KSMC) from February 2022 to June 2022 after being approved by the KSMC's institutional review board, with reference number H1RI-06-Feb22-01. The questionnaire was developed and validated by experts. A pilot study was conducted before the official study to test the validity of the questionnaire, and the pilot study participants were excluded from this study. All participants gave their written informed consent before they were included in the study. Each participant's vaccination status was checked using the Tawakkalna mobile application, which showed the vaccination status (number of doses, dates, and type of vaccines). This application is mandatory for all citizens, whether Saudi or nonSaudi. In this study, all women admitted to the postpartum

ward who were more than 18 years old and had received the COVID-19 vaccine (Pfizer-BioNTech, Moderna, or Oxford-AstraZeneca) either before or during pregnancy were included as one arm and compared to non-vaccinated women as a second arm. We excluded women who either did not have proof of their vaccination status or refused to complete the questionnaire.

The questionnaire had two parts; the first part included demographic data, including the patient's age, past obstetrical history, and vaccination status (number of doses, time of each dose, and type of vaccine). The second part included the gestational age at delivery and the newborn's birth weight, Apgar score, and neonatal intensive care unit (NICU) admission. The participants were divided into two groups, the vaccinated and nonvaccinated women. The primary outcome was the effect of the COVID-19 vaccine on gestational age and birth weight. The secondary outcomes included the development of polyhydramnios, oligohydramnios, mode of delivery, Apgar score, postpartum hemorrhage, and NICU admission. The mother and the newborn were followed up till the time of discharge from the hospital. Data were collected, cleaned, and verified in an excel sheet, after which they were coded and analyzed using SPSS (version 26). The chi-square and ANOVA tests were used to compare variables to each other.

Results:

Data were collected by professionals from the postpartum ward. A total of 365 women filled out the questionnaire. The mean body mass index was 28.6 ± 5.1 years, and the modal age range was 26–35 years. A total of 289 participants had taken the first dose of the COVID-19 vaccine, 266 had taken the second dose, and 102 had taken the third dose. Approximately 57% of the subject had COVID-19 previously, either before or during pregnancy. It was noticed that some subjects were getting an infection with COVID-19 after vaccination; 88 (24%) during pregnancy and 116 (32%) after delivery. We found that 32 women had gestational diabetes, 26 had hypertension, and 33 had preeclampsia.

Regarding amniotic fluid changes, it was noticed that 14 participants had oligohydramnios and 14 had polyhydramnios. It was found that 197 women had vaginal delivery, 166 underwent cesarean delivery, and only two newborns delivered by vacuum. It was also found that 14 participants had placenta abruption and 26 experienced postpartum hemorrhage. These complications affected the length of hospitalization as it was found that 184 women were hospitalized for one day, 141 for 2–3 days, and 40 for more than three days, as shown in Table 1.

The main finding results showed that the mean gestational age for the unvaccinated women was 38.83 ± 1.62 weeks, which is considered significantly higher ($p = 0.001$) than that for vaccinated women (37.69 ± 2.9 weeks). However, the average gestational age of vaccinated women with the second and third doses was similar to that of vaccinated women with the first dose (37.63 weeks and 37.89 weeks, respectively).

Corresponding results showed that the mean birth weight for unvaccinated women was 2.96 ± 0.4 kg, which did not differ significantly (with $p = 0.89$) from the mean birth weight for vaccinated women (2.97 ± 0.66 kg). It increased after the second and third dose to (2.98 ± 0.68 kg, 3.11 ± 0.56 kg) respectively. All these variations were not statistically significant, as shown in Tables 2 and 3. A comparison of the gestational age at delivery and birth weight between vaccinated and unvaccinated delivered women is shown in Figure 1, together with data for the second and third doses.

Conversely, regarding the perinatal outcome for newborns (NBs), we found that 14 NBs had respiratory complications, two had a fever, and 24 NB were admitted to the NICU, we noticed that none tested positive for COVID-19 irrespective of whether the mothers were vaccinated or unvaccinated.

Figure 1: Gestational age in weeks and birth weight for NBs after delivery for vaccinated and unvaccinated women. The figure also shows differences between vaccinated women with different doses.

Discussion:

The Saudi government offered free COVID-19 vaccines to all clients, irrespective of whether they were Saudi or nonSaudi citizens. The Saudi minister of health approved Pfizer-BioNTech, Moderna, Oxford-AstraZeneca,

and Johnson & Johnson COVID-19 vaccines; however, the participants of this study received all types of vaccines except for the Johnson & Johnson Vaccine. King Saud Medical City (KSMC) is a tertiary center in Riyadh with approximately 6000 deliveries annually, according to KSMC statistics. This study demonstrated that hypertension-related diseases were more in the vaccinated group than in the nonvaccinated group, and this result is comparable to that of a previously published study, which showed that the COVID-19 vaccine might play a role in acute blood pressure elevation due to an imbalance between angiotensin II (overactivity) and angiotensin⁽¹⁶⁾. Preeclampsia was noticed more frequently among vaccinated women than among nonvaccinated ones. It is already known that COVID-19 causes pathophysiological changes that can cause preeclampsia during pregnancy⁽¹⁷⁾. On the other hand, a recent study demonstrated that the COVID-19 vaccine does not cause or lead to preeclampsia⁽¹⁸⁾. It was noticed in this study that thyroid dysfunction was more common in the vaccinated group, irrespective of whether the diagnosis was made before pregnancy or just discovered during pregnancy workup; however, no one of them had a thyroid crisis or was admitted to the ICU. Some reports mentioned that the COVID-19 vaccine could induce some autoimmune or inflammatory adverse effects⁽¹⁹⁾. Despite that, the benefits of the COVID-19 vaccine outweigh the risk of dysfunctional thyroid disorders⁽²⁰⁾. Our study shows that the COVID-19 vaccine does not increase the rate of gestational diabetes. This result is similar to that of a previous report that showed the Safety of the COVID-19 vaccine and did not link it to an increased risk of gestational diabetes⁽²¹⁾. A systematic review could not prove any relationship between the COVID-19 vaccine and gestational diabetes⁽²²⁾. This study showed that the COVID-19 vaccine caused neither polyhydramnios nor oligohydramnios. These findings are comparable to the results of a previous study⁽⁹⁾. This study showed more NICU admissions for newborns delivered to vaccinated women than for those born to nonvaccinated women, and most of these admissions were due to low Apgar scores and respiratory complications. These findings were not linked to any type of vaccine or if the women received the vaccine before or during pregnancy. No neonatal death was reported. A previous observational study found that exposure to mRNA was not associated with higher adverse pregnancy or neonatal outcomes in terms of NICU admission⁽²³⁾. Another published study investigating the relationship between COVID-19 vaccination in pregnancy and adverse perinatal outcomes showed no increase in the rate of NICU admission or low Apgar score⁽²⁴⁾. Another recent review did not show any relationship between COVID-19 vaccination and adverse perinatal outcomes⁽²⁵⁾. Regarding the gestational age and birth weight in women who received the COVID-19 vaccine during pregnancy, our study revealed that the average gestational age of unvaccinated women was longer than that of vaccinated women. Evidence from prior research also supports this finding⁽²⁶⁾. It was also noted that the mean gestational age of vaccinated women for the second and third doses was nearly identical to that of vaccinated women for the first dose. In contrast to this result, one study demonstrated that the gestational age of women who received a second dose of the COVID-19 vaccine was higher than that of women who had received only one dose⁽²⁷⁾. Moreover, the average birth weight of newborns delivered by unvaccinated women was similar to that of newborns delivered by vaccinated women; however, the birth weight increased after the second dose and even more after the third dose. As confirmed by previously published studies, no difference in gestational age and birth weight was observed between vaccinated and unvaccinated pregnant women^(27–31).

Strength : This study examines women who received the COVID-19 vaccine before or during pregnancy with all the available types of vaccine at the time of the study.

Limitations : It is a single-center study that lacks extended follow-up of newborns

Conclusion:

COVID-19 vaccination for pregnant women before, during, or after pregnancy has no adverse perinatal outcomes for either pregnant women or newborns regardless of the type of vaccine. Moreover, the vaccines from Pfizer, Moderna, and AstraZeneca were all safe with minor changes in the prolongation of the gestational age and birth weight.

Author Contributions:

All authors had equal contributions in preparing, writing, and editing the manuscript

Conflict of interest t authors have no conflicts of interest to declare.

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Ethical Approval statement :

The Institutional Review Board (IRB) committee found that the research met the applicability criteria and was eligible for exempt review, Reference No. : H1RI-06-Feb22-01

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