

Araştırma Makalesi/ Research Article

## Effect of Prenatal Maternal COVID-19 Vaccine on Pregnancy Outcomes

### Prenatal Maternal COVID-19 Aşısının Gebelik Sonuçları Üzerine Etkisi

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#### ABSTRACT

**Objective:** The aim of this study is to compare the pregnancy results of prenatal COVID-19 vaccinated and unvaccinated pregnant women who gave birth in our clinic and to present the statistical analyses of the obtained data.

**Methods:** We retrospectively scanned and compared 301 vaccinated and 653 unvaccinated total 954 pregnant data who gave birth between August 2021 and January 2023 in a tertiary university hospital, gynecology and obstetrics clinic in the statistical evaluation, skewness/kurtosis tests were used to assess normality; Student's t-test was applied for parametric data, the Mann-Whitney U test for non-parametric data, and the Paired t-test for comparing 1st and 5th minute APGAR scores.

**Results:** No significant difference was found between the vaccinated and unvaccinated groups in terms of weeks of birth and birth weights. There was no difference between the two groups in terms of blood pH values and 1st/ 5th minute APGAR scores in newborns. The rates of delivery patterns, abortions, presence of complications, and preterm birth were found to have similar frequencies in the two groups.

**Conclusions:** Our study found that the administration of the maternal COVID-19 vaccine during pregnancy is not related to adverse prenatal outcomes. It was determined that only the placental abruption ratio was seen more frequently in the unvaccinated group.

**Keywords:** Pregnancy, COVID-19, Vaccine, Nursing

#### ÖZ

**Amaç:** Çalışmanın amacı, kliniğimizde doğum yapan, prenatal COVID-19 aşılı ve aşısız gebelerin gebelik sonuçlarını karşılaştırmak ve elde edilen verilerin istatistiksel analizlerini sunmaktır.

**Yöntem:** Üçüncü basamak üniversite hastanesi kadın hastalıkları ve doğum kliniğinde Ağustos 2021 ile Ocak 2023 tarihleri arasında doğum yapan 301 aşılı ve 653 aşısız olmak üzere toplam 954 gebenin verileri retrospektif olarak tarandı ve karşılaştırıldı. İstatistiksel değerlendirmede normallik dağılım için skewness/kurtosis testleri, parametrik verilerde Student t testi, parametrik olmayanlarda Mann-Whitney U, 1. ve 5. dakika APGAR karşılaştırmalarında Paired t testi kullanıldı.

**Bulgular:** Doğum haftası ve doğum ağırlığına göre aşılı ve aşısız gruplar arasında anlamlı fark bulunamadı. Yenidoğanlarda kan pH değerleri ve APGAR skorlarının 1./5. dakika skorları arasında anlamlı fark yoktu. İki grubun doğum şekli, abortus oranları, komplikasyon varlığı ve erken doğum oranları benzer bulundu.

**Sonuç:** Çalışmamız gebelikte anneye COVID-19 aşısı uygulanmasının olumsuz doğum öncesi sonuçlarla ilişkili olmadığını gösterdi. Aşılanmayan grupta ablasyo plasenta oranının daha fazla olduğu görüldüğü belirlendi.

**Anahtar Kelimeler:** Gebelik, COVID-19, Aşı, Hemşirelik

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## Introduction

Pregnancy is characterized by a series of changes in the female body, which places the mother's immune system in a down-regulated state. As a result, pregnant women are often considered vulnerable to infectious diseases such as Coronavirus Disease-2019 (COVID-19) (Lone and Ahmad, 2020). Compared to non-pregnant women of childbearing age, pregnant women were found to need intensive care, invasive ventilation, extracorporeal membrane oxygenation, and have higher mortality rates (Harapan et al., 2020). It is already known that women become more prone to viral infections during pregnancy because of the partial weakness in their immune systems. Even seasonal infections in the winter months increase the morbidity rate in pregnant women (Ozcan et al., 2020). Therefore, the COVID-19 pandemic can cause serious health problems in pregnant women. Vaccine hesitancy, a complex social process, refers to the reluctance to receive vaccines when vaccination services are available and accessible. It is one of the greatest threats to global health, and its effects were more discussed during the COVID-19 pandemic than ever before. As in other past viral pandemics, herd immunity through vaccination has become the most effective method of eradication (Goncu Ayhan et al., 2021). Emergency use authorization was granted by World Health Organization (WHO) for some vaccines that were developed on a global scale, but the exclusion of pregnant women from early vaccine studies has led to insufficient data for evidence-based recommendations, which excluded pregnant women from vaccine implementation plans (Abu-Raya, 2021). As a result, pregnant women are reluctant to get vaccinated because they are worried that vaccination will harm their unborn children, due to a lack of knowledge about COVID-19 vaccination safety and efficacy in this population. However they are at increased risk of preterm birth (PTB), small for gestational age (SGA), decreased birth weight, morbidity and mortality from maternal COVID-19 infections (Ozcan et al., 2020). Providing immunity in the fight against this global pandemic is essential to eradicate the disease. Still, a considerable amount of time is required to gather sufficient evidence about the disease and the vaccine's effects. It is also required to obtain results about the vaccination of pregnant women in terms of the mother's and the infant's health. Previous studies have reported that vertical transmission from mother to fetus may occur; however, it was shown that there is no need

to change the mode of birth, late cord clamping, prevent breastfeeding, prevent skin-to-skin contact, and keep the mother and infant in separate environments (Sánchez-Luna et al., 2021). Reactions to the disease or vaccines might differ depending on social characteristics. The types of vaccines for COVID-19 were: Nucleic Acid-Based Vaccines (mRNA and DNA vaccines), inactivated virus vaccines, protein-based vaccines, vector vaccines, virus-like particle vaccines, and live attenuated virus vaccines (Callaway, 2020). The COVID-19 vaccination program was launched in Türkiye first with Sinovac/CoronaVac and later with BioNTech's mRNA BNT162b2 in 2021. Turcovac was implemented in July 2021 (Goncu Ayhan et al., 2021). In our hospital, however, Turcovac has remained unavailable, so pregnant women are vaccinated only with the Sinovac/CoronaVac and BioNTech/Pfizer vaccines.

The rapid spread of the pandemic and the lack of experience with the disease process have increased concerns related to pregnancy. Preventing infection and controlling the disease process in pregnant women is essential because the mortality rates of pregnant women were higher than those of non-pregnant women in other coronavirus infections, such as Middle East Respiratory Syndrome and Severe Acute Respiratory Syndrome, which were seen before (Mullins et al., 2020; Oshay et al., 2021). If the relationship between pregnancy and the COVID-19 vaccine is evaluated, within the framework of ethical rules, it is not appropriate for pregnant women to be included in the clinical phase steps of vaccine and drug research (Rasmussen et al., 2021). Based on these data, the basis of our present study was to evaluate the pregnancy outcomes of expectant mothers who were vaccinated during pregnancy. The study also aimed to evaluate the maternal and fetal/newborn outcomes of patients who received BioNTech's mRNA COVID-19 vaccine or Sinovac/CoronaVac at any stage of their pregnancy.

## Method

The study was designed as a retrospective observational cohort study. A total of 954 women who gave birth at the tertiary university hospital, Department of Gynecology and Obstetrics, between August 2021 and January 2023 were included. Data were obtained retrospectively from electronic medical records and patient files, including demographic characteristics, obstetric history, delivery outcomes, and neonatal findings.

Vaccination status of the participants was verified through the hospital's electronic medical record system. The records including age birth, the type of birth, the number of pregnancies, previous parity and abortion numbers, the week of birth, the presence of preterm labor and low birth weight (SGA), the infant's birth weight, 1st and 5th minute APGAR scores, neonatal cord blood gas values, presentation type of the fetus, presence of oligohydramnios or polyhydramnios, presence of meconium, presence of placenta abruption at birth, presence of gestational diabetes and gestational hypertension were scanned, recorded and compared statistically in vaccinated and unvaccinated pregnant women. Pregnant women who were under the age of 18, who had COVID-19 during pregnancy or known fetal anomalies, and patients with multiple pregnancies were excluded from the study. Term and preterm classifications were made following ACOG recommendations, and infants born before 37 weeks were recorded as preterm birth (Theiler et al., 2021a). Newborn infants were evaluated to determine whether they were SGA or not by considering the values in the percentile curves at birth weeks.

Data were retrospectively collected from the electronic medical records and patient files of women who gave birth at our tertiary university hospital between August 2021 and January 2023. Demographic characteristics, obstetric history,

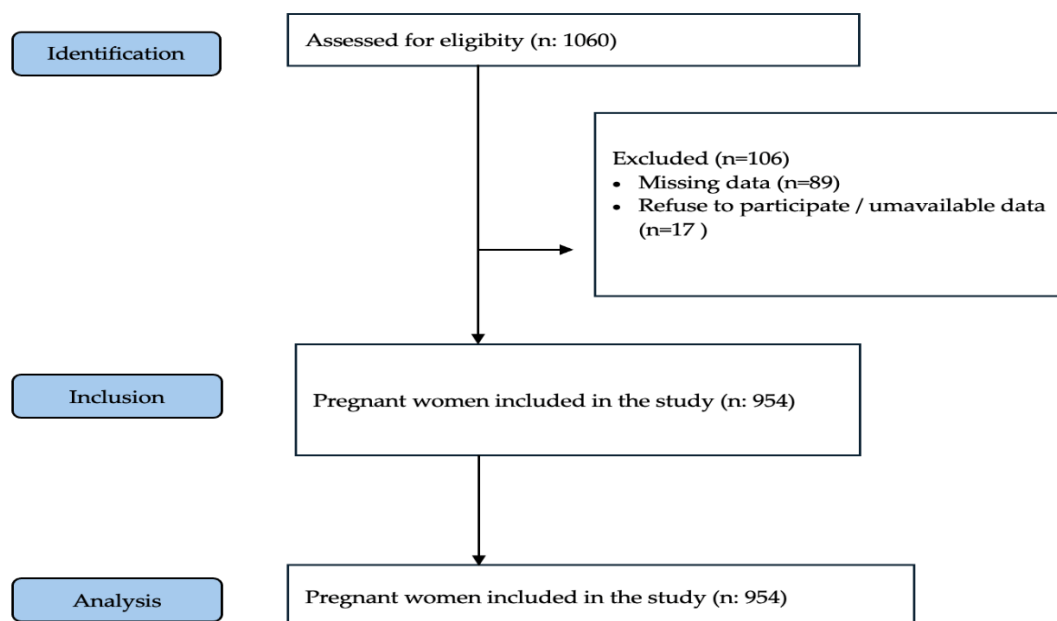
delivery outcomes, and neonatal findings were reviewed and recorded.

#### Ethical Issues

Local Ethics Committee Approval for this study was obtained from Clinical Research Ethics Committee of Çanakkale Onsekiz Mart University (date: 18/05/2022; no: 2022-09-03). In addition, institutional permission was obtained from the hospital administration to access and use patient medical records.

#### Data Analysis

Findings were evaluated using the SPSS Windows version 23.0 package program (Statistical Package for the Social Sciences, IBM Corporation, Chicago, United States), and the statistical significance level was set at 0.05 for all tests. Skewness and Kurtosis tests were used for performing statistical analysis. While the Student's t-test was used to compare normally distributed characteristics between vaccinated and unvaccinated groups, the Mann-Whitney U test was used to compare non-normally distributed attributes between the two independent groups. The measurements of usually distributed APGAR scores at the 1st and 5th minutes in the group were made by using the Independent t-test. As descriptive statistics, mean  $\pm$  standard deviation, minimum, and maximum values were used for numerical variables, and number and % values were given for categorical variables.



**Figure1.** Strengthening the Reporting of Observational Studies in Epidemiology (STROBE). Flow diagram of patients recruitment.

**Results**

The socio-demographic and clinical characteristics of the patients were compared and found to be similar between the three groups (Table 1). While 31.6% (n=301) of the patients had received the COVID-19 vaccine, 68.4% (n=653) had not been vaccinated. While the mean age of all

pregnant women was  $29.50 \pm 5.59$ , the vaccinated and unvaccinated pregnant women were  $29.86 \pm 5.4$  and  $29.34 \pm 5.67$ , respectively (Table1). Overall, maternal demographic and obstetric characteristics, including gravida, parity, abortion history, and the incidence of GDM and GHT, were comparable between vaccinated and unvaccinated women.

**Table 1.** The demographic data and clinical characteristics of the pregnant women.

|            | Vaccinated<br>Mean $\pm$ SD<br>(n:301) | Unvaccinated Mean $\pm$ SD<br>(n:653) | Total<br>(n:954) | p     |
|------------|----------------------------------------|---------------------------------------|------------------|-------|
| Age (year) | $29.86 \pm 5.4$                        | $29.34 \pm 5.67$                      | $29.50 \pm 5.59$ | 0.187 |
| Gravidity  | $2 \pm 1.28$                           | $2 \pm 1.33$                          | $2.17 \pm 1.32$  | 0.187 |
| Parity     | $1.36 \pm 0.56$                        | $1.47 \pm 0.9$                        | $1.43 \pm 0.79$  | 0.169 |
| Abortion   | $1.54 \pm 0.92$                        | $1.54 \pm 0.96$                       | $1.54 \pm 0.94$  | 0.980 |
|            | n(%)                                   | n(%)                                  | n(%)             | p     |
| GDM        | 47 (15.6)                              | 82 (12.6)                             | 129 (13.5)       | 0.199 |
| GHT        | 20 (6.6)                               | 45 (6.9)                              | 65 (6.8)         | 0.888 |

\*GDM: Gestational Diabetes Mellitus, GHT: Gestational Hypertension, SD: standard deviation

When pregnant women were compared in terms of delivery method according to vaccination status, vaginal and cesarean delivery rates were similar in

both groups. Our study also showed that receiving a COVID-19 vaccination during pregnancy did not lead to abortion in pregnant women (Table 2).

**Table 2.** Comparison of maternal and neonatal outcomes between vaccinated and unvaccinated patients

| Maternal and Neonatal Outcomes   | Vaccinated (n:301)   | Unvaccinated (n:653) | p value | Test statistic |
|----------------------------------|----------------------|----------------------|---------|----------------|
|                                  | Mean $\pm$ SD        | Mean $\pm$ SD        |         |                |
| Newborn pH                       | $7.35 \pm 0.05$      | $7.35 \pm 0.06$      | 0.611   | t=0.51         |
| Apgar 1 <sup>st</sup> min. score | $8.59 \pm 0.88$      | $8.57 \pm 1.00$      | 0.660   | t=0.44         |
| Apgar 5 <sup>th</sup> min. score | $9.70 \pm 0.62$      | $9.64 \pm 0.74$      | 0.238   | t=1.18         |
|                                  | Median (Min–Max)     | Median (Min–Max)     |         |                |
| Birth Week                       | 38.71 (32.57- 43.00) | 38.71 (30.71- 41.57) | 0.493   | U              |
| Birth Weight                     | 3220 (1640-4860)     | 3210 (1650-4610)     | 0.665   | U              |
|                                  | n(%)                 | n(%)                 |         |                |
| Cesarean section                 | 231 (76.7)           | 494 (75.7)           | 0.713   | $\chi^2=0.14$  |
| Oligohydramnios                  | 12 (4.0)             | 31 (4.7)             | 0.599   | $\chi^2=0.28$  |
| Polyhydramnios                   | 10 (3.3)             | 30 (4.6)             | 0.362   | $\chi^2=0.83$  |
| Placental abruption              | 2 (0.7)              | 18 (2.8)             | 0.036   | $\chi^2=4.40$  |
| SGA                              | 19 (6.3)             | 50 (7.7)             | 0.456   | $\chi^2=0.55$  |
| Preterm Birth                    | 27 (9.0)             | 64 (9.8)             | 0.680   | $\chi^2=0.17$  |
| Meconium                         | 6 (2.0)              | 10 (1.5)             | 0.606   | $\chi^2=0.26$  |

\*SGA: small for gestational age, SD: standard deviation

Chi-square or Fisher's exact test was used for categorical variables, Student's t-test for normally distributed continuous variables, and Mann-Whitney U test for non-normally distributed continuous variables. A p-value of  $<0.05$  was considered statistically significant.

Maternal-fetal outcomes of the patients who were and were not vaccinated against COVID-19 during pregnancy were evaluated. (Table 2). Among the maternal outcomes, there were no significant differences between the two groups in terms of the Caesarean section rate, gestational age at birth, presence of Gestational Diabetes Mellitus (GDM), presence of Gestational Hypertension (GHT), presence of oligohydramnios, and polyhydramnios. Among the fetal results, there were no significant differences between the two groups in terms of the infants' birth weeks, birth weights, SGA, presence of preterm birth, presence of meconium, newborn cord blood gas pH, APGAR 1st and 5th minute scores. Overall, neonatal outcomes such as gestational age at delivery, birth weight, and APGAR scores were similar between the groups, while placental abruption occurred more frequently in unvaccinated women. The distribution of all variables (except for the presence of placental abruption) was observed at similar frequencies in vaccinated and unvaccinated mothers ( $p>0.05$ ). The incidence of placental abruption in unvaccinated mothers (2.8%) was found to be significantly higher than the incidence of placental abruption in vaccinated mothers (0.7%) ( $p=0.036$ ).

### Discussion

It is hard to conduct any new investigation, like vaccination studies on pregnant women, because of ethical rules. COVID-19, which was first detected in the world in 2019, was first detected in Türkiye in March 2020. With the development of vaccines, they started to be used in Türkiye in 2021. Although there is not enough data on the vaccination results of pregnant women, no serious side effects have been reported in previous studies. In a study conducted by Shimabukuro et al., which included 35.691 pregnant women aged 16-54, it was found that mRNA COVID-19 vaccines did not show any obvious side effects (Shimabukuro et al., 2021a). For these reasons, COVID-19 vaccinations were performed with the consent of pregnant women in Türkiye. The women who gave birth in our clinic during the study were divided into two groups based on whether they had received the COVID-19 vaccine with mRNA technology during pregnancy or not. A comparison was also made between the birth outcomes of the two groups. Goldshtein et al. reported that the average age of patients who received the COVID-19 vaccine was 31.3, and that of those who did not have it was 30.4. Theiler et al. found that the average age of patients who received the COVID-19 vaccine was

31.8 years, and 30.5 years for those who did not. Those who were vaccinated were found to have a statistically significantly higher age (Goldshtein et al., 2021; Theiler et al., 2021b). The average age of vaccinated patients was 29.8 years, and for unvaccinated patients, it was 29.3 years. In the present study, no statistically significant differences were detected between the two groups. In a previous study that evaluated the incidence of GDM and GHT, no differences were detected between vaccinated and unvaccinated groups in either case. (Rottenstreich et al., 2022a). In the present study, no differences were detected in terms of GDM and GHT in the two groups. In a previous study conducted by Rottenstreich et al. in Israel, it was reported that the mean gravidity was 4 in the groups, and the mean parity was (Rottenstreich et al., 2022a). In the present study, the mean gravidity was found to be 2 in the two groups, the mean parity was 1.3 in the vaccinated and 1.4 in the unvaccinated. It is considered that the variation in the number of pregnancies between countries might be related to the socio-cultural and economic levels of the societies. In a previous study that compared pregnant women according to their previous miscarriages, it was found that vaccinated mothers had a higher number of miscarriages. According to our data, no significant differences were detected in the number of abortions between the groups. In a different study conducted in London, it was reported that the cesarean section rate among patients who received at least one dose of the COVID-19 vaccine was 30.8%, compared to 34.1% among those who were not vaccinated. Cesarean section rates were found to be 43.9% in vaccinated patients and 51.3% in unvaccinated patients in a study conducted in Saudi Arabia (Almutairi et al., 2023). In our study, the cesarean section rate was 76.7% in vaccinated patients and 75.7% in unvaccinated patients. In Türkiye, unlike the literature, as a result of high cesarean section rates, the baby's gestational age and weight are lower. In our study, although the gestational age and weight of the babies were lower in both groups, no statistically significant difference was found between the vaccinated and unvaccinated groups. In a previous study that was conducted in the USA, it was reported that 3.2% of patients who received the COVID-19 vaccine during pregnancy had low birth weights and 9.4% had preterm births (Shimabukuro et al., 2021b). In Goldshtein's study, 6.6% of the infants of vaccinated patients had low birth weight, and 4.4% had preterm birth. The rates for the non-vaccinated patients were 6.7% for low

birth weight and 4.1% for preterm birth. The infants of unvaccinated patients had preterm birth. No differences were found between the groups (Goldshtein et al., 2021). The low birth weight rate in infants of vaccinated patients was 6.3%. In our study, the preterm birth rate was 9%, the low birth weight rate in infants of unvaccinated patients was 7.7%, the preterm birth rate was 9.8%, and the two groups were similar. When compared to data from other countries, it was determined that the data obtained here were similar. In a large-scale retrospective study, newborn APGAR scores at 1st and 5th minutes were compared between vaccinated and unvaccinated patients, and no significant differences were reported (Rottenstreich et al., 2022b). The data obtained in correlation with the studies showed that the COVID-19 vaccine during pregnancy did not change newborn APGAR scores. Also, cord blood gas pH values at birth were compared in both groups in our study, and the results of the two groups were found to be similar. In another study that compared the incidence rates of oligohydramnios and polyhydramnios, oligohydramnios was 4.8% in vaccinated mothers, 0% in unvaccinated mothers, polyhydramnios was found to be 4.3% in vaccinated mothers and 1.3% in unvaccinated mothers, and vaccination status did not make a significant difference for these values. In the same study, the presence of meconium was 8.7% in vaccinated mothers and 5.3% in unvaccinated mothers; similarly, no increase was detected in the frequency of meconium due to vaccination. In a retrospective cohort study conducted with 6531 participants, no significant differences were found in the frequency of oligohydramnios, polyhydramnios, and meconium-containing amniotic fluid among pregnant women who received COVID-19 vaccines. The data obtained in the present study were consistent with those in the literature. No increase in the incidence of oligohydramnios, polyhydramnios, and meconium-containing amniotic fluid was detected because of vaccination. A study examining the rate of placental abruption reported rates of 1.1% in vaccinated pregnant women and 2.4% in unvaccinated pregnant women. Another study that reported similar findings found no increase in the incidence of placental abruption due to vaccination. In the data obtained here, placental abruption was detected at a rate of 0.7% in vaccinated pregnant women and 2.8% in unvaccinated pregnant women, indicating that vaccination did not lead to an increase in this condition. However, the rate of placental abruption

was statistically and significantly higher in the unvaccinated group. The higher rate of placental abruption observed in the unvaccinated group may be explained by the fact that the diagnosis is often based on clinical findings without pathological confirmation, as well as by the possibility of undiagnosed or asymptomatic COVID-19 infections during the pandemic period (Schwartz, 2022). It is considered that this difference might have occurred because the diagnosis of abruptio placentae is primarily based on clinical findings, and pathological confirmation is not made. It was also considered that the rate of placental abruption might be high because of undiagnosed COVID-19 infections during the pandemic period. As a result, the lack of an increase in the vaccinated group provided evidence of the vaccine's safety. The vaccinated group received at least one dose of the vaccine. The vaccine was administered in different doses, as part of the Sinovac/CoronaVac and BioNTech/Pfizer groups. Currently, it is believed that COVID-19 vaccine groups do not differ in their effectiveness during pregnancy and breastfeeding. These findings provide important evidence supporting the safety of COVID-19 vaccination during pregnancy and may contribute to reducing vaccine hesitancy among pregnant women, which is of critical importance for both clinical practice and public health.

### Limitations

The retrospective design of our study inevitably imposes certain limitations. Important potential confounders such as maternal body mass index, socioeconomic status, and comorbidities could not be fully assessed, and the exact timing of vaccine exposure during pregnancy could not be controlled. Furthermore, due to the retrospective nature of the study, subgroup analyses according to vaccine type (BioNTech vs. CoronaVac) and number of doses could not be performed. These inherent limitations should be taken into account when interpreting the findings.

### Conclusion and Recommendations

Vaccine studies were accelerated in many countries, and vaccines for COVID-19 were developed and approved for use. Pregnant women were not included in vaccination studies, but they were vaccinated with their consent. The first studies, conducted based on the data obtained from vaccinated women who later became pregnant, showed that the vaccines could also be administered

to pregnant women. As a result of the initial findings, many countries supported the vaccination of pregnant women, and in this way, data on the safety of COVID-19 vaccines during pregnancy began to accumulate. The purpose of the present study was to provide evidence on the reliability of vaccines based on data obtained in our clinic. As a result, the COVID-19 vaccine did not cause an increase in the rate of cesarean section and abortion in pregnant women. The results support that COVID-19 vaccination during pregnancy is not associated with adverse prenatal outcomes in the early period. The conclusion of the present study was to encourage pregnant women to get vaccinated by informing them about the safety of vaccines and their potential to protect against the proven adverse effects of COVID-19. We believe that with new and large-scale studies being conducted, information on the safety of vaccines will be updated regularly and will contribute to the advancement of the scientific world.

Future multicenter and prospective studies with larger sample sizes are recommended to validate the findings of this study and to further investigate the long-term effects of COVID-19 vaccination during pregnancy. Additionally, assessing maternal and neonatal outcomes by vaccine type and gestational timing could provide more detailed guidance for clinical practice.

**Ethics Committee Approval:** The study was conducted in accordance with the Declaration of Helsinki and approved by Clinical Research Ethics Committee of Çanakkale Onsekiz Mart University (date: 18/05/2022; no: 2022-09-03) for studies involving humans.

**Peer-review:** External referee evaluation.

**Author Contributions:** Idea/concept: MAŞ, BD; Design: MAŞ, BD; Consultancy: MND, MAŞ, BD; Data collection and/or Data Processing: MND; Analysis and/or Interpretation: BD, MND, IDA; Source scanning: IDA, BD, MND; Writing of the article: MAŞ, IDA; Critical review: BD, IDA

**Conflict of interest:** The authors declare no conflicts of interest.

**Financial Disclosure:** This research received no external funding.

#### What did the study add to the literature?

- This study provides up-to-date, national-level data by comparing the pregnancy outcomes of women who received the COVID-19 vaccine during pregnancy with those who did not in Türkiye. It contributes to the limited body of research on prenatal vaccine safety and

demonstrates that the incidence of placental abruption was higher in unvaccinated pregnant women.

- The findings indicate that maternal COVID-19 vaccination during pregnancy is not associated with adverse perinatal outcomes.
- In this context, the study offers important critical scientific evidence that may help reduce vaccine hesitancy and support efforts to increase vaccination rates among pregnant women.

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