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Effect of Maternal Covid-19 Vaccine on Pregnancy Outcomes

[1]Merve Senol Avci, Department of Obstetrics and Gynecology, Medical Faculty of Canakkale Onsekiz Mart University, Turkey

[2]Mehmet Nuri Duran, Associate Professor, Department of Obstetrics and Gynecology, Medical Faculty of Canakkale Onsekiz Mart University, Turkey

[3]Bulent Demir, Professor, Department of Obstetrics and Gynecology, Medical Faculty of Çanakkale Onsekiz Mart University, Turkey.

Corresponding Author: Mehmet Nuri Duran, Associate Professor, Department of Obstetrics and Gynecology, Medical Faculty of Canakkale Onsekiz Mart University, Turkey

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Abstract

Objective: Covid-19 is an infectious disease that emerged in 2019 and caused major health problems worldwide in a short time. The experience of treatment and prevention of disease is increasing day by day. It is aimed to prevent the disease with a large number of developed vaccines. Pregnant women should also be protected from Covid-19 in terms of maternal and infant health. The aim of this study is to compare the pregnancy results of women who gave birth in our clinic with prenatal Covid-19 vaccine and women who did not, and to present the statistical analyzes of the obtained data to the literature.

Methods: Our study included 954 women who gave birth in Çanakkale 18 Mart University Health Practice and Research Hospital, Gynecology and Obstetrics Clinic. The data of pregnant women who gave birth in our clinic between 2021 and 2023 were scanned retrospectively and the pregnancy results of those who had the Covid-19 vaccine and those who did not were compared. In the two groups in the study, maternal age, number of gravida, type and week of delivery, baby's birth weight, low birth weight, preterm birth, APGAR scoring, pH values, infant presentation type, oligohydramnios, polyhydramnios, meconium presence, ablatio placenta presence, gestational diabetes, and gestational hypertension rates have been compared.

Results: The rates of delivery, delivery patterns, presence of SGA, oligohydramnios, polyhydramnios, meconium, ablatio placenta, preterm birth, gestational diabetes, and gestational hypertension were compared in women with and without vaccination, and they were observed at similar frequencies in the two groups ($p>0.05$). The incidence of ablatio placentae in unvaccinated mothers (2.8%) was found to be significantly higher than the incidence of ablatio placentae in vaccinated mothers (0.7%) ($p=0.036$).

Conclusion: The data we obtained because of our study showed that the administration of maternal Covid-19 vaccine during pregnancy is not related to negative prenatal outcomes.

Keywords: Pregnancy, Covid-19, Vaccine, mRNA, SARS-CoV-2

Introduction

Coronavirus was first detected in the city of Wuhan in China in the last month of 2019 (COVID-19) and turned quickly into a global pandemic, which was reported by the World Health Organization in March 2020 (1). Although this virus, which caused Covid-19 infection, was initially called 2019-nCoV, it was later named SARS-CoV-2 (Severe Acute Respiratory Syndrome) (2). COVID-19 presents with a wide clinical spectrum that ranges from asymptomatic patients to septic shock and multiorgan dysfunction. Common symptoms include cough, fever, fatigue, nausea, and diarrhea (3). Pregnancy is characterized by a series of changes in the female body, placing the mother's immunity in a down-regulated state, and as a result, pregnant women are often considered vulnerable to infectious diseases (4). 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 (5). As in other viral pandemics in the past, herd immunity through vaccination has become the most effective method of eradication (6). Emergency use authorization was granted by 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 (7). Providing immunity in the fight against this global pandemic is essential to eradicate the disease, but a long time is required to obtain sufficient evidence about the disease and the effects of the vaccine. It is also required to obtain results about the vaccination of pregnant women in terms of the mother's and infant's health. Reactions to the disease or vaccines might differ depending on social characteristics. Based on these data, the basis of the present study, which aimed to evaluate the pregnancy outcomes of expectant mothers who were vaccinated during pregnancy, was provided. The study also aimed to evaluate the maternal and fetal/newborn outcomes of patients who received the mRNA COVID-19 vaccine at any stage of their pregnancy. It is already known that there is human-to-human transmission in most Covid-19 cases (8). The infection is typically characterized by respiratory symptoms, which show droplet transmission (9)Although previous studies reported that vertical transmission from mother to fetus might occur rarely, 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 to prevent this (10).

The types of vaccines for COVID-19 were; Nucleic Acid-Based Vaccines (mRNA and DNA vaccines), inactivated virus vaccines, protein-based vaccines, vector vaccines and virus-like particle vaccines, and live

attenuated virus vaccines (11). It is already known that women become more prone to viral infections during pregnancy because of the partial weakness in their immune systems (12). Even seasonal infections in the winter months increase the morbidity rate in pregnant women (13). Therefore, the Covid-19 pandemic can cause serious health problems in pregnant women. The rapid spread of the pandemic and the lack of experience with the disease process have increased the concerns related to pregnancy. Preventing infection and controlling the disease process in pregnant women is important Was determined that the mortality rates of pregnant women were higher than non-pregnant women in other coronavirus infections, such as Middle East Respiratory Syndrome and Severe Acute Respiratory Syndrome, which were seen before (14,15). No evidence was reported for intrauterine infection transmission from the mother to the newborn In two separate studies conducted with three pregnant women who each had Covid-19 infection in the late stages of pregnancy (16) WHO stated that a mother who had Covid-19 can breastfeed her infant. If pregnancy and the Covid-19 vaccine relation 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 (17). There are a large number of pregnant healthcare staff on a global scale involved in the development of Covid-19 vaccines at the phase 3 clinical stage and after receiving emergency use approval. Some vaccine development steps, which continued for a long time during the pandemic, had to be skipped very quickly, and the Food and Drug Administration (FDA) approved the use of several vaccines in December 2020. There were also vaccines approved by WHO in the following months. As the vaccination process continues, available scientific data are constantly updated. It is considered that both the mother and the newborn infant can be protected by vaccinating pregnant patients. Although there is no difference in terms of side effects of the vaccine in pregnant and non-pregnant women, there has been limited theoretical concern about the possibility of neural tube defects and other congenital defects because of fever, which was partially more common after the second dose of vaccine (approximately 32%) (18,19) However, no increase in the rate of development of any complications, including abortion, was found in previous studies (20)

Centers for Disease (CDC) reported that there is an increase in preterm birth or stillbirth rates and other complications in pregnant women with COVID-19. The high rates of these negative outcomes increase the importance of vaccination during pregnancy to protect the health of the mother and the newborn. In light of these data, the CDC recommended that pregnant or breastfeeding women receive the Covid-19 vaccine (21). Two organizations approved COVID-19 vaccines for pregnant women in the early stages without restrictions (the International Federation of Obstetrics and Gynecology and the Canadian Association of Obstetricians and Gynecologists). The Royal College of Obstetricians and Gynecologists (RCOG) argued that there is no harm in women who are planning pregnancy, during pregnancy or breastfeeding, having the Covid-19 vaccine and reported that there was no change in fertility rates because of the vaccine. It was argued that pregnant women could consult their physicians or get vaccinated without consulting, depending on their wishes (22). considering the risks that might arise as a result of COVID-19 infection, the American College of Obstetricians and Gynecologists (ACOG) stated that the vaccination status of pregnant women must be questioned at every examination and pregnant women

must be encouraged about vaccination (23). As one of the associations in Turkey, the Turkish Gynecology and Obstetrics Association stated that the COVID-19 vaccine must be administered to women who are planning pregnancy, at any week of pregnancy, or who are breastfeeding (24) The Turkish Maternal-Fetal Medicine and Perinatology Association recommended that all pregnant women must be informed about the vaccine and that the vaccine must be vaccinated after the first trimester as much as possible in the group that has risk factors and at the patient's request. The Ministry of Health of Turkiye recommended that pregnant women get COVID-19 vaccines and said that pregnant women can receive mRNA vaccines and inactivated virus vaccines as they decide. As a result of previous studies, it was reported that the abortion rates did not increase for either vaccine (25).

Methods

A total of 954 women who gave birth at Çanakkale Onsekiz Mart University Health Practice and Research Hospital Gynecology and Obstetrics Clinic between August 2021 and January 2023 were included in the present study, which had a retrospective nature and all data were obtained based on the data recorded in the system and patient files of the patients. The records were scanned to determine whether the patients were vaccinated against Covid-19, their age at birth, the type of birth, the number of pregnancies, previous parity and abortion numbers, the week of birth, whether there was a preterm birth, the infant's birth weight, the presence of low birth weight (SGA), 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 recorded. Those who were under the age of 18, those who had COVID-19 during pregnancy, pregnant women with known fetal anomalies, and patients with multiple pregnancies were not included. Term preterm classification was made following ACOG recommendations, and infants born under 37 weeks were recorded as preterm birth (27). Newborn infants were evaluated whether they were SGA or not by evaluating the values in the percentile curves at birth weeks. Appropriate statistical analyses were performed and the findings were evaluated after the data were uploaded to the SPSS program. When performing statistical analysis, the suitability of the data for normal distribution was evaluated using Skewness and Kurtosis. Student's ***t***-test was used to compare normally distributed characteristics in the vaccinated and non-vaccinated groups, and the Mann-Whitney U test was used to compare non-normally distributed characteristics in the vaccinated and non-vaccinated independent groups. The measurements of normally distributed APGAR scores at the 1st minute and 5th minute in the group were made by using the Paired t-test. As descriptive statistics, mean±standard deviation, minimum, and maximum values were used for numerical variables, and number and % values were given for categorical variables. The SPSS Windows version 23.0 (Statistical Package for 4Social Sciences, IBM Corporation, Chicago, United States) package program was used for statistical analysis, and the statistical significance level was taken as 0.05 in all tests.

Results

The socio-demographic and clinical characteristics of the patients were compared (Table 1). It was found that 31.6% (n=301) of the patients had received the Covid-19 vaccine, but 68.4% (n=653) had not been vaccinated. The mean age was 29.50 ± 5.59, the mean gravida was

2.17±1.32, the mean week of birth was 38.61±1.43, the mean birth weight was 3211.04±504.33, the APGAR score average was 8.57±0,96 at the 1st minute and 9.66±0.70 at the 5th minute. Also, 24% (n=229) of the patients had vaginal delivery, 7.2% (n=69) had SGA, 94.8% (n=904) had cephalic presentation, 4.5% (n= 43) had oligohydramnios, 4.2% (n=40) had polyhydramnios, 1.7% (n=16) had meconium, 2.1% had placenta abruption, 13.5% had gestational diabetes, and gestational hypertension was detected in 13.5% and preterm birth was detected in 9.5%.

Table 1. The demographic data and clinical characteristics of the patients

GDM: Gestational Diabetes Mellitus, GHT: Gestational Hypertension, SGA: Small for Gestational Age, avr: average, sd: standard deviation

		n(SAYI)	%
Vaccination	Yes	301	31.6
	No	653	68.4
SGA	Yes	69	7.2
	No	885	92.8
Type of Birth	Vaginal birth	229	24
	Cesarean section	725	76
Preterm Birth	Yes	91	9,5
	No	862	90.5
Oligohydramnios	Yes	43	4,5
	No	911	95.5
Polyhydramnios	Yes	40	4,2
	No	914	95.8
Meconium	Yes	16	1,7
	No	938	98.3
Ablation Placenta	Yes	20	2,1
	No	934	97.9
GDM	Yes	129	13.5
	No	825	86.5
GHT	Yes	65	6,8
	No	889	93.2
	avr±sd	min-max	
Age	29.50±5.59	18-47	
Gravida	2.17±1.32	1-11	
Birth Week	38,61±1.43	30,71-43	
Birth Weigh	3211.04±504.33	1640-4680	

Apgar 1st min. score	8.57±0.96	1-10	
Apgar 5st min. score	9.66±0.70	4-10	
Yenidoğan pH	7.35±0.06	6.89-7.49	
Abortus	1.54±0.94	1-6	
Parite	0.76±0.93	0-9	

Maternal-fetal outcomes of the patients who were and were not vaccinated against COVID-19 during pregnancy were evaluated (Table 2). Among the maternal results, there were no significant differences between the two groups in terms of the Caesarean section rate, weeks of 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, presence of Small for Gestational Age (SGA), presence of preterm birth, presence of meconium, newborn cord blood gas pH, APGAR 1st and 5th-minute scores. The distribution of all variables (except for the presence of abruption placenta) was observed at similar frequencies in vaccinated and unvaccinated mothers ($p>0.05$). It was also found that the incidence of placental abruption was distributed at statistically and significantly different frequencies in vaccinated and unvaccinated patients ($p = 0.036$).

Table 2. The comparison of the average ages of vaccinated and unvaccinated patients

GDM: Gestational Diabetes Mellitus, GHT: Gestational Hypertension, SGA: Small for Gestational Age, avr: average, sd: standard deviation

	Vaccinated (n:301) avr±sd	Unvaccinated (n:653) avr±sd	*p* value
Cesarean section	231 (76.7)	494 (75.7)	0.713
GDM	47 (15.6)	82 (12.6)	0.199
GHT	20 (6.6)	45 (6.9)	0.888
Oligohydramnios	12 (4.0)	31 (4.7)	0.599
Polyhydramnios	10 (3.3)	30 (4.6)	0.362
Ablation Placenta	2 (0.7)	18 (2.8)	**0.036**
Birth Week	38.71 [32.57- 43]	38.71 [30.71- 41.57]	0.493
Birth Weigh	3220 [1640-4860]	3210 [1650-4610]	0.665
SGA	19 (6.3)	50 (7.7)	0.456
Preterm Birth	27 (9)	64 (9.8)	0.680
Meconium	6 (2)	10 (1.5)	0.606
Newborn pH	7.35±0.05	7.35±0.06	0.611

Apgar 1st min. score	8.59 ± 0.88	8.57 ± 1	0.660
Apgar 5st min. score	9.70 ± 0.62	9.64 ± 0.74	0.238

Discussion

Covid-19, which was first detected in the world in 2019, started to be detected in our country for the first time in March 2020. As part of the measures that were taken against the COVID-19 pandemic throughout the country, our clinic served only COVID-19 patients between March and May 2020. Wards started to be provided to all patients within certain restrictions as of June 2020. According to the COVID-19 PCR results of the patients, hospitalizations were performed under appropriate isolation conditions. With the development of vaccines, they started to be used in our country 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 that was conducted by Shimabukuro et al., which included 35.691 pregnant women who were aged 16-54, it was found that mRNA Covid-19 vaccines did not show any obvious side effects (20). For these reasons, Covid-19 vaccinations were performed with the consent of pregnant women in our country. The women who gave birth in our clinic in our study were divided into two groups depending 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 had the COVID-19 vaccine was 31.8 and 30.5 for those who did not, and those who were vaccinated were found to have a statistically significantly higher age (26,27). The average age of vaccinated patients was 29.8 and for unvaccinated patients was 29.3 In the present study, no statistically significant differences were detected between the two groups. In a previous study that was conducted by Rottenstreich et al. in Israel, it was reported that the mean gravida was 4 in the groups and the mean parity was 3 (28). In the present study, the mean gravida 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 miscarriage (28). According to our data, no significant differences were detected in the number of abortions between the groups. In a different study that was conducted in London, it was reported that the cesarean section rate of patients who received at least 1 dose of the COVID-19 vaccine was 30.8%, and that of those who were not vaccinated was 34.1%. Cesarean section rates were found to be 43.9% in vaccinated patients and 51.3% in non-vaccinated patients In a study conducted in Saudi Arabia (29). In the present study, the cesarean section rate was 76.7% in vaccinated patients and 75.7% in unvaccinated patients. Although no differences were detected in the groups, the high cesarean section rates differed from the literature. Also, when the results of the studies were examined, it was determined that there were differences between the cesarean section rates between the countries. The expected time for vaginal birth is not expected in elective cesarean section cases Because of the high cesarean section rates in our country, therefore, the birth week is considered to be lower. When

evaluated in terms of birth weights, no differences were detected between vaccinated and unvaccinated groups, which supports the literature data.

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 (30). In Goldshtein's study, 6.6% low birth weight and 4.4% preterm birth were detected in the infants of vaccinated patients, 6.7% low birth weight and 4.1% preterm birth were determined in the infants of unvaccinated patients, and no differences were found between the groups. The low birth weight rate in the infants of vaccinated patients was 6.3% In our study, the preterm birth rate was 9%, the low birth weight rate in the infants of unvaccinated patients was 7.7%, the preterm birth rate was 9.8%, and the two groups were similar. When compared to the data of other countries, it was determined that the data obtained here were similar. In a large-scale retrospective study, newborn APGAR 1st and 5th-minute scores were compared between vaccinated and unvaccinated patients and no significant differences were reported (31) 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, and similarly, no increase was detected in the frequency of meconium because of vaccination. In a retrospective cohort study that was conducted with 6531 participants, no significant differences were found in the frequency of oligohydramnios, polyhydramnios, and meconium-containing amniotic fluid between pregnant women who received Covid-19 vaccines (32). The data obtained in the present study were similar to the data in the literature. No increase in the incidence of oligohydramnios, polyhydramnios, and meconium-containing amniotic fluid was detected because of vaccination. When the rate of placental abruption was examined in a study it was reported that the rate was 1.1% in vaccinated pregnant women and 2.4% in unvaccinated pregnant women. Another study that reported similar findings reported that there was no increase in the incidence of placental abruption because of vaccination (5). 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, and it did not show an increase because of vaccination. However, the rate of placental abruption was statistically and significantly higher in the unvaccinated group. It is considered that this difference might have occurred because the diagnosis of abruptio placenta is mostly 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 safety of the vaccine. In a previous study that evaluated the incidence of Gestational Diabetes Mellitus and Gestational Hypertension, no differences were detected between vaccinated and unvaccinated groups in both cases (31) In the present study, no differences were

detected in terms of gestational diabetes and gestational hypertension in the two groups.

Conclusion and Recommendations

COVID-19 was declared a global pandemic by the World Health Administration (WHO) on March 11, 2020, and studies on better recognition and treatment of the disease have been continuing rapidly since then and the data obtained are increasing rapidly day by day. Preventing the disease as well as treating it is of great importance for public healthcare. Vaccine studies were accelerated in many countries and vaccines for Covid-19 were produced and approval for use was obtained. Pregnant women were not included in vaccination studies but were vaccinated with their consent, and the first studies conducted based on the data obtained as a result of the fact that some vaccinated women were later found to be pregnant, showed that the vaccines could also be administered to pregnant women. As a result of the initial findings, many countries supported pregnant women to be vaccinated, and in this way, the data on the safety of COVID-19 vaccines during pregnancy began to increase. In the present study, the purpose was to provide evidence about the reliability of vaccines based on the data obtained in our clinic. The results support that COVID-19 vaccination during pregnancy is not associated with negative prenatal outcomes in the early period. Our conclusion in the present study was to encourage pregnant women to get vaccinated by informing them about the safety of vaccines to protect them from the proven negative effects of Covid-19. We believe that with new and large-scale studies to be conducted, information on the safety of vaccines will be updated day by day and will contribute to the scientific world.

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