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Research Article

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Maternal and Neonatal Outcomes Following COVID-19 Vaccination in Pregnancy

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Abstract

Objective: *The present study was done with the aim of investigating maternal and neonatal outcomes following COVID-19 vaccination in Pregnancy.*

Materials and Methods: *This cross-sectional study was carried out on 1645 pregnant women (685 COVID-19 vaccinated during pregnancy and 960 non- vaccinated). The study was conducted in the public hospitals of Kerman, located in southeastern of Iran, from January to March ,2022. Maternal and neonatal outcomes were measured by interview and observation during labor, delivery and postpartum.*

Results and Discussions: *All vaccinated women had received the Sinopharm vaccine The mean birth weight of the neonates was 2778.9 ± 877.9 grams in the vaccinated and 2827± 843.6 grams in the non-vaccinated group. The first minute Apgar score was 8.05 ± 1.89 in the vaccinated and 8.15 ± 2.05 in the non-vaccinated group. The risk of maternal morbidities was not significantly different in two groups (p>0.001). Only the risk of NICU admission was higher in vaccinated women than in non-vaccinated women (OR=3.39, P < 0.001).*

Conclusion: *Since serious complications associated with receiving COVID-19 vaccines during pregnancy were not observed in the present study, and COVID-19 can have serious and fatal effects during pregnancy, it seems reasonable to recommend vaccination during pregnancy to prevent the potential risk posed by COVID-19.*

Keywords: COVID-19. Vaccination, Morbidity, Obstetric Outcomes

1. Introduction

During the COVID-19 pandemic, pregnant and lactating women were considered among the high-risk groups. Very little is known about the consequences of this emerging virus on pregnancy and the fetus [1]. There is currently no evidence that COVID-19 is transmitted from mother to fetus. Although the overall effect of MERS-CoV on mothers and birth outcomes requires further evaluation, a descriptive research has shown that MERS-CoV may pose serious risks to maternal and infant health [2]. Moreover, it can cause sudden bleeding with premature rupture of membranes (PROM), mild to moderate fluctuation of fetal heart rate, and placental abruption leading to an emergency C-section [3]. Studies conducted during the outbreak of severe acute respiratory syndrome coronavirus 1 (SARS-CoV) during pregnancy reported consequences such as miscarriage, preterm delivery, intrauterine growth restriction (IUGR), intensive care unit

admission, renal failure, and coagulation disorder [4,5]. Fetal complications of COVID-19b include miscarriage (2%), IUGR (10%), and preterm delivery (39%) [6]. Physiological changes that occur during pregnancy make the mother susceptible to severe infections [7]. Anatomical changes such as an increase in the transverse diameter of the ribcage and elevated diaphragm reduce maternal tolerance to hypoxia [8]. Changes in the lung volume and vasodilation can lead to mucositis and increased secretions in the upper respiratory tract. Additionally, changes in the cell-mediated immune system make pregnant women more susceptible to infection with intracellular organisms such as viruses [9].

Vaccination is a fundamental strategy to prevent diseases. Previous studies have confirmed the favorable effect of the influenza vaccine in reducing the severity of maternal and neonatal disease and have not reported any pregnancy complications caused by vaccination [10,11]. However, there is no evidence of the effectiveness of COVID-19 vaccines on the severity of the disease or its maternal and neonatal complications. Therefore, the present study was conducted to investigate the maternal and neonatal outcomes in mothers receiving COVID-19 vaccines during pregnancy.

2. Materials and Methods

The present study was a descriptive-comparative cross-sectional study. The samples included women who were pregnant during the COVID-19 pandemic. The study was conducted in the public hospitals of Kerman, located in southeastern Iran, from January to March. Inclusion criteria were mothers' consent to participate in the project, singleton pregnancy, absence of chronic diseases, such as diabetes, hypertension, asthma, etc., before pregnancy, and no COVID-19 infection during pregnancy. After receiving the ethics code of IR.KMU.REC.1400.593, the researchers referred to the public hospitals of Kerman and interviewed the pregnant women who had referred to those centers for their delivery. If these women met the inclusion criteria, they were included in the study by providing informed written consent after the study objectives were explained to them. During the study period, 1821 pregnant women referred to public centers for their delivery. One hundred and Seventy-six of these women did not meet the inclusion criteria, and finally, 1645 women were included. During the research process, the participants were asked about their pregnancy information, and the rest of the information was recorded by direct observation of labor, delivery, and neonatal outcomes.

2.1 Research Tools

1. Questionnaire for demographic characteristics and maternal medical history during the pregnancy
2. An observation checklist: This researcher-made checklist, which the researcher completed through observation, collected information on the clinical and obstetric status of the mother and fetus during labor and after childbirth. Content validity was used to evaluate the scientific validity of this checklist. Ten members of the obstetrics faculty reviewed the content of the checklist, and their comments were applied. A concurrent observation test was used to evaluate the reliability of the checklist. For this purpose, the checklist was completed for ten of the samples simultaneously by the researcher and a colleague who was scientifically on par with the researcher.

2.2 Data Analysis

The data obtained from the samples were statistically analyzed using SPSS version 20.0. In the present study, descriptive statistics, including central tendency, dispersion, and drawing tables of statistical information of individuals, and analytical statistics, including the independent t-test for quantitative variables, the Mann-Whitney test for ranked variables, chi-squared for dichotomous variables, and logistic regression with the significance level of $P \leq 0.05$ were used to compare the outcomes of the two groups.

3. Results

Among the 1645 participants of the present study, 685 had been vaccinated during pregnancy; all had received the Sinopharm vaccine. The other 960 had not received the vaccine during pregnancy. The mean age of the vaccinated group was 30.4 ± 6.32, and the mean age of the non-vaccinated group was 29.95 ±6.52. The mean gestational age was 35.7 ± 3.98 in the vaccinated group and 36.5 ± 4.09 weeks in the non-vaccinated group. The number of pregnancies in most people in the vaccinated and non-vaccinated groups was 3 and 1, respectively. The majority of the participants in both groups did not have a diploma and were homemakers (Table 1).

Variable		**With Covid 19-vaccine in pregnancy**	**Without covid19- vaccine in pregnancy**
Job	Housekeeper	425 (62.04%)	675 (70.31%)
	others	260 (37.95%)	285 (29.68%)
Education level	High school education	465 (67.88%)	693 (72.18%)
	Diploma	85 (12.4%)	144(15%)
	University education	135 (19.7%)	123 (12.81%)
Variable		**Mean ± SD**	**P value**
Age (year)		30.4±6.32	29.95±6.52	P=0.3
Gestational age (week)		35.7±3.98	36.5±4.09	P= 0.41

Table 1: Demographic characteristics of participants

3.1 Pregnancy and Delivery Complications

59.88% of the non-vaccinated women had vaginal delivery, while most participants in the vaccinated group (84.67%) had cesarean delivery, which was mainly due to breech presentation. The mean birth weight of the neonates was 2778.9 ± 877.9 grams in the vaccinated and 2827± 843.6 grams in the non-vaccinated group(P=0.3). The mean of first minute Apgar score was 8.05 ± 1.89 in the vaccinated and 8.5 ± 2.05 in the non-vaccinated group (P= 0.41). In both groups, the most common reason for Neonatal Intensive Care Unit (NICU) admission was transient tachypnea of the newborn (TTN)(Table2).

Variable		**With Covid 19-vaccine in pregnancy**		**Without covid19- vaccine in pregnancy**
Cause of NICU admission	TTN (Transient Tachypnea of Neonatal)	185(59.67%)		252(62.22%)
	RDS	70(22.58%)		81(20. %)
	Meconium Aspiration	40(12.9%)		51(12.59%)
	Addiction of mother	15(4.83%)		21(12.59%)
Total NICU Admission		310(45.25%)		405(42.18%)
Variable		**Mean ± SD**		**P value**
Birthweight(gr)		2778.9 ± 877.9	2827± 843.6	P=0.3
First minute Apgar		8.05±1.89	8.15±2.05	P= 0.41
Fifth minute Apgar		9.19±2.03	9.17±2.25	P= 0.11

Table 2: Comparison of Neonatal outcomes between two groups

As shown in Table 3, there is no significant difference in the probability of developing gestational diabetes (OR = 0.62, P = 0.31), pre-eclampsia (OR = 0.50, P = 0.34), Preterm labor (OR = 0.75, P = 0.82), post-term (OR = 0.84, P = 0.32), Placenta Abruption (OR = 1.59, P = 0.70), Atony (OR = 0.21, P = 0.07), etc. in women who received and did not receive the vaccine. Only the probability of admission of the newborn in the intensive care unit was higher than that of the unvaccinated mothers (OR =3.39, P=0.01).

Variable		**Frequency (Percent)**	**Covid 19 vaccine**		**Odds ratio**	**95% C.I.**		**Sig.**
			yes	**no**		**Lower**	**Upper**	
GDM	yes	1454 (87.96)	620 (90.5)	834 (86.9)	0.62	0.14	7.93	0.31
	no	191 (12.04)	65 (9.5)	126 (13.1)				
preeclampsia	yes	230 (14.44)	80 (11.7)	150 (15.6)	0.50	0.12	2.13	0.34
	no	1415 (85.56)	605 (88.3)	810 (84.4)				
Preterm labor	yes	203 (12.47)	80 (11.7)	123 (12.8)	0.75	0.07	8.42	0.82
	no	1442 (87.53)	605 (88.3)	837 (87.2)				
prom	yes	1393 (86.87)	505 (73.7)	888 (92.5)	0.63	0.08	4.23	0.51
	no	252(13.13)	180 (26.3)	72 (7.5)				
Fetal Movement decrease	yes	1564 (95.40)	640 (93.4)	924 (96.3)	0.93	0.18	3.52	0.24
	no	81 (4.60)	45 (6.6)	36 (3.8)				
Placenta Abruption	yes	91 (5.91)	25 (3.6)	66 (6.9)	1.59	0.15	16.42	0.70
	no	1554 (94.09)	660 (96.4)	894 (93.1)				
post term	yes	1042 (93.65)	645 (94.2)	397 (93.4)	0.84	0.09	5.14	0.32
	no	103 (6.35)	40 (5.8)	63 (6.6)				
Delivery type	vaginal	678 (46.39)	105 (15.3)	573(59.7)	0.52	0.19	1.42	0.20
	cesarean	958 (53.61)	580 (84.7)	387 (40.3)				
Atony	yes	113 (7.22)	35 (5.1)	78 (8.1)	0.21	0.04	1.14	0.07
	no	1229 (79.43)	350 (51.1)	879 (91.6)				
Oligohydramnios	yes	194(12.18)	80 (12.30)	114 (12.14)	0.63	0.08	2.13	0.21
	no	1395 (87.81)	570 (87.69)	825 (87.85)				

Excretion of meconium	yes	58 (3.06)	40 (5.8)	18 (1.9)	2.88	0.18	46.79	0.46
	no	1561 (95.19)	640 (93.4)	921 (95.9)				
Neonate Resuscitation need	yes	115 (8.10)	10 (1.5)	105 (10.9)	1.21	0.03	46.91	0.92
	no	1174 (75.71)	340 (49.6)	834 (86.9)				
NICU admission	yes	715 (43.11)	310 (45.3)	405 (42.2)	3.39	1.37	8.39	0.01
	no	899 (54.92)	365 (53.3)	534 (55.6)				
NST	nonreactive	14(0.88)	5 (.7)	9 (.9)	5.65	0.35	90.53	0.22
Mother Hypertension	yes	25 (1.53)	10 (1.5)	15 (1.6)	2.05	0.01	367.04	0.79
	no	1617 (98.25)	675 (98.5)	942 (98.1)				
First minute Apgar	7<	392 (18.82)	335 (48.9)	57 (5.9)	0.33	0.00	48.18	0.66
	>7	1227 (79.43)	345 (50.4)	882 (91.9)				
Fifth minute Apgar	7<	81 (5.03)	30 (4.4)	51 (5.3)	0.80	0.31	2.08	0.65
	7>	1538 (93.22)	650 (94.9)	888 (92.5)				
Birthweight	2500<	844 (35.01)	640 (67.2)	204 (21.3)	0.35	0.02	7.60	0.50
	2500>	907(59.74)	220 (32.1)	687 (71.5)				

Table 3: Adjusted odds ratio of maternal and neonatal outcomes

4. Discussion

The present study's findings indicated that the women who had received COVID-19 vaccines during their pregnancy did not experience any pregnancy and neonatal complications that would require long-term hospitalization or special treatments. The results were in line with previous studies demonstrating that preterm delivery and low birth weight are not associated with receiving COVID-19 vaccines during pregnancy. However, preterm labor was associated with vaccination in the second trimester of pregnancy [12-14]. The women in the present study had received the vaccines in different trimesters, but preterm labor did not increase among them. Postpartum complications such as infection, embolism, atony, and hysterectomy were not different in the vaccinated and non-vaccinated groups. As demonstrated in other studies, the rate of postpartum hemorrhage, pulmonary embolism, and maternal ICU admission did not differ between the two groups [14,15]. There was no difference between the rates of placental abruption, preeclampsia, coagulation disorders, and maternal hypertension in the two groups. This was in line with the results of previously published articles reporting that the rates of placental abruption and blood pressure disorders during pregnancy were not different between vaccinated and non-vaccinated groups [14,16]. However, Trostle argued that the increase in blood pressure disorders was associated with receiving COVID-19 vaccines [17].

Findings indicated that a high percentage of vaccinated women had C-sections, mainly due to breech presentation. However, previous studies have shown that the C-section rate is not different in the two groups [7,16]. According to the findings, women who were vaccinated during pregnancy had no higher risks of complications such as GDM, PROM, reduced fetal motility and post-term pregnancy, compared to non-vaccinated women. However, various studies have shown that COVID-19 vaccines cause no significant pregnancy complications. Moreover, increased blood pressure or changes in blood glucose levels in diabetic or non-diabetic individuals have not been reported in vaccine trial data [18]. However, Mishra reported three cases in India that had mild to moderate increase in blood glucose following COVID-19 vaccination [19]. The chance of NICU admission was higher in the vaccinated compared to the non-vaccinated group. Other studies have reported that the rate of NICU admission is not different between the two groups [14,15]. However, Trostle stated that 15.3% of neonates of vaccinated mothers were admitted to the NICU and that the main cause of admission was hypoglycemia in the present study, the main reason for NICU admission was tachypnea but, the reason for the difference with the non-vaccinated group was respiratory distress [17].

4.1 Limitations of the Study

Lack of access to participants' medical records and self-report of medical conditions before and during pregnancy were the main limitations of the present study. The governmental study environment were other limitations of the study. Despite the complete and high-quality equipment of public hospitals in childbirth and neonatal intensive care, as Kerman public hospitals were also the centers for the admission of COVID-19 patients, the fear of entering such places reduced the number of referrals to these centers. Another limitation of the present study was that we could not evaluate the rates of miscarriages, ectopic pregnancies, and stillbirths associated with vaccines because the mothers did not have accurate information about the time of receiving the vaccines during their pregnancy.

5. Conclusion

As COVID-19 vaccination didn't have serious and fatal effects during pregnancy, it seems reasonable to recommend vaccination during pregnancy to prevent the potential risk posed by COVID-19.

Abbreviations

IUGR: Intra Uterine Growth Restriction GDM: Gestational Diabetes Mellitus

PROM: Preterm Rupture of Membrane NICU: Neonatal Intensive Care Unit

Declarations

Ethics Approval and Consent to Participate

This manuscript was derived from a project that was approved by the Ethics Committee of Kerman University of Medical Sciences, Iran (the code of ethics No. IR.KMU.REC.1400.593). Written informed consent was obtained from the parents to enter the study. At the request of the ethics committee, the study was conducted in accordance with the Declaration of Helsinki and Ethics Publication on Committee (COPE).

Consent for Publication

Written informed consent was obtained from the participants for publication.

Availability of Data and Materials

The data generated during the current study are not publicly available due to privacy or ethical restrictions.

Competing Interests

The authors declare that they have no competing interests.

Authors' Contributions

Conception and design : KA,AH.SHS
Administrative support : MM,MK
Provision of study materials or patients : MK,KA
Collection and assembly of data : KA,AH
Data analysis and interpretation : MM,SHS
All authors contributed to data collecting, data analysis have agreed on the manuscript and approved the final manuscript.

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