



Evaluating the Newborn-Related Outcomes of Pregnancy After COVID-19 Sinopharm Vaccination

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Abstract

Background: In December 2019, acute respiratory infection caused by coronavirus 2 (SARS-CoV-2) was diagnosed for the first time, leading to the COVID-19 pandemic. Pregnancy is known to be an independent risk factor for severe COVID-19 infection. Therefore, pregnant women have been among the priorities to receive the COVID-19 vaccines. The results following the injection of these vaccines are still unknown.

Objectives: The present study evaluated the effects of Sinopharm vaccination on newborns.

Methods: This study is a retrospective cohort study conducted among pregnant women aged 40 years or younger and their newborns, who were admitted to Baharloo Hospital, Tehran, in the year 2023. A total of 427 cases were reviewed, 144 of which were injected with the Sinopharm vaccine 3 months before pregnancy, 124 cases had been vaccinated during the first trimester, and 157 cases were unvaccinated. The data gathered from the files included: Name, date of admission, history of parity, the number of previous childbirths and the method (vaginal or caesarian section), drug history, date of injection according to the vaccination certificate, type of vaccine, and the number of doses up to the date of childbirth. The data gathered concerning the newborns included: Sex, 1st and 5th minute Apgar score, weight, indication for admission to neonatal intensive care unit and the duration, need for resuscitation, TTN, and newborn's death. The information was gathered from the newborn files by midwives and doctors. The data was then analyzed by SPSS version 26 software.

Results: According to the data analysis, unvaccinated individuals exhibited significant differences in delivery type ($P = 0.012$), history of COVID-19 ($P < 0.001$), presence of a positive past medical history ($P < 0.001$), and a positive drug history ($P < 0.001$) compared to vaccinated individuals. Furthermore, there was a significant difference in preterm birth and stillbirth rates between the two groups (odds of preterm: 0.84 (0.79 - 0.93), $P = 0.04$, odds of stillbirth: 0.83 (0.43 - 0.81), $P < 0.001$), which remained significant even after accounting for potential confounding factors (odds of preterm: 0.86 (0.67 - 0.89), $P < 0.001$, odds of stillbirth: 0.83 (0.43 - 0.79), $P < 0.001$).

Conclusions: There was no relativity discovered between Sinopharm vaccination and a higher rate of stillbirth and newborn mortality. However, newborns of mothers vaccinated in the first trimester showed a significantly lower 5th minute Apgar.

Keywords: Covid-19, Vaccination, Prenatal Outcome

1. Background

In December 2019, infections related to acute respiratory syndrome caused by Coronavirus 2 (SARS-CoV-2) were observed for the first time, which then led to the COVID-19 pandemic (1). Since its breakthrough, COVID-19 has caused vast financial and health consequences worldwide (2, 3). Pregnant individuals

and infants may be more vulnerable to COVID-19 because the physiological changes that occur during pregnancy, such as those affecting the cardiorespiratory and immune systems, can alter the body's response to SARS-CoV-2 infection during pregnancy (4). Additionally, certain perinatal outcomes were more common in newborns born to mothers infected with COVID-19 during pregnancy, including preterm birth (especially

via cesarean section), low 5-minute Apgar scores, admission to the neonatal intensive care unit, and neonatal death (5).

The development of vaccines has proved to be one of the most satisfying means to prevent COVID-19 infections, saving millions of lives annually worldwide. Furthermore, the preferred approach is to develop safe and effective vaccines with minimum side effects (6). Vaccination against SARS-CoV-2 during pregnancy is considered an important factor in preventing illness in pregnant individuals. Despite this, the International Federation of Gynecology and Obstetrics and the US Centers for Disease Control and Prevention have subsequently recommended that COVID-19 vaccination be unrestricted for women who are currently pregnant (7). Studies have shown that pregnant women who receive the COVID-19 vaccine develop a robust immune response, which is stronger than the response seen with COVID-19 infection (8). Specifically, vaccinated pregnant women were found to have IgG (including subpopulations IgG1, IgG2, IgG3), IgM, and IgA antibodies against the SARS-CoV-2 spike protein (S1 and S2), receptor-binding domain (RBD), as well as pseudovirus neutralizing antibodies and Fc receptor-binding antibodies in their maternal serum. Additionally, IgG antibodies were detected in the blood of nearly all vaccinated pregnant women and their newborns' umbilical cord blood just four weeks after the first vaccine dose (9-11).

The Sinopharm vaccine, which is an inactivated vaccine type, was one of the first COVID-19 vaccines to receive approval for use in Iran's general population, and subsequently for use in pregnant women as well. This vaccine utilizes inactivated viral antigens to stimulate the body's immune system to generate antibodies, thereby priming the immune system to respond to future SARS-CoV-2 infections (10). Clinical trials of COVID-19 vaccines have shown that recipients commonly experienced short-term side effects like pain, redness or swelling at the injection site, fatigue, headache, chills, fever, and muscle/joint pain, when compared to the placebo group. However, the incidence of serious adverse events was similar between the vaccine and placebo groups. Additionally, in the phase 1 and 2 clinical trials of the Sinopharm vaccine involving 640 participants in China, the most frequently reported side effects among vaccine recipients were mild and self-limiting injection site pain and fever, which did not require any treatment (6,12).

One of the most critical aspects of the COVID-19 vaccine clinical trials was the exclusion of pregnant women from participation. This was despite the fact

that pregnant individuals face a higher risk of severe COVID-19 illness, hospitalization, preterm birth, and other complications compared to non-pregnant women (13). The World Health Organization recommends the administration of the COVID-19 Sinopharm vaccine to pregnant women, as long as the benefits are assessed to outweigh the risks (14). However, the information available regarding the use of the Sinopharm vaccine in pregnancy is insufficient to determine any potential complications. Additionally, due to concerns about the vaccine's safety and the lack of adequate data, some pregnant patients may be less inclined to get vaccinated (15).

2. Objectives

As mentioned earlier, several studies have been conducted to evaluate the side effects of COVID-19 vaccines. However, these studies are limited, and certain populations, such as pregnant women, have been overlooked. It is crucial to understand the potential risks of COVID-19 vaccines and to ensure that pregnant women are properly informed, in order to improve the overall perception and acceptance of vaccination during pregnancy.

3. Methods

This study is a retrospective cohort analysis that reviewed the medical records of all singleton births to women aged 40 years or younger and their newborns, who were admitted to Baharloo Hospital, Tehran, Iran in 2021. The study obtained information about maternal age, education, previous medical conditions, and other background characteristics, as well as perinatal outcomes, from the Iranian Maternal and Neonatal (IMaN) Network. Additionally, data on vaccinated pregnant individuals, including the gestational age at the time of vaccination and the number of vaccine doses received, was obtained from the maternal vaccination cards. For the purposes of this study, women who received at least one dose of the Sinopharm COVID-19 vaccine between conception and childbirth were classified as the vaccinated group.

A total of 427 women were evaluated in this study, 144 of whom were vaccinated with the Sinopharm vaccine 3 months before pregnancy, 124 patients were vaccinated during the first trimester, and 157 were unvaccinated for COVID-19. The data gathered from the mothers' files included name, date of hospitalization, history of parity and previous childbirths, the method of childbirth (vaginal or caesarian section), birth outcomes, including live births and stillbirths, intrauterine growth restriction, date of vaccination according to the vaccine

certificate, prior COVID-19 infection, and the number of vaccine doses received until the date of childbirth. The data gathered from the newborns' files included gender, 1st and 5th minute Apgar score, birth weight, the need for admission in the neonatal intensive care unit, and the death of the newborn, which were gathered by the midwives and the practitioners.

The incidence of all perinatal outcomes was adjusted for factors including maternal age (continuous variable), nulliparity (yes/no), mother's educational level (≤ 9 years, 10 - 12 years, > 12 years), pre-pregnancy Body Mass Index (< 18.5 , 18.5 - 24.9, 25 - 29.9, ≥ 30), smoking or other substance use during pregnancy (yes/no), and maternal underlying medical conditions (yes/no). The maternal underlying conditions included chronic hypertension, hypertensive disorders of pregnancy (including eclampsia or preeclampsia), cardiovascular disease, diabetes, and gestational diabetes.

Univariate logistic regression was used to obtain unadjusted odds ratios for all perinatal outcomes. The primary goal of the study was to compare the incidence of perinatal outcomes in pregnant women exposed to the Sinopharm COVID-19 vaccine. The secondary goal was to evaluate any differences in the risk of adverse perinatal outcomes based on the trimester of pregnancy in which the vaccination occurred or the number of vaccine doses received. Vaccination in different trimesters was defined as receiving the first vaccine dose during the first ($\leq 13 + 6$ gestational weeks), second ($14 + 0$ to $27 + 6$ gestational weeks), or third ($\geq 28 + 0$ gestational weeks) trimester of pregnancy. Adjusted odds ratios were obtained using multiple logistic regression. The incidence of all outcomes was adjusted for all the predictors mentioned earlier. In the logistic regression analysis, the software SPSS 26 used listwise deletion of observations with missing values in any of the predictors. Univariate logistic regression was used to compare categorical characteristic features between the vaccinated and unvaccinated groups. A P-value of less than 0.05 was considered statistically significant.

4. Results

A total of 427 cases were studied, with 144 of them getting vaccinated with the Sinopharm vaccine at least 3 months before pregnancy, 124 of them vaccinated during the first trimester, and 157 cases not vaccinated for COVID-19. The mean age of the participants was 28.3 ± 6.35 years. The mean number of parities was 2.3 ± 1.14 . On average, the patients had a history of one previous labor and 0.66 ± 0.3 miscarriages (Table 1).

According to the results presented in Table 2, a total of 5.62% of all births are classified as preterm. The rates are 6.28% among unvaccinated individuals, compared to 6.09%, 4.44%, and 5.88% among those who received one, two, and three doses of the vaccine, respectively. Following an adjusted analysis, a significant reduction in the incidence of preterm births was observed in pregnant individuals who received more than one dose of the CoV-2 vaccine ($P < 0.001$). Specifically, the incidence rates were 0.76 (95% CI: 0.67 - 0.89) for those with two doses and 0.73 (95% CI: 0.71 - 0.86) for those with three doses. When examining the impact of vaccination doses during pregnancy, it was found that a single dose of the Sinopharm vaccine did not alter the risk of preterm birth. In contrast, two and three doses were linked to a lower incidence of preterm births.

Further analysis indicated that among the total of 16 cases of stillbirths, which represent 3.74% of the overall population, 5.66% were associated with the unvaccinated group. In contrast, 6.07% were observed in the one-dose group, while rates in the two-dose and three-dose groups were 0.74% and 1.96%, respectively. Significant differences were noted in the groups that received two or three vaccine doses ($P < 0.001$ for both conditions). However, other outcomes did not show significant results after adjustment.

5. Discussion

This study sought to compare pregnancy outcomes, focusing on particular maternal and newborn results, for pregnant women who were unvaccinated against COVID-19 and those who received one, two, or three doses of the vaccine. Importantly, women who received two or three doses of the vaccine had a significantly lower risk of preterm birth and stillbirth. Consistent with the findings of this study, Hatami et al. found that exposure to the Sinopharm vaccine during pregnancy significantly reduced the occurrence of preterm birth [$P = 0.006$, OR = 0.91 (95% CI, 0.85 to 0.97)], extremely preterm birth [$P < 0.001$, OR = 0.55 (95% CI, 0.45 to 0.66)], and stillbirth ($P < 0.001$) (16). The study by Magnus et al. also indicated that vaccination not only does not elevate the rate of premature birth but also reduces it (17). In a retrospective multicenter cohort study conducted in Melbourne by Hui et al., vaccination was associated with a significant reduction in total preterm births (5.1% vs 9.2%; adjusted odds ratio, 0.60; 95% confidence interval, 0.51 - 0.71; $P < 0.001$) and stillbirth (0.2% vs 0.8%; adjusted odds ratio, 0.18; 95% confidence interval, 0.09 - 0.37; $P < 0.001$) (18). These findings were also confirmed by Yazigi et al. and Baden et al. (19, 20).

Table 1. Background Characteristics of Study Population Based on Vaccination Status ^a

Variables	Total (N = 427)	Vaccinated Three Months Before Pregnancy (n = 144)	Vaccinated During the First 3 Months of Pregnancy (n = 142)	Unvaccinated (n = 159)	P-Value
Age (y)	28.3 ± 6.35	29.6 ± 10.00	28.5 ± 6.00	27.7 ± 6.80	0.225
Number of pregnancies (gravida)	1: 125 (29.27)	1: 45 (31.25)	1: 30	1: 50	0.757
	2: 146 (34.19)	2: 48 (33.33)	2: 48	2: 50	
	3+: 156 (36.53)	3+: 51 (35.41)	3+: 46	+3: 59	
Number of deliveries (para)	0: 141 (33.2)	0: 50 (0.006)	0: 35	0: 56	0.354
	1: 177 (41.45)	1: 62 (43.05)	1: 55	1: 60	
	2+: 109 (25.52)	2+: 32 (22.22)	2+: 34	+2: 43	
Number of abortions (abortion)	0: 344 (80.56)	0: 118 (81.94)	0: 102	0: 124;	0.871
	1: 61 (14.28)	1: 18 (12.5)	1: 17	1: 26	
	2+: 22 (5.15)	2+: 8 (5.55)	2+: 5	+2: 9	
Type of delivery					
NVD	119 (27.9)	24 (16.7)	28 (22.6)	67 (42.1)	0.012
Caesarian	216 (50.6)	69 (47.9)	60 (48.4)	87 (54.7)	
DC	91 (21.3)	50 (34.7)	36 (29.0)	5 (3.2)	
Prior covid infection	19 (4.4)	13 (0.9)	6 (4.8)	0	< 0.001
History of underlying pregnancy complication	80 (18.7)	37 (25.7)	30 (24.2)	13 (8.2)	< 0.001
History of drug use	87 (20.4)	44 (30.6)	32 (8.25)	11 (6.9)	< 0.001
Vaccine doses					< 0.001
One dose	82 (19.2)	40 (27.8)	42 (23.9)	0	
Two doses	135 (31.6)	78 (54.2)	67 (46.0)	0	
Three doses	51 (11.9)	26 (18.1)	25 (20.2)	0	
Unvaccinated	159 (37.2)	0	0	159 (100)	

^a Values are expressed as No. (%) or mean ± SD.

The biological and social factors that contribute to the decrease in spontaneous preterm births need further exploration, particularly the nonspecific inflammatory processes linked to preterm birth, as well as the protective effects of vaccinations for COVID-19 and other illnesses. Additionally, vaccination status might serve as an indicator of unmeasured social health determinants, alongside the established demographic factors analyzed in this study. This "healthy vaccinee bias" could indicate the strength of the relationship between a pregnant woman and her healthcare provider, since personal recommendations from healthcare practitioners significantly influence vaccine acceptance. This relationship is also associated with trust in the government. A better understanding of these confounding factors, along with the development of new methods to assess them, would enhance future research on vaccination during pregnancy and its impact on perinatal outcomes.

To explain the potential impact of vaccination on the reduced incidence of stillbirth, it is logical to consider that vaccination may lower the risk. This is particularly relevant due to the strong link between severe COVID-19 infections and a heightened risk of stillbirth. No resuscitation was needed for any of the newborns. Therefore, it was not possible to evaluate these outcomes among our study groups. There was no significant difference in birthweight or 1st minute Apgar score among the newborns of the three groups. However, the babies born to vaccinated mothers during the first trimester had a lower 5th-minute Apgar score.

According to 26 studies on prenatal outcomes after vaccination, the overall number of prenatal complications did not increase following the vaccination. The rate of premature labor, intrauterine growth restriction, caesarian section, and admission to NICU were different in various studies, which is probably explained by the heterogeneity of their study

Table 2. Raw and Adjusted Odds Ratios for Negative Perinatal Outcomes Based on the Number of COVID-19 Vaccination Time During the Trimester of Pregnancy^a

Perinatal Outcome	Doses of Vaccines	Total Cases	Univariate Odds Ratio (Unadjusted) (95% CI)	Unadjusted P-Value	Multiple Odds Ratio (Adjusted) (95% Confidence Level) ^b	Adjusted P-Value
Preterm birth						
Unvaccinated	159 (37.2)	10 (6.28)	Baseline	-	-	-
One dose	82 (19.2)	5 (6.09)	1.06 (0.84 - 1.34)	0.18	1.01 (0.93 - 1.23)	0.43
Two doses	135 (31.6)	6 (4.44)	0.84 (0.79 - 0.93)	0.04	0.76 (0.67 - 0.89)	< 0.001 ^c
Three doses	51 (11.9)	3 (5.88)	0.79 (0.71 - 0.86)	0.02	0.73 (0.71 - 0.86)	< 0.001 ^c
Stillbirth						
Unvaccinated	159 (37.2)	9 (5.66)	Baseline	-	-	-
One dose	82 (19.2)	5 (6.07)	1.06 (0.56 - 1.16)	0.53	1.04 (0.45 - 1.19)	0.51
Two doses	135 (31.6)	1 (0.74)	0.83 (0.43 - 0.81)	< 0.001	0.83 (0.43 - 0.79)	< 0.001 ^c
Three doses	51 (11.9)	1 (1.96)	0.66 (0.22 - 0.83)	< 0.001	0.64 (0.41 - 0.76)	< 0.001 ^c
Intrauterine growth restriction						
Unvaccinated	159 (37.2)	4 (2.51)	Baseline	-	-	-
One dose	82 (19.2)	2 (2.43)	1.39 (0.67 - 1.62)	0.71	1.49 (0.45 - 1.67)	0.73
Two doses	135 (31.6)	3 (2.22)	1.36 (0.54 - 1.73)	0.76	1.32 (0.48 - 1.77)	0.77
Three doses	51 (11.9)	1 (1.96)	1.42 (0.72 - 1.11)	0.77	1.48 (0.64 - 1.39)	0.77
Low birth weight						
Unvaccinated	159 (37.2)	15 (9.4)	Baseline	-	-	-
One dose	82 (19.2)	4 (4.87)	1.06 (0.56 - 1.37)	0.71	1.03 (0.66 - 1.87)	0.73
Two doses	135 (31.6)	6 (4.44)	1.04 (0.66 - 1.68)	0.74	1.06 (0.68 - 1.58)	0.77
Three doses	51 (11.9)	2 (3.92)	1.02 (0.51 - 1.79)	0.76	0.76 (0.31 - 1.59)	0.74
NICU admission						
Unvaccinated	159 (37.2)	10 (6.28)	Baseline	-	-	-
One dose	82 (19.2)	4 (4.87)	1.54 (0.64 - 1.68)	0.66	1.51 (0.53 - 1.76)	0.68
Two doses	135 (31.6)	7 (5.18)	1.48 (0.73 - 1.45)	0.43	1.42 (0.46 - 1.49)	0.54
Three doses	51 (11.9)	1 (1.96)	1.26 (0.71 - 1.32)	0.46	1.19 (0.69 - 1.41)	0.51
Low 5-minute Apgar score						
Unvaccinated	159 (37.2)	9 (5.66)	Baseline	-	-	-
One dose	82 (19.2)	3 (3.65)	0.76 (0.68 - 1.15)	0.14	0.75 (0.41 - 1.27)	0.26
Two doses	135 (31.6)	5 (3.70)	0.74 (0.65 - 1.43)	0.17	0.73 (0.32 - 1.56)	0.37
Three doses	51 (11.9)	1 (1.96)	0.71 (0.71 - 1.47)	0.17	0.69 (0.53 - 1.49)	0.24
Neonatal death						
Unvaccinated	159 (37.2)	5 (3.14)	Baseline	-	-	-
One dose	82 (19.2)	1 (1.21)	0.45 (0.21 - 1.49)	0.31	0.66 (0.2 - 1.87)	0.39
Two doses	135 (31.6)	2 (1.48)	0.76 (0.24 - 1.37)	0.33	0.69 (0.21 - 1.69)	0.43
Three doses	51 (11.9)	1 (1.96)	0.71 (0.23 - 1.36)	0.33	0.65 (0.19 - 1.57)	0.45

^a Values are presented as No. (%).^b All analysis is modified based on maternal age, underlying health conditions, history of drug use during pregnancy, maternal educational attainment, prior covid infection, number of abortions, gravida and parity.^c A P-value of ≤ 0.05 is considered statistically significant.

population. Still, there was no significant increase in these outcomes compared to the unvaccinated women (21-31).

In this study, the vaccinated women had a significantly higher number of underlying diseases. More willingness of this group towards immunization might be due to their higher susceptibility to COVID-19

infection because of these comorbidities. Similarly, the vaccinated group had a higher frequency of drug consumption. A history of a prior COVID-19 infection was seen more often among the vaccinated group. The reason for this could be that the vaccinated women, being more concerned about getting infected, have a stronger recollection of the slightest upper respiratory

symptoms and presume all of them to be a COVID-19 disease. On the contrary, unvaccinated individuals did not pay as much attention to the respiratory symptoms. On the other hand, considering the higher prevalence of a positive past medical and drug history among the vaccinated group, they can be more immune-compromised compared to the other group.

The findings should be interpreted in light of several potential limitations. First, the study's retrospective nature is subjected to several biases, and we cannot infer causal effects due to the lack of randomization. We suggest the conduction of future studies with a prospective method, which may provide stronger evidence on this matter. Second, our study has been afflicted with missing data; this should be considered while using our analyses. The retrospective nature of the study, delivery in facilities other than our hospital, and the long interval between gathering baseline data and the studied outcomes might be contributing factors to the presence of these missing data. Finally, despite the Sinopharm vaccine being one of the major vaccines against COVID-19, retesting the results of this study using other vaccines may clarify this subject even more.

5.1. Conclusions

Our study shows a relationship between a prior COVID-19 infection and the willingness to get the vaccine. There was no association between the Sinopharm vaccine and an increase in morbidity and mortality for newborns, and therefore, the Sinopharm vaccine can be considered safe for pregnant women.

Footnotes

Authors' Contribution: Study concept and design: Sh. M., N. A., Z. Gh., and E. E.; Acquisition of data: N. A. and Z. Gh.; Analysis and interpretation of data: Sh. M., N. A., Z. Gh., E. E.; Drafting of the manuscript: Sh. M., N. A., Z. Gh., and E. E.; Critical revision of the manuscript for important intellectual content: Sh. M., N. A., Z. Gh., and E. E.; Statistical analysis: Sh. M., N. A., Z. Gh., and E. E.; Administrative, technical, and material support: Sh. M., Z. Gh., and E. E.; Study supervision: Sh. M.

Conflict of Interests Statement: The authors declare no conflict of interest.

Data Availability: No new data were created or analyzed in this study. Data sharing does not apply to this article.

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