Comparative between Pregnancy Outcomes in Non- versus Vaccinated Females by Covid-19 Vaccine: A Retrospective Comparative Study

Amr Ahmed Mahmoud Riad ,
Mostafa Ibrahim Ibrahim Abdel Moneim,
Aya Amr Samih Badr,
Abdelrahman Mohamed Saleh
Obstetrics & Gynaecology Department, Faculty of Medicine, Ain Shams University

Abstract

Background: Over two years, the coronavirus disease 2019 (COVID-19) pandemic has impacted a significant number of individuals worldwide, emerging as a major public health concern and compelling medical facilities to reorganize their medical departments, including obstetrical and gynecologic services.

Aim of the Work : to retrospectively explore the maternal, fetal, and neonatal outcomes in COVID-19- vaccinated pregnant women compared with those not receiving COVID-19 vaccine.

Patients and Methods: This was a retrospective cohort study that was conducted at Ain Shams University Maternity Hospital (ASUMH). Pregnant women who attended ASUMH for delivery were divided into two groups: **Group A** consisted of 200 COVID-19 vaccinated women who received at least one vaccine dose six months or more prior to labor (the study group); **Group B** consisted of an age-matched control group of 200 unvaccinated women.

Results: Our study demonstrated the relation between age and two study groups, the mean age of non-vaccinated group was 27.23 ± 4.78, while it was 27.21 ± 4.66 for vaccinated group without statistically significant difference between two study group as P-value was >0.05. Our study illustrated the relation between pre-eclampsia as a complication and two study groups, the number of patients who had PE within non-vaccinated group were 10 (5%), while they were 9 (4.5%) within vaccinated group without statistically significant difference between two study group as P-value was >0.05. Our study showed the relation between NICU admission as a complication and two study groups, the number of patients who admitted to NICU within non-vaccinated group were 39 (19.5%), while they were 28 (14%) within vaccinated group without statistically significant difference between two study group as P-value was >0.05. Our study demonstrated the relation between preterm labour as a complication and two study groups, the number of patients who had preterm labour within non-vaccinated group were 9 (4.5%), while

Corresponding author:
Aya Amr Samih Badr
Phone No.: (+2) 01234500253
E-mail: ayaamrbadr1393@gmail.com

they were 13 (6.5%) within vaccinated group without statistically significant difference between two study group as P-value was >0.05.

Conclusion: Given the lack of significant differences in these maternal complications and neonatal outcomes between the vaccinated and unvaccinated groups, our study supports the safety of COVID-19 vaccination during pregnancy in terms of it not leading to increased major poor outcomes for mother or baby. More research is still warranted to further establish the risks versus benefits with larger sample sizes.

Keywords: Non-versus Vaccinated, Covid-19 Vaccine.

INTRODUCTION

COVID-19 is considered a global epidemic of catastrophic proportions. Since the discovery of the first instances of COVID-19 induced by SARS-CoV-2 in December 2019 in Wuhan, China, and the virus has swiftly spread globally. Almost 207 million people have been infected globally, resulting in over 4 million fatalities.[1]

As of August 15, 2021, about 620,000 people have perished from COVID-19 in the USA alone.[2]

Several researches on COVID-19 health issues, including investigations on the mental and physical impacts of COVID-19 for the duration of pregnancy, have been published.[3]

The lower lung capacity associated with fetal development, together with the normal prenatal inhibition of the maternal immune reaction, may result in significant COVID-19 expression in pregnant women.[4]

Vaccine reluctance among pregnant women has been influenced by a number of factors, including the absence of knowledge with mRNA vaccine portals from outside research settings, the exemption of pregnant women from preliminary COVID-19 vaccine trials, and the resulting mutable and uncertain vaccination guidelines from formal bodies, in addition to antivaccine misinformation.[5]

Fears about the safety of vaccines within pregnant women are a continuing barrier to vaccination during pregnancy. Previous investigations on the correlation between maternal COVID-19 immunization and newborn outcomes were restricted by small sample sizes or the absence of an unvaccinated group.[6]

According to statistics from the UK Obstetric Surveillance System (UKOSS), the vast majority of pregnant women who needed medication or intensive care unit (ICU) care for COVID-19 during the delta wave were not vaccinated.[7]

Currently, clinical trials are investigating the unanswered concerns with COVID-19 immunization in pregnancy, such as the ideal dose schedule, the durability and effectiveness of antibodies transmitted transplacentally and via lactation, and the optimal dosing schedule.[8]

Currently, the following three COVID-19 vaccinations are available: Two mRNA vaccines, one from Pfizer-BioNTech (Germany and New York) and another one from Moderna (Cambridge, MA) were tested, and one adenoviral vector vaccination (Johnson & JohnsoneJanssen, Belgium). The CDC stipulates that any of the presently permitted vaccinations may be delivered to women who are pregnant or breastfeeding, regardless of vaccine type.[9]

The Royal College of Obstetricians and Gynecologists in the United Kingdom suggests mRNA immunization for pregnant women because mRNA vaccines have better safety evidence than adenoviral vaccinations. There is an acute need for high-quality, accurate data to assist pregnant women considering COVID-19 vaccination in the absence of fresh updates from large national registries and the outcomes of current studies.[10]

AIM OF THE WORK

To retrospectively explore the maternal, fetal, and neonatal outcomes in COVID-19-vaccinated pregnant women compared with those not receiving COVID-19 vaccine.

PATIENTS AND METHODS

A retrospective cohort study that included all pregnant women who attended Ain Shams University Maternity Hospital for delivery for 3 years (from Jan 2020 till Dec. 2022) at least 200 patients, to measure the effect of COVID-19 vaccination on the pregnancy outcomes.

Ethical and Safety Consideration: The Ethics Committee of the Department of Obstetrics and Gynaecology, Faculty of Medicine, Ain Shams University, gave its clearance before this study could be carried out. A pledge was executed. All information was gathered in confidence. The researcher's own funds served as the foundation for the investigation.

Inclusion criteria: age: 18 - 35 years, gestational age: any gestational age. Gestational age will be confirmed as regard documented 1st day of last menstrual period or 1st trimester ultrasound, singleton viable healthy fetus, uncomplicated pregnancy or labor, vaginal or cesarean deliveries at the period between starting of 2022 until now and COVID vaccinated women - as a study group - with at least one shot of vaccine six months or more before labour and age matched non-vaccinated women – as a control group.

Exclusion criteria: 1- women with incomplete data or unwilling to participate in the study, 2- women with systemic medical disorders before pregnancy, 3- known structural or chromosomal fetal abnormalities and 4- women with risk factors of preterm labour as: multifetal pregnancy, poly- or oligohydramnios, preterm premature rupture of membranes (PPROM), antepartum hemorrhage (placenta Previa or abruption placenta) and cervical incompetence. 5- Women received different types of COVID-19 vaccine.

Sample Size: A retrospective cohort study was conducted to include all pregnant women who attended Ain Shams University Maternity Hospital for delivery for 3 years (from Jan 2020 till Dec. 2022) at least 200 patients, to measure the effect of COVID-19 vaccination on the pregnancy outcomes.

Study procedures and interventions: after approval of study protocol, patient's records were enrolled into the study according to inclusion and exclusion criteria and eligible patients were divided into two groups: **Group A (Vaccinated women):** COVID vaccinated women - as a study group - with at least one shot of vaccine six months or more before labour. **Group B (unvaccinated women):** age matched un vaccinated women – as a control group.

Methodology: The following data were collected from patient's records: History: Including the following points: **Personal history:** age, maritalstatus, special habits, occupation, address and phone number. **Present history** of her pregnancy as gravidity, parity, gestational age, etc. **Menstrual history** as regularity and date of 1st day of last menstrual period. **Obstetric history:** gravidity, parity, previous abortion, gestational age, associated medical conditions, history of maternal or fetal complications. **Medical history:** of systemic medical disorders. **Surgical history:** of previous cesarean sections ant its maternal and fetal outcomes. **History of COVID-19 vaccination:** type, date, number of doses and associated adverse effects. **Examination:** Complete general, abdominal "obstetric" and local examinations for confirmation of inclusion and exclusion criteria. **Conventional 2D ultrasonography:** for documented basic fatal biometry data. All women were called on their phones to ask about their vaccination certificates and record their pregnancy outcomes.

Outcomes: ***Maternal outcomes:*** preeclampsia (PET) and venous thromboembolism (VTE). ***Neonatal outcomes:*** neonatal intensive care unit (NICU) admission and Preterm labor.

Data Management and Analysis: After revision, coding, tabulation, and introduction to a PC, the gathered data was processed through the Statistical Package for Social Science (SPSS 26). Data were shown, and appropriate analysis was carried out in accordance with the kind of data found for each parameter.

Descriptive statistics: include the mean, range, and standard deviation (± SD) for parametric numerical data, and the median, interquartile range (IQR), frequency, and percentage of non-numerical data for non-parametric numerical data.

Statistics for analysis: The statistical significance of the difference between the means of the two research groups was evaluated using the Student T Test. To investigate the association between two qualitative variables, ***the Chi-Square test*** was employed

P- value: level of significance: P>0.05: Non significant (NS). -P< 0.05: Significant (S).

RESULTS

Table 1: Demographic data for the whole study group.

		Mean / N	SD / %	Median (IQR)	Range
Age "years"		27.22	4.72	27 (23 - 31)	(18 - 38)
Group	**Non-Vaccinated**	200	50.0%		
	Vaccinated	200	50.0%		

This study was conducted on 400 female pregnant patients divided equally into two groups according to the vaccination history of COVID-19, (table 1) shows that the mean age of the study group was 27.22 ± 4.72 and ranged from 18 to 38 years old.

Table 2: Perinatal and postnatal complications for the whole study group.

		N	%
PE	**No**	381	95.3%
	Yes	19	4.8%
VTE	**No**	400	100.0%
	Yes	0	0.0%
NICU	**No**	333	83.3%
	Yes	67	16.8%
Preterm	**No**	378	94.5%
	Yes	22	5.5%

(Table 2) shows the prevalence of perinatal and postnatal complications for the whole study group, the most frequent complication was NICU admission by 67 (16.8%) of patients followed by preterm by 22 (5.5%), then pre-eclampsia by 19 (4.8%), while no one had VTE.

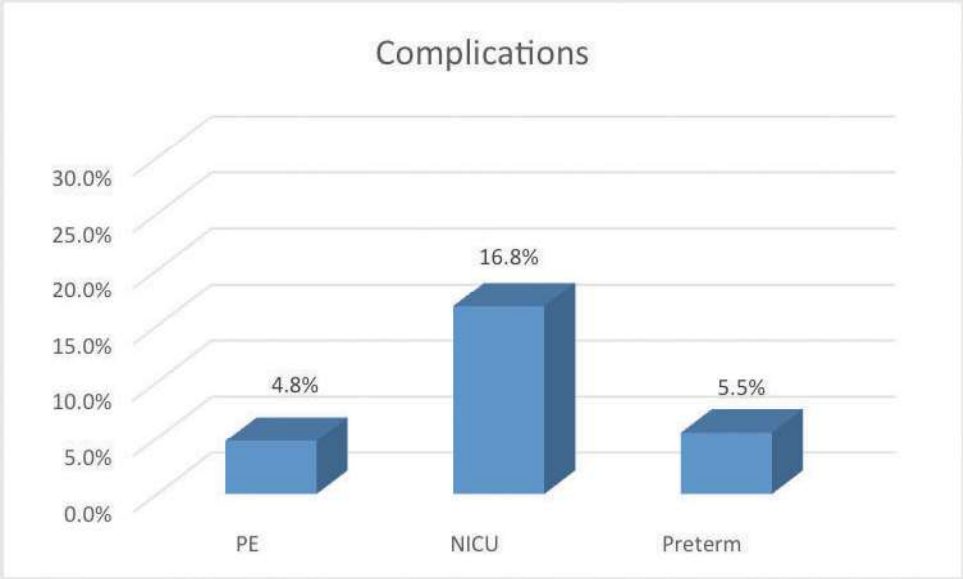

Figure (1): shows perinatal and postnatal complications distribution among the study group.

Table 3: Relation between age and two study groups.

		Group		Student t-test		
		Non-Vaccinated	**Vaccinated**	**t**	**P-Value**	**Sig.**
Age "years"	**Mean ± SD**	27.23 ± 4.78	27.21 ± 4.66	0.042	0.966	NS
	Range	(18 -36)	(18 -38)			

(Table 3) demonstrates the relation between age and two study groups, the mean age of non-vaccinated group was 27.23 ± 4.78, while it was 27.21 ± 4.66 for vaccinated group ***without statistically significant difference*** between two study group as P-value was >0.05.

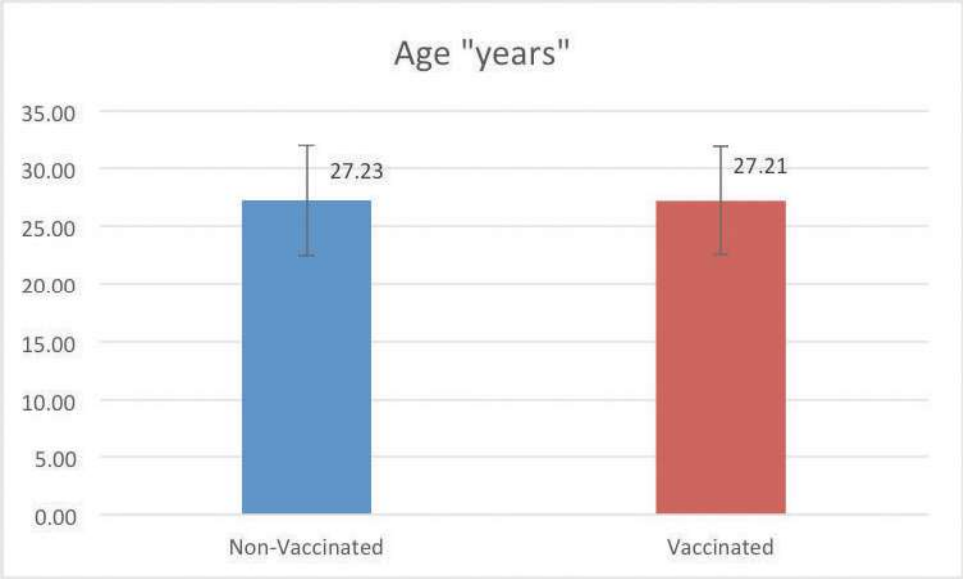

Figure (2): Shows age difference between two the study group.

Table 4: Relation between pre-eclampsia as a complication and two study groups.

		Group		Chi-Square test		
		Non-Vaccinated	Vaccinated			
		N (%)	N (%)	X^2	P-Value	Sig.
PE	No	190 (95%)	191 (95.5%)	0.055	0.814	NS
	Yes	10 (5%)	9 (4.5%)			

(Table 4) illustrates the relation between pre-eclampsia as a complication and two study groups, the number of patients who had PE within non-vaccinated group was 10 (5%), while they were 9 (4.5%) within vaccinated group ***without statistically significant difference*** between two study groups as P-value was >0.05.

Table 5: Relation between neonatal intensive care unit as a complication and two study groups.

		Group		Chi-Square test		
		Non-Vaccinated	Vaccinated			
		N (%)	N (%)	X^2	P-Value	Sig.
NICU	No	161 (80.5%)	172 (86%)	2.169	0.141	NS
	Yes	39 (19.5%)	28 (14%)			

(Table 5) shows the relation between NICU admission as a complication and two study groups, the number of patients admitted to NICU within the non-vaccinated group was 39 (19.5%), while they were 28 (14%) within vaccinated group ***without statistically significant difference*** between two study group as P-value was >0.05.

Table 6: Relation between preterm labor as a complication and two study groups.

		Group		Chi-Square test		
		Non-Vaccinated	Vaccinated			
		N (%)	N (%)	X^2	P-Value	Sig.
Preterm	No	191 (95.5%)	187 (93.5%)	0.77	0.38	NS
	Yes	9 (4.5%)	13 (6.5%)			

(Table 6) demonstrates the relation between preterm labor as a complication and two study groups, the number of patients who had preterm labor within non-vaccinated group were 9 (4.5%), while they were 13 (6.5%) within vaccinated group ***without statistically significant difference*** between two study group as P-value was >0.05.

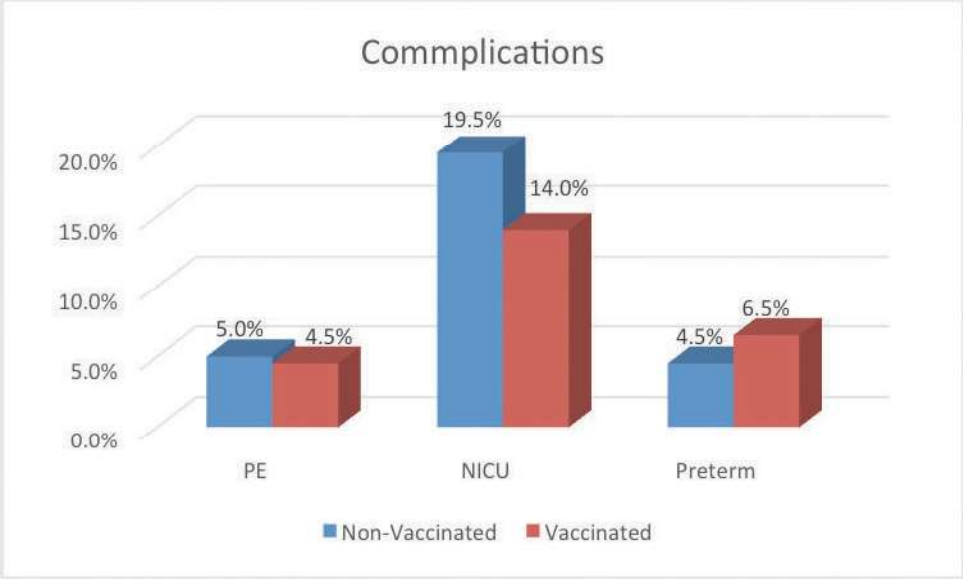

Figure (3): Shows relation between perinatal & postnatal complications and two the study group.

DISCUSSION

Preterm birth, caesarean section, and pre-eclampsia have all been linked to the novel coronavirus disease 2019 (COVID-19), which may cause more severe illness during pregnancy. There is a dearth of information on the safety and effectiveness of the COVID-19 vaccinations in foetuses, newborns, and pregnant women. This is mostly because pregnant women are not allowed to participate in clinical vaccine trials.[11]

the Centers for Disease Control and Prevention (CDC), advises pregnant women to get vaccinated against COVID-19 due to the possible severity of the disease. Nonetheless, despite the paucity of safety information, it was suggested that expectant mothers receive a clear, balanced assessment of their risk of contracting COVID-19 during pregnancy as well as an overview of the possible advantages of COVID-19 vaccinations.[12]

Goldshtein et al. (2021) demonstrated that severe acute respiratory syndrome coronavirus (SARS-CoV-2) messenger RNA (mRNA) vaccination in pregnant women was associated with a significantly lower risk of COVID-19 infection compared with unvaccinated women.[13]

Furthermore, after immunisation, there was reportedly a very low incidence of obstetrical problems, such as preterm rupture of membranes, vaginal bleeding, and uterine contractions. However, due to a lack of information regarding the COVID-19 vaccine's safety during pregnancy, many expectant mothers refuse to receive the shot.[14]

Although the COVID-19 vaccine reduces the risk of being infected with a life-threatening virus, as long as the risks to the fetus are unknown, an informed woman's choice should be honored.[15]

Data regarding perinatal outcomes following the COVID-19 vaccination is still limited. Self-reported pregnancy outcomes among 827 pregnant participants in a vaccination surveillance system were similar to historic controls before the COVID-19 pandemic including preterm birth and small for gestational age 6. Another small cohort study found no significant difference in adverse pregnancy outcomes between 133 women who received at least one vaccine dose and

399 unvaccinated pregnant women.[16]

The current study aimed to retrospectively explore the maternal, fetal, and neonatal outcomes in COVID-19- vaccinated pregnant women compared with those not receiving COVID-19 vaccine.

This was a retrospective cohort study that was conducted at Ain Shams University Maternity Hospital (ASUMH). Pregnant women who attended ASUMH for delivery were divided into two groups: **Group A** consisted of 200 COVID-19 vaccinated women who received at least one vaccine dose six months or more prior to labor (the study group); **Group B** consisted of an age-matched control group of 200 unvaccinated women.

Our study demonstrated the relation between age and two study groups, the mean age of non-vaccinated group was 27.23 ± 4.78, while it was 27.21 ± 4.66 for vaccinated group ***without statistically significant difference*** between two study groups as P-value was >0.05.

In accordance, ***Kugelman et al. (2023)*** found no statistically significant differences in maternal characteristics between vaccinated and unvaccinated pregnant women.[17]

However, ***Theiler et al. (2021)*** found older age to be significantly associated with increased likelihood of vaccination.[18]

Also, ***Carbone et al. (2022)*** aimed to explore perinatal outcomes in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-vaccinated pregnant women compared with unvaccinated counterparts. They observed differences among vaccinated and unvaccinated women in relation to age.[19]

Our study illustrated the relation between pre-eclampsia as a complication and two study groups, the number of patients who had PE within non-vaccinated group was 10 (5%), while they were 9 (4.5%) within vaccinated group ***without statistically significant difference*** between two study group as P-value was >0.05.

Accordingly, ***Theiler et al. (2021)*** compared 1862 pregnant women who were not vaccinated with 140 women who received vaccinations in their third trimester of pregnancy (212 of them had contracted COVID-19 during the present pregnancy) in a manuscript that was released online before peer review. When it came to severe composite unfavourable outcomes, which encompassed issues for both the mother and the newborn, as well as particular maternal or delivery outcomes, there was no discernible difference between pregnant women who had received vaccinations and those who had not.[18]

In agreement, ***Wainstock et al. (2021)*** performed a subgroup analysis, observing no differences in the rate of pregnancy-related hypertensive disorders.[20]

According to two recent observational studies conducted in Palestine, there was no significant difference in maternal outcomes between pregnant women who received the mRNA COVID-19 immunisation and those who did not.[21, 22]

Another retrospective cohort study by ***Piekos et al. (2023)*** concluded that, COVID-19 vaccination protects against adverse maternal–fetal outcomes, with booster doses conferring additional protection.[23]

The results of ***Carbone et al. (2022)*** reinforced the idea that receiving the SARS-CoV-2 vaccine during pregnancy is not associated with an increased probability of adverse outcomes for mothers.[19]

Both ***Goldshtein et al. (2021)*** and ***Theiler et al. (2021)*** found that pregnant women who received the BNT162b2 mRNA vaccine during pregnancy had significantly lower risk of COVID-19 infection, further supporting the importance of this vaccination during the COVID-19 epidemic.[13, 18]

Our study showed the relation between NICU admission as a complication and two study groups, the number of patients who

admitted to NICU within non-vaccinated group were 39 (19.5%), while they were 28 (14%) within vaccinated group ***without statistically significant difference*** between two study group as P-value was >0.05.

The results of ***Blakeway et al. (2021)*** are also in agreement with ours, showing similar rates of NICU admissions, when they compared 141 vaccinated pregnant women with 1187 unvaccinated pregnant women. In their study, 86% and 14% were vaccinated in the third and second trimester, respectively.[16]

Accordingly, ***Kugelman et al. (2023)*** showed that the rate of the composite adverse perinatal outcome was similar for pregnant women who had received vaccinations and those who had not; no appreciable differences were observed in the rate of the composite adverse perinatal outcome or the individual adverse perinatal outcomes, such as the rate of NICU admission, when compared to unvaccinated parturient.[17]

Our study demonstrated the relation between preterm labor as a complication and two study groups, the number of patients who had preterm labor within non-vaccinated group was 9 (4.5%), while they were 13 (6.5%) within vaccinated group ***without statistically significant difference*** between two study group as P-value was >0.05.

Similar to our findings, ***Goldshtein et al. (2021)*** reported no notable differences between the vaccinated and unvaccinated groups regarding preterm birth <37 weeks. However, their study design did not provide adequate power to statistically assess differences in adverse events.[13]

In accordance, ***Shimabukuro et al., (2021)*** in a study based on data from the v-safe after vaccination registry, found that adverse neonatal outcomes including preterm birth before 37 weeks, in vaccinated pregnant women were similar to incidences reported in studies involving pregnant women that were conducted before the COVID-19 pandemic.[6]

Neonatal outcomes in a different study, which included digitised questionnaire responses from 57 pregnant women who received vaccinations, were similar to those of the overall pregnant population; however, pregnant women who did not receive vaccinations were not included in the comparison.14 Therefore, all of the studies published thus far show that COVID-19 vaccination during pregnancy did not increase the risk for adverse maternal or neonatal outcomes.

In harmony, ***Kugelman et al. (2023)*** [17] showed that the rate of the composite adverse perinatal outcome was the same for pregnant women who received the vaccination and those who did not; no discernible differences were observed in the rate of the composite adverse perinatal outcome or the individual adverse perinatal outcomes, such as preterm delivery of less than 35 weeks, when compared to unvaccinated parturients.

Similar to our study results, ***Pratam et al. (2021)*** in their meta-analysis and systematic review, found that the administration of mRNA vaccine to pregnant women effectively reduced the incidence of further SARS-CoV-2 infections and also found that the vaccine had no significant effect on neonatal outcomes.[24]

Moreover, ***Goldshtein et al. (2022)*** observed no differences in the rate of preterm delivery, between pregnant women vaccinated during the first trimester and unvaccinated pregnant women.[13]

On the contrary, ***Marchand et al. (2023)*** found that the vaccinated group had significantly lower odds of preterm delivery than the non-infected unvaccinated group. [25]

Ciapponi et al. (2023) discovered that none of the aluminum-based adjuvants or AS03 exposures from mother vaccinations were statistically substantially linked to unfavourable pregnancy outcomes. In certain cases (preterm birth), these vaccinations even shown protective effects linked to particular exposure durations.[26]

A large, multisite, retrospective cohort study in the USA found that receipt of mRNA COVID-19 vaccine during pregnancy was not associated with increased risk for preterm birth. In that study, only 4.2% of pregnant persons received a vector vaccine.[27]

It is possible to speculate that women who received the immunisation also securely self-managed their pregnancies, lowering physical stressors and therefore lowering the chance of different pregnancy problems, including premature birth.[19]

Lipkind et al. (2022) found that pregnant women who received vaccinations had no higher risk of preterm birth than those who did not receive the shots; additionally, they demonstrated that the prevalence of preterm birth was lower following two doses than following one dose, and they found that vaccination in the third trimester had an adjusted OR less than 1.[27]

Dick et al. (2022) showed an increased preterm birth rate and lower overall gestational age at delivery in women vaccinated during the second trimester compared with unvaccinated pregnant women.[28]

INTRODUCTION

Our research confirms the safety of COVID-19 vaccination during pregnancy in terms of its potential to prevent serious adverse outcomes for either the mother or the unborn child, as there were no appreciable differences found in these maternal complications and neonatal outcomes between the vaccinated and unvaccinated groups. To further determine the hazards vs advantages with bigger sample numbers, more research is still necessary.

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