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Effectiveness, Immunogenicity and Safety of COVID-19 Vaccination in Pregnant Women: A Rapid Review Study

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Abstract

Background: Pregnant women infected with the coronavirus disease 2019 (COVID-19) are at risk for adverse pregnancy outcomes, and the only real preventive strategy against COVID-19 is mass vaccination. This study aimed to examine the effectiveness, immunogenicity, and safety of Covid-19 vaccination in pregnant women.

Methods: A combination of search terms was performed by 2 researchers independently in the Web of Science, PubMed, and Scopus databases, the World Health Organization website, and the US Centers for Disease Control (CDC) website up to February 2022. After the selection of eligible studies, the review process, description, and summarization of the selected studies were performed by the research team.

Results: Finally, 22 articles were included in this study. Evidence supports the safety of COVID-19 vaccination during pregnancy. There is no risk of transmitting COVID-19 to infants during lactation. In addition, antibodies made by vaccination can protect infants through breast milk.

Conclusion: The scientific community believes that being vaccinated as soon as possible is the best course of action because there is no evidence to suggest that the COVID-19 vaccine poses a risk to expectant or nursing women.

Keywords: Vaccination, COVID-19, Pregnancy, Safety, Immunogenicity, Effectiveness

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Introduction

On December 31, 2019, a cluster of cases of pneumonia was reported to the World Health Organization (WHO) from Wuhan, China. A novel coronavirus was identified—severe acute respiratory syndrome coronavirus2 (SARS-CoV-2)—and the outbreak was declared as a public health emergency of international concern in January 2020.

In previous outbreaks of other coronavirus infections, such as severe acute respiratory syndrome (SARS) and middle east respiratory syndrome (MERS), serious complications were reported in pregnant women (1). Changes in the immune and respiratory systems during pregnancy increase the risk of pneumonia and other complications. Women are also more susceptible to serious infections such as the flu (2).

Pregnant women are more at risk than others for developing severe coronavirus disease 2019 (COVID-19) dis-

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↑What is "already known" in this topic:
Pregnant women infected with the coronavirus disease 2019 (COVID 19) are at risk for adverse pregnancy outcomes, and the only real preventive strategy against COVID-19 is mass vaccination.

→What this article adds:
The results of this study showed no risk of acquiring COVID-19 from the vaccines. Infants can be protected by antibodies produced during vaccination through breast milk, and following vaccination, particularly after the second dose, IgG and anti-spike antibody titers increased. In addition, COVID-19 vaccination does not have a role in congenital anomalies.

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ease. Outbreaks appear to be exacerbated during pregnancy and in women with preeclampsia, depression, nausea during pregnancy, preterm birth, low birth weight, and low Apgar score in the infant (3, 4).

Vaccination is an important strategy for the prevention and control of pandemics and endemics. Vaccines have also been developed for COVID-19. Sputnik was the first vaccine to be registered in August 2020, followed by AstraZeneca, the second vaccine to be licensed in the United Kingdom in December 2020, and Pfizer to be licensed for emergency use by the US Food and Drug Administration in the same month (5).

Vaccination is done during pregnancy to prevent the death of the mother and the infant from infectious diseases, especially diseases such as influenza. There is a lot of information about the safety and efficacy of the flu vaccine (6). Although the clinical phases of vaccine studies did not include pregnant women, the US Food and Drug Administration and the Committee on Advisory Studies on Immunogenicity have ruled that COVID-19 vaccination is safe for pregnant and lactating women (7, 8). The British Committee for Vaccination and Safety identified pregnant women as a high-risk group on December 16, 2021, and emphasized the importance of vaccination as well as booster dosing in this group to prevent COVID-19 complications and admission to intensive care units for both the mother and the fetus (9).

Since the beginning of vaccination for pregnant women, various studies have been performed to evaluate the side effects of the vaccine and the immunogenicity of the vaccine. The purpose of this review study was to evaluate the efficacy and immunogenicity reported in various studies after vaccination in pregnant women.

Methods

A rapid review of the published literature was performed to provide a brief report of the available research evidence related to the effectiveness and safety of COVID-19 vaccination in pregnant women.

Search Strategy

We performed a literature search using the online databases of Web of Science, PubMed, Scopus, the WHO website, and the US CDC website for relevant publications up to February 2022. The search strategy was as follows:

(("2019-nCoV") OR (COVID-19) OR (SARS-Cov2)) AND ((Pregnancy OR (Pregnant women) OR (gestation)) AND ((Vaccine*)) AND ((safety) OR (immunogenicity) OR (effectiveness) OR ("adverse event")).

Inclusion and Exclusion Criteria

The inclusion criteria were as follows: (1) studies published in English; and (2) studies on the effectiveness, immunogenicity, and safety of COVID-19 vaccination in pregnant women. The exclusion criteria were as follows: (1) duplicate articles; and (2) unofficial country reports such as nonpeer-reviewed dissertations, conference proceedings/papers, statements by professional organizations, and et cetera.

Study Selection and Data Collection

Once duplicates were removed, the initial search results were screened by 2 independent researchers based on abstracts and titles. Then, the full texts of related articles were evaluated based on the inclusion and exclusion criteria and eligible studies were selected. Studies in which researchers did not reach a decision were reviewed by a third researcher.

Two authors independently extracted data from eligible studies using a data extraction form. The following information was extracted from the full text of selected studies: the first author's name, study type, study design, sample size, gestational age, vaccine type, number of injected doses, pregnancy outcome, effectiveness, immunogenicity, and safety of COVID-19 vaccination.

Risk of Bias and Quality Assessment

The risk of bias was assessed using the Newcastle Ottawa scale (NOS) as recommended by Cochran (10) by 2 independent reviewers for the cohort, case-control, and cross-sectional studies. The NOS score ranged from 0 to 9 based on 3 sections such as selection, comparability, and assessment of outcome in a study. Based on this scale, a maximum of 9 points can be awarded to each study. In the present study, articles with a NOS score ≥5 were considered as having high-quality methodologies.

Results

We identified 238 studies from 5 databases after removing duplicates and then screened articles by title and full text according to study objectives. Finally, 22 studies were included in the present study (Figure 1).

For quality assessment, we used the NOS for cohort, case-control, and cross-sectional studies. Among the 22 observational study reports, 5 studies (22.72%) scored 9, 9 studies (40.90%) scored 8, 6 studies (27.27%) scored 7, and 2 studies (9.09%) scored 6 points. Therefore, all studies had a score >5 and were of high quality.

Types of COVID-19 Vaccines and Pregnancy

Despite the fact that there are several different COVID-19 vaccinations available, only 3 were officially licensed for use in pregnant women before February 2022. COVID-19 vaccines that have been recommended for pregnant women include mRNA vaccines such as Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273 or inactivated vaccines such as Sinopharm BIBP COVID-19 vaccine (11, 12). There are only a few reports on the safety and effectiveness of AstraZeneca/Oxford and Janssen vaccines, and in these studies, pregnancy was the exclusion criterion (13, 14). In fact, reported cases are based on accidental pregnancies during trials (15). On February 15, 2022, the WHO updated its statements that available COVID-19 vaccines such as Pfizer, Moderna, AstraZeneca, Janssen, Sinovac, and Novavax are safe for pregnant and lactating women. Despite the fact that pregnant women were excluded from part of the COVID-19 trial vaccines, there is evidence to support the safety of COVID-19 vaccines during pregnancy, including monitoring of pregnant women who had received the vaccine and animal

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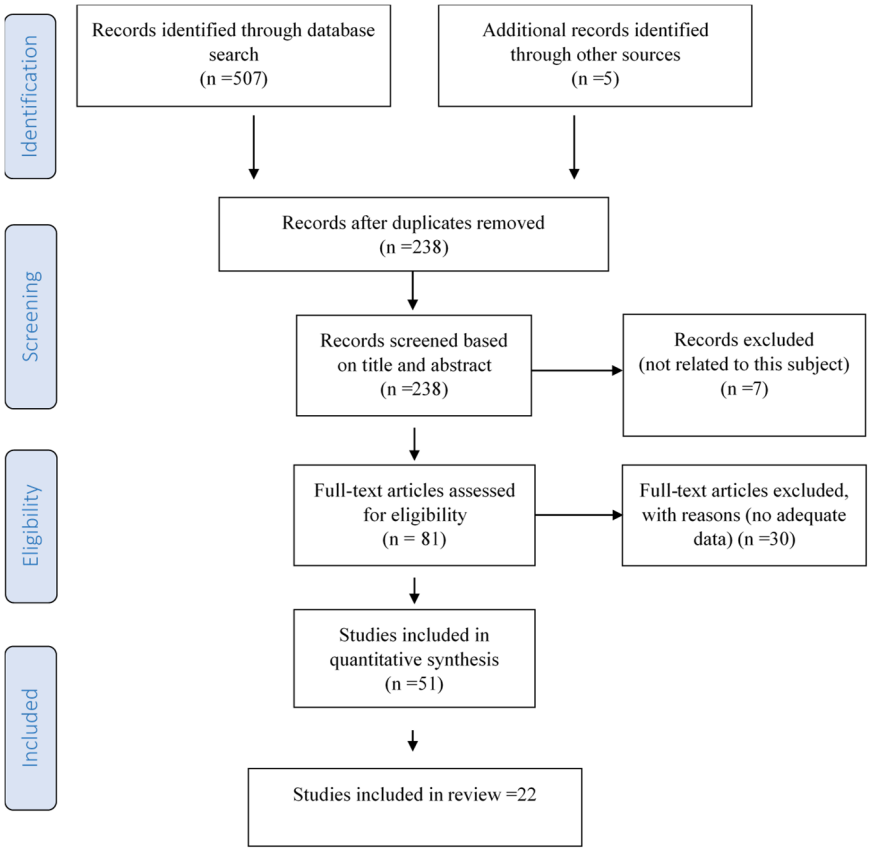

Figure 1. Flow diagram of the studies' selection

studies that did not find any negative effects (16). None of the COVID-19 vaccinations mentioned above that are approved for use during pregnancy include live virus. Therefore, these vaccinations cannot spread the infection to unborn children or pregnant women (11, 12).

Immunogenicity and Vaccine Effectiveness

The features of the studies that assessed immunogenicity and vaccine effectiveness are shown in Supplementary Table 1. Most of them were observational cohort studies. These studies used a variety of methods, including case reports, case series, and cohort studies to simply describe pregnant women who had received vaccinations. Other studies compared the safety and efficacy of vaccines in vaccinated, infected, and noninfected pregnant and nonpregnant women (Supplementary Table 1).

After reviewing the 14 related studies, it was observed that all the results are based on a positive immune response in the mother's blood serum, positive antibodies in cord blood samples, and breast milk (17-19, 21-29). In other words, all of them imply that IgG and anti-spike antibody titers were increased after vaccination, especially after a second dose. While in Bookstein et al study, it was reported that serum antibody (IgG) was positive among pregnant and nonpregnant women, pregnant women had significantly lower serum SARS-CoV-2 IgG levels compared with nonpregnant women (24). Another study reported that higher levels of cord blood antibodies were detected in vaccinated women compared with COVID-19-recovered women (19). Also, in Gray et al study, it was reported that the antibody titres after vaccination among pregnant and lactating women was similar to nonpregnant women (21). As a result, even though pregnant women are considered a high-risk population, immunization can still be successful.

According to the results of Mithal et al study, from 22 deliveries, only 3 neonates (1 set of twins) did not have positive IgG tests (27). The reason was the short interval between vaccination and delivery. Two of the mentioned mothers were vaccinated <3 weeks before delivery. Therefore, the time between the injection and delivery should be taken into account for the newborns' optimum immunogenicity.

In 3 studies vaccines' effectiveness during pregnancy have been reported (20, 29, 30). The vaccine effectiveness has been reported as an association between a vaccine and the risk of SARS-CoV-2 infection among pregnant women. In these studies, the risk of SARS-Cov-2 infections was reduced after vaccination (20, 29). In addition, Dagan et al reported that the effectiveness of COVID-19 related hospitalization was 89% after 7 to 56 days after the second dose among vaccinated pregnant women (30).

Vaccine Safety

The characteristics of studies that assessed the safety of vaccines are described in Supplementary Table 2. Cohort studies (n = 10), surveillance studies (n = 1), cross-sectional studies (n = 1), and case reports (n = 1) were the

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most popular study types. The main aim of these studies was the assessment of safety and complications associated with vaccines among vaccinated and nonvaccinated pregnant women, or among pregnant women compared with nonpregnant women (Supplementary Table 2). After reviewing the related studies, no difference was observed in reported vaccine-related reactions in vaccinated pregnant women compared with other groups, such as unvaccinated pregnant women or nonpregnant women (24, 34-38). Most reported vaccine-related complications were local reactions at the injection site (pain, swelling) and systemic reactions (fever >38ºC, headache, malaise, myalgia, fatigue) (24, 29, 31, 36-38). In reality, a similar pattern of reactogenicity among pregnant women compared with others was reported. We can say that complications after vaccination is a usual event. In fact, side effects are the result of the body's reaction to develop antibodies to protect against COVID-19. Thus, the chances of occurrence of any of these complications after vaccination depends on the personality features.

In these studies, vaccine-related pregnancy outcomes were assessed. Pregnancy outcomes, such as stillbirth, preterm delivery, spontaneous abortion, and fetal growth restriction/small gestational age, were reported and the most reported neonatal outcomes were congenital anomalies and low birth weight (20, 21, 29, 32-38). Although these outcomes have been reported in vaccinated pregnant women, vaccine-related pregnancy outcomes among vaccinated pregnant women were not higher than other groups. Thus, more research and postdelivery surveillance systems are needed to prove that vaccination is associated with pregnancy outcomes.

Anomalies after vaccination among pregnant women have been assessed in another study by Shimabukuro et al. Among the participants with completed pregnancies who reported congenital anomalies, none of them had received COVID-19 vaccines in the first trimester or before conception. All pregnancies with major congenital anomalies had received COVID-19 vaccination only in the third trimester of pregnancy (after the period of organogenesis) (38). Thus, it seems that vaccination does not have a role in congenital anomalies.

In addition, in a study by Blakeway et al, 3 types of fetal malformations (spina bifida, ventriculomegaly, and hydronephrosis) were reported in women who received the COVID-19 vaccine. Spina bifida was diagnosed before receiving the first dose of the vaccine and was not related to vaccination. Ventriculomegaly was diagnosed and isolated at 37 weeks of gestation, with no related brain abnormalities. Hydronephrosis was mild, with no related abnormalities at birth. As a result, according to the researcher reports, the observed outcomes were not associated with the vaccination (36).

Three studies reported on the risk reduction of adverse outcomes and reactions among those pregnant after vaccination (31, 33, 34). These studies implied that vaccination of women in the third trimester of pregnancy was not associated with adverse maternal outcomes. In fact, vaccination was not associated with adverse pregnancy outcomes or neonatal complications (31, 34). In addition, it was observed that a 2-dose vaccination among pregnant women was associated with longer gestational period, and consequently increased birth weight compared with the single dose (33).

There is inadequate evidence of deleterious effects on either the mother or the fetus from vaccination of pregnant women with the COVID-19 vaccinations, despite reports of certain vaccine-related problems. Therefore, there is evidence that the COVID-19 immunization is safe to get during pregnancy, and the benefits of receiving the vaccination outweigh any potential risks of contracting SAS-Cov-2 infection during pregnancy. For instance, a recent publication concerning a national recommendation for the COVID-19 vaccine stated that none of the health organizations suggested delaying the COVID-19 vaccination when pregnant, nursing, or trying to conceive. Therefore, women who are attempting to get pregnant or who are already pregnant shouldn't have any reservations about receiving the COVID-19 vaccine. Because there are no safety issues related to COVID-19 immunization, according to the evidence currently available (39).

WHO and CDC Recommendations

Based on the WHO statements, during pregnancy, the risk of serious illness caused by COVID-19 is high. Also, pregnant women are at higher risk of delivering their neonate prematurely if exposed to COVID-19. Although there is less information on immunizing pregnant women, there is evidence that the safety of the COVID-19 vaccine during pregnancy has been improving, and there are currently no documented concerns regarding safety. Particularly in countries with high transmission rates or if people work in a high-risk industry, which raises their risk of exposure to COVID-19, the benefits of receiving the vaccination outweigh the possible risks. There is absolutely no probability that the vaccination could result in COVID-19. There is no risk of COVID-19 transmission to newborns while breastfeeding because the current vaccinations do not contain live viruses. Additionally, the antibodies produced by immunization can shield infants when given breast milk (40, 41).

There is no biological evidence at this time that COVID-19 vaccination antibodies or vaccine components could affect reproductive organs or reduce fertility, which is relevant if you intend to get pregnant in the future (40).

Discussion

Women during pregnancy experience physiological, immunological, and coagulation system changes. Evidence shows that women during pregnancy have a robust immune response to non–fetal specific antigens (42). Therefore, compared to the general population, they are likely to be more susceptible to SARS-Cov-2 infection and hypoxia due to these changes during pregnancy, especially alterations in the respiratory system, such as a decrease in lung volume and an increase in oxygen use (43).

Many clinical trials do not assess the effects of pharmacological materials in these groups as a result of the "Revitalization Act," which forbids women of reproductive age from participating in phase I and early phase II of

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clinical trials (8). Only mRNA vaccines have been investigated among pregnant women in various stages of the clinical trials for COVID-19 vaccinations, out of all the produced vaccines (11, 12). About other COVID-19 vaccines, reported cases are based on accidental pregnancies during trials. In light of the information gaps on the efficiency and safety of the COVID-19 vaccination among expectant mothers, post-vaccination safety monitoring and evaluation are crucial and necessary.

Studies have generally shown that vaccination is effective in pregnant women, and because of the unique circumstances of this high-risk group, strong immunity against COVID-19 is developed after vaccination and is the same as in non-pregnant people, so pregnancy or breastfeeding have no effect on the vaccine's efficacy. Vaccination is recommended in this period to save the life of the fetus and the mother. Regarding the safety of the vaccine, although studies have reported some consequences of pregnancy after vaccination (32, 36), they are still not sure whether these consequences are really related to the vaccine or not. Therefore, it is necessary to conduct observational studies along with active care to find the cause of this type of outcome in the support of pregnant mothers.

It can be said that the experience of systemic and local complication is one of the common complications of vaccination and does not pose a risk to human life (24, 29, 31, 34, 36-38). The benefits of vaccination in high-risk groups will therefore outweigh the drawbacks. Because of this, becoming immunized is advised during the first, second, or third trimesters or the first few weeks after giving birth, depending on the health guidelines of different countries. There is no reason to wait at any of those times because the vaccine is safe (44, 45).

The results of a systematic review suggested that maternal vaccination protects the fetus and reduces the SARS-Cov-2 infection. Additionally, pregnant, nursing, and nonpregnant women had considerably greater antibody titers from the vaccine than women who had previously contracted SARS-CoV-2 during pregnancy. The same outcomes about unfavorable incidents as what we conclude were seen in this study (46). A literature reviews also showed that IgG after vaccination in pregnant, lactating, and nonpregnant women increased significantly and was stronger than pregnant women who were previously infected with SARS-CoV-2 (47). Another systematic review study revealed an association between longer intervals between receiving the first dose of the vaccination and delivery and rising placental transfer ratios in cord blood. According to safety data, rates of vaccine-related responses in lactating and pregnant women were comparable to those in the general population. There was no observed increase in the probability of unfavorable obstetrical or neonatal outcomes. One study demonstrated that pregnant women were less likely to experience COVID-19 when vaccinated (48).

The lack of long-term follow-up is a weakness in the designs of these studies. We still need adequate data to determine the ideal time for vaccination to trigger the placental immune transfer because some studies only select women who were vaccinated in the third trimester and some studies only compare before and after delivery status for a few periods of time, such as 6 weeks after birth. Thus, the degree of infants' protection against COVID-19 or the duration of such potential protection need to be further studied. Additionally, more studies and postdelivery surveillance programs are required to demonstrate the association between the vaccine and successful pregnancies and to better convince expectant mothers to get vaccinated. Currently studies cover only included data from 3 FDA- and WHO-approved COVID-19 vaccines that conducted on pregnant women. There has not yet been research on other vaccinations. It is advised to conduct more research into the efficacy and safety of other COVID-19 vaccine types, such as inactivated vaccines (such as the Sinopharm BIBP COVID-19 vaccine), particularly in countries where access to mRNA vaccines like Moderna mRNA-1273 and Pfizer-BioNTech BNT162b2 is restricted.

Conclusion

In general, it can be said that vaccination of pregnant women is a good protective factor against COVID-19 and the pregnancy-related consequences observed after vaccination are not related to the COVID-19 vaccine. The scientific community believes that being vaccinated as soon as feasible is the best course of action because there is no evidence to suggest that the COVID-19 vaccine poses a risk to expectant or nursing women. The researchers' findings show that vaccination in this group of people is better than no vaccination, even though assessing the vaccine's long-term effects involves further observational studies and involves maintaining track of pregnant women who have received the vaccine. Naturally, pregnant women who work in clinical settings or in occupations that need a lot of interpersonal interaction should pay particular attention to this matter.

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Authors Contribution

Idea and study design: S.S.H.N. Data collection: S.S.G. and N.T. Methodology: S.S.H.N., N.T. and S.S.G. Writing the original draft: S.S.G., N.T., K.F.B. and ER. Draft revision: S.S.H.N. Writing supervision: S.S.H.N. Searching team: S.S.G., N.T., K.F.B., E.R. and RF. All authors have read the manuscript and approved this submission.

Conflict of Interests

The authors declare that they have no competing interests.

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Supplementary Table 1. Immunoassay results and vaccine effectiveness among pregnant women

Study	Study type	Sample size	Vaccine type	Number of injected doses	Gestational age	Pregnancy out-come	Immunoassay results/ efficacy
Gilbert Paul, et al (17)	Case report	1	Moderna	First dose in pregnancy	36 weeks+3 weeks	Full term	Cord blood antibodies (IgG) were detected to SARS-CoV-2 at a level of 1.31U/mL.
Nadine El Kassis, et al (18)	Case report	1	Pfizer	Two dosages	33+3 weeks (first dose) 36+3 weeks (second dose)	Delivery at 36+6 weeks	The titres of vaccine-generated antibodies were present in the umbilical cord with IgG spike >100 AU/ml.
Omer Nir, et al (19)	Prospective cohort	75 (n= 64 vaccinated pregnant women, n= 11 COVID-19-recovered pregnant women)	Pfizer	Two dosages vaccine at least 14 days before delivery.	-	-	Maternal serum IgG: 26.1 (22.0−39.7) Neonatal cord blood IgG: 20.2 (12.7−29.0) *Higher levels of cord blood antibodies were detected in vaccinated women than in COVID-19-recovered women (P<0.001). Neonatal dried blood spot samples: 11.0 (7.2−12.8) Breast milk IgG: 4.9 (3.8−6.0) Neonatal and breast milk antibody levels were positively correlated with maternal serum antibody levels.
Inna Bleicher, et al (20)	Prospective obser-vational study	326 pregnant women (202 vaccinated and 124 non-vaccinated	Pfizer	Seventy-eight women (38.6%) received one dose, and 124 women (61.4%) received two vaccina-tion doses.	36 (17.8%) were vaccinated during first trimester, 110 (54.5%) during second trimester and 56 (27.7%) during third trimester	-	In the non- vaccinated group, the odds for COVID-19 were about five times higher than in the vaccinated group (8 (6.5%) vs. 3 (1.5%); OR= 4.5, 95% CI (1.19–17.6)

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Supplementary Table 1. Continued

Study	Study type	Sample size	Vaccine type	Number of injected doses	Gestational age	Pregnancy outcome	Immunoassay results/ efficacy
Kathryn J. Gray,et al (21)	prospective cohort	131 (84 pregnant, 31 lactating, and 16 non-pregnant women)	mRNA vaccines	Two dosages	Median gestational age at first vaccine dose: 23.2 (16.3-32.1) Median gestational age at delivery: 39.3 (39 - 40.3)	From 13 delivered, one of them was preterm	Median antibody titres in pregnant was (5.74 (5.06-6.22)) and in lactating women was (5.62 (4.77-5.98)), who had titres similar to those of non-pregnant women (5.59 (4.68-5.89)).
Irene Cassaniti, et al (22)	Editorial issue	9 pregnant women (seven women who experienced SARS-CoV-2 infection during pregnancy, two vaccinated pregnant women	Pfizer	Two dosages	Woman 1: first dose at 31 weeks' gestation and 4 days / days between 2nd dose vaccination and delivery: 37 Woman 2: first dose at 27 weeks' gestation and 6 days/ days between 2nd dose vaccination and delivery: 42	-	SARS-CoV-2 Spike-specific IgA antibodies were documented in the two vaccinated women; IgA were absent in the two newborns. Spike-specific IgG were detectable in two newborns. The neutralizing antibody titre was detected in mothers and newborns.
Lisa Gill, et al (23)	Case report	1	Pfizer	Two dosages	first dose of the vaccine at 32 + 6/7 weeks of gestation and her second dose at 35 + 2/7 weeks	Term	Mother and her neonate were positive for antibodies at a titer of 1:25,600.
S.Bookstein Peretz, et al (24)	Observational	390 pregnant and 260 non-pregnant women	Pfizer	Two dosages	2–40 weeks	Term	pregnant women had significantly lower serum SARS-CoV-2 IgG levels compared to non-pregnant women (27.03 vs 34.35; P<0.001).
Ai-Ris Y Collier, et al (25)	prospective cohort	103 women (30 pregnant, 16 lactating, and 57 neither pregnant nor lactating	mRNA vaccines	Two dosages	Gestational age at first dose vaccination: 5 women in 1st trimester 15 in 2nd trimester 10 in 3rd trimester	Nine infants delivered	Maternal blood antibodies and umbilical cord blood antibodies after vaccination were positive.

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Supplementary Table 1. Continued

Study	Study type	Sample size	Vaccine type	Number of injected doses	Gestational age	Pregnancy outcome	Immunoassay results/ efficacy
Ofer Beharier, et al (26)	Multicenter Cohort study	86 vaccinated pregnant women 65 infected during pregnancy 62 unvaccinated and non-infected during pregnancy	Pfizer	Two dosages	Gestational age, mean ± SD, weeks: 39.3 ± 1.3	4 delivered neonates were preterm	was observed that strong maternal humoral IgG response crosses the placenta barrier and approaches maternal titers in the fetus within 15 days following the first dose
Leena B. Mithal, et al (27)	prospective case series	27 vaccinated pregnant women	mRNA vaccines and other (manufacturer unknown)	22 women (74%) received both vaccine doses	average gestational age at first vaccine dose was 33±2 weeks	Delivered	26 women had a positive SARS-CoV-2 IgG test at the time of delivery. Only 3 neonates did not have positive IgG tests.
Malavika Prabhu, et al (28)	observational	122 pregnant women	mRNA vaccines	55 pregnant women received one dose; 67 women received two doses	gestational age between 35 0/7 and 41 2/7 weeks	Delivered	Number of women with Positive maternal antibodies: 106 Number of positive cord blood antibodies after 55 first dose vaccination: 24 Number of positive cord blood antibodies after 67 two doses vaccination: 65
Inbal Goldshtein,et al (29)	Retrospective cohort	7530 vaccinated and 7530 matched unvaccinated women	Pfizer	First dose	46% and 33% in the second and third trimester	Stillbirth: one in vaccinated and two in non-vaccinated group.5.6% of neonates in vaccinated,6% of neonates among non-vaccinated were preterm.	vaccination was associated with an adjusted hazard ratio for incident SARS-CoV-2 infection of 0.22(95% CI, 0.11-0.43); after first dose. (78% risk reduction)
Noa Dagan, et al (30)	observational cohort study	10,861 vaccinated pregnant women were matched to 10,861 unvaccinated pregnant	Pfizer	Two dosages	-	-	Effectiveness of two dosages vaccination was 96% (95%CI: 89–100%) for any documented infection, 97% (95%CI: 91–100%) for infections with documented symptoms and 89% (95% CI: 43–100%) for COVID-19-related hospitalization.

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Supplementary Table 2. Safety of vaccination among pregnant women

Study	Study type	Sample size	Vaccine type	Number of injected doses	Gestational age	Pregnancy outcome	Safety results
Inna Bleicher, et al (20)	Prospective observational study	326 pregnant women (202 vaccinated and 124 non-vaccinated)	Pfizer	Seventy-eight women (38.6%) received one dose, and 124 women (61.4%) received two vaccination doses.	36 (17.8%) were vaccinated during first trimester, 110 (54.5%) during second trimester and 56 (27.7%) during third trimester	Fetal growth restriction: 3/202	134 women (66%) reported local reactions at the injection site; weakness was reported by 16.8%, headache (10.9%), and nausea (5.4%). three women reported fever ≥ 38℃. The rate of composite pregnancy complications was similar between the vaccinated and non-vaccinated groups (15.8% vs 20.1%, p = 0.37), respectively.
Gray 2021 (21)	Prospective cohort	131 women (84 pregnant, 31 lactating, and 16 nonpregnant women)	mRNA vaccines	First dose + second dose + third dose ("boost")	Median gestational age at first vaccine dose: 23.2 (16.3-32.1) Median gestational age at delivery: 39.3 (39 - 40.3)	From 13 delivered, one of them was preterm. NICU admissions: 2	Vaccine-related fevers or chills after boost dose: 32% among pregnant women (25 of 77) 50% in non-pregnant women (p=0.25). The cumulative symptom score after the first dose was low, but after the second dose, there was no significant difference between groups with respect to cumulative symptom score in pregnant, lactating, and non-pregnant groups respectively; p = 0.40).
Lisa Gill, et al (23)	Case report	1	Pfizer	Two dosages	first dose of the vaccine at 32 + 6/7 weeks of gestation and her second dose at 35 + 2/7 weeks	Term	Reported no adverse effects from vaccine administration, except for soreness at the injection site.

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Supplementary Table 2. Continued

Study	Study type	Sample size	Vaccine type	Number of injected doses	Gestational age	Pregnancy outcome	Safety results
S.Bookstein Peretz, et al (24)	Observational	390 pregnant and 260 non-pregnant women	Pfizer	Two dosages	2–40 weeks	Gestational diabetes= 4 Vacuum/forceps-assisted delivery= 2 Elective Cesarean section= 3 Emergency Cesarean section= 7 Postpartum hemorrhage= 6 NICU = 2	Myalgia, arthralgia, headache, local pain or swelling and axillary lymphadenopathy were significantly less common among pregnant women after each dose, while paresthesia was significantly more common among the pregnant population after the second dose. There was no significant difference in the rate of side effects based on whether the vaccine was given in the first, second or third trimester of pregnancy, except for local pain / swelling, which was significantly less common after the first dose.
Inbal Goldshtein,et al (29)	Retrospective cohort	7530 vaccinated and 7530 matched unvaccinated women	Pfizer	First dose	46% and 33% in the second and third trimester	Stillbirth: 1 in vaccinated and 2 in non-vaccinated group Abortion: 128 in vaccinated and 118 in non-vaccinated group. Intrauterine growth restriction: 36 in vaccinated and 38 in non-vaccinated group. Preeclampsia: 20 in vaccinated and 21 in non-vaccinated group. Preterm birth: 77 in vaccinated and 85 in non-vaccinated group.	The rate of SARS-CoV-2–related hospitalizations was 0.2% among the vaccinated group vs 0.3% among the unvaccinated group. Vaccine-related Adverse effects: none of them was severe. The most commonly reported symptoms were headache (n = 10, 0.1%), general weakness (n = 8, 0.1%), non-specified pain (n = 6, <0.1%), and stomachache (n = 5, <0.1%).
Kachikis A, et al (31)	Prospective cohort	17525 women (7809 pregnant, 6815 lactating, and 2901 neither pregnant nor lactating)	Pfizer Moderna Janssen	15 055 (85.9%) reported receiving 2 doses	-	288 individuals (4.3%) had delivered and 49 individuals (0.7%) reported miscarriages	The most common reactions were pain at the injection site (16 019 individuals [91.4%]) and fatigue (5489 individuals [31.3%]). The frequency of reactions after the second dose was higher than after the first dose. Odds of several reactions were decreased among individuals who were pregnant (eg, fever after BNT162b2 dose 2: OR, 0.44; 95% CI, 0.38-0.52; P < .001 and after mRNA-1273 dose 2: OR, 0.48; 95% CI, 0.40-0.57; P < .001) compared with individuals who were neither pregnant nor lactating.

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Supplementary Table 2. Continued

Study	Study type	Sample size	Vaccine type	Number of injected doses	Gestational age	Pregnancy outcome	Safety results
Kharbanda EO, et al (32)	Case-control surveillance	105 446 unique pregnancies (13 160 spontaneous abortions, and 92 286 ongoing pregnancies).	Pfizer Moderna Janssen	Two dosages	7.8% of women received 1 or more Pfizer-BioNTech vaccines; 6.0% received 1 or more Moderna vaccines, and 0.5% received a Janssen vaccine during pregnancy and before 20 weeks' gestation.	13 160 spontaneous abortions, and 92 286 ongoing pregnancies	The proportion of women with spontaneous abortions was higher (38.7%) than with ongoing pregnancies (22.3%). A COVID-19 vaccine was received among 8.0% of ongoing pregnancy periods vs 8.6% of spontaneous abortions. Spontaneous abortions did not have an increased odds of exposure to a COVID-19 vaccination in the prior 28 days compared with ongoing pregnancies (adjusted odds ratio, 1.02; 95% CI, 0.96-1.08).
Wainstock T, et al (33)	Retrospective cohort	4,399 women (913 vaccinated and 3,486 non-vaccinated)	Pfizer	155 (17.0%) received one dose, and 758 (83.0%) received two doses	The mean time interval between first dose and delivery was 7.5 weeks (±4.1). The mean time interval between second dose and delivery was 5.4 weeks (±3.6).	Cesarean delivery: aOR 0.93 (0.75–1.16) Vacuum delivery: aOR 0.99 (0.63–1.57) Placental abruption: aOR 1.04 (0.29–3.74) Postpartum hemorrhage: aOR 1.46 (0.63–3.38) Maternal postpartum fever: aOR 0.73 (0.15–3.51) Small gestational age: aOR 0.79 (0.48–1.31) Newborn respiratory complications: aOR 0.88 (0.44–1.79) Newborn fever: aOR 1.45 (0.26–8.11)	Prenatal Pfizer-BioNTech COVID-19 vaccination was not associated with adverse immediate pregnancy outcomes or newborn complications. Women who received the 2-dose vaccination delivered at slightly higher gestational age and birth weight.

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Supplementary Table 2. Continued

Study	Study type	Sample size	Vaccine type	Number of injected doses	Gestational age	Pregnancy outcome	Safety results
Rottenstreich M, et al (34)	Multicentre retrospective cohort	712 vaccinated compared with 1063 unvaccinated	Pfizer	Two dosages	Gestational age, mean ± SD, weeks: 39.1 ± 1.6	Induction of labour: aOR 1.66 (1.08 2.55) Hypertensive disorders of pregnancy: aOR 1.38 (0.52 3.68) Multifetal gestation: aOR 1.30 (0.51 3.27)	COVID-19 vaccination in pregnant women was not associated with adverse maternal outcomes. A significant reduction in the risk for neonatal composite adverse outcomes was observed (aOR 0.5, 95% CI 0.36–0.74).
Theiler RN, et al (35)	Retrospective cohort	2002 pregnant women (140 vaccinated and 1862 non-vaccinated)	Pfizer Moderna	73.6% of the 140 patients received both vaccine doses	The median gestational age at first vaccination was 32 weeks (range, 13 6/7−40 4/7 weeks), and at the second vaccination was 35 2/7 (range, 17 1/7−44 1/7 weeks).	Eclampsia or preeclampsia up to 72 h from delivery: 1 in vaccinated and 23 in non-vaccinated group Gestational hypertension: 19 in vaccinated and 225 in non-vaccinated group Low birthweight (<2500 g): 11 in vaccinated and 121 in non-vaccinated group Very low birthweight: 3 in vaccinated and 21 in non-vaccinated group Stillbirth: 0 in vaccinated and 6 in non-vaccinated group	There was no statistically significant difference between vaccinated and unvaccinated individuals in the composite adverse outcome (7/ 140 [5.0%] vs 91/1862 [4.9%]; P=.95)
Blakeway H, et al (36)	Retrospective cohort	140 vaccinated during pregnancy 1182 unvaccinated during pregnancy	mRNA vaccines and, a viral vector vaccine	At least 1 dose	120 women (85.7%) received the first dose during the third trimester of pregnancy and 20 women (14.3%) in the second trimester of pregnancy	Postpartum hemorrhage: 13/133 Small for gestational age at birth: 16/133 Fetal abnormalities: 3/133 Cesarean delivery: 41/133	There was no significant difference in intrapartum complications with the exception of intrapartum fever (OR, 3.85; 95% CI, 1.01–14.6; P=.046) between women who received COVID-19 vaccination and unvaccinated women during pregnancy.

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Supplementary Table 2. Continued

Study	Study type	Sample size	Vaccine type	Number of injected doses	Gestational age	Pregnancy outcome	Safety results
Kadali RA, et al (37)	Cross-sectional	1029 women (38 pregnant, 991 non pregnant)	mRNA vaccines	81.58% (31 of 38) of the pregnant women received both doses of the mRNA vaccine.	-	Miscarriage [1 in 38], and premature delivery [1 in 38])	Adverse effects: fatigue 22/38; headache 19/38; myalgia 13/38; nausea 11/38; fever 6/38; rash 4/38; joint pains 3/38; swelling 3/38; flushing 3/38; brain fogging or reduced mental 3/38; clarity 3/38; itching 2/38; palpitations or increased heart rate 2/38; vomiting 1/38. No statistically significant differences were found between pregnant and non-pregnant women for all reported symptoms.
Shimabukuro TT, et al (38)	Retrospective cohort	35,691 pregnant women	mRNA vaccines	16,982 received one dose, and 12,273 received two doses	2.3% were vaccinated during the preconception period, 1132 (28.6%) were vaccinated during the first trimester, 1714 (43.3%) during the second trimester and 1019 (25.7%) during	Spontaneous abortion: 104 Stillbirth: 1 Preterm birth: 60 Small size for gestational age: 23 Congenital anomalies: 16 Neonatal death: 0	Injection-site pain, fatigue, headache, and myalgia were the most frequent local and systemic reactions after either dose for both vaccines. Adverse neonatal outcomes included preterm birth (in 9.4%) and small gestational age (3.2%). Among 221 pregnancy-related adverse events, the most frequently reported event was spontaneous abortion (46 cases).

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