ORIGINAL ARTICLE

Immunogenicity Response and Adverse Drug Reaction of Covid-19 Vaccine in Pregnancy and Lactation: Rapid Review

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ABSTRACT

Vaccines have emerged as a solution to COVID-19 and have been demonstrated to be effective in preventing severe complications. However, evidence regarding their safety and immunogenicity in pregnant and lactating women remains limited. This rapid review synthesized available evidence on the immunogenicity and safety of COVID-19 vaccines during pregnancy and lactation. Article selection was conducted using PubMed, ScienceDirect, and MEDLINE from database inception until June 10, 2023, using the search strategy ("COVID-19 vaccine") AND ("Pregnancy") AND/OR ("Lactation"). Studies included English-language randomized controlled trials and clinical trials involving human subjects who received COVID-19 vaccines, and methodological quality was assessed using the Jadad and MINORS scores. Based on the 9 articles included, IgA and IgG levels increased in maternal blood and breastmilk following vaccination with mRNA, viral vector, and recombinant protein subunit vaccines, with responses varying by vaccine type, dose, and sampling time. The immunogenicity response generated by the vaccine may boost the infant immunity by transferring antibodies through the placenta and breastmilk. The results indicate that no serious vaccine-related adverse effects have been observed with COVID-19 vaccines administered during pregnancy and lactation in mothers or infants across studies.

Keywords: COVID-19 vaccine; response; lactation; pregnancy

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Introduction

COVID-19 was initially identified in East Asia which causes severe respiratory illness. The virus rapidly disseminates through airborne droplets, contributing to the highly contagious nature of COVID-19 [1]. The disease primarily impacts the lungs and is distinguished by the development of lesions in the lobes, leading to breathing difficulties [2]. Currently, therapeutic progress against COVID-19 encompasses the use of antiviral medications, anti-inflammatory agents, immunomodulators, and antithrombotic drugs to mitigate the severity of the illness [3].

As of 14 June 2023, World Health Organization (WHO) reported almost 768 million have become infected with COVID-19, with deaths reaching more than 6.9 million people. The recent data shows the death rate for COVID-19 is decreasing. This can occur due to the ongoing global distribution of the COVID-19 vaccine, of which almost 13.4 million doses have been administered [4]. Several studies have proven the effectiveness of vaccines against infections, including preventing complications, intensive hospitalization, and death [5], [6], [7], [8], [9].

Several vulnerable groups, including pregnant women, have an elevated risk of severe COVID-19, with increased risks of maternal death, intensive care unit admission, preterm birth, stillbirth, and neonatal intensive care unit admission. Therefore, these groups should be prioritized in the administration of vaccines. In pregnant women,

vaccination may also provide additional protection to the fetus through the transplacentaltransfer of maternal antibodies. During lactation, vaccination can induce antibodies that are detectable in breastmilk, potentially contributing to passive immune protection in breastfed infants [10].

Available evidence also suggests that COVID-19 vaccination during pregnancy and lactation is generally well tolerated, with mostly mild and transient adverse events reported in mothers and no consistent evidence of serious vaccine-related effects in infants. However, early trials of these vaccines excluded pregnant and breastfeeding women, which led to the unproven safety and efficacy of the vaccine utilization within these demographics. In addition, the lack of promotive education targeted toward pregnant and breastfeeding women regarding the COVID-19 vaccine may contribute to hesitancy in these populations [11]. Hence, this review was conducted to evaluate the safety and immunogenicity of COVID-19 vaccines in pregnant and breastfeeding women, focusing on maternal and infant outcomes.

METHODS

Article Selections

This rapid review was conducted to provide a timely synthesis of available evidence regarding the immunogenicity and safety of COVID-19 vaccines during pregnancy and/or lactation. The literature search was conducted across multiple databases, including PubMed, ScienceDirect, and MEDLINE, using the search strategy ("COVID-19 vaccine") AND ("Pregnancy") AND/OR ("Lactation"). The literature search was conducted from database inception until June 10, 2023. The inclusion criteria were English-language randomized controlled trials and/or clinical trials involving human subjects who received COVID-19 vaccines at various doses. Articles unrelated to the review's purpose and animals study were excluded.

The data extraction process involved screening articles based on title and abstract by M.F.A. and S.R.A., followed by a full article review by H.N. and N.A.S to determine eligibility, which was then assessed and approved by D.P.D. A review matrix was developed using Microsoft Excel, capturing author names, publication year, subject characteristics including sample size (pregnant and/or lactating), vaccine type and dose, adverse event to mother and infant, and immunogenicity response (IgA & IgG) including sampling time. Due to differences in study characteristics and reported outcomes, the findings were synthesized based on the relevant outcomes and study characteristics. The risk of bias was considered to interpreting the findings. This rapid review followed PRISMA guideline.

Outcomes

The review question was structured according to the PICO framework. The population (P) included pregnant and/or lactating women. The intervention (I) was COVID-19 vaccination, including different vaccine types and doses. The comparison (C) included differences in vaccine types, vaccination doses, or comparator groups when available in the included studies. The immunogenicity outcomes (O) included IgA and IgG antibody levels in maternal blood and breastmilk, while safety outcomes included local and systemic adverse events reported in mothers and infants. Additionally, the study takes into consideration the timing of sample collection for evaluating these responses.

Sample Processing

Breastmilk

Breastmilk samples from lactating women were collected in the included studies using a breast pump into sterile containers and centrifuged for 10-15 minutes. Supernatant was aliquoted and stored in a freezer before analysis.

Blood

Depending on the method requirements, blood samples were collected from pregnant women in the included studies several weeks after vaccine administration. Blood was diluted and centrifuged for 30 minutes and kept at -80 °C freezer before analysis.

Data Extraction and Risk of Bias

The Jadad score and MINORS score was used to evaluate the risk of bias of the included studies. The

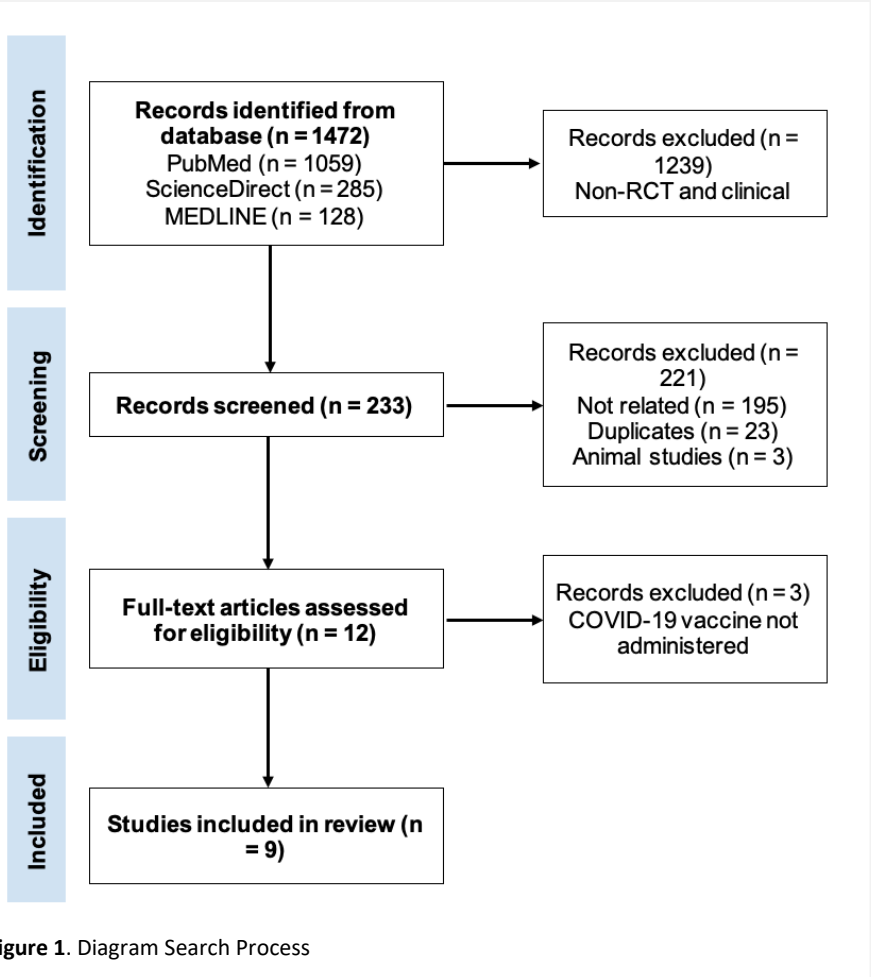

Figure 1. Diagram Search Process

Jadad score was selected to assess the methodological quality of randomized controlled trials, particularly in terms of randomization, blinding, and withdrawals or dropouts. Five specific questions needed to be answered within 10 minutes: Was the study described as randomized (this includes the use of words such as randomly, random, and randomization)? Was the randomization sequence generation method described and suitable? Was the study described as double blind? Was the double blinding method described and adequate? Was there a description of withdrawals and dropouts? [7], [12], [13]. While the MINORS score was selected to assess the methodological quality of non-randomized studies, involved seven key criteria for non-randomization and five score in case of comparative studies [14]

RESULT AND DISCUSSION

Study Selection

The following rapid review was conducted by selecting articles published until June 10, 2023, without imposing any date restriction. Article selection was conducted across multiple databases, including PubMed, ScienceDirect, and MEDLINE. Based on the search keywords, a total of 1472 articles were retrieved, of which only 233 were categorized as clinical trials and RCTs. Based on the inclusion criteria, only 12 were included and through full-text screening, only 9 articles were accepted in this study (**Figure 1**).

Study Characteristics and Interventions

The study's total number of participants consisted of 459 lactating and 115 pregnant women who had received the vaccine at different times (**Table 1**). The participants' demographic data varied, with a total of 55 participants reported having pulmonary comorbidities. There were no severe adverse events following vaccination, while commonly adverse events reported included myalgia, fever, headache, and localized pain causing numbness in the injection area (**Table 2**).

Table 1. Subjects Characteristics

Author	Sample Size (n)		Vaccine Type	Dose
	Pregnant	Lactating		
Atyeo, et al., 2023	31	12	BNT162B2, mRNA-1273	Booster
Bäuerl, et al., 2023	0	84	ChAdOx1, mRNA-1273, Comirnaty	1st, 2nd, 3rd
Charepe, et al., 2021	0	14	BNT162b2	1st and 2nd
Golan, et al., 2021	0	50	BNT162B2, mRNA-1273	1st and 2nd
Gray, et al., 2021	84	31	BNT162b2, mRNA-1273	1st and 2nd
Juncker, et al., 2022	0	134	BNT162B2, mRNA-1273, AZD1222, AD26.COV2.S	1st
Lee, et al., 2022	0	13	BNT162b2	1st and 2nd
Pérez-Bernal, et al., 2022	0	103	Abdalla	3rd
Ricciardi, et al., 2022	0	18	BNT162B2	1st and 2nd

Table 2. Adverse Events

Author	Adverse Event (%)	
	Mother	Infant
Atyeo, et al., 2023	NR*	NR*
Bäuerl, et al., 202	NR*	NR*
Charepe, et al., 2021	Myalgia (57), Headache (42.9), local pain (35.7), fever (7.1), photophobia (7.1), arthralgia (7.1), arm numbness (7.1%)	NR*
Golan, et al., 2021	Pain (88), redness (4), swelling (17), itching (4), rash (2), fever (12), headache (21), fatigue (44), Nausea (2), Diarrhea (4), decrease in milk supply (2)	After 1st vaccination: none (88), tired (2), pooping a lot (2), diaper rash (2), face rash (2), disrupted sleep (2) After 2nd vaccination: none (100)
Gray, et al., 2021	Fever (32), headache (32), muscle aches (48), fatigue (53), injection soreness (57), other (9)**	Supplemental oxygen (8), TTN*** (8), NICU*** admission (15)
Juncker, et al., 2022	NR*	NR*
Lee, et al., 2022	Symptoms were reported but none are described	NR*
Pérez-Bernal, et al., 2022	NR*	NR*
Ricciardi, et al., 2022	Myalgia (16.6), Headache (16.6), Local pain (5.5), arm lymph node swelling (5.5), Fever (5.5), Skin rash (5.5), Arthralgia (5.5), arm numbness (5.5)	None

* NR, Not Reported
**Other adverse effect including joint pain, nausea, sore throat, dizziness, stomachache, night sweats, clogged ears, swollen eyes.
***NICU, neonatal intensive care unit; TTN, Transient tachypnea of the newborn;

Quality Assessment of the Included Studies

Evaluating the effectiveness of compelling evidence presented in an article, it is crucial to include a scoring 1

and a MINORS score in order to determine the study's strength. In this particular article, one randomized articles with a minimum score of 4 by Jadad Score, while the MINORS score includes eight articles with a minimum score of 13 (**Supplementary Tables S1 and S2**).

Supplementary Table S1. Quality Assessment was Conducted Using The Jadad Score

Author	Randomization	Description of randomization	Double-blind method	Description of the blinding method	Description of participant withdrawal/drop-out	Total score
Lee et al., 2022	1	1	1	1	0	4

Supplementary Table S1. Quality Assessment was Conducted Using The Jadad Score

Author	A stated aim of the study	Inclusion of consecutive patients	Inclusion of consecutive patients	Inclusion of consecutive patients the aim of the study	Unbiased assessment of the study endpoint	Follow-up period appropriate to the aim of the study	Loss to follow up less than 5%	Prospective calculation of the study size	An adequate control group	Contemporary groups	Baseline equivalence of groups	Baseline equivalence of groups	Skor
Atyeo et al., 2023	2	0	2	2	0	2	0	0	2	2	2	2	16
Bäuerl et al., 2023	2	2	2	2	0	0	0	0	2	1	1	2	14
Charepe, et al., 2021	2	0	2	2	0	2	2	0	2	1	2	2	17
Golan et al., 2021	2	0	2	2	0	2	0	2	0	2	2	2	16
Gray et al., 2021	2	1	2	2	2	2	0	2	2	2	2	2	21
Juncker et al., 2022	2	1	2	2	0	2	0	0	0	2	2	2	15
Pérez-Bernal et al., 2022	2	1	0	2	0	2	0	0	2	2	2	2	15
Ricciardi et al., 2022	2	1	2	2	0	2	0	0	0	2	0	2	13

Vaccine Type

Five vaccine types were identified in the included studies, representing three vaccine platforms. There are mRNA vaccines (BNT162b2/Comirnaty and mRNA-1273), viral vector vaccines (AZD1222/ChAdOx1 and Ad26.COV2-S), and a recombinant protein subunit vaccine (Abdala) [15], [16], [17], [18]. Adverse events reported following mRNA vaccination were generally mild and included fever, myalgia, headache, and local injection-site reactions, while no serious vaccine-related adverse events were reported in mothers or infants across the included studies (**Table 2**).

The outcome of this review was to assess the effectiveness and safety of the vaccine during pregnancy and lactation. Effectiveness was assessed by the immunogenicity response, specifically, the concentration of IgA and IgG antibodies formed in mothers and infants (**Table 3**). Safety was assessed by post-vaccination effects, including local and systemic effects and other conditions (**Table 2**).

Maternal Antibody Response

IgA represents the most produced immunoglobulin in the body and is found in both the bloodstream and tissues. It exhibits activity against various pathogens, including COVID-19. IgA plays an essential part in safeguarding the epithelial barrier from pathogens and regulating excessive immune responses in inflammatory conditions [19]. IgG is also an antibody produced post-infection, characterized by its capability to recognize antigens with high affinity. Both IgA and IgG can be transmitted from a mother to her infant. IgA is transferable through breastmilk, while IgG traverses the placenta, entering the fetal bloodstream. Consequently, the newborn attains IgG levels similar to those of the mother following vaccination.

Studies included assessed the outcome of IgA and IgG antibody responses in both blood and breastmilk. There was an increase in IgA and IgG concentration in all participants who received the vaccine [10], [20], [21], [22], [23], [24], [25], [26]. With reports indicating that IgA is more predominant in breastmilk than IgG. However, there are several studies that found IgA levels decreased after some time. For instance, one study reported a decline in IgA levels six months after the first dose of the vaccine [26], while another observed a decrease after nine weeks of vaccination [25]. Additionally, certain results demonstrated a reduction in IgA levels after the second vaccine dose [22].

The decline in IgA levels may be attributed to the limited ability of intramuscular vaccine administration to stimulate a robust mucosal response over an extended period. Consequently, intramuscular vaccine administration is effective primarily in eliciting a strong systemic antibody response [10], [26]. The decline in IgA that occurred was also attributed to its kinetic nature [25]. The immune composition of breast milk changes during breastfeeding. Even though the concentration of IgA in breastmilk decreases gradually over time, research suggests that frequent breastfeeding is likely to cause a buildup of IgA, which continues to have a neutralizing impact against COVID-19 [27]. Antibodies to COVID-19 can be transmitted to infants through breastmilk from vaccinated mothers, suggesting the potential for passive immunity.

Adverse Events

The study included revealed that certain participants encountered adverse effects following the administration of the vaccine. The adverse effects occurred in the form of local and systemic effects. Maternal adverse events reported were mostly caused by BNT162b2 [10], [22], [23], [26] mRNA-1273 [10], [23] with the highest incidence being fever[10], [22], [23], [26] myalgia[22], [26] headache [5, 9, 11, 26] and localized pain [10], [22], [23], [26]. Among the 9 included studies, no severe effects were reported such as death, life-threatening, hospitalization and disability. No maternal vaccination-related adverse effects were reported in infants. However, decreased milk supply was reported in 2% of participants following BNT162B2 and mRNA-1273 vaccination [23]. In Gray's study, a vaccinated mother encountered preterm labor, resulting in the newborn requiring supplemental oxygen and one of the two instances necessitated NICU admission. The second admission to the NICU involved a full-term baby with growth restriction, admitted due to sustained low blood sugar levels [10]. While study by Golan et al, stated that the first dose of mRNA vaccine caused a decrease in milk supply in one participant, and another after the second

dose [23].

A study showed that booster vaccine administration did not significantly increase IgA in breastmilk compared with primary vaccine administration [10]. However, other studies have reported an increase antibody following the second or third vaccine dose [10], [20], [22], [23], [26], [28]. Several studies also reported difference antibody responses between mRNA and vector vaccines, with more substantial elevation in IgA and IgG responses identified in those who received mRNA vaccines compared to those who received vector vaccines [21], [24].

Discussion

The distinct patterns observed in the immune responses of IgA and IgG antibodies can be attributed to their diverse role. IgA is essential in the early immunologic response, acting as the major immune barrier, whereas IgG mainly participates in the secondary immune response. Variations in antibody concentrations in breastmilk and serum are interrelated, as antibodies in breastmilk are mainly produced by plasma cells located in the mammary glands. This reflects the antigen exposure experienced by the mother's immune system. The accelerated increase in antibodies following the second dose aligns with immunological memory, resulting in a quicker and more robust response with higher antibody levels upon subsequent exposure to the antigen [24].

Administering the COVID-19 vaccine during pregnancy is advisable, as it can facilitate the passive transfer of antibodies to the fetus. The transmission of COVID-19 antibodies from mother to fetus has been identified both through the placenta and breastmilk [10] Although the antibody provided by breastmilk to infants is not expected to endure significantly beyond the breastfeeding period, this is because mucosal IgA antibodies do not possess the long-term persistence seen in IgG antibodies circulating in the bloodstream [29], the protection provided to this vulnerable group should not be overlooked.

Table 3. Immunogenicity Response

Author	Sampling Time	Ig A & IgG Response
Atyeo, et al., 2023	4 weeks after booster dose	Both Ig A and IgG showed higher levels than primary vaccination
Bäuerl, et al., 2023	1st dose, 2nd dose, 3rd dose	mRNA vaccine induced higher levels of IgA and IgG than vector vaccine
Charepe, et al., 2021	1st dose, 2nd dose	IgA and IgG increased after 1st dose, but IgA slightly decreased after 2nd dose
Golan, et al., 2021	1st dose, 2nd dose, 4-10 weeks after 2nd dose	IgA and IgG Increased significantly after 2nd dose
Gray, et al., 2021	1st dose, 2nd dose, 2-6 weeks after 2nd dose	Significant increase of IgA, IgG and IgM, but a further increase of IgG after the 2nd dose
Juncker, et al., 2022	15 days after 1st dose 70 days after 1st dose	mRNA vaccine showed higher increase of IgA and IgG than vector vaccine
Lee, et al., 2022	4 months after 2nd dose	After 2nd dose, concentration of RBD-binding IgG 4 to 5-fold higher in post-partum women than non-post-partum women
Pérez-Bernal, et al., 2022	5 weeks and 9 weeks after vaccination	Both IgA and IgG showed higher reactivity in 5 weeks after vaccination but decline in 9 weeks after vaccination
Ricciardi, et al., 2022	Before vaccination At 2nd dose 3 weeks after 2nd dose 6 months after 1st dose	IgA and IgG increase significantly, but IgA decrease 6 months after 1st dose

The production of breast milk is affected by various hormones and neurotransmitters. The process of milk production is referred to lactogenesis which is stimulated by the hormone prolactin. Following delivery and removal of the placenta, there is a fall in estrogen and progesterone levels leading to an increase in prolactin hormone. Prolactin is secreted by the anterior pituitary, and is inhibited by the dopamine gland in the hypothalamus [30]. When the baby is breastfeeding, nerves stimulate the release of prolactin, which causes milk production, and oxytocin, which causes muscle contraction, pushing milk out into the milk ducts [31]. Decreased milk production is common in early pregnancy in the range of 24-48 hours after pregnancy due to postpartum adjustment of progesterone and estrogen hormones. Milk production is also affected if the baby is born prematurely. Stressful maternal conditions also increase cortisol hormone levels which can inhibit prolactin secretion [30]. To be precise, there are no studies or reports from WHO that explain the direct effect of vaccines on breast milk production, but the condition may be caused by stress that arises due to systemic reactions following vaccination. Based on the reports of decreased milk supply during lactation following COVID-19 vaccination should be further investigated to rule out the cause.

This rapid review has several limitations. Some methodological processes were streamlined to facilitate a timely synthesis of the available evidence, including the use of three databases and a simplified data extraction process using a review matrix. In addition, the included studies differed in vaccine platforms, vaccination schedules, study populations, outcome measurements, and sampling times, which limited direct comparison of the findings. Therefore, the findings should be interpreted considering these methodological and clinical variations.

CONCLUSION

These data findings indicate the efficacy and safety of the COVID-19 vaccine are favorable for pregnant and lactating women. Based on the study included, IgA and IgG antibody levels increased in maternal blood and breastmilk following vaccination, with responses varying according to vaccine type and sampling time. There are no major effects related to the administration of the COVID-19 vaccine, although decreased milk supply was reported in some lactating women. COVID-19 vaccination during pregnancy may also contribute to improving the infant immunity through the transfer of antibodies across the placenta and breastmilk.

CONFLICT OF INTEREST

The authors have no conflicts of interest regarding this investigation.

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