



# Awareness and Safety of COVID-19 Vaccination in Pregnancy

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## Abstract

**Background** COVID-19 vaccines are safe in pregnancy, as they do not contain a live attenuated virus. Mass vaccination is a key to control the pandemic. Neonates have been shown to be susceptible to severe illness, so maternal vaccination is important to provide neonatal vaccination.

**Methods** The present study was conducted for a period of one year from November 21, 2021 to October 20, 2022 at the Department of Obstetrics and Gynecology A.S.J.S.A.T.D.S. medical college, Fatehpur. It was a hospital-based cross-sectional study. This study aimed to investigate the efficacy, safety, attitude, side effect and maternal neonatal outcome of COVID-19 vaccination among pregnant women.

**Results** Out of 3320 pregnant women delivered, only 1170 (35.24%) received at least one dose of COVID-19 vaccine. 69.23% were unaware of the type of COVID-19 vaccine. 66.15% were vaccinated for both the doses before pregnancy. 12.30% of women had taken only the first dose of COVID vaccine before pregnancy. Majority had fever with chills after the first dose. Fatigue was most common side effect after second dose, and no one had any rash or allergic reaction. 56.15% delivered vaginally, 37.69% had LSCS for different obstetric indications, and 6.15% had instrumental delivery. During the antenatal period, 38.46% developed anemia, 11.54% had preterm labor, 2.05% had gestational diabetes, 2.30% developed preeclampsia, and 3.85% developed hypothyroidism. 3.07% prolonged labor in intrapartum period, and 6.92% women developed PPH. 50.77% newborns were between 2.5 and 2.9 kg, and majority 71.54% newborns had an APGAR score of 7 or more at 5 minutes. 14.62% newborns had meconium aspiration syndrome, 3.84% had respiratory distress syndrome, and 20.34% needed NICU admission more than 24 hours.

**Conclusion** Available data do not support increased risk of adverse outcome following COVID-19 vaccination. We recommend vaccination during pregnancy as benefit outweigh the potential risk.

**Keywords** COVID-19 · SARS-CoV 2 · Vaccine

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The World Health Organization declared the SARS-CoV-2 outbreak a worldwide pandemic on March 11, 2020 [1]. Pregnant patients with symptomatic COVID-19 infection are at risk of increased rates of hospital admission with ICU requirements [2, 3]. SARS-CoV-2 infection during pregnancy also includes the risk of preterm delivery and preeclampsia, which have been linked to inflammatory mechanisms [4]. Theoretically, COVID-19 vaccines are safe in pregnancy, as they do not contain a live attenuated virus. Mass vaccination is a key to control the pandemic [5].

In the UK, COVID-19 vaccines—messenger RNA (mRNA) vaccines (Moderna, Pfizer-BioNTech) and viral vector vaccine (Oxford-AstraZeneca)—are approved. However, the Federation of Obstetric and Gynaecological Societies of India's statement on COVID-19 vaccination for pregnant and breastfeeding women states that protection from

vaccination should extend to pregnant and lactating women, given that the benefits seem to far outweigh any theoretical and remote risks of vaccination [6]. The International Society of Infectious Diseases in Obstetrics and Gynaecology prioritizes pregnant women to receive vaccination against SARS-CoV-2 and favors the mRNA vaccines until further safety information becomes available [7].

The mRNA vaccines act by releasing mRNA that encodes for the SARS-CoV-2 spike protein into cells, allowing the cell's machinery to produce the spike protein. The body's immune cells then generate a response to the spike protein, creating the antibodies that provide immunity to SARS-CoV-2. The other vaccines with data on safety in pregnancy, the Oxford-AstraZeneca and Johnson & Johnson-Janssen vaccines, rely on an adenovirus vector to introduce DNA for the SARS-CoV-2 spike protein into the body's cells. The DNA is first copied into mRNA, and then, as with the mRNA vaccines, RNA is used to produce copies of the spike protein, which then stimulates the immune system to create antibodies [8].

Neonates have been shown to be susceptible to severe illness from SARS-CoV-2 infection, so maternal vaccination is important to provide neonatal vaccination. Vaccination during pregnancy has the potential to protect both mother and neonate as neonates rely on the active placental transfer of maternal IgG for their protection against pathogens during the first six months of life. Therefore, this study aimed to investigate the efficacy, safety, attitude, side effect and maternal neonatal outcome of COVID-19 vaccination among pregnant women.

The present study was conducted for a period of one year from November 21, 2021 to October 20, 2022 at the Department of Obstetrics and Gynaecology A.S.J.S.A.T.D.S. medical college, Fatehpur. It was a hospital-based cross-sectional study. All the pregnant women admitted in labor emergency room and delivered at our hospital were included in the study and women who refused to participate in the study were excluded. A preformed questionnaire form was filled regarding COVID-19 vaccinations and any complication during labor or in postpartum period was noted.

#### Inclusion criteria-

All pregnant females with a known COVID-19 vaccination status admitting in labor room.

#### Exclusion criteria-

- Non-vaccinated pregnant female
- Pregnant females who refused to participate in the study

In total, 3320 pregnant women were delivered at our hospital. Out of which, 1170 (35.24%) received at least one dose of COVID-19 vaccine and were included in the study. Knowledge regarding COVID-19 vaccinations and safety profile was assessed. Timing of COVID-19 vaccination

(both 1st and 2nd dose), type of vaccine (Covishield or Covaxin) and any side effects after 1st or 2nd dose of vaccine (e.g., rash, fever with chills, headache, fatigue, muscle ache or any allergic reaction) were noted. Maternal outcome in the form of mode of delivery, antenatal complications (e.g., anemia, preterm labor, gestational diabetes, preeclampsia or hypothyroidism), intrapartum complication (e.g., prolonged labor) and postpartum complications (e.g., PPH, sepsis or mortality) were noted. Neonatal outcomes including birth weight, Apgar score and any neonatal complications, e.g., respiratory distress syndrome (RDS), meconium aspiration syndrome (MAS), intrauterine death (IUD), COVID-positive newborn and NICU admissions, were noted.

All the data were collected and summarized. Statistical analysis was done using SPSS 20.

## Results

In the present study, 3320 pregnant women delivered in the District Women Hospital eligible for the COVID-19 vaccine, Fatehpur, out of which only 1170 women (35.24%) received at least one dose of COVID-19 vaccine.

In the present study, a total of 1170 pregnant women were screened for COVID-19 vaccination status. The majority of women (52.30%), i.e., 612 out of 1170, were between 26 and 29 years of age. The rest of 24.62% (288/1170) were aged 20–25 years and 270 out of 1170 (23.07%) were in the age group of 30–35 years.

468/1170 (40%) of women were primigravida, 441/1170 (37.69%) were gravida 2, and the rest of 261/1170 (22.30%) were gravida 3 or more.

The majority of 720/1170 (61.54%) were belonging to rural areas, and rest 450/1170 (38.46%) belonged to urban demographic areas.

261/1170 (22.30%) were illiterate, 441/1170 (37.69%) were below 10th pass out, 333/1170 (28.46%) were 12th pass out, and the rest 135/1170 (11.54%) women were graduated. (Table 1).

In the present study, the majority of 810/1170 (69.23%) women were unaware of the type of COVID-19 vaccine administered to them. 207/1170 (17.69%) women were administered Covishield and 153/1170 (13.08% women were administered Covaxin (Table 2)).

Majority 774/1170 (66.15%) of pregnant women in our study were vaccinated for both the doses of COVID-19 vaccine before pregnancy. The rest of 33.85% of women received COVID vaccine during the pregnancy.

12.30% of women had taken only the first dose of COVID vaccine before pregnancy and did not take the second dose. 9.23% of women took the first dose of COVID-19 before pregnancy and the second dose during the first trimester. Similarly, 9.23% of women took the first dose of COVID-19

**Table 1** Demographic distribution

Parameter		Number	Percentage
Age	20–25	288	24.62
	26–29	612	52.30
	30–35	270	23.07
Parity	G1	468	40.0
	G2	441	37.69
	≥ G3	261	22.30
Demographic area	Rural	720	61.54
	Urban	450	38.46
Education	Illiterate	261	22.30
	Less than 10th	441	37.69
	12th	333	28.46
	Graduate	135	11.54

**Table 2** Awareness about type of COVID-19 vaccine

Type	Number	Percentage
Covishield	207	17.69
Covaxin	153	13.08
Not known	810	69.23
Total	1170	100

**Table 3** Timing of Administration of Covid-19 vaccine

Timing	1st Dose	2nd Dose
Before pregnancy	144(12.30%)	–
First trimester	9(0.76%)	108(9.23%)
Second trimester	10(0.85%)	108(9.23%)
Third trimester	8(0.68%)	9(0.76%)

**Table 4** Side effects after COVID-19 vaccination during pregnancy

Side effects	After 1st dose			After 2nd dose		
	1st trim. (n=9)	2nd trim (n=10)	3rd trim (n=8)	1st trim. (n=108)	2nd trim (n=108)	3rd trim (n=9)
Rash	–	–	–	–	–	–
Fever with chills	8 (88.9%)	8 (80%)	7 (87.5%)	40 (37%)	45 (41.7%)	3 (33.3%)
Headache	4 (44.4%)	3 (30.0%)	4 (50%)	44 (40.7%)	49 (45.4%)	2 (2.22%)
Fatigue	6 (66.7%)	7 (70%)	5 (62.5%)	66(61.1%)	57(52.7%)	5(55.5%)
Muscle ache	5 (55.6%)	5 (50%)	4 (50%)	50 (46.3%)	42 (38.9%)	4 (44.4%)
Allergic reaction	–	–	–	–	–	–

before pregnancy and second dose during their second trimester. 0.76% of women took the first dose before pregnancy and second dose of vaccine during their third trimester.

0.76% of women took only the first dose in their first trimester, 0.85% of women took only the first dose in their second trimester, and similarly, 0.68% of women took only

the first dose in their third trimester and all these patients did not take the second dose of vaccine (Table 3).

In present study out of 9 women who had 1st dose of vaccine during 1st trimester, fever with chills developed in 8 (88.9%), headache in 4 (44.4%), fatigue in 6 (66.7%) and muscle ache in 5 (55.6%) of women. Out of 10 women who took 1st dose during 2nd trimester, fever with chills developed in 8 (80%), headache in 3 (30%), fatigue in 7 (70%) and muscle ache in 5 (50%) of women. Out of eight women who received 1st dose of vaccine in 3rd trimester, fever with chills developed in 4 (50%), headache in 6 (75%), fatigue in 5 (62.5%) and muscle ache in 4 (50%) of women.

A total of 108 women who received 2nd dose of vaccine in 1st trimester, fever with chills developed in 40 (37%), headache in 44 (40.7%), fatigue in 66 (61.1%) and muscle ache in 50 (46.3%). Out of 108 women who received 2nd dose of vaccine in 2nd trimester fever with chills developed in 45 (41.7%), headache in 49 (45.4%), fatigue in 57 (52.7%) and muscle ache in 42 (38.9%) of women. Out of nine women who received 2nd dose of vaccine in 3rd trimester fever with chills developed in 3 (33.3%), headache in 2 (22.2%), fatigue in 5 (55.5%) and muscle ache in 4 (44.4%) of women. No one developed any rash or allergic reaction. (Table 4).

In the present study, 657/1170 (56.15%) delivered vaginally, 441/1170 (37.69%) had LSCS for different obstetric indications, and 72/1170 (6.15%) had instrumental delivery. During the antenatal period, 450/1170 (38.46%) developed anemia, 135/1170 (11.54%) had preterm labor, 24/1170 (2.05%) had gestational diabetes, 27/1170 (2.30%) developed preeclampsia, and 45/1170 (3.85%) developed hypothyroidism. 36/1170 (3.07%) women had prolonged labor in intrapartum period and 81/1170 (6.92%) women developed postpartum hemorrhage during their postpartum period. No

one developed sepsis in the postpartum period and no maternal mortality was there in our study. (Table 5).

In the present study, the majority of 594/1170 (50.77%) newborns were between 2.5–2.9 kg, 281/1170 (24.61%) were between 2–2.4 kg, 180/1170 (15.38%) were between

**Table 5** Maternal outcome

<i>Mode of delivery</i>	
NVD	657 (56.15%)
Instrumental	72 (6.15%)
LSCS	441 (37.69%)
<i>Antenatal complications</i>	
Anemia	450 (38.46%)
Preterm labor	135 (11.54%)
Gestational diabetes	24 (2.05%)
Preeclampsia	27 (2.30%)
Hypothyroidism	45 (3.85%)
<i>Intrapartum complications</i>	
Prolonged labor	36 (3.07%)
<i>Postpartum complications</i>	
PPH	81 (6.92%)
Sepsis	–
Mortality	–

**Table 6** Neonatal outcome

<i>Birth weight</i>	
1.5–1.9 kg	90 (7.69%)
2–2.4 kg	288 (24.61%)
2.5–2.9 kg	594 (50.77%)
3–3.4 kg	180 (15.38%)
≥ 3.5 kg	18 (1.54%)
<i>Apgar score at 5 min</i>	
≥ 7	837 (71.54%)
< 7	333 (28.64%)
<i>Neonatal complications</i>	
RDS	45 (3.84%)
MAS	171 (14.62%)
IUD	9 (0.77%)
COVID + ve	–
NICU Admissions more than 24 h	238 (20.34%)

3–3.4 kg, 90/1170 (7.69%) were between 1.5–1.9 kg, and 18/1170 (1.54%) were 3.5 kg or more.

837/1170 (71.54%) newborns had an Apgar score of 7 or more at 5 min and 333/1170 (28.64%) newborns had an Apgar score of less than 7.

171/1170 (14.62%) newborns had meconium aspiration syndrome, 45/1170 (3.84%) newborns had respiratory distress syndrome, and 238/1170 (20.34%) newborns needed NICU admission more than 24 h. Only 9/1170 (0.77%) newborns were IUD (Table 6).

## Discussion

Out of 3320 pregnant women delivered in the District Women Hospital eligible for the COVID-19 vaccine, Fatehpur, during our study period, 1170 women (35.24%) received at least one dose of COVID-19 vaccine. The Blakeway et al. study reported vaccine uptake in 28.5% of eligible pregnant women [8]. In the Kumari A et al. study, 21% of pregnant women were fully vaccinated, as against 30.09% in our study [9].

In the present study, we observed that the majority of women who received COVID-19 vaccination were in the age group of 25–29 years (52.03%). In contrast, Blakeway et al. reported the mean age of pregnant women receiving COVID-19 vaccination as 35 years [8].

In our study, most pregnant women receiving COVID-19 vaccination were primigravida (40%) followed by second gravida (37%). Only 22% women were third gravida and higher pregnancy order. In contrast, the Dhakal et al. study (2021) reported 19% acceptance in 52.2% women with more than one child and 21.85% women with at least one child [10].

In this study, the majority of women were residing in rural areas (61.54%) and the rest were the residents of urban areas (38.46%). Our finding is different from a study by Kumari et al. who reported COVID-19 acceptance in 80.77% urban and 19.23% rural pregnant women [9].

In our study, 22.3% of vaccinated pregnant women were illiterate while 77.7% of women were educated. These findings are consistent with the Theiler et al. study who reported the maximum number of COVID vaccination recipients (53.4%) got formal education for 12–16 years. The study also reported that factors significantly associated with an increased likelihood of vaccination in a multivariable logistic regression model included older age, higher level of maternal education and lower gravidity [11]. A study by Ghamri et al. stated that educated women are more likely to receive COVID-19 vaccine than uneducated women [12].

In this study, the majority (69.23%) of women receiving COVID-19 vaccinations were unaware of the type of vaccine administered to them. Seven percent women were administered Covishield vaccine (nonreplicating viral vector vaccine) and 13% were given Covaxin (inactivated virus). Though pregnant and lactating women were excluded from COVID-19 vaccination in the initial rollout of two vaccines available, on recommendation of the National Technical Advisory Group on Immunization (NTAGI), Ministry of Health and Family Welfare (MoHFW), Government of India approved COVID-19 vaccination of pregnant women in July 2021. This decision empowers pregnant women to make an informed choice to take COVID-19 vaccine [13].

In our study, out of 1170 participants, 999 (85.38%) were fully vaccinated while the rest received at least on dose of COVID-19 vaccine. 66.15% of women received both doses of COVID-19 vaccine before pregnancy. 12.3% of women were partially vaccinated (received one dose of COVID-19 vaccine) prior pregnancy. In the antenatal period, 2.28% of women received only the first dose of the COVID-19 vaccine and 19.22% women received both doses of COVID-19 vaccine. The majority of women received COVID-19 vaccine in first (9.99%) and second (10.08%) trimester, while 1.44% received COVID-19 vaccine in the third trimester.

In the Blakeway et al. study, 85.7% of pregnant women received at least first dose of COVID-19 vaccine in first trimester. In a systematic review on mRNA COVID-19 vaccines in pregnancy, the median [interquartile range (IQR)] of the mean or median gestational age across the studies was 32 (31.5–33.2) weeks (8). This is in contrast with our study, where an equal number of pregnant women received 19 vaccines in the first and second trimester.

The most commonly reported side effects after the first dose of COVID-19 vaccinations were fever with chills followed by fatigue, muscle aches and headache. Fatigue was the most common side effect reported after the second dose, followed by muscle aches. The findings in our study were similar to the Gray et al. (2021) study which reported fatigue (14%) as the most common side effect following first dose of vaccine and muscle aches (48%) after second dose [14]. Adverse events like severe allergic reactions and rash were not reported in our study.

In the present study, 62.3% of women delivered vaginally out of which 6.15% had assisted vaginal delivery and 37.69% had cesarean section for obstetric indication. Theiler et al. reported spontaneous vaginal delivery (66.5%) as the most common mode of delivery in vaccinated individuals, followed by cesarean delivery (29.8%) which are similar in our study [11].

The most common antenatal complications in our study were anemia (38.4%), preterm labor (11.4%) followed by hypothyroidism (3.85%) and pregnancy-induced hypertension (2.30%). The most common intranatal complication in our study was prolonged labor (3.07%). Postpartum hemorrhage was reported in 3.07% of women. No maternal mortality was recorded in our study.

On the contrary, Goldshtein et al. reported abortion as the most common adverse pregnancy outcome followed by preeclampsia in vaccinated pregnant women with no maternal mortality [15]. In a multi-national observational study (2023), Villar et al. reported that unvaccinated women with COVID-19 symptoms were at significantly increased risks of Maternal Mortality and Morbidity Index; preeclampsia, eclampsia or HELLP syndrome; and referral to higher care or ICU admission, or death [16]. Rottenstreich et al. reported

postpartum hemorrhage in 7.3% of vaccinated women and puerperal fever in 3.2% of women [17].

In our study, 32.3% of women had babies with a birth weight of less than 2500 gm, 66.15% of women delivered babies with a birth weight of 2500–3500 gm and 1.54% of women had a birth weight of more than 3500 gm. Their et al. reported low birth weight (< 2.500gm) in 6% and very low birth weight (1500gm) in 1% of vaccinated pregnant women, which was not statistically different significantly from non-vaccinated pregnant women ( $p = 1$ ) [11].

The APGAR score at 5 min was recorded less than seven in 28.64% women and  $\geq 7$  in 71.54% women. Meconium aspiration syndrome (14.62%) was the most common neonatal complication, followed by RDS (3.8%). In contrast, Peretz-Mchluf R et al. reported that the risk for meconium-stained amniotic fluid was significantly lower in the vaccinated group, suggesting that the vaccine may have a protective effect against it. The same study recorded APGAR score less than seven at 5 min minutes only in 0.31% of neonates of vaccinated women [18].

In this study, stillbirths were recorded in 0.77% of women. Prasad et al. reported that the risk of stillbirth was significantly lower in the vaccinated cohort by 15% (pooled OR 0.85; 95% CI 0.73–0.99, 66,067 vaccinated vs. 424,624 unvaccinated,  $I^2 = 93.9\%$ ) [19].

In our study, NICU admission more than 24 h was reported in neonates of 20.34% women. Newborns with APGAR score less than 7 were 28.64%, in which 20.34% got NICU admission and rest recovered immediately. In contrast, Beharier et al. (2021) reported NICU admission in 4.3% vaccinated women [20]. Theilar et al. study recorded no maternal or early neonatal death in vaccinated pregnant women, which is the same finding in our study.

## Conclusion

All pregnant women are eligible for COVID-19 vaccination, but less than one-third of pregnant women took the vaccination. However, the optimal timing of vaccination in pregnancy for neonates or infant benefit remains unclear.

Available data do not support an increased risk of adverse outcome following COVID-19 vaccination. We recommend vaccination during pregnancy as the benefits outweigh the potential risks. Proper communication to improve the awareness among pregnant women and healthcare professionals on vaccine safety is needed.

## Limitations

Long-term safety profile was not assessed in both mothers and neonates in this study. There may be a recall bias as the

study was done in a questionnaire form. The sample size was small.

**Supplementary Information** The online version contains supplementary material available at <https://doi.org/10.1007/s13224-023-01918-w>.

## Declarations

**Ethics Statement** All procedures performed in studies involving human participants were in accordance with the ethical standards of institution which complies with the 1964 Declaration of Helsinki and its later amendments.

**Conflict of interest** All authors have no conflict of interest.

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