International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Sitimani A et al. Int J Reprod Contracept Obstet Gynecol. 2023 Jan;12(1):170-174
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20223489

Original Research Article

A cross sectional study on COVID-19 vaccination during pregnancy and its safety, perinatal and neonatal outcomes in a tertiary care hospital

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Received: 03 November 2022
Accepted: 30 November 2022

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ABSTRACT

Background: Pregnant women are more likely to suffer severe COVID-19 illness, during the second wave of the COVID-19 pandemic in India, there were increased pregnant cases of severe COVID-19. Following first wave due to the wild alpha variant, the vaccine efficacy was questioned during second wave caused by beta and omicron. When compared to receiving only two doses, a third dose (booster dose) that was given at least five months following the second dose significantly decreased the rate of COVID-19 symptoms and severe COVID-19 caused by all variants.
Methods: A prospective hospital based cross-sectional study was undertaken at SSIMS AND RC, Davangere. This study was conducted on pregnant women visiting antenatal clinics and delivering at the department of OBG at S. S. hospital, Davangere.
Results: The data was collected from Feb 2022 to April 2022 at our institute in women undergoing delivery with history of COVID 19 vaccination during pregnancy. A total of 188 cases were studied in the following duration, majority of the women belonged to the age group of 26 to 35 years. 54.8% of the cases were multiparous followed by 45.2% of the cases who were primigravida's. The mean gestational age during admission and delivery of the patients involved in the study was 37.33 weeks, ranging from as early as 27 weeks of gestation to 40 weeks of gestation. There was no significant correlation between the neonatal and maternal complications seen in the study to the number of doses, gestational age and type of vaccine.
Conclusions: Vaccinating everyone is the most effective method of battling the current COVID-19 outbreak. Despite the lack of sufficient clinical data on long-term side effects, the decline in the number of new cases, critically sick patients, and mortality in many nations suggests that vaccines will put an end to the pandemic.

Keywords: COVID-19 Vaccination, Covisheild, Pregnancy

INTRODUCTION

Corona virus disease 2019 (COVID-19) caused by SARS-CoV-2 and their variants have wreaked havoc around the globe, resulting in a substantial number of fatalities and resource damage. Research indicates that pregnant women are more likely to suffer severe COVID-19 illness, particularly if infection occurs during the third trimester of pregnancy.[1] The second wave of the COVID-19 pandemic, has caused over 25 million illnesses and over 0.3 million fatalities, in India as of May 2021. Throughout the second wave of the COVID-19 pandemic in India, there were increased pregnant cases of severe COVID-19, admissions to intensive care units, and maternal fatalities.[2] The mother should be educated on the significant advantage of preventing asymptomatic infections, and possible infection transfer to others, major illness, long-term effects, and death, the acceptance has been growing.[3] The Government of India currently allows the immunisation of pregnant women against COVID-19 based on the recommendations from the National technical advisory group on immunization. A pregnant woman who satisfies the

requirements may select from one of the three vaccines that are currently authorized in India: Covishield (85% effective) (ChAdOx1 nCoV-19 Corona virus vaccine (recombinant), the local version of the AstraZeneca vaccine; Sputnik V (Gam-COVID-Vac, an adenovirus vaccine imported from Russia); or Covaxin (81% effective) (whole-virion inactivated vero cell, India's homegrown vaccine), a pregnant woman has the option to have the vaccination at any time during her pregnancy.[1,4-9] Studies have shown that if the vaccine is given near the delivery time it confers immunity to the neonate. Following first wave which was due to the wild alpha variant, the vaccine efficacy was questioned during second wave caused by beta and omicron. When compared to receiving only two doses, a third dose (Booster dose) that was given at least five months following the second dose significantly decreased the rate of COVID-19 symptoms and severe COVID-19.[5,9] Experts have concluded that the COVID-19 vaccine is unlikely to endanger a pregnant woman or the foetus based on the available scientific data and the long term consequences on mother and the baby is yet to be established.[9] Majority of the studies that have tested the safety of these vaccines were done on mRNA vaccines and very limited data is available on safety of locally sourced vaccines in India. The current study aims to bridge the gap.

METHODS

A prospective hospital based cross-sectional study was undertaken at SSIMS and RC, Davangere. This study was conducted on pregnant women visiting antenatal clinics and delivering at the department of OBG at S.S. Hospital, Davangere. Pregnant women aged 18 to 35 years who have received COVID-19 vaccination during pregnancy with signed informed consent to participate in this study were included. Patients refusing the vaccination and Pregnancy with anomalous fetus on USG (before vaccination) were excluded from the study. Detailed questionnaire-based history was taken, general physical and obstetric examination was done. Provisional diagnosis and possible outcomes and associated conditions were noted down and neonatal outcomes were followed up post-delivery. The collected data was analyzed and sub-classified based on different variables considered in the study. Suitable tests of significance were applied during statistical analysis to establish the correlation and effects of the variables considered in the study. Probability values $p<0.05$ were considered statistically significant.

RESULTS

The data was collected from Feb 2022 to April 2022 at our institute in women undergoing delivery with history of COVID 19 vaccination during pregnancy. A total of 188 cases were studied in the following duration, majority of the women belonged to the age group of 26 to 35 years. The mean age group of the participants involved in the study was 27.46 years. 63.8% of the patients belonged in the age group of 26 to 35 years, 34% between 18 t0 25 years and 4 patients were above 35 years. 54.8% of the cases were multiparous followed by 45.2% of the cases who were primigravida's.

Table 1: Distribution of the subjects based on maternal history.

Parameters		N	%
Previous LSCS	No	136	72.3
	Yes	52	27.7
Mode of delivery	FTVD	40	21.3
	LSCS	137	72.9
	PTVD	10	5.3
	Vacuum assisted FTVD	1	0.5
Sex of baby	Female	90	47.9
	Male	98	52.1
Birth weight	LBW	54	28.7
	Normal	127	67.6
	VLBW	7	3.7
Term	Early preterm	1	0.5
	Preterm	31	16.5
	Term	156	83.0

Table 2: Mean weeks of gestation.

Weeks of gestation	N	Minimum	Maximum	Mean	SD
1st dose of vaccination	188	9.0	38.0	22.84	7.53
2nd dose of vaccine	156	13.0	35.0	24.95	5.77

The mean gestational age during admission and delivery of the patients involved in the study was 37.33 weeks, ranging from as early as 27 weeks of gestation to 40 weeks of gestation. 6.4% of the cases had history of gestational hypertension and mild preeclampsia, 3.7% had history of severe preeclampsia or eclampsia, 5.3% had history of gestational diabetes mellitus and 10.6% had history of hypothyroidism. The demographics of births following COVID-19 vaccination are depicted in (Table 1), there were a total of 31 preterm births and one early preterm birth. The mean gestational age during first dose of vaccination in pregnancy was 22 to 23 weeks, of which 7% receiving in first trimester, 64% receiving in 2nd trimester and 29 in 3rd trimester. 42 of them took only one booster dose and 146 participants gave history of 2 doses of vaccination. The (Table 3-4) shows the immediate side-effects following 1st and second dose of vaccinations.

Table 3: Distribution of the subjects based on complication post 1st dose of vaccination.

Parameters		N	%
Fatigue	No	147	78.2
	Yes	41	21.8
Fever	No	147	78.2
	Yes	41	21.8
Chills	No	160	85.1
	Yes	28	14.9
Myalgia	No	162	86.2
	Yes	26	13.8
Arthralgia	No	171	91.0
	Yes	17	9.0
Head ache	No	175	93.1
	Yes	13	6.9
Injection site pain	No	146	77.7
	Yes	42	22.3
Lymphadenopathy	No	183	97.3
	Yes	5	2.7
Abdominal pain	No	178	94.7
	Yes	10	5.3
Vomiting	No	159	84.6
	Yes	29	15.4
Others	No	181	96.3
	Yes	7	3.7

Table 4: Distribution of the subjects based on complication post 2nd dose of vaccination.

Parameters		N	%
Fatigue	No	139	73.9
	Yes	49	26.1
Fever	No	163	86.7
	Yes	25	13.3
Chills	No	156	83.0
	Yes	32	17.0
Myalgia	No	160	85.1
	Yes	28	14.9
Arthralgia	No	162	86.2
	Yes	26	13.8
Head ache	No	168	89.4
	Yes	20	10.6
Injection Site pain	No	160	85.1
	Yes	28	14.9
Lymphadenopathy	No	165	87.8
	Yes	23	12.2
Abdominal Pain	No	174	92.6
	Yes	14	7.4
Vomiting	No	172	91.5
	Yes	16	8.5
Others	No	188	100.0
	Yes	0	0.0

The most common neonatal complications seen in the study as shown in (Table 5) were low birthweight and neonatal sepsis (4.3%), respiratory distress syndrome (2.7%) and transient tachypnoea of new-born (1.1%).

Table 5: distribution of the subjects based on neonatal complications.

Parameters	N	%
Extremely LBW and neonatal sepsis	1	0.5
A-LBW, B-LBW	1	0.5
A-LBW and RDS, B-LBW and RDS, C-LBW and RDS	1	0.5
Birth asphyxia HIE grade 1	2	1.1
Extremely lbw and necrotizing enterocolitis	1	0.5
Extremely LBW and RDS	1	0.5
LBW and necrotizing enterocolitis	1	0.5
LBW and neonatal hyperbilirubinemia	3	1.6
LBW and neonatal sepsis	8	4.3
LBW and RDS	5	2.7
LBW and TTN	2	1.1
LBW AND TTN	1	0.5
Necrotizing enterocolitis	1	0.5
Neonatal death	1	0.5
Neonatal hyperbilirubinemia	2	1.1
NIL	150	79.8
RDS	2	1.1
TTN	2	1.1
Very LBW and meningitis	1	0.5
Very LBW and necrotizing enterocolitis	1	0.5
Very LBW and RDS	1	0.5
Total	188	100.0

The maternal complications of the subjects involved in the study most common being post-partum haemorrage followed by puerperal pyrexia and sepsis is depicted in (Table 6). The other obstetric or medical conditions prior to the delivery which might interfere with the outcomes include, oligohydramnios in 3.7% of the cases, Prelabour rupture of membranes in 1.6% of cases, vaginitis and urinary tract infections in 1.6% of cases and 0.5% each for meconium-stained liquor, anaemia, foetal distress and hypertensive disorders of pregnancy.

Table 6: distribution of the subjects based on maternal complications.

Parameters	N	%
Nil	175	93.1
Post-partum depression	1	.5
PPH	6	3.2
Puerperal pyrexia	3	1.6
Puerperal sepsis	2	1.1
Venous thromboembolism	1	.5
Total	188	100.0

DISCUSSION

Although women's immune, cardiovascular, and respiratory systems go through considerable physiological changes during pregnancy, it's possible that

a small bit of stress can make the condition worse. On the other side, pregnancy causes hypercoagulability, which puts lives in danger because of venous and arterial thromboembolism.[1] In a retrospective cohort of more than 40,000 pregnant women, COVID-19 immunisation during pregnancy was not linked with preterm birth or small-for-gestational-age at delivery overall, stratified by vaccination, trimester or number of vaccine doses received during pregnancy, compared to unvaccinated pregnant women.[6] In the current study patients had preterm birth and babies born to these mothers were small for gestational age, there was no significant association between COVID-19 vaccination and onset of preterm labour or babies with small for gestational age. The 3958 participants in the v-safe pregnancy registry were reported to have had 827 completed pregnancies, with 115 (13.9%) ending in a miscarriage and 712 (86.1%) in a live birth in which the participants had received the vaccine in the third trimester. Negative neonatal outcomes included preterm delivery in 9.4% of cases and small for gestational age in 3.2%; no newborn fatalities were recorded. The computed percentage of unfavourable pregnancy and newborn outcomes in women who had a full-term pregnancy after receiving the COVID-19 vaccine was similar to occurrences reported in women before the COVID-19 outbreak, similar results were noted in the current study.[12] According to the most recent research, there is no evidence that giving COVID-19 vaccinations to pregnant mothers increases the risk of adverse pregnancy, maternal, or neonatal outcomes. Nevertheless, it should be remembered when interpreting the results because the majority of the immunizations received by the pregnant women were mRNA vaccines given during the second and third trimesters of pregnancy.[5] The COVID-19 vaccines Vaxzevria and Covishield have been linked to a very uncommon new form of the adverse event known as Thrombosis with Thrombocytopenia Syndrome (TTS), which involves unusual and severe blood clotting events associated with low platelet counts.[7] All COVID-19 vaccinations lack the live virus that causes the disease. As a result, neither pregnant women nor the babies they are delivering will become infected as a result of the immunizations.[8] Another study involving 97 590 individuals, 22 660 (23%) received at least 1 dose of COVID-19 vaccine during pregnancy Comparing those vaccinated during vs after pregnancy, there were no significantly increased risks of postpartum haemorrhage, chorioamnionitis, caesarean delivery, NICU admission or low Apgar score. Findings were qualitatively similar when compared with individuals who did not receive COVID-19 vaccination at any point similar findings were noted in the present study.[10]

CONCLUSION

Vaccinating everyone is the most effective method of battling the current COVID-19 outbreak. Despite the lack of sufficient clinical data on long-term side effects, the decline in the number of new cases, critically sick patients, and mortality in many nations suggests that vaccines will put an end to the pandemic. It will be crucial to get more data for various COVID-19 vaccines, including inactivated virus vaccines, vector-based vaccines, and protein-based vaccinations, as safety information was primarily gathered after the administration of the mRNA vaccine. Additionally, more safety information regarding immunisation during the first trimester is required, and research is necessary to determine whether vaccination against COVID-19 lowers the risk of COVID-19-related pregnancy problems.

ACKNOWLEDGMENTS

Authors would like to thank staff working at S. S. institute of medical sciences for working as front-line worriers during the pandemic.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Sitimani A, Achala KP, Bandamma NS. A cross sectional study on COVID-19 vaccination during pregnancy and its safety, perinatal and neonatal outcomes in a tertiary care hospital. Int J Reprod Contracept Obstet Gynecol 2023;12:170-4.