

COVID-19 Vaccination Status and Pregnancy Outcome during Third Wave

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ABSTRACT

OBJECTIVES: Omicron was declared as a variant of concern by WHO on 26 Nov 2021. Omicron is highly transmissible, but the disease severity and morbidity were lesser compared to the Delta variant. However, COVID-19 Vaccine efficacy was reduced for the Omicron variant whereas it was highly efficacious for the Delta variant. Hence, for evidence-based counseling in pregnant patients about expected outcomes depending on their vaccination status, this prospective cohort study was conducted.

STUDY DESIGN: This study was conducted in Base Hospital Delhi Cantt, New Delhi, India during the third wave of SARS-CoV-2 i.e. from Jan 2022 to Mar 2022. All COVID-19-positive patients who were admitted for delivery were followed up till discharge from the hospital. The outcomes in terms of severity of COVID-19 infection, period of gestation at the time of delivery, intrapartum/postpartum complications, fetal distress, meconium staining of liquor, the requirement of neonatal intensive care unit admission were documented and data was analyzed to assess clinical severity of the disease in fully/partially vaccinated+unvaccinated women.

RESULTS: During the specified period, 22.32% was the positivity rate among the delivered patients. Of 61.78% were fully vaccinated and 24.39% were either not vaccinated or partially vaccinated. The risk of symptomatic COVID-19 illness, the requirement of supportive management, and maternal and neonatal outcomes in both groups were comparable.

CONCLUSION: Unvaccinated or partially vaccinated parturient had no increased risk of symptomatic COVID-19 illness or requirement of supportive management in terms of oxygen inhalation or ventilation as compared with fully vaccinated pregnant women. The study also reported comparable maternal and fetal outcomes in vaccinated and unvaccinated/ partially vaccinated pregnant women. Further studies are required to ascertain whether the comparable outcomes were due to the decreased severity of the disease caused by the omicron variant.

Keywords: COVID-19, Neonatal intensive care unit, Omicron, Reverse transcriptase polymerase chain reaction, Vaccination

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Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has caused major disruptions worldwide since its first detected. Countries have been struggling to manage an overwhelming number of infections. During its replication, thousands of spontaneous mutations have occurred since its emergence. In the year 2021, the Delta (B.1.617.2) variant created havoc in several regions of the world and by the end of the year 2021, a new variant B.1.1.529 i.e. 'Omicron' was detected in South Africa and was declared as a variant of concern (VOC) by the World Health Organization (WHO) on 26 Nov 2021, due to several mutations including mutations in the

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receptor-binding domain (RBD) of spike protein (1) and its increased transmissibility (2,3). The affected countries exhibited new infection peaks much faster than earlier strains.

Omicron, SARS-CoV-2 variant (B.1.1.529), had become a predominant strain in several countries causing a massive surge in COVID-19 cases with nearly 300 million cumulative cases and 5.5 million deaths reported as of January 5, 2022, globally (4). India too suffered an exponential increase in the new cases, also considered the third wave, and reported around 317,000 new COVID-19 cases on 19 January 2022. The confirmation of Omicron predominance was based upon the genomic sequencing, which was done on a small subset of confirmed COVID-19 cases. In the following weeks, most of the genetically sequenced samples were found to be Omicron variants. In Delhi, up to 90 percent of the total samples sequenced were Omicron. However, up to 80 to 90 percent of newly confirmed cases were asymptomatic or mildly symptomatic (5).

Although previous study outcomes cannot be extrapolated to new variants and new cases, the historic perspective on the evolution of COVID-19 infection and the clinical presentation in various waves enriches the medical fraternity and gives confidence in dealing with future mutations. COVID-19 infection in pregnancy had a significant impact on maternal and fetal outcomes in earlier mutations. A multinational study involving 18 countries including 4 low-middle income countries compared pregnancy outcomes between COVID-infected and non-infected pregnant individuals during the period March to October 2020. The results confirmed that COVID-19 infection was associated with a substantial increase in severe maternal morbidity, mortality, and neonatal complications (6). Another study conducted by Sahin et al compares pregnancy outcomes in COVID-19 infection in pre-variant and post-variant groups i.e. pre Delta and Delta groups. They concluded that the rates of severe and critical cases, ICU admissions, the requirement of respiratory support, maternal mortality, rates of preterm delivery, and neonatal intensive care unit (NICU) admissions were significantly increased in the post-variant group (7).

The hazardous effects of COVID-19 infection on pregnancy outcomes necessitated a vaccination drive globally and it had indeed been a game changer in tackling the pandemic. Vaccination is a secure method of boosting immunity and can protect people by triggering an antibody response without causing illness (8). All scientific societies emphasize the value of continuing vaccination programs to protect patients from severe forms of COVID-19 and to slow the circulation of the virus and its variants (9).

Broadly, there are four types of platforms used in making the vaccine worldwide. They are RNA, viral vectors, inactivated viruses, and protein-based platforms. India has majorly relied on the viral vector vaccine Covishield and inactivated virus vaccine Covaxin for its vaccination drive (10).

The most common side effects after receiving the COVID-19 vaccine included injection site tenderness, pain, fatigue, headache, malaise, myalgia, and pyrexia (11). Serious and uncommon side effects of the vaccine include anaphylaxis and thrombosis with thrombocytopenia syndrome (TTS) which occurs 5 in one million and 4 in one million vaccine doses respectively as per CDC. The incidence of severe thrombotic events appeared to be low in a study conducted by Elalamy, et al (12). Other rare side effects are myocarditis and Guillain-Barre Syndrome.

On 16 January 2021, India rolled out the world's largest vaccination program, marking the beginning of an effort to vaccinate a population of 1.3 billion against Covid-19. The vaccines available in India were one developed by AstraZeneca with Oxford University (Covishield) and another by the Indian firm Bharat Biotech (Covaxin). Russia's Sputnik V was approved for use in April 2021 (13). The study by Anil A et al revealed a good level of vaccination acceptance among the population studied. The predominant concerns regarding the vaccine included adverse reactions and efficacy (14). According to government data, Delhi achieved the target of nearly universal at-least single-dose vaccination coverage for its eligible adult population by November-December 2021 (15).

The COVID-19 vaccination drive in India had been one the fastest, most massive, and most successful drives and has averted many deaths. Current vaccines remained effective against severe COVID illnesses and deaths including against the Delta variant and boosters reinforce the protection (16), but the Omicron might be able to evade immunity from vaccines or previous infections and blunt the potency of neutralizing antibodies more extensively than any other variant rendering the existing vaccines less effective against the Omicron (17). The Omicron variant of SARS-CoV-2 was 3 to 6 times more transmissible and affected middle-aged, but the disease severity and morbidity were lesser compared to the Delta variant. COVID-19 vaccine efficacy was 33% for the Omicron variant whereas it was 80% efficacious for the Delta variant (18). Despite being less efficacious, Birol Ilter et al, in their study about the clinical severity of SARS-CoV-2 infection among vaccinated and unvaccinated pregnancies during the Omicron wave found that fully vaccinated pregnant women had a milder illness and were less likely to require oxygen supplementation and intensive care compared with their unvaccinated counterparts (19,20). In contrast, Floyd et al, in their single center's experience showed that infection with the Omicron variant in pregnancy was associated with mild symptoms and minimal requirement for medical intervention. They reported minimal symptoms in vaccinated patients and a low burden of symptoms in unvaccinated patients (21).

There is a considerable lack of detailed information about patients with COVID-19 caused by the Omicron VOC, especially for Indian patients. Our study aims at adding our observation and enriching the medical fraternity about the evolution

of SARS-CoV-2 viral infection and its effect on pregnancy outcomes during the Omicron wave in vaccinated and unvaccinated patients. Hence, for evidence-based counseling in pregnant patients about expected outcomes depending on their vaccination status, we conducted a prospective cohort study on the study population. All pregnant women admitted to the hospital for delivery and tested positive for COVID-19 by rapid antigen test (RAT) or real-time reverse transcriptase polymerase chain reaction (RT-PCR) during the specified period were studied for fetal and maternal outcomes. Like in most studies, we have taken the approach of using the date of SARS-CoV-2 infection as a surrogate for the viral variant, as genotyping of each infection is not commonly available.

Material and Method

This prospective cohort study was conducted in Base Hospital Delhi Cantt, New Delhi, India during the third wave of SARS-CoV-2 i.e. from Jan 2022 to Mar 2022 in the obstetric patients admitted in the maternity ward for delivery and who tested COVID-19 positive by RTPCR or RAT. These patients were observed from admission till discharge from the hospital. The predominant strain of SARS-CoV-2 during this period was Omicron (B.1.1.529).

The institutional ethical committee of Base Hospital & Army College of Medical Sciences, Delhi Cantt, New Delhi India approved the study protocol on 11 Jul 2020 (Approval No 1156/IEC/07/22/01) and it was a continuation of our previous research on pregnancy outcome in COVID-19 positive patients. Informed consent from the study participants was taken and the study was conducted in accordance with the Declaration of Helsinki.

On arrival, the COVID-19 vaccination status of these patients was documented at reception by checking vaccination certificates issued by the Ministry of Health and Family Welfare (MoHFW). Vaccination with a single-dose, double-dose, or booster was meticulously registered. A detailed history was taken to look for any COVID-19-related respiratory, gastrointestinal, or other symptoms. Due to the small sample size, the study population was divided into 2 groups for the analysis i.e. fully vaccinated (Group A) and partially vaccinated and unvaccinated (Group B) were placed in another group. Clinical examination and investigations were done as indicated to confirm the severity of the infection and patients were followed up till recovery and discharge from the hospital. The clinical severity of COVID-19 infection was categorized according to the National Institutes of Health classification (22). Cases were classified as mild if they had symptoms of COVID-19 without lower respiratory tract involvement (no dyspnoea), moderate if they had lower respiratory tract involvement without significant hypoxemia (oxygen saturation on room air $\geq 94\%$) and severe if cases showed signs of hypoxemia, as evidenced by oxygen saturation ($<94\%$) or imag-

ing showing lung infiltrates $>50\%$. Cases without any symptoms were classified as asymptomatic.

Baseline demographic characteristics of the study population were recorded which included maternal age, gravida, parity, socioeconomic status, and body mass index. Existing comorbidities like chronic hypertension, pre-gestational diabetes, and pulmonary disease were noted along with obstetric high-risk factors like hypertensive disorders of pregnancy, gestational diabetes mellitus, twin/multifetal pregnancy, ART pregnancy, intrahepatic cholestasis, and fetal growth restriction. The obstetric outcomes in terms of mode of delivery, period of gestation, intrapartum/postpartum complications, neonatal status at birth, meconium staining of liquor, fetal distress (as diagnosed by FHR tracing category II and III), and requirement of Neonatal Intensive Care Unit (NICU) admission were documented. The compiled data were then analyzed to assess the clinical severity of COVID-19 infection in two groups. All neonates in our study underwent COVID-19 RTPCR/Gene expert pharyngeal swabs.

Statistical analysis

All analyses were done using the Windows-based SPSS-22 statistical package. Estimates were expressed as percentages or proportions. Comparison of continuous variables was done using analysis of variance by one-way ANOVA tests, two-tailed t-tests as applicable, and the Chi-square test was used to test the difference in proportions. $P < 0.05$ was considered statistically significant.

Results

During the specified period, out of a total of 551 deliveries in the hospital, 123 (22.32%) pregnant women tested positive for SARS-CoV-2 infection, confirmed by RAT/ RT-PCR. Out of SARS-CoV-2 infected parturient, 76 (61.78%) were fully vaccinated, 17 (13.82%) had received one dose of COVID vaccination and 30 (24.39%) were unvaccinated.

The socio-demographic characteristics of the study population are tabulated in table I. The baseline characteristics of the study population showed no significant difference between groups A and B. These included age ($p=0.588$), gravidity ($p=0.180$) socioeconomic status ($p=0.731$), and body mass index ($p=0.310$).

Table II suggests that there was no statistical difference between the two groups in the distribution of comorbidities like chronic hypertension ($p=1.00$), pre-gestational diabetes mellitus ($p=0.760$), pulmonary diseases ($p=0.760$), and other obstetric high-risk factors like hypertensive disorders of pregnancy ($p=0.740$), gestational diabetes mellitus ($p=0.680$), intra-hepatic cholestasis of pregnancy (IHCP) ($p=0.710$), fetal growth restriction (FGR) ($p=0.730$), post-IVF pregnancies ($p=0.750$), twin pregnancies ($p=0.720$), and post-caesarean pregnancy ($p=0.670$).

Table I: Comparison of demographic characteristics among SARS-CoV-2 infected, vaccinated, partially vaccinated, and unvaccinated parturients

Variables	Fully Vaccinated (Group A)	Partially Vaccinated	Unvaccinated	Total (Partially/Unvaccinated) (Group B)	<i>p</i>
Age (Years)	n=76	n=17	n=30	n=47	
< 20	1 (1.31%)	1 (5.88%)	6 (20.00%)	7 (14.89%)	0.588
20 to 30	52 (68.42%)	10 (58.82%)	20 (66.66%)	30 (63.8%)	
> 30	23 (30.26%)	6 (35.29%)	4 (13.33%)	10 (21.27 %)	
Gravida					
Primigravida	31 (40.78%)	8 (47.05%)	17 (56.66%)	25 (53.19%)	0.180
Multigravida	45 (59.21%)	9 (52.94%)	13 (43.33%)	22 (46.80%)	
Socioeconomic status					
Low	1 (1.31%)	0 (0%)	1 (3.33%)	1 (2.12%)	0.731
Middle	70 (92.10%)	14 (82.35%)	29 (96.66%)	43 (91.48%)	
High	5 (6.57%)	3 (17.64%)	0 (0%)	3 (6.38%)	
BMI (kg/m ²)					
< 25	21 (27.63%)	6 (35.29%)	9 (30.00%)	15 (31.91%)	0.314
25 to 30	14 (18.42%)	4 (23.52%)	8 (26.66%)	12 (25.52%)	
> 30	41 (53.94%)	7 (41.17%)	13 (43.33%)	20 (42.55%)	

Table II: Maternal high-risk factors

Medical co-morbidities Groups	Fully Vaccinated (Group A)	Partially vaccinated + unvaccinated (Group B)	<i>p</i>
Chronic Hypertension	1 (1.31%)	0 (0%)	1.000
Pre-Gestational Diabetes Mellitus	3 (3.94%)	1 (2.12%)	0.760
Pulmonary diseases	1 (1.31%)	2 (4.25%)	0.760
Obstetric high-risk factors			
Hypertensive Disorders of Pregnancy	3 (3.94%)	5 (10.63%)	0.740
Gestational Diabetes Mellitus	12 (15.78%)	6 (12.76%)	0.680
Intrahepatic cholestasis of pregnancy	6 (7.89%)	10 (21.27%)	0.710
Fetal growth restriction	5 (6.57%)	5 (10.63%)	0.730
ART pregnancy	3 (3.94%)	4 (8.51%)	0.750
Twin pregnancy	6 (7.89%)	4 (8.51%)	0.720
Post cesarean pregnancy	12 (15.78%)	8 (17.02%)	0.670

In Group A, 51 (67.1%) were asymptomatic, 24 (31.57%) were mildly symptomatic, and only 1 (1.31%) patient suffered moderate COVID-19 infection. In Group B, 28 (59.57%) were asymptomatic, 17 (36.17%) were mildly symptomatic, and 2 (4.25%) were moderately symptomatic. The difference in the clinical presentation was not significant ($p=0.580$). (Table III)

None of the groups had severely symptomatic patients. Two patients in both Group A and B required nasal oxygen

support and 1 in Group B showed bilateral lung infiltrates, raised inflammatory markers, and required Continuous positive airway pressure (CPAP). The analysis was statistically insignificant. No patients needed mechanical ventilation and no fatalities were recorded in either group. Preterm births in Group A and Group B were 28.94% vs 29.78% and term deliveries were 71.05% vs. 70.21%, respectively ($p=0.920$). Fetal distress and meconium staining of liquor occurred in

Table III: Clinical Presentation at admission

Groups	Fully Vaccinated (Group A)	Partially vaccinated + unvaccinated (Group B)	<i>p</i>
Asymptomatic	51 (67.1%)	28 (59.57%)	0.580
Mild COVID-19 infection	24 (31.57%)	17 (36.17%)	
Moderate COVID-19 infection	1 (1.31%)	2 (4.25%)	

5.26% and 7.89% of babies in Group A and 7.89% and 8.51% of babies in Group B, respectively ($p=0.800$ and 0.900). Neonatal Intensive Care Unit (NICU) admission was required in 3.94% of neonates in group A and 4.25% of babies in Group B ($p=0.930$). In Group A, 3.94% of mothers had premature rupture of membranes (PROM), and 8.51% in Group B ($p=0.280$). In Group A, 3.94% of patients had non-progress of labor and 8.51% of patients in Group B. None of the outcome variables showed any statistically significant association between vaccinated (Group A) and unvaccinated+partially vaccinated groups (Group B) (Table IV).

In Group A, 61.84% of patients delivered vaginally vs. 51.06% in Group B ($p=0.230$). Of 10.52% and 27.63% of patients in Group A vs 12.76% and 36.17% in Group B underwent elective and emergency cesarean section, respectively ($p=0.900$). The difference was statistically insignificant.

There were no cases of severe COVID-19 infection, or thromboembolism, in either group, and none of the cases required mechanical ventilation. There were no maternal deaths in both group. No cases of neonatal COVID-19 infections or neonatal deaths were documented in an entire study population.

Discussion

During the study period, the positivity rate of SARS-CoV-2 was 22.23% among the delivered patients in the hospital. In our study conducted in the hospital, SARS-CoV-2 positive unvaccinated or partially vaccinated parturient admitted for delivery had no increased risk of symptomatic COVID-19 illness and no increased risk of the requirement of supportive

management in terms of oxygen inhalation or ventilation as compared with fully vaccinated pregnant women.

Kalafat et al in their study inferred that fully vaccinated pregnant women infected with SARS-CoV-2 during the Omicron wave had a milder illness and were less likely to require oxygen supplementation and intensive care compared with their unvaccinated counterparts (23). However, in the study by Bager and colleagues, it was found that infection with the SARS-CoV-2 omicron variant was associated with an inherently lower risk of severe disease and admission to hospital compared with Delta. They observed that this reduced risk was observed across unvaccinated people and those who received only one vaccine dose, as well as individuals who received two and three doses of vaccine (24). This notion of reduced severity and reduced requirement of hospitalization in the SARS-CoV-2 Omicron variant was corroborated by our findings in the study in vaccinated and partially vaccinated or unvaccinated pregnant patients as discussed above. No patients in our study were found to be suffering from severe COVID-19 infection irrespective of vaccination status and none required ventilatory support. Only one patient in group B showed bilateral lung infiltrates, raised inflammatory markers, and required continuous positive airway pressure (CPAP). There were no cases of thromboembolism or life-threatening complications of severe pre-eclampsia and there were no fatalities in either group.

Also, in our study, there was no significant difference in neonatal outcomes in terms of fetal distress, meconium-stained liquor, NICU admission, stillbirths, FGR, and maternal outcomes like term or preterm delivery, mode of delivery, premature rupture of membranes, emergency/elective ce-

Table IV: Feto-maternal outcomes

Maternal adverse outcomes			
Groups	Fully Vaccinated (Group A)	Partially Vaccinated+ Unvaccinated) (Group B)	<i>p</i>
Nasal oxygen support	2 (2.63%)	2 (4.25%)	0.620
Continuous positive pressure airway (CPAP) or High flow oxygen	0 (0%)	1 (2.12%)	
Obstetric outcomes and intrapartum/postpartum complications			
Preterm birth	22 (28.94%)	14 (29.78%)	0.920
Term Birth	54 (71.05%)	33 (70.21%)	
Fetal distress	4 (5.26%)	2 (4.25%)	0.800
Meconium stained liquor	6 (7.89%)	4 (8.51%)	0.900
Stillbirth	0 (0%)	0 (0%)	
Neonatal intensive care unit admission	3 (3.94%)	2 (4.25%)	0.930
Premature rupture of membranes	3 (3.94%)	4 (8.51%)	0.280
Nonprogress of labor	3 (3.94%)	4 (8.51%)	0.280
Vaginal Delivery	47 (61.84%)	24 (51.06%)	0.230
Elective cesarean delivery	8 (10.52%)	6 (12.76%)	0.900
Emergency cesarean delivery	21 (27.63%)	17 (36.17%)	
Post-partum hemorrhage	2 (2.63%)	1 (2.12%)	0.840

sarean section delivery and also there was no significant postpartum hemorrhage (PPH) in either group.

All neonates were allowed to room in and breastfeed. Pharyngeal swabs were tested for all neonates by a COVID-19 RTPCR/Gene expert. In our study, we didn't find any neonate to be positive for SARS-CoV-2. This finding was in line with our previous pilot study done to assess materno-fetal transmission of SARS-CoV-2 conducted during the first wave, where RT-PCR test of amniotic fluid, cord blood, and nasal and throat swab of all new-borns delivered by SARS-CoV-2-positive pregnant women were tested negative for the virus suggesting that possibility of intrauterine vertical transmission of SARS-CoV-2 infection was unlikely (25).

Our findings are limited by the sample size and inclusion based on the time period rather than viral genotyping i.e. during the time when Omicron accounted for the majority of cases in Delhi.

Conclusion

In our study, unvaccinated or partially vaccinated parturients had no increased risk of symptomatic COVID-19 illness or requirement of supportive management in terms of oxygen inhalation or ventilation as compared with fully vaccinated pregnant women. The study also reported comparable maternal and fetal outcomes in SARS-CoV-2 parturients in vaccinated and unvaccinated/partially vaccinated pregnant women. Further studies are required to ascertain whether the comparable outcomes were due to the decreased severity of the disease caused by the omicron variant.

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Compliance with Ethical Requirements: Additional informed consent was obtained from all patients for whom identifying information is included in this article.

Availability of data and materials: The data supporting this study is available through the corresponding author upon reasonable request. The dataset used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' Contributions: Each author contributed to the conception and design, data collection and analysis, experiments, writing the first draft, and supervision. Each author contributed to the writing of the paper and has read and approved the final manuscript

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