ORIGINAL ARTICLE

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Assessment of outcomes of newborns

born to mothers with COVID-19 reverse

transcription-polymerase chain reaction

single center study from Eastern India

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positivity before delivery in January 2022 - A

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ABSTRACT

Background: There have been successive waves of SARS-CoV-2 variants since January 2020, the B.1.1.529 (Omicron) variant has led to a third upsurge in India since December 2021. Neonates constitute a vulnerable population and there is limited literature about natural history, management, and outcomes of Omicron infected newborns. Aims and Objectives: The study was conducted to study the outcomes among newborns born to COVID-19 positive mothers during the Omicron upsurge. Materials and Methods: Between December 2021 and January 2022, this study was conducted on newborns born to COVID-19 positive mothers in a single center during the Omicron upsurge. We investigated the maternal pregnancy complications, methods of delivery, neonatal resuscitation, neonatal conditions, suspicious infectious status, and morbidity based on maternal infections. Results: A total of 39 neonates were born to mothers with a history of Omicron COVID-19 infected during delivery. None were positive when tested or developed any disease specific symptoms in the postnatal period. Among the neonates, 5 needed admissions in newborn units. Birth asphyxia, transient tachypnea of the newborn and meconium aspiration syndrome was seen along with minor problems such as feed intolerance and hyperbilirubinemia. Rest all had been stable throughout the hospital course. All infants had been developmentally stable on followup up to 6 months post-discharge. Conclusion: During Omicron COVID-19, newborns had very less complications and we advise giving breast milk to babies with proper precautions along with rooming-in for the lower income countries.

Key words: Omicron; SARS-COV-2; Neonate; Vertical transmission; COVID-19

INTRODUCTION

World has been going through Covid-19 pandemic after WHO declaration in January 2020. Novel coronavirus was first detected in China in December 2019 and then quickly spread to other parts of the world. The disease caused by coronavirus has been named as SARS-CoV-2 diseases. Transmission of SARS-CoV-2 can occur through contact with infected people through infected secretions such as saliva and respiratory secretions or their respiratory droplets.¹ Available studies indicate that risk of vertical transmission from mother to baby is very less.^{2,3} Pregnant women constitute to be vulnerable group of the population susceptible to SARS-COV-2 infection due to different physiological changes in the immunological and circulatory parameters.

Since the beginning of the pandemic, we have seen fluctuation of the incidence and severity of the

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infection which is partly related to the emergence of variants due to mutational changes. Although the situation improved during 2022, recent worsening of the situation with significant increase in infection in several countries, esp. in China indicates that the impact of the pandemic is still not over.4 Several studies have focused on the outcome of the newborn to mothers with SARS COVID 2 infections during pregnancy and perinatal period. Different routes of transmission include post-partum transmission (horizontal) along with trans placental *in utero*, the immediate peripartum period through fetoplacental bleed and breast milk.⁴ Most of the studies done during the initial phase of the pandemic suggested Transmission of SARS-CoV-2 from mother to baby is rare.5 Several studies also looked at the neonatal outcome which has been mostly favorable. But as mentioned earlier many of these studies were done in the initial phase of the pandemic, and we have hypothesized that the effect might be different with the spread of new variants and effect of mass vaccination and background immunity due to the previous clinical or subclinical infection.

After the declaration of the COVID-19 pandemic by the World Health Organization (WHO) on March 11, 2020, India, has been one of the most affected countries and there has been recorded 27,547,705 cases during the pandemic.^{6,7} Centers for Disease Control and Prevention (CDC) has reported more morbidity among pregnant women with higher risk of ICU admissions and mechanical ventilation due to state of immune suppression and higher susceptibility to respiratory pathogens. Furthermore, patients might be more prone to more rapid clinical deterioration with COVID-19 during pregnancy because of decreased lung volume caused by increases in uterus size during pregnancy. All these factors might lead to adverse neonatal outcomes.^{8,9}

Most studies have shown very less chance of transmission of the virus in breastmilk viral particles have been detected in breastmilk, breastfeeding recommendations have not changed.^{10,11} From the reports of the CDC, it is evident that there is no difference in the risk of infection between neonates who were roomed-in with the mother and those cared for in separate rooms.¹² Despite these factors, which show that the spread of infection from the mother to the child is low, there is an increased risk of transmission of infection to the neonate from the mother, unless adequate infection prevention measures are followed by the mother. Thus, this study aimed to assess the outcome of neonates born to mothers with COVID-19 in India in the phase when increased infection by the Omicron strain of SARS CoV2 was noted.13

Table 1: Baseline characteristics of COVID-19-positive mothers

Parameters	Percentage/Mean
COVID-19 infection of mother	
Asymptomatic	30 (76.9%)
Mild	7 (17.9%)
Moderate	2 (5.12%)
Obstetric complications	
None	27 (69.23%)
Diabetes mellitus	2 (5.1%)
GDM	2 (5.1%)
Hypertension	3 (7.7%)
Pre-eclampsia	5 (12.8%)
Hypothyroidism	5 (12.8%)
Thalassemia trait	2 (5.1%)
Mean maternal age (years) (SD)	27.6±3.16
Primigravida	17 (43.5%)
Multiple gestation	2 (5.1%)
Type of delivery	
Vaginal delivery	1 (2.56%)
Elective cesarean section	15 (38.46%)
Emergency cesarean section	23 (58.9%)

Table 2: Neonatal characteristics among study population

Characteristics	n=39
Gender	
Female	17
Male	22
Gestation	
Mean gestation (weeks)	37.4±1.3 weeks
	(32.6±1.1–39.5±2.2
	weeks range)
Term	15
Preterm	11
Post-term	1
Birth weight (g)	
Mean±SD	2.79±0.45
LBW	5
Normal birth weight	34
EBM/Donor milk feeds	
Breast feeding or EBM from day 1	32
Donor milk feed	4
Both	39

Aims and objectives

The study was conducted to study the outcomes among newborns born to COVID-19 positive mothers during the Omicron upsurge.

MATERIALS AND METHODS

Study participants

This study assessed the association between maternal COVID-19 infection around the time of delivery and neonatal outcomes following delivery. A total of 39 pregnant women were enrolled in our study whose nasopharyngeal swab had been collected within 24 h before after delivery, before administration of any medication and were positive

Table 3: Neonatal complications among thestudy population

Parameters	COVID-19 status, n=39 RT-PCR were done in all, and all were negative
Characteristics	
Stayed with mother	34
Admitted to NICU	5
Respiratory	
TTNB	2
Meconium aspiration syndrome	1
Gastrointestinal	
Feed intolerance	1
Necrotizing enterocolitis	0
Cardiovascular	
Shock	1
Cong heart disease	1
Metabolic	
Hypoglycemia	1
Dyselectrolytemia	1
Neonatal unconjugated	5
hyperbilirubinemia needing phototherapy	
CNS	
Birth asphyxia	1
Treatment	
Antibiotics	6
Intravenous fluids	6
Surfactant	1
Inotropes	1
CPAP	2
Mechanical ventilation	1
Outcome	
Deaths (total)	1

NICU: Neonatal intensive care unit, CNS: Central nervous system, TTNB: Transient tachypnea of the newborn, CPAP: Continuous positive airway pressure

for SARS-CoV-2. All samples (nasopharyngeal swab) were tested by real-time polymerase chain reaction (RT-PCR) for SARS-CoV-2.

Study settings

This is a hospital-based prospective observational study conducted at a tertiary care hospital in Eastern India. Our hospital was providing services as a "dedicated COVID-19 hospital" and here we managed pregnant mothers with SARS Co V2 infections and their neonates.

Informed consent was taken from expectant mothers coming for delivery who tested positive for viral RNA in their nasopharyngeal swab by RT-PCR during the time of hospital admission or tested within 24 h after delivery. We planned to collect net promoter score (NPS) samples from the neonates within 24 h of delivery.

The neonates were assessed after birth and well babies stayed with mother in a separate cot when mother was clinically stable. All other babies were transferred to a designated "COVID newborn nursery" or neonatal intensive care unit (NICU) depending on their clinical condition. All babies were monitored for signs and symptoms as per departmental protocol. As the Government policy for performing NPA for SARS-CoV-2 was changed during the study, NPS was not routinely sent from all the babies. Newborns who stayed with their mother were all breast fed after taking standard infection control measures. Babies who were transferred to nursery/NICU were fed with either expressed mother or donor breast milk depending on the clinical condition of the baby.

Mothers and neonates were discharged as per institutional protocol when both were clinically stable. Mothers were advised to keep the babies in a separate cot and to continue exclusively breast feed their babies after taking standard precautions such as wearing masks covering their nose and mouth and proper hand washing. Danger signs were explained in detail and appropriate follow-up was planned including for routine checkup in newborn clinics and was also advised for immunization at 6 weeks of age.

RESULTS

Thirty pregnant mothers were asymptomatic, seven had mild symptoms (in the form of fever, malaise, rhinitis, and sore throat), and two women were diagnosed as having moderate COVID-19 (needed non-invasive oxygen supplementation). The baseline characteristics of COVID-19-positive mothers is shown in Table 1. The neonatal characteristics among study population is presented in Table 2. Neonatal complications among the study population has been illustrated in details in Table 3.

DISCUSSION

Our study was done in the phase of the pandemic when increasing circulation of the Omicron variant of 2019nCoV was noted in India. In our knowledge, this has been the first study in Indian settings which investigated this specific aspect at the time when the Omicron variant of SARS-CoV-2 affected India. Omicron variant has been showed to have low pathogenicity along with high transmissibility, unlike previous variants. This has resulted in a global spike in the incidence of COVID-19.^{14,15}

Maternal to neonatal transmission

Out of 39 newborns, 7 were tested for SARS-CoV-2 within 24 h after birth and all were negative. As the Government policy for RTPCR testing for SARS CoV2 was changed after the onset of our study. Hence, we could not collect NPA sample from the all the babies. For neonatal infection, possible routes of transmission of SARS-CoV-2 can be transplacental, during delivery and by droplet infection

during postnatal period and breast milk. Most studies have found low rate of perinatal transmission, also depending on the time of sample collection, it may not always be possible to rule out early neonatal infection or exact time of neonatal infection especially in asymptomatic babies.

Sheth et al., reviewed 39 studies including 326 mothers and 3% neonates had suspected vertical transmission.¹⁶ In another study by Angelidou et al., 2.2% newborns were tested positive out of total 255 neonates.¹⁷ Mirbeyk et al., in their systematic review had shown 5% positivity rate for SARS-CoV-2 of the 219 neonates who were tested.¹⁸

While study from Ponprobha et al.,¹⁹ has shown the vertical transmission rate to be 6.12% while Kotlyar et al., show that to be 3.2%.²⁰

Maternal morbidity and mortality

In our study, most (76.9%) of the pregnant women were asymptomatic, 15.38% of pregnant women showed mild COVID-19 symptoms while 5.12% showed moderate symptoms. Our findings of mild COVID-19 infection among pregnant women are similar to existing data on severity of COVID-19 infection among pregnant women. Various studies conducted worldwide including India by Ponprabha et al., and Nanavati et al., show that 88–90% of the pregnant women manifest mild disease and only 1–2% of pregnant women manifest severe COVID-19 infection.^{19,21}

Neonatal characteristics

Our study has shown a male predominance among the infected newborns (66.7%) similar to studies conducted by Sheth et al., and Buonsenso et al.^{16,22} Preterm and low birth weight consisted 35.9% of all neonates and 66.7% of infected neonate in both. Poor health seeking behavior among the low-middle class population might also be responsible for low birth weight and prematurity among study population. Sheth et al., reported around 30% rate of prematurity among infected neonates in their review literature.¹⁶ However, the systematic review conducted by Karabay et al., had shown no relationship between birth weight and infection.²³

In our study, most of the pregnant women underwent C-section due to previous and present obstetrical causes. This has been comparable with data on previous years of hospital records on C-sections during pre-COVID times. The study from China had shown that there is no difference in neonatal COVID-19 infection, neonatal deaths, and maternal deaths between vaginal delivery and C-section.²⁴

Neonatal morbidity and mortality

We did not observe any increased requirement of resuscitation in our study. This finding has been consistent

with other studies.^{16,23} Most of the babies in our cohort were asymptomatic. As far as symptoms of neonatal infection were concerned, we did not have any baby with fever or confirmed COVID pneumonia. In our study, 5 babies needed NICU admission. The only baby who died had ventilatory support due to perinatal asphysia and meconium aspiration syndrome. Other 2 babies with respiratory distress (transient tachypnea of the newborn/respiratory distress syndrome) were settled with CPAP support. All the babies admitted to NICU were tested for SARS-CoV-2 and all were negative. Apart from minor problems such as feeding intolerance and unconjugated hyperbilirubinemia, most of the newborns were asymptomatic throughout.

A Korean study by Choi et al., had shown 34 infants with gestational age >35 weeks conducted between Dec 2020 and December 2021 born to mothers who were SARS-CoV-2-positive and 5 (14.7%) neonates presented with respiratory distress who were diagnosed with transient tachypnea of newborn, meconium aspiration, and delayed transition. Furthermore, 1 (2.9%) presented with feeding intolerance. Interestingly SARS-CoV-2 PCR test results of all 34 newborns were negative at 24 h and 48 h.²⁵

A recent Indian study conducted by Nanavati et al.,²¹ where it was shown that the infected neonates developed symptoms, commonly with gastrointestinal (5%) and respiratory manifestations (30%). Similarly, a meta-analysis had shown that up to 55% of infected neonates developed symptoms with 30% having gastrointestinal manifestations and 25% respiratory manifestations.¹⁸ Few other studies, however, have shown that like other variants, the Omicron variant 2019-nCoV increases respiratory morbidity and the exact cause is unknown.²⁶ In their systemic review and meta-analysis, Allotey et al., had shown there was higher risk of preterm birth and neonatal death, but the overall number of neonatal death due to the disease was small (0.03%, 0.0% to 0.2%; 100 studies; 23 698 neonates.²⁷

With regards to postnatal care, most babies in our study stayed with mother in a separate cot and standard precautions were taken as recommended by the WHO.²⁸ Newborns can acquire infection after birth during postnatal period. But the risk is low and there is no increased risk of harm to the baby when babies are kept with the mother and breast fed which has been recommended by the WHO and Indian Academy of Pediatrics.^{10,29} Most studies have shown no chances of virus transmission through breast milk. Our study supports this finding as most of our babies were kept with mother and breast fed and all of them remained well and asymptomatic.

Most of the mother in our study were not fully vaccinated, but as the sample size of the study was too

low to pick up any difference of outcome, we are unable to comment on that. Follow-up of all neonates had been done till 1 month of age either in neonatal follow-up clinic or by telephonic interview. All babies were well and gaining weight appropriately. Furthermore, none of the babies developed fever or required unplanned hospital attendance.

Limitations of the study

Our study was done in a single hospital and so total number of the subjects were relatively small and this might affect the significance in our study result. Also because of lack of resources, we could not genotype the virus samples, which could bring bias to our results during the Omicron surge especially as this might impact the clinical phenotype. As already mentioned, we were unable to test nasopharyngeal samples of all our newborns due change of the government recommendation for mandatory testing during the study.

But the findings of our study are reassuring that at that stage of the pandemic, when omicron strain was significantly circulating, almost all the babies had good outcome. In a vast country like India, mass scale testing of all the mothers might not be possible before every delivery and targeted testing might be inadequate as many mothers can be asymptomatic. So even in the absence of routine/ mass scale testing of mothers at the time of delivery and newborns in the postnatal period, most babies are expected to do well. Of course, change of the pathogenicity with further mutation cannot be ruled out and we need to monitor the situation closely.

CONCLUSION

Our study did not show any significant effect on the babies in the new born period if mothers were detected positive of SARS-CoV-2 on RTPCR around the time of delivery. Babies can stay with mother and can be breast fed without any obvious risk of adverse effects in the newborn period. This is also important for health planning and use of resources in an appropriate manner. But active surveillance is needed with close monitoring of the SARS-CoV-2 positive mothers and the newborn infants for early detection of any change of pathogenicity which can adversely affect the clinical outcome as there is frequent change of the mutation.

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Authors' Contributions:

SB- Definition of intellectual content, literature survey, prepared first draft of manuscript, implementation of study protocol, data collection, data analysis, manuscript preparation, and submission of article; **SK-** Concept, design, clinical protocol, manuscript preparation, editing, and manuscript revision; **JS-** Design of study, statistical Analysis and Interpretation; **SD-** Review Manuscript; **SB-** Review Manuscript; **SK-** Literature survey; **JS-** Coordination and Manuscript revision.

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