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SHORT COMMUNICATION

Outcomes in neonates born to mothers with COVID-19 during the second wave in India

Sushma Malik[1] · Dipty Jain[2] · Chandrakant M. Bokade[3] · Shakira Savaskar[4] · Laxmikant S. Deshmukh[5] · Poonam Wade[1] · Abhishek D. Madhura[2] · Milind Suryawanshi[3] · Sachin T. Bandichhode[4] · Sachin B. Bodhgire[5] · Sarika Zala[6] · Smita D. Mahale[7] · Deepak N. Modi[8] · Rakesh Waghmare[9] · Suchitra V. Surve[10] · Rahul K. Gajbhiye[6]

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Abstract

COVID-19 pandemic has affected all age groups globally including pregnant women and their neonates. The aim of the study was to understand outcomes in neonates of mothers with COVID-19 during the first and second waves of COVID-19 pandemic. A retrospective analysis of 2524 neonates born to SARS-CoV-2-infected mothers was conducted during the first wave ($n = 1782$) and second wave ($n = 742$) of the COVID-19 pandemic at five study sites of the PregCovid registry in Maharashtra, India. A significant difference was noted in preterm birth, which was higher in the second wave (15.0%, 111/742) compared to the first wave (7.8%, 139/1782) ($P < 0.001$). The proportion of neonates requiring NICU admission was significantly higher in the second wave (19.0%, 141/742) as compared to that in the first wave (14.8%, 264/1782) ($P < 0.05$). On comparing regional differences, significantly higher neonatal complications were reported from Mumbai metropolitan region ($P < 0.05$). During the second wave of COVID-19, birth asphyxia and prematurity were 3.8- and 2.1-fold higher respectively ($P < 0.001$). Neonatal resuscitation at birth was significantly higher in second wave (3.4%, 25/742 vs 1.8%, 32/1782) ($P < 0.05$). The prevalence of SARS-CoV-2 infection in neonates was comparable (4.2% vs 4.6%) with no significant difference between the two waves.

Conclusion: Higher incidence of adverse outcomes in neonates born to SARS-CoV-2-infected mothers in the second wave of COVID-19 as compared to the first wave.

Trial registration: PregCovid study is registered with the Clinical Trial Registry of India (CTRI/2020/05/025423, Registered on 28/05/2020).

What is Known:

• *The second wave of COVID-19 was more lethal to pregnant women than the first wave. Newborns are at risk of developing complications.*

What is New:

• *Birth asphyxia, prematurity, and neonatal resuscitation at birth were significantly higher in the second wave as compared to those in the first wave of the COVID-19 pandemic in India.*

Keywords Neonatal complications · NICU · SARS-CoV-2 · Second wave

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Sushma Malik, Dipty Jain, Chandrakant M. Bokade, Shakira Savaskar and Laxmikant S. Deshmukh contributed equally.

✉ Rakesh Waghmare
rakeshbw0326@gmail.com

✉ Suchitra V. Surve
dr.suchi172@gmail.com

✉ Rahul K. Gajbhiye
gajbhiyer@nirrch.res.in

Extended author information available on the last page of the article

Abbreviations

COVID-19	Coronavirus disease 2019
NICU	Neonatal intensive care unit
SARS-CoV-2	Severe acute respiratory syndrome coronavirus-2

Introduction

COVID-19 pandemic has affected all age groups globally including pregnant women, their foetuses, and infants [1]. Despite several measures to fight COVID-19, new variants of concerns are reported worldwide, which are responsible for multiple resurgences in the form of second and third waves [2]. Our earlier studies reported adverse maternal outcomes during the first and second waves of COVID-19 [3–6]. We reported a high risk of adverse outcomes in SARS-CoV-2-infected neonates during the early phase of the first wave of COVID-19 pandemic [7]. While there are multiple reports on the effects of SARS-CoV-2 infection in neonates in general, there is limited information comparing the presentations and outcomes of neonates born to mothers with COVID-19 during the first wave and second wave of the COVID-19 pandemic. Therefore, the aim of the present study was to understand outcomes in neonates of mothers with COVID-19 during the first and second waves.

Materials and methods

A retrospective analysis of 2524 neonates born to SARS-CoV-2-infected mothers was conducted during the first wave ($n = 1782$) and second wave ($n = 742$) of the COVID-19 pandemic at five study sites of the PregCovid registry in Maharashtra, India (Fig. 1). The details on the data collection, quality controls, and study protocol are described elsewhere [8]. Maternal outcomes from the 19 study sites in Maharashtra state during the first wave of COVID-19 (March 2020 to January 2021) were reported previously [3]. The data reported herein is a representation of four geographical regions in the state of Maharashtra, India. The data on the clinical profile of newborns, complications, and outcomes were extracted from the PregCovid registry database. The first wave of COVID-19 was defined as April 1, 2020–January 31, 2021; and the second wave of COVID-19 was defined to be between February 1 and July 15, 2021. The primary outcome was the prevalence of SARS-CoV-2 infection in neonates, Neonatal Intensive Care Unit (NICU) admissions, and mortality. Secondary outcomes were the incidence of preterm births and other neonatal complications. Low-birth-weight baby was defined as a live infant whose birth weight is less than 2500 g [9]. Preterm delivery was defined as the delivery of a baby less than 37 completed weeks of gestation [10]. Birth asphyxia was defined as the failure to initiate and sustain breathing at birth [11]. Neonatal respiratory distress syndrome was defined as respiratory distress in a newborn, presenting within hours after birth, most often immediately after delivery [12]. Neonatal death is defined as death within the first 28 days of life [13]. The meconium aspiration syndrome was defined as respiratory distress occurring soon after birth in an infant born from a meconium-stained milieu with compatible radiological findings which cannot be otherwise explained [14].

Newborn testing strategies

For mother-to-child transmission of SARS-CoV-2 infection, we followed the WHO definition and classification [15]. The first nasopharyngeal swab was sent for all babies for a real-time reverse-transcription–polymerase chain reaction assay for SARS-CoV-2 after 24 h of birth and the second swab after 72 h of birth as per guidelines [16]. With the change of national policy, from June 2020 to 31 July 2020 in India, the first swab was sent at birth/within 12 h of life. All the newborns were managed as per guidelines by expert group consensus. The antibiotics were given only if indicated in clinically suspected sepsis or proven sepsis [17]. The resuscitation guidelines for newborns were followed [18].

Results

In our study cohort, a significant difference was noted in preterm birth, which was higher in the second wave (15.0%, 111/742) compared to the first wave (7.8%, 139/1782) ($P < 0.001$) (Table 1). The proportion of neonates requiring NICU admission was significantly higher in the second wave (19.0%, 141/742) as compared to the first wave (14.8%, 264/1782) ($P < 0.05$). On comparing regional differences, significantly higher neonatal complications were reported from Mumbai metropolitan region ($P < 0.05$). Prematurity and NICU admissions were significantly higher in the Marathwada region ($P < 0.05$), whereas the incidence of low birth weight was higher in western Maharashtra (Table 2). During the second wave of COVID-19, birth asphyxia and prematurity were 3.8- and 2.1-fold higher respectively ($P < 0.001$). Neonatal resuscitation at birth was significantly higher in the second wave (3.4%, 25/742 vs 1.8%, 32/1782) ($P < 0.05$). The prevalence of SARS-CoV-2 infection in neonates was comparable (4.2% vs 4.6%) with no significant difference between the two waves. Neonatal deaths were also comparable during the two COVID-19 waves (2.3% vs 2.1%). The proportion of male (51.6%) and female newborns (48.3%) was similar.

Diffusion of different viral strains in first and second waves of COVID-19 in India

India started sequencing SARS-CoV-2 viral genomes in early 2020. The Indian SARS-CoV-2 Genomics Consortium provides information on sequence SARS-CoV-2 RNA from COVID-19 cases in India to monitor the emergence and community circulation of viral variants and variants of concern (VOC) [19]. During the Jan 2020 and December 2020 period of the COVID-19 pandemic, B.1 lineage was the most common with B.1.1 and B.1.36 being seen

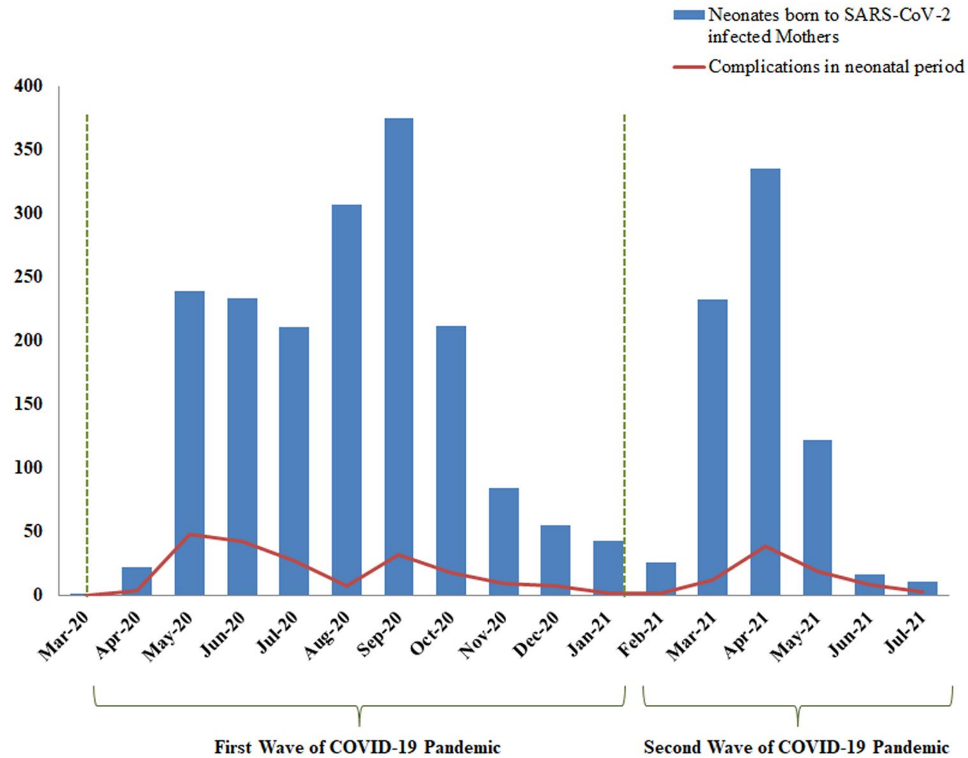

Fig. 1 Timeline of first and second waves of coronavirus disease 2019 (COVID-19) in India. Total 2524 neonates born to SARS-COV-2 infected mothers from 12 March 2020 to 31 June 2021 from five sites in Maharashtra, India (BYL Nair Charitable Hospital, Mumbai; Government Medical College Nagpur; Indira Gandhi Government Medical College, Nagpur; Vaishampayan Memorial Government Medical College, Solapur; Government Medical College, Aurangabad), which are part of the National Registry of Pregnant women with COVID-19

Table 1 Clinical characteristics of neonates born to SARS -CoV-2 infected mothers during the first and second waves of COVID-19 pandemic

Total neonates [n=2524 (%)]				
Characteristics	First wave n=1782 (%)	Second wave n=742 (%)	OR	*P*-value
Preterm	139 (7.8)	111 (15.0)	2.1 (1.6 – 2.7)	<0.001
Term	1643 (92.2)	631 (85.0)	0.4 (0.4 – 0.6)	
Low birth weight	436 (24.5)	213 (28.7)	1.2 (1.0 – 1.5)	0.02
Complications in neonatal period	196 (11.0)	83 (11.2)	1.0 (0.7 – 1.3)	0.89
SARS-CoV-2 infected	82/1781 (4.6)*	31 (4.2)	0.9 (0.6 – 1.4)	0.63
NICU admissions	264 (14.8)	141 (19·0)	1.3 (1.0 – 1.7)	0.009
Birth asphyxia	18 (1.0)	28 (3.8)	3.8 (2.1 – 7.0)	<0.001
Meconium aspiration syndrome	15 (0.8)	9 (1.2)	1.6 (0.6 – 3.6)	0.30
Respiratory distress	54 (3.0)	28 (3.8)	1.3 (0.8 – 2.0)	0.33
Sepsis	30 (1.7)	17 (2.3)	1.4 (0.6 – 2.4)	0.30
Feeding difficulties	30 (1.7)	17 (2.3)	1.4 (0.6 – 2.4)	0.30
Hyperbilirubinemia	81 (4.5)	21 (2.8)	0.6 (0.4 – 1.0)	0.04
Management				
Neonatal resuscitation at birth	32 (1.8)	25 (3.4)	1.9 (1.1 – 3.2)	0.01
Bag and mask	28 (1.6)	21 (2.8)	1.8 (1.0 – 3.2)	0.03
CPAP	35 (2.0)	12 (1.6)	0.8 (0.4 – 1.6)	0.55
Intubation	25 (1.4)	13 (1.8)	1.3 (0.6 – 2.4)	0.51
Ventilator support	35 (2.0)	23 (3.1)	1.6 (0.9 – 2.7)	0.08
Death	38 (2.1)	17 (2.3)	1.1 (0.6 – 2.0)	0.80

*1 Neonatal death before COVID-19 testing

First wave, April 1, 2020 – January 31, 2021; Second wave, February 1 – July 15, 2021; *CI*, confidence interval; *CPAP*, continuous positive airway pressure; *LBW*, low Birth weight; *NICU*, Neonatal Intensive Care Unit; *OR*, odds ratio

Table 2 Characteristics of neonates born to SARS-CoV-2 infected mothers during the first and second waves of COVID-19 pandemic in four geographical regions in Maharashtra, India (n=2524)

Neonate outcomes	Marathwada region (n=215) n (%)	Vidarbha region (n=1038) n (%)	Mumbai Metropolitan region (n=1046) n (%)	Western Maharashtra (n=225) n (%)
Preterm birth	40 (18.6)	112 (10.8)	79 (7.6)	19 (8.4)
Low birth weight (< 2.5 kg)	67 (31.2)	236 (22.7)	270 (25.8)	76 (33.8)
Neonate complications	26 (12.1)	27 (2.6)	214 (20.5)	12 (5.3)
NICU admissions	78 (36.3)	33 (3.2)	150 (14.3)	12 (5.3)
SARS-CoV-2 positive	14 (6.5)	47 (4.5)	40 (3.8)	12 (5.3)
Neonatal death	8 (3.7)	15 (1.4)	29 (2.8)	3 (1.3)

NICU - Neonatal Intensive Care Unit

frequently. During this period, B.6 variant was identified as associated with a spike in cases in India. There were no concerning mutations in B.6 variant and the surge in COVID-19 cases was a super-spreading event, and not related to increased transmissibility. Subsequently, B.6 was replaced by B.1 variants with D614G mutation that led to increased transmissibility. During the first wave of the COVID-19 pandemic (January–June 2020), B.1 lineages were the default strain across the nation and were responsible for the surge in COVID-19 cases in India in June 2020. B.1 is the parent strain of all current VOC in India [20].

In early 2021, a novel variant characterised by mutations L452R, E484Q, and P681R was reported in Maharashtra which was later named lineage B.1.617. From May 2021 to 20 June 2021, the Delta variant B.1.617.2 was the dominant lineage responsible for surges all over India during the second-wave period. New sub-lineages within Delta (Delta plus variants), AY.1, and AY.2 were reported in India during the second-wave period [21])

Discussion

In the present cohort, as compared to the first wave, a significantly higher proportion of neonates born to mothers with COVID-19 had preterm births, low birth weight, and NICU admissions in the second wave of COVID-19. These observations suggest that there is an increased adversity in the clinical course of the newborns of mothers with COVID-19 in the second wave in India. Increased risk of preterm delivery and NICU admission was reported amongst neonates of mothers with SARS-CoV-2 infection in the US population and UK registry [22, 23]. However, the overall prematurity rate of 9.9% (250/2524) is much lesser than that in UK registry and National Neonatology Forum, India [22, 24]. Our previous studies have reported higher spontaneous preterm births and lower iatrogenic preterm births during the second wave than in the first wave [5]. The findings suggest that SARS-CoV-2 infection at late gestational is an important factor in influencing negative clinical outcomes in the offspring as reported earlier [25].

Increased risk of preterm delivery, lower birth weight, neonatal infection, and NICU admission were also reported in pregnant women with moderate to severe COVID-19 in U.A.E [26]. The neonates mainly presented with feeding difficulties (1.8%), respiratory distress (3.2%), and hyperbilirubinemia (4.04%) The fever and gastrointestinal symptoms were rare, similar to data from National Neonatology Forum, India, [24] not as common as reported in earlier studies [27]. In our study, the higher incidence of complications in the neonatal period and intensive care including resuscitation at birth could have been attributed to increased severe COVID-19 disease in mothers with COVID-19 during the second wave of the pandemic [4]. Similar observations were also reported during the Omicron variant dominant COVID-19 wave in the UK [28]. In our study cohort, increased incidence of NICU admissions was not due to an excessive increase in the numbers of neonates as their numbers were comparable in both waves. These observations are in contrast to the data in the Spanish population reporting a higher incidence of SARS-CoV-2 infection in newborns during the second wave [29].

The publically available data on SARS-CoV-2 viral genomics from India demonstrated the diffusion of different viral strains during the first- and second-wave periods. During the first-wave period, B.1 lineage was reported as the most common variant whereas Delta variant B.1.617.2 was the dominant lineage responsible for the second wave in India. The differences in the clinical presentations and neonatal complications observed in our study cohort could be due to the diffusion of different viral strains in circulation during the first and second waves of COVID-19 in Maharashtra, India. Comparative analysis of the pathogenicity of B.1.617.2 (Delta) and B.1.617.3 lineage of SARS-CoV-2 with that of B.1 demonstrated higher levels of SARS-CoV-2 sub genomic RNA in the respiratory tract of hamsters infected with the Delta variant for 14 days [30]. Another study demonstrated B.1.617.2 (Delta variant) as highly fusogenic due to P681R mutation in the spike protein that facilitates cleavage of the spike protein and enhances viral fusogenicity [31].

We speculate that the severity in clinical profile and complications in neonates may be associated with the highly virulent strain B.1.617.2 (Delta) variant reported during the second wave of the pandemic in India [32]. However, we have not conducted genotyping of the virus in the mothers to determine this association. The possible reasons for such differential presentation in the first and the second wave of the COVID-19 pandemic need to be determined. The differences in the SARS-CoV-2 strains, differences in the access to health care facilities and reporting of pregnant women during the first and second wave, and change in population dynamics during the lockdown in the first wave and second wave could contribute towards such differential observations. During both the waves of COVID-19 pandemic, schools were closed in India which may have affected maternal stress and also circulation of common viruses [33].

The reduction in respirable particulates during the COVID-19 lockdown in India has been reported [34]. However, other factors responsible for these differences in two waves can be attributed to different situations at two time points. During the first wave, the system was not prepared for the pandemic and the guidelines for management of pregnant women and neonates gradually evolved. However, during second wave, the guidelines were already in place. Private system was geared up and the SARS–CoV-2-infected mothers were also being delivered at the private hospitals which could be the possible reason for less number of admissions at government hospitals and could have led to differences in numbers in two waves.

The impact of COVID-19 in pregnancy may go beyond the early neonatal outcomes as a cohort study of the newborns of the mothers with SARS-CoV-2 infection from Italy reported 15% of the offspring followed up to 7 months showed retinal abnormalities [35]. Another study from the USA suggested an increased risk for neurodevelopmental disorders of motor function or speech and language in offspring of mothers with COVID-19 when followed up for 12 months [36]. These findings suggest that offspring of mothers with COVID-19 should be followed up for years to understand the long-term impact of the SARS-CoV-2 infection.

In summary, our study reveals a higher incidence of adverse outcomes in neonates born to SARS-CoV-2-infected mothers in the second wave of COVID-19 as compared to the first wave. Based on our observations, we emphasise the need to devise evidence-based approaches for managing neonates born to SARS-CoV-2-infected mothers. The study highlights the need for counselling of pregnant women for COVID-19 vaccination to avoid detrimental outcomes in neonates.

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Authors contributions Dr. Gajbhiye conceptualised, designed, and implemented the study. Dr. Gajbhiye, Dr. Surve, and Dr. Waghmare were involved in data quality controls, data analysis, and interpretation, drafted the initial manuscript, and revised the manuscript. Drs. Malik, Jain, Bokade, Sawaskar, and Deshmukh designed the data collection instruments, collected data, carried out the initial analyses, and were involved in drafting and revising the manuscript. Drs. Wade, Madhura, Suryawanshi, Bandichhode, and Bodhgire coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content. Ms. Zala, Dr. Modi, and Dr. Mahale coordinated the study and provided inputs in data analysis, data interpretation, and revision of the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Availability of data and material The authors confirm that the data supporting the findings of this study are available within the article.

Code availability Not applicable.

Declarations

Ethical approval The study was approved by the Ethics Committees of TNMC (No. ECARP/2020/63; dated 27.05.2020); GMC Nagpur (No. 2070/EC/Pharmac/GMC/NGP dated 30.05.2020), IGGMC Nagpur (IGGMC /Pharmacology/IEC/422–23/2020, dated 24.06.2020); VMGMC, Solapur (O.No. Pharma Dept/IEC/Approval letter /15/2020; dated 30.07.2020); GMC Aurangabad (No. Pharmac/IEC-GMCA/Approval/176/2020, dated 22.05.2020); and ICMR-NIRRH (IEC no. D/ICEC/Sci-53/55/2020 dated 04.06.2020).

Consent to participate A waiver of consent was granted by IECs as the data is collected from the medical case records.

Consent for publication Not applicable.

Conflict of interest The authors declare no competing interests.

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Authors and Affiliations

Sushma Malik[1] · Dipty Jain[2] · Chandrakant M. Bokade[3] · Shakira Savaskar[4] · Laxmikant S. Deshmukh[5] · Poonam Wade[1] · Abhishek D. Madhura[2] · Milind Suryawanshi[3] · Sachin T. Bandichhode[4] · Sachin B. Bodhgire[5] · Sarika Zala[6] · Smita D. Mahale[7] · Deepak N. Modi[8] · Rakesh Waghmare[9] · Suchitra V. Surve[10] · Rahul K. Gajbhiye[6]

Sushma Malik
sushmamalik@gmail.com

Dipty Jain
diptyjain57@gmail.com

Chandrakant M. Bokade
cmbokade77@gmail.com

Shakira Savaskar
shakira.savaskar@gmail.com

Laxmikant S. Deshmukh
lsdeshmukh65@gmail.com

Poonam Wade
poonamwade@gmail.com

Abhishek D. Madhura
abhishekmadhura.am@gmail.com

Milind Suryawanshi
dr.milind.suryawanshi@gmail.com

Sachin T. Bandichhode
bandichhodest@rediffmail.com

Sachin B. Bodhgire
sbbodhgire15@gmail.com

Sarika Zala
sarika.sara01@gmail.com

Smita D. Mahale
smitamahale@hotmail.com

Deepak N. Modi
deepaknmodi@yahoo.com

1 Department of Paediartrics, Topiwala National Medical College & BYL Nair Charitable Hospital, Mumbai, Maharashtra, India

2 Department of Paediartrics, Government Medical College, Nagpur, Maharashtra, India

3 Department of Paediartrics, Indira Gandhi Government Medical College, Nagpur, Maharashtra, India

4 Department of Paediartrics, Dr Vaishampayan Memorial Government Medical College, Solapur, Maharashtra, India

5 Department of Paediatrics, Government Medical College, Aurangabad, Maharashtra, India

6 Clinical Research Lab, ICMR-National Institute for Research in Reproductive and Child Health, Parel, Mumbai, India

7 Emeritus Scientist, ICMR-National Institute for Research in Reproductive and Child Health, Parel, Mumbai, India

8 Molecular and Cellular Biology Laboratory, ICMR-National Institute for Research in Reproductive and Child Health, Parel, Mumbai, India

9 Medical Education and Drugs Department, Government of Maharashtra, Mumbai, India

10 Child Health Research Department, ICMR-National Institute for Research in Reproductive and Child Health, Maharashtra, Parel, Mumbai, India