ORIGINAL ARTICLE

Perinatal COVID-19 Infection and Outcomes: A Retrospective Observational Study from a Low–Middle Income Setting

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Abstract

Aim: Coronavirus disease 2019 (COVID-19) pandemic is an ongoing emergency with limited data on perinatal outcomes. The aim of the study was to describe key maternal, perinatal, and neonatal outcomes of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection from low–middle income settings.

Materials and methods: We conducted a retrospective observational study in a tertiary level public hospital in India. All pregnant women admitted from May 2020 to July 2020 were included in the study. Maternal demography, medical and obstetric complications, clinical characteristics, and investigations were described. Symptomatic infected women were compared with the asymptomatic group for important outcomes. Key perinatal outcomes such as early pregnancy losses, fetal distress, stillbirths, and placental changes were evaluated. Neonatal characteristics of SARS-CoV-2 positive and negative pregnancies were described and compared.

Results: Among the 702 pregnant women enrolled, the incidence of SARS-CoV-2 infection was 16.2%, with the majority being asymptomatic. Infected women had an increased mortality, while symptomatic women had a significant risk of stillbirth. Mean placental weight of infected women was significantly higher. Neonatal infection rate was 9.1%, with 50% manifesting mild respiratory symptoms without any mortality.

Conclusion: This study provides a comprehensive description of important antenatal, intrapartum and neonatal complications and outcomes in a low–middle income setting characterized by high disease burden and an overwhelmed health care system.

Clinical significance: Incidence of SARS-CoV-2 infection in pregnancy was 16.2%. The symptomatic infected women had increased stillbirth and mortality. Neonatal transmission was seen in 9.1% with good survival.

Keywords: India, Neonatal outcome, Observational study, Perinatal outcome, Pregnant women, SARS-CoV-2.

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Introduction

The COVID-19 caused by the SARS-CoV-2 is a global health emergency declared by World Health Organization as a pandemic on 11 March 2020,[1] with over 196 million cases recorded so far with a mortality rate of 2.1%.[2] The SARS-CoV-2 infection in pregnant women was found to be associated with an increased requirement for intensive care unit (ICU) admission, invasive ventilation, and need for extra corporeal membrane oxygenation in a living systematic review.[3] Another recent meta-analysis found an increased risk of hypertensive disorders and adverse maternal outcomes associated with gestational diabetes in infected women.[4] Observational studies in SARS-CoV-2 infected women detected fetal distress in 10–60% of the pregnancies, and stillbirth rates in 2.4–2.7%.[5–7] They have also reported increased rates of cesarean section of around 80% in these women, commonly for worsening maternal respiratory condition or fetal distress.

Preterm birth (<37 weeks) has been described between 21.2 and 63.8% in various studies, most of which were after 34 weeks.[5–7] Neonatal outcomes such as low Apgar scores, low birth weight, neonatal ICU admission rates, and neonatal deaths were also found to be increased in pregnancies complicated with SARS-CoV-2 infection.[6,7] The mode of transmission in these studies has not been clearly identified and continues to be an area of active research.[8–11]

Currently, the literature available on perinatal outcomes of SARS-CoV-2 infections from low–middle income settings, particularly in the Indian subcontinent, is limited, despite sharing the second highest global burden of cases.[2] This study aims to describe the maternal, perinatal, and neonatal outcomes associated with maternal SARS-CoV-2 infection in Indian population.

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Materials and Methods

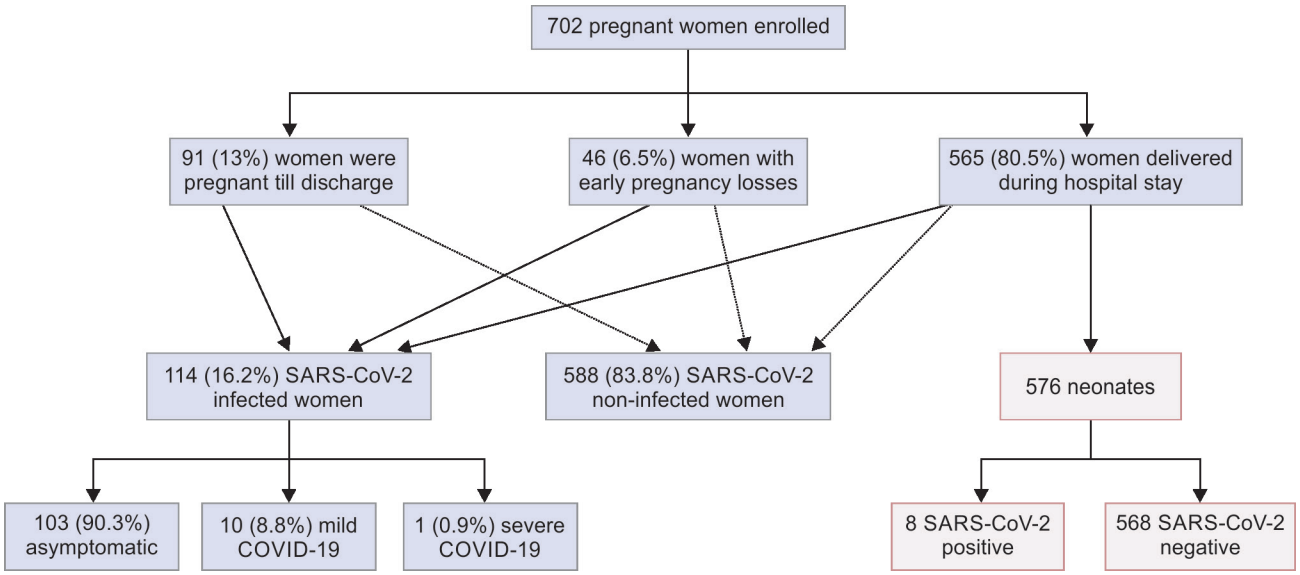
Study Design and Setting

The study was a retrospective single center observational study conducted in a tertiary level public hospital in Maharashtra which is an important referral center in Western India. All pregnant women admitted in Department of Obstetrics and Gynecology from 1 May 202 to 31 July 2020 were included in the study.

Testing Policy

A universal testing policy was followed for all pregnant women admitted to the hospital. A throat swab for reverse transcriptase polymerase chain reaction (RT-PCR) for SARS-CoV-2 infection

Flowchart 1: Study profile



was sent within 24 hours of admission. Neonates were tested by nasopharyngeal swabs for RT-PCR as per national guidelines. Neonates born to mothers with antenatally diagnosed SARS-CoV-2 infection were tested within the first 24 hours of life. Those neonates whose mothers tested positive at the time of admission were tested as soon as the mothers' reports were available. Any symptomatic neonate suspected to have SARS-CoV-2 infection was also tested.

Data Collection and Statistical Analysis

The study data was recorded from maternal and neonatal case sheets. Maternal characteristics such as demographic details, medical and obstetric complications, antenatal ultrasound/Doppler studies, intrapartum fetal monitoring, and mode of delivery were documented. The maternal laboratory investigations such as complete blood counts, liver transaminases, and throat swab were noted. The details of pregnancy losses and stillbirths were also collected. Neonatal demographic characteristics such as birth weight, sex, gestational age, and resuscitation details with Apgar scores, along with neonatal testing and outcomes were obtained. Final outcome in the form of discharge or death of mother and neonate was recorded.

Data was entered in MS excel and analyzed using SPSS software, version 23. The categorical variables were represented as percentages while continuous variables were depicted as mean (standard deviation) and median (range). An independent *t*-test was used for continuous data and Chi-squared and Fischer exact test were used for the categorical data. A $p < 0.05$ was considered statistically significant.

Ethical Approval

The study was initiated after obtaining permission from Institutional Ethics Committee (IEC). (EC/OA-130/2020; 28 September 2020). The study was registered at Clinical Trial Registry – India (CTRI/2021/07/034800).

Results

A total of 702 women were included in this study, of which 91 (13%) were pregnant at the time of discharge, 46 (6.6%) had early pregnancy losses, and 565 (80.4%) subsequently delivered in hospital during the study period as depicted in Flowchart 1.

Maternal Characteristics

Of the 702 women enrolled, the most common symptoms were fever (70%), cough (40%), shortness of breath (26.7%), vomiting (16.7%), and myalgia (6.7%). The incidence of SARS-CoV-2 in the study population was 16.2% (114 women). As per the WHO classification of COVID-19 patients, 10 (8.8%) had mild disease, and 1 (0.9%) had critical disease.[12] The maternal demographic profile and clinical characteristics of SARS-CoV-2 positive and negative groups are described in Table 1. Primigravida mothers were significantly more likely to be infected with SARS-CoV-2 virus as compared to multiparous mothers, a finding that has not been previously described in literature. This could possibly be due to the multiparous women being more home-bound and cautious, for fear of infecting the other children. This hypothesis, however, requires more exploration in larger studies.

Perinatal Outcomes

Of the 565 women who had delivered, 554 had singleton gestations while 11 had twins, a total of 576 births. The complications and outcomes of the pregnant women in the study are described in Table 2. The common indications for cesarean section in SARS-CoV-2 infected women were fetal distress (31.3%), previous cesarean section (20.8%), meconium-stained amniotic fluid (10.4%), and failure of induction (8.3%).

Symptomatic SARS-CoV-2 infected women had a significantly higher risk of stillbirth as compared to asymptomatic infected women ($p = 0.013$). However, there were no significant differences between these groups with regard to adverse perinatal outcomes such as fetal growth restriction, fetal distress, meconium-stained amniotic fluid, cesarean delivery, preterm births, and neonatal SARS-CoV-2 infection. Maternal adverse outcomes and deranged laboratory parameters also did not show any significant difference.

Neonatal Outcomes

The neonatal outcomes of the SARS-CoV-2 positive and negative pregnancies are described in Table 3. A total of eight neonates

Table 1: Comparison of maternal demographic and clinical characteristics of SARS-CoV-2 positive and negative women

S. No.	*Characteristic [n (%)]*	*SARS-CoV-2 positive (n = 114)*	*SARS-CoV-2 negative (n = 588)*	*p*
1.	Maternal age (years)	25.9 ± 4.76	27.0 ± 4.79	0.03
2.	Primigravida	63 (55.3%)	230 (39.1%)	0.001
3.	Maternal symptoms			
	Asymptomatic	103 (90.4%)	569 (96.8%)	0.002
	Fever	4 (3.5%)	17 (2.9%)	0.76
	Cough	7 (6.1%)	5 (0.9%)	<0.001
	Shortness of breath	2 (1.8%)	6 (1.0%)	0.62
	Vomiting	3 (2.6%)	2 (0.3%)	0.03
	Myalgia	2 (1.8%)	0 (0%)	0.03
4.	Medical disorders			
	Diabetes mellitus	0 (0%)	2 (0.3%)	1.0
	Hypertension	1 (0.9%)	10 (1.7%)	1.0
5.	Obstetric complications			
	Hypertensive disorders of pregnancy	17 (14.9%)	81 (13.8%)	0.75
	Gestational diabetes mellitus	0 (0%)	16 (2.7%)	0.09
	Premature rupture of membranes	4 (3.5%)	42 (7.1%)	0.21
	Spontaneous preterm labor	0 (0%)	3 (0.5%)	1.0
6.	Antenatal oligohydramnios	6/30 (20%)	33/148 (22.3%)	0.78
7.	Abnormal Doppler	2/5 (40%)	17/33 (51.5%)	0.63
8.	Laboratory investigations			
	Total leukocyte count (cells/mm^3) [median (range)]	9,500 (2,200–27,200)	10,400 (1,500–36,000)	
	Leukocytosis (%)	36.5%	39.8%	0.564
	Leucopenia (%)	5.9%	0.9%	0.008
	Lymphocyte (%) [median (range)]	30 (7–43)	28 (6–69)	
	Lymphopenia (%)	2.4%	1.2%	0.32
	Aspartate aminotransferase (U/L) [median (range)]	31 (11–1,535)	28 (4–275)	
	Alanine aminotransferase (U/L) [median (range)]	16 (5–833)	15 (5–222)	
	Raised transaminases (%)	26.8%	24.1%	0.67
9.	Mechanical ventilation	1 (0.9%)	1 (0.2%)	0.30
10.	Need for ICU admission	1 (0.9%)	1 (0.2%)	0.30
11.	Mortality	1 (0.9%)	1 (0.2%)	0.30

Table 2: Perinatal outcomes of the SARS-CoV-2 positive and negative pregnant women

S. No.	*Characteristic [n (%)]*	*SARS-CoV-2 positive (n = 114)*	*SARS-CoV-2 negative (n = 588)*	*p*
1.	Early pregnancy losses	6 (5.3%)	40 (6.8%)	0.54
2.	Fetal growth restriction	9 (7.9%)	51 (8.7%)	0.78
3.	Postpartum women	(*n* = 92)	(*n* = 473)	

3.1	Intrapartum complications			
	Fetal distress	13 (14.1%)	70 (14.8%)	0.87
	Meconium-stained liquor	6 (6.5%)	33 (7%)	0.88
	Decreased fetal movements	3 (3.3%)	4 (0.8%)	0.09
3.2	Mode of delivery			
	Vaginal	41 (44.6%)	219 (46.3%)	0.76
	Assisted vaginal	3 (3.3%)	17 (3.6%)	1.0
	Cesarean section	48 (52.2%)	237 (50.1%)	0.71
3.3	Stillbirths	7 (7.6%)	30 (6.3%)	0.65
	Macerated stillbirth	6 (6.5%)	21 (4.4%)	0.39
	Fresh stillbirth	1 (1.1%)	9 (1.9%)	1.0
3.4	Preterm deliveries	18 (19.6%)	133 (28.1%)	0.09
3.5	Mean placental weight (gm)	543 ± 91	518 ± 103	0.04

Table 3: Neonatal outcomes of SARS-CoV-2 positive and negative women

S. No.	*Characteristics [n (%)]*	*Neonates born to SARS-CoV-2 positive mothers*	*Neonate born to SARS-CoV-2 negative mothers*	*p*
1.	Total births	(*n* = 95)	(*n* = 481)	
	Live births	88 (92.6%)	451 (93.8%)	0.66
2.	Neonatal characteristics	(*n* = 88)	(*n* = 451)	
2.1	Male	46 (52.3%)	251 (55.7%)	0.56
2.2	Gestation age			
	Mean (weeks)	38.19 ± 1.75	37.22 ± 2.89	0.003
	Term births	73 (85.9%)	330 (74.5%)	0.02
	Preterm births	12 (14.1%)	113 (25.5%)	
	<28 weeks	1 (1.1%)	13 (2.9%)	
	28–31 (+ 6 or 7) weeks	2 (2.3%)	31 (6.9%)	
	32–33 (+ 6 or 7) weeks	2 (2.3%)	14 (3.1%)	
	34–36 (+ 6 or 7) weeks	14 (15.9%)	83 (18.4%)	
2.3	Birth weight			
	Mean (gm)	2,705 ± 461	2,580 ± 617	0.073
	<1,000 gm	2 (2.3%)	20 (4.4%)	
	1,000–1,499 gm	1 (1.1%)	27 (6%)	
	1,500–1,999 gm	7 (8%)	41 (9.1%)	
	2,000–2,499 gm	18 (20.5%)	108 (24%)	
	≥2,500 gm	67 (76.1%)	286 (6.4%)	
2.4	Small for gestation age	32 (36.4%)	152 (33.7%)	0.63
2.5	Resuscitation at birth	1 (1.1%)	13 (2.9%)	0.48
2.6	Median Apgar score at 1 minute	9 (10.2%)	9 (2%)	
2.7	Neonatal SARS-CoV-2 infection	8 (9.1%)	2 (0.4%)	<0.001
2.8	Symptomatic neonates	5 (5.7%)	19 (4.2%)	0.54
2.9	Mortality	0 (0%)	5 (1.1%)	1.0

tested positive for SARS-CoV-2 infection, of whom 4 (50%) were symptomatic with respiratory distress. Two neonates were preterm and had respiratory distress syndrome and two were term who had transient tachypnea of newborn. None of the infants required ventilatory support and improved with supportive care.

Discussion

This study describes the perinatal outcomes of a large cohort of 702 pregnant women and their 576 neonates during the SARS-CoV-2 pandemic from a low–middle income setting. The incidence of SARS-CoV-2 infection in pregnant women was 16.2% which was comparable to a recent meta-analysis which included studies from developed and developing nations (16.0%).[13]

A majority of the SARS-CoV-2 infected women were asymptomatic (90.4%) similar to a study by Agarwal et al (88.4%);[14] however, it was considerably higher as compared to other reports (6.8–32.6%).[4,7,10,15] This could have been due to the universal testing policy adopted in our institution resulting in a large number of asymptomatic patients testing positive. Among the symptomatic women, the clinical spectrum included fever, cough, shortness of breath, vomiting, and myalgia which was similar to that reported in literature.[10,15,16] We found no significant difference in need of invasive respiratory support and ICU admission between infected and non-infected pregnant women, as reported in an Indian study.[14] The mortality in the SARS-CoV-2 infected pregnant women was 0.87% which was higher than the non-infected subgroup (0.21%) suggesting a non-significant trend toward increased mortality. This rate was also higher than that reported from developed nations (0.5%).[15] Furthermore, an increased predisposition for ICU admission has also been described.[11,13] This recognizes infected pregnant women as a high-risk sub-group with increased need of monitoring, an essential consideration while triaging in a resource limited setting.

The SARS-CoV-2 positive women did not show an increased predilection toward hypertensive disorders, gestational diabetes, preterm premature rupture of membranes, and spontaneous preterm labor, mirroring the findings of a study in similar settings.[17] These findings, however, need further elucidation as recent meta-analyses have reported conflicting evidences.[4,11,13] Analyzing subset of pregnant women from developing nations in these studies can highlight the contribution of racial and genetic variations. The SARS-CoV-2 infected pregnant women have, however, been detected to have deranged hematological and biochemical parameters such as leukopenia, elevated transaminases, and acute phase reactants.[18] Similarly, we found a significantly higher incidence of leucopenia in infected as compared to non-infected women. Leukocytosis (36.5%) in the infected group was comparable to a large meta-analysis (36%),[19] though higher than other reviews (8.8%).[18] However, lymphopenia often correlated with disease severity was not significantly different and raised transaminases in one-fourth of the infected women was comparable to other studies.[18,20] Abnormalities in laboratory parameters, however, did not correlate with presence of symptoms in the study population.

Furthermore, SARS-CoV-2 has been hypothesized to alter the maternal-fetal immune tolerance by increasing interferon release, natural killer and T-cell activation, and pro-inflammatory cytokine levels leading to immunological injury and early fetal losses.[21] Early pregnancy loss (5.3%) was comparable to that reported in a similar setting (4.2%).[17] The percentage of stillbirths was not found to be higher in SARS-CoV-2 infected women (7.6%), though contrasting with the literature from developed nations with considerably lower stillbirth rates (0.9–1.1%).[13,22] Additionally, the stillbirth rate was significantly higher in symptomatic infected women, possibly due to the inflammatory response affecting organs with high angiotensin converting enzyme (ACE)-II receptor density including placenta, leading to fetal vascular malperfusion, villitis, fibrin deposition, placental infarcts, thrombosis, and stem vessel obliteration leading to fetal malperfusion.[23] The rate of cesarean deliveries was not impacted by SARS-CoV-2 infection corroborating with current Indian literature.[4,13,24] We found no increase in the meconium staining of amniotic fluid, fetal distress, and need for resuscitation despite the theoretical postulation of impaired feto-maternal gas exchange by fibrin deposition in placenta, leading to increased fetal distress.[25]The mean placental weight was found to be significantly higher in the infected women. The proposed theories include effect of maternal treatment with antivirals, chloroquine, low molecular weight heparin and antibiotics on increased placental weight.[26] However, our study was limited by lack of testing of the placentae for SARS-CoV-2 virus and absence of correlation with therapeutic details.

The neonatal SARS-CoV-2 infection rate was 9.1% among infants born to SARS-CoV-2 infected mothers, which was significantly higher than those born to non-infected mothers. This was comparable to the infectivity rates of 9.1–13% described in other studies.[9–11,27] As there was lack of testing facilities of placenta and amniotic fluid, and continuation of rooming-in and breastfeeding, a definite conclusion on mode of transmission could not be drawn. The preterm birth rate was not significantly higher in the infected group, corroborating with results of a study by Nayak et al.[17] In addition, meta-analyses including data from developed nations also established similar results,[11,13] suggesting no increased risk of preterm births as speculated by Wei et al.[4] An additional robust data would be required to establish a definite cause-effect relationship between SARS-CoV-2 infection and preterm birth. Surprisingly, we noted a significantly higher proportion of term births in the SARS-CoV-2 infected women. This could be due to the referral bias of sicker and high-risk infected pregnant women to a dedicated COVID-19 hospital during pandemic. Dang et al. suggested a possibility of SARS-CoV-2 binding to ACE-II receptors affecting the placental oxygen supply leading to severe fetal hypoxia with resultant increase in fetal growth restriction and small for gestational age (SGA) neonates.[21] However, we did not find an increase in these outcomes in SARS-CoV-2 infected pregnancies similar to the other reviews.[11,13] This could be attributable to a baseline high incidence of fetal growth restriction in developing countries, further compounded by compromised antenatal care, reduced health seeking behavior and stress during the pandemic. The SARS-CoV-2 infected pregnant women in our study were significantly more likely to have SARS-CoV-2 infected infants, although there was no increase in adverse neonatal outcomes such as need for resuscitation, ICU admission, and mortality. This suggests a milder clinical course in neonatal COVID-19 as described by other studies.[10,13,14]

Our study is, however, limited by lack of tissue testing and maternal viral load estimation. In addition, the study may not be adequately powered to provide definitive clinical correlations for every outcome. The strengths of the study include a comprehensive description of antenatal, intrapartum and postnatal aspects of SARS-CoV-2 infection. This study was conducted in a high-burden low–middle income setting during the first wave of pandemic. Alarmingly, the studies describing the subset of pregnant women

Table 4: Comparison of key outcomes in the SARS-CoV-2 infected pregnant women and neonates during the first and second wave of COVID-19 pandemic[28–30]

Outcome	*First wave (%)*	*Second wave (%)*
Asymptomatic maternal presentation	61.9–65.5	39.1–71.1
Cesarean section rate	39.6–64.6	37.1–78.8
Preterm deliveries	9.3–27.8	12.9–26.3
Neonatal SARS-CoV-2 infection	1.6–2.9	1.2–3.2
Stillbirth rate	1.5–4.3	1.9–5.3
Neonatal mortality	0–2.4	1.2–5.3
Maternal mortality	0.0–1.1	3.6–7.0

infected by SARS-CoV-2 during the second wave of pandemic are reporting an increase in severity of the infection and need of ICU admission as shown in Table 4, for which the cause is currently not clear.[28–30] An intensification in the pathogenic nature of the emergent strain resulting in increased number of pregnant women contracting infection has been proposed.[31] This implies a pressing need in the country to understand the nature of infection and its implications in pregnant women and their neonates as well as local guidelines and recommendations.[32–34]

Conclusion

This study provides a comprehensive description of key antenatal, intrapartum, and neonatal outcomes in a low–middle income setting, characterized by a distinct population subset with high incidence of fetal growth restriction, perinatal infections, stillbirth, and preterm births. Factors such as high baseline disease burden, along with an overwhelmed health care system further make the management a challenging task, indicating an imperative need of local guidelines with management protocols tailored within the existing infrastructure.

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Author Contributions

Authors MG, DM, JS, AR, RN, and NM conceived and designed the study; data collection was done by MG, DM, JS, and AR MG, DM, RN, and NM analyzed the data; MG and DM wrote the manuscript; and RN and NM critically reviewed and revised the manuscript. All authors approved and read the final manuscript.

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