

## RESEARCH ARTICLE

# Prospective study of maternal and fetal outcome in pregnancy affected by Covid 19 infection, as well as risk of vertical transmission in pregnancy

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## ABSTRACT

**Objective:** To evaluate the impact of Covid-19 infection on maternal and fetal outcomes in a universally tested pregnant population admitted for delivery. **Methods:** We conducted a prospective cohort study of all delivery hospitalisations between May 1, 2020, to October 31, 2020. Maternal and fetal outcomes in Covid-19 infected pregnant women, confirmed by RT-PCR (Reverse Transcriptase Polymerase Chain Reaction), were compared with those without infection during the same study period. **Results:** 864 pregnant women admitted for delivery were studied, including 86 women with SARS-CoV-2 infection. Most of the patients in the Covid-19 group (96.5%) were asymptomatic or had mild symptoms. Mean gestational age, medical comorbidities, and rates of caesarian deliveries were similar in both groups. Preeclampsia/eclampsia was significantly higher in the pregnant women with SARS-CoV-2 infection (15.1% vs 6.9%,  $p<0.01$ ), and the relative risk were 2.17 (95% CI, 1.24 to 3.82). Preterm deliveries (23.2% vs 13.7%,  $p<0.01$ ) and premature rupture of membranes (PROM) (12.8% vs 5.8%,  $p=0.01$ ) also occurred more frequently in the infected pregnant women. Fetal outcomes, including fetal distress, intrauterine growth retardation (IUGR), and mean birthweight, were similar. However, stillbirths were significantly more common in Covid-19 positive pregnancies (5.8% vs 1.9%,  $p=0.05$ ; RR:3.01, 95% CI, 1.12 to 8.09). **Conclusion:** The majority of pregnant women at delivery hospitalization were asymptomatic. However, still, they were at a considerably higher risk of unfavourable outcomes, including preeclampsia/eclampsia, preterm birth, PROM, and stillbirth.

**Keywords:** Covid -19, stillbirth, preterm birth, preeclampsia, South Asian.

The ongoing coronavirus disease 2019 (Covid-19) pandemic, caused by SARS-CoV-2 infection, has led to unprecedented global morbidity and mortality. Pregnant women are susceptible to Covid-19 related complications due to changes in cell mediated immunity and impaired cardiopulmonary function, particularly during labour and delivery<sup>1,2</sup>. Emerging evidence from recent studies suggests that the infected mothers and newborns are at a higher risk of adverse outcomes<sup>2-5</sup>. In a large multicentric study from the US, which included delivery hospitalizations, the risk of preterm labour, acute respiratory distress syndrome, sepsis, mechanical ventilation, and maternal death was increased<sup>5</sup>.

Unfortunately, most of the research on the impact of Covid-19 infection on maternal and perinatal outcomes is confined to only high income countries (HICs). This is concerning because pregnant women in low to middle income countries (LMICs) may be at higher risk of maternal and neonatal complications<sup>6,7</sup>. In a meta-analysis, the overall risk of adverse pregnancy outcomes in LMICs was twice as common as HICs<sup>8</sup>. This occurred even though women in the HICs suffered from more severe Covid-19 related symptoms. This may be related to reduced access to care, malnutrition, co-infections, and the breakdown of their precarious economies by the impact of the Covid-19 pandemic.

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Most of the available studies from LMICs are retrospective, without appropriate comparison groups, and inconsistent in definition and reporting of outcomes<sup>8</sup>. India, the most populous country among the LMICs, has been severely affected by the Covid-19 pandemic. However, to the best of our knowledge, there is no prospective comparative data available on the outcomes of delivery hospitalizations from India. The objective of this prospective study was to assess the impact of Covid-19 infection on maternal and fetal outcomes in a universally tested pregnant population admitted for delivery.

### **Materials and methods**

We conducted a prospective cohort study of all delivery hospitalizations at the institute of medical sciences (IMS), Banaras Hindu University (BHU), Varanasi (India), between May 1, 2020, to October 31, 2020. It is the largest tertiary care hospital in eastern Uttar Pradesh, serving nearly 200 million people, mainly belonging to the underprivileged section of the surrounding region. As per the institute's protocol, universal testing for SARS-CoV-2 was done in all pregnant women admitted for delivery by RT-PCR (Reverse Transcriptase Polymerase Chain Reaction) if not done within 14 days. In pregnant women presenting for emergency delivery rapid antigen test was done, and later, RT-PCR was repeated. Pregnant females who underwent delivery during the study period and were COVID-19 negative were used for comparison. COVID-19 positive women were transferred to a dedicated facility for isolation or intensive care unit (ICU) as per disease severity. Mothers were encouraged to follow hand hygiene, wear masks and follow social distancing protocols. Management of mothers and neonates was done according to the ICMR (Indian Council of Medical Research) guidelines. Data on the maternal outcomes were available till discharge from the hospital.

Sample collection and RT-PCR test for COVID-19: According to ICMR guidelines, the standard test for Covid-19 diagnosis was the detection of the viral RNA by RT-PCR. Combined nasopharyngeal and oropharyngeal secretions from mothers and only nasopharyngeal swabs from neonates were collected in a 3ml viral transport medium and transported to the viral research diagnostic laboratory (VDRL), department of microbiology, IMS, BHU, Varanasi. Viral nucleic acid extraction was done by automated MagMAX Kits (ThermoFisher Scientific), as per manufacturer instructions. The KingFisher™ 96 Deep-Well Plates were used for RNA extraction, eluted in 60µl of AVE buffer, and stored at -20°C. A one step qRT-PCR system

with VIRALDTECT-II Multiplex Real-time PCR kit from Genes2me Pvt Ltd, Gurugram, was used to detect Covid-19 targets along with positive and negative controls. A volume of 20µL reaction mixture composition having 10µL of 2×One step MasterMix, one µL of target primers/probemix containing E/RdRp/N/RNase P gene primer-probe mix, and 9µL of the extracted RNA was used for SARS-CoV-2 detection. The amplification assay was executed using CFX96TM Optical Reaction Module using CFX Manager™ Software (Bio-Rad). The Ct value of 37 was taken as a cut-off for differentiating between positive and negative results.

Maternal characteristics and outcomes: All women were assessed for Covid -19 related symptoms at presentation, including fever, cough, shortness of breath, fatigue, or loss of taste or smell. We recorded baseline information comprising age, gestational age at delivery, gravidity, parity, history of prior cesarean delivery, multiple gestations, viral co-infections including HIV, hepatitis B and C, and medical comorbidities including anaemia and diabetes mellitus, hypertension, and hypothyroidism. Prospective collection of details of maternal and obstetric outcomes, including mode of delivery, type of delivery (term or preterm), indications of cesarean delivery, gestational diabetes mellitus, preeclampsia/eclampsia, antepartum haemorrhage, postpartum haemorrhage, meconium - stained amniotic fluid, cholestasis of pregnancy, oligohydramnios, and premature rupture of the membrane was done. Additionally, fetal outcomes such as fetal distress, intrauterine growth retardation (IUGR), stillbirth and birth weight were noted.

Definitions: Any mother with a positive swab for SARS-CoV-2 by RT-PCR was defined as Covid-19 positive. The severity of Covid-19 was classified according to the existing ministry of health and family welfare (MOHFW) guidelines, India (mohfw.gov.in). Mild Covid-19 was defined as having upper respiratory tract infection symptoms without shortness of breath or hypoxia. In contrast, severe Covid-19 was defined as the presence of respiratory rate >30/min and/or SpO2 <90% on room air. Preterm birth was defined as live birth at <37 weeks of gestation. Gestational diabetes mellitus (GDM) was defined as any degree of glucose intolerance with onset or first recognition during pregnancy. Preeclampsia is defined as new onset hypertension and proteinuria in pregnancy, and eclampsia refers to seizures with preeclampsia. Premature rupture of membranes (PROM) is defined as rupture occurring before labour onset, and preterm premature rupture of membranes (PPROM) is

defined as rupture occurring before 37 weeks of gestation. Spontaneous preterm birth is live birth following spontaneous preterm birth or PPRM. Stillbirth is a fetal loss at the 20th week of pregnancy or later. Birth weight <2500 g was defined as a low birth weight (LBW), and birth weight <1500 g was described as very low birth weight (VLBW).

Statistical analysis: The data entry was done in MS Excel Software and analysed using SPSS version 28.0 (IBM, Armonk, NY, USA). Continuous variables were presented as means, and standard deviations and categorical variables were expressed as frequencies and percentages. The p-value for comparing two independent continuous variables was obtained from the unpaired student t-test. The chi-square test was used to compare two proportions. All tests were 2-sided, and statistically significant associations were considered at a p-value < 0.05.

**Results**

Eight hundred sixty four pregnant women were admitted for delivery to the Obstetrics and Gynecology Department from May 1 to October 31, 2020. Of these, 86 women (9.9%) were confirmed Covid-19 positive by molecular detection of SARS-CoV-2 by RT-PCR. The demographic profile and clinical characteristics are presented in table 1. Maternal and fetal outcomes are shown in tables 2 and 3, respectively. Significantly different outcomes have been presented separately in table 4 with relative risks.

**Table 1: Demographic profile and clinical characteristics of the patients (n = 864)**

Parameters	Covid negative * (n=778)	Covid positive* (n=86)	p value
Age (years), mean ±SD	26.1 ± 4.1	25.8 ± 4.6	0.48
Primigravida	295 (37.9)	30 (34.8)	0.54
Gestational age (days), mean ±SD	261.8 ± 21.3	262.7 ± 14.4	0.08
Prior caesarean	110 (14.1)	15 (17.4)	0.40
Hypothyroidism	33 (4.2)	6 (7)	0.26
Severe anemia (Hb<7g/dL)	40 (5.1)	8 (9.3)	0.13
Hepatitis B	26 (3.3)	8 (9.3)	<0.01
Hepatitis C	8 (1)	Nil	NA
HIV	12 (1.5)	Nil	NA
Thrombocytopenia	23 (3)	4 (4.7)	0.33
Malpresentation	30 (6)	4 (7.1)	0.39
Multiple gestations	30 (3.9)	1 (1.2)	0.35
Covid-19 symptoms	7 (0.9)	3 (3.5)	0.05
Admission to ICU	2 (0.2)	1 (1.1)	0.21
Maternal death	Nil	Nil	NA

SD - Standard deviation; ICU - Intensive care unit; COVID - Coronavirus disease; HIV- Human immunodeficiency virus; \*SARS-CoV-2 RT-PCR positive/negative; Values shown represent numbers (percentages), except where otherwise noted.

The mean age was 25.8 ± 4.6 years (range 18-40 years) in Covid positive women, which was statistically similar to

Covid negative patients who had a mean age of 26.1 ± 4.1 years (range 18-45 years). Mean gestational age in both groups was similar, and nearly 2/3<sup>rd</sup> of women in both groups were multigravida. Medical comorbidities including hypothyroidism, severe anaemia, and thrombocytopenia were comparable between the two groups. Similarly, multiple gestations and malpresentation were not significantly different. Hepatitis B co-infection was more common in the covid positive group than the covid negative group (9.3% vs 3.3%, p=0.03). In Covid negative group, hepatitis C infection was seen in 8 and HIV in 12 pregnant females, but none in the Covid positive group. Most of the patients in the Covid-19 group (96.5%) were asymptomatic or had mild symptoms. Only one patient had symptoms severe enough for hospitalization in ICU. 7 patients (0.9%) in the Covid negative group also had Covid-19-related symptoms but were negative on the RT-PCR test.

**Table 2: Maternal outcomes (n = 864)**

Gestational diabetes mellitus	32 (4.1)	5 (5.8)	0.45
Pre-eclampsia/eclampsia	54 (6.9)	13(15.1)	<0.01
APH (antepartum haemorrhage)	26 (3.3)	4 (4.7)	0.53
PPH (postpartum haemorrhage)	13 (1.7)	4 (4.7)	0.08
Meconium-stained amniotic fluid	89 (11.4)	9 (10.5)	0.78
Cholestasis of pregnancy	51 (6.6)	5 (8.9)	0.79
Oligohydramnios	41 (5.3)	6 (7)	0.46
Premature rupture of membrane	45 (5.8)	11 (12.8)	0.01
Caesarean delivery	482 (62.1)	56 (65.1)	0.55
Preterm birth	107 (13.7)	20 (23.2)	0.015
Spontaneous preterm birth	57(7.2)	9 (10.5)	0.33
Preterm birth <34 weeks	39 (5)	3 (3.5)	0.79

Covid - Coronavirus disease; APH - Antepartum haemorrhage; PPH - Postpartum haemorrhage; Values shown represent numbers (percentages); \*SARS-CoV-2 RT-PCR positive/negative

**Table 3: Fetal outcomes**

Parameters	Covid negative	Covid positive	P value
Fetal distress	136 (17.8)	17 (19.8)	0.65
Intrauterine growth retardation	171 (22.4)	24 (27.9)	0.48
Still birth	15 (1.9)	5 (5.8)	0.05
Birth weight (g), mean ±SD	2577.8±635.1	2613.9 ± 546.6	0.61
Low birth weight (<2.5Kg)	283 (37.1)	29 (35.8)	0.82
Very low birth weight (<1.5Kg)	109 (14.2)	9 (11.1)	0.44
Small for gestational age (<10th centile)	48 (6.3)	4 (4.7)	0.57

Values shown represent numbers (percentages), except where otherwise noted

The number of patients who were delivered by LSCS in the Covid positive group (65.1%) was higher as compared to Covid negative group (62.1%), but the difference between the two groups was not statistically significant (p=0.58). The most common indications of lower segment cesarean section (LSCS) in the Covid group were previous cesarean section (21.4%), non-reassuring fetal status (19.6%), and severe preeclampsia/eclampsia (14.3%). In the non-Covid group, the most common indications were nonreassuring fetal status (30.5%), previous cesarean section (20.2%), and severe preeclampsia/eclampsia (16.2%). Gestational diabetes

mellitus was statistically similar in Covid vs non-Covid group (5.8% vs 4.1%; p=0.45). A significantly higher rate of preterm deliveries was seen in Covid positive patients (23.2% vs 13.7%, p<0.01). The associated

relative risk was 1.69 (95% CI, 1.10 to 2.57). However, spontaneous preterm birth was similar in both groups (10.5% vs 7.2%, p=0.33). Preterm birth of less than 34 weeks was comparable in both groups (3% vs 5%, p=0.79). Premature rupture of membranes (PROM) occurred more frequently in the infected pregnant women (12.8% vs 5.8%; RR=2.21, 95% CI=1.18 to 4.11; p=0.01). This was driven by a significantly higher occurrence of preterm premature rupture of membranes (PPROM) (7% vs 2.7%; RR=2.58, 95% CI=1.07 to 6.22; p=0.03). Gestational diabetes mellitus was observed in 5.8% of Covid positive and 4.1% of Covid negative group (p=0.45). Preeclampsia/eclampsia was significantly higher in the pregnant women with SARS-CoV-2 infection (15.1% vs 6.9%, p<0.01), and the relative risk were 2.17 (95% CI, 1.24 to 3.82). Obstetric complications, including antepartum haemorrhage (APH), postpartum haemorrhage (PPH), meconium stained amniotic fluid, and cholestasis of pregnancy, were comparable between the two groups.

Fetal distress and intrauterine growth retardation (IUGR)

in these studies. Moreover, undiagnosed asymptomatic cases in early pregnancy may have been missed. A pooled multicentric study from Maharashtra (India) employing universal screening found that 88.5% of pregnant women admitted for delivery were asymptomatic<sup>10</sup>. Moreover, it is reported in a meta-analysis that more than two-thirds of pregnant women infected with Covid-19 may be asymptomatic<sup>11</sup>. Interestingly, symptomatic presentations in LMICs were less common than the HICs (odds ratio=0.38)<sup>6</sup>.

The prevalence of SARS-CoV-2 infection in our cohort (9.9%) was similar to the 12.3% prevalence reported from the Preg Covid registry (India) earlier<sup>10</sup>. Although the prevalence reported among studies has been quite variable, a recent living systematic review and meta-analysis found that 10% of pregnant women attending or admitted to hospital were diagnosed as having suspected or confirmed Covid-19<sup>11</sup>.

One Covid-19 positive pregnant woman in our study required ICU admission, but there was no mortality. Similarly, in a prior Indian study of 108 Covid positive pregnant women, 2 (1.85%) SARS-CoV-2 positive pregnant women required ICU admission, and one (0.9%) woman died, which was unrelated to the infection<sup>12</sup>. Allotey et al, in a meta-analysis, found that the odds of death in pregnant

**Table 4: Relative risk in statistically significantly outcomes**

Parameters	Covid negative *	Covid positive*	Relative risk (95% CI)
Covid-19 related symptoms	7 (0.9%)	3 (3.5%)	3.87 (1.02 to 14.71)
Pre-eclampsia/eclampsia	54 (6.9%)	13(15.1%)	2.17 (1.24 to 3.82)
Premature rupture of membrane	45 (5.8)	11 (12.8)	2.21 (1.18 to 4.11)
Preterm birth	107 (13.7%)	20 (23.2%)	1.69 (1.10 to 2.57)
Still birth	15 (1.9%)	5 (5.8%)	3.01 (1.12 to 8.09)

\* SARS-CoV-2 RT-PCR positive/negative

were similar in both groups and statistically not different. However, stillbirths were significantly more common in Covid-19 positive pregnancies (5.8% vs 1.9%, P=0.05) with a relative risk of 3.01 (95% CI, 1.12 to 8.09). There was no significant difference in mean birth weight (2613.98 ± 546.6 gm in Covid positive group and 2577.8 ± 635.1gm in Covid negative group, p=0.61). There was similar incidence of low birth weight (35.8% vs 37.1%, p=0.82) and very low birth weight (11.1% vs 14.2%, p=0.44). Moreover, small for gestational age (SGA) babies were not significantly different between the two groups (4.7% vs 6.3%, p=0.57).

### Discussion

In our study, 96.5% of Covid-19 positive mothers were asymptomatic at presentation. Similar findings were seen in a preliminary study from India, where most pregnant women (97%) were asymptomatic or had mild symptoms<sup>9</sup>. This may be partly explained by the universal testing strategy applied

people with Covid-19 were not higher than in non-pregnant reproductive age females with Covid-19 (OR=0.96)<sup>11</sup>. However, emerging evidence, mainly from HICs, suggests a higher risk of severe covid complications in pregnant women<sup>2-4</sup>. Differences in outcomes may arise due to the inclusion of all delivery hospitalisations in our study and a relatively younger pregnant population. Indeed, a large US-based study, including all delivery hospitalisations, showed a lower risk of adverse maternal events<sup>5</sup>. Moreover, there was no maternal mortality in a multicenter prospective study from 45 centres in Spain, including 1009 delivery admissions<sup>13</sup>.

Preeclampsia/eclampsia is a frequent complication in pregnant women infected with SARS-CoV-2<sup>4,5,14</sup>. In our study, preeclampsia/eclampsia was two times more common in the Covid positive group (15.1% vs 6.9%, p<0.01). The national cohort study from England, including birth episodes

in women with SARS-CoV-2 infection, reported a 50% increase in preeclampsia or eclampsia (odds ratio, 1.55; 95% CI, 1.29-1.85)<sup>4</sup>. The underlying mechanism can be possibly direct and indirect endothelial damage caused by SARS-CoV-2. It can also induce a systemic inflammatory state of hypercoagulability, alter immune response, and dysregulate angiotensin-converting enzyme (ACE2) expression at the maternal-fetal interface<sup>15</sup>. SARS-CoV-2 infection being a pro-inflammatory state, even in asymptomatic patients, could result in preeclampsia. Indeed, in the multinational Intercovid study, the severity of Covid-19 did not increase the association with preeclampsia<sup>16</sup>. On the contrary, gestational diabetes mellitus (GDM) may be related to the Covid-19 severity. In a recent meta-analysis, severe Covid-19 was strongly associated with GDM (OR 1.99) but not mild Covid-19<sup>14</sup>. In a predominantly asymptomatic population, we did not find any significant association between SARS-CoV-2 infection with GDM.

We encountered a higher rate of preterm birth in pregnant women with SARS-CoV-2 infection (23.2 % vs 13.7%, relative risk= 1.69, 95% CI=1.10 to 2.57)), while the rate of spontaneous preterm birth was statistically similar (10.5% vs 7.2%, p=0.33). High rates of preterm birth in Covid-19 infected women have been established in previous studies and meta-analyses<sup>2-5,12-14,17</sup>. Most of the deliveries in these studies, including ours, were iatrogenic, and there was no significant increase in spontaneous preterm delivery. These preterm births may be medically indicated mainly due to preeclampsia/eclampsia. However, Covid-19 infection can increase preterm births by dysregulated immune response, fever, hypoxia, and placental-fetal vascular mal-perfusion<sup>14</sup>. This is quite concerning because India already has the highest number of preterm births globally and accounts for 33% of the total global deaths due to preterm births<sup>18</sup>. Data from HICs, mostly from western European countries, show that preterm birth and spontaneous preterm births were reduced during the Covid-19 pandemic<sup>14</sup>. This finding suggests that adverse outcomes might be mainly caused by the inefficiency of healthcare systems and population behaviours in LMIC settings. Interestingly, PROM was also two times more common in the Covid positive group (12.8% versus 5.8%, p=0.01). This can likely be explained by increased inflammatory mediators like IL-6 seen in patients with SARS-CoV-2 infection<sup>13</sup>.

Another finding was a significantly higher rate of stillbirth in the infected pregnant women (5.8% vs 1.9%; relative risk=3.01, 95% CI=1.12 to 8.09). Studies from India

during the early Covid-19 pandemic also show a significant increase in stillbirths<sup>19,20</sup>. In a prospective study from Nepal, the institutional stillbirth rate significantly increased from 1.4% to 2.1% after the lockdown<sup>21</sup>. Stillbirth is observed to be two times more frequent in LMICs compared to HICs<sup>8</sup>. The mechanism of stillbirth may differ between the high-resource and low-resource settings. In HICs, it may be related to the disease severity and placental involvement by SARS-CoV-2 infection<sup>4</sup>. In a resource poor country like ours, it may be due to disruption of healthcare services, institutional childbirth reduction, decreased quality of care, and reduced access to food and hospitals<sup>22,23</sup>.

This study highlights the importance of recommending mitigation strategies to reduce the risk of SARS-CoV-2 infection during pregnancy. Proper counselling and management protocol is required in all infected pregnant women, given the fact that even asymptomatic individuals are at increased risk of unfavourable outcomes. The major strengths of our study area prospective design, the presence of a contemporary comparison group, deployment of RT-PCR for testing, and universal screening of all delivery hospitalisations in the largest tertiary care centre in the region. However, the study has several limitations, including no maternal serological study, no data on neonatal outcomes, and data being limited until hospital discharge. The study is further limited by the accuracy of the RT-PCR test and the missing out of possible infections in early pregnancy.

### Conclusions

Universal screening of pregnant women at delivery hospitalization found that majority of them were asymptomatic. However, still, they were at considerably higher risk of unfavourable outcomes, including preeclampsia/eclampsia, preterm birth, PROM, and stillbirths. Pregnant women should be counselled of increased risk and encouraged to follow hand hygiene, wear masks and follow social distancing protocols. Healthcare providers should recommend SARS-CoV-2 vaccination in pregnant women in accordance with local guidelines. Long-term close follow-up may be required to discover any untoward adverse event of Covid-19 in both mother and child.

**Conflict of interest:** None. **Disclaimer:** Nil.

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