RESEARCH ARTICLE

Maternal and Neonatal Outcomes of Pregnant Women with COVID-19: A Case–Control Study at a Tertiary Care Center in India

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Abstract

Aim and background: Coronavirus disease-2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), how it affects pregnancy very little is known. To identify maternal and neonatal risks associated with COVID-19 in pregnancy and to describe outcome a matched case–control study was done.

Materials and methods: In this study, COVID-19 reverse transcription polymerase chain reaction (RT-PCR) positive women who delivered from May 1, 2020, to August 31, 2020, were included. Cases were classified according to their severity and investigations. Controls were selected from COVID-19 negative women in a 1:1 ratio who delivered in the study period. Data were collected, analyzed in terms of maternal and neonatal outcomes.

Results: Of the total 181 COVID-19 cases delivered during the study period, there were 97.23% mild, 2.76% moderate, and 0.55% severe cases. A total of 178 (98.34%) were diagnosed in the third trimester. More COVID-19 cases were from urban areas. Mean gestational age in the mild category was 38.1 weeks and the moderate/severe category was 37.5 weeks. Around 154 (85.08%) were asymptomatic. Cases had more medical and pregnancy morbidity than controls, which was statistically significant. About 52.49% of cases and 33% of controls had cesarean. Length of hospital stay was more in cases. Mean birth weight was 2.7 ± 0.59 kg in cases and 2.5 ± 0.56 kg in control. There were 7 stillbirths in each group. A total of 14 in cases and 16 in controls were transferred to the newborn intensive care unit (NICU).

Conclusion: The majority of COVID-19 infected women who are asymptomatic are in the mild category and there are no adverse maternal and neonatal outcomes due to the disease. The adversity of maternal and neonatal outcomes depends on the severity and severity of the disease is dependent on advanced maternal age and presence of comorbidities.

Keywords: Case–Control, COVID-19 in pregnancy, Maternal and neonatal outcome, Medical morbidity, Pregnancy-related morbidity.

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Introduction

Coronavirus disease-2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) belongs to the family Coronaviridae.[1] The other two β-coronaviruses, severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) have infected thousands, with high mortality rates.[2,3] WHO declared COVID-19 as a Public Health Emergency of International Concern on January 30, 2020.[4] More than 180 countries have reported laboratory-confirmed cases of COVID-19.[5] As of October 27, 2020, in India, the number of cases is 7,946,429 and 1,195,36 deaths and are still rising.[6] Coronaviruses can be asymptomatic and causes illness ranging from the common cold to severe respiratory illness and death. The abnormal investigation includes chest radiographic imaging, lymphopenia, leukopenia, and thrombocytopenia.[7] Pregnant women are likely to develop a severe illness due to physiological changes in immune and cardiopulmonary systems, after respiratory virus infection. In SARS-CoV and MERS-CoV infections, severe complications occur during the third trimester, like pneumonia, admission to ICU, need for mechanical ventilation with a high fatality rate. Currently, there is no evidence that pregnant women are more susceptible to COVID-19 infection or are more prone to developing severe pneumonia.[8] The symptoms reported and treatment options in a few studies vary for pregnant women.[9,10] A study carried out in India on 141 COVID-19 patients, reported mild respiratory symptoms and patients with co-morbidities had good maternal and fetal outcome.[11] To date, our knowledge is largely based on case series or epidemiologic studies that lacked a control group. Therefore, to identify maternal and neonatal risks associated with COVID-19 in pregnancy and to describe associations and risk factors for morbidity; we undertook a matched case–control study.

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Materials and Methods

This case–control study was conducted at the Department of Obstetrics and Gynecology of Government Medical College, Nagpur, Maharashtra, India. It is a tertiary care center located in central India, getting referrals from nearby districts and states, having 10–12,000 deliveries annually. Institutional Ethics Committee approval was taken for conducting the study. All COVID-19 positive women who delivered from May 1, 2020, to August 31, 2020, were included. Women with symptoms (e.g., fever, cough, breathlessness), women in close contact with known COVID-19 case, who had a history of travel from high-risk areas, women coming from containment zone having their expected date of delivery within five days were tested by the Indian Council of Medical Research's (ICMR) guidelines. Their throat swab was collected and subjected to RT-PCR test at State Level Viral Research and Diagnostic Laboratory, Government Medical College, Nagpur. All women who tested positive were admitted to the dedicated COVID Care Hospital (CCH) which is well equipped with a labor room, operation theatre, and intensive care unit (ICU). In the later part of the pandemic, ICMR approved private laboratories to do tests and Municipal Corporation made it compulsory to test all pregnant women near their expected date of delivery, so all positive women at other facilities who were referred were also included.

All women were categorized as mild, moderate, and severe depending on their symptoms, comorbidities, and radiological findings as per ICMR guidelines and managed according to protocols given by the Ministry of Health and Family Welfare (MOHFW), Government of India.[12] Women coming in labor were delivered at CCH with all personal protective equipment. Asymptomatic women after investigations (complete blood count, renal function test, liver function test, electrocardiogram) were discharged for home quarantine or shifted to a quarantine center. Symptomatic women were advised to have X-ray chest and oxygen saturation monitoring. Symptomatic women with comorbidities were advised erythrocyte sedimentation rate, C-reactive protein, lactate dehydrogenase, serum ferritin, D-dimer. Computerized tomography (CT) scan was advised in all symptomatic women who had X-ray changes and low oxygen saturation. Patients were accordingly treated with the anti-COVID-19 treatment protocol, consisting of oxygen therapy, hydroxychloroquine, azithromycin, vitamin C, and zinc tablet.

Antiviral therapy (Faviparaivir), injection Remdesivir, steroids, and low-molecular-weight heparin (LMWH) were used when indicated. After delivery, babies were isolated from the mother, throat swab RT-PCR was done at 24 h. All women and their neonates were followed unto discharge and the outcome was noted.

Women who delivered during the study period who were COVID-19 negative, after matching age, parity, and gestational age were selected as controls.

Data Collection

Demographic data, symptoms, history of contact, preexisting medical disease, pregnancy-related disorder, laboratory investigations, classification of category, mode of delivery, and the fetal and maternal outcome noted and filled in pre-designed forms. Proper consent was taken from the women for inclusion in the study.

Patients were considered to be cases if they were RT-PCR positive and delivered at CCH during the study period. Untested patients were eligible to be cases if they were admitted in labor, and tested positive during delivery. Patients were excluded if they were persons under investigation who had negative COVID-19 testing or if they were positive but discharged before delivery.

The maternal adverse outcome included length of hospital stay more than 10 days, ICU admission, need for mechanical ventilation, supplemental oxygen, and maternal death. The adverse neonatal outcome included low birth weight, stillbirth, low Apgar score, NICU admission, and neonatal death.

Statistical Analysis

Data was entered in MS Excel, coded, and analyzed in statistical software STATA, version 10.1, 2011. Descriptive statistics were used to summarize quantitative variables with mean and standard deviation, while frequency and percentages were used to summarize categorical (qualitative) variables.

Inferential statistics included tests of significance and *p*-values. The significance of the mean difference in the two groups was tested by a two-independent sample t-test with equal variances. The significance of the difference in proportions in the two groups was assessed by Pearson's Chi-square test or Fisher's exact test (for small frequencies).

Risk analysis was performed to quantify associations in terms of odds ratios (OR) along with 95% confidence intervals (CIs). Binary multiple logistic regression analysis was also performed to identify predictors of adverse fetal outcome adjusting odds ratios for maternal and fetal characteristics. A *p*-value <0.05 was considered statistically significant.

Results

During the study period from May 1, 2020, to August 31, 2020, around 222 pregnant women were COVID-19 positive, of which 38 were discharged undelivered and 3 were spontaneous abortions, so were excluded,181 were included in the study. The majority 98.34% were diagnosed in the third trimester as they got tested before delivery. Three women (1.65%) tested earlier as they came with obstetric complications like intrauterine death or eclampsia. According to disease severity, there were mild 177 cases, moderate 3 cases, and severe 1 case. There was a history of contact in 7.18% of

Table 1: Demographic characteristics

Maternal characteristics	*Case*	*Control*	*p-value*	*Odds ratio 95% CI*
Age in years	26.96 ± 4.151	26.97 ± 4.158	0.954	
Parity				
Primi	69 (38.12%)	79 (43.64%)	0.285	
Multi	112 (61.88%)	102 (56.35%)		
Residence				
Rural	30 (16.57%)	113 (62.43%)	0.000	8.36 (4.97–14.18)
Urban	151 (83.43%)	68 (37.57%)		
Gestational age	38.19 ± 2.28	38.14 ± 2.44		

CI, confidence interval

cases. Demographic characteristics are shown in Table 1. When the mean age of cases with moderate/severe disease was considered, it was 32.98 years while in mild it was 26.91 years which is comparable with controls in which it was 26.96 years. Cases were mostly from urban areas showing the trend of positivity in urban areas. This is statistically significant with OR 8.36 (95% CI 4.97–14.18).

Mean gestational age in the moderate/severe category was 37.5 weeks and 3 out of 4 delivered preterm. Mean gestational age in the mild category (38.1 weeks) was comparable to controls (38.14 weeks). This shows an increased risk of preterm delivery in the moderate/severe category.

The majority of cases (97.23%) were in the mild category and 2.76% were in the moderate to severe category (Table 2). The majority of the cases 154 (85.08%) were asymptomatic while only 27 (14.91%) had symptoms; few had more than one symptom. In mild cases, 58.01% were asymptomatic and in symptomatic commonest symptoms were fever, cough followed by sore throat, myalgia, and diarrhea and 49 (27.07%) came with labor pains. While in the moderate/severe category shortness of breath, fever, and cough were the commonest symptoms. Treatment received by symptomatic patients in the mild category is shown in Table 2. In the moderate category, 3 received injection Remdesevir, steroids (methylprednisolone), LMWH, and all patients required oxygenation, 2 patients needed high-flow nasal cannula oxygenation (HFNO), and one in the severe category required endotracheal intubation.

Table 2: Severity classification, symptoms, and treatment

COVID-19 cases	*Mild (n = 176)*	*Moderate and severe (n = 5)*
Severity		
Mild	176 (97.23%)	–
Moderate	–	4 (2.76%)
Severe	–	1 (0.55%)
Symptoms		
Asymptomatic	105 (58.01%)	1 (0.55%)
Fever	11 (6.07%)	1 (0.55%)
Cough	14 (7.73%)	3 (1.65%)
Sore throat	7 (3.86%)	5 (2.76%)
Shortness of breath	1 (0.55%)	
Myalgia	1 (0.55%)	
Diarrhea	2 (1.1%)	
Labor pains	49 (27.07%)	
Treatment		
Hydroxychloroquine	2	
Azithromycin	7	
Favipiravir	18	
LMWH	12	4
Steroids		4
Remdesevir		4
Oxygenation		5
Ventilation		1

LMWH, low-molecular-weight heparin

Maternal Outcomes

When cases and controls were studied for medical conditions, they had chronic illnesses like hypertension, type 2 diabetes mellitus, anemia, hemoglobinopathies (mostly sickle cell), thyroid disorders, epilepsy, infections like HIV and HbsAg (Table 3). Few of them had more than one co-morbidity. Cases (26) had more co-morbidities than controls (14) which were statistically significant. Patients in both groups had pregnancy-related conditions like hypertensive disorders, gestational diabetes, previous cesarean, preterm labor, fetal growth restriction, liquor abnormalities, malpresentation, and multiple pregnancies. Few of them had more than one disorder. Cases (55.24%) had more co-morbidities than controls (29.83%), which were statistically significant. OR was 2 (95% CI 0.96–4.2). When four patients with moderate/severe disease were studied for morbidity, one patient had chronic hypertension, three had preterm labor, and two had previous caesarian.

More cases (52.49%) had caesarian delivery than controls (33%). This was also statistically significant. OR was 2.4 (95% CI 1.4–3.6). Out of four cases of moderate/severe category, three were delivered by cesarean and 1 was delivered vaginally. Most of the cesarean sections were for obstetric indications and none due to disease.

Length of hospital stay was more in cases than controls; this is because of added morbidity due to disease. This was also statistically significant. OR was 8.95 (95% CI 4.02–22.45). All cases in the moderate category had hospital stay more than 14 days, while severe the case died on the 14th day. While maximum cases in the mild category

Table 3: Maternal outcome (morbidity and mortality)

Characteristics	*Cases (n = 181)*	*Controls (n = 181)*	*p-value*	*Odds ratio 95% CI*
Medical morbidity	26 (14.36%)	14 (7.73%)	0.04	2 (0.96–4.2)
Pregnancy morbidity	100 (55.24%)	54	0.000	2.9 (1.9–4.5)
Mode of delivery				
Vaginal	85 (46.96%)	122 (67.4%)	0.000	2.3 (1.4–3.6)
Cesarean	95 (52.49%)	57 (31.49%)		
Instrumental	1 (0.55%)	2 (1.10%)		
Duration of hospital stay				
≤7days	128 (70.72%)	173 (95.58%)	0.001	8.95 (4.02–22.45)
8–14 days	45 (24.86%)	8 (4.42%)		
>14 days	8 (4.42%)	0		
Labor complication				
APH	2	3	0.04	
PPH	2	2		
Retained placenta	1	0		
ICU admission	1	2		
Mortality	1	2		

CI, confidence interval; APH, antepartum hemorrhage; PPH, postpartum hemorrhage

Table 4: Neonatal outcome

Neonatal outcome	*Case (n = 187)*	*Control*	*p-value*	*Odds ratio*
Birth weight (kg)	2.7 ± 0.59	2.5 ± 0.56	0.04	
Stillbirth	7	7	1	
NICU admission	14	16	0.7	0.86
Neonatal death	1	3	1	

had hospital stay ≤7 days which was comparable to controls. The mean length of hospital stay was 7.68 ± 9.01 days in cases and 4.74 ± 2.12 days in controls. Among labor complications, 2 cases and 3 controls had an antepartum hemorrhage, 2 cases and 3 controls had a postpartum hemorrhage, 1 case had retained placenta. One case from the mild category had postpartum psychosis.

Infection in the form of wound sepsis was seen in one woman in each group. One woman with severe disease was admitted to ICU with acute respiratory distress syndrome and was on mechanical ventilation for three days. She developed septicemia with multiorgan failure and succumbed on the 14th day after admission. There were no deaths in the control group.

Neonatal Outcome (Table 4)

Mean birth weight was 2.7 ± 0.59 kg in cases and 2.5 ± 0.56 kg in controls which was statistically significant (*p*-value = 0.004). This difference may be because almost 39.77% of cases had a birth weight of more than 3 kg as compared to 23.20% of controls. Most cases came from the urban area with good nutrition while the majority of controls belonged to rural areas with poor nutrition due to low income during the pandemic lockdown. The mean birth weight in the moderate/severe category was 2.42 kg. There were seven stillbirths in each group. The underlying cause of stillbirth was being pre-eclampsia and intrauterine growth restriction. A total of 14 in cases and 16 in controls were transferred to NICU due to low birth weight, prematurity, respiratory distress syndrome, meconium aspiration syndrome, hypoxic-ischemic encephalopathy, or hyperbilirubinemia. There was one neonatal death in cases on the 4th day due to severe birth asphyxia and three deaths in the control group. In cases, there was one stillbirth in the moderate/severe group, while three babies no morbidity. Four babies were COVID-19 positive after birth in cases; these babies were of mothers whose COVID-19 report came after delivery and were not separated from mother, all were healthy at discharge from hospital. Those babies who were separated from their mother at birth, none were positive.

Binary multiple logistic regression (MLR) analysis was performed to find predictors of outcome of delivery (morbidity and morbidity) in COVID-19 cases adjusting for other medical and pregnancy-related factors and maternal characteristics (Table 5). Urban residence, gestational age <37 weeks, presence of medical morbidity, presence of pregnancy-related morbidity, labor complications, low birth weight of new-born, NICU admission, and hospital stay >7 days were important predictors of maternal and neonatal morbidity and mortality in COVID-19 positive mothers when adjusted for other factors.

Discussion

This is the first large case–control study involving 362 subjects to compare maternal and neonatal outcomes of pregnant women with COVID-19 to those with non-COVID. As per data from other coronaviruses, pregnant women are more likely to develop viral pneumonitis, with higher morbidity and mortality.[11] But very limited data are currently available on COVID-19 infection in pregnancy. So we tried to evaluate the risk factors that drive the associations between COVID-19 and adverse maternal and neonatal outcomes.

The main findings in our study were that majority of women who come with COVID-19 infection are in the mild category and asymptomatic. This may be because as universal testing became mandatory more asymptomatic cases were diagnosed. Due to this, as compared to the number of asymptomatic cases the severe cases of Covid bronchopneumonia are less in this part if India. This may be because as universal testing became mandatory more asymptomatic cases were diagnosed. Fever, cough, and sore throat were common symptoms. This was similar to other studies carried out in China.[13,14]

Only 7.18% of cases had a history of contact that means the remaining acquired infection from the community. This is because the majorities of the general public are asymptomatic and may not follow rules to prevent transmission of the infection.

The majority (83.43%) of women belonged to the urban area, this reflects the fact that initially due to the lockdown, the interdistrict migration was prohibited hence the infection was limited to the urban area and as the lockdown was lifted in July, it spread to rural areas and we started getting cases from there.

Hospital stay in cases was more, which was statistically significant. This may be because of the associated medical and pregnancy-related morbidities being more in cases and more

Table 5: Multiple logistic regression analysis

Logistic regression: Number of obs = 362
LR Chi-square (9) = 140.65
Prob > chi2 = 0.0000
Log-likelihood = −180.59188, Pseudo R2 = 0.2803

Case–control	*Odds ratio*	*Std. error*	*z*	*p > z*	*95% CI*
Urban	7.463146	2.062591	7.27	0.000	4.341853–12.82829
Gest age <37 weeks	3.628633	2.651974	1.76	0.078	0.8662544–15.1999
Low birth weight	0.6940712	0.2341798	−1.08	0.279	0.3582683–1.34462
Hospital stay >7days	7.390011	3.297881	4.48	0.000	3.08167–17.72164
Medical morbidity	1.938303	0.8533541	1.50	0.133	0.817849–4.593781
Pregnancy morbidity	3.278768	0.9413891	4.14	0.000	1.86774–5.755789
Labor complications	0.4312269	0.2985141	−1.22	0.224	0.1110368–1.67473
NICU admission	0.5614711	0.31859	−1.07	0.283	0.1957506–1.61046

CI, confidence interval, Number of obs, number of observations

cesarean delivery as compared to controls. One study had hospital stays ranging from 3 to 26 days median being 6.5 days.[13]

Many initial studies reported cesarean births in all cases due to uncertainty in the outcome and vertical transmission of disease.[14,16,17] But in our study caesarian was done only for obstetric indications but still, the rate was high as most of the cases were admitted with pregnancy and medical morbidities that required cesarean. Most of the studies had similar findings.[14–17]

Adverse maternal outcomes, in terms of increased hospital stay, operative delivery, preterm labor, admission to ICU, ventilation, are mere common in moderate/severe cases than mild cases. The adverse maternal outcome increases with age, presence of medical morbidity, and the severity of the disease.

Adverse neonatal outcomes in terms of low birth weight, stillbirth, NICU admission, and neonatal death were not more due to the disease. Maternal and neonatal outcome in the severe category was adverse in terms of mortality while in moderate category fetal outcome was good and there was maternal morbidity in terms of increased hospital stay. A study carried out in India showed that there is no effect of COVID-19 infection on maternal and perinatal outcome.[11] Overall there was no increased maternal and neonatal adverse outcome, and it is determined by the severity of the disease. Other studies also had similar findings.[13,15]

Conclusion

In this case–control study, we tried to compare the effect of COVID-19 infections on maternal and neonatal outcomes. The results suggest that the majority of the COVID-19 infected women are asymptomatic, mild category, and no adverse maternal–neonatal outcome due to disease, in this part of the world, at this phase of the pandemic. The adversity of maternal and neonatal outcomes depends on the severity and severity of the disease depends on advanced maternal age and the presence of co-morbidities. Regular screening of women to detect coronavirus infection early will avoid complications and reduce the severity and improve maternal and fetal outcomes.

Strength and Limitations

Being a case–control study, we could compare maternal and neonatal outcomes in COVID-19 cases with matched controls. Most published studies so far are case series,[9,14,16] cohort studies.[18,19] Most patients in our study being young, there were fewer moderate/severe cases. As our facility is not the only COVID-19 treating facility many severe cases may have been treated elsewhere, so the outcome in severe cases cannot be determined from our study. The outcome of our study was guided by the referrals that we got and it may not reflect the true picture of the entire community. We could not compare any differences in laboratory investigations due to large study subjects and all investigations not being done in all due to cost constraints.

Areas of Research

The effect of COVID-19 on pregnancy if infected in early pregnancy is not known so these women may be followed and its effect on vertical transmission and other neonatal outcomes may be seen. Large microbiological studies involving amniotic fluid, cord blood, and histopathological study of the placenta are future areas of research.

Declarations

Institutional Ethics Committee approval was taken for the start of the study, vide letter number 2034 EC/Pharmac/GMC/NGP dated 4/4/2020.

Consent for publication: Not applicable

Author's contribution: MPT conceptualized the study, collected data, analyzed, and wrote the manuscript. PS collected data and analyzed it. MW analyzed and approved the manuscript.

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