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# FETO MATERNAL OUTCOME IN COVID-19 INFECTION EXPERIENCE IN A COVID DESIGNATED HOSPITAL IN NORTH KERALA

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#### Abstract

**Background:** The COVID 19 pandemic had affected over a 100 million people worldwide. The impact of coronavirus on health of the pregnant woman and the newborn was studied in our hospital. **Materials and Methods:** Our observational study was conducted in Government Medical College, Manjeri, Malappuram, Kerala, on 538 pregnant women with Covid 19 infection for a period of 6 months from June 2020 to December 2020.RTPCR or RAT (Rapid Antigen Test)was used to confirm COVID infection. **Result:** Majority of the women were asymptomatic and fever was the most common symptom noted.3 women had dyspnea and required ICU care. All the women were treated with a course of Azithromycin and Hydroxychloroquine. 54.6% patients delivered vaginally and 35.5% by LSCS. There were 6 abortions, 3 IUDs and 4 preterm births.40 patients continued pregnancy. Out of the 492 deliveries, 115 (23.4%) babies were tested COVID positive. **Conclusion:** COVID 19 infection during pregnancy and delivery did not result in severe complications in the majority of women and vertical transmission was found in a quarter of the deliveries.

# **INTRODUCTION**

The Covid 19 pandemic caused by SARS-COV2 had infected over a 100 million people worldwide with a mortality of 2.3 million people.<sup>[1]</sup> As of 7th February, Among the 10 million infected in India, close to a million (962363) are from Kerala and the district of Malappuram is the third district with the most number of active cases (108375).<sup>[2]</sup> Despite the huge numbers, The state, however, had the lowest case fatality rate in India (0.35%), compared to the national average of 1.44%.<sup>[1]</sup>

The novel CoV was first identified in Wuhan City, Hubei Province, China, on 12 December 2019. On 11 February 2020, the World Health Organization (WHO) had declared it as a global pandemic. It is an RNA virus belonging to the Coronaviridae family (subfamily Coronavirinae), they cause diseases ranging from the common cold to severe illnesses, such as SARS, MERS, and, presently, COVID-19. The virus generally causes a flu like illness with constitutional symptoms like fever, myalgia, headache, diarrhea, loss of taste and smell, URI and less commonly LRI (Viral pneumonia) The mean incubation period of COVID-19 was found to be 6.4 days, ranging from 2.1 to 11.1 days.<sup>[3]</sup>

Covid 19 infection in pregnant women and the foetus with the potential risk of vertical transmission is a major health concern. The physiological changes during pregnancy with altered cell immunity can lead to increased susceptibility of infection with severe complications of the disease and higher mortality compared to the non-pregnant population. The corona viruses can cause adverse outcomes for the fetus, such as intrauterine growth restriction, spontaneous abortion, preterm delivery, and perinatal death.<sup>[4]</sup> Hence, prevention of Covid 19 infection and care of the pregnant women is of utmost importance at this juncture. But with limited understanding of the effects of Covid 19 in pregnancy, clinicians and patients are forced to make uninformed decisions.

This study will evaluate the maternal risk factors, symptoms at presentation, laboratory parameters, the obstetric outcome and neonatal status among the antenatal women who presented from July 2020 to December 2020.

#### Objectives

- 1. To evaluate epidemiological risk factors
- 2. Course and severity of the disease in the mother.
- 3. Obstetric outcome

## **MATERIALS AND METHODS**

GMC Manjeri where the study is conducted is a major tertiary care centre which is a Covid designated hospital. The hospital had admitted and treated the highest number of Covid positive Antenatal cases in the entire state of Kerala during the study period. This is an observational study for a period of 6months from June 2020. About 500 pregnant women with Covid 19 infection tested positive by the RT-PCR of nasopharyngeal swab. The demographic and obstetric data were collected from the clinical records of patients as detailed in the proforma maintaining confidentiality.

Exclusion: Covid Negative Women

#### **Review of Literature**

Following the pandemic, numerous studies were done to understand the effects of the COVID infection among antenatal women. Pregnancy itself is considered high risk due to altered immune response rendering them more susceptible to severe forms of the disease especially in the second and third trimesters and due to difficulty in delivering intensive care such as intubation and mechanical ventilation during pregnancy because of altered pulmonary function and difficult positioning.<sup>[5]</sup>

A study conducted at Ahmedabad, Gujarat at NHL Municipal Medical College recruited 125 pregnant women who were tested to be RTPCR positive for SARS CoV2 from April to June 2020.

They found the most common symptoms at presentation to be cough in 61.6% and fever in 46.4%. Other symptoms such as sore throat and myalgia were seen in 13.6% and 10.4% respectively while 38.4% patients had no symptoms. All patients were treated with antibiotic, multivitamin and vitamin C while 30 of them received steroids and 19 received Hydroxychloroquine.3 women required ICU admissions and no deaths were reported. The laboratory parameters were also evaluated and was found leucocytosis, increased as CRP,LDH,SGOT/SGPT in 39.2%,64%,35.2%,36% of the women respectively.18 women had patchy haziness on CXR and 1 woman had pleural effusion while the remaining had normal X ray findings.. Among the total 97 deliveries, 52 had caesarean section, 3 cases had IUD and 8 had preterm birth.3 patients had a missed abortion. Ninety-six babies were tested for SARS-CoV-2 viral nucleic acid on nasopharyngeal and pharyngeal samples and 16 were tested positive. They concluded that no higher risk was seen among the pregnant women due to COVID infection but there is possibility of vertical transmission when presented in the third trimester.<sup>[6]</sup> A retrospective cohort study conducted in Wuhan, China observed 11,078 pregnant women out of which 65 women had COVID infection from January to March 2020. No maternal or neonatal deaths were reported. The adverse birth outcomes were observed to be preterm birth, low birth weight, neonatal asphyxia, premature rupture of membrane (PROM), and caesarean section delivery. When compared to pregnant women without COVID-19,

COVID-19 infection had an increased risk of preterm birth (OR 3.34, 95% CI 1.60–7.00) and caesarean section (OR 3.63, 95% CI 1.95–6.76). No statistical difference in low birth weight, neonatal asphyxia, and PROM was observed. They concluded that among the women infected with COVID-19, risk of preterm birth and caesarean delivery was increased while there was little evidence for vertical transmission.<sup>[7]</sup> A study conducted at Sir Ganga Ram Hospital, Lahore, Pakistan from April to May 2020 included 20 pregnant women who were RTPCR. They found the most common presenting complaints to be fever(40%) followed by dry cough (33%), myalgia and dyspnea.5 women were hypertensive,2 were diabetic and 2 were hypothyroid. Raised CRP and Lymphopenia were observed in 21 % of the patients while 26% had infiltrates on chest X-ray. Post operatively 5 patients needed ICU admission. Nine women were delivered by lower segment caesarean section and 1 was 1 a preterm birth.2 babies developed respiratory distress syndrome and required ICU admission. None of the newborns were tested positive for COVID infection. They concluded that not much difference was noted between COVID-19 in pregnancy when compared to the general population. They reported a good fetomaternal outcome.<sup>[8]</sup>

An observational cohort study of fetomaternal outcomes among delivered women with and without SARS-CoV-2 during pregnancy conducted from March to August 2020, at Parkland Health and Hospital System (Dallas, Texas), recruited 252 SARS-CoV-2-positive and 3122 negative pregnant women. The outcomes that were measured were primarily outcome preterm birth (iatrogenic or spontaneous), preeclampsia with severe features, or caesarean delivery for abnormal fetal indication among women delivered after 20 weeks of gestation and secondarily these were analyzed individually. No differences were observed in age, parity, diabetes among the delivered women with and without SARS-CoV-2. No difference in the composite primary outcome of preterm birth, preeclampsia with severe features, and caesarean delivery for fetal indication among women with and without SARS-CoV-2 infection was observed. No stillbirths were reported. Among 239 women (95%) with asymptomatic or mild disease at initially, 6 of those women (3%) later developed severe or critical illness. There were no maternal mortalities.3% of the babies were tested to be positive.<sup>[9]</sup>

A study conducted in areas outside Wuhan, China observed all hospitalized pregnant patients with laboratory-confirmed SARS-CoV-2 infection between December and February, 2020 officially reported by the central government, a total of 13 patients.10 of them presented with fever while 3 had complaints of dyspnea. Among the 13 women 10 underwent caesarean section and 6 had preterm births. 1 patient ICU admission with multiple organ dysfunction syndrome (MODS) including acute respiratory distress syndrome (ARDS) requiring intubation and mechanical ventilation, acute hepatic failure, acute renal failure and septic shock and needed support of Extracorporeal Membrane Oxygenation (ECMO) till the study ended. No clinical or serologic evidence of vertical transmission of SARS-CoV-2 was noted.<sup>[10]</sup>

A Swedish study reviewed 18 studies which included 108 COVID positive pregnancies from December 2019 and to April 2020.Most of them reported with presenting symptom of fever (68%) and cough (34%). Lymphocytopenia (59%) was noted with elevated C-reactive protein (70%).91% of these women were delivered by cesarean section. Three ICU admissions were reported with no maternal deaths. There was 1 each of neonatal and intrauterine deaths. They concluded that while the majority of the women were discharged without any major complications, severe maternal morbidity as a result of COVID-19 and perinatal deaths were also reported. The possibility of vertical transmission of the COVID-19 could not be ruled out.<sup>[11]</sup>

In a retrospective national-based study, conducted at New-Jahra Hospital (NJH), Kuwait, from March and May 2020, 185 pregnant women who had COVID infection were studied. Fever (58%) was observed to be the most common presenting symptom followed by cough (50.6%). 3 of the women had a miscarriage and 1 had IUD. 2 women developed severe pneumonia and required intensive care. 2 babies tested positive on day 5 by nasopharyngeal swab testing. They concluded that most of the women had mild symptoms and though vertical transmission is possible, infection may not lead to unfavourable maternal and neonatal outcomes.<sup>[12]</sup>

In a cohort study conducted in a tertiary maternity unit, Birmingham University, 23 pregnant patients tested positive for COVID-19 between February 2020 and April 2020 were inclusive to analyse the effect of COVID-19 on pregnancy, and neonatal outcomes. 4 women developed severe adult respiratory distress syndrome complications requiring ICU support, with one of whom led to maternal death 1/23 .11 women had pre-existing comorbidities, most commonly being morbid obesity and diabetes. 16 women were delivered by C-section and 7 had preterm birth. They concluded that there was a higher prevalence of preterm birth and caesarean section in COVID infected pregnant women compared to nonCOVID pregnancies. There were no neonates who tested positive.<sup>[13]</sup>

Finally, though the RCOG update of February 2021 based on PregCOV-19 systematic review which has included over 64000 pregnant women with suspected or confirmed infection worldwide stated that pregnant women did not appear more likely to contract the disease that the general population, they did observe higher rates of ICU admissions. The risk of maternal mortality remained low. The majority of the women often were asymptomatic and those with symptoms experienced only mild to moderate flu like symptoms, commonly being cough (41%) and fever (40%). The risk of preterm birth was found to be 17%; mostly being iatrogenic.59% of the women had caesarean births. There was no evidence of an increase in stillbirth rate or neonatal death rates and evidence for risk of miscarriage was found to be insufficient.[14]

**Statistical Analysis:** Statistical analysis was done using SPSS 16.0. Data was expressed as numbers and percentages.

### **RESULTS**

1.Clinical Characteristics: There were 538 patients in our study group. The patient characteristics such as age, gestational age and risk factors at presentation are summarized in [Table 1]. The maximum number of women were aged between 21 to 30 years (62.8%) and presented in the third trimester (95.5%). This could be due to the higher number of visits to hospital for antenatal checkups during the third trimester thereby increasing risk of exposure to the virus. Majority of the patients were multi gravidas, 372 (69.1%). For 95.4% of the women the source of transmission could not be located while 10 women had history of exposure to people who had a recent history of international travel. This pattern was noted as in the initial periods of study, months of June and July the pandemic was in the early phase where the transmission was primarily through contact and towards the end of study the number of cases had risen due to community transmission.4 women were Health care workers, 3 being Doctors and 1 Nurse who had history of exposure at workplace.14 women had direct contact with COVID positive individuals.94.4% of the women were asymptomatic at presentation and were found to be Positive on routine testing prior to admission for delivery/management of obstetric/medical/surgical co morbidities.

2.Clinical Features and associated co morbidities: 94.4 % of the women were asymptomatic at presentation (508 women). Remaining 30 women had symptoms at presentation, most common being fever (12 women) followed by cough (9women) as shown in [Figure 1]. Myalgia was noted in 7 women while 2 women had headache not attributable to any other causes.3 patients presented with shortness of breath requiring ICU care and 1 woman developed dyspnea, tachypnea and saturation fall post operatively with systemic symptoms such as raised transaminases, leucocytosis and features of sepsis. She recovered after steroid and Remdesivir therapy and was discharged to home. 1 woman had self limiting Diarrhea and 2 had presented with anosmia. 72.9% of the women had no pregnancy co morbidities and were admitted for delivery. The majority of the women (72.8%) had uncomplicated pregnancies. The most common co morbidities were GDM (47.9%); gestational hypertension (27.3%) and anemia (26%).4.7% of the women had both GDM and gestational hypertension as shown in the [Figure 2]. 3. Virological testing: Nasopharyngeal swab was used for testing in most of the cases (74.2%) when

used for testing in most of the cases (74.2%) when compared to oropharyngeal. Rapid antigen test was the most common test done to diagnose COVID-19 infection (74.9%), followed by RTPCR (22.3%) and TRUNAAT (2.8%) as depicted in figure 3.Following a positive test, repeat testing by RAT was done on the 10th day of testing and 13 (2.4%) patients were positive in the subsequent test also.

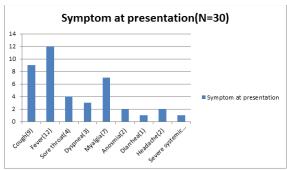


Figure 1: Graph showing distribution of clinical features among 30 symptomatic women

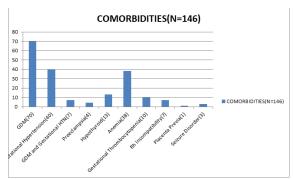
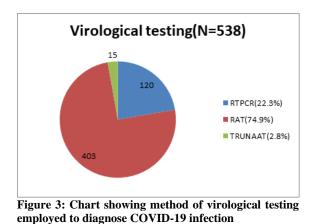


Figure 2: Graph showing distribution of co morbidities among 146 women



4.Treatment, Obstetric and Neonatal outcome: All the patients received Tablet Azithromycin (500 mg one dose followed by 250 mg daily for 4 days), Tablet Hydroxychloroquine (400 mg BD for one day followed by 200 mg BD for 4 days if no QT prolongation on ECG) and Multivitamin tablets. Tablet Tenofovir 75 mg OD was prescribed in the beginning of the pandemic for 45 patients (8.4%).Only 1 patient required Remdesivir and Dexamethasone therapy following COVID pneumonia operatively (0.2%).The post remaining(91.4%) recovered Tablet with Azithromycin and Hydroxychloroquine alone as depicted in Figure 4.As shown in Figure 5, 54.6% patients delivered vaginally and 35.5% by LSCS.

There were 6 abortions, 3 IUDs and 4 preterm births.40 patients continued pregnancy.

There was only one case of neonatal death. Out of the 492 babies delivered, 115 (23.4%) babies were tested COVID positive.

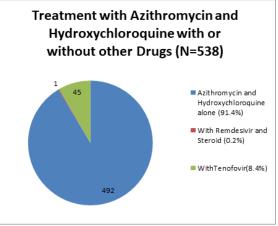
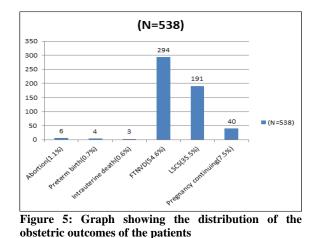
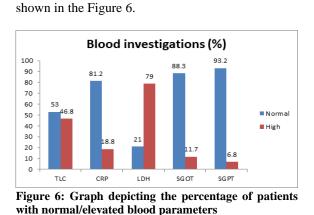


Figure 4: Graph depicting the treatment given



**5.Laboratory Investigations:** Among the blood investigations leucocytosis was observed in only 46.8% of those tested. One patient had decreased TLC. The remaining had normal values. CRP was normal in majority of the patients (81.2%) within 0.6mg/dL. LDH was elevated in 79% of the patients tested (above 280 U/L).The hepatic Transaminases , SGOT and SGPT were both found to be normal in the majority patients, 88.3% and 93.2% respectively as



Chest X ray was done only for patients with persistent cough, dyspnea, intractable fever or saturation fall. Out of the 8 patients who had a shielded X ray taken, 6 of them had normal findings,1 had patchy haziness and 1 had pleural effusion.D- dimer testing was only done for those with the above symptoms, for 11 patients.

**6.Clinical outcome:** There were no maternal deaths.518 (96.3%) patients were discharged home

after being swab negative.13 (2.4%) were shifted to Corona First Line Treatment Centre (CFLTC), a Government approved center for managing COVID patients till they were swab negative.7 (1.4%) patients were referred to Calicut IMCH due to complications such as Pulmonary artery Hypertension, Severe pre-eclampsia, severe thrombocytopenia and previous 3 LSCS.

 Table 1: Frequency of Clinical characteristics (Age, gestational age and risk factors at presentation) of patients with

 COVID -19 infection.

Clinical Characteristics	Number of patients N (%) (Total 538 patients)
Age	
<20	70(13.0)
21-30	338(62.8)
> 30	130(24.2)
Gestational age	
<13 wks	7(1.3)
13- 28 wks	13(2.4)
28-40 wks	514(95.5)
>40 wks	4(0.7)
Risk factor	
Travel	10(1.9)
HCW	1(0.2)
Unknown	513(95.4)
Primary contact	14(2.6)

#### **DISCUSSION**

The current study summarises the fetomaternal outcome of 538 pregnant patients who were tested as COVID positive either following routine testing prior to admission to hospital or with history of exposure or symptomatic women.

Among the symptomatic women the most common symptoms were fever (40%) and cough(30%) which is comparable to the studies conducted by Munir SI et al,<sup>[8]</sup> conducted at Lahore, Pakistan and the RCOG guidelines published in March 2021.<sup>[14]</sup> 13.3% women had sore throat and 23.3% women presented with myalgia at admission. In comparison to other studies the proportion of asymptomatic women (94.4%) was higher due to the Hospital being the only designated centre for COVID positive patients in the district at the time. Hence all pregnant women who were COVID positive were admitted and observed at our centre. Other symptoms such as dyspnoea, headache, anosmia and diarrhea accounted to less than 10% of cases. Majority of the women had no comorbidities while the most common comorbidities was Gestational Diabetes Mellitus (47.9%) which is comparable to the study by Antoun L,<sup>[13]</sup> followed by gestational hypertension and anemia. There was no case of increased severity of COVID infection in the women with the comorbidities.

The virological testing of the women were multimodal, primarily by RAT (74.9%) followed by RTPCR and TRUNAAT testing unlike the study conducted by Shah P,<sup>[6]</sup> which confirmed the infection by RTPCR testing. These varied methods of virological testing were noted due to the referral of the patients to our centre from multiple centres with different testing protocols.

The patients were treated with Azithromycin, Hydroxychloroquineand multivitamins unless contraindicated as per the state guidelines. Antiretroviraldrug, Tenofovir was given prophylactically for the patients in the months of August and September and was later discontinued. Antiviral Remdisivir, anadenosine nucleoside analog which interferes with the viral RNA polymerase, is indicated in hospitalised patients with severe COVID disease. A single patient received 6 day course of Injection Remdisivir in her post-operative period due to saturation fall <94% in room air. In the study conducted by Shah P et al,<sup>[6]</sup> routine treatment with antibiotic, multivitamin and vitamin C was observed while 30 of them received steroids and 19 received Hydroxychloroquine among the 125 women studied. In the present study, 4 women had shortness of breath at presentation and required ICU care with 3 of them maintaining saturation >94% at room air. Only 1 patient developed severe disease (0.1%) which is significantly lower compared to 2% in study by Shah P et al,<sup>[6]</sup> and Zaigham M,<sup>[11]</sup> 7% by Liu et al,<sup>[10]</sup> and 17% in Antoun L.<sup>[13]</sup> none of the patients developed ARDS features or needed mechanical ventilation. The caesarean rate was 35.5%, done for obstetric

Ine caesarean rate was 55.5%, done for obstetric indications while 6 abortions, 3 IUDs and 4 preterm births were noted. The rates of abortion, IUD and preterm birth was lesser in our study compared to the study by Shah P et al,<sup>[6]</sup> Munir SI et al,<sup>[8]</sup> Zaigham M et al,<sup>[11]</sup> and Ayed A et al,<sup>[12]</sup> as majority of the women had uncomplicated course during the hospital stay. Similar to the study by Zaigham M,<sup>[11]</sup> A single neonatal death was seen 23.4% neonates were tested COVID positive which is lower than 76% as observed in study by Shah P et al.<sup>[6]</sup> In the studies by Munir SI et al,<sup>[8]</sup> and Ayed A et al,<sup>[12]</sup> 0 and 1% neonates were infected respectively.

Among the abnormal laboratory parameters, leucocytosis was observed in 46.8% of those tested with a single patient with lymphopenia which is similar to Shah P et al,<sup>[6]</sup> in which 39.2% cases had leucocytosis and in contrast to Zaigham M,<sup>[11]</sup> which observed 59% lymphopenia. CRP was normal in majority (81.2%) as opposed to Zaigham M et al,<sup>[11]</sup> with 70%, Shah et al,<sup>[6]</sup> with 64% and comparable to Munir SI,<sup>[8]</sup> with 21% women having elevated levels. LDH elevation was noted in 79% of the women which was higher than observed in Shah P et al,<sup>[6]</sup> study (35.2%). SGOT and SGPT were both found to be normal in the majoritysimilar to the study by Shah et al.<sup>[6]</sup> Chest X ray was taken only for selected women and majority had normal findings in contrast to the study by Shah P et al,<sup>[6]</sup> which reported higher number of women with patchy haziness and Munir SI et al,<sup>[8]</sup> with 26% women having infiltrates.

Similar to most of the studies, no maternal deaths were reported and a good fetomaternal outcome was observed.

#### CONCLUSION

The study conducted concludes the overall favourable fetomaternal outcomes in he population studied. With majority of women being asymptomatic at presentation there were no cases of maternal death with a single neonatal death. The fetomaternal transmission rate was 23.4%. There were no major morbidities observed due to the Covid infection. The modes of the delivery were decided primarily by the obstetric indication.

The large sample size of the study (538 women) provided for a strong basis to analyse the trend of the outcomes of COVID infection among the pregnant women which forms the strength of the study. As all the neonates were tested it provided a parallel analysis of transmission to the neonates.

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