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Original Research Article

Fetomaternal outcome in COVID-19 infected pregnant women: a preliminary clinical study

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ABSTRACT

Background: WHO has declared COVID-19 infection a health emergency of international concern on 11th March, 2020. It is not clear whether clinical characteristics of pregnant women with COVID-19 differ from those of nonpregnant women and whether it aggravates COVID-19 symptoms and whether antiviral therapy is necessary for COVID-19 infected pregnant women.

Methods: This is prospective study of 125 cases based on the compiled clinical data for pregnant women with COVID-19 between 15th April 2020 and 10th June 2020. A laboratory confirmed positive case of COVID-19 infection in pregnant women were included.

Results: The most common symptoms at presentation were cough in 61.6% (77/125) and fever in 46.4% (58/125). Other reported symptoms were sore throat in 13.6% (17/125), myalgia in 10.4% (13/125) while 38.4% (48/125) were asymptomatic. There were total 97 deliveries (including 2 twins' deliveries) among which 3 cases had IUD. Present study reported 96 live births. The incidence of missed abortion was 2.4% (3/125). The incidence of preterm birth before 37 weeks was 8.2% (8/97). Ninety-six (96.9%) of neonates were tested for SARS-CoV-2 viral nucleic acid on nasopharyngeal and pharyngeal samples and 16.67% (16/96) were resulted positive.

Conclusions: At present, there is no evidence regarding the greater risk of pregnant women to succumb to COVID-19 infection and experience severe pneumonia. The risks of spontaneous abortion and preterm birth are not increased as reported in this study but shows possibility of vertical transmission when it manifests during the third trimester of pregnancy.

Keywords: COVID-19, Maternal morbidity, Pneumonia, Pregnancy, SARS-CoV-2

INTRODUCTION

On March 11, 2020 World Health Organization (WHO) declared corona virus disease (COVID-19) a public health emergency of international concern since its outbreak in Wuhan, China.¹ Coronaviruses are enveloped RNA viruses that are distributed widely among humans, other mammals and birds and they cause respiratory, neurologic, hepatic and enteric diseases.^{2,3} Six coronavirus species are known to cause human disease and four of them - 229E, OC43, NL63, and HKU1 are

less pathogenic causing common cold symptoms in immunocompetent individuals.⁴ The two other strains - severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) - are zoonotic in origin and sometimes causes fatal illness.⁵ Due to its high prevalence and wide distribution, the large genetic diversity and frequent genetic recombination, and increasing human-animal interface activities, novel coronaviruses emerge periodically in humans owing to frequent cross-species infections.⁵ There is 82% homology between the genome

of the virus that causes COVID-19 infection, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and human severe acute respiratory syndrome coronavirus (SARS-CoV).⁶

There have been extensive studies on the HRCT and clinical manifestations of patients with COVID-19 infection and treatment monitoring but studies of pregnant women with COVID-19 infection remains relatively rare. Still it is doubtful whether clinical characteristics of pregnant women with COVID-19 infection differ from those of nonpregnant women with COVID-19 infection and pregnant women with SARS-CoV, whether pregnancy and labour aggravate COVID-19 symptoms and whether antiviral therapy is essential for COVID-19 affected pregnant women.

According to the guidelines from the Royal College of obstetricians and gynaecologists (RCOG), pregnant women do not appear more likely to contract the COVID-19 infection than the general population.³ The centres for disease control and prevention (CDC) report that pregnant women manifest a more severe illness when infected with viruses from the same family as the SARS CoV-2 virus and from other respiratory tract viruses such as the influenza virus.⁸ This depicts that once the coronavirus has been infected this can theoretically lead to more severe symptoms than not, since it is known that in pregnant women there is alteration of the immune system and response to viral infections. These findings of increased severity of clinical manifestations in pregnancy are more prominent towards the end of pregnancy. Hence, there is a possibility that pregnant women infected with COVID-19 may potentially develop more severe symptoms such as pneumonia and marked hypoxia, similar to people who are elderly, immunosuppressed or have existing morbidity such as diabetes, cancer or chronic lung disease. The RCOG guidelines have contrastingly reported that the absolute risk of this is low.⁷

The purpose of this study was to describe the clinical manifestations and fetomaternal outcome of pregnant women infected with COVID-19, monitor for changes before and after delivery, and provide some initial evidence for guiding the management of pregnant women with COVID-19 infection.

METHODS

This preliminary study is prospective study of 125 cases based on compiled clinical and outcome data for pregnant women infected with COVID-19 between 15th April 2020 and 10th June 2020 at a tertiary level hospital. A laboratory confirmed case of COVID-19 is defined as a positive result by quantitative reverse transcriptase polymerase chain reaction (qRT-PCR) assay of maternal pharyngeal and nasopharyngeal swab specimens. All the mandatory safety precautional measures- personal protective equipment (PPE) including jumpsuit, gloves,

N-95 mask, splash resistant face shield, goggles were used by all the health care professionals in labour wards and operation theatres. Separate premises were assigned as donning and doffing areas.

Inclusion criteria

A laboratory confirmed positive case of COVID-19 infection in pregnant women were included in this study.

Exclusion criteria

Pregnancy with clinical signs and symptoms similar to SARS-CoV-2 but nasopharyngeal and pharyngeal swab were reported negative were excluded from this study.

Complete epidemiologic history, obstetric history, clinical symptoms, signs, specific obstetric condition, laboratory and radiologic investigations, treatment measures, complications and outcome data were collected from electronic medical records software ARCUS and curated within customized data collection format. All laboratory investigations and radiologic assessments were performed according to the clinical care needs of the present pregnancy. Laboratory investigations included complete blood cell count (CBC), liver function test (LFT), renal function test (RFT), C-reactive protein (CRP), serum lactate dehydrogenase (LDH), thyroid function test (TFT) and HbA1C. Data on pregnancy and neonatal outcome, including gestational age at delivery, mode of delivery, indication for cesarean delivery, complications, neonatal birthweight and neonatal intensive care unit (NICU) admission were analyzed. The date of data cut-off for outcomes was 10th June 2020. Neonatal pharyngeal and nasopharyngeal swab samples were collected immediately after delivery in the NICU and tested for SARS-CoV-2 using qRT-PCR. Sample collection, processing, and laboratory testing were complied with WHO guidance.⁹

Data were compiled, tabulated, analyzed, interpreted by the authors. All the authors involved in the study reviewed the manuscript and vouched for the accuracy and completeness of the data.

RESULTS

The characteristics and outcomes of the study population of 125 laboratory confirmed COVID-19 positive cases are demonstrated in Table 1. The mean age was 25.2 (range 18-40) years with 73.6% cases between age of 21-30 years. In 31.2% (39/125) cases contact history was present with infected persons. The most common symptoms at presentation were cough in 61.6% (77/125) and fever in 46.4% (58/125). Other reported symptoms were sore throat in 13.6% (17/125), myalgia or arthralgia in 10.4% (13/125), dyspnoea in 8% (10/125) while 38.4% (48/125) of cases were asymptomatic. All these cases underwent necessary laboratory and radiological investigations and detailed epidemiologic history.

Table 1: Demographics, clinical characteristics and clinical outcomes of COVID-19 infection in pregnant women.

Clinical characteristics	Number of patients N (%)
Age group (years)	
≤20	13 (10.4)
21-30	92 (73.6)
>30	20 (16)
Obstetric status on admission	
Antenatal	67 (53.6)
Postnatal	55 (44)
Aborted	3 (2.4)
Gestational age of antenatal cases on admission	
≤13 weeks	10 (14.9)
14-28 weeks	12 (17.9)
28-40 weeks	39 (58.2)
≥40 weeks	6 (8.9)
Gravidity	
Primigravida	27 (21.6)
Multigravida	98 (78.4)
Contact with infected person	
Yes	39 (31.2)
No	86 (68.8)
Covid-19 related clinical features	
Cough	77 (61.6)
Fever	58 (46.4)
Sore throat	17 (13.6)
Myalgia or arthralgia	13 (10.4)
Dyspnoea	10 (8)
Diarrhoea	4 (3.2)
No symptoms	48 (38.4)
Pregnancy associated with	
Gestational diabetes mellitus	6 (4.8)
Gestational hypertension	7 (5.6)
Preeclampsia	2 (1.6)
Treatment	
Antibiotic therapy	125 (100)
Antiviral therapy	0 (0.0)
Multivitamins containing zinc	125 (100)
Tablet vitamin C	125 (100)
Use of corticosteroids	30 (24)
Hydroxychloroquine	19 (15.2)
ICU admission	3 (2.4)
Tocilizumab	0 (0.0)
Clinical outcome	
Discharged after double negative swab report	17 (13.6)
Remained asymptomatic and discharged (as per revised discharge policy by MoHWF ¹⁰)	89 (71.2)
Remained in ward	19 (15.2)
Died	0 (0.0)

Table 2: Laboratory and radiologic findings.

Laboratory and radiological investigations	Number of patients (N) %
Leucocytes (normal range: 4 to 11 kU/L)	
Decreased	0 (0.0)
Normal	86 (68.8)
Increased	39 (31.2)
Neutrophil/Lymphocyte ratio (NLR) (normal: 1-3)	
Normal	36 (28.8)
Increased	89 (71.2)
C-reactive protein (normal range: <0.6 mg/dL)	
Positive	80 (64)
Negative	45 (36)
Serum lactate dehydrogenase (LDH) (normal range: 140-280 U/L)	
Normal	81 (64.8)
Increased	44 (35.2)
SGPT/SGOT (normal range: 5-40 U/L)	
Normal	80 (64)
Elevated	45 (36)
Chest X-ray findings (in 85 cases)	
No abnormality	66 (77.6)
Pleural effusion	1 (1.17)
Patchy haziness/ changes of pneumonia	18 (21.2)

Out of 125 cases on admission, 53.6% (67/125) cases were antenatal and 44% (55/125) cases were postnatal women which were delivered at other allied corporation hospitals and transferred to our COVID dedicated institute, 2.4% (3/125) had missed abortion. The pregnancy was in first trimester in 14.9% (10/67), second trimester in 17.9% (12/67), third trimester in 58.2% (39/67) and post term in 8.9% (6/67) cases. All the full-term pregnant women were motivated, counselled, explained the daily fetal movement counting (DFMC), undergone USG foetus including fetal doppler study on admission and fetal surveillance was done by non-stress test (NST) twice a week.

In this study, there were 6 cases (4.8%) with gestational diabetes and 7 cases (5.6%) with gestational hypertension and 2 cases (1.6%) with preeclampsia including 1 case (0.8%) of HELLP syndrome and these pregnancy complications were unrelated to COVID-19 infection. There were 19 patients (15.2%) with mild pneumonia who were shifted on oxygen bed and oxygen saturation (SPO₂) was monitored. These 19 patients were treated with Injection methyl-prednisone and tablet hydroxychloroquine 400 mg 12 hourly loading dose on day 1 followed by 200 mg 12 hourly for next 4 days and improvement in symptoms was noted. All these 19 patients were postnatal and tablet hydroxychloroquine has not been given to any antenatal patients due to its potential teratogenicity. Antibiotics and supportive multivitamins including vitamin C were given in all the 125 patients. Steroids was administered in 24% (30/125)

cases. Three patients required ICU admission (1 severe pneumonia, 1 HELLP syndrome, 1 severe preeclampsia). A total of 106 (84.8%) cases had been discharged and there was no maternal death.

On admission, total leucocyte count (TLC) was increased in 31.2% (39/125) of the patients and neutrophil/lymphocyte ratio (NLR) was elevated in 71.2% (89/125) of patients. Elevated levels of C-reactive protein were found in 64% of the patients. In view of increased TLC, injection methyl-prednisone was administered alongside monitoring blood sugar level and found to be very effective in controlling the inflammation. Patients with severe disease had more prominent laboratory abnormalities than those with mild disease. In the 85 cases that underwent chest X-ray (antenatal patients with lead shield) at the time of admission, 22.3% (19/85) revealed abnormal results (1 bilateral pleural effusion and 18 showed patchy haziness and peripheral opacities). Liver enzymes - SGPT/SGOT were elevated in 36% (45/125) patients and 35.2% (44/125) reported increased serum levels of LDH

Pregnancy outcomes

Of the 125 cases, 3 cases (2.4%) had missed abortion at 10 weeks, 14 weeks and 18 weeks (retained placental tissue) respectively and dilatation and evacuation (D and E) was performed in these cases. The one case with 14 weeks abortion was complicated with uterine perforation during D and E (performed outside) and required emergency laparotomy. Ectopic pregnancy was reported in 2 (1.6%) cases out of which 1 case of 10 weeks cornual ectopic was managed by emergency laparotomy and salpingectomy performed and 1 case of chronic ectopic (3x3 cm G-sac) managed conservatively.

Table 3: Pregnancy outcomes of COVID-19 disease.

Outcome	Number of patients N (%)	
Fate of pregnancy		
Missed abortion	3 (2.4)	
Ectopic pregnancy	2 (1.6)	
IUD	3 (2.4)	
Live birth	94 (75.2)	
Continuance of pregnancy	23 (18.4)	
Mode of delivery (total deliveries = 97)		
Caesarean delivery	Live	51 (52.5)
	IUD	1 (1.03)
Normal delivery	40 (41.2)	
Preterm vaginal delivery	2 (2.06)	
Hysterotomy	Live	2 (2.06)
	IUD	1 (1.03)

A total of 97 pregnant women including 2 twins delivered their babies of whom 53.6% (52/97) underwent caesarean delivery, 3.1% (3/97) required hysterotomy and 43.26% (42/97) had vaginal delivery including 2 preterm vaginal

delivery at 28 weeks and 32 weeks. Caesarean delivery was indicated for previous caesarean delivery in COVID-19 infection in 36.5% (19/52), prolonged first stage in 9.6% (5/52), induction failure in 5.7% (3/52), postdate pregnancy in 5.7% (3/52), abnormal fetal doppler in 3.8% (2/52), arrest in 2nd stage of labour in 3.8% (2/52), severe preeclampsia in 1.9% (1/52), placenta previa in 1.9% (1/52), and abruption in 1.9% (1/52). The incidence of preterm delivery was 3.1% (3/97) before 28 weeks, 3.1% (3/97) cases between 28 weeks and 34 weeks and it was 2.03% (2/97) between 34 weeks and 37 weeks gestation. Among the 8 preterm deliveries, there were 3 hysterotomies (1 for IUFD with failed induction of labour, 2 for abnormal fetal doppler with previous 2 CS), 3 caesarean sections (1 for abruption and 1 for bad obstetric history and 1 for prev2cs+ threatened rupture) and 2 were preterm vaginal delivery at 28 weeks and 32 weeks respectively. There were no cases with spontaneous onset of labour. The incidence of preterm birth before 37 weeks was therefore 8.2% (8/97). There were no cases of spontaneous preterm delivery before 34 weeks.

Table 4: Neonatal outcomes of COVID-19 deliveries.

Outcome	Number of patients N (%) (Total neonates: 99)
Live (including 2 twins' delivery)	96 (96.9)
Live and infected with COVID-19	16 (16.1)
Live and non-infected	80 (80.8)
Neonatal deaths	2 (2.02)
Still born	0 (0.0)
Intrauterine fetal death	3 (3.03)

In the remaining 23 ongoing pregnancy, USG foetus revealed normal fetal growth and normal doppler study with 1 patient with twins, 2 with precious pregnancy and 1 with breech and none showing fetal growth restriction (FGR) till cut-off date 10th June 2020. There is 1 patient with gestational diabetes mellitus and hypertension and the other 22 patients with no fetal or maternal complications reported as of 10th June 2020.

There were total 97 deliveries in this study including 2 twins' deliveries among which 3 were IUD (96 live born and 3 IUD deliveries). All the 96 live born neonates were admitted to the NICU for further treatment and to rule out COVID-19 infection. There were 2 neonatal deaths. Both of them were delivered at 27 weeks maturity as during antenatal scan, fetal doppler study reported reverse end diastolic flow with severe utero-placental insufficiency. Both of these neonates were <1 kg and were treated with invasive ventilation in view of severe neonatal asphyxia and died within 12 hours of birth. There were 96.9% (96/99) of neonates who underwent testing for SARS-CoV-2 viral nucleic acid on nasopharyngeal and

pharyngeal swab samples and the results were positive in 16.67% (16/96).

DISCUSSION

In this preliminary study of 125 cases, authors observed that the clinical characteristics of the women with COVID-19 infection during pregnancy were similar to those of nonpregnant adults with COVID-19 infection comparable with studies by Guan et al and Wu et al.^{11,12} Till date, summarized data from 125 cases, with a total of 23 women with ongoing pregnancy, indicated that the most common symptoms at presentation were cough (61.6%) and fever (46.4%); 48 (38.4%) of pregnant patients did not present with symptoms, but most of these patients were diagnosed as having COVID-19 infection by intensive field testing and contact tracing during the initial phase of outbreak in India. FOGSI guidelines recommends that pregnant women residing in containment areas or in large migration gatherings/evacuees centre from hotspot districts presenting in labour or likely to deliver in next 5 days should be tested even if asymptomatic.¹³ Out of 125 cases, two-third of the patients had lymphopenia (increased NLR) and increased C-reactive protein, and 52% (65 cases) showed patchy haziness and peripheral opacities on chest radiograph. Authors had reported clinical, laboratory, and radiologic characteristics that are similar to published pregnant and nonpregnant cases of COVID-19 infection.^{11,12}

In normal pregnancy there is physiological activation of the innate limb of the immune response but study by Nacaasha et al reported that pregnant women with acute infection display a more aggressive immune response.¹⁴ In present study, 7 of 125 (5.6%) pregnant women experienced severe COVID-19 infection, which is in significantly lower to the 15.6% of severe disease that has been reported in studies from China.^{11,12} This finding are encouraging and can be attributed to our proactive and aggressive management of diagnosed pregnant cases to minimize the risk of disease progression. Elderly population, immunosuppressed and having comorbidities like diabetes, cancer, chronic lung disease is at greater risk of having severe disease with COVID-19 infection. ICU admission was required in 2.4% (3/125) of patients in view of severe pneumonia and preeclampsia and none died as of 10th June 2020. Immunomodulators like IL-6 inhibitors - tocilizumab has been used for treating selected cases of severe pneumonia in ICU admitted patients in study institute but has not been administered in any of the 125 cases in this study. Study by Alattar et al reported that use of tocilizumab in patients with severe COVID-19 was associated with dramatic decline in inflammatory markers, radiological improvement and reduced ventilatory support requirements.¹⁵ There was a lack of clarity at the beginning of this outbreak and authors could only base our practice on past experience with SARS-CoV. As authors came across a greater number of COVID-19 cases, authors adapted our

management, and care was provided by a multidisciplinary team.

It has been reported that viral pneumonia in pregnant women is associated with an increased risk of preterm birth, fetal growth restriction (FGR), and perinatal mortality by Madinger et al.¹⁶ It is reported by Chen et al that pregnant patients infected with viral pneumonia other than SARS-CoV-2 have increased risk of fetal growth restriction (FGR), preterm delivery, low birthweight and Apgar score <7 at 5 minutes.¹⁷ A case series of 12 COVID-19 infected pregnant women in Hong Kong reported 3 maternal deaths; 4 of 7 patients (57%) had spontaneous abortion in first trimester, 4 of 5 patients (80%) had preterm birth, and 2 pregnant women recovered but their ongoing pregnancies were complicated by FGR.¹⁸ In 23 ongoing pregnancy in present study, none of them reported FGR till cut-off date 10th June 2020.

It is reported from this study that the risk of spontaneous abortion is not increased in pregnant women infected with SARS-CoV-2 from the background risk of the healthy pregnant women.¹⁹ This study also suggests that although the risk of any preterm birth before 37 weeks' gestation is increased, COVID-19 is not associated with an increased risk of spontaneous preterm birth before 37 weeks. There were 8 cases of preterm birth (3 by cesarean delivery, 3 by hysterotomy and 2 preterm vaginal delivery) due to obstetric indication.

RCOG, in consultation with the RCPCH, have provided guidance for delivery and neonatal care, which recommends that mode of delivery be determined primarily by obstetric indication, and recommends against routine separation of COVID-19-affected mothers and their babies.⁷ Ninety-six (96.9%) of neonates were tested for SARS-CoV-2 viral nucleic acid on nasopharyngeal and pharyngeal samples and 16.67% (16/96) were resulted positive.

One of the main purposes of this study was to look for the possibility of vertical transmission of SARS-CoV-2 infection. Authors could only evaluate neonatal nasopharyngeal and pharyngeal swab samples at birth to ascertain the possibility of vertical transmission. This study results indicated that SARS-CoV-2 was positive in 16 (16.67%) out of 96 neonates at birth suggesting that there could be possibility of intrauterine fetal infection because of SARS-CoV-2 infection during the third trimester of pregnancy. This study findings are in agreement with 2 recent research letters reported on 3 neonates born to women with confirmed COVID-19 who tested positive for immunoglobulin G and immunoglobulin M antibodies despite having a negative viral nucleic acid result, raising the possibility of vertical transmission, but more data are needed.^{20,21}

There is controversy between guidance for delayed cord clamping, which is due to lack of evidence. Consensus

guidance from China advises that 'delayed cord clamping is not recommended', in order to reduce the risk of vertical transmission, and that infants should be separated from mothers affected by COVID-19.²² Delayed cord clamping is not practiced in the study institute and the same was followed in deliveries of COVID-19 infected pregnant women. Interim guidance from ISUOG advises clinicians to consider not undertaking delayed cord clamping.²³ RCOG guidance does not concur, advising that delayed cord clamping should be practiced as normal. It can be argued that further 1 min of perfusion from the placenta is highly unlikely to affect the risk of vertical transmission due to fact that there is already enough exposure to maternal secretions and blood during vaginal delivery. Infants may contract infection after delivery from their mothers through normal mode of transmission. All the neonates in this study were top-fed in NICU with expressed breastmilk. WHO guidelines states that 'the benefits of skin-to-skin contact and breastfeeding substantially outweigh the potential risks of transmission and illness associated with COVID-19 infection' while guidance from China states that 'Infants shouldn't be given feeding with the expressed breast milk from confirmed or suspected COVID-19 mothers'.²⁴ Guidance from the Centres for Disease Control and Prevention is less clear but is still precautionary.⁸

CONCLUSION

In pregnancy, due to the physiological alterations in cardiovascular, respiratory and immune system, the pregnant women are at greater risk and vulnerable to become the victims of pathogens, especially in the case of outbreak like SARS-CoV-2. Currently, there is no evidence that pregnant women are at greater risk to succumb to COVID-19 infection and experience severe pneumonia. This preliminary study however does not rule out the possibility of vertical transmission of SARS-CoV-2 when it manifests towards the end of pregnancy. This study does not report any increased risks of spontaneous abortion and spontaneous preterm deliveries.

Currently there is worldwide collection of clinical data and research with the aim to answer some of the questions in relation to the risk of teratogenicity, congenital infection, labour management and mode of delivery. Early data analysis regarding the pregnancy outcomes in COVID-19 are optimistic but due to the limited availability of study in the literature on this new disease in pregnancy and restricted sample size, there is worldwide need for systematic data collection and judicious follow-up of disease in pregnancy. This would lead us to evidence-based management, treatment and prevention of SARS-CoV-2 among pregnant population.

The life of health care professionals engaged in the battle against SARS-CoV-2 is equally important and adequate safety measures were ensured by using fully equipped PPE kits including N-95 masks.

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