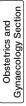
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Impact of COVID-19 on Maternal and Neonatal Outcomes in Pregnancy: A Prospective Study

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ABSTRACT

Introduction: The Coronavirus Disease-2019 (COVID-19), caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), is a global public health crisis. Pregnant women are known to be disproportionately affected by respiratory illnesses, which are associated with increased infectious morbidity and high maternal mortality rates.

Aim: To study the management of COVID-19 in pregnancy and its perinatal outcome.

Materials and Methods: This prospective observational study was conducted in the Obstetrics and Gynaecology Department from March 2020 to September 2020. To evaluate the effects of COVID-19 in pregnancy and to determine the maternal and fetal outcomes in COVID-19 positive patients. In order to evaluate the pattern of caesarean and vaginal

deliveries in COVID-19 and non COVID-19 patients, chisquare test was done.

Results: A total of 150 COVID-19 positive patients were admitted to the COVID-19 labour room and out of them 142 (94.67%) were antenatal and 8 (5.33%) were postnatal. Total number of the deliveries in this period was 80 (53.33%) and out of them vaginal deliveries were 35 (23.33%) and caesarean section were 45 (30%). A 6 (7.50%) babies with poor Appearance, Pulse, Grimace, Activity, Respiration (APGAR) score were admitted to the Neonatal Intensive Care Unit (NICU) and 70 (87.50%) had good APGAR after delivery, four had Intrauterine Death (IUD).

Conclusion: The pregnant women with suspected COVID-19 who need medical care should be transferred to a hospital equipped with sufficient health facilities and fully trained clinicians to take proper care of critically ill obstetric patients for effective management.

Keywords: Antenatal, Caesarean, Neonatal outcome

INTRODUCTION

The SARS-COV-2 is a new mutant strain of coronavirus causing COVID-19. It was declared as pandemic by WHO on 11th March 2020 and first case of COVID-19 was reported from Wuhan, a city in Hubaei province of China. The first case in India was reported at Thrissur city in Kerala on 30th January 2020. COVID-19 cause illness ranging in severity from the common cold to severe and fatal illness and are single-stranded positive sense RNA, nonsegmented, enveloped viruses [1]. Various studies shows that patients commonly develop severe pneumonia and out of them, 17-29% of cases progress to Acute Respiratory Distress Syndrome (ARDS) with 23-32% getting admitted to the intensive care unit [2]. The most common symptoms and signs among hospitalised patients were fever (83-100%) and cough (59-82%) followed by myalgia (11-35%), headache (7-8%), breathlessness and diarrhea (2-10%). This infection can even spread to the lungs with abnormalities on radiographic imaging of the chest [3].

Among pregnant women, viral pneumonia is one of the important causes of mortality and morbidity. Several adverse obstetrical outcomes are associated with maternal pneumonias, which include Preterm Labour (PTL) and Premature Rupture of Membranes (PROM), Intrauterine Fetal Demise (IUFD), Fetal Growth Restriction (FGR) and neonatal death after delivery. However, there is very limited data about the adverse outcomes in pregnant women with COVID-19, as coronavirus was not previously seen in humans [4]. According to ICMR (Indian Council of Medical Research), the antenatal visits should be tailored to minimum at 12, 20, 28 and 36 weeks of gestation and women should report immediately in case of emergencies. The recommended indications for testing for COVID-19 in pregnancy are all symptomatic patients with Influenza like Illness like fever, cough, sore throat, runny nose at any gestation and term or near-term pregnant patients who needs admission in hospital or likely to deliver in next 5 days even if asymptomatic [5]. The guidelines further states that the testing should be carried out in the centre where the woman is admitted for delivery and she should not be referred out for testing [6]. Now-a-days, the asymptomatic COVID-19 women should be home isolated if she doesn't require any intervention in the hospital [7]. To evaluate the effects of COVID-19 in pregnancy and to determine the maternal and fetal outcomes in COVID-19 positive patients.

MATERIALS AND METHODS

This prospective observational study was undertaken in the Obstetrics and Gynaecology Department in Government Medical College and Rajindra Hospital, Patiala from 20, March 2020 to 30, September 2020 to evaluate the effects of COVID-19 on pregnancy and to determine the maternal and fetal outcomes in COVID-19 positive patients. The ethical clearance was taken from the ethical committee of our institute with reference number Trg.9 (310)2020/2599.

Inclusion criteria: All COVID-19 positive antenatal and postnatal patients that came to the institute- both symptomatic and asymptomatic.

Exclusion criteria: All the COVID-19 negative antenatal and postnatal patients admitted in the clean labour room were excluded from the study subject however they were considered for comparison.

Since the start of pandemic, our Obstetrics and Gynaecology department was divided into clean labour room where the routine non COVID-19 emergencies were admitted, the suspect labour room where all the COVID-19 suspected patients were admitted, getting tested for COVID-19 and were managed accordingly and the COVID-19 labour room where the antenatal or the postnatal COVID-19 positive patients were directly admitted. The patients were triaged at the entrance of our department and were sent to the suspect labour room if they had fever, cough or any respiratory symptoms. The nasopharyngeal swabs

of the suspected patients were sent for Reverse Transcription-Polymerase Chain Reaction (RT-PCR)/ Cartridge Based Nucleic Acid Test (CBNAAT/TRUENAT) as a confirmatory test for COVID-19. The pregnant patients who had pre-eclampsia, eclampsia, oligohydramnios, gestational diabetes, previous caesarean and with various other high risk factors with COVID-19 positive status were also admitted and managed accordingly. The complete data was compiled to evaluate the maternal and fetal outcome of the COVID-19 positive pregnant patients. The investigations like complete blood count, Renal function tests, liver function tests, C-reactive protein, Serum Ferritin and d dimer was sent in all the patients. The neonatal outcomes were measured as number of NICU admissions and neonatal deaths. The COVID-19 status of babies was also tested by the nasopharyngeal samples taken within 24 hours of delivery and on 5th day of delivery. The patients with Severe Acute Respiratory Infection (SARI) requiring oxygen or ventilatory support were directly sent to COVID-19 intensive care unit.

STATISTICAL ANALYSIS

Chi-square test was used to evaluate the pattern of the caesarean and vaginal deliveries in the COVID-19 and non COVID-19 patients, p-value < 0.05 was considered statistically significant.

RESULTS

The number of the COVID-19 positive patients admitted to the COVID labour room was 150 and out of them 142 (94.67%) were antenatal and 8 (5.33%) were postnatal patients. Total numbers of deliveries were 80 in six months study and out of them vaginal deliveries were 35 (23.33%) and caesarean section was 45 (30%) [Table/Fig-1].

Out of 35 (23,33%) vaginal deliveries, preterm vaginal deliveries were 16 (45.71%) and full term vaginal deliveries were 19 (54.29%). Out of 45 caesarean section, the elective caesarean section done was 24 (53.33%) and emergency was 21 (46.67%). 68 (45.33%) patients had undergone conservative treatment and no intervention was done in them [Table/Fig-1].

Variables	Number	Percentage
Total COVID-19 Positive Patients	150	100%
Antenatal care	142	94.67%
Postnatal care	8	5.33%
Vaginal Deliveries	35	23.33%
Preterm vaginal deliveries	16	45.71%
Full term vaginal deliveries	19	54.29%
Caesarean Section	45	30.00%
Elective Caesarean Section	24	53.33%
Emergency Caesarean Section	21	46.67%
Conservative Management	68	45.33%
Missed abortion in whom Dilatation and Curettage was done	2	1.3%

[Table/Fig-1]: No. of COVID-19 positive patients and their outcomes.

As far as the age is concerned, 52 (34.67%) patients were ≤25 years of age, 94(62.67%) were at 26-35 years of age, 2 (1.33%) at 35-40 years and 2(1.33%) came at ≥40 years of age [Table/ Fig-2]. A 69% women reported from the urban area and 31% from the rural areas [Table/Fig-3]. 62(43.67%) patients reported at >37 weeks and 80 (56.33%) at <37 weeks gestation [Table/Fig-4].

Age group (years)	Number	Percentage
≤25	52	34.67%
26-35	94	62.67%
35-40	2	1.33%
≥40	2	1.33%
[Table/Fig-2]: Age group.		

Variable		Number	Percentage
Locality	Rural	47	31%
	Urban	104	69%
Region	From Patiala District	82	54.63%
	Outside Patiala District	68	45.37%

[Table/Fig-3]:	Patients de	mographic	profile.
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Gestation (in weeks)	Number	Percentage
<35	38	26.76%
35-37	42	29.58%
37-40	56	39.44%
>40	6	4.23%
Total	142	100%

[Table/Fig-4]: Gestation period.

Amongst all the COVID-19 positive patients who were referred, six patients came with abortion and out of them, two patients were diagnosed with missed abortion at eight weeks gestation, one with inevitable abortion and one was admitted for medical termination of pregnancy. In these four patients, no intervention was done. The rest of two patients reported at 10 weeks and six weeks with missed abortion in whom dilatation and curettage was done.

Eleven patients reported with Pregnancy-Induced Hypertension (PIH), two with Gestational Diabetes Mellitus (GDM), four with severe anaemia, one patient with eclampsia, five with Intrahepatic Cholestasis of Pregnancy (IHCP) and 26 patients reported with previous caesarean (LSCS) [Table/Fig-5]. Emergency caesarean section were done in three patients due to failed induction, five due to meconium stained liquor and fetal distress (MSL+FD), two due to previous LSCS with Scar tenderness, three due to abnormal colour doppler of the fetus, three due to Nonprogression Of Labour (NPOL), 1 due to Deep Transverse Arrest (DTA), one due to cervical dystocia and one due to Cephalopelvic Disproportion (CPD) and another one due to twins due to CPD and one due to obstructed labour [Table/Fig-6]. There was only one COVID-19 positive maternal death. She came at 26 weeks gestation with Intrauterine Death (IUD) with SARI.

High risk patients	Number	
Pregnancy-induced hypertension	11	
Gestational diabetes mellitus	2	
Oligohyramnios	3	
Eclampsia	1	
Previous caesarean	26	
Intrahepatic cholestasis of pregnancy	5	
Peripartum Hysterectomy	2	
Severe Anaemia	4	
[Table/Fig-5]: High risk nationts		

Emergency caesarean	Number
Failed Induction	3
MSL+FD	5
Derranged Colour Doppler	3
Deep Transverse Arrest	1
Cervical Dystocia	1
Twins & Cephalopelvic Disproportion	1
Cephalopelvic disproportion	1
Previous caesarean with ST	2
Obstructed labour	1
Nonprogression of labour	3

Out of total COVID-19 positive patients, 140 patients came in a stable condition with ${\rm spo}_2>\!\!95\%$ (on the room air). A total of 56 (39.44%) patients came at term and out of them, induction of labour was done in 23. One patient underwent exploration under anaesthesia out of four patients which came with postpartum haemorrhage. There was one Peripartum Hysterectomy (PPH) due to placenta previa with atonic PPH. Only 8 (5.33%) pregnant patients presented with the symptoms of cough, cold, fever to our hospital and rest were all asymptomatic.

There were four IUDs in our study. Three patients reported with an IUD and one had it in hospital due to cord prolapse. There was found no direct association of the pregnant patients between COVID and IUD in this study because these patients were totally asymptomatic during their admission. Regarding the outcome, 6 (7.50%) babies with poor APGAR score were admitted to the NICU and 70 (87.50%) had good APGAR after delivery [Table/Fig-7]. Birth weight of the babies were <2 kg in 9 (11.25%), 2-3kg in 37 (46.25%), 3-3.5 kg in 23 (28.75%) and >3.5 kg in 11 (13.75%) mothers respectively [Table/Fig-8]. A total of 38 (47.50%) females and 42 (52.50%) males were born [Table/Fig-9] in this study. There were four neonatal deaths after delivery. These babies were preterm and died of the birth asphyxia and out of them, two babies had malformations. One had pulmonary hypoplasia and other had complex congenital heart disease. None of the live babies came positive for COVID-19. The nasopharyngeal swabs of all the babies were sent within 24 hours of the delivery/caesarean. Two babies were tested positive for TRUNAAT within 24 hours of the delivery but their test was repeated after 48 hours and 5 days of delivery and which were negative. The patients were sent to COVID-19 care centre after 24 hours of the vaginal delivery and after 48 hours of caesarean section if they remained stable. The patients on conservative management were sent after 10 days to the COVID-19 centre or home isolation after the fulfilment of the criterias. The total duration of the isolation was 17 days. According to ICMR (advisory on strategy for testing COVID-19 in India, no repeat testing was required [12]. In clean labour room, 333 patients had caesarean section, 173 had preterm vaginal deliveries and 300 were vaginal deliveries. When the caesarean section, preterm vaginal deliveries and full term vaginal deliveries of COVID-19 labour room was

Babies	Number
IUD	4
Poor APGAR	6
Good APGAR	70
Neonatal deaths after delivery	4

[Table/Fig-7]: Outcome of babies.

Birth Weights	Number	Percentage
<2 Kg	9	11.25%
2-3 Kg	37	46.25%
3-3.5 Kg	23	28.75%
>3.5 Kg	11	13.75%
[Table/Fig-8]: Birth weights.		

Babies	Number	Percentage
Male	42	52.50%
Female	38	47.50%
[Table/Fig-9]: Babies		

Variables	COVID-19	Non COVID-19
Caesarean	45	333
PTVD	16	173
FTVD	19	300
Chi-square, df, p-value	7.546, 2, 0.023	

[Table/Fig-10]: Outcome of patients in COVID-19 and non COVID-19 labour room.

compared with non-COVID-19 labour room emergencies, the value was found to be significant (p=0.023) [Table/Fig-10].

DISCUSSION

The retrospective studies conducted by Wu YT and Juan J et al., in pregnant women with COVID-19 concluded that there are few maternal and neonatal complications associated with pregnancy but as the disease is very recent, so more concrete evidence is required because these studies involved a small number of women over a short period. Importantly the pregnant women may be more vulnerable to COVID-19 and require prioritized medical care as viral respiratory illnesses, such as infuenza, can easily develop during pregnancy [8,9]. In a study by Wu YT et al, 29 pregnant women with COVID-19 infection delivered in two designated general hospitals in Wuhan, China between January and March, 2020. Pregnancy complications occurred in 11 of 29 women and 27 had to undergo cesarean section. Of 30 neonates, 12 were discharged after birth without any symptoms and had normal follow-up whereas 18 were admitted to Wuhan Children's Hospital for quarantine and care [8]. In our study, 142 pregnant women were admitted in whom 21 had emergency caesarean. There were only four neonatal deaths and only six neonates had poor APGAR score. Changes in fetal heart rate pattern and need for mechanical ventilation in severe cases in pregnant women might occur although more wide research is required in this context [10]. A study was conducted by Juan J et al., in which they used RT-PCR for the testing of the COVID-19 in the pregnant patients [9]. In this study, we did RT-PCR testing in the patients was done but in the middle of the pandemic, the TRUNAAT testing was also started in the institute for emergency cases. One of the study was conducted by Zaigham M and Andersson O, with 108 COVID-19 positive pregnant patients, there were 50 deliveries in their study and concluded that COVID-19 may be associated with severe maternal morbidity during pregnancy whereas in present study mostly asymptomatic patients with COVID-19 with only one maternal mortality [11].

Royal College of Obstetricians and Gynaecologists (RCOG) advices that pregnant women who are admitted in isolation should receive prophylactic low molecular weight heparin unless expected to deliver within next 12 hours although we didn't give this drug to any of our antenatal patients [7].

Limitation(s)

The major limitation of this study was the small sample size. Moreover, serum test for Anti COVID-19 antibody was also not done. Antibody titer test could have compensated for false negative RT-PCR test.

CONCLUSION(S)

No association of the pregnant patients between COVID and IUD in this study was found. However, when preterm vaginal deliveries and full term vaginal deliveries of COVID labour room was compared with non-COVID labour room emergencies, the value was found to be significant. The pregnant women with suspected COVID-19 who need medical care should be transferred to a hospital equipped with sufficient health facilities and fully trained clinicians to take proper care of critically ill obstetric patients for effective management. The women should be guided properly to limit the antenatal visits and to follow all safe practices like maintaining social distancing, frequent handwashing, use of face masks etc. The safety of COVID-19 vaccine is not established yet although numerous researches are going on in this section. All women to have access to safe maternity services should be our primary responsibility. So we should remain up to date with the evidence for the management of COVID-19 in the pregnant population and to stem the spread of disease within our own units by ensuring strict infection control measures.

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