Section: Pathology

Research

NOVEL CORONAVIRUS AND PERINATAL WOMEN: A STUDY ON DEMOGRAPHIC PROFILE AND LABORATORY PARAMETERS

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Abstract

Background: The COVID-19 pandemic implicated great threat to human lives irrespective of age, gender and co-morbidities. Amongst them, those who suffered extensively were the elderly, patients with associated co-morbidities and pregnant women. Pregnancy is a major physiological change occurring in a woman's life. With various hormonal changes manoeuvring, the pandemic also inflicted severe complications. This study was done during the peak wave of the COVID 19 pandemic, which shut the whole country into a state of doom. In this study, we have evaluated the changes in the values of various laboratory parameters in COVID-19 positive pregnant population. This study aims to differentiate the standardized cut off value for pregnant and non-pregnant women. **Materials and Methods:** We enrolled fifty antenatal COVID-19 positive inpatients admitted for delivery and 139 non-pregnant female inpatients as control cases for the study. Socio-demographic data, clinical details and the laboratory parameters of the study population were collected. Mode of delivery, mean duration of stay in hospital (days) and outcome of pregnancy were also included. The data was analysed with appropriate statistical tests. **Result:** Total WBC count, mean neutrophil count in pregnant females were significantly higher in pregnant females. Lymphopenia and thrombocytopenia were also seen significantly higher in pregnant females than non-pregnant females ($p<0.05$). The serum total protein in pregnant females was significantly less than that of non-pregnant females ($p<0.05$). Significantly higher mean alkaline phosphatase levels and significantly lower mean SGPT levels were seen in pregnant females. Significantly lower serum ferritin levels were seen in pregnant females than in non- pregnant females ($p<0.05$). **Conclusion:** COVID-19 continues to be of public health interest despite declining rates. There are very few studies conducted among COVID-19 positive pregnant patients. In our study, most of the COVID-19 pregnant patients had high neutrophil count, lymphopenia, thrombocytopenia and deranged liver function tests.

INTRODUCTION

Coronavirus is a severe acute respiratory syndrome caused by SARS-CoV2 virus. More suitable titled as COVID-19, the disease and its magnitude shook the globe, leading it to be termed, the Public Health Emergency of International concern.[1]

The COVID-19 infection spreads through many modes, most commonly through airborne transmission.[2,3] With the progressing pandemic, it was also confirmed that the disease was easily transmitted during pregnancy (vertical transmission).[4] From the fewer studies available in the past, it is found that the disease has had its implications on the mother and the child. However, the case fatality rate is found to be minimal.[4]

The symptom presentation in pregnancy is very similar to others.[5] However, the complications include severe pneumonia, acute respiratory distress syndrome, cardiac abnormalities, respiratory tract

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superinfections, sepsis, septic shock, and multiorgan failure.[6,7,8]

Considering the multi-organ involvement of the disease, the study was conducted to determine the demographic features & variations in the laboratory parameters in COVID-19 positive perinatal women. The study is aimed to compare the effect of COVID-19 on laboratory parameters among pregnant and non-pregnant women.

MATERIALS AND METHODS

This was a retrospective and prospective observational study carried out at KMCH Institute of Health Science and Research, Coimbatore, Tamil Nadu, India. The duration of the study period was July 2020 to December 2020. The study included COVID-19 positive pregnant and non-pregnant women (random selection). Informed consent was not taken for the study because this is a retrospective study using medical records without any intervention to subjects.

This study was verified and approved by the Institutional Human Ethics Committee.

The data on each patient was retrieved from the Medical Records Department. The electronic medical records were derived from the Backbone software maintained by the KMCH Hospital management.

The inclusion criteria were patients presenting with fever, cough, sore throat, nasal congestion, malaise, headache with/without breathlessness (SPO2 less than/equal to 94% on room air). The study excluded outpatients and patients who died at the time of admission and hospital stay.

Along with the above data, we also collected socio-demographic details, mode of delivery, mean duration of stay in hospital in days and the outcome of pregnancy were included. All the patients underwent investigations like Complete Blood Count, erythrocyte sedimentation rate, liver function tests, renal function tests, D-Dimer, serum ferritin and Interleukin- 6(IL-6).

Out of the 112 pregnant patients admitted during the study period, 52 patients were COVID-19 positive. Two patients died due to several complications and were excluded from the study. For control, female patients in all age groups were included. Of 308, 139 patients were found to be COVID-19 positive. The variations in laboratory parameters in COVID -19 pregnant patients were compared with non-pregnant patients.

Statistical Method

Data entry was done in MS Office excel.Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. The association between categorical explanatory variables and quantitative outcome was assessed by comparing the mean values. The association between categorical explanatory variables and the categorical outcome was assessed using Chi-square test. P value < 0.05 was considered statistically significant. The above data is evaluated on the IBM SPSS version 22.

RESULTS

In our study, the mean age of the pregnant women was 28.30± 4.2 years and the mean age of non-pregnant women was 46.85± 19.5 years. In pregnant patients all samples collected were nasal swabs. In non-pregnant patients 40 were oral samples and 99 were nasal swabs.

In pregnant females 92% delivered by caesarean section and 8% delivered by normal vaginal delivery. Mean duration of stay in the hospital among the pregnant woman was 7.08±1.8 days and in non-pregnant woman, it was 8.08± 3.5 days [Table 1].

Total WBC count in pregnant woman was 10200.00 ±3276.8 per mm^3 and in non-pregnant woman was 6974.82 ± 2480.74 per mm^3. The difference between them was statistically significant and found to be p<0.001. The mean neutrophil count in pregnant woman was 72.74±7% and in non-pregnantwoman was 64.15± 13.8%. This difference was statistically significant and found to be p<0.001. The mean lymphocyte count in pregnant woman was 22.66 ±7.2 % while in non-pregnant woman it was 27.91± 12.9 %.

The mean monocyte in pregnant female was 4.7 ± 2.1 % and in non-pregnant female it was 5.91± 3.4 %. This difference was statistically not significant. The mean eosinophil level in pregnant and non-pregnant women was 2.09 ±0.5% and 1.92 ± 1.2% respectively. The mean haemoglobin level in pregnant woman was 12.19 ± 1.08 g/dl and in non-pregnant woman, it was 12.52 ± 1.74 g/dl. The mean platelet counts in pregnant female (226732.0 ± 78932.1 per mm^3) was significantly lessthan non-pregnant female (281798.56 ± 108103.4 per mm^3) [Table 2].

The mean erythrocyte sedimentation rate (ESR) in pregnant woman was 21.08 ±10.94 mm/hr and in non-pregnant woman, it was 25.47 ± 22.72 mm/hr. The difference between them was statistically not significant (p= 0.195). Mean prothrombin time in pregnant female (12.28 ±2.45 mm/hr) was significantly less than in non-pregnantwoman; 13.65 ±1.74 mm/hr (p= 0.001).

Activated Partial Thromboplastin Time (APTT) in pregnant woman was 28.72 ± 4.53 seconds and in non-pregnant woman it was 32 ± 5.17 seconds. Total protein in pregnant female was significantly less than non-pregnant females and it was p<0.05. D-Dimer level in pregnant female was 1.77 ±1.09 and in non-pregnant female it was 1.99 ± 4.37 [Table 3].

Mean Total bilirubin level in pregnantwoman was 0.88±1.67 mg/dl and in non-pregnant woman it was 0.70 ± 0.98 mg/dl. This difference was statistically

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notsignificant. The mean direct bilirubin level in pregnant woman was 0.17 ± 0.7 mg/dl and in non-pregnant woman it was 0.35 ± 0.93 mg/dl.

The mean Alkaline phosphatase level in pregnant woman was 135.6 ± 44.17 IU/L and found to be significantly higher than in non-pregnant woman, it was 68.88 ± 30.5 IU/L, (p<0.001).

Mean SGOT level in pregnant woman and non-pregnant woman was 27.6 ± 12.15 IU/L, 27.75 ±16.75 IU/L respectively. This difference was statistically not significant (p=0.95). Mean SGPT level in pregnant woman (16.54±10.92 IU/L) was significantly lower than in non-pregnant woman (34.44 ± 36.6 IU/L), (p=0.001).

Mean LDH level in pregnant woman was 215.48 ± 94.7IU/L and in non- pregnant woman it was 252.41 ± 105.119IU/L. This difference was statistically not significant (P=0.30).

Mean urea level in pregnant woman was 14.37 ± 5.95 mmol/L and in non-pregnant woman, it was 23.52 ± 10.9 mmol/L. This difference was statistically not significant. Mean Serum creatinine level in pregnant woman was 0.99 ± 1.47 µmol/L and in non-pregnant woman, it was 1.04 ± 3.17 µmol/L. This difference was statistically not significant (p=0.925).

Mean uric acid level in pregnant and non- pregnant women was 4.84±1.38 mg/dl and 4.21±1.63 mg/dl. Mean Serum ferritin level in pregnant woman was 81.56± 63.25 µg/L and in non- pregnant woman, it was 180.37± 316.5 µg/L. This difference was statistically significant. Mean IL-6 level in pregnant woman was 14.20± 57.84 pg/ml and in non-pregnant woman it was 10.77±13.56 pg/ml [Table 4].

Table 1: Distribution of patients according to duration of stay in both pregnant and non-pregnant patients

Parameters	Group	Sample	Mean	Standard Deviation	P value (Independent t test)
Age	Pregnancy	50	28.3	4.2	0.0001
	Non-Pregnancy	139	46.85	19.5	
Duration of stay	Pregnancy	50	7.08	1.88	0.064
	Non-Pregnancy	139	8.08	3.6	

Table 2: Complete Blood Count in both pregnant and non-pregnant COVID-19 positive patients

Parameters	Group	Sample	Mean	Standard Deviation	P value (Independent t test)
Total count	Pregnancy	50	10200.00	3276.82	0.0001
	Non Pregnancy	139	6974.82	2480.74	
Neutrophil	Pregnancy	50	72.74	7.0	0.0001
	Non Pregnancy	139	64.15	13.8	
Lymphocyte	Pregnancy	50	22.66	7.3	0.007
	Non Pregnancy	139	27.91	12.9	
Neutrophil Lymphocyte ratio	Pregnancy	50	3.860600	1.76	0.087
	Non Pregnancy	139	3.198633	2.5	
Monocyte	Pregnancy	50	4.70	2.13	0.034
	Non Pregnancy	139	5.91	3.4	
Eosinophil	Pregnancy	50	2.09	0.59	0.528
	Non Pregnancy	139	1.92	1.25	
Hemoglobin	Pregnancy	50	12.1980	1.08	0.214
	Non Pregnancy	139	12.5273	1.74	
Platelets	Pregnancy	50	226732.00	78932.1	0.001
	Non Pregnancy	139	281798.56	108103.5	

Table 3: Laboratory parameters in both pregnant and non-pregnant COVID-19 positive patients

Parameter	Group	Sample	Mean	Standard Deviation	P value (Independent t test)
ESR	Pregnancy	50	21.08	10.9	0.195
	Non Pregnancy	139	25.47	22.7	
PT	Pregnancy	50	12.28	2.4	0.0001
	Non Pregnancy	139	13.65	1.7	
APTT	Pregnancy	50	28.72	4.5	0.038
	Non Pregnancy	139	32.00	5.2	
Total protein	Pregnancy	50	6.046600	1.1	0.002
	Non Pregnancy	139	6.449784	0.69	
D-dimer	Pregnancy	50	1.770600	1.1	0.722
	Non Pregnancy	139	1.994317	4.4	

ESR- Erythrocyte sedimentation rate

PT- Prothrombin time

APTT- Activated partial thromboplastin time

Table 4: Biochemical and other laboratory parameters in both pregnant and non-pregnant COVID-19 positive patients

Parameters	Group	Sample	Mean	Standard Deviation	P value (Independent t test)
Total bilirubin	Pregnancy	50	0.88	1.68	0.365
	Non Pregnancy	139	0.71	0.98	
Direct bilirubin	Pregnancy	50	0.17	0.076	0.177

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	Non Pregnancy	139	0.35	0.93	
Alkaline phosphatase	Pregnancy	50	135.6	44.17	0.0001
	Non Pregnancy	139	68.88	30.51	
SGOT	Pregnancy	50	27.6	12.16	0.952
	Non Pregnancy	139	27.7	16.76	
SGPT	Pregnancy	50	16.5	10.92	0.001
	Non Pregnancy	139	34.4	36.67	
Lactate dehydrogenase	Pregnancy	50	215.5	94.72	0.030
	Non Pregnancy	139	252.41	105.12	
Urea	Pregnancy	50	14.38	5.96	0.0001
	Non Pregnancy	139	23.52	10.99	
Creatinine	Pregnancy	50	0.99	1.48	0.925
	Non Pregnancy	139	1.04	3.17	
Uric acid	Pregnancy	50	4.85	1.39	0.016
	Non Pregnancy	139	4.2	1.63	
Ferritin	Pregnancy	50	81.5	63.25	0.030
	Non Pregnancy	139	180.37	316.51	
Interleukin-6	Pregnancy	50	14.2	57.84	0.514
	Non Pregnancy	139	10.7	13.56	

SGOT-Serum glutamic-oxaloacetic transaminase/aspartate aminotransferase
SGPT- Serum glutamic pyruvic transaminase/alanine aminotransferase

DISCUSSION

COVID-19 is caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2).Itwas preliminarily reported from Wuhan, China, in December 2019. Since then, it has spread globally, causing a massive pandemic outbreak, and it still exists, leading to remarkable morbidity and mortality. Although many studies on COVID-19 have been increasing daily to update our awareness, very few statistics are available on COVID-19 among pregnant women.

Ferrazzi et al. conducted a study on 42 COVID-19 positive pregnant patients, 43% of whom had caesareans, and the remaining 57% had vaginal deliveries.[9] In our study, 92% of patients were delivered by caesarean section, and only 8% had a vaginal delivery. The Royal College of Obstetricians and Gynaecologists had not mentioned COVID-19 as a contraindication to vaginal delivery.[9,10,11] Even now, there is no evidence to suggest a mode of delivery to reduce the risk of infection in newborns.

In our study, the duration of hospital stay in pregnant patients was 7.08±1.8 days and in non-pregnant patients, it was 8.08± 3.5 days. The total WBC count and mean neutrophil count in pregnant females were significantly higher than in non-pregnant females. Lymphopenia and thrombocytopenia were substantially more common in pregnant females than in non-pregnant females. Like our study, Chen et al. also observed lymphopenia in 44% of pregnant females.[12]

Muhammed Kermali et al. wrote a review article on the role of biomarkers in the assessment of clinical progression and outcome in COVID-19 patients. They showed a significant association between lymphopenia and disease severity, which is identical to our study. They concluded that this could be an adjunct in clinical trials and help guide treatment.[13]

Danying Liao et al. conducted a study on haematological parameters and risk factors in the classification and prognostic evaluation of COVID-19 patients.[14] A retrospective observational study on 380 patients was done. Thrombocytopenia was found in patients with a critical form of the disease, similar to our research. Moreover, in our study, the platelet count was lower in pregnant females compared to non-pregnant females. In contrast to our study, prothrombin time and D-dimer were significantly elevated with disease severity in their study.

Maurizio et al. conducted a retrospective study on early predictors of clinical deterioration in a cohort of hospitalizedCOVID-19 patients. About 66.5% of patients had at least one coexisting medical condition. Lymphopenia was present in 50.6% of the patients, thrombocytopenia in 26.5%, and leukocytosis in 20.1%. Our study also showed similar findings with lymphopenia, thrombocytopenia, and leukocytosis. Furthermore, these findings were more prominent in pregnant females when compared with non-pregnant females. Most patients had high levels of lactate dehydrogenase (74.7%), which is in contrast to our study. Their study revealed elevated levels of creatinine, aspartate aminotransferase, and alanine aminotransferase in 31.8%, 28.5%, and 9.4% of the patients, respectively. Compared to their study, our findings showed mild elevations in all three variables in a smaller proportion of patients.[15]

In a study by B. Zhou et al., laboratory parameters like ferritin, lactate dehydrogenase, and C-reactive protein were highly elevated in very severe cases.The persistent elevation indicated a severe bacterial infection coexisting, leading to an exaggeration of severity. They opined that disease severity was often associated with secondary infections, leading to a critical scenario. Our study shows significantly lower serum ferritin levels in pregnant patients than in non-pregnant patients.[16]

Previous research indicates that pregnant women infected with COVID-19 are more likely to present with mild respiratory symptoms, but the risk of severe pneumonia is high.[17,18] Liu et al. and Fan et

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al. independently reported that most pregnant women acquired the infection in the third trimester of pregnancy.[19,20] Our study findings also corroborated their results. The emergence of a disease with respiratory complications in the third trimester of pregnancy is usually associated with a higher risk of caesarean section, preterm births, low Apgar indexes, and low birth weight.[21] In addition, COVID-19 positive patients have a higher rate of caesarean section, according to our findings.

Based on the currently available information, The US Centers for Disease Control and Prevention (CDC) have stated that pregnant women seem to have the same risk as adults who are not pregnant,[22] which is similar to our study.

CONCLUSION

COVID-19 continues to be of public health interest despite declining rates. From this study, we confirmed that pregnant women showed high neutrophil count, lymphopenia, thrombocytopenia, and deranged liver function tests. This enables us to define a cut-off value to determine the disease severity. However, the major limitation that we face is the number of cases as the trend of the infection varies over time. Also, studies done with reference to the laboratory parameters in COVID-19 affected mothers are restricted. Hence we recommend more studies to absolutely define a cut-off in COVID 19 affected pregnancy.

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