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Original Research Article

Correlation of SARS-Cov2 viral load with severity of COVID-19 disease in pregnant women at term: an observational study

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ABSTRACT

Background: COVID-19 disease raised global health concerns especially for the pregnant women who are more susceptible to respiratory viral illnesses due to their bodily immunological and physiological changes to accommodate the foetus. The aim of the study is to evaluate the relationship between the SARS-CoV 2 specific RdRp gene Ct values and the severity of the COVID-19 disease in SARS-CoV2 positive pregnant women at term.
Methods: A retrospective cohort study was conducted in the Department of Microbiology, Government Medical College, Amritsar on a subset of 46 COVID-19 positive, ante natal mothers, who presented in the labour room for delivery from August 2020 to January 2022.
Results: A cohort of 4.8% (46/949) women tested positive in the RT-PCR test for viral RNA. Average age of the group was 25.5years and 89.1% were asymptomatic. 10.9% women reported mild symptoms and 95% had no pre-existing co morbidities. Obstetric complications like premature rupture of membranes were 4.3%, pre-term births 17.33%. Miscarriage and IUD was recorded in 4.34% and 2.17% patients respectively. When compared to values seen in symptomatic women with fever (Ct 25.8), dyspnoea (Ct 28.7), and respiratory distress (Ct 29.1), the mean Ct value reported in asymptomatic women (27.49 SD±5.4) was identical. SARS-CoV2 was not present in any newborns. Despite 24% having low birth weights for their gestational ages, 93% of babies were asymptomatic.
Conclusions: The severity of the COVID-19 illness did not correspond with the SARS CoV2 virus RdRp gene Ct levels. The presence of SARS-CoV2 did not appear to independently cause poor maternal and new-born outcomes.

Keywords: COVID-19 disease, Ct value, Viral load, Perinatal women

INTRODUCTION

Pregnant women are a major vulnerable population group due to an altered maternal immunological and physiological state. Early in the COVID-19 pandemic Brazil reported 124 maternal deaths between 20th February 2020 and 18th June 2020.[1] Limited data on COVID-19 positive pregnant women was available and previous experience with SARS, MERS and respiratory infections too, suggested an adverse clinical course for expecting mothers.

A retrospective study was conducted in the Department of Microbiology, Government Medical College, Amritsar, to study the relation of severity of COVID-19 disease with Ct values of RdRp, a SARS-CoV2 specific gene. The lower Ct value indicated that the PCR equipment required fewer cycles to detect SARS CoV 2 specific genes as the viral load in that subject was hugh.

Objectives

Objectives were to study adverse events in SARS-CoV2 positive pregnant women near term in relation to the Ct values of RdRp genes and to compare perinatal outcome in COVID-19 positive and negative pregnant females.

METHODS

A retrospective cohort study was conducted by Department of Microbiology, Government Medical College, Amritsar on a subset of 46 COVID-19 positive antenatal mothers who presented at term for delivery to the labour room of the attached Tertiary care hospital, Bebe Nanki Mother and Child care centre, between August 2020 to January 2022, regardless of any COVID-19 disease related signs and symptoms.

Inclusion criteria

All consecutive, laboratory confirmed COVID-19 RNA positive, pregnant women, with or without signs and symptons, presenting to the labour room for delivery. For comparison of morbidity, contemporary SARS-CoV2 negative pregnant women in the labour room were considered controls.

Exclusion criteria

Non-pregnant and pregnant women admitted in the Department of Obstetrics and Gynaecology for any other complaint or medical intervention.

Study procedure

Since the beginning of the pandemic, all incoming patients to the labour room were triaged in a ward where after thorough clinical assessment, suspected patients were tested for SARS-CoV2 virus, using molecular techniques. A dedicated laboratory was created for these patients with a True lab Quattro Real time Quantitative micro-PCR analyser and qualified technicians to expedite isolation of suspected SARS-CoV2 positive women from the triage area. Truenat is a point of care RT-PCR platform that decentralizes the gold standard RT-PCR test. It has a turnaround time of 60 minutes and does not require batch testing. The Government of India implemented it nationwide in district hospitals and medical college hospitals to facilitate early testing, early treatment, and management while also preventing community spread and spread in healthcare facilities.

Nasopharyngeal and oropharyngeal swabs of the women were collected aseptically and transported in cold chain to the laboratory in viral transport media provided by the manufacturer. All samples were initially screened semi quantitatively for SARS-CoV2 RNA, using Beta CoV assay for E gene of Beta Corona Virus, one of the four genera of Corona viruses. This was followed by confirmation by the specific RdRp gene detection, with SARS-CoV2 PCR chip in E gene positive samples. The cut off Cycle threshold value was <35 as stipulated by the manufacturer. SARS-CoV2 positive cases were defined as, women who had a nasopharyngeal/ oropharyngeal swab for SARS-CoV2 RNA by an RT-PCR result positive at our centre on admission or 3 days postnatal. Patients were selected according to the pre-determined criteria and Birth/Medical records of the hospital were accessed for clinical data including demographics, medical history, obstetric history, maternal and neonatal outcomes and complications.

Statistical analysis

Data was entered into Microsoft excel and statistical analysis was performed by statistical software SPSS version 21.0. The quantitative variables (numerical) were present in the form of mean and SD and the qualitative variables (categorical) were present in the form of frequency and percentage. The student t-test was used for comparing mean values of two groups and chi square test to compare the frequency. The p value was considered significant when less than 0.05.

RESULTS

In our study, 4.84% (46/949) pregnant women in labour were found positive for presence of SARS CoV2 RNA. The median age in years of these patients was 25.5 with an interquartile range of 19.5-29.5 (Table 1).

Table 1: Age wise distribution.

Age group (years)	N	%
<20	24	2.52
21-30	759	79.97
31-40	135	14.2
>40	31	3.2
Total	949	100

September and October 2020 saw the highest number of SARS-CoV2 positive patients in our study, 15.6% (24/147) and 5.4% (12/202) respectively (Table 2). Majority 89.1% (41/46) of the SARS-CoV2 positive women were asymptomatic. Fever >38*C was present in 4.3% women (2/46), cough and dyspnoea in 6.5% (3/46) out of which only 2.1% (1/46) showed radiographic evidence of pneumonia, elevated CRP was a feature in 10.8% (5/46). Obesity, hypertension and diabetes as maternal co morbidities was seen in 2%, 6.5% and 6.5% women, respectively. Premature rupture of membranes was observed in only 4.3% (2/46) cases. Normal vaginal delivery was recorded for 36.95% (17/46) patients while 56.52% (26/46) underwent LSCS. Preterm births were recorded in 17.39% (8/46) cases as opposed to the control group which had 44%. Miscarriage and IUD were seen in 4.34% (2/46) and 2.17% (1/46) patient respectively. All neonates (n=43) tested negative for SARS-CoV2 and 93% (40/43) were asymptomatic. Fever was detected in 6.9% (N=3) and 24% (11/43) were low birth weight for their

gestational age. (Table 3). Mean Ct value of asymptomatic women recorded was 27.49 SD±5.4 which was not much different from patients with fever (Ct value 25.8) and dyspnoea (Ct value 28.7). The Ct value for the only patient to exhibit radiographic evidence of pneumonia and seek assisted ventilation in our study was 29.1 (Table 4).

Table 2: Monthly distribution of tests

Test done	Beta-CoV screening test			Sars-CoV confirmatory test		
Month, Year	**Total tests done**	**Positive**	**Negative**	**Total tests done**	**Positive**	**Negative**
August, 2020	54	7	47	7	6	1
September, 2020	147	26	121	26	22	4
October, 2020	152	14	138	14	8	6
November, 2020	87	1	86	1	1	0
December, 2020	145	1	144	1	1	0
January, 2021	52	0	52	0	0	0
February, 2021	81	2	79	2	1	1
March, 2021	54	1	53	1	1	0
April, 2021	32	3	29	3	2	1
May, 2021	22	1	21	1	1	0
June, 2021	18	1	17	1	1	0
July 2021 to Dec. 2021	103	0	103	0	0	0
Jan 2022	2	2	0	2	2	0
Total	949	59	890	59	46	13

Table 3: Cohort clinical profile.

Clinical finding of mothers	COVID Positive % (frequency) (N=46)	COVID Negative % (frequency) (N=903)
Fever	4.3 (2)	4.0 (36)
Myalgia	4.3 (2)	2.0 (18)
Respiratory symptoms- cough, sore throat, dyspnea	6.5 (3)	2.0 (18)
Pneumonia	2.0 (1)	0
GI symptoms	2.0 (1)	0
Elevated CRP	10.8 (5)	8.0 (72)
Lymphopenia	2.0 (1)	2.0 (18)
Fetal distress	2.0 (1)	24.0 (216)
Premature rupture of membranes	4.3 (2)	8.0 (72)
Prolonged hospitalisation	4.3 (2)	4.0 (36)
Comorbidity		
Obesity	2.0 (1)	4.0 (36)
Hypertension	6.5 (3)	28.0 (253)
Diabetes	6.5 (3)	10.0 (90)
Maternal outcome		
Miscarriage	2 (1)	4 (36)
Preterm	17.39 (8)	44 (397)
Still birth	2.0 (1)	6 (54)
NVD/LSCS	38/62 (16/26)	46/54 (397/506)
Neonatal outcome		
Asymptomatic	93 (40)	92 (831)
Fever	6.9 (3)	8 (72)
Low birth weight	24.0 (11)	50 (452)
COVID 19 Status	0	0

Mean Ct value of asymptomatic women recorded was 27.49 SD±5.4 which was not much different from patients with fever (Ct value 25.8) and dyspnoea (Ct value 28.7). The Ct value for the only patient to exhibit radiographic evidence of pneumonia and seek assisted ventilation in our study was 29.1 (Table 4).

Table 4: Mean CT values observed (n=47).

Parameters	Mean Ct values	N (%)
Asymptomatic	27.49 (±5.37)	41 (87.2)
Fever	25.8	2 (4.2)
Respiratory distress	28.9	3 (6.3)
Diarrhoea	28.7	1 (2.12)

DISCUSSION

Following the recommendations of ICMR to test pregnant patients likely to deliver in next five days, a cohort of 46/949 (4.8%) SARS-CoV2 positive women were detected at our tertiary care hospital. The youthful profile of our patient group (average age of patient 25.5, Interquartile range of 19.5 to 29.5), is similar to the Indian studies by Bachani et al i.e., 26.7 yrs.[2] In contrast the average age reported in England by Wilkinson was 30 yrs. (interquartile range of 26-34) and by Canadian pregnancy registry of 37.5% women between 30-34 years of age.[3,4] The number of samples tested, peaked in September and October of 2020, to fall once in January 2021. Countrywide India witnessed, the peak of the first wave in September 2020 and second wave peaked in April 2021.[5]

Most women, 89.1% (41/46) were asymptomatic. Mild fever and cough were the important presenting symptoms in the few patients reporting sick. Only 1/46 (2%) patient had radiographic evidence of pneumonia which required aggressive treatment and assisted ventilation. Obesity, hypertension, and diabetes was present in a fraction of the young positive patients, 2%, 6.5% and 6.5% respectively.[2,6,7] The two comparison groups did not differ in maternal and neonatal outcomes and SARS-CoV 2 status was the only difference between them.[2,9] Edlow et al reported 16% SARS-CoV-2 infected pregnant women with severe COVID-19 disease, and 3% with critical disease.[10] However an overview from Ciapponi A., et. al. presented an entire spectrum of presentations with fever in 28-100% pregnant women, mild respiratory symptoms in 20-79%, raised C reactive protein level in 20-96% and pneumonia in diagnostic imaging in 20-96%.[8] Preterm delivery (PTB) in our study group was much less in SARS CoV2 positive group than controls (17% vs. 44%) while Ciapponi in his review stated incidence of preterm delivery to be 14-64%. Decreased incidence of PTB was reported worldwide due to confounders like work from home, better family support, nutrition etc. but that is a subject for another study.[11,12] All neonates tested negative for SARS-CoV2. This presentation was consistent with similar studies from India and abroad.[3,6,7,9]

There was no statistically significant association between Ct values, clinical symptoms in mothers and newborns, and obstetric problems (p value > 0.05). The Ct values of several asymptomatic women (Mean Ct value 29.4 SD±5.4) and the 5/46 (10.8%) patients exhibiting fever, cough, and diarrhoea were the same (25.8 to 28.7). The Ct value was 28.9 for the patient who needed assisted ventilation due to respiratory distress. Similar findings have been reported by Bachani et al.[2,9]

Limitations

A small sample size, homogenous group of young, generally healthy pregnant women who are primarily from lower socioeconomic groups make up the research population. To ascertain the effects of COVID-19 infection in pregnancy, various age groups and co-morbid women from various socioeconomic tiers and geographic areas must be researched. Infants born during the pandemic must also undergo long-term monitoring to detect any growth, developmental, and neurological deficits.

CONCLUSION

With higher rates of anaemia and malnutrition and lower rates of obesity, diabetes, and hypertension, lower middle-class households accounted for most young pregnant women giving birth at our government hospital. Even though the SARS-CoV2 pandemic and the COVID-19 disease spread widely, up to 89% of pregnant women who tested positive for the virus showed no symptoms in our study group of women who were near term. In the two comparison groups, any adverse outcome for mothers and newborns did not correspond with COVID positivity, viral load, or Ct levels. Hence, the presence of SARS-CoV2 did not appear to independently cause poor maternal and new-born outcomes. No foetus had a positive SARS-CoV2 test at birth. In our investigation, vertical transmission was not a characteristic of the virus.

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