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Research Article

CORRELATION BETWEEN CYCLE THRESHOLD VALUE AND CT SEVERITY SCORE DURING COVID 19 PANDEMIC

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Abstract

Introduction: The novel SARS CoV-2 was declared as a public health emergency in January 2020. Patients infected with this virus show different severity of disease symptoms ranging from mild disease to that requiring intensive care and death. Therefore, it is important to have a test with the ability to predict the prognosis of patients at diagnosis and can aid in management decisions.

Materials and methods: This study is a hospital based prospective observational study. The study includes the patients who are tested RTPCR positive within 72 hours of onset of symptoms. Patient who underwent Chest CT between 5th-7th day after the onset of symptoms were included in the study. Patients with RTPCR negative, RTPCR positive without Chest CT, asymptomatic RTPCR positive patients were excluded from the study. Viral RNA will be extracted by using extraction kits, and RT-PCR performed in VRDL laboratory, SIMS, Shimoga. Using primers and probes targeting the RNA-dependent RNA polymerase (RdRp) gene fragment will be detected in the sample. A positive and a negative control were included in each run to generate a valid result. A Ct valueof 15-35 was defined as a positive result. Computed tomography images of the chest will be obtained using 64 Slice Phillips CT machine. CT severity score will be calculated by looking for the presence of inflammatory abnormalities (like ground-glassopacities, mixed ground-glass opacities, or consolidation) in each lobe.

Each lobe will then be awarded 0 to 4 points, depending on the percentage of involvement in each lobe: 0 (0%), 1 (1-25%), 2 (26-50%), 3 (51-75%), or 4 (76-100%). Total severity score will then be calculated with cut off being 7 for mild disease.

Results: The mean age in the mild COVID-19 group was 49.52 years and in the moderate COVID-19 group was 51.84 years. The gender distribution showed that 68% (68/100) of the subjects were males while 32% (32/100) of them were females. On comparison of the haematological parameters, there was a statistically significant difference in the mean platelet count between the mild and moderate COVID-19 group (3.04 L versus 2.19 L, respectively, p-value=0.01). Among the biochemical parameters, a statistically significant difference between the mild and moderate COVID-19 groups were found in the following parameters- mean AST, mean ALT, mean D-dimer and mean serum ferritin.

Conclusion: Viral load can be used as an early prognostic marker to assess severity. The utility of CT severity score, RT-PCR Ct value and other various clinical, radiological and immunological indices for supplementing the clinical diagnosis of COVID-19 cannot be overemphasized especially in a pandemic situation. CT chest severity score correlates with cycle threshold values in assessing severity of disease. However since the sample size is small further studies are required to prove the same.

Key Words: novel SARS CoV-2, CT severity score, RT-PCR Ct value, RNA-dependent RNA polymerase

INTRODUCTION

The novel SARS CoV-2 was declared as a public health emergency in January 2020. Patients infected with this virus show different severity of disease symptoms ranging from mild disease to that requiring intensive care and death. Therefore, it is important to have a test with the ability to predict the prognosis of patients at diagnosis and can aid in management decisions.[1]

The standard method for diagnosis of corona virus disease is done using real-time reverse transcription polymerase chain reaction (RT-PCR). Real-time RT-PCR cycle threshold (Ct) value is defined as the number of amplication cycles required for the target gene in the sample to exceed a threshold level. Therefore, Ct values are inversely related to viral load. They are an indirect estimate of the copy number of viral RNA in the sample.[2]

Computed tomography (CT) chest is an important and fast imaging tool for diagnosis of COVID pneumonia. Typical findings include multifocal peripheral ground glass opacities, patchy consolidation and interstitial changes. The severity of disease can also be assessed on chest CT by observing the percentage of lung involvement and hence is a useful prognostic marker.[3]

There are a limited number of studies that compare viral load with chest CT severity.

Hence, on comparing these parameters in the present study, we would like to see if viral load can be used as an early prognostic marker for disease severity. Many studies have evaluated the relationships

Many studies have evaluated the relationships among SARS-CoV-2 viral load and clinical severity and it points towards a positive correlation, mortality and disease progression.[4] Since the declaration of COVID-19 as a pandemic by the World Health Organisation (WHO) on March 11, 2020, India had witnessed three waves, with concerns about varying severity and mortality. So far the literature is sparse regarding the correlation of viral load and clinical severity in the region.[5] In this context, the study is primarily aimed to find the correlation between Ct value and clinical severity and also to compare the baseline characteristics between the first two waves of the pandemic

AIM AND OBJECTIVES

1. To correlate the severity of COVID 19 on computed tomography of the chest with cycle threshold values of SARS CoV-2 on RT-PCR
2. To establish if viral load can be used as an early prognostic marker to assess disaese severity.

MATERIALS AND METHODS

Source of data:
Patients presenting to in-patient and outpatient facilities at Mc Gann hospital, Shimoga with symptoms of acute respiratory illness.

Method of collection of data:

Study period: April 2021 to August 2021

Study design: This study is a hospital based prospective observational study

Sample size: Sample size is based on a previous study by Yagci et al, and 100 samples will be studied in the present study.

Inclusion criteria:

1.The study includes the patients who are tested RTPCR positive within 72 hours of onset of symptoms.
2. Patient who underwent Chest CT between 5^{th}-7^{th} day after the onset of symptoms.

Exclusion criteria:

Patients with RTPCR negative, RTPCR positive without Chest CT, asymptomatic RTPCR positive patients.

Methodology:

All patients with history of acute respiratory illness (fever and atleast one sign/ symptom of respiratory disease like cough, shortness of breath) reporting to inpatient/ outpatient department of McGann hospital will be tested for SARS CoV-2 infection.

Viral RNA will be extracted by using extraction kits, and RT-PCR performed in VRDL laboratory, SIMS, Shimoga. Using primers and probes targeting the RNA-

dependent RNA polymerase (RdRp) gene fragment will be detected in the sample. A positive and a negative control were included in each run to generate a valid result. A Ct valueof 15-35 was defined as a positive result.

Computed tomography images of the chest will be obtained using 64 Slice Phillips CT machine. CT severity score will be calculated by looking for the presence of inflammatory abnormalities (like ground-glassopacities, mixed ground-glass opacities, or consolidation) in each lobe. Each lobe will then be awarded 0 to 4 points, depending on the percentage of involvement in each lobe: 0 (0%), 1 (1-25%), 2 (26-50%), 3 (51-75%), or 4 (76-100%). Total severity score will then be calculated with cut off being 7 for mild disease.

Statistical analysis:

Data obtained from the study will be analysed and qualitative variables will be presented in the form of frequency and percentages. Categorical variables will be compared using the Chi-squared and Fisher's exact tests.

RESULTS

The mean age in the mild COVID-19 group was 49.52 years and in the moderate COVID-19 group was 51.84 years. The gender distribution showed that 68% (68/100) of the subjects were males while 32% (32/100) of them were females.

Age group (years)	Mild COVID-19 (n, %)	Moderate COVID-19 (n, %)	Total (n, %)
21-30	6 (24%)	3 (12%)	18 (18%)
31-40	2 (4%)	2 (8%)	6 (6%)
41-50	8 (16%)	8 (32%)	24 (24%)
51-60	14 (28%)	4 (16%)	22 (22%)
61-70	12 (24%)	5 (20%)	22 (22%)
>70	2 (4%)	3 (12%)	8 (8%)
Mean±SD	49.52±17.45	51.84±15.19	

Table 1: Age distribution of patients (N=100)

On comparison of the haematological parameters, there was a statistically significant difference in the mean platelet count between the mild and moderate COVID-19 group (3.04 L versus 2.19 L, respectively, p-value=0.01). Among the biochemical parameters, a statistically significant difference between the mild and moderate COVID-19 groups were found in the following parameters- mean AST, mean ALT, mean D-dimer and mean serum ferritin.

Parameter	Mild COVID-19 (n, %)	Moderate COVID-19 (n, %)	Total (n, %)
Serum creatinine (NRR:	0.9	0.9	0.79

0.6-1.2 mg/dL)			
AST (NRR: 5-40 U/L)	38.72	58.76	<0.01
ALT (NRR: 5-40U/L)	44.29	72.44	<0.01
ALP (NRR: 50-150 U/L)	92.28	120.16	0.05
CPK (NRR: 55-170U/L)	65	70	0.57
D-dimer (NRR: 0-500 ng/mL)	500	1200	0.03
Serum ferritin (NRR: 17-465 mg/dL)	467	900	0.01

Table 2: Mean biochemical parameters in study subjects.

Parameters	COVID-19 severity		P value
	Mild COVID-19 (n=25)	Moderate COVID-19 (n=25)	
Ct value Rdrp gene			
Mean±SD	24.56±6.85	23.72±5.82	0.54
Range	12-33	12-35	
CT severity score			
Mean±SD	3.92±5.29	9.88±7.21	
Range	0-16	0-20	

Table 3: Mean RT-PCR Ct value and CT severity score in study subjects.

Clinical outcome	Mild COVID-19 (n, %)	Moderate COVID-19 (n, %)	Total (n, %)	p-value (Chi-square test)
Discharged	46 (92%)	30 (60%)	**76 (76%)**	0.01
Sepsis (TLC >11000/mm3)	0	12 (24%)	12 (24%)	0.02
Respiratory failure (PaO_2 <60 mmHg on ABG) and ICU transfer	4(8%)	8 (16%)	12 (12%)	0.66

Table 4: Clinical outcome variables in study subjects.

Duration between admission and outcome (days)	COVID-19 severity		p-value
	Mild COVID-19 (n=25)	Moderate COVID-19 (n=25)	
Mean±SD	9.04±4.08	7.44±2.88	0.10
Range	2-20	3-15	

Table 5: Mean duration between admission and outcome in study subjects.

CT-Value		CT severity Score
E gene	r-value	-0.05
	p-Value	0.73
RdRp gene	r-value	-0.06
	p-value	0.68

Table 6: Correlation between RT-PCR Ct value and CT severity score

DISCUSSION

The study aimed to assess the correlation between NEWS which is a marker of clinical severity, RT-PCR Ct value which is a marker of viral load and CT-SS which is a marker of radiological severity of COVID-19. This study is probably the first study till date to incorporate all the three parameters together in the assessment of COVID-19 severity.[6]

The radiological severity as determined by CT severity score corroborated with the clinical severity as determined by NEWS. The mean CT-SS in the moderate COVID-19 group was significantly greater than that of the mild COVID-19 group (p-value <0.01). Similar findings were reported in other studies; in a study by Abbasi B et al., a positive correlation between CT severity score and mortality and clinical severity (as determined by time to ICU admission, time to intubation and time to death) was found.[7]

The correlation between RT-PCR Ct value of E gene and CT severity score (r-value=-0.05, p-value=0.73) and that of Ct value of Rdrp gene and CT severity score (r-value=-0.06, p-value=0.68) was also negative but insignificant. A similar study conducted by Bakir A et al., analysed the relationship between the chest CT score and Ct value as a proxy for viral load; the results showed a positive correlation between the Ct value and chest CT score (r-value=0.197, p-value=0.01).[8]

Since chest CT score and CT-SS are similar measures used for quantification of lung involvement in COVID-19, the results of our study can be said to concur with this study. Another study by Liu Z et al., examined the correlation between Lung Severity Score (LSS) which is similar to CT-SS and RT-PCR Ct value and found that LSS was inversely related to Ct value (r-value=-0.588, p-value=0.003).[9]

However, this study categorised patients into severe and non-severe COVID-19 and this negative correlation between LSS and Ct value was found only in severe COVID-19. Hence, there is paucity of data in the literature describing the relationship between the RT-PCR Ct value and CT Severity Score. Hence, the present study is one of the first studies which describes the correlation between these parameters in a specific subset of COVID-19 patients.[10]

CONCLUSION

Viral load can be used as an early prognostic marker to assess severity. The utility of CT severity score, RT-PCR Ct value and other various clinical, radiological and immunological indices for supplementing the clinical diagnosis of COVID-19 cannot be overemphasized especially in a pandemic situation. CT chest severity score correlates

with cycle threshold values in assessing severity of disease. However since the sample size is small further studies are required to prove the same.

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