



ORIGINAL RESEARCH PAPER

Medical Science

EVALUATION OF CLINICOPATHOLOGICAL FEATURES AND RT-PCR Ct VALUE OF COVID-19 PATIENTS

KEY WORDS: Severe acute respiratory syndrome coronavirus 2, Real time polymerase chain reaction, Cycle threshold, Middle east respiratory syndrome coronavirus.

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ABSTRACT

Purpose: - To evaluate clinicopathological features of COVID-19 patients and their RT-PCR Ct value. **Methods:** - Coronavirus disease 2019 (COVID-19) is an acute respiratory illness caused by infection with severe acute respiratory syndrome coronavirus 2 (SARSCoV-2). It has a high rate of hospitalization, critical care requirement, and mortality. Total 694 patients were selected for the study who were positive for RT-PCR Ct value. In this retrospective study, we collected the data and the sample of nasopharyngeal or oropharyngeal swabs received with filled ICMR referral form which was registered and detailed of the form was recorded in excel sheet. Swab sample was collected using plastic swab with polypropylene fiber head. Sample preserved at virus transport media (VTM) after collection. We separated sample into allocates for RNA extraction. **Result:** - A total of 694 confirmed COVID-19 patients, 59.7% male and 40.3% female with a mean ± SD age of 48 ± 17.6 (range 1 to 97) years were included in the study. Out of the 694 confirmed COVID-19 patients' majority of 284 (40.9%) patients were in 41-60 years of age group, 214 (30.8%) patients were between 18-40 years of age group, 165 (23.8) patients were >60 years of age group and 31 (4.5%) patients <18 years of age group. Our data revealed that 43.23% of the study's patients had one or more underlying comorbid conditions such as hypertension in 18.9% of patients followed by diabetic in 17.4%, COPD in 2.4% of patients, Asthma in 2.2% of patients and tuberculosis in 2.2% of patients. On the basis of RT-PCR Ct value out of 694 patients were positive in which 345 (49.71%) patients had Ct value <25, 211 (30.40%) patients had Ct value between 25-30 and 138 (19.88%) patients had Ct value >30. **Conclusion:** - Majority of 284 (40.9%) patients were in 41-60 years of age group followed by 214 (30.8%) patients came under 18-40 years of age group, 165 (23.8%) patients were >60 years and 31 (4.5%) patients were <18 years. Out of 694 patients 414 (59.7%) were males and 280 (40.3%) were females. Out of 694 patients' fever was seen in most cases followed by cough/cold, breathlessness, weakness and loss of smell and taste. Most common associated comorbidity is hypertension followed by diabetic, COPD, asthma and tuberculosis. Majority of the patients were alive (65.6%) whereas (34.4%) were dead

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is an acute respiratory illness caused by infection with severe acute respiratory syndrome coronavirus 2 (SARSCoV-2). It has a high rate of hospitalization, critical care requirement, and mortality. The outbreak of novel coronavirus disease in Wuhan, China started in November 2019. It was declared a public health emergency of international concern on 30 January 2020 by the World Health Organization (WHO).

In India, the first patient was detected in Kerala on 30 January 2020. COVID19 is the name given by WHO on 11 February 2020 for the disease caused by the corona virus SARS-CoV-2. It was finally declared a pandemic on March 11, 2020 and since then the disease has suddenly changed the global health scenario due to its spread to more than 200 countries^[1]. Real Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) is the gold standard test for detection of SARS-CoV-2. This test enables early detection of viral genome in clinical samples. A positive test enables the clinicians and public health professionals to quickly isolate the patient and prevent the spread of the disease.

The cycle threshold (Ct) value of a RT-PCR reaction is the number of cycles at which fluorescence of the PCR product is detectable over and above the background signal. The Ct-value is inversely proportional to the amount of genetic material (RNA) in the starting sample the lower Ct values generally correlate with high viral load^[2]. COVID-19 shows a wide spectrum of clinical presentations with significant number of asymptomatic carriers. The median incubation period of disease is 5.1 days, ranging from 2 to 14 days^[3]. The symptoms commonly vary from mild to moderate upper respiratory tract infection in the form of fever with associated fatigue, cough and sore throat, while about 15% of patients show non-respiratory symptoms like palpitation, headache,

abdominal pain and vomiting^[4]. Thus, we studied the correlation between clinicopathological features and RTPCR Ct value in COVID-19 suspects and patients.

MATERIAL AND METHOD

This present study was a retrospective hospital-based case study. Total 694 patients were selected for the study who were positive for RT-PCR Ct value

METHODOLOGY

In this retrospective study, we collected the data and the sample of nasopharyngeal or oropharyngeal swabs received with filled ICMR referral form which was registered and detailed of the form was recorded in excel sheet. Swab sample was collected using plastic swab with polypropylene fiber head. Sample preserved at virus transport media (VTM) after collection. We separated sample into allocates for RNA extraction. We classified the patients into the following

Mild- having mild clinical symptoms, no sign of pneumonia observed in imaging, Moderate- having fever and respiratory symptoms, with signs of pneumonia observed in imaging, Severe- having dyspnea, respiratory rate ≥ 30 breaths/min, oxygen saturation (SpO2) ≤ 93%.

All the data of patients who were enrolled in the study and registration of all the cases with the preliminary particulars of the patient such as name, age, sex, occupation, socio-economic status, education and address was done.

The following were the inclusion and exclusion criteria of the study:

Inclusion Criteria

1. Completely filled ICMR forms,
2. Adequate sample from nasopharyngeal/oropharyngeal swabs with, no error in processing from RT-PCR,

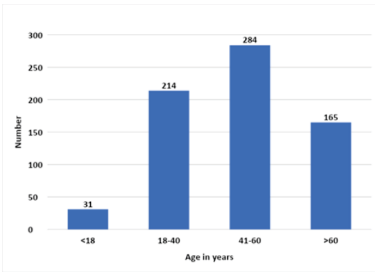
3. Patient having RT-PCR result positive,

Exclusion Criteria

1. Patient who recovered from shortness of breath, cough and fever within three days,
2. RT-PCR negative for COVID-19 suspects.

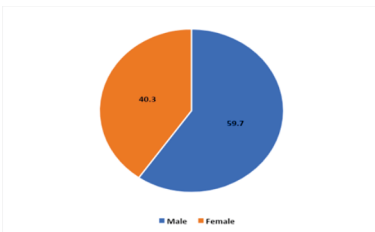
RESULTS

A total of 694 confirmed COVID-19 patients, 59.7% male and 40.3% female with a mean ± SD age of 48 ± 17.6 (range 1 to 97) years were included in the study. Out of the 694 confirmed COVID-19 patients' majority of 284 (40.9%) patients were in 41-60 years of age group, 214 (30.8%) patients were between 18-40 years of age group, 165 (23.8) patients were >60 years of age group and 31 (4.5%) patients <18 years of age group.



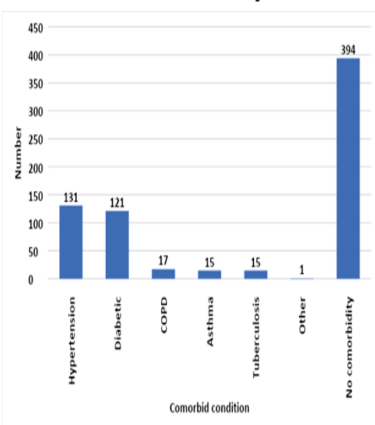
Graph No. 1 - Age Distribution Of The Subjects (n=694 patients)

Graph no. 1. shows out of the 694 confirmed COVID-19 patients' majority of 284 (40.9%) patients were in 41-60 years of age group, 214 (30.8%) patients were between 18-40 years of age group, 165 (23.8) patients were >60 years of age group and 31 (4.5%) patients <18 years of age group.



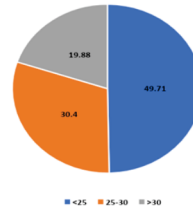
Graph No. 2- Gender Distribution Of The Subjects (n=694 patients)

Graph no. 2 shows that from 694 patients 414 (59.7%) were male and 280 (40.3%) were females. So, we have a slight preponderance of females in our study.



Graph No. 3 Showing Associated Comorbid Condition

Graph no. 3 shows that 43.23% of the study's patients had one or more underlying comorbid conditions such as hypertension in 18.9% of patients followed by diabetic in 17.4%, COPD in 2.4% of patients, Asthma in 2.2% of patients and tuberculosis in 2.2% of patients.



Graph no. 4 – RT-PCR Ct Value Category

Graph no. 4 Shows out of 694 patients were positive in which 345 (49.71%) patients had Ct value <25, 211 (30.40%) patients had Ct value between 25-30 and 138 (19.88%) patients had Ct value >30.

DISCUSSION

COVID-19 is a novel disease caused by a newly identified virus, SARS-CoV-2. We studied 694 RT-PCR positive patients with COVID-19 infection who were ranging from 1 to 97 years. The mean age of patient was 48 ± 17.65 years. The maximum number of the patients were between 41 to 60 years of age group followed by 18-40 years of age (p=0.053) similar to study performed by Singanayagam et al, where the age 41– 60 years was found to be most affected [6]. Yun Feng et al showed that the majority (51%) of COVID-19 patients were in the age group between 40-64 years [6].

Out of 694 positive patients 414 (59.7%) were males and 280 (40.3%) were females. Both males and females were equally affected as no significant difference among gender infectivity (p=0.523) was detected. Rihab et al study on 1153 cases found 64.4% males and 35.6% females [7] similarly Rodrigo da rosa et al [8], Goshayeshi et al [9], Allameh et al [10], and Trunfio et al [11] showed no significant gender difference of COVID-19 infectivity.

the distribution of patients based on Ct value of RT-PCR. Out of all patients, 49.71% (Ct value <25, Group A) patients were having high viral load while 19.88% patients were having low viral load (Ct value >30, Group C). Dres et al. showed that the Ct value of RT-PCR were used as the indicators of the RNA viral load in the samples, the lower the Ct value, the higher the viral load [12]. Patients with high infectivity and acute infection are usually presented by low Ct values (high viral load).

There was statistical significant association (p=0.00) between patients having high viral load on RT-PCR and who were presented with at least one of the comorbidities. In our study, 21% patients had hypertension, 18% patients had diabetes and 5% of the patients had tuberculosis and asthma. Hypertension was the most prevalent presentation and statistically significant correlation was found between high viral load (low Ct value) and the number of patients having hypertension along with diabetes (p=0.00). Jitender Sharma et al found that most of the patients with high viral load had history of hypertension [13].

CONCLUSION

Our study concludes that most common age group affected was 41-60 years. Majority of patients were males 414 (59.7%) whereas 280 (40.3%) were females. Out of 694 positive patients, most of the patients had Ct value <25 i.e., 345 (49.71%) followed by 211 (30.40%) patients had Ct value between 25-30, 138 (19.88%) patients had Ct value >30.

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