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Original Research Article

Viral clearance in COVID-19 patients admitted in designated COVID hospital in Western India

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ABSTRACT

Background: COVID-19 pandemic is one of the greatest challenges faced worldwide and has not only posed health crisis but also had social, economic and political devastating effects. The speedy transmission risk enforced bygone practices of quarantine of healthy persons and isolation of all positive patients. The basis of all key policy making is the understanding of virus clearance from the body so that transmission can be ceased. The aim of the study was to understand the viral clearance and its' co-relates for guiding infection control and transmission practices in COVID-19.
Methods: Cross sectional study in a tertiary care hospital. A cross-sectional study of total 398 patients admitted for COVID-19 between June 2020 and November 2020 at a tertiary care centre. Statistical analysis used: frequency, percentage, and chi square test Chi square test for linear trend and was used to find association.
Results: 88.19% were males and 11.81% were female patients, mean age of study participants was 34.84 years. 61.56% were symptomatic and among them 1.64% presented with severe symptoms. Mean duration to turn RT-PCR negative was 11.83 days. No significant difference in time taken to turn RT-PCR negative among asymptomatic and symptomatic cases is suggestive of no difference in viral load and its clearance in symptomatic vs asymptomatic cases.
Conclusions: The disease profile of COVID-19 in our setup was alike the national disease profile and the recovery rate being 98.76%. Presence of co-morbidities affects viral clearance in COVID-19.

Keywords: COVID-19 cases, Tertiary care centre, Virus clearance

INTRODUCTION

COVID-19 pandemic created an unprecedented crisis due to the explosive transmission and not only the healthcare services but other sectors across the world also faced a grim situation. The high transmission risk driven enforcement of quarantine, lockdowns, contact tracing, isolation and hospitalisation of all positive patients and their close contacts. The discharge from the hospital was governed by viral clearance confirmed by a negative RT-PCR result for SARS-CoV-2 as the positive patient posed a very high transmission risk.

At the initiation of pandemic WHO and Indian Council of Medical Research (ICMR) advocated discharge from isolation/ treatment centre after confirmation of viral clearance which required a patient to be clinically recovered and to have two negative RT-PCR results on sequential samples taken at least 24 hours apart. This recommendation was based on the existing knowledge and

experience with similar corona viruses, including those that cause SARS and MERS.[1]

With the evolution of pandemic and new emerging evidences, the guidelines further evolved and by last of May 2020, WHO formulated criteria for discontinuation of transmission precautions or discharge from healthcare or isolation facility without mandatory testing. Criteria for discharging patients from isolation or hospital without requiring re-testing laid down by WHO was as under.[2,3]

For symptomatic patients

10 days after symptom onset, plus at least 3 additional days without symptoms (including without fever and without respiratory symptoms).

For asymptomatic cases

10 days after positive test for SARS-CoV-2. As per WHO, the revised discharge criteria balances the risks and benefits of discharging patients without mandatory testing. However, this criteria of WHO's expert networks and the Strategic and Technical Advisory Group for Infectious Hazards (STAG-IH) were also based on limited laboratory supplies, requisite infrastructure, equipment and trained manpower in areas with intense transmission. This discharge criterion was fraught with some degree of transmission post recovery or discontinuation of transmission precautions. Hence, this research was undertaken to study the time taken for viral clearance and its' corelates to strengthen infection control and transmission practices in COVID-19.

METHODS

Hospital based study was undertaken among consecutive COVID-19 positive patients admitted in tertiary care hospital and affiliated COVID care centre in western India from the month of June to November 2020. All COVID-19 positive patients admitted (except the fatal cases) during the period between June 2020 to November 2020 were included the study. Data on demographic factors, symptoms, co-morbidities and severity of disease was collected from the medical records of COVID-19 positive patients.

Ethical clearance was undertaken from the ethics committee of the institute prior to initiation of the study. Informed consent of patients or guardians was obtained. Negative RT-PCR for SARS-CoV-2 test was made mandatory prior to discharge from hospital. Nasal, naso-pharyngeal or oro-pharyngeal swabs were used as per the ICMR guidelines for collecting samples for RT-PCR testing of patients. Swab specimens were collected in individual vials containing transport media by a trained healthcare worker and transported to the designated laboratory following all aseptic and cold chain protocols. The first mandatory testing with RT-PCR for SARS-CoV-2 was conducted after 10 days of testing positive with RT-PCR for SARS-CoV-2 in asymptomatic patients and 10 days from symptom onset coupled with 3 days without fever (without use of antipyretics) and respiratory symptoms in symptomatic patients. Any repeat testing if required (in patients testing positive after 10 days or later) was conducted every 72 hours from positive repeat sample. COVID-19 virus qualitative RT-PCR test was used for the study and all guidelines outlined by the manufacturer of kits were adhered while conducting the tests. Numerical cyclic threshold (Ct) values were not used for determining infectiousness or release from healthcare facility as laid down by Indian Council of Medical Research (ICMR).[4] SPPS version 21.0 was used for analysing the data collected in the study and results were obtained utilizing appropriate statistical techniques.

RESULTS

All consecutive COVID-19 positive patients admitted to the designated hospital and affiliated COVID Care Centre between June 2020 and November 2020 were included in the present research. Data for 398 patients was analyzed post exclusion of 5 deaths of COVID-19 positive patients occurring during the study period. The mean age of study participants was 34.84 years with range of 3 to 75 years. The male preponderance was noted among our study participants; males 88.19% viz-a-viz females 11.81%. The important demographic and disease parameters are described in Table 1.

Table 1: Demographic and disease parameters (N=398).

Variables	Values		
Age (years)	Mean, median, mode		SD, range
	34.84, 34.0, 27.0		11.56, 3-75
Sex	Male (%)		Female (%)
	351 (88.19)		47 (11.81%)
Type of COVID-19 disease	Asymptomatic (%)		Symptomatic (%)
	153 (38.44)		245 (61.56)
Severity of COVID-19 disease (N=245)	Mild (%)	Moderate (%)	Severe (%)
	228 (93.06)	13 (5.30)	04 (1.64%)
Days to turn RT-PCR negative for COVID-19	Mean, median, mode		SD, range
	11.83, 10.0, 10.0		3.59, 10-35

Table 2: Correlates of turning RT-PCR negative for COVID-19.

Parameters	Days to turn RT-PCR negative for COVID-19		Chi square, p value
	Upto 10 days	>10 days	
Age (years)			
Upto 50	261	91	0.012, 0.97
>50	34	12	
Sex			
Male	263	88	1.01, 0.314
Female	32	15	
Type of disease			
Asymptomatic	116	37	0.37, 0.54
Symptomatic	179	66	
Co-morbidity			
Present	02	05	7.70, 0.005
Absent	293	98	

74.19% patients turned RT-PCR negative for COVID-19 in 10 days and 93.96% turned negative in 17 days period. The mean time taken for viral clearance in our research was 11.83±3.59 days. 35 days was the longest period taken to turn RT-PCR negative for COVID-19 in this study. The present research found no significant difference in the number of days taken to turn RT-PCR negative for COVID-19 between asymptomatic and symptomatic patients; 24.15% asymptomatic patients and 26.93% symptomatic patients turned RT-PCR negative for COVID-19 in more than 10 days.

Co-morbidities play a major role in time taken in turning RT-PCR negative for COVID-19 and a statistically significant difference was observed in the present study among patients with and without co-morbidities. The possible correlates to turn RT-PCR negative for COVID-19 were studied and are illustrated in Table 2.

DISCUSSION

The time from infection to recovery in COVID-19 is measured as number of days from first positive to negative SARS-CoV-2 RT-PCR test result. This study revealed a mean time period of 11.89±3.59 days to turn COVID-19 negative which is similar to European study on mild to moderate cases of COVID-19.[5] The existing literature suggests increasing age has negative correlation with viral clearance and recovery.[6] Our study showed a similar association of age and viral clearance; age more than 50 years of age had an effect on the viral clearance (Table 2). Further, subset analysis of ages showed a negative correlation between age and recovery. Severe acute respiratory distress (ARDS) or fatal outcome following SARS-CoV-2 infection is less likely among women and the reasons for this difference are unclear.[7] However, it has been hypothesized that the higher plasma levels of androgen hormones in men compared with women, drive the transcription of the gene TMPRSS2 responsible for coding of the protease essential for SARS-CoV-2 cell entry following the binding of its spike protein to cell membrane ACE2.[8]

No such difference in severity of disease has been observed in the present research and the probable reason might be a smaller number of female participants (11.81%) in this study. The recovery from COVID-19 or viral clearance depends on disease severity and a research suggests an average 8 days longer viral clearance in severe cases, however no such difference was observed in our analysis of mild vs moderate to severe disease (mean number of days for viral clearance: mild disease- 11.78 days vs moderate to severe disease- 13.05 days, p value=0.21). The small data set and the exclusion of cases with fatal outcome is probably responsible for this variation from the existing studies. The presence of co-morbidities in COVID-19 positive patients has a bearing on the recovery and viral clearance and our study reported similar findings (Table 2).

The circulation of an aggressively spreading SARS-CoV-2 can be potentially stopped only on release of COVID-19 positive patient after reversion to RT-PCR negative for SARS-CoV-2 status from isolation and infection transmission precautions. The criteria formulated by WHO and ICMR for release from infection prevention protocols after stipulated number of days without negative RT-PCR test report can release potentially infective persons in the community and lead to localized or widespread outbreaks. The release from infection control precautions of asymptomatic patients on 10th day and symptomatic patients after 10 days after symptom onset, plus at least 3 additional days without symptoms potentially poses a risk of releasing patients with a potential to spread infection in the household and community and the potential transmission might translate into outbreaks. The pandemic is at waning phase in our country but the western world is still bearing the brunt of pandemic and at this juncture it is not advisable to allow release of COVID-19 positive patients without a negative test into the community especially in areas with high population density, with poor living conditions or conglomeration of persons like in schools, colleges, religious or cultural gatherings, military barracks etc.

CONCLUSION

Our dataset is very small to draw such conclusions on national and international levels; hence we recommend a multi-centric analysis of data sets available with the states and countries to formulate guidelines on testing prior to release of isolation and infection control precautions to maintain the decline of COVID-19 pandemic.

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