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Evaluation of SARS Cov-2 disease epidemiology, clinical and diagnostic profile-a regional study from tertiary care center of North India

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ABSTRACT

Background: A novel coronavirus severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) that emerged in China in December 2019 has spread rapidly globally to many countries including India and World Health Organization declared it as a pandemic on March 11th, 2020. **Aims and Objectives:** The current study endeavors to determine the SARS-CoV-2 positivity rate as well as epidemiological, clinical, and diagnostic profiles from the second wave. **Materials and Methods:** We performed a retrospective analysis of all suspected COVID-19 cases from January 2021 to October 2021 presenting at a large testing center for SARS-CoV-2 infection by real-time polymerase chain reaction (RT-PCR). Descriptive analysis has been performed for profiling of clinical-epidemiological aspects of suspected cases. **Results:** A total of 694427 participants were enrolled during the study from January 2021 to October 2021. Overall RT-PCR positivity rate was found to be 1.7% in the year 2021 and the positivity was maximum in April 2021 which represents the second wave of COVID-19 infection in India. In the study population, more than half (57.07%) of the persons screened for COVID-19 infection were between 21 and 40 years of age, and about two-thirds (65.20%) of the persons screened were male followed by 34.79% were female. **Conclusions:** SARS-CoV-2 poses a high burden of infections in the community. Males had a higher RT-PCR detection rate as compared to females. The younger age group (<20 years) expressed the least RT-PCR positivity rate and the elderly population (>80 years) expressed the highest positivity rate.

Key words: Cartridge-based nucleic acid amplification test; Indian Council of Medical Research; Influenza-like illness; Real-time polymerase chain reaction; Severe acute respiratory illnesses; Severe acute respiratory syndrome corona virus-2; World Health Organization

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INTRODUCTION

In December 2019, a novel beta coronavirus named severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) emerged in Wuhan, China, causing an outbreak in humans. A medical student from Thrissur, Kerala, who returned from Wuhan, China, on January 23rd, 2020,[1] was the first case that was reported in India as COVID-19 positive on June 30, 2020. COVID-19 cases from India in the beginning were associated with international travelers from COVID-19 affected countries then SARS-CoV-2 infection spread across all states including Uttar Pradesh. The first case of COVID-19 in North India was reported from Agra. Five members of a family, who had returned from Italy, had tested positive for the virus on March 2nd, 2020. Worldwide there have been reports of more than

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97 million cases and more than 2 million deaths as of January 21st, 2021.[2]

In India, more than 10.5 million cases of COVID-19 have been reported till January 21st, 2021, and the mortality rate was quite low as compared to Western countries.[3] In India, different states have reported different patterns of disease manifestations; some states such as Maharashtra, Delhi, Tamil Nadu, and Andhra Pradesh have been severely affected. In Asia, India had reported the largest number of COVID-19 cases and ranked second worldwide during the first wave. The rise of the second wave has been much steeper than the first wave which peaked in September of 2020. It was the 3rd week of April when the SARS-CoV-2 started to spread more rapidly than ever and recorded a massive surge when the daily number of cases crossed the 2-lakh mark.[4]

COVID-19 disease is characterized by high fever, cough, shortness of breath, pneumonia, loss the sense of taste/smell, and other respiratory tract infections.[5] The real-time polymerase chain reaction (RT-PCR) analysis was used to detect the SARS-CoV-2 virus from respiratory specimens such as nasopharyngeal and oropharyngeal swabs.[6] RT-PCR is a gold standard diagnostic tool and has provided more accuracy and quick diagnosis for SARS-CoV-2 detection.

In this study, we retrospectively analyzed RT-PCR results of cases from January 2021 to October 2021 to evaluate the epidemiological, clinical, and diagnostic profile with special emphasis on transmission dynamics of asymptomatic and symptomatic cases in a tertiary care center in North India.

Aims and objectives

To determine the SARS-CoV-2 positivity rate as well as epidemiological, clinical and diagnostic profile from the second wave.

MATERIALS AND METHODS

Study population

This is a retrospective study and includes all cases referred by the district surveillance officer, the integrated disease surveillance program team to the dedicated COVID-19 testing facility of S.N. Medical College, Agra, approved by the Indian Council of Medical Research (ICMR) for testing of COVID-19 by RT-PCR from January 2021 to October 2021.

Case definitions

A suspect case of COVID-19 was based on the criteria defined by the Ministry of Health and Family Welfare, Government of India.[6] The individuals included in this study were people who were suspected to be exposed to a confirmed case of COVID-19, symptomatic frontline workers, individuals who had undertaken international travel or domestic travel from high-burden states of Maharashtra, Gujarat, Delhi, and Tamil Nadu, individuals undergoing surgery and individuals from containment zones, quarantine centers or self-isolation.[7] After the first guidelines were released on March 20th and April 9th, 2020, the testing criteria were broadened to include patients with severe acute respiratory illnesses (SARI) and with influenza-like illness (ILI) belonging to hotspots and gatherings. Another major testing strategy was introduced on September 4th, 2020, in which routine surveillance in containment areas by rapid antigen test was introduced.[8] In this policy, all patients of ILI/SARI and asymptomatic high-risk patients hospitalized or requiring hospitalization due to any comorbidity had to be tested by RT-PCR/True Nat/cartridge-based nucleic acid amplification test.

Laboratory testing

Nasopharyngeal and oropharyngeal swab samples were collected by the trained personnel using standard guidelines laid down by ICMR.[8] Both swabs were placed in a viral transport medium tube in triple-layered packing and transported under cold chain to the S.N. Medical College, Agra.

Samples from suspected cases were subjected to quantitative RT-PCR for detection of SARS-CoV-2 using the ICMR guidelines for testing.[9,10] Five RT-PCR kits approved by ICMR were used in the study and the details are provided in Table 1. The results of the tests were entered immediately into the UP laboratory COVID-19 portal and shared with the district/surveillance teams to facilitate immediate tracing of patients and the contacts.

Data collection

All the sociodemographic, clinical, and risk factor details such as travel history and symptoms for every suspected case were collected and entered into a standardized line list by the surveillance teams in the respective districts/cities. The line list also included information about the type of sample, date of sample collection, date of testing, type of RT-PCR kit used, and the test results. All the data were maintained in a centralized database by the state

Table 1: Characteristics of study population

Variable	n (%)
Age (in years)	
0–20	110318 (15.88)
21–40	396276 (57.07)
41–60	150679 (21.70)
61–80	35398 (5.10)
>80	1756 (0.25)
Gender	
Transgender	57 (0.01)
Male	452804 (65.20)
Female	241566 (34.79)
Total	694427 (100.00)

surveillance officer. All contacts were traced based on the information provided by the individual and subjected to testing as per the national guidelines.[10]

Statistical analysis

Data were collected from COVID-19 testing laboratory, Department of Microbiology, Sarojini Naidu Medical College, Agra. It was validated and cleaned for analysis. Further statistical analysis was done using SPSS Software version 2.2. Qualitative data are being presented in frequencies and their related percentages. Unadjusted frequencies of positive screening through various kits among total screening tests done were calculated with 95% confidence interval. Adjusted odds ratio was calculated using RT-PCR results as a dependent variable and age and gender as independent variables at 95% confidence interval by applying multinomial logistic regression analysis. Confounding factors were adjusted. Comparison between different groups was done using the Chi-square test with a P=0.05 as the level of significance.

RESULTS

A total of 694,427 subjects were enrolled from January 2021 to October 2021 as shown in Table 1. Most of the samples (>98.8%) for screening for COVID-19 were received from Agra District Surveillance Officer. More than 99% of the screening was done using RT-PCR whereas only 0.7% had true Nat test done for screening of suspected cases. The age- and gender-wise distribution in both RT-PCR-positive and negative cases are presented in Table 2. Out of the 694,427 patients enrolled in the study, 452,804 (65.20%) were male and 241,566 (34.79%) were female. The mean age of the study population was 33.61±14.26 years. In the study population, more than half (57.07%) of the persons screened for COVID-19 infection, were between 21 and 40 years of age. There were only 57 transgender who were screened and their percentage is negligible (Table 1). The age distribution revealed that 72.95% of the cases were <40 years of age. Among the positive cases, 70% were asymptomatic while 30% were symptomatic. Figure 1 shows the common symptoms in COVID-19 suspected cases. Among the study population, transgender category showed a higher risk of getting COVID-19 infection (adjusted OR 4.36, 95% confidence interval [CI] is 1.55–12.20) and males showed slightly higher risk than females for getting the COVID-19 infection as detected by positive RT-PCR test adjusted OR was 1.056, 95% CI (1.01–1.09). It was found that the risk of acquiring COVID-19 infection was higher among the elderly population, being the highest among the age group >80 years, as the adjusted OR was 7.11, 95% CI (5.79–8.73) (Table 2). Figure 2 depicts the month-wise positivity rate

Table 2: Epidemiological profile of severe acute respiratory syndrome coronavirus-2 polymerase chain reaction positive population

Variable	RT-PCR positive (%)*	RT-PCR negative	Adjusted odds ratio
Age (in years)			
0–20	1043 (0.94)	107861	1
21–40	5496 (1.39)	387050	1.47 (1.37–1.57)
41–60	3813 (2.53)	144236	2.74 (2.56–2.94)
61–80	1476 (4.17)	32779	4.67 (4.30–5.06)
>80	107 (6.09)	1558	7.11 (5.79–8.73)
Gender			
Transgender	4 (7.02)	51	4.36 (1.55–12.20)
Male	7831 (1.73)	439312	1.056 (1.01–1.09)
Female	4100 (1.70)	234121	1
Total	11935	673484	

*Percentage is the RT-PCR positivity rate among various age groups and genders, RT-PCR: Real-time polymerase chain reaction

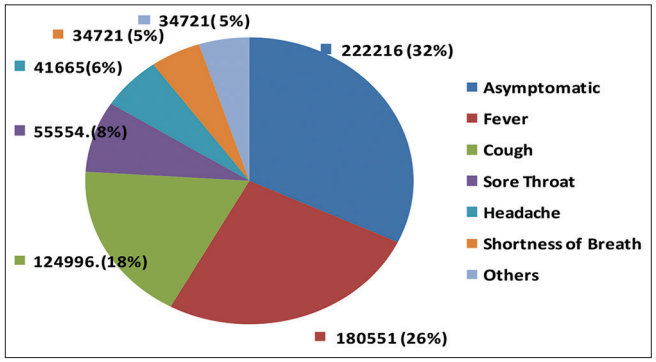

Figure 1: Common symptoms among COVID-19 suspected cases

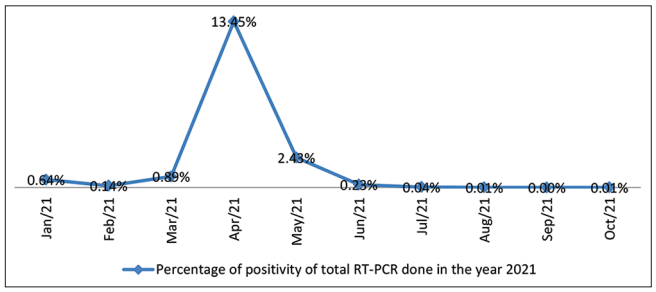

Figure 2: Month-wise percentage of positivity rate of total real-time polymerase chain reaction tests done in 2021

of total RT-PCR tests done in 2021 which shows that the peak of COVID-19 cases was reached in April 2021 followed by May 2021. Figure 3 shows the status of various RT-PCR kits used in the diagnosis of COVID-19 which indicates that the maximum tests were performed by GB SARS CoV-2 RT-PCR Kit followed by Genes2Me VIRAL DETECT II Multiplex real-time PCR Kit.

DISCUSSION

The present study was carried out at a tertiary care center in North India, and included samples of all patients received

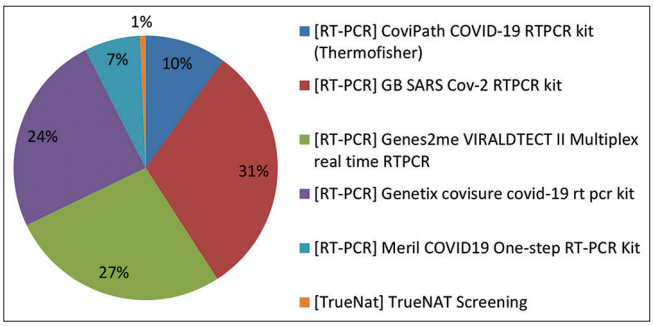

Figure 3: Various kits used in the laboratory for COVID-19 testing

in the viral diagnostic and research laboratory from January 1st, 2021, to October 31st, 2021. The proportion of males was found to be slightly higher than females, which is similar to the findings of the other studies from India.[11] The reason for male predominance in most of the studies may be due to the fact that males tend to travel more and are more actively engaged in outdoor activities during the lockdown period as compared to females. Some studies have also shown that males suffered from more severe forms of COVID-19 than females and this is the main reason why there were more males among the hospitalized patients than females in the present study.[12] However, the male preponderance to infection has been explained by some studies that mast cells in females are able to trigger a more active immune response, which may help them fight infectious diseases better than males and other genetic components such as X chromosomes and hormones, typically estrogens, both predominantly found in females which play an important role in innate and adaptive immunity to provide some significant level of protection against SARS-CoV2.[13,14]

The overall mean age of the affected cases was 39.85 years. Young people are generally more engaged in work during the lockdown period, which might increase their chances of getting exposed to COVID-19, while older people prefer to stay at home.[11] Close contact with a known case of COVID-19, symptomatic or asymptomatic, is the main source of transmission.[15] In the present study, 56.11% of patients had some risk factors for COVID-19 exposure, such as contact with a confirmed case of COVID-19, travel history outside the state in the recent past, or being a health-care worker involved in COVID-19 patient care. Almost one-fourth of the cases (24.04%) were healthcare workers of which the most common group affected was nursing staff followed by clinicians and non-treating support staff. Similar findings were reported from Qatar where the nursing staff was found to be the most common group affected by COVID-19.[11] Among the healthcare workers who were diagnosed with COVID-19, the majority were not directly involved in patient care in COVID-19-designated areas which may explain on the basis that the health-care workers involved in patient care of COVID-19 were following the prevention guidelines.

Being a hospital-based study, the true proportion of COVID-19 patients based on different categories of severity could not be assessed in a way that could be extrapolated to the general population; however, from our findings, we can still draw inferences about the effect of age and comorbidities on the severity and admission pattern. The present study shows that as the age of the patient increases, the chance to have more severe disease increases which may be due to physiological changes that come with ageing and compromised immune response.[16] The young population is more likely to be asymptomatic, and similar finding has been reported from other studies.[12,17] Associated comorbidities are considered to be an important factor to determine the disease outcomes.[18,19] Our study revealed that patients with co-morbidities, particularly diabetes and/or chronic kidney disease, had more severe forms of disease and higher mortality when compared to the patient without comorbidities. Similar findings were noted in other studies and the most common associated comorbidities observed were diabetes, coronary artery disease, chronic obstructive pulmonary disease, and chronic kidney disease.[19-22]

Majority of the patients were from the urban area. The reason for this was that initially, the cases were more in the urban area, and also because of the lockdown; there was a restriction in movement from urban to rural areas, so cases were not there in the rural area. Similar findings were reported by other studies.[23,24] The main clinical manifestations of COVID-19 are fever, cough, breathlessness, and sore throat. Apart from these symptoms, the present study also reported the gastrointestinal manifestations such as diarrhea, vomiting, and abdominal pain in few cases. However, the studies carried out during the initial phase of the pandemic mainly reported fever and cough as the predominant symptoms and gastrointestinal symptoms were uncommon. Gastrointestinal manifestations have also been reported by other studies.[16,25]

In an Indian study of 522 cases, fever was the most common symptom, followed by cough and breathlessness.[20] In another Indian study, including 197 confirmed cases, where most patients were symptomatic, the most common symptom being shortness of breath, cough, and fever, in that order.[19] This data are in stark contrast to 26% (fever) and 18% (cough) seen in the present study.

Diversity in the presentation of COVID-19 may lead to difficulty in diagnosis as sometimes patients may not always manifest fever and it may be missed during surveillance as the case definition includes fever.

Studies conducted in different parts of the world have shown that the presence of comorbidities increases the chance of COVID-19.[18] People with underlying uncontrolled medical conditions such as diabetes, hypertension, chronic lung disease, liver disease, or renal disease and patients on immunosuppressants are at increased risk of COVID-19 infection. Underlying medical conditions also affect the severity of symptoms, clinical outcome, and the length of stay in hospitalized patients.

Limitations of the study

The limitation of the study is that we have not recorded the mortality data and details about the cause of death.

CONCLUSION

SARS-CoV-2 poses a high burden of infections in the community. Males had higher RT-PCR detection rate as compared to females. The younger age group (less than 20 years) expressed the least RT-PCR positivity rate and the elderly population (>80 years) expressed the highest positivity rate.

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AA- Definition of intellectual content, literature survey, prepared first draft of manuscript, implementation of study protocol, manuscript preparation; **A-** Concept, design, manuscript preparation, editing, and manuscript revision; **VK-** Review of manuscript; **DK-** Coordination and manuscript revision; **NT-** Design of study, statistical analysis and interpretation; **SK-** Literature survey and preparation of figures, definition of intellectual content, literature survey, implementation of study protocol, data collection, manuscript preparation and submission of article.

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