# ORIGINAL RESEARCH Clinico-Epidemiological Profile of COVID-19 Patients with Omicron Variant Admitted in a Tertiary Care Center, South India

Theranirajan Ethirajan<sup>1,\*</sup>, Gopalakrishnan Natarajan<sup>2,\*</sup>, Rajendran Velayudham<sup>3,\*</sup>, Pavithra Jayakumaran<sup>4</sup>, Indumathi Karnan<sup>1</sup>, Karthick Rajendran<sup>5</sup>, Sudhakaran Doraisamy<sup>6</sup>, Sripriya Chenakeswarar Sridhar<sup>7</sup>, Purushoth Kumaran<sup>1</sup>, Kabilan Kamaraj<sup>1</sup>, Anuradha Kandasamy<sup>7</sup>, Murugan Natarajan<sup>8</sup>

<sup>1</sup>Madras Medical College, Chennai, India; <sup>2</sup>Institute of Nephrology, Madras Medical College, Chennai, India; <sup>3</sup>Institute of Internal Medicine, Madras Medical College, Chennai, India; <sup>4</sup>Institute of Pathology, Madras Medical College, Chennai, India; <sup>5</sup>Multidisciplinary Research Unit (MRU), Madras Medical College, Chennai, India; <sup>6</sup>Critical Care Medicine, Madras Medical College, Chennai, India; <sup>7</sup>Viral Research and Diagnostic Laboratory, Madras Medical College, Chennai, India; <sup>8</sup>Institute of Thoracic Medicine, Madras Medical College, Chennai, India

\*These authors contributed equally to this work

Correspondence: Murugan Natarajan, Institute of Thoracic Medicine, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai, Tamil Nadu, 600003, India, Email stanleymurugan@gmail.com

Background and Objectives: Omicron, a variant of SARS COV2, is looming large as a cause of global concern. Its high transmissibility can pose challenges in healthcare allocation in a highly populous country like India. Studying the behaviour of the virus among the Indian population will definitely help in planning for the impending omicron surge, so we conducted a preliminary analysis of the clinical and epidemiological characteristics of the suspected omicron cases in the early part of the surge.

Methodology: The study was conducted in the Rajiv Gandhi Government General Hospital, from 17th December 2021 to 11th January 2022. A total number of 159 consecutive patients  $\geq$ 18 years of age with the S gene target failure were enrolled and clinically followed up during hospitalisation.

**Results:** Nearly half (n = 79, 49.7%) were aged between 18 and 30 years and the mean (SD) age of the patients was 35.1 (14.9); 52.8% (n =84) were males and 54.7% (n = 87) were healthcare workers. The NLR ratio and CRP were raised in unvaccinated individuals. Out of 159 patients, only 4 patients required oxygen and all the others showed a mild course of illness and there was no mortality.

Conclusion: The clinical course of suspected omicron patients was mild in those who were vaccinated. Unvaccinated individuals with comorbid illness need to be closely monitored for prompt referral for acute care. Further studies are needed in the high-risk group with omicron. Keywords: COVID-19, coronavirus, SARS-CoV-2, omicron, variant of concern, S gene target failure

### Introduction

The recent emergence of the omicron variant has become a cause of global concern. Omicron was first identified in South Africa<sup>1</sup> and on 25th November 2021, WHO designated B.1.1.529 (Omicron) as the variant of concern [VOC];<sup>2</sup> Omicron VOC not only holds a high number of mutations as previously seen in other SARS-CoV-2 variants of concern (VOC) including delta but also possesses other additional mutations that are novel.<sup>3</sup> Cases of omicron VOC have been reported from more than 100 countries.<sup>4</sup> S gene target failure (SGTF) is considered a proxy marker to screen for omicron.<sup>5</sup> COVID-19 cases are rising rapidly in countries where omicron VOC has been reported, indicating its high transmissibility.<sup>6</sup> Worldwide, researchers are exploring various novel modality of treatment for COVID-19.<sup>7</sup>

India has done a phenomenal job in the vaccination front. As of 29th January 2022, India has administered over 1.65 billion doses overall, including first, second and precautionary (booster) doses of the currently approved vaccines. In India, 91% of the eligible population has received at least one shot, and 68% of the eligible population is fully vaccinated.<sup>8</sup> As per the Indian Council of Medical Research's latest sero-surveillance report, nearly two-thirds of

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individuals aged  $\geq 6$  from the general population and 85% of healthcare workers had antibodies against SARS CoV-2 by June–July 2021.<sup>9</sup> This can be either because of being vaccinated or having contracted the infection previously. The degree of protection offered by current vaccines against severe illness related to the omicron variant requires careful monitoring,<sup>10</sup> since 83% of cases occurred in fully or booster-vaccinated people in a Danish cohort.<sup>11</sup> This might be secondary to the evasion of the immunity acquired naturally as well as by vaccination by the omicron VOC.<sup>12</sup> Clinical outcome is different among the various chronic disease subgroup of patients.<sup>13</sup> Since the inception of COVID–19, there is a risk of psychological fear with each wave of the COVID–19 outbreak.<sup>14</sup>

While some studies claim that the clinical severity of patients with omicron was mild in nature, a report from Denmark suggests that the infection caused by omicron may not be less severe than that caused by Delta.<sup>12,15</sup> India is witnessing a surge in COVID-19 infections since the last week of December.<sup>16</sup> Given the huge population of India, how the surge is going to pan out is a matter of huge concern. Few studies from India have documented the course of illness among omicron infected COVID-19 patients. In this context, we conducted a study to document the clinical and epidemiological characteristics of the suspected omicron cases. The information about severity will help in planning for health-care resources to respond suitably to a potential surge of omicron in the country.

#### **Methods**

The study was conducted in the Rajiv Gandhi Government General Hospital, Madras Medical College Hospital between 17th December 2021 and 11th January 2022. The patients who were positive for COVID-19 as confirmed by LabGun™ COVID-19 ExoFast RT-PCR Kit were further tested with the Thermo fisher TaqPathCOVID-19 combo kit to detect the presence of SGTF. Later, the samples were sent to the State Public Health Laboratory, Chennai, for viral genome sequencing and confirmed as omicron variant. However, those with SGTF were considered to be omicron suspect cases and were admitted in the study hospital for close medical monitoring and clinical management, irrespective of their clinical status. We consecutively enrolled for the study such willing SGTF patients considered to be infected with omicron. These patients underwent routine biochemical and radiologic investigations as per the COVID-19 management protocol adopted in the hospital. The study team abstracted information on their demographic details, vaccination history, signs and symptoms, previous infection details, laboratory and radiologic findings, treatment details along with clinical outcome at the time of discharge. The data was abstracted using a structured questionnaire. A descriptive analysis was done. Continuous variables were expressed as mean with SD or median with IQR, whereas the categorical variables were expressed as percentages. The study protocol was approved by the Madras Medical College Ethics committee (IEC No.04042020). Informed consent was obtained from the study participants prior to study commencement. The study was conducted conforming to the Helsinki declaration of 1975, as revised in 2000 and 2008 concerning human and animal rights.

### Results

We enrolled 159 COVID-19 patients with SGTF. The demographics, laboratory and clinical features of the patients are summarized in Table 1. Nearly half (n = 79, 49.7%) were aged between 18 and 30 and the mean (SD) age of the patients was 35.1 (14.9). Of the 159, 52.8% (n = 84) were males and 54.7% (n = 87) were healthcare workers. Around one-fifth (20.8%, n = 33) reported at least one comorbidity, with diabetes mellitus (16/33, 48.5%) and hypertension (9/33, 27.3%) being the predominant comorbidities. Out of the 159, 29 (18.2%) did not receive any COVID-19 vaccine, whereas 18 (11.3%) and 112 (70.4%) had received one and two doses, respectively.

Clinical symptoms are summarized in Table 2. Around one-fourth remained asymptomatic throughout the course of illness. All the symptomatic patients expressed one or more of the eight symptoms including fever, cough, sore throat, myalgia, runny nose, headache, cold and fatigue. The major symptoms include fever (n = 81, 66.1%), cough (n = 58, 48.4%), and sore throat (n = 47, 38.7%), and these happened to be the most common constellation of symptoms because 99 patients (79.8%) presented with any of these three symptoms. Few reported loss of taste (7.3%), loss of smell (5.6%), rigors (6.5%), diarrhea (4.5%) and shortness of breath (4.8%). Of the 17 (10.7%) who reported history of laboratory confirmed previous COVID-19 infection, two had reported being infected twice before the current infection. The median duration between the RT-PCR turning negative from the first positive test was 5 days (IQR: 3–7).

Characteristics	Number of Study Participants (% of the Total) N = 159
Age (in years)	
18–30	79 (49.7)
31–45	41 (25.8)
46–60	31 (19.5)
61–85	8 (5.0)
Mean (SD)	35.1 (14.9)
Gender	
Male	84 (52.8)
Female	75 (47.2)
Health care Worker	
Yes	87 (54.7)
No	72 (45.3)
Co-morbidities	
Yes	33 (20.8)
No	126 (79.2)
Presence of symptom	
Asymptomatic throughout the course of illness	38 (23.9)
Symptomatic	121 (76.1)
Symptoms (n = 121)	
Fever	81 (50.9)
Cough	58 (36.5)
Sore Throat	47 (29.6)
Muscle ache/body pain	38 (23.9)
Runny Nose	31 (19.5)
Headache	30 (18.9)
Fatigue/Tiredness	16 (10.1)
Loss of taste	9 (5.7)
Loss of smell	7 (4.4)
Shortness of Breath	6 (3.8)
History of previous COVID-19 infection	17 (10.7)
COVID-19 vaccination status	. ,
Unvaccinated	29 (18.2)
One dose	18 (11.3)
Two doses	112 (70.4)
Laboratory and radiologic investigations	. ,
Neutrophil Lymphocyte ratio (n = 131)	
Less than 3.3	79 (60.3)
3.4-8.0	38 (29.0)
More than 8	14 (10.7)
C reactive Protein (mg/l) (n = 131)	
0–10 (Normal)	85 (64.9)
11–50	40 (30.5)
More than 50	6 (4.6)
X-ray Findings (n = 157)	
Normal	151 (96.2)
Features suggestive of COVID-19	6 (3.8)

 Table I Demographic and Clinical Characteristics of the Study Participants

(Continued)

Characteristics	Number of Study Participants (% of the Total) N = 159
Required Oxygen supplementation	
Yes	4 (2.5)
No	155 (97.5)
Required Corticosteroids	
Yes	5 (3.1)
No	154 (96.9)
Required Remdesivir	
Yes	7 (4.4)
No	152 (95.6)

Table I	(Continued).
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Table 2 Symptoms of Patients in This Study

Symptoms	Frequency	Percentage
Fever	81	66.1
Cough	60	48.4
Sore Throat	47	38.7
Myalgia	38	30.6
Runny Nose	31	25
Head Ache	31	25
Cold	23	18.5
Fatigue	16	12.9
Loss of Taste	9	7.3
Loss of Smell	7	5.6
Rigors	8	6.5
Diarrhea	6	4.5
SOB	6	4.8
Arthralgia	4	3.2
Back Pain	1	0.8
Burning eyes	1	0.8
Burning sensation	1	0.8
Chest Pain	1	0.8
Generalised weakness	1	0.8
Jandice	1	0.8
Nasal congestion	1	0.8
Wheezing problem	1	0.8

The neutrophil lymphocyte ratio was found elevated in 40% of the patients. With regard to the NLR value, for 38 (29.0%) patients it was between 3.8 and 8.0 and 14 (10.7%) patients had more than 8.0. Similarly, CRP was found elevated in 46 patients, with 40 (30.5%) of them having values between 11 and 50 mg/l, whereas 6 (4.6%) had CRP more than 50mg/l. The proportion of patients with elevated NLR and CRP was higher in the unvaccinated group than the vaccinated group (NLR: 2.51 vs 7.04; CRP: 11.4 vs 69.8). A majority (96.2%, n = 151) of the patients had a normal chest X-ray finding. Out of the 159 patients, 130 were vaccinated and 29 unvaccinated. It was found that 96 patients were vaccinated with Covishield, while 34 were vaccinated with Covaxin.

Among the 159, only four (2.5%) needed oxygen support, five (3.1%) were administered corticosteroids and 7 (4.4) received anti-viral, namely, Remdesivir. Out of the four patients who needed oxygen supplementation, three were unvaccinated and three had comorbidities. All the patients were discharged alive.

#### Discussion

Our study describes the clinical and laboratory findings of 159 COVID-19 patients with SGTF who were admitted in a tertiary care centre for medical observation during the initial period of the third wave in Chennai, India. Clinical and laboratory profiles from our study indicate mild course of illness among the study participants. A mild course of the illness observed among the study participants might be due to the immunity induced both by vaccination and the fact that they have contracted the infection at an earlier time and the intrinsically low virulence nature of the omicron variant itself.<sup>17</sup>

Unvaccinated patients appear to have elevated CRP and NLR at admission than the vaccinated patients. Unvaccinated individuals with comorbidities seem to have disease progression requiring oxygen supplementation. Hence, unvaccinated patients with comorbidities should be identified in the community triage centres and referred to higher medical centres for early and better clinical management to prevent mortality.

Most of the patients in our study had upper respiratory tract infection symptoms and had a normal chest X-ray. This is consistent with findings from animal studies indicating the reduced ability of the omicron variant to replicate in the lungs.<sup>18</sup> Also, nearly one-tenth experienced reinfection and 80% had a vaccination history indicating the immune evasive nature of the omicron variant. This observation seems to correlate well with the observation of other studies as well.<sup>19</sup> A recent report from Denmark involving 785 cases with the omicron variant of SARS-CoV-2, 83% of cases occurred in fully or booster-vaccinated people.<sup>12</sup>

Fever with chills and rigor seems to be a new addition to the constellation of symptoms seen in other SARS CO V2 variants. Loss of smell and taste, although not a very specific symptom of Covid 19, was seen in a majority of those infected with the Delta and the original wild variant strain. Only very few patients with SGTF complained of loss of smell or taste. On the contrary, most patients had severe sore throat that was not responding to paracetamol, although the symptoms lasted only a few days. The most common symptoms reported among users of the Zoe Covid app in the United Kingdom was running nose, headaches, fatigue, sneezing and sore throats, according to the study's most recent analysis of confirmed cases in London. Even in our analysis, the commonly reported symptoms were fever (n = 81, 66.1%), cough (n = 58, 48.4%) and sore throat (n = 47, 38.7%). Few reported myalgia, runny nose, headache, cold and fatigue. Night sweats, reported as one of the new symptoms in western counterparts, was not seen in our preliminary set of patients.<sup>20</sup>

The mean duration of swab conversion in the RT PCR test was approximately 5 days. Although the numbers are too small to conclude, this requires further study. The peak infectiousness of SARS happened around 7–10 days after symptom onset.<sup>21</sup> Studies comparing the clinical data on virus shedding with epidemiologic data on incubation periods and serial intervals concluded that the peak transmission and viral shedding of patients with laboratory-confirmed COVID-19 happened 1 or 2 days before symptom onset.<sup>22</sup> However, in a recent study from Japan, the amount of viral RNA was highest from 3–6 days after diagnosis or 3–6 days after symptom onset, and then gradually decreased over time, with a marked decrease after 10 days since diagnosis or symptom onset.<sup>23</sup> Given the high transmission of omicron, its peak infectiousness and the duration of transmissibility is a matter that requires larger clinical study. If peak transmission occurs after symptom onset containment measures like contact tracing and isolation might be fruitful.

#### Limitations

Our study has certain limitations. The majority of the patients in our study were healthcare workers in productive age group. Hence, the severity of illness among elderly could not be described. Also, all these patients were admitted during the early stage of third wave as part of admission protocol for medical observation and hence were monitored closely. Laboratory and radiologic investigations could not be performed in all patients due to the change in clinical management protocol during the study period.

### Conclusion

Our study finding indicates mild course of illness in most of the omicron patients. However, unvaccinated patients with comorbidities need to be identified quickly for early clinical care to reduce mortality.

### **Ethical Approval**

The study protocol was approved by Madras Medical College Ethics committee.

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### Disclosure

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