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Original Research Article

Study of Clinical Profile and Outcome among COVID-19 Patients during Hospitalization in a Tertiary Care Hospital in Central India

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Abstract

Background: The COVID-19 outbreak in 2019 has presented in the form of pneumonia of unknown etiology in Wuhan. The complete clinical profile including the prevalence of different clinical symptoms of COVID-19 infection among Indian patients who develop a severe disease is largely unknown. This study is aimed to provide a detailed clinical characterization of the cohort of patients who visited our institute with signs and symptoms of COVID-19.

Material and Methods: This was for inpatient hospital (inpatient) based prospective cohort study involving 520 COVID-19 patients admitted to the hospital. The adverse outcome included death and mechanical ventilation.

Results: Total 520 participants enrolled in the study, (6.9%) participants died, (8.3%) participants required ICU and (5.5%) participants required mechanical ventilation. only signs and symptoms suggestive of severe respiratory system involvement or widespread infection were associated with adverse outcomes, T presence of dyspnoea, cyanosis and hypoxia. The most common chronic disease among patients with adverse outcomes were diabetes, hypertension and pre-existing respiratory disease, personal habit both smoking, and alcoholism was also associated with adverse clinical outcome.

Conclusions: The adverse clinical outcome among COVID-19 patients is determined by several factors including advanced age, multi-morbidities, and the presence of severe respiratory symptoms.

Keywords: COVID-19, Clinical Features, Mortality, Morbidities.

Introduction

Corona virus disease (Covid-19), it was caused by severe acute respiratory syndrome corona virus, it was continued to surge the world. The ongoing pandemic of COVID-19 began as a focal outbreak of Pneumonia in Wuhan city of China in December 2019[1,2]. On 11th March 2020, the WHO declared COVID-19 as a global pandemic [1,2]. Within six months since the detection of the first case of Covid-19, the centre of the pandemic had already shifted from China to Europe with more than 100,000 daily cases [3,4]. The daily increase in the number of new cases of Covid-19 quickly saturated the hospitals including intensive care units all over the world [5-7]. This prompted governments of several countries to announce stringent lockdown measures to contain the spread of the virus [5-7].

The clinical signs and symptoms of Covid-19 in patients range from being absent (asymptomatic infections) to mild or moderate infection with symptoms such as dry cough, abdominal pain, fever, fatigue, body aches , sore throat, dyspnea, loos stool, headache, conjunctivitis, ageusia/ anosmia, skin rashes, and so on. Those who develop the severe disease shows more serious symptoms such as acute respiratory distress syndrome, multiple organ dysfunction syndrome and death. The severe form of Covid-19 is characterized by pneumonia, hypoxemic respiratory failure, cardiac and renal dysfunction, and considerable mortality and morbidity. However, it still unclear why some patients develop severe diseases requiring ICU admission and mechanical ventilation whereas most other patients recover on basic supportive therapy alone. Furthermore, it is even mysterious why some young healthy individuals die from Covid-19 whereas several multimorbid geriatric patients survive. Reports of case fatality rates from studies conducted in different parts of the world under varied settings have also been inconsistent. The World Health Organization suggested an overall crude mortality rate of 2-3%. Early studies involving patients requiring mechanical ventilation showed high mortality ranging from 50% to 97% [5-8]. An analyses of patients requiring ICU admission and mechanical ventilation support have higher mortality rates [9]. The mortality of critically ill patients with Covid-19 was reported as high as 85–98% [3,5-8]. Preliminary studies indicate that geriatric patients and patients with cardiovascular disease, chronic lung disease, hypertension, and diabetes or multimorbid patients are at particular risk for death from Covid-19, often due to the development of severe acute respiratory distress syndrome (ARDS) [3-5]. Although children often experience milder illnesses SARS-CoV-2 can cause severe pediatric disease via both acute Covid-19 and multisystem inflammatory syndrome. Treatment remains largely supportive with the severe cases requiring intensive care, oxygen supplementation and immune suppressor drugs.

Unfortunately, the complete clinical profile including the prevalence of different clinical symptoms of Covid-19 infection among Indian patients who develop a severe disease is largely unknown. As a new disease and a new global health issue, Covid-19 infection is understandable that its emergence and spread cause anxiety and fear among the morbid population. Thus, we need empirical data from the local population on the need for mechanical ventilation, length of stay, and outcomes including mortality rates to advance the global understanding of Covid-19 disease. Thus, we need to regularly collect, record, and analyze the clinical characteristics and risk factors for severe outcomes in Covid-19 patients admitted to

hospitals. Hence, we conducted this study with the objective to provide a detailed clinical characterization of the cohort of adult patients who visited our institute with signs and symptoms or contact history of Covid-19. For this study, we hypothesized we could identify risk factors for higher severity disease among hospitalized patients and identify differences in risk factors and outcomes between patients.

Material and Methods

Study Design: This was a hospital-based, single-centre, prospective, observational study.

Study Settings: The present study was conducted at the Department of Pulmonary Medicine, LN Medical College, Bhopal. It is a tertiary care institute.

Study Duration: The total duration of the study was 18 months.

Study Outcomes: Primary outcome parameters were the following clinical outcomes among the Covid-19 patients: admission to ICU, the requirement for mechanical ventilation, and death.

Sample Size Calculation: We enrolled all participants fulfilling the selection criteria in the present study. Following this approach, we recruited 520 participants for the present study.

Case Definition: A patient presenting with signs and symptoms suggestive of Covid-19 and fulfilling the below-mentioned selection criteria.

Inclusion Criteria:

a. Age>= 18years
b. Patients tested Covid-19 positive on RT PCR
c. Laboratory confirmed RAT positive.
d. The patient was admitted to the inpatient department.
e. Patients gave consent to participate in the study.

Exclusion Criteria:

a. Patients recommended home isolation/ quarantine.
b. Patients without the known outcomes i.e., LAMA, referred out etc.

Informed Consent: A bi-lingual (Hindi & English) consent form was drafted following the prescribed guidelines for research on human participants. The contents of the consent form were explained to all the prospective participants. All the questions from participants about the study, procedure, follow-up, and data privacy were answered. The participants were informed and explained that they have the right to withdraw from the study at any point in time.

Data Collection: The data were collected in a paper-based proforma. The proforma had three parts as follows: (i) Clinical details. (ii) Laboratory findings and (iii) Radiological findings.

Source of Data: There were two sources of data. First was the interview with the participants containing details about the demographic details, clinical history, symptoms, signs, and previous treatments (if any). The second source of the data was clinical records containing details about the clinical examination, laboratory & radiographic findings, treatment given, complications developed etc.

Statistical Analysis Plan

The primary independent variable was the adverse outcome(s) among laboratory-confirmed Covid-19 patients admitted to our institute. We aimed to identify from the collected data the clinical features among patients suffering adverse outcomes. The data were analysed using Stata 17.1 version. For the interval and ratio data types, the author calculated the mean, median, mode, and standard deviation [8]. For the nominal and ordinal data, the author calculated the frequency, percentage, and proportion. The interval and the ratio data variables were

analysed using a student's t-test test. Categorical variables were analysed using chi-square ($\chi 2$) tests [9]. A P-value < 0.05 was considered statistically significant.

Results

During the period of the study, a total of 934 Covid-19 patients came to the emergency/inpatient department of the institute. After clinical and laboratory examination, about 387 Covid-19 patients were recommended home isolation and 547 patients were admitted to the hospital. Of the 547 enrolled participants, the clinical outcome wasn't available for 27 patients. Thus, data on only 520 patients were included in the present study. Overall, the mean age of the participants was 59.7 years. Among 520 participants, 306 (58.8%) were male and 214 (41.2%) participants were female. The mean BMI of the participants was 26.73 kg/sqm and about 22.5% of participants were obese. About 130 (25.0%) participants consumed alcohol (at least once a week) and 109 (21.0%) participants smoked tobacco. Of the total 520 participants enrolled in the study, 36 (6.9%) participants died, 43 (8.3%) participants required admission to ICU and 29 (5.5%) participants required mechanical ventilation. The mean time from admission at the hospital to death was 105 (±18.96) hours (4.3 days). Further, 14 (32.6%) out of the total 43 patients were admitted/shifted to the ICU within 24 hours of hospitalization.

Table 1 illustrates the key descriptive features of the study participants. The mean age of the participants who had favourable and adverse outcomes was 49.3 and 63.9 years, respectively (p=0.031). The mean BMI among the participants with favourable and unfavourable outcomes was 23.9 and 29.8 Kg/sqm (p=0.048). The distribution of gender (male & female) among the participants having favourable and unfavourable outcomes was statistically nonsignificant (p=0.065). A significantly higher proportion of participants who suffered unfavourable outcomes consumed alcohol and smoked tobacco (p<0.05).

Table 1: Descriptive Characteristics of Study Participants (n=520)

Variable	Favourable Outcomes (n=477)	Adverse Outcome (n=43)	P-value
Age	49.3(±7.3)	63.9(±8.4)	0.031
Gender			
Male	279 (58.5%)	27 (62.8%)	0.065
Female	198 (41.5%)	16 (37.2%)	
Anthropometric Parameters			
Weight	56.8 (±5.9)	63.3 (±8.5)	0.078
Height	159 (±4.6)	156 (±5.2)	0.14
BMI	23.9 (±2.2)	29.8 (±2.4)	0.048
Obese	91 (19.1%)	29 (67.4%)	0.014
Substance Use			
Smoker	82 (17.2%)	27 (62.8%)	0.021
Alcohol	98 (20.5)	32 (74.4)	0.029

Table 2 shows the distribution of participants having favourable and unfavourable outcomes based on pre-existing morbidities. Most of the patients with unfavourable outcomes were multimorbid (3 or more morbidities): 32 (74.4%) with the unfavourable outcome and 59 (12.4%) with favourable outcomes, the difference was statistically highly significant (p<0.0001). Among the study participants: 18.8 % had cardiovascular disease, 21.9% had hypertension, 21.2% had pre-

existing pulmonary disease (p = 0.048), 10% had chronic renal diseases, and 90.7% had diabetes (p <0.001).

Table 2: Pre-existing co-morbidities among Study Participants (n=520)

Variable	Favourable Outcomes (n=477)	Adverse Outcome (n=43)	P-value
Cardiovascular Ds	81 (17%)	17 (39.5%)	0.078
Hypertension	93 (19.5%)	21 (48.8%)	0.14
Pulmonary Ds	94(19.7%)	16 (37.2%)	0.048
Cerebrovascular Ds	78 (16.3%)	18 (41.9%)	0.014
Diabetes	163 (34.2%)	39 (90.7%)	<0.001
Renal Ds	41 (8.5%)	11 (25.6%)	0.14
Liver Ds	37 (7.7%)	14 (32.5%)	0.043
Malignancy	22 (4.6%)	7 (16.3%)	0.014
Immunosuppressive therapy	17 (3.6%)	6 (14.0%)	0.078

Table 3 illustrates the presenting signs, symptoms, and complaints of the participants. Among all the presenting complaints/signs only the distribution of dyspnoea (14% versus 44%; p = 0.012), cyanosis (10% versus 93%; p <0.001), hypoxia (10.9% versus 95.3%; p <0.001), SPO2<94% (10% versus 62%; p< 0.001) was significantly different among participants that had a favourable and unfavourable outcome in our study.

Table 3: Presenting Signs and Symptoms among Study Participants (n=520)

Variable	Favourable Outcomes (n=477)	Adverse Outcome (n=43)	P- value
Fever	408 (85.6%)	40 (93.0%)	0.82
Cough	377 (79.0%)	37(86.0%)	0.19
Dyspnoea	67 (14.1%)	19 (44.2)	0.012
Cyanosis	48 (10.0%)	40 (93.0%)	<0.001
Hypoxia	52 (10.9%)	41 (95.3%)	<0.001
Fatigue	306 (64.1%)	35 (81.4%)	0.074
Expectoration	249 (52.2%)	27(62.8%)	0.21
Abdominal pain	86 (18.2%)	11 (25.6)	0.078
Nausea/Vomiting	108 (22.6%)	9 (20.9%)	0.84
Anosmia	67 (14.1%)	12 (27.9%)	0.069
Ageusia	53 (11.1%)	9 (20.9%)	0.073
Myalgia	74 (15.5%)	12 (27.9%)	0.072
SPO_2	96.6 (±1.7)	92.5 (±2.4)	0.084
SPO_2<94%	49 (10.4%)	27 (62.8%)	<0.001
Temperature	100.8′ F	101.2′ F	0.068

Discussion

Covid-19 caused by the novel SARS-Corona-2 virus is a relatively new disease. Not much was known about the natural history and epidemiology of the disease and its causative agent before the current pandemic. At the time of the beginning of this pandemic, the diagnostic accuracy of various radiological and laboratory investigations was unknown for predicting the outcome of Covid-19 [10,11]. Validating the diagnostic utility and

accuracy of any test requires considerable time [10,11]. Moreover, the availability of several high-end tests and equipment has always remained challenged in low- and middle-income countries including India. Under these scenarios, the clinical features of any disease including Covid-19 and host characteristics remain the mainstay and only option for triage and management of patients including admission to the ICU [12,13]. Towards this end, we conducted this descriptive observational study, to record and analyse the clinical symptoms and signs among the COVID-19 positive patients and study if there is an association between any clinical feature(s) and adverse outcomes among patients. As mentioned earlier, for this study, we studied the following three adverse outcomes viz. ICU admission, mechanical ventilation, and death.

Among the biophysical features, only the age of patients and their BMI (especially obese patients) was associated with adverse clinical outcome. In addition, among personal habit, both smoking and alcoholism (daily consumption) was also associated with adverse clinical outcome ($p<0.05$).Studies conducted all over the world have concluded that individuals of any age can acquire SARS-CoV-2 infection, although adults of middle age and older are most commonly affected, and older adults are more likely to have severe disease [14]. In several cohorts of hospitalized patients with confirmed COVID-19, the median age ranged from 49 to 56 years. In a report from the Chinese Center for Disease Control and Prevention that included approximately 44,500 confirmed infections, 87% of patients were between 30 and 79 years old. Additionally, older age is also associated with increased mortality [15]. In a report from the Chinese Center for Disease Control and Prevention, case fatality rates were 8 and 15 percent among those aged 70 to 79 years and 80 years or older, respectively, in contrast to the 2.3 percent case fatality rate among the entire cohort [15]. Symptomatic infection in children and adolescents is usually mild, although a small proportion experiences severe and even fatal disease. In the present study, other biophysical parameters viz. gender, weight, and height of the participants were not associated with adverse clinical outcomes. In comparison to our findings, several other studies have reported that maleshave comprised a disproportionately high number of critical cases and deaths in multiple cohorts worldwide [16].

In the present study, the factor associated most strongly with the adverse outcome especially mortality was being multi-morbid i.e., having 3 or more chronic diseases: 32 (74.4%) with unfavourable outcomes and 59 (12.4%) with favourable outcomes ($p<0.0001$). The most common chronic disease among patients with adverse outcomes was diabetes (90%) in comparison to only 34% of participants with favourable outcomes ($p <0.001$). The second and third most common morbidities were hypertension (21.9%) and pre-existing respiratory disease (21.2%) e.g., COPD, and asthma. Like our findings, several studies have also reported adverse outcomes including morbidity was seen as significantly higher among patients having pre-existing comorbidities [17,18]. Furthermore, diabetes is significantly higher among those who did not survive or who required mechanical ventilation. Several hospital-based cohort studies have reported that multiple comorbidities and underlying conditions have been associated with severe illness (ie, infection resulting in hospitalization, admission to the ICU, intubation or mechanical ventilation, or death) [17,18]. In a report of 355 patients who died of COVID-19 in Italy, the mean number of pre-existing comorbidities was 2.7, and only 3 patients had no underlying condition [19]. In our study, the highest mortality rate and admission to ICU were seen among the

multimorbid geriatric population. Among patients with advanced age and medical comorbidities, COVID-19 is frequently severe. In an analysis of nearly 300,000 confirmed COVID-19 cases reported in the United States, the mortality rate was 12 times as high among patients with reported co-morbidities compared with those with none [20].

In the present study, we noted that patient presented with an array of symptoms that affected almost every organ system of the body. However, the most common system was the respiratory system followed by the Musco-skeletal system. Similar to our findings, Li X *et al*. also reported that among patients with symptomatic COVID-19, cough, myalgias, and headache are the most commonly reported symptoms [16]. Other features, including diarrhoea, sore throat, and smell or taste abnormalities, are also well described. In a report of over 370,000 confirmed COVID-19 cases from January to May 2020 with known symptom status reported to the CDC in the United States, cough (50%), fever (43%), myalgias (36%), and headache (34%) were the most common presenting symptoms [20].

Nevertheless, in the present study, only signs and symptoms suggestive of severe respiratory system involvement or widespread infection were associated with adverse outcomes. For example, presence of dyspnoea (14% versus 44%; p = 0.012), cyanosis (10% versus 93%; p <0.001), hypoxia (10.9% versus 95.3%; p <0.001), SPO2<94% (10% versus 62%; p< 0.001) was significantly different among participants that had a favourable and unfavourable outcome in our study. Pneumonia is the most frequent serious manifestation of infection, characterized primarily by fever, cough, dyspnea, and bilateral infiltrates on chest imaging [21]. Although some clinical features (in particular smell or taste disorders) are more common with COVID-19 than with other viral respiratory infections, there are no specific symptoms or signs that can reliably distinguish COVID-19 [21]. However, the development of dyspnea approximately one week after the onset of initial symptoms may be suggestive of COVID-19.

Conclusion

The adverse clinical outcome among covid-19 patients is determined by several factors including advanced age, multi-morbidities, and the presence of severe respiratory symptoms.

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