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Research Article

BASELINE RISK AND CLINICAL CHARACTERISTICS OF HOSPITALIZED COVID-19 PATIENTS - RETROSPECTIVE COHORT STUDY

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A B S T R A C T

Background: The current COVID 19 pandemic has affected 29.1 million people worldwide out of which 4.2% have been fatal cases. In India, Mumbai has shown some of the highest fatalities, with rate reaching 5.4%. There is a need to study different characteristics of patients diagnosed with COVID 19, in order to gain more insights of this disease to plan preventive as well as therapeutic protocols.

Materials and methods: We conducted a retrospective study including patients admitted at NeuroGen Brain and Spine Institute, a dedicated COVID-19 hospital with 75 beds, including 20 ICU beds from 05.06.2020 to 24.08.2020. We included patients of all genders and age groups which were diagnosed based on COVID RT-PCR/chest CT scan/X-ray findings corroborating clinical features and blood biomarkers. We explored the effect of age, gender, comorbidities, diet and baseline serum biomarkers on severity and outcome of the disease using a percentage analysis, Pearson's correlation analysis. We also used a percentage analysis to calculate the frequency of symptoms occurrence, effect of different medicines on outcome of the disease.

***Results and conclusion*:** 70.93% of the patients recovered without any progression of the disease, 20.89% of the patients progressed in severity of the disease during the course of hospital admission however, recovered completely. We observed a mortality rate of 4.7% which was much lesser than the current average mortality in the region. Multiple factors like age, gender, presence of comorbidities like diabetes and hypertension were found to be responsible for increased severity of the disease along with symptoms like fever, breathlessness and cough. Biomarkers like CRP and IL-6 showed significant correlation with the severity of the disease. This study provides insight of various aspects of COVID-19 in hospitalized patients.

INTRODUCTION

Outbreaks of viral infections ranging from mild, severe to lethal have been experienced several times in the recent past [1,2]. Since50 years, Corona viruses have been known to cause respiratory infections of varying severities including common cold, a mild intensity upper respiratory tract infection [3]. However, recent outbreaks of Middle East Acute Respiratory Distress Syndrome (MERS) and Severe Acute Respiratory Distress Syndrome (SARS) hinted at the mutation potential of the corona viruses and a possibility of much severe and lethal infection [4].

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Infact, scientists forewarned a probable novel coronavirus outbreak of pandemic proportion [5].

Currently, we are experiencing such a pandemic that originated in late 2019 in the Wuhan, Hubei Province, China. This pandemic is caused by SARS-CoV-2 virus resulting in COVID-19, a disease characterized by acute respiratory distress syndrome [6]. Unlike its predecessors it causes much less fatalities however, it is much more infectious [7]. It is difficult to strategize containment due to airborne transmission and a larger incubation period [8]. So far, the SARS-CoV-2 infection is still spreading. Due to the lack of antiviral medicines and vaccines, the disease has caused considerable fatalities [9].

It is suspected that there may be different strains of SARS-C0V-2 due to high mutation capability [10]. This is reinforced by clinical variations observed in the symptomatology of COVID-19 [11]. Lack of definitive treatment has also given rise to various putative treatment protocols. There is a need to study different characteristics of patients diagnosed with COVID 19, in order to gain more insights of this disease to plan preventive as well as therapeutic protocols. Various healthcare facilities have been created or converted from existing facilities to dedicated COVID hospitals to service the increasing demand of treatment and care of COVID-19 patients [12]. Our hospital was also converted into a dedicated COVID hospital with 75 beds, including 20 ICU beds. In this retrospective study we have analysed the baseline characteristics of patients at admission treated at our hospital from 05th June 2020 to 24th August 2020. We have analysed the effect of different co-morbidities and medicines on the severity of COVID-19 and outcome after the treatment. This study would help to further our understanding of prognostic factors and treatments for COVID-19.

MATERIALS AND METHODS

Aim

Aim of the study was to observe, analyse and report the epidemiologic and clinical findings of patients with COVID-19 treated at our hospital.

Study design

We conducted a retrospective observational cohort study of COVID-19 patients admitted in a dedicated COVID hospital between 05.06.2020 to 24.08.2020 to study effect of age, gender, different co-morbidities and blood bio-markers on severity and outcome of treatment in patients with COVID-19. We have described the symptomatology of the disease across varying severities and compared the effect of evolving treatment protocols.

Inclusion criteria

Patients diagnosed with COVID-19 based on RT-PCR or Chest CT scan or Chest X-ray and Clinical features were included in the study. Patients of all age groups and genders were included.

Exclusion criteria

Patients with a negative RT-PCR test; absence of significant clinical symptoms and radiological findings suggestive of COVID-19 were excluded from the study. Patients that were shifted to another hospital due to medical or non-medical reasons were excluded from the outcome analysis in the study.

Data collection

Records of all the patients admitted to NeuroGen Brain and Spine Institute (NGBSI) a dedicated COVID hospital with 75 beds including 20 beds for Intensive Care Unit (ICU) between 05.06.2020 to 24.08.2020 were considered for the analysis.

All the patients were screened for admission by designated triage doctors, patients diagnosed as COVID-19 based on clinical symptoms and radiological findings like chest X-ray or high-resolution computed tomography (HRCT) scan of the chest, antigen test or RT-PCR test were admitted to the hospital. Based on the severity of the disease and presence of co-morbidities a personalized treatment protocol was decided by a team of pulmonologist, intensivist and physicians.

All the treatment protocols in the hospital were based on the guidelines of the Ministry of Health and Family Welfare (MoHFW). Treatment protocol consisted of combination of medications like antibiotics (cephalosporin, ivermectin, doxycycline), one of the antivirals (Lopinavir/ritonavir or Favipiravir or Remdisivir), low molecular weight heparin, methylprednisolone, vitamin supplements (vitamin E, vitamin C, zinc, multivitamins), anti-inflammatory medicines (tocilizumab) and antacids (pantoprazole). Other medicines were administered for symptomatic relief such as paracetamol for fever, antitussive for cough, etc. Supplemental oxygen was given to patients who had oxygen saturation (SpO2) below 95% on room air.

Severity of the disease was decided based on MoHFW guidelines [13]. The criteria used as suggested in the guidelines are given below.

Criteria to determine severity of patients diagnosed with COVID-19

1. Mild severity - Without evidence of breathlessness or Hypoxia (normal saturation) on room air,
2. Moderate severity - Presence of clinical features of dyspnoea and or hypoxia, fever, cough, SpO2 < 94% (range 90-94%) on room air, respiratory rate more or equal to 24 per minute
3. Severe disease - Clinical signs of Pneumonia plus one of the following; respiratory rate > 30 breaths/min, severe respiratory distress, SpO2 <90% on room air

The discharge of patients from hospital was according to discharge criteria laid down by guidelines from MoHFW[14]. In addition to the medical criteria for discharge there were some socio-economic factors that also influenced the discharge of the patients from the hospital.

Outcome at discharge was considered in 3 categories: a) recovered, patients whose clinical condition did not worsen before complete recovery, b) progressed and recovered, patients whose clinical condition worsened as compared to admission however they recovered completely, c) patients who progressed to mortality.

Data Analysis

Demographic data

The records of the patients were screened as per the inclusion and exclusion criteria. Eligible patients' demographic and clinical information as well as radiological and laboratory investigations were tabulated. Baseline demographic and risk factors analysis was performed by computing mean age, percentage distribution of gender, different co-morbidities, symptoms, radiological findings and laboratory findings.

Correlation analysis

To explore the association between age vs severity of the disease as well as age vs outcome of the disease Pearson's correlation test was conducted with the significance value set at $p = / < 0.05$. Along with that a percentage analysis was conducted to understand the proportion of patients with varying disease severity and outcome in each age group.

A percentage analysis was conducted to find out the proportion of patients with varying severities and outcomes based on gender.

Percentage analysis was carried out to compare the effects of diet i.e. vegetarian or non-vegetarian on disease severity and outcome.

We further explored association between disease severity and disease outcome, measured as per the criteria described earlier, using Pearson's correlation coefficient.

Association of co-morbidities with severity of the disease and outcome at discharge

Further, to find out association of various co-morbidities like Diabetes Mellitus (DM), Hypertension (HTN) and other co-morbidities with severity of disease on admission and outcome at discharge; a percentage analysis was performed. For the percentage analysis we computed the percentage of patients with varying severity and outcome at discahrge in the group that presented with a particular co-morbidity and compared it with the group that did not exhibit that comorbidity.

Analysis of symptom occurrence

Similarly, percentage analysis was performed for various symptoms to understand frequency of symptom occurrence based on severity of the disease and its association with the outcome at discharge. To understand frequency of symptom occurrence based on severity of the disease, we computed percentages of different symptoms in the three groups based on severity i.e mild, moderate and severe and compared the percentages across the groups. To understand its association with the outcome at discharge, we grouped the patients based on individual symptoms and computed the percentage distribution based on different outcomes in patients that exhibited particular symptoms and compared that with those who did show that symptom.

Analysis of radiological findings

Radiological findings of the patients (Chest X -ray findings) were tabulated. Percentage distribution analysis was performed to calculate proportion of patients showing normal radiograph, peripheral ground glass opacification, involvement of individual lung lobes (upper, middle, lower) or multiple lobes.

Analysis of laboratory biomarkers

Correlation analysis was performed using Pearson's correlation test. A percentage analysis was carried out to explore the effect of biomarker abnormality on the outcome of the disease.

Analysis of effect of medicines on the outcome of the disease

We also performed a comparative percentage analysis for different medicines administered to understand association of administration of various medicines with the outcome at discharge.

Analysis of group of patients that progressed to mortality

A separate percentage analysis for co-morbidities, symptoms and bio-markers was performed in the group of patients that progressed to mortality to understand the factors that might have influenced the outcome.

Statistical analysis

Statistical analysis was performed using SPSS 20 software. Pearson's correlation coefficient was computed for correlation analysis. Statistical significance was determined using calculated probability and was assigned at $p < 0.05$.

RESULTS

Demographic data

There were 405 patients admitted between 05.06.2020 and 24.08.2020 out of these 3 patients showed symptoms of cough or sore throat however the RT-PCR test was negative and there was no radiological evidence of COVID-19 and therefore were excluded from the analysis. In 402 patients112 (27.86%) were females and 290 (72.13%) were males.Ageranged between 8 monthsto 82 years with an average age of 45.9 (15.12) years. Patients stayed in the hospital for an average of 10.29 (5.03) days, the duration of stay ranged from 2 to 49 days. Longer duration of stay was associated with medical factors as well as social-economic factors such as mandatory requirement of a negative RT-PCR at the place of residence which increased the duration of stay despite being medically fit to be discharged earlier. We found that in the patients admitted to our hospital; 98 patients i.e 24.37% cases were severe, 40 (9.9%) were moderate and 264 (65.67%) patients were of mild disease severity. (Table 1) 327 patients were admitted in regular wards (Routine isolation bed), 75 patients were admitted in intensive care unit (ICU).

Table 1 Demographic details of study population

Parameter	Minimum	Maximum	Mean	Std Dev
Age	8 months	82 years	45.9	15.12
Time to discharge	2 days	49 days	10.29	5.03
Parameter			**Number (Percentage)**	
Gender	Male		290 (72.13%)	
	Female	Total	112 (27.86%)	
		Pre-menopausal	38 (33.92%)	
		Post-menopausal	65 (58.03%)	
		Info NA	9 (8.03%)	
Severity of the disease (n=402)	Mild		264 (65.67%)	
	Moderate		40 (9.95%)	
	Severe		98 (24.37%)	
Comorbidities	Diabetes	Present	103 (25.62%)	
		Absent	299 (73.37%)	
	Hypertension	Present	116 (28.85%)	
		Absent	286 (71.14%)	
	Cardiac disorders	Present	17(4.2%)	
		Absent	385 (95.77%)	
	Malignancy	Present	4 (1%)	
		Absent	398 (99%)	
	COPD	Present	0	
		Absent	402 (100%)	
	Hypothyroidism	Present	16 (3.9%)	
		Absent	386 (96%)	
	History of TB	Present	4 (1%)	
		Absent	398 (99%)	
	H/O Epilepsy	Present	0	
		Absent	402 (100%)	
	Bronchial Asthma	Present	2 (0.4%)	
		Absent	400 (99.50%)	
	Hyperthyroidism	Present	1(0.2%)	
		Absent	401 (99.75%)	
	Bleeding tendency	Present	1 (0.2%)	
		Absent	401 (99.75%)	
	Other	Present	20 (4.97%)	
		Absent	382 (95.02%)	
	Smoking	Yes	5 (1.24%)	
		No	379 (94.27%)	
		NA	18 (4.47%)	
	Alcohol	Yes	12 (2.98%)	
		No	372 (92.53%)	
		NA	18 (4.47%)	
	Tobacco chewing	Yes	5(1.24%)	
		No	378 (94.02%)	
		NA	19 (4.72%)	
	Other drug abuse	No	402 (100%)	
	Drug allergies	Yes	13 (3.23%)	

	No	379 (94.27%)
	NA	10 (2.48%)
Food allergies	Yes	6 (1.49%)
	No	385 (95.77%)
	NA	11 (2.73%)
Any other allergy	Yes	10 (2.48%)
	No	380 (94.52%)
	NA	12 (2.98%)
Past surgical history	Yes	83 (20.6%)
	No	314 (78.10%)
	NA	5 (1.24%)
Diet	Veg	130 (32.33%)
	Non veg	147 (36.56%)
	NA	125 (31.09%)

Analysis of serum biomarkers at baseline

Biomarker	Number of patients in which it was tested	Range	Mean (SD)	Number (Percentage) of patients that showed abnormality
CRP (mg/l)	351	0.5 to 335	52.98 (60.19)	279 (79.4%)
Ferritin (ng/ml)	241(Males) 60 (Females)	7.28 - 6170	467.34 (661.09)	149 (61.8%)
D-Dimer (ng/ml)	350	10 to 50000	1328.42 (4475.43)	184 (52.57%)
IL-6 (pg/ml)	220	0.042 to 1339.18	141.19 (209.21)	201 (91.36%)

There were 38 females who were pre-menopausal & 65 females who were post -menopausal. 114 patients gave history of coming in contact with COVID 19 patients. Number of patients on BiPAP were 17, No. of patients on high flow mask (HFM)were 54, no. of patients on NRBM were 16, no. of patients on nasal prongs (NP) were 51, no. of patients on both NRBM & NP were 3 & no. of patients on both NP & HFNM were 1. Total no. of patients who had HRCT done at admission were 22. Out of these, 13 scan reports show CORAD score 5 or above. Other 9 scan shows ground glass opacities or signs of pneumonitis. Total no. of patients who had tested positive on swab test were 350. Out of these, 32 tested negative on swab test.

Patients presented with various co-morbidities (Table 1) like diabetes mellitus (DM) (n=103,25.6%), hypertension (HTN) (n=116,28.9%), both DM and HTN (n=60,14.9%), Malignancies (n=4,1%), Cardiac disorders (n=17,4.2%), Hyperthyroidism (n=16,3.9%), history of Tuberculosis (n=4,1%), h/o epilepsy (n=1,0.2%), bronchial asthma (n=2, 0.4%), hyperthyroidism (n=1,0.2%), HIV (n=1,0.2%), Bleeding disorders (n=1,0.2%), Other renal and hepatic disorders (n=24,5.9%). Reliable data on substance usage could not be obtained as many of the patients did not report their consumption of tobacco and alcohol due to social stigma associated with the same. Food or drug allergies were seen in 19 (4.7%) patients. History of surgeries was observed in 83 (20.6%) patients. 130 (32.3%) patients were vegetarian and 145 (36.06%).

Findings of laboratory investigations for various bio-markers are summarized in Table 1.

Association of demographic characteristics of the individuals with severity and outcome of the disease

Association of age with severity and outcome

In our analysis it was observed that as the age progresses the severity increases, and outcome worsens (Table 2, Figure 1). There were no mortalities observed in patients below the age of 40 years and highest percentage mortality was observed in the age group of 60 years and above.

Association of gender with severity and outcome

The percentage analysis showed no association of gender with severity of the disease or the outcome of the disease (Table 2, Figure 2). However, prevalence of the disease was much higher in males as compared to females (Table 1).

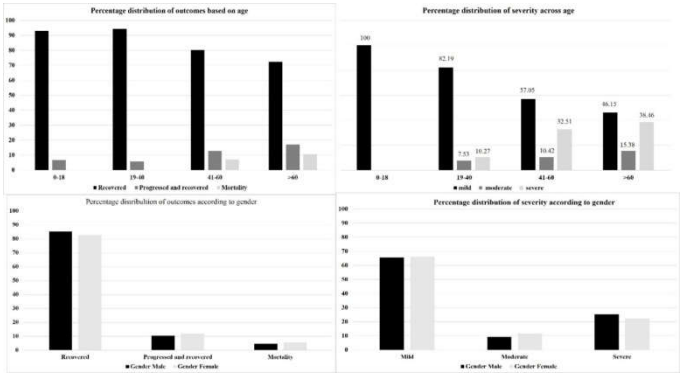

Figure 1 Association of age and gender with severity and outcome

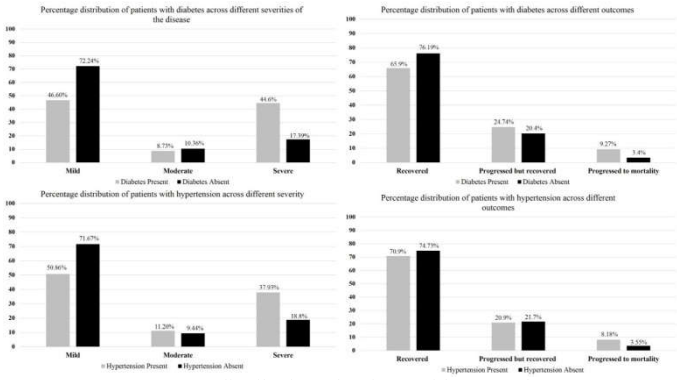

Figure 2 Percentage distribution of patients with DM and HTN across different severities and outcome of the disease

Table 2 Association of demographic characteristics with outcome and severity of the disease

Disease outcome					
Factor	**Group**	**Sample Size**	**Number (%) of patients who recovered**	**Number (%) of patients who progressed and recovered**	**Number (%) of patients who progressed to mortality**
Age in years	0-18	15	14 (93.33%)	1 (6.66%)	0
	19-40	143	135 (94.40%)	8(5.59%)	0
	41-60	157	126(80.25%)	20 (12.73%)	11(7.0%)
	>60	76	55 (72.36%)	13 (17.10%)	8 (10.52%)
Gender	Male	290	240 (85.10%)	29 (10.28%)	13 (4.60%)
	Female	112	90 (82.56%)	13(11.92%)	6 (5.50%)
Diabetes mellitus	Present	97	64 (65.9%)	24 (24.74%)	9 (9.27%)
	Absent	294	224 (76.19%)	60 (20.40%)	10 (3.40%)
Hypertension	Present	110	78 (70.90%)	23 (20.90%)	9 (8.18%)
	Absent	281	210 (74.73%)	61 (21.7%)	10 (3.55%)
Other co-morbidities	Present	60	45 (75%)	13 (21.66%)	2 (3.33%)
	Absent	331	243 (73.41%)	71 (21.45%)	17 (5.13%)
Disease severity					
Factor	**Group**	**n**	**Number (%) of patients with mild disease**	**Number (%) of patients with moderate disease**	**Number (%) of patients with severe disease**
Age in years	0-18	15	15 (100%)	0	0
	19-40	146	120 (82.19%)	11 (7.53%)	15 (10.27%)
	41-60	163	93 (57.05%)	17 (10.42%)	53 (32.51%)
	>60	78	36 (46.15%)	12 (15.38%)	30 (38.46%)
Gender	Male	290	190(65.51%)	27(9.31%)	73(25.17%)
	Female	112	74(66.07%)	13(11.60%)	25(22.32%)
Diabetes mellitus	Present	103	48 (46.60%)	9 (8.73%)	46 (44.6%)
	Absent	299	216 (72.24%)	31 (10.36%)	52 (17.39%)
Hypertension	Present	116	59 (50.86%)	13 (11.20%)	44 (37.93%)
	Absent	286	205 (71.67%)	27 (9.44%)	54 (18.8%)
Other co-morbidities	Present	61	35 (57.37%)	10 (16.39%)	16 (26.22%)
	Absent	341	229 (67.15%)	30 (8.79%)	82 (24.04%)

Association of presence of co-morbidities with severity at admission and outcome at discharge

For the purpose of this comparison DM, HTN was considered independently and all of the other co morbidities were combined together due to smaller numbers of patients presenting those co-morbidities individually. Table 2 and Figures 2 summarize the percentage analysis of severity of the disease and disease outcome in patients with and without DM, HTN, and other co-morbidities.

In patients with diabetes mellitus, there was a remarkable increase in the percentage of severe disease presentation as compared to those who did not have diabetes. Similar pattern was observed in patients with HTN compared to those without HTN. For other co-morbidities this difference wasn't as stark as DM and HTN. HTN and DM are associated with the risk of greater disease severity.

Table 2 summarize the percentage analysis of outcome of the disease in patients with or without different co-morbidities.

In patients with DM, there was an increase of 5.87% in the mortality of patients as compared to those who did not have DM; whereas percentage of patients who recovered without progression was 11% less in patients with DM. Similar pattern was observed in patients with HTN compared to those without HTN. There wasn't significant difference in the outcome of patients who had and did not have other co-morbidities. HTN and DM are mainly associated with worse prognosis as compared to other co-morbidities. (Figure 2, Table 2)

Symptom occurrence

Various symptoms seen in the patients were fever (n=330, 82.1%), cough (n=244, 60.6%), sputum (n=40,9.9%), Breathlessness (n=190,40.2%), Sore throat (n=108,26.9%), Chest pain (n=46, 11.4%), Gastrointestinal disturbances like constipation, diarrhoea or vomiting (n = 87,21.6%), Loss of appetite (n=161, 40.0%), Loss of taste (n=65, 16.2%), Loss of smell (n=19,4.7%), Headache (n=42,10.4%), Bodyache (n=125, 31.09%), Generalized weakness (n=89,22.13%) (Figure 3)

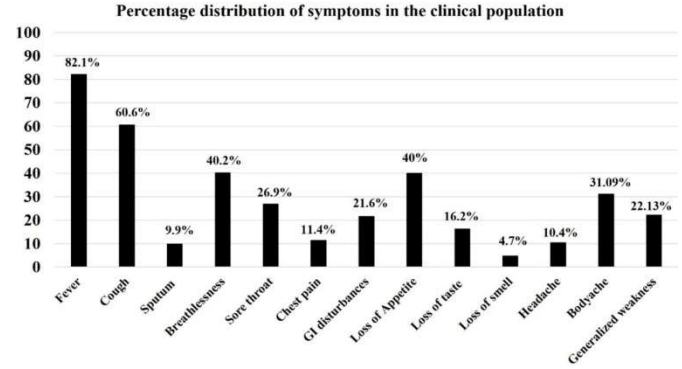

Figure 3 Percentage distribution of difference symptoms in the clinical population

Comparison of symptoms occurrence based on severity of the disease

Comparison of frequency of symptoms in patients with varying severity is given in Table 3. The comparison shows that presence of cough, fever and breathlessness can be associated with a greater severity of the disease.

Effect of drug administration on outcome of the disease

Various drugs administered showed beneficial effects on the outcome. Usage of antiviral drugs showed reduced percentage mortality. Similar results were found with Tocilizumab and Corticosteroids. (Figure 4)

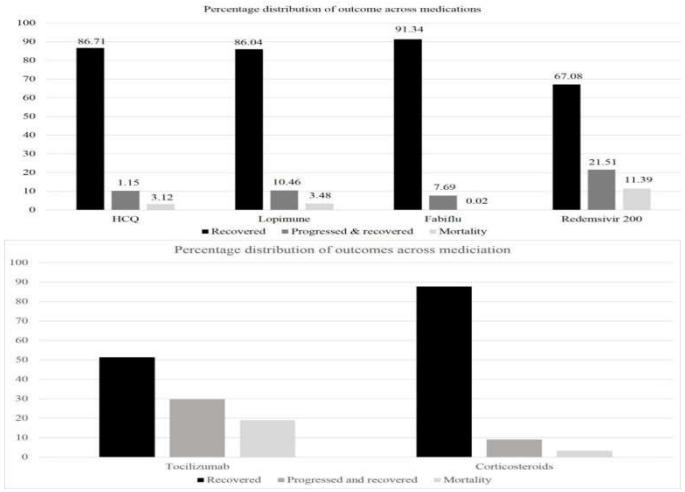

Figure 4 Outcomes observed in patients using different antivirals and anti-inflammatory medicines

Effect of baseline levels of biomarkers on severity and outcome of the disease

Although majority of patients showed abnormality in baseline biomarker levels (Table 2). Correlation analysis conducted with Pearson's correlation coefficient showed that a) Serum CRP levels have moderate positive correlation with the severity of the disease (R=0.465) which was statistically significant (p=0.05) b) Serum Ferritin levels had poor positive correlation (R=0.207, p=o.oo5) c) Serum D-dimer levels had poor positive correlation (R=0.189, p=0.05) d) Serum IL-6 levels showed moderate strength positive correlation with severity (R = 0.371, p=0.000). The correlation analysis showed as the disease severity increases, the serum blood levels of these biomarkers increase. Despite this correlation, outcome analysis showed that majority of these patients that showed abnormal values of biomarkers recovered without any progression of the disease (Figure 5).

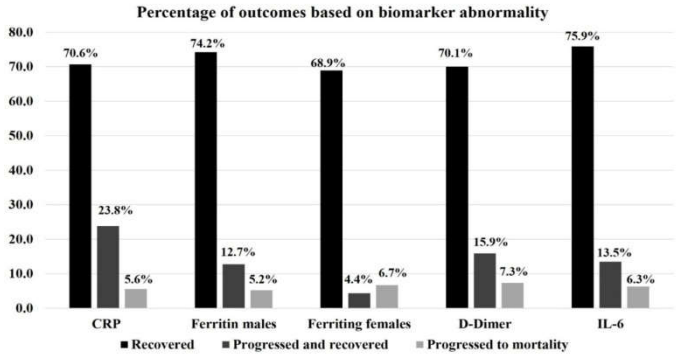

Figure 5 Percentage outcome based on biomarker abnormality

Percentage analysis of patients who suffered mortality

19 out of 402 patients in the study had expired. The mean age of these patients was 57.68 years (range 41-77 years). 13 were males and 6 were females. 8 patients preferred a vegetarian diet while 11 consumed non-vegetarian diet. 9 out of 19 patients had history of diabetes mellitus and hypertension while 2 had other comorbidities such as HIV and rheumatoid arthritis.

Table 3 Frequency of severity of the disease and outcome of the disease across various symptoms

Severity of the disease				
Symptom		**Number (%) of patients with mild disease**	**Number (%) of patients with moderate disease**	**Number (%) of patients with severe disease**
Fever	Present (330)	215 (65.15%)	30 (9.09%)	85 (25.75%)
	Absent (72)	49 (68.05%)	10 (13.88%)	13 (18.05%)
Cough	Present (213)	121 (56.80%)	29 (13.61%)	63(29.57%)
	Absent (157)	121(77.07%)	9(5.73%)	27(17.19%)
Sputum	Present (39)	19(48.71%)	7(17.94%)	13(33.33%)
	Absent (360)	245 (68.05%)	32 (8.88%)	83 (23.05%)
Breathlessness	Present (150)	47(31.33%)	24(16%)	79(52.66%)
	Absent (212)	195 (91.98%)	10 (4.71%)	7 (3.30%)
Sore throat	Present (103)	64(62.13%)	17(16.50%)	22(21.35%)
	Absent (294)	197 (67.00%)	22 (7.48%)	75 (25.51%)
chest pain	Present (45)	21(46.66%)	8 (17.77%)	16 (35.55%)
	Absent (356)	242 (67.97%)	32(8.98%)	82(23.03%)
Diarrhea	Present (85)	54(63.52%)	9(10.58%)	22(25.88%)
	Absent (315)	208 (66.03%)	31 (9.84%)	76 (24.12%)
GI disturbances	Present (1)	1(100%)	0	0
	Absent (398)	260 (65.32%)	40 (10.05%)	98 (24.62%)
Dizziness / Giddiness	Present (19)	14(73.68%)	1(11.11%)	4(21.05%)
	Absent (359)	234(65.18%)	37(10.30%)	88(24.51%)
Loss of Appetite	Present (159)	87 (54.71%)	18 (11.32%)	54 (33.96%)
	Absent (238)	173 (72.68%)	22 (9.24%)	43 (18.06%)
Loss of taste	Present (65)	46(70.76%)	6(9.23%)	13(20%)
	Absent (332)	214 (64.45%)	34(10.24%)	84 (25.30%)
Loss of smell	Present (19)	14(73.68%)	3(15.78%)	2(10.52%)
	Absent (378)	246(65.07%)	37(9.78%)	95(25.13%)
Headache	Present (42)	25(59.52%)	2(4.76%)	15(35.71%)
	Absent (349)	232(66.47%)	37(10.60%)	80(22.92%)
Muscle aches and pains, myalgia, bodyache	Present (125)	89(71.2%)	13(10.4%)	23(18.4%)
	Absent (266)	168(63.15%)	26(9.77%)	72(27.06%)
Generalized weakness or fatigue	Present (72)	37(51.38%)	8(11.11%)	27(37.5%)
	Absent (193)	131(67.87%)	18(9.32%)	44(22.79%)
Outcome of the disease				
Symptom		Recovered	Progressed & Recovered	Mortality
Fever	Present (319)	266(83.38)	35(10.97)	18(5.64)
	Absent (72)	64(88.88)	7(9.72)	1(1.38)
Cough	Present (238)	197(82.77)	26(10.92)	15(6.30)
	Absent (153)	133(86.92)	16(10.45)	4(2.61)
Sputum	Present (40)	33(82.5)	6(15)	1(2.5)
	Absent (350)	297(84.85)	36(10.28)	17(4.85)
Breathlessness	Present (183)	149(81.42)	20(10.92)	14(7.65)
	Absent (208)	181(87.01)	22(10.57)	5(2.40)
Sore throat	Present (104)	96(92.30)	4(3.84)	4(3.84)
	Absent (283)	231(81.62)	37(13.07)	15(5.30)
chest pain	Present (45)	41(91.11)	1(2.22)	3(6.66)
	Absent (345)	288(83.47)	41(11.88)	16(4.63)
Diarrhea	Present (82)	69(81.14)	7(8.53)	6(7.31)
	Absent (307)	259(84.36)	35(11.40)	13(4.23)
GI disturbances	Present (1)	1(100)	0(0)	0(0)
	Absent(387)	327(84.49)	41(10.59)	19(4.90)
Dizziness / Giddiness	Present(20)	17(85.00)	2(10.00)	1(5.00)
	Absent(351)	297(84.61)	37(10.54)	17(4.84)
Loss of Appetite	Present(154)	129(83.75)	19(12.33)	6(3.89)
	Absent(236)	201(85.16)	23(9.74)	12(5.08)
Loss of taste	Present(65)	59(90.76)	5(7.69)	1(1.53)
	Absent(325)	271(83.38)	37(11.38)	17(5.23)
Loss of smell	Present(319)	315(98.74)	3(0.94)	1(0.31)
	Absent(371)	315(84.90)	39(10.51)	17(4.58)
Headache	Present(40)	35(87.50)	4(10.00)	1(2.50)
	Absent(344)	291(84.59)	35(10.17)	18(5.23)
Muscle aches and pains, myalgia, bodyache	Present(121)	106(87.60)	12(9.91)	3(2.47)
	Absent(263)	220(83.65)	27(10.26)	16(6.08)
Generalized weakness or fatigue	Present(85)	70(82.35)	9(10.58)	6(7.05)
	Absent(389)	260(66.83)	32(8.22)	12(3.08)

On evaluating the severity of disease based on oxygen support, 15 out of 19 were severe, 1 was moderate and 3 were mild at admission.

At the time of admission, 18 out of these 19 patients had fever, 15 had cough, 14 complained of breathlessness, 6 had diarrhoea, 6 had generalized weakness and fatigue, 4 complained of sore throat, 3 had chest pain, muscle aches and pains, myalgia, body ache while 1 each had sputum, headache, loss of taste, loss of smell and dizziness.

On admission, all patients had abnormal levels of CRP and Ferritin, 13 out of 14 had increased levels of D-Dimer and 12 out of 13 had increased levels of IL6.

DISCUSSION

CoronaVirus Disease (COVID-19) is a respiratory illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV2). Currently, world is amidst the pandemic of COVID-19 that originatedin Wuhan, China in December 2019[15]. Amongst other, uncontrolled immune reaction termed as Cytokine storm is considered to immunopathological injury to lungs, leading to severe decline of the patients [16].

COVID-19 has shown variable clinical course ranging from mild symptoms such as fever, dry cough, and dyspnoea to acute respiratory distress syndrome (ARDS) which may also cause death [17,18]. Variability in the prognosis and clinical presentation has made it important to understand the factors that can affect the severity and outcome of the disease.

Now there are 29.1 million COVID -19 patients worldwide out of which 19.7 million have recovered completely and 925000 have succumbed to this disease. Worldwide mortality percentage is 4.2%. The mortality rate in some countries is higher than others based on socio-economic factors and availability of healthcare services. In India, till today there have been 4.85 million cases out of which 3.78 million cases have recovered completely and 79,722 patients have passed away. Which means so far in India, 77.93% of patients have recovered completely whereas case fatality rate is 1.64%. Some states and cities in India show a higher case fatality rate. Maharashtra has 1.06 million cases with 29,531 fatalities which is 2.7%. However, Mumbai has shown the highest fatality rate reaching 5.4% [19]. We found that in the patients admitted to our hospital, 24.37% cases were severe with a fatality rate of 4.7% which has been lower than the cities average fatality rate.

Association of demographic factors with severity and disease outcome

Older age, male gender, associated comorbidities including diabetes, hypertension, other medical conditions such as pregnancy and cancer are some of the known factors which can negatively affect the outcome [17,18,20,21]. An advanced age has been identified as an independent factor responsible for increased risk of hospitalization, ICU admission and mortality [22]. In our study we observed that the disease was more prevalent in men and increasing age was found to be positively correlated to the increasing severity of the disease. Aging results in a weakened immune modulation along with increased levels of chronic inflammation. This can lead to impaired immune response at the time of acute phase of COVID infection and chronic inflammation can facilitate the course of cytokine storm [21]. Older age also increases the probability of having associated co-morbidities, which is another prognostic factor known to cause poor outcome. A retrospective observation from 113 deaths due to SARS-CoV2 in a cohort of 799 patients admitted in Tongji Hospital in Wuhan, displayed that the median age of deceased patients was 68 years, which was significantly older than the median

age of those who recovered (51 years) [22].We found a similar pattern in our population with highest percentage of death in the group of people aged 60 years or above (10.52%) and 0% mortality in people aged 40 years or below.

Effect of co-morbidities on disease severity and outcome
Diabetes mellitus

Diabetes has been found to be an independent factor which can lead to poor prognosis. A recent report has shown that, the 10.1–20% of total patients with COVID-19 have diabetes mellitus and 22.2% patients who had severe complications are with diabetes mellitus [22]. In our population we observed that the percentage of patients with severe disease was significantly higher in people with diabetes (44.6%) as compared to those without diabetes (17.39%). We also observed that a 5% higher percentage of mortality was associated with presence of diabetes. Diabetes is known to increase the risk of respiratory tract infection. In diabetes, decreased NKT cell activity and lesser number of immune cells cause impaired immunological function, which increases the chances of viral infections and the risk of poor outcome [23,24]. Impaired inflammatory cytokine reaction can also lead to severe complications in COVID patients having associated diabetes [22,23,24].

Hypertension

Hypertension HTN was found to be associated with COVID-19 in approximately 30% patients. In our population we observed (28.85%) of people had HTN. Percentage of patients with severe disease and mortality was almost doubled in people with hypertensionas compared to those without hypertension (Table 2). Hypertensive disorders as well as other cardiovascular diseases are commonly treated with the help of angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs). It has been that these medications can potentially increase the ACE 2 in the body. COVID-19 virus enters the host body by binding onto the ACE 2 receptors in the lungs which make antihypertensive drugs use a major factor in increasing the risk of infection.[25,26].

Other comorbidities that can lead to poor prognosis in COVID 19 are identified as COPD, cancer, and asthma [27,28]. We could not analyze the effect of these co-morbidities in our population due to lack of sufficient numbers.

Symptom occurrence

As per published literature, clinical course of COVID-19 can vary from fever, cough and fatigue to ARDS leading to death. Most of the people (85%) have mild symptoms. Symptoms usually start to appear after 2-14 days of infection; the average period of incubation was said to be 5.2 days [28,29]. We found similar results with our population. Most common symptoms being fever, cough, breathlessness, loss of appetite and bodyache. Presence of breathlessness was a significant determinant of severity and mortality (Table 3. Figure 3).

Treatment protocols for COVID-19

Unfortunately, there is no evidence of any effective treatment for COVID-19 until this date. Medical therapies that are being used to treat the disease are antiviral drugs, antimalarial drugs, antibiotics and symptomatic drug management [30,31]. Antiviral drugs possess vitro inhibitory properties that help to reduce the severity of the disease[32]. Our analysis showed lesser percentage mortality in patients that were administered antiviral medicines. *Hydroxychlroroquine (HCQ),* antimalarial as well as antirheumatic drug is usually prescribed to patients in the early and mild stage of the disease [33]. In our population 31% of the patients were given HCQ. Our analysis showed reduction in the percentage mortality in patients that took HCQ compared to those that did not. In case of increased levels of IL-6, *Tocilizumab,* a humanized monoclonal antibody administered in severe cases that show signs of cytokine storm [34]. Our analysis showed reduction in the percentage mortality upon administration of Tocilizumab. *Corticosteroids* have the ability to modulate the inflammatory response and immunopathological damage caused by COVID-19. These drugs are administered in moderate and severe disease. In our study 68.9% of patients were administered corticosteroids [35]. Majority of the patients that were administered combination of these medicines recovered completely without worsening of the disease severity.

Influence of biomarkers on severity and outcome of the disease

Significant literature has come in the light regarding the cytokine storm in COVID-19 which can further increase the complications and is responsible for poor prognosis. It is characterized by hyperinflammation, which leads to elevated serum C-reactive protein (CRP), IL-6, D-dimer, and hyperferritinemia. [36].In our study it was observed that the patients with severe disease had significantly elevated levels of CRP, D-dimer, IL-6 and Ferritin compared to the mild or non-severe patients. CRP showed moderate positive correlation with the severity of the disease suggesting that as the CRP levels rise disease severity increases.D-dimer is a useful as an indicator for development of acute respiratory distress syndrome (ARDS) in COVID-19 patients [38].In our study, increased D-dimer levels were suggestive of a poor outcome in COVID-19 patients. Ferritin is a key mediator of immune dysregulation [36]. In our study we found that ferritin levels on admission corelated poorly with the disease severity however, higher ferritin levels showed poor outcome. IL-6 is a primary mediator of inflammation. Elevated levels of IL-6 in COVID-19 patients was reported to be associated with an inflammatory response, respiratory failure, need of mechanical ventilation and/or intubation as well as mortality. Meta-analysis and meta regression studies consisting, showed that the mean IL-6 levels were more than three times higher in patients with severe or complicated COVID-19 compared to those with uncomplicated disease, and higher IL-6 levels were also associated with greater mortality[36]. We found a statistically significant moderate correlation between IL-6 and the severity of the disease suggesting increasing IL-6 levels are a marker of worsening of the disease. Although it is associated with poor prognosis, the majority of the patients with increased IL-6 levels showed complete recovery without progression.

Radiological findings in COVID-19

Bilateral lung involvement has been observed in 98% of the patients. In ICU patients, most common radiological finding on admission is bilateral multiple lobular, subsegmental areas of consolidation and bilateral ground-glass opacity. [37]Chest X-ray can play an important role in an early detection of COVID-19. The most common findings seen on Chest X-ray in COVID-19 patients are consolidation and ground glass opacities. In our study, 32.19% of patients showed multiple lobe involvement and almost everyone had a bilateral involvement. Another common chest X-ray finding seen was

peripheral lung opacities which are usually multifocal, either patchy or confluent [38]. Even in our population 31.11% presented with peripheral ground glass opacification and bilateral lower lobe involvement to be present in majority patients (52.99%). Pleural effusions in COVID-19 infected patients rare and late occurrence in the disease [39].

We used only chest X-ray findings to determine lung involvement in our study because of its reduced cost, fast result and easy availability, since the CT scan machines are still not readily available and costly [40].

Factors influencing mortality in COVID-19

When analysed, the we found that 19/402 patients i.e 4.7% of the patients progressed to mortality. Mean age of these patients was 57.68 years. The proportion of men (n = 13) was considerable more than women (n = 6). Maximum patients showed bilateral lung involvement, with ground glass opacification seen mainly in the mid and basal lobes. Almost all of them (15/19) were in severe stage of the disease at admission. This highlights the importance of early intervention. If patient do not seek early medical advice and hospital admission and wait to get admitted in the severe stage, chances of mortality are higher. Majority showed symptoms of cough, fever and breathlessness. It is important to note that majority of the patients had abnormal values of one or more biomarkers (CRP,IL-6, Ferritin, D-dimer). Increased levels of CRP and IL-6 have been shown to cause clinical deterioration in the patients. [18,21]

Limitation of the study

The study was a retrospective analysis of multiple factors on severity and outcome where possibility of effect of confounding factors cannot be excluded. One of the limitations of our study was using chest X-ray as a primary radiological marker of lung involvement. Because even if the chest X-ray is the primary radiographic exam to evaluate pneumonia, it is not accurate or sensitive as compared to chest CT scan.

CONCLUSION

There are multiple baseline risk factors affecting severity and outcome of COVID-19 like age, gender, diabetes and hypertension. Cough, fever and breathlessness were found to be the most commonly occurring clinical symptoms that were also associated with severe disease. On chest X-ray peripheral and lower lobe involvement was observed most often and many patients showed multilobe involvement. CRP and IL-6 showed statistically significant correlation with severity of the disease. Overall mortality in this study population was lower than the current average mortality in the region. Higher mortality was observed in patients with age more than 60 years, exhibiting comorbidities like diabetes and hypertension and having clinical symptoms like fever, cough and breathlessness. This study provides insight of various aspects of COVID-19 in hospitalized patients.

Author's contribution

Alok Sharma - Conceptualization, Supervision, Visualization, Methodology, Resources, Writing – Review & editing

Hemangi Sane – Conceptualization, Methodology, Data Curation, Project Administration, Supervision, Writing – Review & Editing

Nandini Gokulchandran - Project Administration, Writing – Review & Editing

Amruta Paranjape – Data entry, Data Curation, Investigation, Writing – Original Draft Preparation, formal analysis

Shruti Shirke– Data entry, Investigation, writing – original draft

Myola D'sa – Data entry, Investigation

ApekshaKalvit– Data entry, Investigation, writing – original draft

Chandali Mehta– Data entry, Investigation

Nikita Khokhane– Data entry, Investigation

Pooja Kulkarni - Methodology, **Project Administration**

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Consent for publication*:* Consent for publication was included in the informed consent

Availability of data and material*:* Data is available, if required.

Code availability*:* Not applicable

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