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Original Research Article

An observational study of treatment and outcomes of patients admitted in a dedicated Covid hospital in central India during second wave of Covid -19 pandemic

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ABSTRACT

Background and Objectives: The peak of second wave of corona virus disease in India was from mid March to mid May 2021 which was lethal. The present study was carried out with the objectives to find the characteristics, clinical presentation of patients and to co-relate these features with treatment outcomes - mortality and adverse effects.

Materials and Methods: This is an observational study carried out in patients admitted in a Dedicated COVID Hospital (DCH) with severe symptoms of COVID-19 with or without undergoing lab test for diagnosis. The patients were prospectively evaluated for demographics, clinical course, treatment offered and outcomes during a period from 15^{th} April to 19^{th} May 2021.

Results: Patients in age group of 45-61 years were most affected. Men were affected more as compared to women. All patients were offered treatment protocol as per updated National guidelines. Primary outcomes in terms of In- hospital mortality was 24.13% The In- hospital mortality was significantly more in patents above the age of 45 years as compared to patients below 45 years and also in patients with co-morbidity than in patients without it. The biomarkers of patients who died were found to be on higher side. Secondary outcomes –death post discharge was 8.04% and 2.29% of patients developed mucormycosis.

Conclusions: All the admitted patients had severe symptoms irrespective of confirmatory diagnosis and High –resolution computed tomography (HRCT) scores. All of them required mechanical ventilation, injection Remdisivir, injectable antibiotics, anti-coagulants, injection Methyl Prednisolone. Inspite of this management the In-hospital mortality was 24.13%.

1. Introduction

In March 2020, WHO in its press conference predicted India to become the hotspot for COVID -19 or show ways to tackle the pandemic situation to other countries.[1] India has experienced substantial increase of COVID-19 cases and deaths in second wave from mid March to mid May 2021. After USA and Brazil, India was the 3rd leading country based on the identified cases.[2] The second wave of corona virus took India by storm. All eyes set on Indian variant which was a game changer in COVID-19. It was proposed by International researchers that the second wave was due to a new variant indifferent to that of UK, Africa and Brazil. According to Global initiative on sharing all influenza data (GISAID), this variant being more contagious caused surge in cases particularly in some districts of Maharashtra and

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central India in Feb 2021. As the cases increased there was imbalance of demand versus supply of oxygen devices and anti viral medications for COVID -19. The critical care physicians faced an unmatched massive admission of patients with COVID-19 pneumonia requiring mechanical ventilation, leading to ICUs saturation.

It is important to recognize the demographic characteristics, clinical features, treatment offered and outcomes of patients during this second wave considering the substantial heterogeneity of the new variant.

We prospectively evaluated patients admitted to the DCH with following aims and objectives.

1. To study the demographic characteristics, co-morbid conditions, baseline laboratory and radiological findings of lungs, clinical course, treatment offered to the patients admitted in DCH.
2. To co-relate these features with the primary clinical outcomes in terms of in-hospital mortality, discharge on clinical cure
3. To follow up the patients after discharge for secondary outcomes like development of mucormycosis other ADRs including deaths.

2. Materials and Methods

2.1. Study population and settings

This observational prospective study was conducted at a DCH of a state government run tertiary care teaching institute in central India from 15^{th} April to 19^{th} May 2021, when this region had second wave of COVID 19 at its peak. Demographic details, co morbidities if any, vital parameters details, Oxygen saturation (SpO2), baseline laboratory parameters and radiological findings of lungs were recorded at admission and as per need by the treating team subject to availability of investigating kits. The patients were designated as COVID-19 positive by the real-time reverse transcriptase polymerase chain reaction (RT-PCR) test or by rapid antigen test (RAT). The patients admitted without any of these test done were designated as suspects. The patients were categorized as mild moderate and severe according to High –resolution computed tomography (HRCT) score of lungs mentioned on their case paper.[3,4] The patients were offered treatment by physicians treating them following the guidelines of Ministry of Family Health Welfare (MoFHW) for second wave of COVID -19.[5]

The patient who were on medications of Diabetes mellitus (DM) and hypertension (HT) were continued on them.

Patient's respiratory rate, heart rate and oxygen requirement was monitored. HRCT chest and lab monitoring was done as per need and availability.

The protocol of monitoring D –dimer and Interlukin -6 (IL-6) levels to be done if the COVID- 19 patient is deteriorating could not be followed as the kits were not available.

Table 1: Treatment protocol[5]

Drug	Dose regimen
O2 supplement with NIV	From 3-6 liters depending on SPO2
Inj Remdisivir	200 mg IV stat on day 1 followed by 100 mg IV daily for 4 days (5 days in total)
Injection Methyl Prednisolone (MPS)	40mg BD IV for 5 days
Low Molecular Weight Heparin	60mg BD SC for 7 days
Inj Piptaz (Tazobactum 500mg + Piperacillin 4 g))-	BD for7 days
Tab Favipiravir	1800mg BD on first day 400mg BD for day 7 days
Tab Vit C 50mg	1 tab BD for one month
Tab Zinc 50 mg	1 tab BD for one month

NIV –Non-invasive ventilation, SPO2 – Oxygen saturation, IV-intravenous route,

Primary clinical outcomes in terms of in-hospital mortality, clinical cure and discharge or discharge against medical advice (DAMA) was noted. The patients were followed up post discharge for secondary outcomes -adverse drug reactions (ADRs) if any including mucormycosis, multisystem inflammatory syndrome and deaths. The study was approved by the Institutional Ethics Committee.

2.2. Statistical analysis

Data were expressed as mean ± SD, median [interquartile range (IQR)], or percentages, as appropriate. Qualitative or categorical variables were described as proportions. To co-relate primary outcome with demographic characteristics, severity of disease, co-morbidity Fisher Exact test was used. $P < 0.05$ was considered to be statistically significant.

3. Results

Data of 87 admitted patients could be collected. Demographic and baseline characteristics of patients are summarized in Table 2. Maximum patients were in age group of 45-61 years. Males were affected more than females. All patients irrespective of confirmed diagnosis by RT-PCR and severity of disease by HRCT scoring required mechanical ventilation. Age and gender of patient in relation to severity of disease is presented in Table 3. Demographic / clinical characteristics and primary outcomes of patient is presented in Table 4. The gender of patients is not significantly related to severity of the disease and outcomes. In hospital mortality was significantly more in patents above age of 45 years as well as in co-morbid patients but was not significantly related to confirmatory diagnosis of disease. Prognostic laboratory parameters of patients on admission

are presented in Table 5. The investigations like C-Reactive protein (CRP), Aspartate aminotransferase (AST), Alanine aminotrasferase (ALT), total protein, total albumin, serum urea, serum creatinine were carried out in 24 patients only. Lactate Dehydrogenase (LDH) and serum ferritin could be done only in 6 and 3 patients respectively. In rest of the patients these investigations could not be carried out due to unavailability of kits. D-dimer, an important parameter in COVID could not be done in any of the patients. In –hospital mortality was 21(24.13%) and 7(8.04%) patients died after going home. So total mortality is 28(32.18%).

3.1. Details of patients who died in hospital

Ten (11.49%) patients died within 5-7 days of admission, their SPO2 on admission was between 38-58, six (6.89%) patients died within 7- 8 days of admission, their SPO2 on admission was 61-67, five (5.74%) patients died within 9-10 days of admission, their SPO2 on admission was 67-86. Inflammatory bio-markers of patients with in-hospital mortality is shown in table 6. Investigations were not done in all patients due to unavailability of kits, CRP could be done in 10 patients and in all the 10 it was raised. Serum creatinine was done in 7 patients and it was raised in 2 patients. Serum urea was done in 7 patients and it was within normal limits in all 7. Total bilirubin and direct bilirubin was done in 7 patients and raised in all. Total protein was done in 7 patients and raised in 5. Total albumin was done in 7 patients and raised in 2. LDH was done in 2 and raised in both patients while serum ferritin was done in one and that was raised.

4. Discussion

It has been reported in the literature that demographics influences presentation of COVID-19. In the present study patients admitted with symptoms fall in age group of 21-85 years with maximum patients in 45-61 years of age. In the Indian scenario it has been observed that the infections across various age groups in the first and second wave have remained almost the same sparing the childhood age.[6] Jakhmola et al. in their study compared the occurrence of COVID -19 cases and deaths in different age groups and found the least sufferers were in the age group of 0-19 years. The authors explained that this could be due to reduced ACE-2 in children's nasal epithelium.[7] Implementation of lockdown and closure of the educational institutes in India must have reduced the exposure of children and adolescent population to the virus to some extent during both waves. Moreover the middle age population being more productive is exposed more in society and hence vulnerable. In the present study age was not significantly related to severity of the disease but In- hospital mortality was significantly more in patents above age of 45 years than in patients below 45 years. These findings are analogues to that reported earlier.[8]

Table 2: Demographic and baseline characteristics of patients (n=87)

Parameters	Value n(%)
Age(years)	
Mean± SD	55.18±13.72
Range	21-85
IQR	45-61
Median	56
Gender	
Male	58(66.66)
Female	29(33.33)
Diagnosis	
RTPCR positive	54(62.06)
RAT positive	7(8.07)
Suspects	26(29.88)
Severity on admission categorized by HRCT Scores n(%)	
Mild	3(3.44)
Moderate	46(52.87)
Severe	38(43.67)
Co morbidities	
DM	13(14.94)
HTN	11(12.64)
CKD	8(9.19)
Multiple Co morbidities	6(6.89)
On admission per cent oxygen saturation (SPO2) n (%)	
<93	81(93.10)
>93	6(6.89)
On admission Respiratory rate (breaths/min) n (%)	
<30	6(6.89)
>30	81(93.10)
On admission HR n (%)	
<100/min	40(45.97)
>100/min	47(54.02)
Mechanical ventilation	
Non-invasive	87(100)
Invasive	0(0)

Data expressed in number (n) and percentage (%);SD-standard deviation; IQR, inter quartile range; RTPCR-Reverse transcription polymerase chain reaction; RAT- Rapid Antigen Test; HRCT-High Resolution computed tomography; DM –Diabetes Mellitus; HTN-hypertension; CKD- chronic kidney; HR –heart rate.

In the present study men were affected more than women which correlates with findings of other studies.[9–11] Some studies report female sex hormones is protective for COVID-19. In the present study, though the males were affected more than females but the gender of patients is not significantly related to severity of the disease and outcomes. This is contradictory to findings from other studies.[7,12]

In the present study, the In -hospital mortality was significantly more in patients with co-morbidities such as diabetes mellitus, kidney disease, cardiovascular disorders as compared to those without it. Co-existence of co morbidities with COVID-19 have consistently been reported as risk factors for adverse prospects on laboratory parameters. ICU admission. Patients with co morbidity are further liable to develop a more severe course and

Table 3: Age and gender of the patients in relation to severity of disease (n=87)

Parameter	Mild	Moderate	Severe	p-value
Gender				
Female	0	20	9	0.093
Male	3	26	29	
Age in years				
<45	1	8	14	0.077
>45	2	38	24	

Fischer Exact test

Table 4: Demographic / clinical characteristics and primary outcomes of patients (n=87)

Parameter	In hospital Mortality	Survived	Total	p-value
Gender				
Female	8	21	29	0.6046
Male	13	45	58	
Age				
45 and below	1	22	23	0.0098*
Above 45	20	44	64	
Diagnosis				
RTPCR positive	13	40	53	
RAT positive	1	6	7	0.930
Suspects	7	20	27	
Co morbidities				
Present	13	15	28	0.0024*
Absent	8	51	59	

Fischer Exact test
*p<0.001 highly significant

Table 5: Prognostic laboratory parameters of patients on admission

Parameter	Median (IQR)	(n)	Normal range
CRP (mg/dl)	45(37-69)	24	0-10
Se Creatinine (mg/dl)	0.8(0.72-1.3)	24	<1.2
Se Urea (mg/dl)	32(26-34)	24	<50
STB(mg/dl)	1.3(0.9-1.8)	24	<1.1
Direct bilirubin (mg/dl)	0.8(0.43-1.11)	24	<0.3mg/dl
LDH(U/L)	563(451-842)	6	<333
Se Ferritin (ng/ml)	625(600-671)	3	30-300
AST (U/L)	54(40-65)	24	<40
ALT(U/L)	45(35-55)	24	<40
Total protein(gm/dl)	4.14(3.12-6.24)	24	>6.5
Total albumin(gm/dl)	2.15(1.23-3.36)	24	>3.5

n-number of patients; data expressed as median and IQR(inter quartile range); CRP- C-reactive protein; STB-Serum Total bilirubin, AST- aspartate aminotransferase; ALT-alanine aminotransferase; LDH-lactate dehydrogenase

progression of the disease which increases the risks of mortality.[13–16]

In the current study it was found that some patients with severe symptoms of the disease were admitted without undergoing RT-PCR or RAT, and they were labeled as suspects. According to the ICMR, during the second wave labs were facing challenges to meet the expected testing target due to extraordinary case load and staff getting infected with Covid-19.[17] This could be the reason for this discrepancy.

In the present study the biomarkers of patients who died were found to be on higher side but lab investigations could be not be done in all patients on admission due to unavailability of kits. According to Clinical Management Protocol for COVID-19 (in adults) the biomarkers of deteriorating patients was to be done only with subject to availability of kits.[5]

In the present study treatment was given to the patient as per guidelines following management of severe cases.[5] All the patients irrespective of confirmed diagnosis by RTPCR had severe symptoms and they required oxygen

Table 6: Inflammatory bio-markers of patients with in-hospital mortality (n=21)

In hospital mortality (within days)	CRP mg/dl (0-10)	Serum Crea mg/dl (<1.2)	Serum Urea mg/dl (<50)	Total bili mg/dl (<1.1)	Direct Bili mg/dl (<0.3)	AST U/L (<40)	ALT U/L (<40)	Total Prot gm/dl (>6.5)	Total Albumin gm/dl (>3.5)	LDH U/L (<333)	Serum Ferritin ng/ml (30-300)
5-7	13	0.8	32	1.15	0.9	62	55	3.12	2.2	-	-
5-7	45	0.8	30	1.12	0.8	60	60	6.13	3.5	1014	-
5-7	84	-	-	-	-	-	-	-	-	-	-
5-7	59	1.3	32	1.6	0.9	58	36	4.14	2.2		-
5-7	65	-	-	-	-	-	-	-	-	-	-
5-7	69	0.7	34	1.17	0.9	54	45	5.13	2.2	575	625
5-7	71	-	-	-	-	-	-	-	-	-	-
5-7	72	-	-	-	-	-	-	-	-	-	-
5-7	80	-	-	-	-	-	-	-	-	-	-
5-7	99	-	-	-	-	-	-	-	-	-	-
7-8	-	0.68	28	2.01	1.41	82	78	7.82	4.1	-	-
7-8	-	-	-	-	-	-	-	-	-	-	-
7-8	-	-	-	-	-	-	-	-	-	-	-
7-8	-	2.1	34	1.8	0.43	45	32	2.5	1.1	-	-
7-8	-	0.74	23	1.32	1.1	26	23	2.1	1.1	-	-
7-8	-	-	-	-	-	-	-	-	-	-	-
9-10	-	-	-	-	-	-	-	-	-	-	-
9-10	-	-	-	-	-	-	-	-	-	-	-
9-10	-	-	-	-	-	-	-	-	-	-	-
9-10	-	-	-	-	-	-	-	-	-	-	-

CRP- C-reactive protein; Crea- Creatinine, bili=bilirubin, AST- aspartate aminotransferase; ALT-alanine aminotransferase; LDH-lactate dehydrogenase. (-) Indicates NA

therapy, anti-virals for COVID -19, anti-inflammatory Inj Methylprednisolone, pharmacological prophylaxis with low molecular-weight heparin for reducing incidence of venous thromboembolism, histamine-2 receptor blockers for protection of GI bleeding and stress ulcers. Investigational drug inj Remdesivir was also administered to each patient.

In the present study, primary outcomes in terms of In-hospital mortality was 24.13%. Secondary outcomes death at home after discharge was 8.04%, The Institute for Health Metrics and Evaluation (IHME) estimated COVID-19 killed an average 2,600 deaths a day (April 19, 2021), or 18,271 a week. The pandemic jumped from the 26th position (on Feb 22), causing an average 180 deaths per day, or 1,273 a week to 2^{nd} position on April 29,2021with 18271 deaths.[18] Mutation of virus caused increased mortality. The disease has heightened risk, but more importantly, an already poor healthcare infrastructure deteriorated across the country; lack of medical oxygen endangered lives.

The anti viral drug Inj Remdisivir has been introduced as potential drug for controlling mortality in COVID-19. Some studies support the use of this drug for this particular indication.[19] On 20 April 2021,the ICMR and Health ministry has said that the anti-viral drug Remdesivir is “not a life-saving drug in Covid-19" and does not reduce mortality. It said it is one of the investigational drugs approved for emergency use in treating hospitalized Covid-19 patients. - Emergency use authorisation allows Remdesivir to be used as experimental investigational drug in selected clinical condition of Covid-19. In the present study also in hospital mortality of patients is more in spite of use of Remdisivir.

When the patients were followed up after discharge it was found 2.29% patients developed mucormycosis. The reason could be associated, comorbidities corticosteroid therapy, ventilation, these are risk factors which make the patients prone to develop severe opportunistic infections.[20]

5. Conclusions

In the present study all patients had severe symptoms irrespective of confirmatory diagnosis and HRCT scores. All of them required mechanical ventilation, injection Remdisivir, injectable antibiotics, LMWH, MPS. Primary outcomes in terms of in hospital mortality was 24.13%. It was significantly more in the patents above the age of 45 years and in patients with co-morbidities. The gender of patients was not significantly related to severity of the disease and outcomes. 8.04% patient died post discharge, 2.29% of patients developed mucormycosis.

6. Limitations

The present study included patients admitted in only one hospital.

None of the women was pregnant in the present study group. Hence, we could not comment on outcome of these patients.

None of the admitted patient was vaccinated with COVID -19 vaccine hence we could not make a remark on vaccination status of the patient and development as well as course of COVID-19 in relation to vaccination.

7. Source of Funding

None.

8. Conflicts of Interest

No conflicts of interest.

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