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MORTALITY ANALYSIS OF COVID 19 CASES AT A TERTIARY CARE CENTRE IN WESTERN MAHARASHTRA

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ARTICLE INFO	ABSTRACT			
Article History: Received 13 th September, 2021	COVID 19 disease emerged in Wuhan, China and spread like a storm throughout the world including India. Mortality due to covid was of high concern during the pandemic.			
Received in revised form 11 th October 2021	Aim: The study was designed to analyze the various parameters in covid 19 non survivors and their correlation with mortality at a tertiary care hospital.			
Accepted 8 th November, 2021 Published online 28 th December, 2021	Material and Methods: This was an observational studyconducted in a dedicated COVID hospital, for 6 months from June 2020 to November 2020. Out of 1376 COVID 19 cases,332 were non-survivors. The various parameters in the non-survivors associated with mortality like age, sex, comprehension of the second study of the second			
Key words:	Results: Mortality showed a positive correlation with older age, male sex, multiple comorbidities,			
Mortality, COVID – 19, SPO2 at time of admission, comorbidities, inflammatory markers, HRCT, IL6, CRP, D-Dimer	low SPO2 level at the time of admission, raised inflammatory markers and high HRCT score. Conclusion: Male gender, advancing age, moderate to severe disease at the time of first visit to hospital, low SPO2 at the time of admission and associated comorbidities were the main factors leading to a high mortality. Inflammatory markers and CTSS played a definite role in predicting mortality.			

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INTRODUCTION

The emergence of coronavirus disease (covid 19) in Wuhan China, in December 2019 spread like a storm throughout the world in a short span of time and WHO declared the covid pandemic on 11thMarch, 2020. First case reported in India was on 30th January,2020 in Kerala, while the first death due to Covid 19 was on 10thMarch,2020 from Karnataka city.[1]

Global mortality till 2ndJanuary 2021 as released by WHO was around 2.2%.[2] Excess mortality was reported from studies done in China, USA, Europe & other countries.[3,4] Similar observations were made by studies done in many parts of India. [5] Even with excellent death reporting systems in many developed countries, covid deaths were undercounts of the true figures.[6]Mortality due to covid remained to be a great concern worldwide. High case fatality rate (CFR) indicated not only the severity of the disease but also the burden on existing infrastructure. Covid 19 infection showed a multisystem involvement with the severity of the disease varying with factors like age, gender, comorbidities, SPO2 at the time of admission, HRCT score, inflammatory markers etc. There may be an interplay between these factors leading to mortality in covid. However, there is no definite data showing the correlation between above parameters and mortality.Keeping this in mind, the current study was undertaken for a better understanding of the mortality due to covid 19. During this learning phase of the pandemic, every experience shared will be valuable to enhance our knowledge enabling us to handle the situation in a better way in relation to patient care and mortality.[3]

MATERIALS AND METHODS

The study was done on retrospective data from patients admitted in our dedicated covid hospital over a period of 6 months from June 2020 to November 2020. The files of the patients were referred to for the clinical data. The reports were received from the clinical laboratory and radiology departments. The parameters included were – covid positive RT PCR report, history of comorbidity, demographic variables, SPO2 at the time of admission, blood investigations like Renal functiontests, Liver function tests, D-Dimer, CRP, Ferritin, IL6, X-ray, HRCT, Antiviral treatment given, time of death after admission and days of survival. The data was filled in excel sheet and analysis was done with the help of statistician. Inclusion criteria: The study included data of all deaths from our institute due to confirmed COVID 19 as per WHO guidelines during the period of 6 months from June to November 2020.

Exclusion criteria: In case the data was not complete as per requirement of the study, these patients were excluded from the study.

Statistical Analysis: Data was analyzed for 332 deaths by using descriptive and inferential statistics. Statistical analysis was done by using SPSS-22 software. (IBM Corp. Armonk, New York, USA).Qualitative data was presented as frequency and percentages while mean and SD were obtained for quantitative data. Z-test (S.E. of mean) was used to check the mean difference in sample mean values and standard values. Unpaired t test (independent t test) was used to compare different laboratory and radiographic characters in patients having comorbidity and not having comorbidities. ANOVA was applied to compare means of laboratory and radiographic characters within 3 different SPO2 groups (<70, 70-90 and >90).

RESULTS

The study included retrospective data of all covid positive non survivors during the period of 6 months. Being a Tertiary care centre, our centre received mainly moderate to severe cases. The various clinical and laboratory parameters were studied and statistical analysis was done. The study includes mortality analysis of 332 deaths.

Case fatality rate

The case fatality rate was calculated as the ratio of number of deaths to total COVID-19 positive cases admitted in the hospital during study period.

Total covid positive cases were 1376; Survivors were 1044 (75.87%) and non-survivors 332, CFR was 332/1376x100 = 24.12%.

The distribution of covid positive patients from June 2020 to November 2020 showed that maximum patients - 455 were admitted in the month of August followed by 435 in September. The case fatality ratio was more in the month of October -35.76%

The median age of non-survivors was 62.5 years. It was seen that 46.3% of the patients who succumbed belonged to the age group between 61 to 80 years while 39.7% were between 41 to 60 years. There was only 1 patient below 20 years who died. In the age group of 21 to 40 years there were 21 (6.33%) patients and 24 (7.23%) were above 80 years.

The gender-wise distribution of patients in different age groups is shown in table 1.

Table 1 Age and gender distribution of non-survivors

Age group	Female - n (%)	Male – n (%)	Total (%)		
< 20	1 (100)	0	1 (100)		
21 - 40	8 (38.1)	13 (61.9)	21 (100)		
41 - 60	40 (30.3)	92 (69.7)	132 (100)		
61 - 80	36 (23.4)	118 (76.6)	154 (100)		
> 80	8 (33.3)	16 (66.7)	24 (100)		
Total	93 (28.0)	239 (72.0)	332 (100)		

It was seen that out of the 332 deaths, 239 (72%) were male patients and 93(28%) were females.

In the age group below 20 years there was only 1 female death. While in all the other age groups there was a male preponderance.

Study of comorbidities in non-survivors

The non-survivors were studied for the presence of one or more comorbidity. Out of total 332 non survivors, 86.14% (286) had at least one comorbidity, while only 15 % patients who died of covid were without any associated illness.

The distribution of patients having comorbidities is shown in table 2.

 Table 2 Comorbidities in non-survivors

Comorbidity	Frequency	Percentage %		
HTN	135	40.66		
DM	130	39.16		
Renal disease	62	18.67		
Anemia	50	15.06		
Cardiac disease	36	10.8		
Obesity	25	7.5		
Respiratory disease	20	6.0		
Neurological disorder	15	4.5		
Hepatic disorder	10	3.0		
Surgical ailment	5	1.5		
Immunocompromised	4	1.2		
state				
Malignancy	2	0.6		

Out of 332 patients, 202 (60.84%) patients had multiple comorbidities. Hypertension was seen as an associated comorbidity in 135 (40.6%) non-survivors, while diabetes mellitus was seen in 130 (39.16%) out of 332 deaths. Renal diseases like Chronic kidney diseases, acute kidney injury etc were seen in 62 (18.67%) out of 332 cases.

Among the other less commonly observed comorbidities anemia was seen in 15.06% cases and heart disease in 10.8% of them.

Study of various parameters in non-survivors at the time of admission

The non survivors were grouped in three as per the time lapse between admission and death. The SPO2 at the time of admission was noted. There were 5 out of total 332 patients who had come with invasive ventilatory support at the time of admission, so the SPO2 was studied in 327 non-survivors. The parameters like CRP, D-Dimer, Ferritin, IL6 and HRCT were studied in the patients who died of covid. The mean values of these parameters are shown in table 3.

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Table 3	Various	parameters	ın	non-survivors

Parameters	Range	Frequency	Percentage	Mean ± SD	
	< 24 hrs	97	29.22		
Time of death from	2 days to 7 days	173	52.11	4 25 + 4 10	
admission	> 7 days	62	18.67	4.55 ± 4.19	
	Total	332	100.00		
SPO2	<=70	88	26.91	77.87 ± 14.8	

	71-90	175	53.52	
	>90	64	19.57	
	Total	327	100.00	
	0-50	33	15.28	
CDD	51-100	50	23.15	105 10 + 44 74
CRP	> 100	133	61.57	105.19 ± 44.74
	Total	216	100.00	
	<1	25	9.90	
D Dimor (n a/ml)	1.1 - 3	113	44.84	466 + 207
D – Dinier (ng/nii)	> 3	114	45.23	4.00 ± 5.97
	Total	252	100.00	
	\leq 350	57	29.69	
Forritin (mag/ml)	351 - 1000	79	41.15	014.0 ± 842.20
Ferritin (meg/mi)	> 1000	56	29.17	914.9 ± 643.30
	Total	192	100.00	
	≤ 100	21	25.30	
II 6 (ng/ml)	101 - 500	25	30.12	$1275.26 \pm$
IL-0 (pg/III)	> 500	37	44.58	1782.35
	Total	83	100.00	
UDOT	Mild 0<=8	0		
	Moderate 8 to 15	17	13.38	Not applicable
TKC I	Severe >15	110	86.62	Not applicable
	Total	127	100.00	

The non-survivors were divided into 3 groups depending upon the time period between their admission and death. It was seen that there were 97 (29.22%) patients who died within 24 hours of admission. The mortality was 52.11% in those patients who were admitted between 2 to 7 days.

Out of 327 cases, 88 (26.91%) had SPO2 below 70%, while 175 (53.52%) had SPO2 between 71 to 90 % and 64 (19.57%) cases had more than 90% oxygen saturation at the time of admission.

Mean CRP, D-Dimer, Ferritin and IL6 were higher than standard values. The HRCT scores of all patients was more than 8 out of 20 and 86.62% non survivors had a score more than 15. Fig.1



Fig 1 CT showing diffuse lung involvement

Comparison of various laboratory parameters and days of survival with SPO2

The non survivors were divided into 3 groups based on SPO2 level of patients at the time of admission as shown in table 4 and the mean Urea, Creatinine, IL6 and days of survival of patients were studied in each group. ANOVA was used to find the statistically significant difference in means.

 Table 4 Comparison of laboratory parameters and days of survival with respect to SPO2 (ANOVA)

	Urea (184)	Creatinine(181)	IL6 (83)	Days of survival (332)
<70	68.61 ± 44.72	2.12 ± 2.09	1410.36 ± 1886.03	2.73 ± 3.06
70 - 90	67.90 ± 54.31	2.02 ± 2.32	777.60 ± 1280.86	4.57 ± 3.79
> 90	100.44 ± 87.49	3.80 ± 4.19	1991.24 ± 2187.20	5.84 ± 5.57
P value	0.013	0.002	0.038	0.000

In this study the mean values of urea, creatinine and IL6 were higher in the patients having SPO2 >90 and their values showed statistically significant difference when compared to the low SPO2 groups (p<0.05). The days of survival were significantly more in the patients having SPO2 >90 (p<0.05).

Comparison between comorbidities and various laboratory parameters in non survivors

The laboratory investigations were compared to see if there is statistically significant difference in the mean values of these parameters in patients with comorbidity and without comorbidity, as shown in table 5.

Table 5 Comparison of various laboratory parameters withrespect to comorbidities (Mean values of each parameter, N =number of cases)

Comorbidity	SGOT (N)	SGPT (N)	Urea (N)	Creatinine (N)	D-Dimer (N)	CRP (N)	Ferritin (N)	IL6 (N)
Vec	75.46	47.14	87.75	3.12	4.91	105.12	835.84	1194.09
1 05	(112)	(112)	(115)	(114)	(49)	(143)	(126)	(51)
No	127.24	81.73	55.06	1.36	4.30	105.33	1065.84	1404.62
	(63)	(63)	(69)	(67)	(32)	(73)	(66)	(32)
p value	0.249	0.195	0.000	0.000	0.497	0.974	0.090	0.608

It was observed that mean urea and creatinine showed statistically significant difference between those patients with and without comorbidity (p < 0.01). Mean D-Dimer was higher, but not significant in patients with comorbidities, whereas mean SGOT, SGPT, Ferritin and IL6 were higher in patients without comorbidities and showed no statistically significant difference (p>0.05).

Antiviral treatment received by non-survivors

The main line of treatment was antiviral therapy. We studied the data of patients who had been given Favipiravir and Remdesivir. Out of 332 non-survivors, Favipiravir was given to 68 (20.48%) patients and Remdisivir to 166 (50%) patients. Antivirals were not started in all due to renal or hepatic derangement at the time of admissions.

DISCUSSION

This study was conducted to analyse the mortality from COVID 19 illness, over a period of 6 months in a Tertiary care centre.

332 non-survivors out of the moderately and severely ill admitted patients were studied which reflected an overall case fatality rate 24.12%. In a study done in USA by Weinberger DM *et al* there was excess mortality during pandemic period (March 1 to May 30^{th} 2020) from 48 states as shown by

National Center for Health Statistics (NCHS) mortality surveillance system. Excess mortality provided an estimation of COVID 19 burden, severity and frequencies of COVID 19 pandemic.[7] Our findings are consistent with the metaanalysis done by Armstrong *et al* on 25 observational studies from centers across Asia, Europe and North America for patients admitted in ICU with COVID 19 infection and showed 41.6% mortality rate upto 31^{st} May 2020.They suggested that the in-ICU mortality from COVID 19 was higher than usual seen in ICU for other viral pneumonias.[8]In a study done by Chaumin Wu *et al* in China, CFR was reported to be 21.9% in February 2020.[9]

The median age of non survivors in our study was 62.5 years, the most affected age group being 61-80 years followed by 41-60 years. It is comparable to studies in China and Central Indiabut younger when compared to US and Italy (63 years).[5] Studies from European countries showed more CFR in elderly age group (> 70-80 years) due to high survival index as compared to Asian Countries. Older people had greater risk of developing ARDS due to less rigorous immune response and multiple comorbidities. [3,4,8]

In our study out of 332 deaths, 72% were male patients. Male preponderance of mortality is documented in many other studies done in US, China, Italy etc. Gender studies showed such distribution could be attributed to many factors like disparity in behavior and the possible effect of osetrogen which is protective in the females.[10,11]

Out of 332 deaths 85% patients had at least one associated pathological condition while 60.8% patients had multiple comorbidities. We observed that 21 cases who expired below 40 years of age had some or the other comorbidities like DM, HTN, CKD, Obesity or presented late for admission. Comorbidities have been identified as a significant factor in younger as well as older population.[3] The most common comorbidities were DM, HTN and renal dysfunction. Other less common associations were Anemia, Cardiac disease, obesity, respiratory diseases, Neurological disorders, Hepatic dysfunction, Malignancies, immune deficiencies, and surgical problems. A study done in Wuhan, China also supported our findings wherein 63% (43 out of 68) of non survivors had comorbidities.[12]

Associated cardiovascular disease with SARS COV 2 infection increased the risk of mortality. The sudden cardiac deaths observed in our patients could be attributed to acute coronary syndrome or myocarditis. A study published by Dalla Sornette *et al* also suggested that elderly and those with underlying medical conditions like DM, Cardiac disease or respiratory disease, immunodeficiency were more likely to develop severe illness.[3]Data from European Surveillance system (TESSy) from 21 countries showed that out of 5378 deaths, only 7.3% patients were without any associated illness. Similarly in Italy only 3.7% cases (out of 1890 deaths) were without comorbidities.[2] Obesity as a risk factor was noted in 7.5% of our cases, which was also reported to be more significant in younger patients by other authors.[13]

It was observed that significant mortality wasseen within 24 hours of admission (29.22%) and between 2 to 7 days (52.11%). Time of death is in direct proportion to the severity of illness and SPO2. There were many factors observed leading to late presentation like unawareness of hypoxia (silent hypoxia) till late stage, neglection of symptoms, self-

medication, social stigma of illness, unavailability of healthcare facilities in rural area, shortage of beds in wellequipped tertiary care hospitals due to surge of cases, economic constraints etc.

Hypoxia was observed to be a significant cause of death in all the non-survivors. A study done by Xie J *et al* in China showed that hypoxia is a major factor associated with high mortality.[14]Dr. Richasel Levitan, an intensivist from US pointed out the different phenomenon of silent hypoxia in COVID 19 pneumonia wherein the virus causes air sacs to collapse instead of filling with fluid or pus. Therefore, patients do not feel hypoxic even though their saturation level drops. As ability to remove O2 is efficient in people, they don't feel shortness of breath.[15]

With the help of pulse oximeter, blood saturation level (SPO2) can be measured easily and effectively. Hidden hypoxia can be detected after a 6-minute walk test even in patients whose SPO2 is > 95% at room air. Drop in SPO2 of more than 3% is significant. We followed the protocol of 6 min walk test for all admitted patients at least twice a day. Early detection of silent hypoxia and early oxygen supplementation showed to reduce mortality significantly.

A recently published article by Jessica Colarosst, Boston University tried to shed light on COVID 19 oxygen level mystery. They used computer modeling to test out different scenarios to explain how and why the lungs are insufficient to provide oxygen to the bloodstream.[16]Jacob Herrman, a biomedical engineer and his team suggested that lung of COVID 19 patients, showed blood vessels with tiny blood clots which drop the oxygen levels.[17]

Better understanding of pathophysiology is necessary to decide proper treatment modalities that could help constrict blood vessels, burst blood clots or correct a mismatched air to flow ratio.Prone positioning can help to oxygenate the posterior parts of lungs which are involved earlier in COVID 19.SPO2 levels can help clinicians to decide regarding treatment modality like supplemental O2, HFNO, NIV or mechanical ventilation.

During the cytokine storm in COVID 19 many inflammatory cytokines are released in blood like IL-1 β , TNF α , IL12, IFN γ , IP 10, VGEF etc which stimulate hepatocytes, macrophages, Kupffer cells to secrete ferritin. This dysfunctional and uncontrolled immune response progresses to DIC with either vascular occlusion or haemorrhage, hypoxia, hypotension leading to thrombotic storm, multiorgan dysfunction and ARDSa resulting in high mortality.[18]

We compared the mean values of parameters like RFT, LFT, IL6, Ferritin, CRP, D-dimer in three groups having mild, moderate & severe ARDS based on their SPO2 level at the time of admission. It was an interesting observation that mean RFT, LFT, IL6, d-dimer were higher in patients having SPO2 > 90%. This might suggest that cause of mortality in this subgroup would be some factor in addition to hypoxia like uraemia, hepatic dysfunction, cardiac, neurological or severe cytokine storm. Sudden cardiac deaths were also observed.

The mean values of CRP, D-Dimer, S.Ferritin and IL6, were quite higher than their normal range. Further research is needed to identify the extent of increase in inflammatory markers caused by SARS COV 2 or additional increase with associated comorbidities like DM, HTN, CKD and other chronic illness. The associated comorbidities weaken the innate immunity of patients and make them more prone for severe COVID 19 disease.Rapid rise in CRP levels along with IL6 in first 48-72 hours of hospitalization is predictor of lung damage and severity of infection.[18] In a study done in Turkey by Tural Onur S et al on Ferritin and mortality, high level of Ferritin was observed in non-survivor group.[19] Meta-analysis done in Beijing China by Linlin Cheng et al on 52 records of COVID 19 cases also suggested poor prognosis with high level of ferritin. Levels of ferritin > 500 mg/ml predicts upto 58% mortality.[20] Meta-analysis done in China by Xie J et al on association of elevated inflammatory markers and severe COVID 19 suggested positive correlation.[14] Study done by Zhang J et al suggested that baseline IL6 concentration was highly predictive of in-hospital death for COVID19. They predicted a high death rate with serum cut-off level of 37.65 pg/ml.[21] In a cohort in Munich, elevated IL6 (>80pg/ml) was strongly associated with a 22 times higher need for mechanical ventilation compared with lower IL6 levels.[22] In our study, the mean values of IL6 in nonsurvivors correlated with these studies.

HRCT was done in 127 (38.25%) cases of our non-survivors. Many patients could not be sent for HRCT due to hypoxic condition. HRCT was found to be not only very effective modality in detecting COVID 19 infection as well as predicting severity of disease and detecting early cases who do not have any symptoms or show no lesions on CXR. CORAD (COVID 19 Reporting and Data System) was followed for reporting. In our study we found that out of 127 HRCT done among non survivors, 110 had score > 15 and 17 had score < 15. Gross analysis of these 17 cases suggested cause of death other than hypoxia like uraemia, cerebrovascular disease, sudden cardiac death, malignancy etc. O2 requirements increased with increase in CT severity. Most patients with CT severity > 15 presented with SPO2 < 70% at RA. They required either high O2, HFNO or NIV in admission. This might be due to direct damage to lung by Virus causing alveolar wall inflammatory changes, that hamper O2 exchange, leading to ARDS pulmonary fibrosis and finally death. In a cohort of 87 asymptomatic carriers (54%) on the international cruise ship "Diamond Princess", CT had shown bilateral GGO in SARS COV 2 positive cases.[23]According to Kaplan - Meire analysis, the risk of death significantly increased with the increase of CT score value using an estimated cut off of ≥ 18 hazard ratio on a 24 day follow up period i.e. short term follow up of mortality.[20] Similar observations were also reported by Colombi et al who demonstrated a positive correlation between HRCT lung involvement & ICU admission and deaths.[24]

Among our non-survivors, 68 patients were on Favipiravir, but discontinued in view of ongoing hypoxia & renal or hepatic dysfunction. Remdesivir another antiviral drug was used rampantly in all moderate to severe illness cases. In our study, Remdesivir was used in 166 (50%) non-survivors. Patients having hepatic or renal dysfunction on admission or developed later on, were not given Remdesivir. A double-blind study done by Beigel JH et al. showed superiority of Remdesivir to placebo. The study demonstrated shortening the period of illness, oxygen requirement, early weaning from HFNO/ NIV, shortening length of stay in hospital. However Kaplan Meier estimate of mortality by day 29 was 11.4% in Remdesivir group & 15.2% in placebo group.[25] FDA issued an emergency use authorization of Remdesivir in May 2020 (

modified in August 2020) to permit its use in adults & children suffering from covid 19. However high mortality despite its use raised a question on its efficacy. Remdesivir alone may not be useful for severely ill patients. [25] Tocilizumab (IL6 inhibitor) was used in 5 of our non survivors. For severe covid 19 pneumonia & ARDS cases – Antiviral drugs, corticosteroids, anticoagulants, immunomodulatory drugs were shown to be in extensive use in China & other Asian countries but less frequently used in Europe & North America. Data suggested that there was no specific therapy that reduced ICU mortality.

Current strategies are evaluating other immunomodulatory drugs like CD4 20 inhibitor (Itolizumab), JAK inhibitor(Baricitinab), Anti VEGF (Bevacizumab) to modify the dysregulated immune response leading to cytokine storm & high mortality.[18]

Emerging data suggests that covid 19 has more protracted course than was previously thought & more research is required to face new threats. Till date no satisfactory solution has been found to encounter these challenges. Vaccination has given a ray of hope amidst current situation. Vaccination has to be introduced in community at a war front to improve herd immunity.

CONCLUSION

Male gender, advancing age, moderate to severe disease at the time of first visit to hospital, low SPO2 at the time of admission and associated comorbidities were the main factors leading to a high mortality. Inflammatory markers and CTSS played a definite role in predicting mortality.

The usefulness of antivirals favipiravir or remdesivir is doubtful in late stages of the disease which needs to be confirmed.

This is for the first time that public health is given priority at such a large scale at global level. The tertiary care centres all over India and Maharashtra with limited resources, infrastructure and manpower did their best to handle the pandemic and cater the covid 19 patients. An effective and collaborative approach by government authorities and medical professionals will help to face such pandemic situations in future.

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