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Clinical Characteristics of Chronic Kidney Disease Patients Hospitalised with SARS-CoV-2 Infection

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Abstract: ***We did a prospective observational study to study the clinical characteristics and mortality due to SARS-CoV-2 infection in chronic kidney disease (CKD) patients. We included CKD patients of stage 3-5 as well as patients who were on maintenance hemodialysis, who were diagnosed with SARS-COV-2 infection. We studied their clinical course. Independent Student's t test/ Mann Whitney U test or one way analysis of variance/ Kruskal- Wallis test, whichever is appropriate was done. We included Seventy eight patients who were on hemodialysis and 100 patients who were on medical management. We found that percentage of patients with critical disease increased with the stage of CKD as was the oxygen therapy requirement and mortality. We found that encephalopathy, oxygen therapy requirement, ICU requirement, critical disease were significantly increased in CKD stage 3-5 when compared to patients on maintenance hemodialysis. Mortality in hemodialysis patients was 15 % which was half the mortality seen in patients who were on medical management. We also found that age more than 60 years, presence of hypotension, encephalopathy during hospital stay and ICU requirement were significantly associated with mortality. SARS CoV-2 infection had worse effects on CKD patients on medical management when compared to patients on hemodialysis.***

Keywords: CKD, mortality, hemodialysis, SARS-CoV-2, severity

1. Introduction

SARS-CoV-2, a novel virus of the Coronaviridae family of RNA viruses caused a widespread outbreak of the disease COVID-19. India reported the first case on 30 January 2020. Since the outbreak, patients flooded the hospitals with varying presentations. Elderly patients, pregnant females, diabetics, hypertensives, patients with chronic kidney disease, malignancy were considered to be at high risk for infection[1]. Chronic kidney disease (CKD) patients on dialysis represent a unique population. The dysregulated immune system puts them at high risk for infection. The associated comorbidities like Diabetes mellitus, hypertension and old age also contribute to high risk. Frequent contact with the dialysis facility and health care workers increase this risk. A metaanalysis indicates that chronic kidney disease patients have a higher likelihood of severe COVID-19 infection without adjusting for other comorbidities.[2] On the other hand, immune blunting in patients with end stage renal disease is postulated to protect them from cytokine storm. Low Angiotensin converting enzyme 2 (ACE 2) levels in chronic kidney disease patients may offer protection as ACE 2 is the receptor for SARS-CoV-2 virus. Protective role of heparin administration during hemodialysis on severe COVID 19 infection is unknown. As these patients are on regular follow up, they are likely to be screened early in case of symptoms like fever, breathlessness, cough leading to early diagnosis and treatment. The clinical characteristics, severity and outcome of SARS-CoV-2 infection in CKD population are unknown. Understanding the same will help in risk stratification and appropriate management.

Aims and Objectives

1) To study the clinical characteristics and outcomes of stage 3-5 chronic kidney disease patients infected with SARS-CoV-2.
2) To study the clinical characteristics and outcomes of patients on maintenance hemodialysis infected with SARS-CoV-2.
3) To compare the disease severity, mortality in CKD stage 3-5 patients and maintenance hemodialysis patients infected with SARS-CoV-2
4) To study the factors associated with mortality in CKD patients admitted with COVID-19 infection.

2. Materials and Methods

Settings and design:
Our study is a prospective observational study. It was conducted in Kilpauk Medical College and Hospital, Chennai, India from May 2020 to January 2021.

Inclusion Criteria:
We included chronic kidney disease patients of stage 3-5 as well as patients who were on maintenance hemodialysis who were diagnosed with SARS-COV-2 infection. COVID 19 was diagnosed either with a nasal swab or throat swab with RT-PCR positive for SARS-COV-2 or with Computed Tomography of chest showing COVID pneumonitis.

Exclusion criteria: We excluded renal transplant patients.

Study Procedure:
Institute ethics committee approval was obtained. Written consent was obtained from the patients or from their relatives if they were critically ill. Demographic details, duration of symptoms and their progression, comorbidities, duration of chronic kidney disease, dialysis vintage details were noted. Vital signs including pulse rate, blood pressure, oxygen saturation, respiratory rate were documented. Patients were followed up during their hospital stay till discharge or death. Investigations which were done during their hospital stay were noted. Presence of hypotension, vasopressor requirement, oxygen therapy requirement, requirement of Intensive care unit (ICU) care, other features like encephalopathy, acute respiratory distress syndrome were documented. Patients with CKD stage 3-5 were followed up and assessed for clinical signs of volume overload. Urine output, serial serum creatinine values, serum electrolytes, acid base gas analysis were monitored and renal replacement therapy was initiated according to clinical indications. Patients were categorized according to Ministry of Health and Family Welfare, Government of India guidelines. Patients were treated according to institutional protocol.

Categorisation of COVID-19.
Asymptomatic illness was defined as throat or nasal swab positive for SARS-CoV-2 infection but no symptoms and signs of COVID-19 illness. Patient is said to have mild disease if any of the signs and symptoms of COVID-19 are present with oxygen saturation more than 94 % on room air. Individuals with signs and symptoms of COVID-19 with saturation 90-94 % on room air were identified to have moderate disease and individuals with signs and symptom s of COVID-19 with saturation less than 90% in room air were classified to have severe disease. Critical illness is characterised by respiratory failure, septic shock, and multiple organ dysfunction.

Definitions
Acute Respiratory Distress Syndrome (ARDS) is defined by acute onset of respiratory failure, hypoxemia defined by PaO2/Fio2 ratio $\leq$ 200 mm Hg and no evidence of left atrial hypertension or a pulmonary capillary wedge pressure <18 mm Hg. Sepsis is defined by life threatening organ dysfunction. Septic shock is defined as patients who fulfill the criteria of sepsis, who despite adequate fluid resuscitation, require vasopressors to maintain a mean arterial pressure $\geq$ 65 mm Hg and have a lactate > 2 mmol/L. Thrombocytopenia is defined by platelet count less than 1 Lakh. Hyponatremia is defined as serum sodium levels less than 135 mEq/L. Hyperkalemia is defined as serum potassium levels more than 5.5mEq/L

Hypotension is defined by a systolic blood pressure less than 90 mm Hg or a mean arterial pressure of less than 65 mm Hg or requirement of vasopressors to maintain blood pressure. Encephalopathy is defined as a decline in mental status, asterixis.

Method of Statistical Analysis:
Patient's demographic details, clinical and laboratory parameters were collected and recorded as per the study protocol. All categorical data related to patient's socio-demography (such as gender, domicile), clinical characteristics (hypotension, ARDS, encephalopathy, thrombocytopenia, outcome (alive/dead), requirement of dialysis, ICU requirement, oxygen therapy requirement were presented as frequencies/ percentages. All continuous variables like age, duration of illness, number of days in hospital, number of days on ventilator were presented as mean ±SD. Data was tested for normality using Kolmogorov Smirnov test. Non normal data was presented as median with range. The comparison of parameters in relation to clinical characteristics were carried out by using Independent Student's t test/ Mann Whitney U test or one way analysis of variance/ Kruskal- Wallis test whichever is appropriate based on the normality of data and number of groups. All statistical analysis was carried out with 5% significance and p value < 0.05 was considered significant.

3. Results

We included 178 chronic disease patients who were admitted with COVID-19. Seventy eight patients were on hemodialysis and 100 patients were on medical management. Almost fifty percentage of patients in both hemodialysis group and medical management group were between 40-60 years. Around 45 percentage of patients who were on medical management were above 60 years in contrast to only 23 percentage of patients in hemodialysis group who were aged more than 60 years. Fifty six percentage of patients who were on medical management and 37 percentage who were in hemodialysis group were diabetics (Table-1).

Table 1: Baseline characteristics of study patients

	CKD patients on dialysis, N = 78	CKD patients on medical management, N = 100
Age group, N (%)		
• 20-39 years	19 (24)	4 (4)
• 40-59 years	41 (53)	51 (51)
• > 60 years	18 (23)	45 (45)
Males, N (%)	49 (62)	73 (73)
Diabetics, N (%)	29 (37)	56 (56)
Hypertensives, N (%)	67 (85)	75 (75)

The incidence of COVID-19 infection in patients undergoing hemodialysis in our centre was 25 %. Among all the CKD patients who were on hemodialysis, twenty-five percentage of hemodialysis patients were diagnosed with COVID-19 illness when they were screened prior to procedure or because they were a contact of a COVID-19 positive patient. Fever, cough and breathlessness were the common symptoms at admission. Fever, breathlessness was present in only 30 % of hemodialysis patients. Patients were categorized based on saturation and clinical features. One third of patients in both the groups had mild disease and another ten percentage had moderate disease. Fifty-one percentage of patients in the medical management group had critical disease when compared to 15 percentage of patients who were on hemodialysis. (Table-2)

Table 2: Symptomatology and disease severity of study patients

	CKD patients on dialysis, N = 78	CKD patients on medical management, N = 100
Symptoms		
Fever, N(%)	24 (31)	47(47)
Cough, N(%)	27 (35)	35 (35)
Breathlessness, N(%)	29 (37)	56(56)
Asymptomatics, N(%)	19 (25)	0
Disease Severity		
i. Mild disease, N(%)	28 (36)	31 (31)
ii. Moderate disease, N(%)	8 (10)	10 (10)
iii. Severe disease, N(%)	11 (14)	8 (8)
iv. Critical disease		
ARDS, N(%)	2 (3)	4 (4)
Sepsis, N(%)	6 (7)	36 (36)
Septic shock, N(%)	4 (5)	11 (11)

During the hospital stay, four hemodialysis patients developed hypotension and required vasopressors. The median duration of vasopressor requirement was 2 days. Eleven patients who were on medical management required vasopressors with the median duration being 2.5 days. More number of patients who were previously on medical management developed encephalopathy.

Oxygen therapy was given for 60 percentage of patients in medical management and only for 38 percentage in hemodialysis group. Median duration of oxygen therapy was 5 days (Table-3).

Overall mortality of chronic kidney patients was 23.5 % in our study. Among the patients who were on hemodialysis infected with COVID-19, the mortality was 15 % which was half of the mortality seen in patients who were on medical management (Table-3). Institute mortality during the same period was fifteen percent.

Table 3: Clinical characteristics of study patients during hospital stay

	CKD patients on dialysis, N = 78	CKD patients on medical management, N = 100
Hypotension during hospital stay, N(%)	4 (5)	11 (11)
Median duration of vasopressor requirement (days)	2	2.5
Encephalopathy, N(%)	6 (8)	28 (28)
Coagulopathy, N(%)	4 (5)	2 (2)
Oxygen therapy requirement, N(%)	28 (38)	60 (60)
NRBM	16	39
High flow nasal oxygen	7	7
Positive pressure ventilation	5	12
Mechanical ventilation	0	2
Median duration of oxygen therapy (days)	5	5
Associated infections, N(%)	7 (9)	15 (15)
	Urinary tract infections (4)	Emphysematous pyelonephritis (2)
	Cathetre associated blood stream infection (2)	Other urinary tract infection (10)
	Bedsore (1)	Diabetic foot ulcer (1)
		Cellulitis (1)
		Rhinocerebral Mucormycosis (1)
Thrombocytopenia, N(%)	9 (11)	10 (10)
Hyponatremia, N(%)	5 (6)	14 (14)
Hyperkalemia,N(%)	4 (5)	14 (14)
Requirement of ICU stay, N(%)	15 (19)	35 (35)
Median duration of ICU stay (days)	6	5
Median duration of hospital stay (days)	8	8.5
Mortality, N(%)	12(15)	30 (30)

Among the 100 patients who were on medical management previously, 47 patients were initiated on renal replacement therapy due to indications like oliguria, refractory metabolic acidosis, refractory hyperkalemia, encephalopathy and refractory volume overload. Twenty one patients were initiated on hemodialysis and 26 patients were put on acute peritoneal dialysis. Acute peritoneal dialysis was done due to hemodynamic instability and inability to shift to hemodialysis room due to severe hypoxia.

In our study, we found that percentage of patients with critical disease increased with the stage of chronic kidney disease as was the oxygen therapy requirement and mortality (Figures-1,2,3).

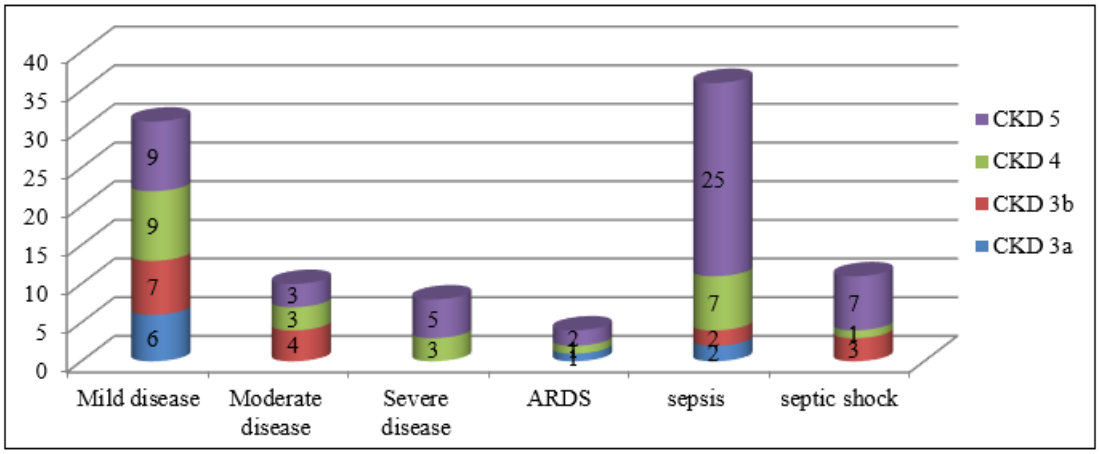

Figure 1: Bar diagram depicting disease severity in each stage of CKD

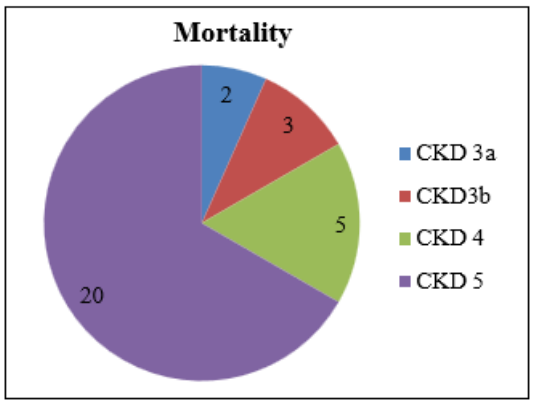

Figure 2: Pie chart showing mortality percentage in each stage of CKD

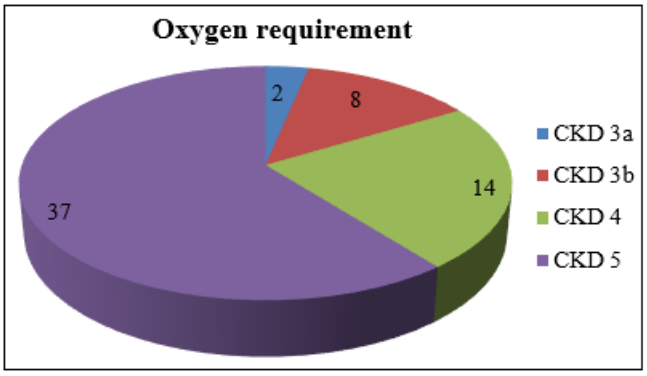

Figure 3: Pie chart showing percentage of patients requiring oxygen therapy in each stage of chronic kidney disease

We compared clinical parameters in patients who were on hemodialysis as well as on medical management (Table-4). We found that encephalopathy, oxygen therapy requirement, ICU requirement, critical disease was significantly increased in CKD stage 3-5 patients on medical management when compared to patients on maintenance hemodialysis. Mortality was also significantly increased in patients on medical management.

Table 4: Comparison of Clinical parameters in CKD patients on medical management and on Hemodialysis.

Variable	CKD on maintenance dialysis, (n=78), N (%)	CKD 3-5, on medical management (n=100), N (%)	Statistical significance, (P value)
Severe disease, n=19	11 (14)	8(8)	0.19
Critical disease, n=63	12 (15)	51 (51)	**<0.05***
Hypotension, n=15	4 (5)	11 (11)	0.39
Encephalopathy, n=34	6 (8)	28 (28)	**0.0006***
Coagulopathy, n=6	4 (5)	2 (2)	0.718
Oxygen therapy requirement, n=88	28 (38)	60 (60)	**0.0007***
Requirement of ICU stay, n= 50	15 (19)	35 (35)	**0.014***
Median duration of hospital stay, days	8 days	8.5 days	0.65
Mortality, n=42	12(15)	30 (30)	**0.022***

*p value < 0.05 – considered statistically significant

We also found that age more than 60 years, presence of hypotension, encephalopathy during hospital stay and ICU requirement were significantly associated with mortality (Table-5).

Table 5: Comparison of clinical parameters between survivors and non-survivors

Variable	Survivors, (n=136), N (%)	Non survivors, (n=42), N (%)	Statistical significance, (P value)
Age > 60 years, n=63	38 (28.6)	25 (66.6)	**0.008***
Male, n=122	90 (66)	32 (76)	0.22
Diabetics, n=85	66 (48.5)	19 (45.2)	0.7

Hypertensives, n=142	111(81)	31 (73)	0.74
Hypotension, n=15	3(2.2)	12(28.5)	**<0.05***
Encephalopathy, n=34	16(11.7)	18(42.8)	**<0.05***
ICU stay, n=50	14(10)	37(88)	**<0.05***

*p value < 0.05 – considered statistically significant

4. Discussion

In our study, we found that the common symptoms at presentation of chronic kidney disease patients who were on medical management were fever and dyspnea. Fever and dyspnea was seen only in around 30 percent of hemodialysis patients. Twenty five percentage of patients who were on hemodialysis were asymptomatic. Other studies also show that patients on hemodialysis with COVID infection had less fever (47% versus 90 %) and dry cough (49 % versus 71%).[3]

We found that oxygen therapy requirement, ICU requirement, critical disease and encephalopathy were more among patients who were in stage 3-5 when compared to hemodialysis patients. Similar findings were seen in a in a study by Ozturk et al. They found that CKD stage 3-5 patients who were infected with COVID-19 were found to have more ICU requirement and mortality when compared with patients on hemodialysis and renal transplant patients.[4] On the contrary, study by Wu J et al found that more patients on hemodialysis received non-invasive ventilation and had a higher rate of complications including shock, acute respiratory distress syndrome, arrhythmia and acute cardiac injury. The authors concluded that patients on hemodialysis with COVID-19 were at a higher risk of death. [3] Another retrospective analysis revealed an association with more severe illness and more adverse outcomes in hemodialysis patients who presented with ARDS, acute heart failure, septic shock. [5]

The ICU requirement of stage 3-5 CKD patients was 39.4 % and mortality was 28.4 % in Ozturk et al study[4]. In our study, ICU requirement among CKD patients on medical management was 35 % when compared to 19% in dialysis patients, which is similar to their study.

Overall mortality in CKD patients in our study was 23.5 %. Other studies have observed a mortality rate varying between 15 % to 30 % in CKD population infected with SARS-CoV-2. [4,6,7,8] The differences in mortality are due to the age group of CKD population in their study. Turgutalp observed a mortality of 16.2 % while a Spanish study and Ng JH et al observed a mortality of 30%.

Mortality rate in CKD patients in both the groups is high when compared with the overall institute mortality rate of 15 % during the same period. In our study, mortality in CKD 3-5 patients was almost double the mortality observed in maintenance hemodialysis patients (30 % in medically managed patients versus 15 % in dialysis patients). It is to be stressed that although the mortality in maintenance hemodialysis patients is less than the CKD patients managed medically, the mortality is high when compared with the general population. CKD patients have a high risk of symptomatic infection mainly due to an impaired immune response, chronic inflammation, increased oxidative stress, uremic toxin accumulation and endothelial dysfunction. [9] This might be the reason behind severity of disease and high mortality in them when compared to the general population. This stresses the need for diagnosis, early stratification and aggressive management in all CKD patients irrespective of stage and their status of renal replacement therapy.

In a study from Wuhan city, patients on hemodialysis with COVID-19 were found to have less lymphopenia, and lower serum levels of inflammatory cytokines.[10] This might explain the less severity of disease in patients on hemodialysis.

The finding of higher need for renal replacement therapy in patients with CKD is secondary to the insult from hypoxemia and systemic organ failure that accompanies the cytokine storm. A retrospective analysis of 14 patients on hemodialysis or with advanced CKD who were initiated HD after COVID-19 diagnosis in South Korea demonstrated a prolonged median length of hospital and ICU stay in these patients. [11]

Risk of requiring renal replacement therapy is higher in moderate CKD. There are many causes that give rise to worsening renal function. First, SARS-CoV-2 virus induces cytotoxicity of renal resident cells. Endothelial cell swelling, renal tubular epithelial swelling, vacuolar degeneration and drop were observed in renal biopsy in COVID-19 patients[12].Second, fever, vomiting, diarrhea, shock are likely to cause renal hypo perfusion. Third, COVID -19 infection is associated with cytokine storm[13]. Nephrotoxicity, organ crosstalk such as cardio renal syndrome, renal injury due to hypoxia, mechanical ventilation and rhabdomyolysis are other causes of worsening renal impairment. [14, 15] Hence CKD patients on medical management should be assessed frequently for indications of renal replacement therapy and initiated on same when indicated. In our study 47 percentage of patients were newly initiated on hemodialysis.

We found that age more than 60 years, hypotension, encephalopathy during hospital stay, requirement of ICU were associated significantly with mortality. Jia et al and Ozturk et al also showed in their study that elderly CKD patients had high mortality [4, 8].

We did not find any association between gender, diabetes, hypertension and worse outcome. This is in contrast to the data from Belgium study which showed an association between these factors.[16]

5. Conclusion

In our study, we found that hemodialysis patients had less fever and dyspnea when compared to CKD patients managed medically. We found that encephalopathy,

oxygen therapy requirement, ICU requirement, critical disease was significantly increased in CKD stage 3-5 patients on medical management when compared to patients on maintenance hemodialysis. Forty seven percentage of patients who were previously managed medically were initiated on renal replacement therapy after COVID-19 disease. Mortality was also significantly increased in patients on medical management. Age more than 60 years, hypotension, encephalopathy during hospital stay, requirement of ICU were associated significantly with mortality. It is to be emphasised that though the mortality in hemodialysis patients is lesser than the CKD patients managed medically, the mortality is still high when compared to the general population. SARS-CoV-2 infection in CKD is associated with adverse clinical outcomes and higher mortality. Hence CKD must be taken into account during risk stratification of patients with suspected or confirmed COVID-19. Early diagnostic test, institutional quarantine and therapeutic intervention at lower thresholds are needed. Detection of worsening renal failure, assessment for indications of renal replacement therapy and timely initiation of renal replacement therapy are essential .Optimal hemodynamic support, administration of nephrotoxic drugs after risk-benefit judgment is essential to ensure better evolution during hospitalization. The need for better recognition of CKD population as a high risk subgroup in this COVID pandemic is warranted. Public and health care workers should be educated about the importance of vaccinating as well as early screening and management of CKD patients.

6. Future Scope

There are not many studies comparing the clinical characteristics in CKD 3-5 and hemodialysis patients infected with COVID-19. Our study is one of its kind from South India. The demerits of the study are the small sample size and the lack of comparison of inflammatory markers like IL-6, CRP, serum ferritin between the two groups.

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