Original Article

COVID-19 in Renal Transplant Recipients – A Single Center Experience from India

Abstract

Introduction: The information on the clinical outcome of renal transplant recipients getting COVID-19 infection is sparse. The aim of this study is to report a single-center experience of renal transplant recipients with COVID-19 from India. **Methods:** This was a retrospective study of 23 consecutive renal transplant recipients with COVID-19 infection presenting to our center from May 2020 to August 2020. Clinical parameters, laboratory values, imaging characteristics, and outcome of the patients were collected and analyzed. **Results:** Median follow-up duration was 36 (range: 10–110) days. Median age of patients was 54 (23–70) years, and 87% were male. Median duration since transplant was 69 (range: 15–132) months. The most common presenting feature was fever (82.6%), followed by breathlessness (43.5%) and cough (30.4%). Hospitalization rate was 52.2%, while 34.8% required ICU care. Severe to critical disease was seen in 39.1% of patients, and 17.4% required mechanical ventilation. Patients with severe disease had a higher incidence of lymphopenia (P = 0.005) when compared to the ones with mild to moderate disease. Acute kidney injury was seen in 39.1% of patients, and 13% required dialysis. Mortality rate was 13% overall, and 25% in those hospitalized. **Conclusion:** Renal transplant recipients with COVID-19 have a poor outcome. Although not all of them need hospitalization, they should be monitored closely. Immunosuppression minimization is an important part of the treatment strategy.

Keywords: *Coronavirus, COVID-19, India, kidney transplantation, pandemic*

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Introduction

COVID-19 is the disease caused by a novel coronavirus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which is a positive-sense RNA virus. It was first detected as a case of atypical pneumonia of unknown origin in Wuhan, China, and soon spread rapidly throughout the world.[1,2] On March 11, 2020, it was declared as a pandemic by the World Health Organization (WHO). As of September 3, 2020, it has infected an estimated 25,842,652 people and caused 858,629 deaths worldwide. In India, the first case was detected on January 30, 2020, and as of September 3, 2020, there were 3,853,406 cases, with 67,376 mortality.[3]

The majority of the patients with COVID-19 have mild symptoms; however, few develop severe disease requiring ICU care. The mortality rate is high in patients with comorbidities such as diabetes mellitus, hypertension, chronic lung disease, cancer, and chronic kidney disease.[4-6] Both innate and adaptive immunity play important role in the clearance of the virus; thus, kidney transplant patients constitute a high-risk group in view of their immunosuppressed status. The first case of COVID-19 in a renal transplant recipient was reported from Wuhan, China.[7] Since then, few case series have been published from various parts of the world.[8-11] From India, Shingare *et al*.[12] published a case report of two patients who got COVID-19 in the immediate post-transplant period. We hereby present our experience of 23 renal transplant patients who got COVID-19.

Materials and Methods

This was a single-center retrospective study of consecutive kidney transplant recipients with a functioning allograft who presented to the out-patient department or were admitted in the in-patient department with COVID-19 from May to August 2020. COVID-19 was diagnosed by a positive SARS-COV-2 real-time polymerase chain reaction (RT-PCR) assay of nasal and/or pharyngeal swab specimens. Patients

How to cite this article: Jha PK, Shukla S, Bansal D, Bansal SB, Sethi S, Jain M, *et al*. COVID-19 in renal transplant recipients – A single center experience from India. Indian J Nephrol 2022;32:416-22.

Received: 07-10-2020
Revised: 12-09-2021
Accepted: 21-10-2021
Published: 11-10-2022

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Access this article online

Website: www.indianjnephrol.org

DOI: 10.4103/ijn.IJN_479_20

Quick Response Code:

were classified based on infection severity into mild/moderate, severe, and critical.[5] One patient had a negative SARS-COV-2 RT-PCR swab, but she had positive anti-COVID antibodies (combined IgG and IgM). She had presented with loss of taste and smell ten days back. Data were collected using an electronic health record system for demographics, history, presenting signs and symptoms, laboratory findings, treatment, immunosuppression modifications, and outcome parameters.

Acute kidney injury (AKI) was defined as an increase in serum creatinine of more than 50% from baseline or an increase of more than or equal to 0.3 mg/dl.[13]

All the CT scan chest were evaluated by an expert radiologist, and a CT scan severity score (CTSS) was assigned as per the scoring system proposed by Yang *et al*.[14] This score was calculated by summing up individual scores from 20 lung regions. Each region was assigned a score of 0–2 depending on the extent of parenchymal opacification (0 for 0%, 1 for less than 50%, and 2 for equal or more than 50% of parenchymal involvement).

Statistical analysis was done using Prism GraphPad for Mac, version 8 (GraphPad Software, San Diego, California). Results for continuous variables were reported as either mean values ± standard deviation or median with range. For categorical variables, this was reported as a percentage. Continuous variables were compared using unpaired *t*-test, while categorical values were compared using Chi-square test or Fisher's exact test. $P < 0.05$ was considered statistically significant.

The study was approved by the local ethics committee of the hospital (MICR 1174/2020).

Results

During the study period, a total of 23 renal transplant patients were diagnosed with COVID-19. Median follow-up duration was 36 (range: 10–110) days. All the patients were living donor transplant recipients, and one of them was a second transplant recipient. Table 1 shows the demographics and baseline characteristics of the patients.

Table 2 shows clinical features, laboratory parameters, and imaging details. The most common presenting feature in our study was fever (82.6%). One of the patients had an asymptomatic presentation. She was 3 months pregnant and had a spontaneous abortion followed by dilatation and curettage for the retained products of conception. During evaluation, her throat swab for SARS-COV-2 RT-PCR came positive. Out of the 23 infected patients, 12 required hospitalization. ICU care was needed in 66.7% of the patients who got hospitalized. Inflammatory markers ferritin, c-reactive protein (CRP), and D-dimer were available for 14, 15, and 12 patients, respectively, while interleukin-6 (IL-6) level was done in 10 patients. CT chest was done in 11 patients, and the median CT severity score was 19 (range: 6–37).

Table 1: Demographics and baseline characteristics

Variable	Value
Age in years - median (range)	54 (23-70)
Gender - no./total no. (%)	
Female	3/23 (13)
Male	20/23 (87)
Comorbidities - no./total no. (%)	
Diabetes mellitus	6/23 (26.1)
Hypertension	19/23 (82.6)
Coronary artery disease	2/23 (8.7)
Hypothyroidism	3/23 (13)
Chronic hepatitis C	2/23 (8.7)
Morbid obesity	2/23 (8.7)
Obstructive sleep apnea	1/23 (4.3)
Time since transplant in months - median (range)	69 (15-132)
Induction immunosuppression - no./total no. (%)	
None	4/23 (17.4)
ATG	6/23 (26.1)
Basiliximab	11/23 (47.8)
Not available	2/23 (8.7)
Baseline immunosuppression - no./total no. (%)	
Tacrolimus	22/23 (95.7)
Cyclosporine	1/23 (4.3)
MMF	19/23 (82.6)
Azathioprine	3/23 (13)
Steroid	23/23 (100)
ABO incompatible transplant	1/23 (4.3)
Past history of acute rejection	7/23 (30.4)

ATG=Anti-thymocyte globulin; MMF=Mycophenolate mofetil

Nine patients had either severe or critical disease while 14 had mild to moderate disease. A comparison was done between these groups. Time since transplant was significantly longer in the mild to moderate group ($P = 0.03$). Also, patients with severe to critical disease had significantly low lymphocyte count ($P = 0.005$). The other parameters were comparable between the two groups [Table 3]. Reports on inflammatory markers were not available for all the patients in the mild to moderate group and hence could not be compared. In patients with severe to critical disease, median ferritin level was 259 (range: 72.6–1440) ng/ml, CRP level was 76.7 (range: 33–346) mg/dl, and IL-6 level was 124 (range: 8–3964) pg/ml.

Table 4 shows the treatment and outcome of the patients. Almost two-third of the patients received an increased dose of steroids, and remdesivir was used in nine out of the 12 (75%) hospitalized patients. Six (26.1%) patients did not receive any COVID-specific treatment. Antimetabolites

Table 2: Clinical features, laboratory values, and imaging

Variable	Value
Presenting symptom - no./total no. (%)	
Fever	19/23 (82.6)
Breathlessness	10/23 (43.5)
Cough	7/23 (30.4)
Sore throat	4/23 (17.4)
Anosmia and loss of taste	3/23 (13)
Loose stools	3/23 (13)
Asymptomatic	1/23 (4.3)
Clinical severity - no./total no. (%)	
Mild/moderate	14/23 (60.9)
Severe	5/23 (21.7)
Critical	4/23 (17.4)
Requirement of hospitalization - no./total no. (%)	12/23 (52.2)
Requirement of ICU care - no./total no. (%)	8/23 (34.8)
Investigations	
Hb in gm/dl - median (range)	12.9 (6.7-14.9)
TLC	
Median (range) per mm^3	6490 (3800-13200)
<4000 per mm^3	1/23 (4.3)
4000-11000 per mm^3	18/23 (78.3)
>11000 per mm^3	4/23 (17.4)
Lymphocytes	
Median (range) per mm^3	834 (106-3761)
<1000 per mm^3	12/23 (52.2)
Platelet	
Median (range) in thousands per mm^3	151 (80-295)
<150 thousand per mm^3	8/23 (34.8)
Ferritin	
Median (range) ng/ml	242 (66.5-1440)
>900 ng/ml	3/14 (21.4)
CRP	
Median (range)	55.6 (5.3-346)
Level >6 mg/dl	14/15 (93.3)
D-dimer	
Level >0.5 mcg/ml	5/12 (41.7)
IL-6 level (<6)	
Median (range) pg/ml	116 (8-3964)
CTSS (out of total score of 40)	
Median score (range)	19 (6-37)

ICU=intensive care unit; TLC=total leucocyte count; CRP=C-reactive protein; IL-6=interleukin-6; CT=computerized tomography; CTSS=CT severity score

were stopped in all but one patient while calcineurin inhibitor was withheld in three critical patients.

Mortality rate was 13% overall, while among the patients getting hospitalized, it was 25%. Three patients died. First one was a 68-year-old patient who had received a transplant kidney from his wife in September 2014. He had received basiliximab induction and was on maintenance immunosuppression of tacrolimus, mycophenolate sodium, and prednisolone. His comorbidities included type 2 diabetes mellitus and hypertension. He had suffered an episode of plasma cell rich acute rejection 2 years post-transplant due to drug noncompliance, which was treated with iv steroid and anti-thymocyte globulin (ATG). His serum creatinine settled at 1.4 mg/dl. He presented with a history of fever, cough, and breathlessness of 7 days duration. He was hypoxic on admission. Investigations revealed lymphopenia (700 per mm^3), thrombocytopenia (80,000 per mm^3), serum ferritin of 1440 ng/ml, a CRP of 80 mg/dl, and serum creatinine of 2 mg/dl. CT scan of chest showed bilateral interstitial pneumonia with CTSS of 26 out of 40. His IL-6 level was 3964 pg/ml (normal value: <6 pg/ml). He received remdesivir, tocilizumab, hydroxychloroquine, azithromycin, convalescent plasma, and high-dose steroid but ultimately succumbed to the illness on the ninth day of hospitalization.

The second patient was a 69-year-old male who had received a second renal transplant in 2015. He had not received any induction and was on maintenance immunosuppression of tacrolimus, azathioprine, and prednisolone. His comorbidities included morbid obesity, type 2 diabetes mellitus, hypertension, and obstructive sleep apnea (OSA). He had a history of acute rejection which responded to iv steroids and the serum creatinine had settled at 1 mg/dl. He also had a history of pneumocystis carinii pneumonia (PCP) infection and was on regular co-trimoxazole prophylaxis. He presented with fever with chills and cough of 5 days duration. Investigations revealed lymphopenia (822 per mm^3), thrombocytopenia (120,000 per mm^3), serum ferritin of 195 ng/ml, and a CRP of 76.7 mg/dl. CT scan of chest showed bilateral interstitial pneumonia with CTSS of 20. His IL-6 level was 2232 pg/ml. He had a prolonged hospital stay and developed AKI and worsening hypoxia requiring mechanical ventilation. His blood culture grew candida albicans. He received remdesivir, tocilizumab, HCQS, convalescent plasma, high-dose steroids, iv antibiotics, and antifungals. His SARS-COV-2 RT PCR repeated on days 14 and 26 was persistently positive. Ultimately, he succumbed on day 28 of hospitalization.

The third patient was a 48-year-old male who had undergone a living unrelated renal transplant in 2011. He had received basiliximab induction and was on maintenance immunosuppression of tacrolimus, mycophenolate sodium, and prednisolone initially. He had a history of antibody-mediated rejection for which he had received plasma exchange, iv steroid, and rituximab in 2018. He developed cytomegalovirus (CMV) colitis subsequently, which was treated, and mycophenolate was stopped. His serum creatinine had increased progressively to 6.7 mg/dl in June 2020. He presented with a history of breathlessness and anasarca. His SARS-COV-2 RT-PCR

Table 3: Baseline characteristics and investigations according to disease severity

Variable	Mild/moderate (*n*=14)	Severe/critical (*n*=9)	*P*
Age (in years)	47.2±14	54.7±12.5	0.25
Gender (male) no./total no.	12/14	8/9	1
Time since transplant (in months)	83.6±34.9	51.5±26.4	0.03*
Comorbidities no./total no.			
DM	3/14	3/9	0.64
HTN	11/14	8/9	1
CAD	1/14	1/9	1
Induction immunosuppression- no./total no.	10/12	7/9	1
Maintenance immunosuppression			
Tacrolimus	13/14	9/9	1
Cyclosporine	1/14	0/9	1
MMF	12/14	7/9	1
Azathioprine	2/14	1/9	1
Steroid	14/14	9/9	1
Past history of acute rejection -no./total no.	4/14	3/9	1
Hemoglobin in gm/dl	12.9±1.2	11.7±2.7	0.16
TLC in per mm^3	7416.4±2775.9	7733.3±3396.9	0.8
Lymphocyte in per mm^3	1966.1±1019.8	851±417	0.005*
Platelets in thousands per mm^3	166.4±43.4	167.1±64.8	0.97

DM=diabetes mellitus; HTN=hypertension; CAD=coronary artery disease; MMF=mycophenolate mofetil; TLC=total leucocyte count

swab came positive and he was treated with HCQS. He was initiated on dialysis and discharged after 7 days. At the time of discharge, his repeat SARS-COV-2 RT-PCR swab was inconclusive. He again got admitted after 59 days with fever and breathlessness. Investigations revealed lymphopenia (106 per mm^3), serum ferritin of 1090 ng/ml, and a CRP of 346 mg/dl. CT scan of chest showed diffuse ground-glass opacity with dense consolidation and air bronchogram; CTSS score was 37. He needed mechanical ventilation. He developed secondary sepsis with Klebsiella pneumoniae and Enterobacter faecium. He was managed with remdesivir, tocilizumab, convalescent plasma, and iv steroid and antibiotics but expired on 20th day of admission due to multi-organ dysfunction. A repeat SARS-COV-2 RT-PCR performed 1 day before was negative.

AKI was seen in nine patients in the present series, of which three required dialysis. All three patients requiring dialysis expired. Mechanical ventilation was required in four patients out of which only one survived. Five patients (21.7%) developed a secondary infection and all the three patients who expired had developed secondary infections.

Table 5 shows the difference in baseline characteristics and investigation between patients who got a secondary infection and those who did not. The patients getting a secondary infection had significantly lower lymphocyte count. They were also relatively older although the difference did not reach statistical significance. Reports on inflammatory markers were not available for all the patients in patients without secondary infection group and hence could not be compared. In patients getting a secondary infection, median ferritin level was 768 (range: 74.5–1440) ng/ml, CRP level was 80 (range: 33–346) mg/dl, and IL-6 level was 808 (range: 108–3964) pg/ml. All the patients getting secondary infection had severe disease and three out of these five patients expired.

Out of the 12 patients needing hospitalization, three expired, six were discharged, and three patients are still admitted.

Discussion

Renal transplant patients are on chronic immunosuppressants and hence at high risk for infections. They also have other comorbidities, which adds to the associated mortality.

COVID-19 is an extremely contagious viral infection that can lead to severe acute respiratory syndrome and is associated with high mortality in such cases. There is a scarcity of data on COVID-19 in renal transplant recipients. Few published series have reported high mortality in this group of patients when compared to the general population. Also, there is a difference in the outcome of COVID-19 infection in the general population in different parts of the world. The mortality rate in the Indian population is reported to be 1.74%, which is lesser than the worldwide average of 3.3%.[3] The present study looked into the clinical features and outcome of COVID-19 infection in renal transplant patients in our setting.

Table 4: Treatment and outcome

Variable	Value
COVID-19 specific treatment - no./total no. (%)	
High dose steroids	15/23 (65.2)
Remdesevir	9/23 (39.1)
Tocilizumab	5/23 (21.7)
HCQS	5/23 (21.7)
Azithromycin	3/23 (13)
Convalescent plasma	5/23 (21.7)
None	6/23 (26.1)
Immunosuppression modification - no./total no. (%)	
Antimetabolites stopped	21/22 (95.4)
CNI stopped	2/23 (8.7)
Mortality - no./total no. (%)	
Overall	3/23 (13)
In hospitalized patients	3/12 (25)
In those requiring ICU care	3/8 (37.5)
Amongst intubated patients	3/4 (75)
Acute kidney injury - no./total no. (%)	9/23 (39.1)
Dialysis requirement - no./total no. (%)	
Overall	3/23 (13)
Amongst hospitalized	3/12 (25)
Supplemental oxygen requirement - no./total no. (%)	9/23 (39.1)
Mechanical ventilation - no./total no. (%)	
Overall	4/23 (17.4)
Days of hospitalization in days - median (range)	10 (5-28)
Secondary infection - no./total no. (%)	5/23 (21.7)

COVID=coronavirus disease; HCQS=hydroxychloroquine sulfate; CNI=calcineurin inhibitor; ICU=intensive care unit

The most common presenting complaint in our study was fever (82.6%) followed by breathlessness (43.5%) and cough (30.4%). In a study of 36 renal transplant recipients by Akalin *et al*.,[9] the most common presenting feature was fever (58%), followed by diarrhea (22%). In the study by Abolghasemi *et al*.,[10] the most common presenting feature was breathlessness in 70.8%, followed by fever (62.5%) and cough (45.8%).

Hospitalization was needed in 52.2% of our patients and the median hospitalization duration was 10 (range: 5–28) days. Hospitalization rate in the study of Akalin *et al*.[9] and Devresse *et al*.[8] was higher at 78% and 82%, respectively, although median hospitalization duration was similar at 9 and 10 days, respectively.

Mortality rate was 13% in the present series. The patients who expired had high net immunosuppression load as they had been treated for acute rejections in the past and one of them was a second transplant recipient with multiple comorbidities, including morbid obesity. Another patient had chronic graft dysfunction. In the series by Akalin *et al*.[9] and Monfared *et al*.[11] the mortality rate was 28% and 27.2%, respectively, while in the study by Devresse *et al*.,[8] it was 11%. The comparatively lower mortality rate in our series could be a reflection of the overall lower COVID-19-related mortality in India. However, this could be because of difference in treatment protocol or difference in demographic factors as well.

In the present series, 39.1% of the patients had severe to critical disease. Supplemental oxygen was required in 39.1%, and mechanical ventilation was required in 17.4% overall. Among those hospitalized, the requirement of mechanical ventilation was in 33.3% of the cases. The need for mechanical ventilation in various studies in hospitalized patients has varied from 11% to 40%.[8,9,15] In the present study, 39% of patients developed AKI, and 25% of admitted patients required dialysis. In the series by Akalin *et al*.[9] dialysis was required in 21%, and in that of Monfared *et al*.,[9, 11] it was required in 54% of the patients. One of the patients in our series who required dialysis already had chronic kidney disease stage 5.

Patients with severe to critical disease had significantly lesser duration since transplant (0.03) and they had significantly low lymphocyte count (P = 0.005). Although studies in the general population have shown lymphopenia as a marker of disease severity in a comparative analysis in renal transplant recipients by Pereira *et al*.,[16] there was no significant difference. As we did not have the complete report of inflammatory markers in all the patients, this could not be compared between the two groups. The patients with severe to critical disease had high levels of inflammatory markers of ferritin, CRP, and IL-6. This has been reported in other studies as well.[17] Patients who got secondary infection were also found to have a significantly higher incidence of lymphopenia. These patients had severe disease and high mortality.

Management of immunosuppression is a very important aspect of treating renal transplant recipients with COVID-19. In most of the series, antimetabolites were stopped, the dose of CNI was reduced, and the dose of steroid was increased. We followed a similar protocol and antimetabolites were stopped in 95.4% of the patients.[8-11] Calcineurin inhibitor was stopped in two of our patients (8.7%) who were critical. COVID-19-specific treatment consisted of iv steroids and remdesivir in most of the cases (65.2% and 39.1%, respectively). Tocilizumab was used in those patients who were critical with high IL-6 levels. The treatment protocol has been different in various studies in view of the changing evidence with time.[9,10,15-17]

There are limitations of the present study. This was a retrospective study. The sample size was small and the follow-up period was short. Not all the laboratory data were available for all the patients. Especially inflammatory markers were not done in all the patients. The treatment was heterogenous in view of evolving evidence.

Table 5: Baseline characteristics and investigations comparison between patients with secondary infections and those without it

Variable	Sec. infn. (*n*=5)	No sec infn. (*n*=18)	*P*
Age (in years)	60.2±8.8	47.7±13.6	0.07
Gender (male) no./total no.	5/5	15/18	1
Time since transplant (in months)	60.2±30	74.1±36.5	0.45
Comorbidities no./total no.			
DM	3/5	3/18	0.09
HTN	5/5	14/18	0.53
CAD	1/5	1/18	0.39
Induction - no./total no.	3/5	16/18	0.19
Maintenance immunosuppression			
Tacrolimus	5/5	17/18	1
Cyclosporine	0/5	1/18	1
MMF	3/5	15/18	0.29
Azathioprine	1/5	3/18	1
Steroid	5/5	18/18	1
Past history of acute rejection -no./total no.	3/5	4/18	0.14
Hemoglobin in gm/dl	11.6±2.8	12.7±1.7	0.28
TLC in per mm^3	7872±3265.3	7448.3±1967.3	0.72
Lymphocyte in per mm^3	697±126	1810.4±945.7	0.02*
Platelets in thousands per mm^3	178±43.4	163.51±38.6	0.47

DM=diabetes mellitus; HTN=hypertension; CAD=coronary artery disease; MMF=mycophenolate mofetil; TLC=total leucocyte count; Sec. infn=patients with secondary infection

In conclusion, despite the above-mentioned limitations, the present study is an important one as it is the single largest study on COVID-19 in renal transplant recipients from India at the time of submission. We found that the mortality rate was lower compared to the other studies as mentioned above.

Not all renal-transplant recipients with COVID-19 need admission, but one must be careful while treating patients with higher age, multiple comorbidities, and higher net immunosuppression. The prolonged hospital stay predisposes them to secondary infection, which can be an important factor contributing to mortality. Long-term follow-up of the patients recovering from COVID-19 is important to know the rate of rehospitalization and residual morbidities.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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