

# Clinical Profile and Outcome of COVID-19 in 250 Kidney Transplant Recipients: A Multicenter Cohort Study From India

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**Background.** There is a scarcity of data on the consequences of coronavirus disease-19 (COVID-19) infections in kidney transplant recipients (KTRs) from emerging countries. **Methods.** Here, we present a cohort study of 13 transplant centers in India including 250 KTR (226 living and 24 deceased donors) with polymerase chain reaction-confirmed COVID-19 positivity from March 23, 2020, until September 15, 2020. We detailed demographics, immunosuppression regimen, clinical profile, treatment, and outcomes. **Results.** Median age of transplant recipients was 43 years, and recipients presented at a median of 3.5 years after transplant. Most common comorbidities (94%) included arterial hypertension (84%) and diabetes (32%); presenting symptoms at the time of COVID-19 included fever (88%), cough (72%), and sputum production (52%). Clinical severity ranged from asymptomatic (6%), mild (60%), and moderate (20%) to severe (14%). Strategies to modify immunosuppressants included discontinuation of antimetabolites without changes in calcineurin inhibitors and steroids (60%). Risk factors for mortality included older age; dyspnea; severe disease; obesity; allograft dysfunction before COVID-19 infection; acute kidney injury; higher levels of inflammatory markers including C-reactive protein, interleukin-6 level, and procalcitonin; chest X-ray abnormality, and intensive care unit/ventilator requirements. Overall patient mortality was 11.6% (29 of 250), 14.5% (29 of 200) in hospitalized patients, 47% (25 of 53) in intensive care unit patients, and 96.7% (29 of 30) in patients requiring ventilation. KTRs with mild COVID-19 symptoms (n=50) were managed as outpatients to optimize the utilization of scarce resources during the COVID-19 pandemic. **Conclusions.** Mortality rates in COVID-19-positive KTR appear to be higher than those in nonimmunosuppressed patients, and high mortality was noted among those requiring intensive care and those on ventilator.

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## INTRODUCTION

A total of 49 155 transplants have been performed in India from 2013 to 2018 including 39 000 living donor and 10 155 deceased donor transplants. Those overall numbers

include 38 332 kidney (living donor=32 584, deceased donor=5748), 9383 liver (living donor=6416, deceased donor=2967), 895 heart, 459 lung, 78 pancreas, and 8 small bowel transplants. Based on the 2018 transplant

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**TABLE 1.**  
**COVID-19 state-wise data, India**

Area	Confirmed	Active	Recovered	Deceased	Death rate (%)
India	5 810 553	960 969	4 849 584	93 379	1.6
Maharashtra	1 265 996	273 190	992 806	34 761	2.74
Delhi	259 303	30 867	228 436	5 147	1.98
Gujarat	126 836	16 478	110 358	3 393	2.67
West Bengal	236 394	25 374	211 020	4 665	1.97
Telangana	182 775	30 334	152 441	1 091	0.6
Rajasthan	123 318	19 030	104 288	1 412	1.14

Total samples tested in India: 5 810 553 as on September 26, 2020, 08:00 IST.  
COVID-19, coronavirus disease 2019.

volume, India currently ranks second worldwide based on transplant volume.<sup>1</sup>

As of September 26, 2020, India reported a total of 5 810 553 confirmed COVID-19-positive individuals including 960 969 (16.28%) requiring medical care, 4 849 584 (82.14%) recovered patients, and 93 379 deaths (1.6%).<sup>2</sup> Tragically, India has at this time the second-highest COVID-19 caseload worldwide (Table 1). To combat the spread of the disease, the Indian Government ordered a national lockdown in a phased manner from March 24 to July 31, 2020.<sup>2</sup> Kidney transplant recipients (KTRs) are at a higher risk of developing severe COVID-19 based on their immunosuppressed state and associated comorbidities. Recent studies have reported on outcomes of COVID-19 positivity in KTRs in the developed world<sup>3-29</sup>; however, there is a lack of data from emerging countries.<sup>30</sup>

To address this knowledge gap, we analyzed demographics, clinical manifestations, immunosuppression regimen, treatment, and outcomes (patient survival, graft survival, graft function) in 250 COVID-19-positive KTRs across 13 transplant centers (2 public and 11 private sectors) in India.

## MATERIALS AND METHODS

The clinical study was approved by the ethics committee based on international standards of Good Clinical Practice per local laws and regulations (Transplant Human Organ Act, India). Our study also abided by the Declaration of Helsinki and Declaration of Istanbul principles. Written informed consent was obtained from all recipients.

### Confirmed Case

The diagnosis of COVID-19 was confirmed by real-time reverse transcription polymerase chain reaction (RT-PCR) from nasopharyngeal (nasal) and oropharyngeal (throat) swab.<sup>2,29</sup>

### Study Population

Adult KTRs with COVID-19 (age >18 y) were included from (1) the Institute of Kidney Diseases and Research Center and Dr. H L Trivedi Institute of Transplantation Sciences, Ahmedabad (n=75); (2) Sir Ganga Ram Hospital, New Delhi (n=27); (3) Muljibhai Patel Urological Hospital, Nadiad (n=25); (4) Indraprastha Apollo Hospitals, New Delhi (n=22); (5) Rabindranath Tagore International Institute of Cardiac Sciences, Kolkata (n=20); (6) Jaslok Hospital and Research Centre, Mumbai (n=17); (7) Nizam's Institute of Medical Sciences, Hyderabad (n=16);

(8) Kidney Care Clinic, Surat (n=13); (9) Apollo Hospitals International Limited, Gandhi Nagar (n=10); (10) Mahatma Gandhi Medical College & Hospital, Jaipur (n=10); (11) Gujarat Kidney Foundation, Ahmedabad (n=8); (12) Jawaharlal Nehru Medical College, Wardha (n=4); and (13) Zydus Hospitals, Ahmedabad (n=3); both inpatients (n=200) and outpatients (n=50) treated from March 23, 2020, to September 15, 2020, were retrospectively assessed.

Clinical severity and assessment parameters were divided into<sup>31</sup>:

- Mild: KTRs with mild symptoms including fever, cough, without shortness of breath or hypoxia, and uncomplicated upper respiratory tract infections.
- Moderate: Patients demonstrated clinical features of pneumonia including fever, cough, dyspnea, hypoxia with oxygen saturation (SpO<sub>2</sub>) <94% (range 90%–94%) on room air, and respiratory rates of 24–30/min.
- Severe: Patients had advanced signs of clinical pneumonia plus 1 of the following clinical criteria: respiratory rate >30/min, severe respiratory distress, and SpO<sub>2</sub> <90% on room air.

### Clinical Management Protocol: COVID-19

Detailed clinical histories including comorbidities were recorded. KTRs were followed daily for body temperature changes, vitals, complete blood counts, and additional evaluations as indicated; chest X-rays (CXR) were obtained daily; target SpO<sub>2</sub> was 92%–96%.

### Anticoagulation

Prophylactic doses of unfractionated heparin and low-molecular-weight heparin (eg, enoxaparin 40 mg/d SC) were applied, and comorbidities were treated.<sup>2,22</sup> Antibiotics were prescribed for clinical suspicion of bacterial infections as per the hospital antibiotic policy. Awake early self-proning was suggested for improving oxygen saturation.

Hydroxychloroquine (HCQ) (400 mg) BID was applied on day 1 of admission followed by 200 mg BID for 4 days under ECG guidance; HCQ dosage was adjusted based on renal function. Intravenous methylprednisolone 0.5–1 mg/kg or dexamethasone 0.2–0.4 mg/kg for 3 days (preferably within 48 h of admission or if oxygen requirement was increasing or when inflammatory markers were increasing) was administered in all moderate and severe cases.

### Convalescent Plasma (Off Label)

This was considered in patients with moderate disease in the absence of clinical improvement (progressively increasing

oxygen requirement) despite the use of steroids. Special prerequisites while considering convalescent plasma included:

- ABO compatibility and crossmatching of the donor plasma.
- Neutralizing titer of donor plasma above the specific threshold (if the latter is not available, plasma IgG titer [against S-protein RBD] above 1:640 have been applied).

Volume of convalescent ranged from 4 to 13 mL/kg (usually, a single dose of 200 mL was given slowly over at least 2 h).

### Tocilizumab (Off Label)

The interleukin-6 (IL-6) receptor antibody tocilizumab may be considered in patients with moderate disease, with progressively increasing oxygen requirements or in mechanically ventilated patients who do not show improvements despite the use of steroids. As the data on long-term safety of tocilizumab in COVID-19 remain largely unknown, special considerations before its use in our study included:

- Presence of increased inflammatory markers (eg, C-reactive protein [CRP], ferritin, IL-6).
- Patients should be carefully monitored posttocilizumab for secondary infections and neutropenia.
- Active infections and tuberculosis should be ruled out before use.

Tocilizumab was applied at 8 mg/kg (maximum 800 mg at 1 time) diluted in 100 mL normal saline and infused over 1 hour.

### Favipiravir

The drug controlling service of the Indian Government approved favipiravir for the treatment of mild to moderate COVID-19 on June 19, 2020. A dosage of 200 mg × 9 tablets BID on day 1 and 200 mg × 4 tablets BID for 14 days is suggested.

### Discharge Policy

A revised discharge policy for COVID-19 has been issued by the Indian Ministry of Health and Family Welfare on May 8, 2020.<sup>32</sup> Earlier criteria for discharging patients with COVID-19 were based on (a) a normal CXR and (b) 2 consecutive negative test results on RT-PCR. Specific additional recommendations included:

- Patient with mild/very mild/presymptomatic signs can be discharged after 10 days of symptom onset and absent fever for 3 days.
- Patients with moderate symptoms can be discharged (1) if asymptomatic for 3 days and (2) after 10 days of symptom onset.
- Patients with severe symptoms, clinical recovery in addition to negative RT-PCR COVID tests (after the resolution of symptoms) are required.

### Home Therapy

This was offered carefully for selected patients with symptoms and controlled comorbidities; this cohort received teleconsultation surveillance until disease resolution; home visits were carried out as required.

### National Organ and Tissue Transplant Organization Transplant-specific Guidelines With Reference to COVID-19 in India

If recipient or donor become COVID-19 positive, then National Organ and Tissue Transplant Organization

suggests treatment as per local authority guidelines; at this time, there are no country-wide standard accepted treatment guidelines. As in other countries, there is also currently no consensus on the modification of immunosuppressants in India. Transplant teams base their decision therefore on a case-by-case evaluation balancing infection control and rejection.<sup>33</sup>

### Statistical Analysis

Statistical analysis was performed using the Statistical Package for Social Science (SPSS) version 17.0 (SPSS Inc., Chicago, IL). Continuous data are presented as median and interquartile ranges (IQRs) and mean ± SD; Student's *t* tests were used to compare 2 groups. Categorical data were compared using  $\chi^2$  tests or Fisher exact tests. A *P* value <0.05 indicated statistical significance. A Cox regression model was performed for multivariate analysis.

## RESULTS

### Demographics

We included 226 living donor and 24 deceased donor KTRs in our analysis. The overall median age of the cohort was 43 years (IQR, 35–51); the majority (86%, *n*=215) of patients were male individuals. We divided patients by age subgroups, including 21–30 years (*n*=35), 31–40 years (*n*=83), 41–50 years (*n*=70), 51–60 years (*n*=53), and 61–70 years (*n*=9). Patients had a median time interval from transplant to COVID-19 diagnosis of 3.5 years (IQR, 1.8–6.2). In detail, time after transplant surgery was <3 months in 11 patients (4.4%), 3–6 months in 19 (7.6%), 6–12 months in 20 (8%), 1–5 years in 113 (45.2%), 5–10 years in 54 (21.6%), 11–20 years in 28 (11.2%), and >20 years in 5 (2%). Baseline demographics, comorbidities, and medications of KTRs with COVID-19 at the time of diagnosis are summarized in Table 2.

### Comorbidities

Comorbidities were present in 235 patients (94%) and included arterial hypertension (84%, *n*=210), diabetes (32%, *n*=80), allograft dysfunction (30.8%, *n*=77), obesity (body mass index >30 kg/m<sup>2</sup>; 23.9%, *n*=53), ischemic heart disease (12%, *n*=30), hepatitis B or C virus (10%, *n*=25), chronic lung disease including asthma and chronic obstructive pulmonary disease (4%, *n*=10), and sickle cell disease (*n*=1); 15 patients (6%) had no comorbidities. Multiple comorbidities were present in 115 patients (46%) with hypertension and diabetes (30%, *n*=75) being the most common. One hundred fifteen patients (46%) demonstrated anxiety (*n*=115); 30 patients (12%) had a history of smoking at time of COVID-19 infection diagnosis; and 75 patients (30%) were on an angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker at the time of COVID diagnosis.

### Immunosuppressive Regimen

One hundred eighty-two recipients (72.8%) had an induction treatment with thymoglobulin, 20 received basiliximab (8%), and 48 patients (19.2%) had not received an induction treatment. Thymoglobulin induction was

**TABLE 2.**  
**Baseline demographics, comorbidities, and medications of kidney transplant recipients with COVID-19 at the time of diagnosis**

	Median (IQR) or n (%)			P
	Total (N = 250)	Survivors (N = 221)	Nonsurvivors (N = 29)	
Age, y	43 (35–51)	42 (35–50)	54 (49–56)	<0.0001
Age ≥60 y	9 (3.6)	4 (1.8)	5 (17.2)	0.0014
Male gender	215 (86)	189 (85.5)	26 (89.6)	0.546
Female gender	35 (14)	32 (14.5)	3 (11.4)	
Transplant to COVID-19 time, y	3.5 (1.8–6.2)	3.5 (1.5–6.5)	3.5 (2.8–4.5)	0.646
≤1	50 (20)	49 (22.2)	1 (3.5)	0.052
>1	200 (80)	172 (77.8)	28 (96.5)	
Living donor	226 (90.4)	201 (90.9)	25 (86.2)	0.415
Deceased donor	24 (9.6)	20 (9.1)	4 (13.8)	
Cause of kidney disease				0.736
Hypertension	121 (48.4)	106 (47.9)	15 (51.7)	
Diabetes mellitus	69 (27.6)	57 (25.7)	12 (41)	
Glomerular disease	40 (16)	35 (15.8)	5 (17.2)	
Others	10 (4)	8 (3.6)	2 (6.8)	
Current immunosuppression				
Prednisolone	250 (100)	221 (100)	29 (100)	1.0
Calcineurin inhibitor	236 (94.4)	209 (94.6)	27 (93.1)	0.747
Antimetabolite	250 (100)	221 (100)	29 (100)	1.0
Sirolimus/everolimus	14 (5.6)	12 (5.4)	2 (6.9)	0.747
Induction				<0.0001
Thymoglobulin	182 (72.8)	162 (73.3)	20 (68)	
Basiliximab	20 (8)	12 (5.4)	8 (27.5)	
No induction	48 (19.2)	47 (21.2)	1 (3.4)	
Antirejection therapy	40 (16)	15 (6.7)	25 (86.2)	0.0001
ACEI, ARB use	75 (30)	66 (29.8)	9 (31)	0.897
Flu vaccination	26 (10.4)	23 (10.4)	3 (10.3)	0.992
Recipient's blood group				
A	63 (25.2)	60 (27.1)	3 (10.3)	0.050
B	92 (36.8)	75 (33.9)	17 (58.6)	0.010
AB	6 (2.4)	6 (2.7)	0 (0)	0.369
O	84 (33.6)	75 (33.9)	9 (31)	0.756
Comorbidities	235 (94)	206 (93.2)	29 (100)	0.148
Hypertension	210 (84)	185 (83.7)	25 (86.2)	0.730
Diabetes	80 (32)	65 (29.4)	15 (51.7)	0.015
Heart disease	30 (12)	25 (11.3)	5 (17.2)	0.3356
Virus (CMV/HCV/HBV)	25 (10)	20 (9)	5 (17.2)	0.167
Allograft dysfunction before COVID-19	77 (30.8)	51 (23)	26 (89.7)	<0.0001
BMI, kg/m <sup>2</sup>				
<25	49 (19.6)	46 (20.8)	3 (10.3)	0.182
25–30	120 (54.3)	110 (49.8)	10 (34.5)	0.121
>30	53 (23.9)	37 (16.7)	16 (55.2)	<0.0001
≥1 comorbidities	115 (46)	87 (39.3)	28 (96.5)	<0.0001
No comorbidities	15 (6)	15 (6.8)	0 (0)	0.148

ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; CMV, cytomegalovirus; COVID-19, coronavirus disease 2019; HBV, hepatitis B virus; HCV, hepatitis C virus; IQR, interquartile range.

applied as a single 1.5 mg/kg dose in Mumbai and Ahmedabad and a single dose of 3 mg/kg in the other participating centers. The most common maintenance immunosuppression regimen included a triple regimen consisting of prednisolone, tacrolimus, and mycophenolate. The total daily dose of prednisolone, tacrolimus, and mycophenolate mofetil at COVID-19 presentation was 5–10 mg/d, 0.06 mg/kg/d, and 1–1.5 g/d, respectively. Recipients have

not been on either belatacept or steroid-free regimen. Twenty patients received high immunological risk transplants including 12 ABO-incompatible and 8 sensitized recipients. Forty patients had a history of rejection treatments (16%), including steroid pulse treatments (16%, n = 40), thymoglobulin (8%, n = 20), rituximab/bortezomib (10%, n = 25), and plasma exchange (12%, n = 30). Table 3 summarizes symptoms and laboratory findings.



**TABLE 3.**  
Symptoms and laboratory findings of kidney transplant recipients with COVID-19

	N	Total (N=250)	Survivors (N=221)	Nonsurvivors (N=29)	P
Clinical symptoms, n (%)	250				
Fever		220 (88)	195 (88.2)	25 (86.2)	0.752
Cough		180 (72)	159 (71.9)	21 (72.4)	0.958
Sputum production		130 (52)	112 (50.6)	18 (62)	0.248
Myalgia		62 (25)	52 (23.5)	10 (34.4)	0.199
Diarrhea		60 (24)	57 (25.7)	3 (10.3)	0.067
Dyspnea		55 (22)	30 (13.5)	25 (86.2)	<0.0001
No symptoms		15 (6)	15 (6.7)	0 (0)	0.148
Chest X-ray, n (%)	220				<0.0001
No abnormalities		108 (49)	108 (48.8)	0 (0)	
Abnormalities		112 (51)	83 (37.5)	29 (100)	
Chest CT scan abnormalities	120	120 (48)	102 (46)	18 (62)	0.107
Laboratory reports, median (IQR)					
Hemoglobin (g/dL)	226	11.2 (9.9–12.5)	11.4 (10–12.5)	10.5 (8.5–12)	0.017
White blood cell (/mm <sup>3</sup> )	226	6737 (5118–9485)	6600 (4978–8900)	11420 (7850–13700)	0.0001
Neutrophil (%)	226	77 (68–86)	77 (67–85)	83 (78–89)	<0.05
Lymphocyte (%)	226	18 (12–24)	19 (14–25)	12 (9–15)	0.0001
Platelet × 10 <sup>3</sup> (/mm <sup>3</sup> )	226	215 (174–254)	218 (176–254)	169 (137–252)	0.35
C-reactive protein (mg/L)	164	52 (24–96)	40 (21–64)	163 (104–175)	<0.0001
Procalcitonin (ng/mL)	141	0.09 (<0.05–0.7)	<0.05 (<0.05–0.64)	0.37 (0.22–1.68)	<0.0001
Interleukin-6 (pg/mL)	95	25 (16–55)	24 (14–38)	111 (67–269)	<0.05
Ferritin (ng/mL)	165	450 (207–994)	345 (174–932)	975 (842–1164)	<0.0001
D-dimer (μg/L)	145	1200 (642–2420)	1085 (589–2324)	2130 (1339–4319)	<0.012
Lactate dehydrogenase (U/L)	141	310 (260–407)	297 (245–345)	543 (348–733)	<0.0001
Alanine aminotransferase (U/L)	169	30 (18–42)	26 (17–39)	50 (33–120)	<0.0001
Albumin (g/dL)	178	3.6 (3.1–3.9)	3.7 (3.3–3.9)	3 (2.9–3.1)	<0.0001
Blood urea (mg/dL)	169	47 (33–74)	43 (32–63)	70 (56–145)	<0.05
Creatinine (mg/dL)					<0.05
Baseline before COVID-19	234	1.4 (1.2–1.8)	1.4 (1.1–1.64)	2.2 (1.5–3.33)	<0.0001
COVID-19 diagnosis/presentation	234	1.8 (1.32–2.62)	1.7 (1.3–2.2)	3 (2–4.5)	0.002
Discharge/death/last follow-up	213	1.55 (1.3–2.35)	1.5 (1.27–2)	3.3 (2.1–4.5)	<0.0001
Clinical severity, n (%)	250				<0.0001
Asymptomatic		15 (6)	15 (6.7)	0 (0)	
Mild		150 (60)	150 (67.8)	0 (0)	
Moderate		50 (20)	47 (21.2)	3 (10.3)	
Severe		35 (14)	9 (4)	26 (89.6)	

COVID-19, coronavirus disease 2019; CT, computed tomography; IQR, interquartile range.

### Clinical Presentation

Presenting symptoms included fever (88%, n=220), cough (72%, n=180), sputum production (52%, n=130), myalgia (25%, n=62), diarrhea (24%, n=60), dyspnea (22%, n=55), rhinorrhea (22%, n=55), sore throat (22%, n=55), headache (20%, n=50), loss of appetite (20%, n=50), fatigue (17%, n=43), loss of taste/smell (15%, n=37), nausea/vomiting (14%, n=35), abdominal pain (10%, n=25), and altered mental state (5%, n=12); 6% (n=15) were asymptomatic.

### Clinical Course

The cause of COVID-19 exposure was frequently related to community transmission (n=81), with an exposure to a family cluster (n=30) or a social cluster (n=51), and a nosocomial/healthcare cluster (n=30). COVID exposure was unknown in 139 recipients, and there was no donor

transmission. The average time between exposure and clinical symptoms was 6–7 days; the time between the onset of symptoms and the first medical visit was 2–3 days, and the average time between the first medical visit and hospital admission was 1–2 days. The time between the onset of symptoms and confirmation of COVID-19 was on average 10 days. Nearly 50% of patients had access to their transplant physician between the onset of symptoms and hospital admission for confirmation and management of COVID-19 by telehealth consultation. The time between the first positive severe acute respiratory syndrome coronavirus 2 sample and the first negative severe acute respiratory syndrome coronavirus 2 sample was 21 days (n=15).

### Laboratory Findings

At presentation, the median hemoglobin was 11.2 g/dL (IQR, 9.9–12.5), total white blood cell count was 6737/

mm<sup>3</sup> (IQR, 5118–9485), polymorphs 77% (68–86), lymphocyte 18% (IQR, 12–24), and platelet count was 215 × 10<sup>3</sup>/mm<sup>3</sup> (IQR, 174–254). Forty-nine percent of patients had normal CXR findings; abnormalities were seen in 51% (n = 112) and included consolidation (n = 112), pulmonary nodules (n = 20), lung cavitation (n = 5), pleural effusion (n = 5), and white lung (n = 10). The most common computed tomography (CT) findings (n = 120) were ground-glass opacities (n = 70), consolidation (n = 40), pulmonary nodules (n = 10), pleural effusion (n = 10), and lung cavitation (n = 10). Fifty patients (20%) showed CXR/CT scan abnormalities before a positive COVID test. Treatment modalities and clinical outcomes of KTRs with COVID-19 are summarized in Table 4.

### Changes in Immunosuppression

Immunosuppressive treatments were modified in the majority of patients. Antimetabolites (mycophenolate/azathioprine) were discontinued in the majority of patients (75%, n = 188); in other patients (23%, n = 57), the dosage was reduced. Calcineurin inhibitors (CNIs) were not changed in most patients (66%, n = 165); 20% (n = 50) underwent a dose reduction of CNIs. The dose of prednisolone was increased in 40% (n = 100) cases, whereas no changes were made in the remaining 60% (n = 150).

### Medical Management

Specific treatments included the application of azithromycin (n = 200, 80%), HCQ (n = 160, 64%), favipiravir (n = 54, 21.6%), remdesivir (n = 35, 14%), tocilizumab (n = 26, 10.4%), convalescent plasma (n = 15, 6%), and cytosorb filter (n = 4, 1.6%). No adverse effects such as prolonged QTc interval requiring early treatment discontinuation were documented with the combination of HCQ and azithromycin. Twenty of 26 recipients who received tocilizumab died, whereas 6 survived. Possible reasons for the poor outcome may have been delayed tocilizumab administration due to resource limitations with the initial dose being administered after the recipients were intubated (n = 2). Fifteen recipients received convalescent plasma, of whom 10 died and 5 were discharged. Thirty-five received remdesivir, of whom 7 died and 28 were discharged. The mortality was attributed to clinical severity at the time of treatment, associated comorbid conditions, multiorgan dysfunction, and secondary bacterial infections. Ten recipients received intravenous immunoglobulin (100 mg/kg for 5–10 d) in COVID treatment in high immunological risk for rejection, and all were discharged with normal kidney allograft function. Fifty-four recipients with mild-moderate disease severity received oral favipiravir, and 49 were discharged with normal kidney allograft function (Table 4).

**TABLE 4.**

**Treatment modalities and clinical outcomes of kidney transplant recipients with COVID-19**

	n (%)			P
	Total (N = 250)	Survivors (N = 221)	Nonsurvivors (N = 29)	
Immunosuppression change				
Steroid				<0.0001
Increased	100 (40)	71 (32)	29 (100)	
No change	150 (60)	150 (67)	0 (0)	
Antimetabolites				0.0002
Discontinued	188 (75.2)	159 (71.9)	29 (100)	
Reduced	62 (24.8)	62 (28)	0 (0)	
Calcineurin inhibitor				<0.0001
No change	165 (66)	165 (74.6)	0 (0)	
Reduced	50 (20)	42 (19)	8 (27.5)	
Discontinued	21 (8.4)	0 (0)	21 (72.4)	
Treatment				
Azithromycin	200 (80)	175 (79.1)	25 (86)	0.374
Hydroxychloroquine	160 (64)	141 (61.5)	19 (65)	0.856
Favipiravir	54 (21)	49 (22.1)	5 (17.2)	0.544
Remdesivir	35 (14)	28 (12.6)	7 (24)	0.094
Tocilizumab	26 (10.4)	6 (2.7)	20 (68.9)	<0.0001
Convalescent plasma	15 (6)	5 (2.3)	10 (34.4)	<0.0001
Cytosorb filter	4 (1.6)	1 (0.5)	3 (10.3)	<0.0001
Iv immunoglobulin	10 (4)	10 (4.5)	0 (0)	0.242
Clinical outcomes				
Home therapy	50 (20)	50 (22.6)	0 (0)	0.0004
Hospital stay	200 (80)	171 (77.3)	29 (100)	
Acute kidney injury	121 (48.4)	93 (42)	28 (96.5)	<0.0001
Renal replacement therapy	24 (9.6)	19 (8.6)	5 (17.2)	0.137
Graft loss	12 (4.8)	10 (4.5)	2 (6.8)	0.574
ICU stay	53 (21)	28 (12.6)	25 (86)	<0.0001
Intubation	30 (12)	1 (0.5)	29 (100)	<0.0001

COVID-19, coronavirus disease 2019; ICU, intensive care unit.

No mortality was reported in any COVID-19 KTR treated as an outpatient. Patients did not receive oseltamivir, chloroquine, colchicine, Chinese traditional medications, lopinavir/ritonavir+interferon, ribavirin, and plasma exchange.

### Hospital Course and Clinical Outcome

Bacterial pneumonia and urinary tract infection were the most common coinfections (n=39, 19.5%). A total of 53 (21%) required admission to the intensive care unit (ICU). Thirty-four percent (n=85) required oxygen supplementation, 10% (n=25) required noninvasive ventilation, and 12% (n=30) required mechanical ventilation (29 died with 1 patient still in the hospital). Acute kidney injury (creatinine increase by 0.3% or >50% of baseline) (48.4%, n=121) was more frequent in moderate to severe cases and uncommon in mild/asymptomatic cases. Twelve (4.8%) recipients reported graft loss during COVID-19 infection, all of whom had baseline chronic kidney graft dysfunction before COVID-19. Of 20 high immunological risk recipients screened for donor-specific antibodies, 10 had de novo donor-specific antibodies, potentially linked to a reduction in maintenance immunosuppression. Fifteen patients (7.5%) remained hospitalized; 156 patients (78%) were discharged from the hospital with a median follow-up of 28 days.

Overall patient mortality was 11.6% (29 of 250) and 14.5% (29 of 200) for hospitalized patients. Mortality rates increased to 47% (25 of 53) for patients in the ICU and 96.7% (29 of 30) for patients on mechanical ventilation. Statistically significant risk factors for increasing mortality were older age ( $P<0.0001$ ), dyspnea ( $P<0.0001$ ), disease severity ( $P<0.0001$ ), allograft dysfunction ( $P<0.05$ ), obesity ( $P<0.0001$ ), higher levels of inflammatory markers, such as CRP ( $P<0.0001$ ), IL-6 level ( $P<0.05$ ), and

procalcitonin ( $P<0.0001$ ), CXR abnormality ( $P<0.0001$ ), and ICU/ventilator requirement ( $P<0.0001$ ) (Tables 2–4). An additional multivariate analysis (Table 5) has been performed, suggesting an elevated baseline creatinine before COVID-19 as a risk factor for mortality ( $P=0.043$ ). Recipients with mild COVID-19 (n=50) were managed as outpatients; no mortalities were observed in this group.

### DISCUSSION

We have detailed a retrospective multi-institutional study on COVID-19-positive KTRs in 13 public and private sector transplant centers in India. To our knowledge, this is the largest transplant cohort with COVID-19 positivity reported from emerging countries. Although all 13 transplant centers in this study are actively involved in pediatric transplants, we did not observe symptomatic COVID-19 infections or COVID-19-positive pediatric recipients. On March 26, 2020, the Indian Government advisory suspended elective living donor and nonurgent deceased donor kidney transplants because of COVID-19 pandemic as a health priority leading to restricted transplant activities during national lockdown from March 24, 2020, to July 31, 2020, potentially explaining that they have seen less frequent cases recently.<sup>2,25</sup> It is also relevant to point out that many patients with COVID-like symptoms have undergone uneventful home treatment for acute febrile illness during the nationwide lockdown when local testing could not be performed because of resource and testing limitations. Those patients were not included in this analysis. Our multicenter study may thus overestimate mortality rates in Indian KTRs as it is possible that many KTRs remained undiagnosed and were never hospitalized or tested.

Mortality rates of 4.8%–33% have been reported in solid organ transplant (SOT) recipients with COVID-19

**TABLE 5.**

#### Cox regression model for multivariate analysis

Variables in the equation	B	SE	Wald	df	P Sig.	HR-Exp(B)	95% CI for Exp(B)	
							Lower	Upper
Group	-13.112	26.211	0.250	1	0.617	0.000	0.000	4.13216
Age	-0.160	0.368	0.190	1	0.663	0.852	0.414	1.753
Hemoglobin	2.251	2.827	0.634	1	0.426	9.500	0.037	2.424E3
White blood cell	0.001	0.001	1.305	1	0.253	1.001	0.999	1.002
Neutrophil	0.337	1.207	0.078	1	0.780	1.401	0.132	14.926
Lymphocyte	0.403	1.481	0.074	1	0.786	1.496	0.082	27.233
Platelet	-0.029	0.042	0.474	1	0.491	0.971	0.894	1.055
Procalcitonin	-1.706	1.649	1.070	1	0.301	0.182	0.007	4.599
C-reactive protein	0.037	0.255	0.021	1	0.886	1.037	0.630	1.709
IL-6 level	0.011	0.120	0.008	1	0.927	1.011	0.800	1.278
Ferritin	-0.003	0.007	0.122	1	0.726	0.997	0.983	1.012
D-dimer	0.002	0.004	0.265	1	0.607	1.002	0.994	1.010
Lactate dehydrogenase	-0.003	0.027	0.015	1	0.901	0.997	0.945	1.051
Alanine aminotransferase	0.045	0.272	0.027	1	0.869	1.046	0.614	1.782
Blood urea	0.040	0.124	0.102	1	0.749	1.040	0.816	1.327
Baseline creatinine before COVID-19	8.599	4.255	4.083	1	<b>0.043</b>	5.424	1.294	2.273E7
Creatinine at COVID-19 diagnosis	-3.964	3.577	1.228	1	0.268	0.019	0.000	21.059
Creatinine at discharge/follow-up	-0.163	2.418	0.005	1	0.946	0.849	0.007	97.178
Albumin	15.340	16.777	0.836	1	0.361	4.592E6	0.000	8.755E20

CI, confidence interval; COVID-19, coronavirus disease 2019; df, degree of freedom; HR, hazard ratio; IL-6, interleukin-6.

**TABLE 6.**  
**Clinical features and outcomes of COVID-19 in the organ transplant recipients**

	Cravedi et al <sup>3</sup>	Pereira et al <sup>4</sup>	Bossini et al <sup>5</sup>	Akalin et al <sup>6</sup>	Caillard et al <sup>7</sup>	Kates et al <sup>8</sup>
Study population	144	90	53	36	279	482
Study location	United States, Italy, Spain	United States	Italy	United States	France	Multicenter cohort, United States
Study duration (2020)	March 2–May 15	March 13–April 3	March 1–April 16	March 16–April 1		March 1–April 15
Type of transplants	Kidney (n = 144)	Kidney (n = 46), lung (n = 17), liver (n = 13), heart (n = 9), 5 dual-organ transplants	Kidney (n = 53)	Kidney (n = 36)	Kidney (n = 268), dual-organ transplant (n = 11)	Kidney (n = 318), liver (n = 73), heart (n = 57), lung (n = 30), 5 dual-organ transplants
Median age of presentation (y)	60	57	60	60	61.6	58
Median transplant age (y)	5	6.6	9.2	N/A	6.1	5
Comorbidities (%)						
Hypertension	95	64	79	94	90.1	77.4
Diabetes	52	46	21	69	41.3	51
Clinical presentation (%)						
Fever	67	70	96	58	80	54.6
Cough	–	59	49	53	63.6	73.2
Dyspnea	67	43	28	44	40.3	58.5
Diarrhea	38	31	17	22	43.5	47.9
Immunosuppression reduction/withheld (%)						
CNI	23	18	50	21	28.7	
Antimetabolite	68	88	100	86	70.8	66
Steroid		7% decrease				
Complications						
Acute kidney injury (%)	52		33	21	43.6	37.8
Acute respiratory distress syndrome (%)	29	35	60	39		
Mortality (%)	32	18 (overall), 24 (hospitalized)	33	28	22.8 (30 d)	18.7 (28 d)
Risk factors for mortality	Older age, lower lymphocyte counts, eGFR, higher serum lactate dehydrogenase, procalcitonin, IL-6 levels	Advanced age	Age >60 y, dyspnea, tacrolimus, and requiring admission		Overweight, fever, dyspnea, age >60 y, CVD	Age >65 y, obesity, chronic lung disease, lymphopenia, radiological abnormality
Median follow-up	52 d	20 d	26 d			28 d
Remark		24% mild, 46% moderate, 30% severe disease	15% outpatient mild disease, 85% inpatient severe disease	75% deceased donor, 22% outpatient, 78% inpatient		

CNI, calcineurin inhibitor; COVID-19, coronavirus disease 2019; CVD, cardiovascular disease; eGFR, estimated glomerular filtration rate; IL-6, interleukin-6.

in recent studies from the developed world<sup>3-28</sup> (Table 6). Rates of COVID-19 in Spain have been high with a more aggressive course in recipients of SOTs.<sup>25</sup> Moreover, hospitalized SOT recipients with COVID-19 had a trend toward higher mortality compared with controls (37% versus 22.9%;  $P=0.51$ ) in a recent study.<sup>26</sup> Recipients in our study had high rates of acute kidney injury similar to reports from the developed world. However, our transplant population seemed to have a lower mortality (11.8%), potentially linked to the relatively younger age of KTRs in India.

Risk factors for mortality in studies of the developed world have been older age (>60 y), lower lymphocyte counts, CRP (cutoff: 100 mg/L), high IL-6 levels (cutoff: 65 ng/L), high procalcitonin, high D-dimer (>960 ng/mL), oxygen requirement  $\geq 6$  L/min, mechanical ventilation, elevated serum creatinine before COVID-19, higher serum lactate dehydrogenase (>300  $\mu$ L), thymoglobulin induction therapy, HCQ,<sup>27</sup> past treatment for acute rejections, disease severity at the time of presentation, >1 comorbidity, or concomitant infections.<sup>3-28</sup> Those risk factors are also present in our study (Tables 2–5). Most KTRs



developed asymptomatic (6%), mild (60%) to moderate (20%) COVID-19, and we observed a low incidence of severe disease (12%) in our KTR population comparable with the recent report of asymptomatic (25%), mild (28%), moderate (34%), and severe (12%) COVID-19 in SOT recipients.<sup>28</sup> The mortality was higher in transplant and waitlisted patients (32% versus 15%;  $P=0.72$ ), and CRP at 48 hours and peak CRP were associated with mortality in 2 groups, whereas quick sequential organ failure assessment score at 48 hours was associated with mortality for transplant patients in the study from London, United Kingdom.<sup>20</sup>

Our study also shows that carefully selected KTRs with mild COVID-19 can be managed at home with favorable outcomes as described in an Italian and United Kingdom cohort.<sup>5,19,22</sup> This finding supports that home treatment is feasible for mild COVID-19 KTRs with relevance for countries of the developing world with limited healthcare resources.<sup>22</sup>

Although our mortality rate appears overall lower compared with that of reports coming from the developed world, mortalities are significantly higher as compared with the general populations (2%–3%) that have undergone COVID-19 testing in India (Table 1). Possible contributing factors for higher mortality of COVID-19 in KTRs may be linked to both immunosuppression and higher rates of comorbidities (94% versus 70%).<sup>2</sup>

For a meaningful conclusion on the risks of morbidity and mortality of COVID-19-positive transplant patients, it appears relevant to assess the risks of the overall population in India.

The All India Institute of Medical Sciences, New Delhi, a tertiary care center in North India, reported a mortality of 1.4% in a single-center study of 144 hospitalized patients with confirmed COVID-19 from March 23 to April 15, 2020.<sup>34</sup> The Indian Government reported on a COVID-19-related mortality of 1.8% due to timely and effective clinical management of patients in critical care.<sup>35</sup> The mortality was 5.1% in a retrospective cohort analysis of 445 COVID-19-positive hospitalized patients in Karnataka from March 9 to April 23, 2020, exceeding the overall national mortality rate of 3.4% as on May 8, 2020.<sup>36</sup> In a retrospective study of 20 patients in a tertiary care hospital at Ahmedabad in Western India receiving tocilizumab for moderate and severe COVID-19, a mortality rate of 11% has been reported.<sup>37</sup> The mortality rate increased furthermore in severely ill patients, and a designated COVID-19 ICU at Pune in Western India reported a mortality rate of 16.7% in 24 critically ill COVID-19 patients from April to May 15, 2020.<sup>38</sup> An analysis of 3000 deaths till August 31, 2020, by the Gujarat state health department revealed that 26% succumbed to viral infections within 3 days of hospital admission. Sixty-five percent of patients had comorbidities, and 58% of deaths were in patients aged  $\geq 60$  years.<sup>39</sup> Thus, the mortality rate of hospitalized COVID-19 nontransplant patients appears to be significantly lower than that of transplant patients in India.<sup>34,40</sup> Differences seem less pronounced with increasing severity of the disease.

Comparing outcomes of COVID-19 in transplant patients with that of COVID-19 in the dialysis population may be of additional relevance. Published data from dialysis centers in India have reported mortality rates between

12% and 37.8%.<sup>41,42</sup> Although those numbers are sobering, they may encourage transplant centers to remain active during the COVID-19 pandemic.

As the epidemiological situation is constantly evolving, it is recommended that each transplant team assess the current scenario that best describes their local situation. Transplant programs are advised that there will be a case-by-case evaluation when carrying out a transplant based on the availability of healthcare resources including ICU; risk/benefit of exposing an immunosuppressed patient to the potential risk of COVID-19 (according to the number of cases and the possibility of admission under ideal isolation conditions) versus the urgent medical need for transplantation (clinical situation of the patient).<sup>33</sup>

We understand that our study has limitations as there was no uniform treatment protocol for COVID-19-positive patients and that treatment changes continued to evolve based on new evidence and new data from the growing number of COVID-19 published reports. It is possible that our data shows an underreporting of COVID-19 in transplant recipients as patients are treated at home with teleconsultation for mild febrile illness. Our report also focused on hospitalized patients, and thus conclusions may not be broadly applicable to all patients diagnosed and managed in the outpatient setting, particularly as testing practices evolve. In summary, our data provides relevant insights into outcomes of kidney transplant patients in India and may thus serve to assess risks and improve outcomes of patients with COVID worldwide.

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