




SHORT COMMUNICATION

COVID-19 in solid organ transplant recipients: No difference in survival compared to general population

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Abstract

Coronavirus disease 2019 (COVID-19) may be associated with worse outcome in solid organ transplant (SOT) recipients. We performed a prospective cohort study of hospitalized patients with confirmed diagnosis of COVID-19, from March 15 to April 30, 2020, at two tertiary hospitals in Emilia-Romagna Region. SOT recipients were compared with non-SOT patients. Primary endpoint was all-cause 30-day mortality. Relationship between SOT status and mortality was investigated by univariable and multivariable Cox regression analysis. Patients were assessed from COVID-19 diagnosis to death or 30-day whichever occurred first. Study cohort consisted of 885 patients, of them 24 SOT recipients (n = 22, kidney, n = 2 liver). SOT recipients were younger, had lower BMI, but higher Charlson Index. At admission they presented less frequently with fever and respiratory failure. No difference in 30-day mortality between the two groups (19% vs 22.1%) was found; however, there was a trend toward higher rate of respiratory failure (50% vs 33.1%, $P = .07$) in SOT recipients. Superinfections were more represented in SOT recipients, (50% vs 15.5%, $P < .001$). At multivariate analysis adjusted for main covariates, there was no association between SOT and 30-day mortality HR 1.15 (95% CI 0.39-3.35) $P = .79$. Our data suggest that mortality among COVID-19 SOT recipients is similar to general population.

KEYWORDS

COVID-19, SARS-CoV-2, solid organ transplantation

1 | INTRODUCTION

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-associated coronavirus disease 2019 (COVID-19) has gripped the world in a pandemic, challenging its culture, economy, and health-care infrastructure. Available epidemiological data depict COVID-19 as a polymorphic disease with several clinical presentations and

severity degrees. Crude fatality rates are on average 5% with notable variation by age groups and settings.^{1,2} Solid organ transplantation (SOT) is a challenging setting for several reasons. Symptoms and imaging findings can be confused with underlying conditions or initially mitigated by the immunosuppressive state.³ Efficacy and safety of antiviral and immunomodulatory drugs used as COVID-19 treatment are unknown in this setting.⁴ Finally, published cases series of SOT

Abbreviations: CMV, cytomegalovirus; CNI, calcineurin inhibitor; COVID-19, coronavirus disease 2019; ICU, intensive care unit; IL-6, interleukin-6; KT, kidney transplant; LOS, length of hospital stay; LT, liver transplant; MMF, mycophenolate mofetil; mTOR, mammalian target of rapamycin; qSOFA, quick sequential organ failure assessment; RT-PCR, real-time polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SOT, solid organ transplant; SRF, severe respiratory failure; WHO, World and Health Organization.

patients diagnosed with COVID-19 have reported high morbidity and mortality, with intensive care unit admission and mortality rates ranging from 0%-39% to 0%-50%, respectively.⁴⁻¹⁰ However, data on differences in symptoms, clinical severity, treatment management and outcome between SOT and non-SOT patients hospitalized with COVID-19 have yet to be investigated. We performed a prospective multicenter cohort study of hospitalized patients with COVID-19 diagnosis to compare clinical presentation, therapeutic management and outcome between SOT and non-SOT recipients.

2 | MATERIALS AND METHODS

2.1 | Study design, population, and setting

Prospective cohort study of adult patients hospitalized at Sant'Orsola-Malpighi Hospital and Rimini Hospital, from March 15 to April 30 2020. Patients with detection of SARS-CoV-2 by RT-PCR on respiratory specimens were included. Patients were followed up to death, or hospital discharge. Diagnostic testing for COVID-19 and hospitalization was performed according to local policy and clinical judgment, and were not dictated by study protocol. Local microbiology databases were used to identify patients. Clinical charts and hospital electronic records were used as data sources. Data were collected de-identified and managed using REDCap electronic data capture tools hosted at University of Bologna.^{11,12} The study was approved by the Ethic Committee of the promoting center (Comitato Etico Indipendente di Area Vasta Emilia Centro, n. 283/2020/Oss/AOUBo).

2.2 | Definitions and variables

Primary endpoint was all-cause 30-day mortality. Secondary endpoints included severe respiratory failure and length of hospital stay. Severe respiratory failure was assessed from diagnosis to hospital discharge and defined according to World and Health Organization (WHO) criteria as: SpO₂ <93% with 100% FiO₂ (reservoir mask or continuous positive airway pressure ventilation or other non-invasive ventilation), respiratory rate >30 bpm, or respiratory distress ([https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-\(ncov\)-infection-is-suspected](https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected), accessed 5 April 2020).

Exposure variables included age, sex, and body mass index. Underlying conditions were assessed according to Charlson comorbidity index. For SOT patients, baseline immunosuppression regimen and management of immunosuppressive drugs after COVID-19 diagnosis were recorded. As for SARS-CoV-2 infection, we collected (a) date of symptoms onset; (b) date and symptoms at hospitalization; (c) vital signs, laboratory tests, and imaging findings at hospitalization; (d) clinical severity at hospitalization classified according to qSOFA, SOFA, and CURB-65; and (e) all administered

antiviral and immunomodulatory treatments. Finally, occurrence of viral, bacterial, and/or fungal superinfection was assessed from COVID-19 diagnosis to hospital discharge. Cytomegalovirus (CMV) infection was diagnosed by evidence of CMV replication regardless of symptoms in any body fluid or tissue specimen.¹³ CMV-DNAemia was detected by quantitative nucleic acid testing on whole blood. Diagnostic testing for CMV infection was requested by attending physicians and was not dictated by study protocol; generally, antiviral treatment was recommended for high levels CMV-DNAemia >100 000 copies/mL. Bacterial infection was assessed according to CDC criteria.¹⁴ Invasive fungal infections were defined according to European Organization for Research and Treatment of Cancer/Invasive Fungal Infections Cooperative Group and the National Institute of Allergy and Infectious Diseases Mycoses Study Group (EORTC/MSG) criteria.¹⁵ Diagnostic testing for infection and its etiology was performed by attending physicians and was not dictated by study protocol.

2.3 | Statistical analysis

Categorical variables were expressed as absolute numbers and their relative frequencies. Continuous variables were expressed as mean \pm standard deviation (SD) if normally distributed, or as median and interquartile range (IQR) if non-normally distributed. For comparison of SOT and non-SOT patients, Pearson chi-square or Fisher's exact test were used for categorical variables. Continuous variables were compared using Student's *t* or Mann-Whitney *U* test according to their distribution. Univariate and multivariate analysis of risk factors for all-cause 30-day mortality was done. After verifying for proportional hazard and collinearity, all variables with a *P* value <.1 were introduced in a Cox regression model adjusted for the SOT condition. Patients were considered from COVID-19 diagnosis to death or 30-days. Statistical significance was considered for *P* <.05. All analysis was performed with SPSS 21.0.

3 | RESULTS

Study cohort consisted of 885 hospitalized patients with COVID-19 diagnosis: median age was 69 (IQR 57-80) years, 66.9% were male (see Table 1). Overall, 24 SOT patients were included: 22 (91.7%) kidney transplant (KT), and 2 (8.3%) liver transplant (LT) recipients. Median time from SOT to COVID-19 diagnosis was 3.8 (0.15-14.3) years; with 4 (16.7%) patients diagnosed of COVID-19 within 1 month after SOT, 5 (20.8%) between 2 and 6 months, and 15 (62.5%) over 6 months. Among KT recipients, 10 (41.7%) presented with renal failure at COVID-19 diagnosis, of them 8 had chronic renal failure and 2 developed an acute worsening of graft function. Baseline immunosuppressive regimens consisted of calcineurin inhibitors (CNI) plus mycophenolate mofetil (MMF) (*n* = 14), CNI plus mammalian target of rapamycin (mTOR) inhibitors (*n* = 4), CNI alone (*n* = 3), mTOR alone (*n* = 1), low dose

TABLE 1 Comparison of SOT and non-SOT hospitalized patients with COVID-19 diagnosis

	Total N = 885 (%)	SOT N = 24 (%)	Non-SOT N = 861 (%)	P
Demographic and comorbidities				
Age (years) [median (IQR)]	69 (57-80)	62 (48-67)	70 (57-80)	0.001
Sex, male	592 (66.9)	15 (62.5)	577 (67)	0.6
BMI [median (IQR)]	26 (24-29)	24.8 (23.5-26)	26 (24-29)	0.03
Charlson Index [median (IQR)]	4 (2-6)	5 (4-7)	3 (1-6)	0.002
Signs and symptoms at hospitalization				
Time from symptoms onset to hospitalization (days) [median (IQR)]	6 (3-9)	3 (0-7)	6 (3-9)	0.017
Fever >38°C	329 (37.5)	5 (20.8)	324 (37.9)	0.02
Cough	473 (54.1)	12 (50)	461 (54.2)	0.7
Dyspnea	384 (43.8)	9 (37.5)	375 (44)	0.5
Diarrhea	73 (8.3)	2 (8.3)	71 (8.3)	0.9
MAP [median (IQR)]	90 (83-97)	93 (88-105)	90 (83-97)	0.03
Pulse rate [median (IQR)]	86 (76-97)	80 (75-88)	86 (76-97)	0.09
Respiratory rate [median (IQR)]	20 (18-24)	19 (15-21)	20 (18-24)	0.02
PaO ₂ /FiO ₂ [median (IQR)]	314 (254-368)	352 (314-410)	314 (252-367)	0.028
Laboratory parameters at hospitalization				
WBC (10 ⁹ /L)	5.9 (4.4-8.1)	5.6 (4.4-7.3)	5.9 (4.4-8.1)	0.7
Lymphocytes count (10 ⁹ /L)	0.95 (0.7-1.3)	0.97 (0.6-1.3)	0.95 (0.7-1.3)	0.4
Creatinine (mg/dL)	0.99 (0.8-1.3)	2.1 (1.5-4.9)	0.98 (0.8-1.2)	<0.001
LDH (U/L)	295 (233-397)	218 (199-351)	297 (237-398)	0.01
CRP (mg/dL)	6.4 (2.4-11.7)	2.1 (0.4-10.2)	6.1 (2.5-11.7)	0.009
PCT (ng/mL)	0.1 (0.1-0.4)	0.5 (0.1-1.9)	0.1 (0.1-0.3)	0.03
Disease severity at admission				
qSOFA	0 (0-1)	0 (0-1)	1 (0-1)	0.04
SOFA	2 (1-3)	3 (2-5)	2 (1-3)	0.001
CURB65	1 (0-1)	1 (0-1)	1 (0-1)	0.6
Needing of oxygen support	462 (52.2)	9 (37.5)	453 (52.6)	0.14
Radiological findings				
Positive chest-Rx	638 (76.1)	13 (59.1)	625 (76.6)	0.55
HRCT lung consolidation	249 (60.9)	3 (16.7)	246 (62.9)	<0.001
HRCT ground glass	359 (87.6)	17 (94.4)	342 (87.2)	0.3
HRCT crazy paving	79 (20.1)	2 (11.1)	77 (20.5)	0.3
COVID-19 treatment				
Hydroxychloroquine	811 (91.6)	23 (95.8)	788 (91.5)	0.4
Azithromycin	150 (16.9)	7 (29.2)	143 (16.6)	0.1
HCQ + AZT	141 (15.9)	6 (25)	135 (15.7)	0.2
DRV/cobi	76 (8.6)	6 (25)	70 (8.1)	0.004
Tocilizumab	177 (20)	12 (50)	165 (19.2)	<0.001
High dose steroids ^a	369 (41.7)	15 (62.5)	349 (40.5)	0.03
Superinfections during hospitalization				
CMV infection	84 (9.5)	9 (37.5)	75 (8.7)	<0.001
Bacterial infection	142 (16.4)	12 (50)	130 (15.5)	<0.001
Fungal infection ^b	15 (1.7)	2 (8.3)	13 (1.5)	0.01
Outcome				
Severe respiratory failure	293 (33.5)	12 (50)	281 (33.1)	0.07

(Continues)

TABLE 1 (Continued)

	Total N = 885 (%)	SOT N = 24 (%)	Non-SOT N = 861 (%)	P
Days from diagnosis to severe respiratory failure [median (IQR)]	2, 0-6	6, 2-9	2, 0-5	<0.001
ICU admission	290 (19.9)	13 (52)	277 (19.3)	<0.001
Days from diagnosis to ICU admission [median (IQR)]	2.5 (0.25-6.75)	7.5 (4.5-10.75)	2 (0-6)	0.005
Length of hospital stay (days) (median, IQR)	10 (6-17)	22 (8-36)	10 (6-17)	0.047
All-cause 30-d mortality	190 (22)	4 (19)	186 (22.1)	0.5
Time to death (days) [median (IQR)]	10, 6-18	20, 7-30	10, 6-17	<0.001

Abbreviations: BMI, Body Mass Index; CMV, Cytomegalovirus; COVID-19, Coronavirus Disease 2019; CRP, C-Reactive Protein; CURB65, Confusion, Urea, Respiratory rate, Blood pressure and age ≥ 65 ; FiO₂, Fraction of inspired oxygen; HRCT, High-resolution computed tomography; ICU, Intensive Care Unit; IL-6, Interleukin-6; IQR, Interquartile Range; LDH, Lactate dehydrogenase; MAP, Mean Arterial Pressure; PaO₂, Partial pressure of arterial oxygen; PCT, Procalcitonin; qSOFA, quick sequential organ failure assessment; Rx, Radiography; SOT, Solid Organ Transplant; WBC, White Blood Cell.

^aDefined as 0.5-1 mg/Kg/daily of prednisone equivalents.

^bIncluded three invasive candidiasis and 12 pulmonary aspergillosis.

prednisone alone (n = 1), and none (n = 1). Low dose prednisone was concomitantly administered to all except three patients. Upon COVID-19 diagnosis, immunosuppressive regimens were modified in all patients. Briefly, mTOR was always discontinued, MMF was discontinued in all but 1 case, CNI was discontinued in 19 out of 21 patients.

Comparison of SOT and non-SOT patients showed several differences (Table 1). SOT recipients showed lower median age (62 vs 70 years, $P < .001$), lower median BMI (24.8 vs 26, $P = .03$), but higher median Charlson Index (5 vs 3, $P = .002$) than non-SOT patients. The median time from symptom onset to hospitalization was significantly lower (3 vs 6 days, $P = .017$) in SOT patients. At hospital admission, significant difference between SOT and non-SOT patients was found for fever (20.8% vs 37.9%, $P = .02$), PaO₂/FiO₂ ratio (352 vs 314, $P = .028$), median LDH (218 vs 297, $P = .01$) and lung consolidations (16.7% vs 72.9%, $P < .001$). As for therapeutic management, SOT patients received more frequently darunavir/cobicistat (25% vs 8.1%, $P = .004$), tocilizumab (50% vs 19.2%, $P < .001$), and high doses steroids (62.5% vs 40.5%, $P = .03$). CMV infection was diagnosed more frequently in SOT recipients (37.5% vs 8.7%, $P < .001$), as well as bacterial (50% vs 15.5%, $P < .001$) and fungal (8.3% vs 1.5%, $P = .01$) infections.

All-cause 30-day mortality rates were similar in the two groups (19% vs 22.1%, $P = .5$). Among KT recipients, mortality rate was 20%, whereas none of LT recipients died. During hospitalization, SOT recipients developed more frequently severe respiratory failure (50% vs 33.1%, $P = .07$), and were more frequently admitted to ICU (52% vs 19.3%, $P < .001$), length of hospital stay was also longer (22 vs 10 days, $P = .047$).

Univariate analysis for 30-day mortality showed significant differences between survivors and non-survivors for age, sex, and Charlson Index. Needing of oxygen support at hospital admission, as well as higher qSOFA and SOFA scores, was associated to death within 30 days from COVID-19 diagnosis (see Table S1). At multivariate analysis, independent predictors of 30-day mortality were age,

TABLE 2 Multivariate analysis of risk factors for 30-d mortality

	HR (95% CI)	P
Age	1.07 (1.05-1.09)	<.001
Female	0.65 (0.46-0.91)	.01
Charlson Index	1.08 (1.01-1.15)	.02
BMI	1.05 (1.01-1.09)	.004
RR	1.04 (1.02-1.06)	<.001
LDH	1.002 (1.001-1.003)	<.001
CRP	1.02 (1.01-1.03)	<.001
SOFA	1.32 (1.21-1.43)	<.001

Abbreviations: BMI, body mass index; CRP, C-reactive protein; HR, hazard ratio; LDH, lactate dehydrogenase; RR, respiratory rate; SOFA, sequential organ failure assessment.

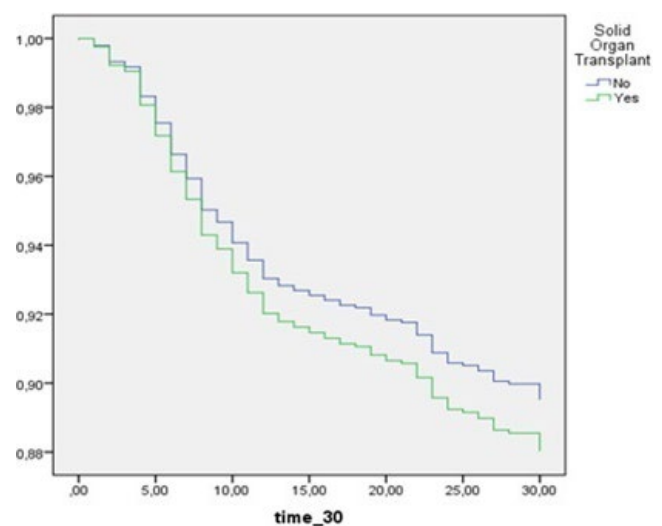


FIGURE 1 Survival between SOT and non-SOT hospitalized patients with COVID-19. Comparison adjusted for independent covariates by Cox regression analysis—SOT HR 1.15 (95% CI 0.39-3.35) $P = .79$

Charlson Index, increased respiratory rate, LDH, elevated C-reactive protein, and SOFA score. Female sex was found to be protective (Table 2). Therefore, SOT was not associated with increased risk of death (Figure 1).

4 | DISCUSSION

Management of SOT recipients diagnosed of COVID-19 is challenging. Although initial clinical presentation is milder compared to general population, progression toward severe respiratory failure is more frequent than in non-SOT recipients. However, there was no significant difference in 30-day survival between SOT recipients and general population, also when adjusted for potential confounders. SOT recipients showed higher rates of superinfection than non-SOT patients with longer duration of hospital stay, confirming the high impact of COVID-19 on morbidity of SOT patients.

In our study, the median time from transplant to COVID-19 diagnosis was shorter compared to other series.^{5,6,8,10} The timeline of transplantation seems to play an important role, as we observed higher rates of severe respiratory failure among patients who undergone transplantation within one year from COVID-19 diagnosis compared to late transplant recipients (66.7% vs 16.7%, respectively—data not showed). This finding suggests that intensity of immunosuppression seems to be strictly related to the risk of developing a more severe disease.

In our cohort, typical symptoms of COVID-19 were uniformly represented in both groups except fever. A recent case series of 36 kidney transplant recipients showed similar results.⁶ In addition, SOT recipients presented with lower respiratory rate, better gas exchanges, and lower pulmonary consolidations at diagnosis than non-SOT patients. These findings may reflect a milder disease at presentation in SOT patients, even if this assumption could be influenced by a more immediate clinical evaluation and diagnosis compared to general population. Indeed, the median time from symptoms onset to hospitalization was of 3 vs 6 days in SOT and non-SOT groups, respectively.

Anyway, clinical evaluation alone could be unfruitful in identifying patients at high risk for complicated course. Indeed, we noted a discrepancy between qSOFA and SOFA score assessment at hospital admission, the median value of the latter was higher among SOT recipients differently for qSOFA. Although in our SOT population SOFA score was influenced by high rates of chronic renal failure, this observation can suggest that upon COVID-19 diagnosis in a SOT patient, laboratory tests along with clinical evaluation are strongly recommended.

Previous case series⁵⁻⁹ of SOT recipients showed high in-hospital mortality rates ranging from 24% to 32%. In our study, mortality rates in SOT and non-SOT patients were similar around 20%. Considering the high incidence of severe respiratory failure among SOT recipients, these relatively low mortality rates may reflect a massive use of healthcare resources. This assumption is supported

by early hospitalization, a significant major use of novel immunosuppressive drugs, such as IL-6 inhibitors, and a greater ease of access to ICU.

Management of chronic immunosuppressive regimen is another important issue. Reductions in immunosuppression are usually applied by many clinicians in order to improve viral clearance; however, this approach could increase the risk of immune reconstitution and rejection. Indeed, a Chinese case report showed an acute rejection in a liver transplant recipient following discontinuation of immunosuppressants and administration of low dose of methylprednisolone.⁴ In our cohort, CNI, MMF, and mTOR inhibitors were mostly discontinued at diagnosis, especially if the patient was eligible to receive an IL-6 inhibitor or high doses of methylprednisolone. No worsening of graft function was observed. Nevertheless, the wide use of immunosuppressive agents in an attempt to contrast the evolving course of COVID-19 illness may lead to other infections. Indeed, half of SOT recipients in our cohort developed at least one bacterial infection, and a quarter of them developed CMV reactivation needing use of antiviral agents. However, CMV infection occurred also in non-SOT patients, suggesting that high doses of steroids and others immunosuppressive drugs used for COVID-19 could play a role in CMV reactivation even in general population.

Our study has some limitations, despite we analyzed a large cohort of hospitalized patients with COVID-19; the number of SOT recipients was low limiting to assess predictors of poor outcome in this setting. The relatively low size of SOT recipients did not allowed further risk stratification analysis. Moreover, kidney transplants were an absolute majority, not allowing a homogeneous distribution of different SOT. Therefore, a 30-day follow-up from diagnosis is useful to depict a short outcome of patients affected by COVID-19; however, it could not consider any late complication of the disease.

To conclude, our study underlines difficulties in the management of SOT patients with COVID-19. Careful assessment seems to be important for recognizing patients at risk of complicated course. Risk-benefit balance of using novel immunosuppressive drugs in this setting should be investigated in larger studies.

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CONFLICT OF INTEREST

Authors declare no conflict of interest related to the content of the present manuscript.

AUTHORS' CONTRIBUTIONS

MR involved in data collection, data analysis, and drafting the manuscript. MB involved in data collection and data analysis. LB involved in data collection. LP involved in data collection. RP involved in data collection. GC involved in study design. MM involved in study design. MR involved in support in study design. MC involved in support in study design. FC involved in support in study design. PV involved in study design and manuscript revision. MG involved in study design, data analysis, and manuscript revision.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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