

COVID-19 Infection and Mortality among Solid Organ Transplant Recipients and Candidates before availability of specific vaccines in Colombia

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Abstract

According to official data provided by the World Health Organization (WHO), China reported the first cases related to the COVID-19 pandemic on December 31, 2019. More than two months later, WHO declared the new infection a pandemic on March 11, 2020.

Key Words: specific vaccines; infection and mortality

Introduction

According to official data provided by the World Health Organization (WHO), China reported the first cases related to the COVID-19 pandemic on December 31, 2019. More than two months later, WHO declared the new infection a pandemic on March 11, 2020 [1].

The SARS-CoV-2 infection was diagnosed for the first time in Colombia in a young woman who returned from Italy on March 6, 2020. Since that day and until February 28, 2021, the country had 2.251.690 accumulated laboratory-confirmed cases, of which 59.766 (2,6%) had died, and 36.659 (1,6%) were still active [2].

Solid organ transplant recipients are considered as a high-risk group for developing COVID-19-related complications [3-4]. Several studies showed poor clinical outcomes and an increased risk of death in these individuals than in those who were waitlisted [5-7]. An earlier investigation from the United States, however, found that waitlisted patients were more likely to require hospitalization (82% vs. 65%) and were at a higher risk of mortality (34% vs. 16%) than transplant patients [7].

The availability of information obtained through interinstitutional strategic collaboration as complimentary sources of data that is being developed in Colombia can be used to, for example, study the impact of COVID-19 in the Colombian population. Under these considerations, the main objective of this paper is to describe epidemiological measures such as positivity rates of infection, deaths, mortality, and case-fatality ratios in both solid organ transplant recipients and waitlisted candidates during the first year from the arrival of COVID-19 to Colombia, the total period before specific viral vaccines were distributed around the country.

Methodology

Design and period of study

We conducted an observational study using several sources of routinely collected health data, with follow-up of the vital status, of both waitlisted candidates and transplant recipients carried out in Colombia. The analysis period runs from March 6, 2020, the day of the first confirmed imported case in Colombia, to February 28, 2021 (cut-off day of the current analysis, also

representing the total pandemic period before COVID-19 vaccines were available in the country). The COVID-19 vaccines program in Colombia began at the end of February/2021, so our results basically reflect the situation of solid organ transplant recipients and candidates (waitlist) before the introduction of specific vaccines in the Colombian population.

Selection of subjects

The complete list of potentially eligible subjects was obtained from the National Donation and Transplant Information System (RedDataINS©) of the National Health Institute of Colombia, the institution in charge of managing the donation and transplantation process in the country. In our study, we included those subjects in the list who had a known result (positive or negative) of a SARS-CoV-2 test by using the National COVID-19 Data Repository (SISMUESTRAS), which is the official dataset of the laboratory results of the COVID-19 tests. There were no additional exclusion criteria

Definition of a positive case of SARS-Cov-2 infection

In this study the presence of an infection was defined as a positive result on real-time polymerase chain reaction (PCR) assay of nasal and/or pharyngeal swab specimens and/or a positive result on a serological or antigen test as it was reported by authorized clinical laboratories throughout the country, either public or private, as part of their function for supporting the clinical diagnostic process or as screening before, for example, of surgical procedures.

Data collection

Baseline sociodemographic and clinical variables related to history of chronic conditions, type of organ affected, results of the COVID-19 test, vital status at the time of cut-off and immediate cause of death were included in the study. An additional variable was created for this study to identify those waitlisted candidates who changed their status to transplant recipient after the COVID-19 test. In accordance to this variable, we established three categories of subjects for the study: those who were transplant recipients before the diagnostic test; those who were on the waiting list both before and after the diagnostic test until death or the cut-off date, and those who received a transplant after the diagnostic test.

Data collection

RedDataINS system let us select subjects and obtain clinical information for each of them. It was complemented, if available to a specific individual, with that from the National Public Health Surveillance System (SIVIGILA).

On the other hand, information of deaths was obtained from the provisional information of a National System of Vital Statistics (RUAF-ND),

which is based on medical death certificates and let to identify if deaths were due to COVID-19 or not. This database may be subject to updating (in our case, it was verified at Jun 30, 2021).

Statistical analysis

We summarize quantitative variables with arithmetic means (standard deviation) or medians (interquartile ranges, IQR) and categorical variables with proportions. We calculated percentages (%) of positivity to infection, number of deaths, case-fatality ratios (CFR), and all-cause mortality for each group and subgroup of analysis.

Ethical aspects

This research used data derived from pre-existing databases in the country. Subjects were not directly interviewed or exposed to any clinical intervention. The study had no any risk or negative consequence for subjects.

Results

Basic demographic and clinical information

At the cut-off date, a total of 9779 persons were registered in the RedData-INS© database. The present analysis includes 2551 (26%) of them, who were tested for SARS-CoV-2 and whose results were reported (see above). Most of the subjects included were men (57,9%), aged between 50 and 59 years old (23,4%) and lived in a low socioeconomic status (i.e., the first two levels of six: 45,8 %), in Bogotá (32,5%) or were affiliated to the contributive regime of health insurance (57,0%).

The median age of individuals was 48 years (range: 0-84; IQR: 34-59), and it was six years higher in who tested positive than in negatives (53 vs 47), and in men (51; IQR: 37-61) than in women (43; IQR: 31-56). Kidney, followed by liver, is the most common organ needed among subjects of the study, 81% of subjects who tested positive and ~73% of those who tested negative were either transplant recipients or waitlisted candidates of kidney.

There was a high prevalence of chronic comorbidities, mainly hypertension (70,1%) and autoimmune diseases (26%), among the subjects. The prevalence of these chronic conditions was, in absolute terms, higher in who tested positive than in negatives, except in those who had an autoimmune disease (Table 1).

Characteristic	Positive (n=602)		Negative (n=1949)		All (n=2551)	
	N	%	N	%	N	%
Male/Female (% male)	401/201	66,7	1077/872	55,3	1478/1073	57,9
Age, years						
Mean (SD)	49,7 (14,6)		44,2 (18,2)		45,5 (17,6)	
Median (IQR)	53 (38-61)		47 (32-58)		48 (34-59)	
Socioeconomic status						
Low (level 1 and 2)	312	51,8	961	49,3	1169	45,8
Medium/High (levels 3 to 6)	286	47,5	900	46,2	1092	42,8
Not data	4	0,7	88	4,5	290	11,4
Ethnicity						
Afrocolombian	28	4,7	101	5,2	129	5,1
Indigenous	7	1,2	23	1,2	30	1,2
Gypsies	1	0,2	1	0,1	2	0,1
Other (white, other)	541	89,9	1731	88,8	2272	89,1

Unknown	25	4,2	93	4,8	118	4,6
City of residence						
Bogotá D.C.	218	36,2	610	31,3	828	32,5
Other	384	63,8	1339	68,7	1723	67,5
Regime of health insurance						
Contributive	383	63,6	1071	55,0	1454	57,0
Subsidized	138	22,9	475	24,4	613	24,0
Other	8	1,3	29	1,5	37	1,5
Unknown	73	12,1	374	19,2	446	17,5
Chronic comorbidities prevalence (yes, %)						
Hypertension	461	76,6	1326	68,0	1787	70,1
Diabetes	143	23,8	304	15,6	447	17,5
Dyslipidemia	103	17,1	263	13,5	366	14,3
Coronary Artery Disease	42	7,0	133	6,8	175	6,9
Autoimmune Diseases	144	23,9	518	26,6	662	26,0
Organ						
Kidney	489	81,2	1419	72,8	1908	74,8
Liver	73	12,1	373	19,1	446	17,5
Heart	22	3,7	88	4,5	110	4,3
Lung	9	1,5	40	2,1	49	1,9
Kidney & Liver	3	0,5	19	1,0	22	0,9
Kidney & Pancreas	3	0,5	8	0,4	11	0,4
Kidney & Heart	2	0,3	0	0,0	2	0,1
Pancreas	1	0,2	2	0,1	3	0,1

Table 1: Distribution of subjects in according to results of SARS-CoV-2 test and selected demographic and clinical conditions, Colombia, 6 March 2020-28 February 2021

The distribution of subjects according to the test results, history of transplant at the testing day and vital status at the end of follow-up, both grouped and by specific organ is shown in Figure 1. About 55% of the subjects were transplant recipients before the COVID-19 test.

Positivity rates to SARS-CoV-2

A total of 602 (23,2%) subjects was diagnosed as having the viral infection as indicated by a positive test. The positive percentages were

similar in both transplant recipients (23,1%) and in waitlisted subjects (24,2%). A positive test was found in 25,6%, 16,3%, 10,4% and 22,4% of the kidney, liver, heart, and lung subjects (for both transplant and waitlisted subjects of each specific organ), respectively. The positivity to infection was similar in transplant and nontransplant subjects of kidney (~25%), but clinically higher in transplant recipients of liver and heart and in those waitlisted for lung than in those of the respective complementary group (Figure 1, inferior boxes).

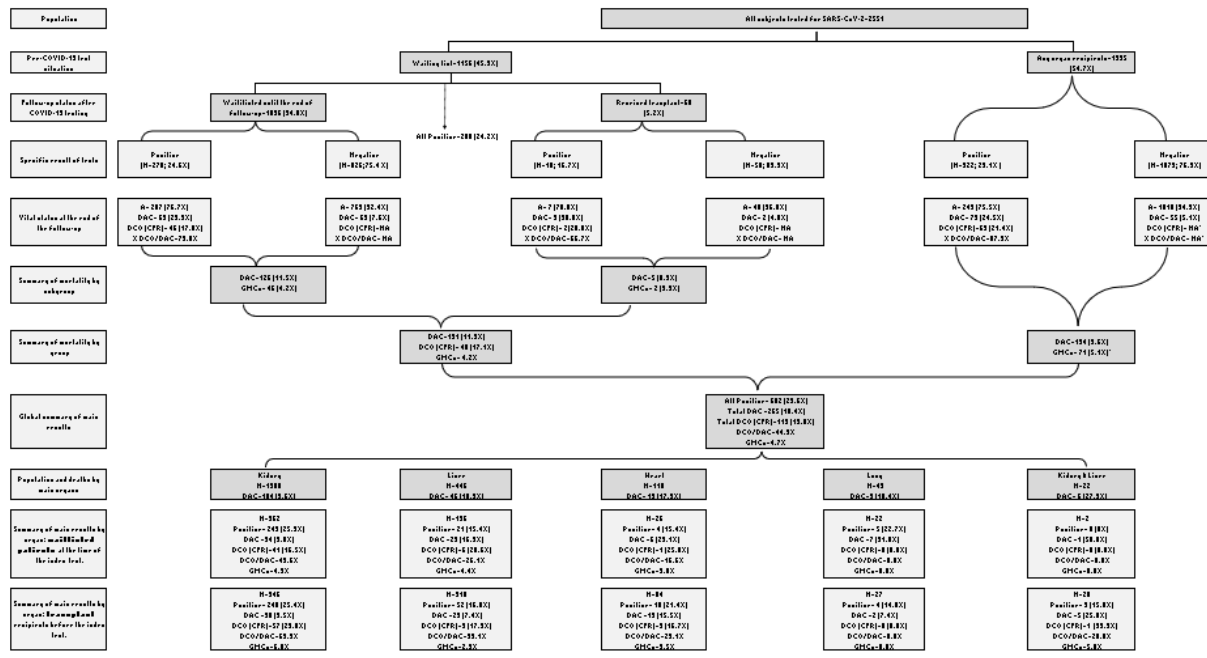


Figure 1. Distribution of subjects in according to the result of SARS-CoV-2 test, vital status at the end of follow-up and cause of death. Transplant recipients and non-transplant (waiting list) patients. All solid organs and by specific organ. Colombia, March 2020-February 2021

Median time of follow-up

The median time elapsed from the day of the COVID-19 test to the end of the study (or death) was 184 days for all the subjects (IQR: 127-239), men (IQR: 127-236) and women (IQR: 126-241); 175 days (IQR: 108-223, range: 0-342) in those who tested positive and 186 days (IQR: 130-246, range: 0-356) in those negative to the infection. The median time was 179 days (IQR: 125-233) in those transplanted subjects before the test and 193 days (IQR: 129-243) in those in waiting list. In the case of kidney, median time of follow-up was 175 days (IQR: 108-223, range: 0-342) in those who tested positive and 186 days (IQR: 130-246, range: 0-356) in those negative to the infection.

Deaths, mortality, and case-fatality ratios

There were 265 (10,4%) deaths from all causes during the follow-up period among all subjects of the study, in 119 (44,9%) of them COVID-19 was the underlying cause of death, resulting in a COVID-19-specific mortality of 4,7% (119/2551) for all the subjects of the study, and in about 1 death of each five subjects who tested positive (119/602; case-fatality ratio=19,8%) (see Figure 1). Of patients who had a positive test for the virus, 28 (4,7%) died from causes other than COVID-19.

Case-fatality ratios were 21,4% and 20% in those subjects who were transplanted before and in those who changed his/her status from waitlisted to transplanted after the index COVID-19 test, respectively, and 17% in those who remained as waitlisted candidates to the end of follow-up or death.

On the other hand, among patients who tested positive for SARS-CoV-2, the probability of die for COVID-19 (i.e., as the underlying cause of death) was higher in transplant recipients (87,3% of them) than in those who remained on waiting list (73%). Besides, mortality rates due to COVID-19 was 5,1% among the total of transplant recipients and 4,1% among those waitlisted candidates.

In patients who died having tested positive for COVID-19, and whose death was attributable to that infection, the median number of days from diagnosis

to death was 22 (IQR: 12-37, range: 0-309). It was 23 days (IQR: 12-39, range: 2-309) in transplant recipients and 21 days (IQR: 12-28, range: 0-176) in those on waiting lists.

There was a higher proportion of deaths from all causes among those who were on the waiting list than in those transplanted for the same organ. The all-causes mortality was lower in patients on waiting list for kidney (9,8%) than in those on waiting list of the other organs (16,9%-31,8%) albeit in transplant patients it was lower in liver and lung than in kidney and heart.

However, COVID-19, as a cause of death, was more frequent in kidney than in the other organs studied in both transplant recipients and waitlisted subjects. In fact, the percentage of COVID-19-related deaths was as high as 63,3% in transplant patients of kidney and ranging from 0,0% to 39,1% in the cases of lung, heart, and liver. Related to this finding, the case-fatality ratio due to COVID-19 was also higher in kidney transplant recipients than in those who had a liver, heart, and lung transplant but, in the case of patients on the waiting list, the CFR was higher for liver and heart than in kidney or lung patients. There were no observed deaths by COVID-19 in the cases of lung and pancreas patients (CFR=0,0% for both).

In dead patients who had tested positive for COVID-19, and whose death was attributable to this infection, the median numbers of days from diagnosis to death were 21 days (IQR: 12-36,5; n=96 deaths), 20 days (IQR: 14-28, n=15) and 63,5 days (IQR: 45-70, n=4) in, respectively, the cases of kidney, liver, and heart in transplant and nontransplant patients. This measure was similar between transplant (median=20 days, IQR: 13-38, n=55) and nontransplant (median=21 days, IQR: 11-29, n=41) subjects of kidney but higher in transplant patients (median=24 days, IQR: 12-33, n=9) than in those waitlisted (median=19,5 days, IQR: 19-26, n=6) patients of liver. Among those 28 patients who were infected and died in follow-up, but their underlying cause of death was other than COVID-19, the most common immediate causes of death were cardiogenic shock (21,4%), haemorrhagic shock (10,7%) and acute myocardial infarction (10,7%) (Table 2).

Type of cause	n	%
Cardiogenic shock	6	21,4
Hemorrhagic/hipovolemic Shock	3	10,7
Acute myocardial infarction	3	10,7
Neurogenic shock	2	7,1
Septic shock	2	7,1
Distributive shock	1	3,6
Cerebral edema	1	3,6
Hypertensive emergency	1	3,6
Multiorgan failure	1	3,6
Severe hipoxemia	1	3,6
Severe Respiratory Insufficiency	1	3,6
Unspecified kidney failure	1	3,6
Sudden death	1	3,6
Other interstitial lung disease	1	3,6
Cardiac arrest	1	3,6
Intracranial hypertension síndrome	1	3,6
Ventricular tachycardia	1	3,6
Total	28	100,0

Notes: Immediate cause of death is the final disease or injury causing the death while underlying cause is that disease or injury that initiated the events resulting in death. Due to restrictions for accessing to vital statistics database, specific underlying cause of death in these patients were no known for authors.

Table 2: Immediate cause of death in infected transplant and nontransplant patients whose underlying cause of death was other than COVID-19 (N=28).

Discussion

These results, based on national data of a middle-income country, indicate that proportions of positivity to SARS-CoV-2 infection were basically the same for solid organ transplant (23,1%) and waitlisted (24,2%) subjects among those with a known result of the test, which was also seen in kidney and liver, the two most common solid organs needed in Colombia. These percentages are higher than those reported for solid organ transplant patients in other countries in a similar period of study ranging from 5% to 11% [9-10]

However, as in general population [11], the true level of transmission of the virus in the transplant and waitlisted population in the country may be even underestimated if we compare with the results of the subjects participants in this study because of several reasons including that a high proportion of individuals with the infection might be undetected (subclinical or asymptomatic presentation of the infection) [12,13], misdiagnosed (e.g., due to clinical- or diagnostic test-related failures) [14,15] or have a lower opportunity for access to healthcare [16], among others.

Solid organ transplant recipients are a very special population given by their chronic immunocompromised state which is linked to a higher risk for severe COVID-19 but being counterbalanced by its beneficial effect on the cytokine storm [17]. Waitlisted patients may also have a high risk of severe complications and death in the course of the infection due to aspects such as a high prevalence of chronic diseases [18].

Of the total of subjects included in our study, 10% died with about 45% (119/2.551) of these deaths were attributable to COVID-19, which also means that 4,2% of subjects in waitlist and 5,1% of those who were transplanted before the index test died due to this infection. Solid organ transplant recipients have a high prevalence of comorbidities, and they are at

increased risk of complications and death from COVID-19, which has been described around the world [19-25]. In the same sense of it, it was noted a high prevalence of chronic disease among subjects included in Colombia.

Comparing our specific results in mortality measures of kidney with those published from France, CFR was higher in our country for both transplant subjects (23,8% and 20,1% (122/606), respectively) and waitlisted candidates (16,5% and 12,6% (60/478), respectively) [26]. However, a more realistic comparison between studies requires additional epidemiological analyses for studying the effects of factors such as age, sex, ethnicity, socioeconomic status, prevalence of comorbid conditions and even duration of follow-up, among others.

The median survival time from the positive test to the COVID-19-related death was similar comparing both kidney (21 days) and liver (20 days) transplant recipients and candidates. That median time was also similar in transplant and nontransplant patients of kidney, but we also found a higher median time in transplant recipients than in waitlisted subjects of liver. During the follow-up, there were no detected COVID-19-attributable deaths for waitlisted or transplant patients of lung or pancreas but their percentage of participation among the total is really low.

Our study offers a general and specific by organ panorama of the effects of COVID-19 on deaths for both transplant and waitlisted population since COVID-19 report was mandatory for public health purposes. However, our study has some limitations that should be considered, which are mainly focused on the representativeness of the subjects whose COVID-19 test results was known with respect to the totality of the individuals being waitlisted candidates or transplant recipients. Since we chose only patients with a known result of SARS CoV-2 test, overall and specific measures of mortality described here might be, however, overestimated comparing to the behavior of the infection in the rest of subjects of the RedDataINS© national

database. The 2020 report of statistics published by the Donation and Transplantation Network Group of the Colombian NIH established that there were 251 deaths (of any cause) among a total of 2978 waitlisted patients, resulting in a mortality of 8,4% [27]. In our study, mortality was estimated in 11,3% for the same group, a difference of about 3 more deaths for each 100 patients, albeit this difference would be lower due the absence of pandemic virus in the country during the first 2 months of the year used for the 2020 annual report but not for our study. It is also noteworthy that the overall mortality in waitlisted patients had been reported in 4,78% in 2018 [28] and 4,87% in 2019 [29]. It means that, in according to the 2020 report, there were 3-4 more deaths per 100 subjects comparing to these pre-pandemic years, or 6 based on our results. If waitlisted subjects who had positive tests included in our study are ignored, our study reduces the overall mortality to 7,4% among waitlisted subjects (negative for SARS-CoV-2), meaning an unexplained excess of about 2,6 deaths for 100 subjects after discarding the effect of COVID-19 diagnosis.

These results show that COVID-19-attributable mortality is high and it could explain the number increased of deaths found in our study, although there is a wide range of demographic characteristics of patients to be considered. The findings described here are important because these patients represent a vulnerable population and are often excluded from clinical trials of vaccines [30]. In addition, 134 cases of death were reported during the study period among patients with solid organ transplants, of which 69 were attributed to COVID-19, that is, more than half of the deaths (51.5%) that occurred in our series were secondary to COVID-19. Because we have included only subjects with a positive or negative result to the COVID-19 test, total numbers of deaths are lower than they are for all solid organ transplant recipient or candidates. In fact, for kidney recipients, other national source of health data shows 138 all-causes deaths (n=138) reported among them in a year (July 2019- June 2020), which means about 53% more deaths than reported in our study (31).

In conclusion, we found a very important role of COVID-19 on deaths of solid organ transplant recipients and candidates during the first year of the pandemic in Colombia, a period in which specific vaccines were unavailable around the country. Our findings support the need of designing combined preventive and therapeutic strategies from clinical and epidemiological perspectives, which should become an integral part of the approach to this special population in Colombia.

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