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SARS-CoV2/COVID-19 Infection in Transplant Recipients and in Patients on the Organ Transplant Waiting List in Colombia

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ABSTRACT
To assess our determination to continue transplant activity in Colombia during the coronavirus disease 2019 (COVID-19) pandemic, this study seeks to describe the risk of infection and mortality of transplanted patients vs those on the waiting list. Therefore, a descriptive study of severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2)/COVID-19 infection in transplant recipients and patients on the waiting list was conducted. The data sources were the information systems of the Instituto Nacional de Salud of Colombia: National Donation and Transplant Information System, the National Public Health Surveillance System, and the National COVID-19 Data Repository. Characteristics of the patients who tested positive were analyzed, and the mortality rate was determined. An Real Time-PCR test for SARS-CoV-2/COVID-19 was performed in 7% of the transplant recipients included in this study, and 14.8% of those recipients tested positive. Among patients on the waiting list, 15.2% were tested, and 16.7% showed positive results. Overall, 1% (84/8108) of the transplant recipients and 2.5% (74/2926) of patients on the waiting list were infected with SARS-CoV-2/COVID-19. There were no differences in mortality between these groups (P = .8748). In conclusion, with the data obtained so far, the hospital availability, and the adoption of safety protocols in the institutions, our findings can support the continuity of the transplant activities in this country.
MATERIAL AND METHODS

This was a descriptive study on SARS-CoV-2/COVID-19 infection among transplant recipients and patients on the organ transplant waiting list in Colombia. The data sources were the National Donation and Transplant Information System (RedDataINS INS, Bogotá, Colombia), the National Public Health Surveillance System (Sistema Nacional de Vigilancia en Salud Pública [SIVIGILA]), and the National COVID-19 Data Repository (SISMUESTRAS) that compiles all the information of the laboratory tests and results for SARS-CoV-2/COVID-19 infection in Colombia. Cross-information of these 3 resources was accomplished to identify positive cases among all the transplant recipients during the last 7 years in Colombia, in addition to those who were on the waiting list on July 31, 2020.

The variables that were analyzed included age, sex, district of residence, socioeconomic status, health social security system regimen, blood group, medical history and pre-existing conditions, type of organ transplanted or to be transplanted, main diagnosis, date of onset of symptoms, consultation and diagnosis, test result for SARS-CoV-2/COVID-19, management center, severity of the disease, vital status, and the date of death.

The severity of the disease was defined as mild for patients who were treated at home, moderate for patients who required hospitalization, and severe for those who were admitted to an intensive care unit.

Statistical Analysis

For the statistical analysis, the quantitative variables were described through measures of central tendency and dispersion and the qualitative variables through absolute and relative frequencies. The first analysis examined the characteristics of patients who tested positive for SARS-CoV-2/COVID-19. A subgroup analysis was later performed considering transplant recipients and patients on the waiting list. Finally, the cases of death due to SARS-CoV-2/COVID-19 infection were analyzed. For these cases, the mean number of days from the onset of symptoms to diagnosis and to the date of death was calculated. Since a multivariate analysis was precluded by the lack of a complete medical record, a relationship between basic information provided by the database and mortality was searched for with a relative risk (RR), an attributable risk (AR), and an attributable risk percent (AR%). The difference in the number of positive cases between the transplant recipients and patients on the waiting list was analyzed by the Fisher exact test, and a P value of less than 0.05 was considered significant. The analyses were performed using the IBM SPSS Statistics 22 (Armonk, New York, USA) and Epidat software (Galicia, España).

Ethical Considerations

This retrospective study used information from secondary sources, without intervention or modification of the biological, physiological, psychological, or social variables of the participating individuals. Therefore, the study was classified as a “risk-free” investigation as established in Resolution 8430 by the Ministry of Health in 1993. The data from the INS RedDataINS, SIVIGILA and SISMUESTRAS information systems were analyzed, maintaining their validity. The confidentiality of the information was protected according to the established guidelines and current regulations applicable to the National Donation and Transplant Network [4,5].

RESULTS

Identification of SARS-CoV-2/COVID-19–Positive Cases

As of the cutoff date for enrollment in the study (July 31, 2020), 11,034 patients were registered in the National Donation and Transplant Information System, of which 8108 had received an organ transplant and 2926 were on the waiting list. Of these, 1011 patients were tested for SARS-CoV-2/COVID-19, and 15.6% (n = 158) tested positive for COVID-19.

Of the total number of transplant recipients, 567 (7.0%) were tested for SARS-CoV-2/COVID-19, and 14.8% (n = 84) showed a positive result. Among those on the waiting list, 444 (15.2%) patients were tested, and 16.7% (n = 74) were positive (P = .4210) for COVID-19. Overall, considering the population of the present study, 1% (84/8108) of the transplant recipients and 2.5% (74/2926) of all patients on the waiting list had SARS-CoV-2/COVID-19 (P = .0000) (Fig 1).

The median age of patients who tested positive was 49 years (minimum 1, maximum 76). In this group, 66% (n = 104) were male, 76% (n = 120) belonged to the contributory health scheme, 49.0% (n = 60) were from socioeconomic status 2, and 70.3% (n = 111) belonged to the O-positive blood group. Regarding the pre-existing conditions, the analysis of medical history records available in the National Donation and Transplant Information System showed that 85.4% (n = 135) of the patients had high blood pressure, 21.5% (n = 34) had diabetes mellitus, and 15.8% (n = 25) had dyslipidemia. The median number of days from the onset of symptoms to the date of consultation was 3 (minimum 0, maximum 22) and to the diagnosis was 9 (minimum 2, maximum 27). The highest percentage of patients with SARS-CoV-2/COVID-19 had their residence in the district of Bogotá (31.0%), Valle (13.3%), and Barranquilla (5.7%) (Table 1). Of the infected patients, 31% (49/70) were reported as recovered.

Patients on the Waiting List Who Tested Positive

The median age of COVID-19–positive cases on the waiting list was 49 years (minimum 20, maximum 71). In this group, 67.6% (n = 50) were male, 47.4% (n = 27) were from socioeconomic status 2, 73.0% (n = 54) belonged to the contributory scheme, and 75.7% (n = 56) belonged to the O-positive blood group. Most of these patients were on the waiting list for kidney (94.6%; n = 70) and liver (5.4%; n = 4) transplants. Regarding pre-existing conditions, 90.5% (n = 67) had a history of hypertension, and 27.0% (n = 20) had diabetes. In this group, 63.0% (n = 46) of these patients were managed at home, and 17.8% (n = 13) had a severe course of the disease, needing intensive care unit management (Table 2).

Transplant Recipients Who Tested Positive

Of the total number of transplant patients who tested positive for SARS-CoV-2/COVID-19, 83.3% (n = 70) had undergone a kidney transplant, 8.3% (n = 7) a liver...
transplant, 6.0% (n = 5) a heart transplant, and 2.4% (n = 2) a lung transplant. Of the 84 positive cases, 6 received a kidney transplant in the first half of 2020, and of these, 4 underwent transplant after March 6, 2020, which was the date of the first confirmed case in Colombia. Of the transplant recipients who tested positive, 3 acquired the SARS-CoV-2/COVID-19 infection in the immediate post-transplant period (first 15 days); 1 recipient reported to SIVIGILA with onset of symptoms at day 11 post-transplant and 2 recipients at day 15 post-transplant. The source of infection in 1 patient was identified as close contact with a caregiver who was infected; however, it could not be identified in the other 2 cases. No positive case was identified in the first 10 days post-transplant.

The median age of transplant recipients who tested positive was 49 years (minimum 1, maximum 76), and 64.3% (n = 54) were male. The other characteristics of the patients are described in Table 2.

Transplant Recipients and Patients on the Waiting List Who Died of SARS-CoV-2/COVID-19

Of the 158 patients who tested positive for SARS-CoV-2/COVID-19, 13.3% (n = 21) died of causes related to this disease. Of these, 57.1% (n = 12) were transplant recipients, which represents a mortality of 14.3% (12/84) for this group. In this group, 42.9% (n = 9) of the deceased were on the waiting list, which corresponds to a mortality of 12.2% (9/74). There were no differences in the rate of mortality between transplant recipients and patients on the waiting list (P = .8980).

The median number of days between the onset of symptoms and the date of death was 18 (minimum 0, maximum 33 days), between the day of hospitalization and death was 13 (minimum 0, maximum 33 days), and between the date of diagnosis and death was 4.5 (minimum -11; maximum 17 days).

Of the deceased, 81.0% (n = 17) were male with a median age of 58 years (minimum 36, maximum 72); all belonged to the “others” category of ethnicity, mostly from socioeconomic status 2 (47.62%; n = 10); with 66.7% belong to the O blood group (n = 13), and 85.7% were covered under a contributory scheme (n = 18). Twenty (95.2%) of the deceased patients had a medical record of hypertension, and 6 (28.6%) had diabetes and dyslipidemia.

The RR estimated between the mortality among those with transplantation and those on the waiting list and hypertension was 3.4 (95% confidence interval [CI]: 3.13-3.77) and higher than dyslipidemia (RR: 2.18, 95% CI: 2.05-2.29) or diabetes (RR: 1.4, 95% CI 1.3-1.47). The AR estimated for hypertension was 10.5% higher than those for patients with other comorbidities, and the AR% estimates that 71% of the mortality among this group is attributable to hypertension, and 29% is attributable to other causes. There were no differences in the variables analyzed in both groups (Table 3).

The longest period since transplant was 9 years and 8 months, and the shortest period was 7 months. Eleven deceased transplant recipients had a history of high blood pressure, 2 had diabetes and high blood pressure, and 3 had dyslipidemia and high blood pressure. Additionally, 1

Table 1. District of Residence of SARS-CoV-2/COVID-19-Positive Cases

| District             | Frequency | Percentage |
|----------------------|-----------|------------|
| Bogotá D.C.          | 49        | 31.0       |
| No data              | 34        | 21.5       |
| Valle                | 21        | 13.3       |
| Barranquilla         | 9         | 5.7        |
| Antioquia            | 8         | 5.1        |
| Atlántico            | 7         | 4.4        |
| Cartagena            | 7         | 4.4        |
| Cauca                | 4         | 2.5        |
| Cundinamarca         | 4         | 2.5        |
| Bolívar              | 2         | 1.3        |
| Guajira              | 2         | 1.3        |
| Magdalena            | 2         | 1.3        |
| Santander            | 2         | 1.3        |
| Santa Marta D.E.     | 2         | 1.3        |
| Sucre                | 2         | 1.3        |
| Cesar                | 1         | 0.6        |
| Choco                | 1         | 0.6        |
| Norte Santander      | 1         | 0.6        |
| Total                | 158       | 100.0      |

Abbreviations: COVID-19, coronavirus disease 2019; SARS-CoV-2, severe acute respiratory syndrome coronavirus type 2.
The kidney transplant recipients who died of COVID-19 required hospitalization on an average at 2 days after the onset of symptoms, with a minimum of 1 day and a maximum of 5 days. They died on an average of 12 days after the onset of symptoms, with a minimum of 1 day and a maximum of 33 days.

Of the 5 recipients of heart transplants who were infected with SARS-CoV-2, 1 patient died. This patient was 66 years old, had a history of high blood pressure, had O-positive blood group, and died 25 days after hospitalization.

Of the 7 recipients of liver transplant infected with SARS-CoV-2, 1 patient died. This patient was 72 years old, had O-positive blood, had a history of high blood pressure, and died 5 days after hospitalization.

All the deceased patients on the waiting list had a history of high blood pressure, 4 patients had diabetes and high blood pressure, 3 patients had dyslipidemia and high blood pressure, and 1 patient had a history of smoking.

**Table 2. Characteristics of Transplant Recipients and Patients on the Waiting List Who Tested Positive for SARS-CoV-2/COVID-19**

| Variables                  | Transplant Recipients | Waiting List | Total | P value |
|----------------------------|-----------------------|--------------|-------|---------|
| **Age, n = 157**           |                       |              |       |         |
| Median (minimum - maximum) | 49.5 (1-76)           | 49 (20-71)   | 49 (1-76) | .4851  |
| 60 years or older          | 19 22.6               | 21 28.8      | 40    |         |
| Younger than 60 years      | 65 77.4               | 52 71.2      | 117   |         |
| **Sex, n = 158**           |                       |              |       |         |
| Male                       | 54 64.3               | 50 67.6      | 104   | .7903   |
| Female                     | 30 35.7               | 24 32.4      | 54    |         |
| **Socioeconomic status, n = 123** |             |              |       |         |
| 1                          | 11 16.7               | 12 21.1      | 23    | .8615   |
| 2                          | 33 50.0               | 27 47.4      | 60    |         |
| 3                          | 16 24.2               | 15 26.3      | 31    |         |
| 4                          | 5 7.6                 | 2 3.5        | 7     |         |
| 6                          | 1 1.5                 | 1 1.8        | 2     |         |
| **Blood group, n = 158**   |                       |              |       |         |
| O                          | 55 65.5               | 56 75.7      | 111   | .3268   |
| A                          | 18 21.4               | 10 13.5      | 28    |         |
| B                          | 7 8.3                 | 7 9.5        | 14    |         |
| AB                         | 4 4.8                 | 1 1.4        | 5     |         |
| **Type of organ, n = 158** |                       |              |       |         |
| Kidney                     | 70 83.3               | 70 94.6      | 140   | .0667   |
| Liver                      | 7 8.3                 | 4 5.4        | 11    |         |
| Heart                      | 5 6.0                 | 0 0.0        | 5     |         |
| Lung                       | 2 2.4                 | 0 0.0        | 2     |         |
| **Pre-existing condition, n = 158** |               |              |       |         |
| High blood pressure        | 68 81.0               | 67 90.5      | 135   | .1391   |
| Diabetes mellitus          | 14 16.7               | 20 27.0      | 34    | .1653   |
| Dyslipidemia               | 13 15.5               | 12 16.2      | 25    | .9273   |
| **Main diagnosis, n = 147**|                       |              |       |         |
| Idiopathic/unknown         | 16 21.9               | 15 20.3      | 31    |         |
| Glomerulonephritis         | 13 17.8               | 14 18.9      | 27    |         |
| Diabetes                   | 9 12.3                | 16 21.6      | 25    |         |
| Other                      | 30 41.1               | 18 24.3      | 48    |         |
| Hypertensive               | 5 6.8                 | 11 14.9      | 16    |         |
| **Severity of the disease, n = 157** |               |              |       |         |
| Mild                       | 37 44.0               | 46 63.0      | 83    | .0584   |
| Moderate                   | 26 31.0               | 14 19.2      | 40    |         |
| Severe                     | 21 25.0               | 13 17.8      | 34    |         |
| **Place of management, n = 157** |               |              |       |         |
| Home                       | 37 44.0               | 46 63.0      | 83    | .0268   |
| Hospital                   | 47 56.0               | 27 37.0      | 74    |         |
| **Vital status n = 158**   |                       |              |       | .8748   |
| Alive                      | 72 85.7               | 65 87.8      | 137   |         |
| Deceased                   | 12 14.3               | 9 12.2       | 21    |         |

Abbreviations: COVID-19, coronavirus disease 2019; SARS-CoV-2, severe acute respiratory syndrome coronavirus type 2.
Of the patients on the waiting list who died of COVID-19, 4 were between 49 and 58 years old, 4 were between 59 and 68 years, and 1 was between 69 and 78 years; the youngest was 49 years old, and the oldest was 71 years old.

The patients on the kidney transplant waiting list who died of COVID-19 required hospitalization on average 6 days after the onset of symptoms, with a minimum of 1 day and a maximum of 20 days. They died on an average of 14 days after the onset of symptoms, with a minimum of 1 day and a maximum of 23 days.

DISCUSSION

Initial Reaction to the Declaration of the COVID-19 Pandemic
A few weeks after the declaration of the SARS-CoV-2 pandemic by the WHO, a group of anesthesiologists in the city of Wuhan, China, called the attention of the medical community to the high morbidity and mortality of patients who were inadvertently infected and referred for elective surgery, including kidney transplants [6]. Since then, many transplant institutes decided to temporarily suspend their surgical practice to determine the best approach to protect patients and their caregivers.

Transplant surgeries have been limited globally, not only because of the impact that the COVID-19 disease might have on the transplant recipients and on patients on the waiting list, but also because of the conditions imposed by the pandemic, such as a decrease in the number of donors, limitations in logistics for performing these procedures, hospital capacity, and the risk of infection among the health professionals of the transplant centers.

Was It Safe to Continue Transplant Activities in the Country?
In general, immunosuppressed patients are at a higher risk of infection, especially during the first year after transplant. The most common viral infections during this period are those caused by cytomegalovirus and polyomavirus BK [7]. Therefore, in the context of a pandemic, the first step was to define whether inducing an immunosuppressed state could increase the risk of infection by COVID-19, while at the same time assessing the impact of this infection in terms of mortality. The best information available at that time was the Spanish waiting list and transplant registry. In a series of 1314 patients, it was reported that the infection rate was lower in transplant recipients who could be confined to their homes during quarantine, compared to patients who had to continue to travel to dialysis units (hemodialysis in centers [63%] vs transplant recipients [33%]). Moreover, the mortality of patients infected with SARS-CoV-2 was lower among transplant recipients (21.6%) compared to that in the dialysis patients (27.1%) [8]. This observation is also corroborated by another European international registry (European renal association – European dialysis and transplant association [ERA – EDTA] COVID-19), which reported a lower rate of mortality among transplant recipients than in patients in dialysis (29% vs 20%) [9].

Nevertheless, there is still limited information about the impact of COVID-19 on the immunosuppressed population. This population, because of its specific conditions, might present a more severe course of the disease; however, the possible protective effects of immunosuppressive therapy and a milder presentation of the COVID-19 disease are being discussed without much clarity [10,11]. To date, there are no known reports of SARS-CoV-2 transmission between organ donors and recipients [10–13].

How to Continue With Transplant Procedures
Since the transplant procedures are nonelective as they depend on the availability of a donor, organizations dealing with organ donation and transplant explored mechanisms to continue with their activities. In Colombia, from the declaration of the pandemic until July 31, 2020, there were on average 2920 patients on the waiting list for a solid organ transplant; hence, continuing with the transplant services was a challenge for the entire health care system.
Therefore, the next step was to define a safe method to perform the organ extraction and transplant procedures. The INS, along with experts and scientific societies, developed national guidelines to ensure the safety of transplant activities for the recipient, the donor, and the health care professionals. These recommendations were based on epidemiologic and clinical criteria to stratify the risk and perform RT-PCR tests to check for the COVID-19 infection, provide post-transplant care, and evaluate the operational feasibility of each institution in accordance with the guidelines issued by the Ministry of Health and Social Protection [14].

Overall Impact of the Pandemic

Of the transplant recipients and patients on the waiting list who underwent a laboratory test for SARS-CoV-2, 16.7% (158/1011) tested positive, as observed in this study. In the general population in Colombia, the percentage of positive tests was 22.7% as of July 31, 2020, according to INS data [2]. In the report of a transplant center in the United States, 15.6% of the transplant recipients tested positive for COVID-19 [15], a percentage close to that observed in this study.

The mortality in our study population was 3 times higher than that of the general population in Colombia (3.4% vs 13.3%), probably owing to the higher number of comorbidities in these patients. However, this mortality was lower than that reported in previous studies among the transplant recipients in other countries, which might be related to the measures adopted in the country, including the strict mandatory isolation implemented since March 17, 2020, 11 days after the first confirmed case in Colombia. The isolation measures included closure of the air and land borders, as well as disallowing large public events, closing down universities and schools, and reducing traffic by implementation of remote work policies. These measures helped to reduce the acceleration of the infection rate in our country and avoided congestion in the intensive care units [3].

At the cutoff date used in this study, 31% of the infected patients, including transplant/waiting list, were confirmed as recovered. In other studies among this population, the percentage of recovery was highly variable, ranging from 33% to 80%, since it is dependent on the stage of the pandemic in each country at the time of the report [11].

Globally, several countries have reported a decrease in transplant procedures owing to the pandemic. According to the INS, as of July 2020, there was a 44.3% decrease in organ transplants from brain dead donors in Colombia, especially between March and May, when a strict quarantine was implemented because of the health emergency, in addition to other measures. This impacted the detection of potential donors, especially from cases of traumatic injury, and there was a high prevalence of positive cases in intensive care units [16].

In the case of living donors, unlike in European countries that restricted the procedures involving live donors owing to the congestion of their units, many groups in Colombia continued this activity since it had variables that were easier to control for both the donor and the recipient. There was a decrease of 13% in this activity in the country [16].

SARS-CoV-2 Infection in Transplant Recipients and Patients on the Waiting List

The results as of July 31, 2020, in Colombia were in accordance with the results from Europe, with a statistically lower incidence of infection of 1.03% (84/8108) in transplant recipients compared to 2.52% (74/2926) in patients on the waiting list, who were mostly (94.6%) patients on dialysis who probably could not comply with a strict quarantine because of this factor.

Because of the higher risk of infection in the transplant population, this group of patients has probably adopted stricter self-isolation and care measures compared to those of the general population, which might also be related to the ongoing education of transplant patients and their families for prevention of infections. Studies in the other countries have shown that kidney transplant patients have modified their behavior, and more than 95% were in isolation at home, thus reducing the risk of infection [17].

The percentage of tests performed in this study was higher in patients on the waiting list than in the transplant recipients, possibly because of the higher risk to which they were exposed because of their dialysis visits. Until the completion of this study, the dialysis units did not have a protocol for periodic assessment of their patients, and the indication for testing was based on symptoms or close contacts. However, this higher testing in patients on the waiting list could play a role on the higher infection rate among this group.

None of the 84 transplant recipients infected with COVID-19 presented signs of infection in the immediate postoperative period (before 10 days), which would exclude an infection derived from the donor or a recipient with undetected infection at the time of transplantation. The 3 cases that presented symptoms after day 10 post-transplant were most likely caused by hospital infection; hence, routes and safe areas for the management of these patients should be reinforced, as should home care measures immediately after hospital discharge.

The incidence of SARS-CoV-2 infection among transplant recipients in Colombia is lower than expected. The study’s cutoff date possibly corresponds to the peak of the epidemic in Colombia, and 5% of the population was expected to be infected at this time. This percentage is slightly lower than that reported by an international multicentric study, which reported the rate of infection to be 1.5% among kidney transplant recipients. Serologic studies in Spain have shown a mean prevalence of 5%, and in some areas with high infection rates, such as Madrid, it reached above 10% [18], which supports the findings of our study that the incidence is lower than in the general population.
SARS-CoV-2 Mortality: Waiting List vs Transplant Recipients

Case series involving kidney transplant recipients have shown a high mortality in some centers (18%-28%) [19-21]. One case series reported rapid progression, associated with a high frequency of immunologic changes that could predispose to a faster progression and possibly higher mortality. In our study as well, transplant patients manifested the disease early, had longer duration of hospitalization than the general population, and died in a short span of time, while those on the waiting list manifested the disease later and stayed longer in the hospital, which suggests that there is a deleterious impact of immunosuppression on the progression of the disease.

In addition to the risk factors due to the usual comorbidities in these patients [22], immunosuppression could be an additional risk factor for mortality. However, despite a slight increase in the percentage of transplant recipients who required intensive care management, this, as well as mortality, was not statistically different compared with infected patients on the waiting list (14.3% vs 12.2%), which might be related to the potential effects of these drugs in modulating the inflammatory storm triggered by the virus [10,11].

Unlike the high mortality rate (28%) reported in a group in New York [19] in the immediate postoperative period that forced the suspension of the program, the outcomes in our country during the period analyzed have been different, since none of the patients infected during the early perioperative period has died until the study’s cutoff date.

The mortality of transplant patients in this study was 14.3%. In an analysis of mortality in the immunosuppressed population, the mortality of the transplanted population is variable, ranging from 5% to 67%. However, compared to other populations with the same condition such as cancer or human immunodeficiency virus, transplant recipients might have a higher risk of mortality [11].

We consider that with the data obtained so far, the availability of hospital beds and resources, and the biosafety protocols adopted, we can continue with the transplantation activity in our country. However, it is necessary to further monitor COVID-19 infection in the transplant recipients in Colombia during the coming months to optimize control measures to prevent infection, as well as to further develop strategies for the education of families, caregivers, as well as reopening of the economic (work) and educational sectors (eg, schools) in the environments of transplant patients.

LIMITATIONS OF THE STUDY

Among the limitations observed in our study is the lack of information on the clinical presentation of patients, which prevents validation of the presence of other comorbidities that affect the risk of infection, hospitalization, or progression in this group of patients. Moreover, there is a lack of information related to the general management of these patients in the follow-up centers that are not registered in the National Donation and Transplant Network.

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