











Pediatric liver transplantation activity in a high-volume program during the COVID-19 pandemic in Brazil

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Funding information

No external funding was received for this work. The authors do not have any commercial or financial connections that would pose a conflict of interest to the findings of this manuscript.

Abstract

Background: The impact of the COVID pandemic on liver transplant (LT) programs varied among countries. Few data are available about that impact in pediatric liver transplant (PLT) programs. This study aimed at comparing the data of our program in Brazil (2019 vs. 2020).

Methods: Retrospective cohort study.

Results: One hundred and seventy-four PLT were performed in the period (93% living donors). Patients were divided into two groups according to the LT date: pre-COVID-19 period (march/2019–February/2020) and COVID-19 period (March/2020–February 2021). In the pre-COVID-19 period, 97 LTs were performed, and 77 LTs were performed in the COVID-19 period. Patients in the COVID-19 period were younger (10.9 months vs. 16 months, p 0.009), had higher PELD scores (15 vs. 14, p 0.04), more ascites (66.2 vs. 51.5%, p 0.03), and more frequently hospitalized before LT (27.3 vs. 17.5%). However, there was no difference in post-LT complications, retransplantation nor survival rates. Six (6.2%) patients from pre-COVID-19 period were COVID positive at a median of 15.5 months (14–17.5), and 6 (7.8%) patients from COVID-19 period were COVID positive at a median of 3 months (20 days–6 months) from LT. There was neither mortality nor complications in those patients. Four (33%) were hospitalized, and one had prolonged intubation. Four (33%) were asymptomatic, 4 (33%) had upper airways symptoms, and the remaining had gastrointestinal symptoms.

Conclusion: Overall, PLT was not affected during COVID-19 period. Even though patients from COVID-19 period were sicker, there was no significant impact in LT outcomes. All the recipients who tested positive for COVID had a favorable outcome.

KEYWORDS

children, COVID-19, infection, liver, outcomes

1 | INTRODUCTION

One year after the global report of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, a total of 114 653 749 confirmed cases and 22 550 500 deaths were registered (until March 3, 2021). Of the global numbers, 10 646 926 confirmed cases and 257 361 deaths were registered in Brazil, the second country with the highest cumulative confirmed cases and deaths.¹

The global impact on liver transplantation (LT) programs was notorious due to several factors: the shortage of intensive care unit (ICU) beds, precluding the performance of high-risk procedures such as LT, and the fear of the medical team and the patients of contracting COVID-19 in the hospital environment.² Additionally, in Brazil, there was a decrease in the number of transplantations due to a drop in the deceased donation rate, as well as in the number of transplants from live donors.³

Countries that rely mainly on living donor liver transplantation (LDLT) also reported a decrease in the number of procedures performed during the pandemic. This effect was predominant in the beginning of the pandemic, improving somewhat after the centers established segregated patient flows to avoid cross-contamination.⁴⁻⁷

The balance between the continuity of transplant activity, while mitigating pre-transplant mortality versus the risk of recipient infection, determines the incorporation of strategic guidelines for COVID-19 that increase patient safety in this pandemic scenario. Such protocols must be adapted according to local and global epidemiological markers for transmission.

Published studies suggest that children (≤ 17 years) infected with COVID-19 are less likely to progress to the severe form of the disease when compared to adults.^{8,9} However, scarce data are available on morbidity and mortality in children with comorbidities—such as candidates on the waiting list for LT—and the evolution of COVID-19 in those patients is still unpredictable.

The aim of this study was to evaluate the impact of the COVID-19 pandemic in the pediatric LT activity in a high-volume program in Brazil and to compare the outcomes for those patients transplanted during the COVID-19 pandemic with those transplanted in the preceding 12 months.

2 | METHODS

During the pandemic period, indications for LT were restricted due to The risks of exposing immunosuppressed recipients to SARS-CoV-2 in a hospital environment—as well as healthy donors, in the case of LDLT. Data on the hospital environment ensuring a COVID-19-free pathway,¹⁰ as well as the severity status of the children on the waiting list, were taken into consideration when deciding to move forward with the LT. Therefore, candidates on the waiting list with higher mortality risk, that is, with higher pediatric end-stage liver disease (PELD) scores and/or with a recent decompensation requiring hospitalization, or in cases of malignancy, were considered for LT.^{6,11} Other markers for waiting-list mortality, such as ascites and hyponatremia,

were also considered a priority for LT in our program.¹² The informed consent form was signed by the parents or guardians of the pediatric candidates, informing them about the risks related to SARS-CoV-2 infection during their hospital stay, and the false-negative rates of the polymerase chain reaction real-time (PCR-RT) test. The same applied to donors, in the case of LDLT. Organs from deceased donors were accepted when epidemiological and clinical screening and PCR-RT test for COVID-19 were negative. The LT procedures for these organs were approved only after the candidate had negative epidemiological and clinical screening; however, it was not possible to obtain the result of the candidate's PCR-RT test prior to LT. These recipients with unknown COVID-19 status were kept in a holding isolation area and triaged into the COVID-free or COVID areas once the PCR-RT results for COVID-19 were ready. These results were available at least 12 h after hospitalization.

As for LDLT, both donors and recipients underwent epidemiological and clinical screening and PCR-RT testing for COVID-19 (nasopharyngeal samples) within 48 h before the planned LT.^{6,11} Only the pair of patients—donor and candidate—who presented full negative screening (epidemiological, clinical, and testing) were considered for LT. When the candidate and/or donor had clinical suspicion or active SARS-CoV-2 infection, the procedure was postponed until 28 days after symptom resolution, in addition to presenting two negative tests taken at least 24 h apart.^{6,13} Patients and donors involved in LDLT were recommended to intensify quarantine and protective measures for at least 2 weeks prior to the scheduled LT. For patients hospitalized prior to transplantation, as well as in the period after the procedure, access to visitors and family members was limited to one person (and always the same person), per patient, for the duration of the hospital stay. These visitors were instructed to practice measures of social isolation and individual protection. In the event the accompanying person presented with epidemiological and clinical screening for COVID-19, they were immediately isolated from the patient. They then underwent PCR-RT testing for COVID-19 and, even with a negative result, were not allowed contact with the patient for 14 days after the end of symptoms, in addition to presenting a new negative test. No changes were made neither to the antibiotic and antifungal prophylaxis, nor to the immunosuppression protocols.

The same medical team was responsible for the surgical procedures, and the pre- and post-transplantation management of the patients at both hospitals. Data were acquired through retrospective review of medical records and from a prospectively collected database. The hospitals' ethics committees approved this study under protocol numbers HSL 2011-21 and AC 2068/15.

Recipient and donor selections were based on ABO blood group compatibility. Pediatric patients with end-stage liver disease who were accepted by the transplant team for LT were placed on the waiting list for DDLT.

The medical staff involved in patient care, as well as healthcare workers (HCW) who had clinical, epidemiological criteria and/or tested positive for COVID-19, were forbidden from contacting the patient for up to 14 days after the end of symptoms and until they

had a negative PCR-RT test. Scientific and clinical round meetings were done remotely. Remote telemedicine follow-up of outpatients was prioritized, and face-to-face returns were selectively requested. Hospital staff was reduced to avoid the risk of cross-contamination. Personal protective equipment (PPE) was used by physicians and HCW.

After the LT, patients were not routinely tested for COVID-19, unless they had a positive epidemiological screening, or developed symptoms suggestive of SARS-CoV-2 infection. Only cases with a positive PCR-RT test were considered positive for COVID-19.

2.1 | Statistical analysis

We performed a retrospective analysis including children (<18 y.o.) who underwent LT between March 11, 2019 and February 19, 2021. The sample was divided into two groups, designated **COVID-19 period group**—which coincided with the initial rise in COVID-19 cases in Brazil (March 4, 2020 to February 19, 2021)—and **pre-COVID-19 period group**, for the same 12-month period in 2019. To determine the impact of the pandemic in the transplantation activity in our program, a comparative analysis of the total number of LTs in each period was performed. Demographic and clinical characteristics, intra-operative parameters, and postoperative outcomes were considered, and a comparative analysis of recipient and graft survival was performed between the groups.

Pre-transplant variables included gender, age at transplantation, diagnosis, recipient body weight (BW), weight-to-age (W/A) and height-to-age (H/A) z scores, PELD/MELD scores, ascites, and pre-LT hospitalization status. Intra-operative parameters were graft-to-recipient weight ratio (GRWR), type of living donor graft, and blood transfusion requirement. Post-transplant outcomes included the occurrence of technical complications such as hepatic vein outflow obstruction (HVOO), biliary stricture (BS), biliary leak (BL), late (>30 days) portal vein thrombosis (LPVT), early (\leq 30 days) PVT (EPVT), hepatic artery thrombosis (HAT), and retransplantation.

Living donors' characteristics and postoperative outcomes, grouped by the Clavien-Dindo classification,¹⁴ were also evaluated in both periods. Means and medians were calculated to summarize continuous effects, and the results were compared using *t*-tests or appropriate non-parametric tests when distributional assumptions were in doubt. Categorical variables are expressed as numbers and percentages. Differences between groups were assessed using chi-square or Fisher's exact tests, when needed. Significant differences were considered at a $p < .05$.

Patient and graft survival analysis was conducted according to the Kaplan-Meier product-limit estimates, and patient subgroups were compared using a two-sided log-rank test.

The incidence of COVID-19 infection was evaluated in both groups. A detailed description of those cases that tested positive for COVID-19 was included, as well as their outcomes. All analyses were performed using the SPSS 21.0 statistical package (IBM, Inc.).

3 | RESULTS

A total of 174 pediatric LTs were performed between March 11, 2019 and February 19, 2021. In the pre-COVID-19 period, 97 LTs were performed, versus 77 LTs performed in the COVID-19 period, representing a decrease of 20.6% in pediatric LT activity during the pandemic. Figure 1 represents the pediatric LT activity in our center for each month during the pandemic. The number of reported COVID-19 confirmed cases in Brazil is shown per week since the beginning of the pandemic.

The majority of LTs were performed with living donors, in both periods: 91 (93.8%) in the **pre-COVID-19 period** and 71 (92.2%) in the **COVID-19 period**, $p = .4$. The comparative analysis of clinical characteristics of children transplanted in the first period (**pre-COVID-19**) with children transplanted in the second period (**COVID-19**), showed that those from the COVID-19 period were younger at LT, with higher PELD/MELD scores and greater prevalence of ascites, and were more frequently hospitalized before the LT (Table 1).

Waiting-list mortality rates in pediatric candidates were 8.4% and 11.9% in the **pre-COVID-19 period** and **COVID-19 period**, respectively.

The postoperative outcomes analysis shows no significant differences between the periods, either in the length of hospital stay, or in the development of post-LT complications (Table 2). Two patients were retransplanted during the follow-up, one in each group. The 1-year patient survival was similar in both groups (95.9%, $p = .9$).

There was no donor mortality, and 2 donors developed pulmonary thromboembolism, equally distributed among the periods, which were properly managed and had a good outcome. None of the donors were COVID-19 positive after the donation.

A total of 12 patients, 6 (6.2%) from the **pre-COVID-19 period** and 6 (7.8%) from the **COVID-19 period** were infected, in a median of 15.5 months (14 to 17.5 months) and 3 months (20 days–6 months) after the LT, respectively. The clinical characteristics and outcomes of recipients diagnosed with COVID-19 are detailed in Table 3.

Most patients developed mild symptoms or were asymptomatic, and only one COVID-19 patient was diagnosed on the first postoperative day. The clinical and epidemiological screening before LT for this patient was negative, but the PCR-RT result for COVID-19 was not available until the moment of LT. All patients who developed COVID-19 had a good recovery, without complications related to the disease, and there was no need to change their immunosuppression. PCR-RT tests for these patients were repeated and resulted in negative.

A total of 3 LDLTs were canceled because of positive PCR-RT results in the pre-LT screening—one recipient, and two donors, and their respective recipients. Only one of these recipients actually developed the disease, while the others were asymptomatic. Only one of these two donors developed mild respiratory symptoms of the disease with favorable evolution. All procedures were postponed and performed after a negative PCR-RT test.

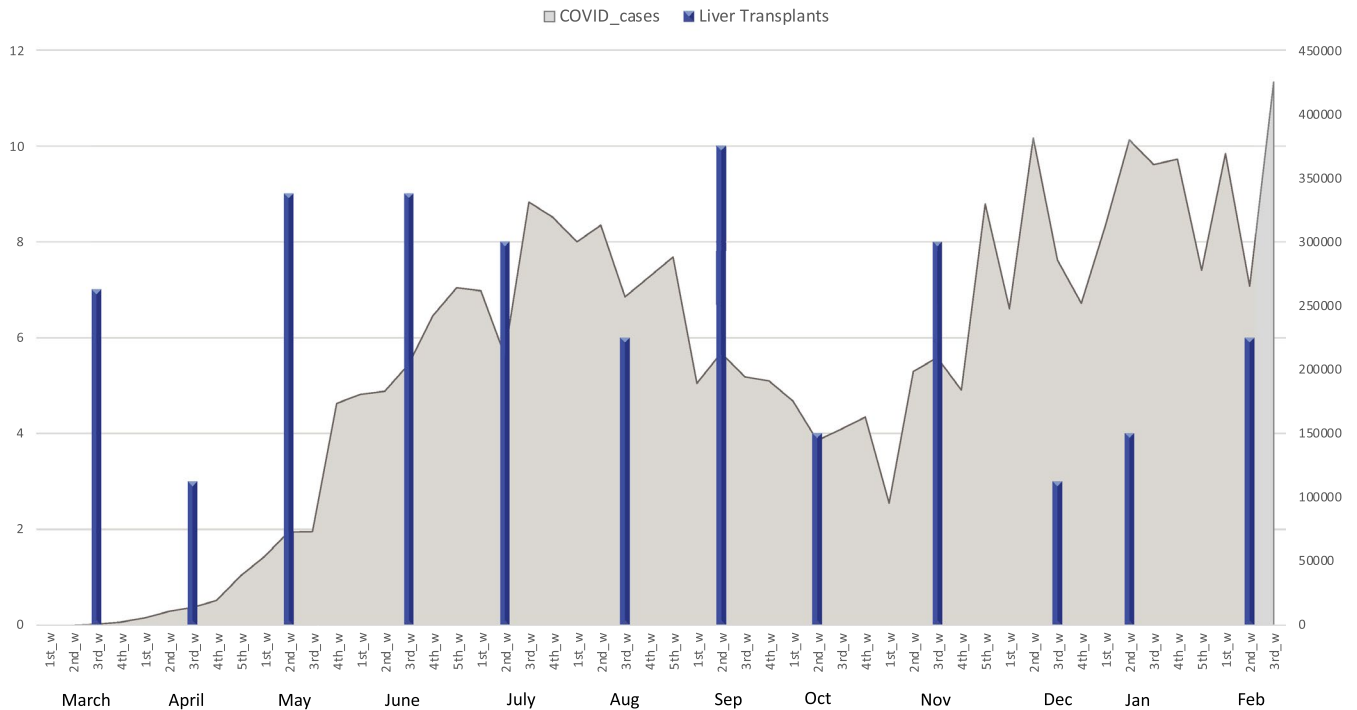


FIGURE 1 Number of pediatric liver transplants according to COVID weeks in Brazil in 2020

In our country, vaccines were not yet widely available at the time these patients were transplanted. In this period, only priority groups such as healthcare workers, people over 60 years of age and individuals with comorbidities had access to vaccination.

Our current protocol recommends the vaccination of donors, when available for the age group, in the preoperative period up to 4 weeks before the procedure. The same time interval is considered for vaccination in the postoperative period.

4 | DISCUSSION

This is the first study offering outcomes in the field of pediatric LT from a single high-volume program in Brazil during the COVID-19 pandemic. One year after the outbreak, Brazil has become the epicenter of the pandemic. The outcome analysis of transplantations performed during this period plays a role in making us rethink our medical practice, in order to establish landmarks toward the safe continuity of transplantation activity.

Initially, the results showed a decrease in our transplantation activity, especially at the beginning of the pandemic in Brazil, as we can see in Figure 1. This was caused by uncertainties about the transmission and severity of the new disease, and the time needed to establish new policies and practices to ensure the safety of patients and medical staff. The continuation of the activity involves the discussion of ethical issues and depends on the availability of public and local resources.¹⁵ Especially, living donation is contingent on local circumstances related to internal hospital adaptation determinants in maintaining transplantation activity. Other local factors may also be crucial, such as the shortage of hospital beds and staff.^{16,17} The

construction of a COVID-19-free pathway for recipients is made possible by efficient communication between the multidisciplinary medical care team and the hospital's resource management. This communication must be agile and quickly adapted to momentary needs.

Questions related to which patients to transplant and which to postpone are relevant in this scenario. Our patients were continuously evaluated considering aspects related to the severity of the liver disease. In this series, LT was considered for those patients who were at real risk of death before LT, while waiting on the list. This is what has been recommended by other authors, and there is a consensus among them that LT should be indicated according to liver disease severity. Therefore, for those at higher risk of mortality on the waiting list, the procedure should not be delayed.¹⁸

Comparative analysis of the clinical characteristics of candidates in the two groups showed sicker candidates in the COVID-19 cohort, with higher PELD scores, greater incidence of ascites, and longer hospitalization before LT.

This can be explained by the delay in referring pediatric patients to transplant centers, as well as the reluctance of family members to seek medical care, for fear of COVID-19 contamination in the hospital environment. This was also observed by other authors.¹⁸ Another determinant that should be considered is the impact of social isolation measures on mobility, which in Brazil made it difficult for people to reach medical care centers.

The fear of subjecting immunosuppressed patients and healthy living donors to a higher risk of disease transmission offset the risks of mortality and/or disease progression in candidates on the waiting list. Asserting the results of this consideration presents a real challenge at this time.

TABLE 1 Recipient and intra-operative characteristics according to the LT period

	Pre-COVID period	COVID period	p
	N = 97	N = 77	
Sex, male, n (%)	48 (49.5)	40 (51.9)	.43
Age at LT(months)	16 (9.4 to 63.2)	10.9 (7.6 to 26.5)	.009
Weight at LT (kg), mean ± SD	13.3 ± 10.1	11.8 ± 9.7	.1
Z-score W/A	-1.1 (2.3 to 0.4)	-0.86 (-2 to -0)	.27
Z-score H/A	-1.6 (-3.1 to -0.9)	-1.2 (-2.1 to -0.5)	.009
PELD/MELD, median (IQR)	14 (9 to 20)	15 (8 to 25)	.04
Wait list time (days), mean + SD	91.6 ± 107	92.1 ± 118.3	.97
BA, n (%)	58 (59.8)	52 (67.5)	.18
Previous surgery, n (%)	36 (37.1)	31 (40.3)	.4
Ascites, n (%)	50 (51.5)	51 (66.2)	.03
Hospitalized before LT, n (%)	17 (17.5)	21 (27.3)	.08
Primary LT, n (%)	93 (95.9)	76 (98.7)	.26
LDLT, n (%)	91 (93.8)	71 (92.2)	.4
Liver segments, n (%)			.46
LLS	81 (92)	66 (90.4)	
LL	7 (8)	7 (9.6)	
GRWR (%)	3 ± 1.3	3.3 ± 1.2	
Intra-operative blood transfusion (ml/kg)	15.7 (10.5 to 28)	19.7 (11.4 to 27.8)	.33

Abbreviation: LT, liver transplant; SD, standard deviation; W/A, weight and age; H/A, height and age; BA, biliary atresia; LDLT, living donor liver transplant; LLS, left lateral segment; LL, left lobe; GRWR, graft-to-recipient weight ratio.

TABLE 2 Post-LT outcomes in both periods

	Pre-COVID period	COVID period	P
	N = 97	N = 77	
Hospital stay (days), median (IQR)	21 (15.5 to 28.5)	20.5 (17 to 28.7)	.91
Biliary leak, n (%)	4 (4.1)	7 (9.1)	.15
Biliary stricture, n (%)	10 (10.3)	9 (11.7)	.47
HAT, n (%)	1 (1)	1 (1.3)	.69
PVT, n (%)	3 (3.1)	5 (6.5)	.24
PV stenosis, n (%)	2 (2.1)	0	.3
Re-LT, n (%)	1 (1)	1 (1.3)	.69
Death, n (%)	5 (5.2)	3 (3.9)	.49

Abbreviations: HAT, hepatic artery thrombosis; LT, liver transplant; PV, portal vein; PVT, portal vein thrombosis.

The LT cannot be considered independently as a factor associated with the risk of death for COVID-19, unlike comorbidities such as increased age, for example.^{19,20} This topic deserves attention when we analyze the risk of SARS-CoV-2 evolving to the severe form per age group. Previous studies demonstrated that severe manifestation of SARS-CoV-2 in children is uncommon.^{21,22}

An Italian study in Bergamo, a location with a high incidence of COVID-19 transmission, involving children monitored for LT or with some degree of liver disease, demonstrated no increase in hospitalization or pulmonary involvement in COVID-19-infected children.²²

Our results demonstrated an incidence of COVID-19 infection in 6.9% of recipients, distributed similarly among the groups. Most patients had a favorable recovery, as published by other authors.^{23,24} Only 1 patient required prolonged intubation and oxygen support but did not present severe pulmonary involvement in imaging.

The epidemiological and clinical screening of this candidate for SARS-CoV-2 was negative; however, the PCR-RT test for COVID-19 was positive 12 h after LT with a deceased donor. Most likely, this patient had an asymptomatic disease, a frequent situation in pediatric patients.²¹ According to the recently published⁶ recommendations for recipient management—included in the consensus-based approach to managing transplantation programs during the pandemic—it is preferable to have the PCR-RT result for COVID-19 before LT; however, for patients with negative epidemiological and clinical screening, waiting for the result may prolong the graft ischemia time to the point where LT is no longer feasible. Therefore, transplantation should not be delayed until the test result is available. However, we need to emphasize the fact that our most severe patient was the one diagnosed within

TABLE 3 LT recipients diagnosed with COVID-19

Patient number	Sex	Age at LT	LT date	Type of LT	Time from LT to COVID	Immunosuppression	Diagnosis	Symptoms	O2 support / Intubation	Hospitalization	Outcome
1	f	7 years	2019	ReLT, LDLT	1 year 3 months	FK + MMF + Pred	PCR	No	No	No	Alive, no complications
2	m	13 years	2019	LDLT	1 year 7 months	FK + Pred	PCR	No	No	No	Alive, no complications
3	f	1 year 8 months	2019	LDLT	1 year 4 months	FK + MMF	PCR	No	No	No	Alive, no complications
4	f	1 year	2019	LDLT	1 year 1 months	FK	PCR	Diarrhea	No	Yes	Alive, no complications
5	f	7 months	2019	LDLT	1 year 3 months	FK + Pred	PCR	Upper air way symptoms	No	No	Alive, no complications
6	m	11 years	2019	Domino	1 year 4 months	FK + Pred + MMF	PCR	No	No	No	Alive, no complications
7	f	5 months	2020	LDLT	2 months	FK + Pred + MMF	PCR	Fever; vomiting	No	Yes	Alive, no complications
8	m	1 year 5 months	2020	LDLT	6 months	FK + Pred + MMF	PCR	Fever; vomiting	No	No	Alive, no complications
9	f	6 months	2020	LDLT	6 months	FK + Pred	PCR	Upper air way symptoms	No	No	Alive, no complications
10	f	1 year 3 months	2020	LDLT	4 months	FK + Pred	PCR	Upper air way symptoms; Diarrhea	No	No	Alive, no complications
11	m	1 year 4 months	2020	DDLT	1 day	FK + Pred	PCR	Respiratory distress;	Yes, intubated for 10 days and 9 days of O2 support	Yes	Alive, no complications
12	f	10 years	2020	LDLT	20 days	FK + Pred + MMF	PCR	Abdominal pain; Vomiting	No	Yes	Alive, no complications

Abbreviations: FK, tacrolimus; LDLT, living donor liver transplant; LT, liver transplant; MMF, mycophenolate; Pred, prednisone.

the shortest time after LT. This is relevant in the scenario of pediatric LT with a deceased donor, since most pediatric candidates do not have a positive clinical screening for COVID-19 and present as asymptomatic. All recipients who had the COVID-19 infection showed good recovery.

The overall clinical outcomes in this study were favorable. The comparative analysis between the groups related to recipient and graft survival, vascular complications, and COVID infection after LT, indeed the end-points of this study, showed no significant difference between the periods. Thus, there was no negative impact on the outcomes of pediatric LT recipients during the pandemic. Donors also presented favorable results in donation-related morbidity according to the Clavien-Dindo criteria, and there was no difference between the two periods.

5 | CONCLUSION

The preliminary publication of our experience in a high-volume program of pediatric LT, at the epicenter of the pandemic, allows us to conclude that an initial reduction in transplant activity is justified until new COVID-free pathways are established to ensure patient safety. The comparative analysis with the period before the pandemic showed no negative impact on the results, supporting the continuation of this activity.

AUTHOR CONTRIBUTION

All the authors listed have contributed to this work and meet the authorship criteria.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Fonseca EA, Feier F, Pugliese R, et al. Pediatric liver transplantation activity in a high-volume program during the COVID-19 pandemic in Brazil. *Pediatr Transplant*. 2021;25:e14112. <https://doi.org/10.1111/petr.14112>