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Collaborative Brazilian pediatric renal transplant registry (CoBrazPed-RTx): A report from 2004 to 2018

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Abbreviations: CAKUT, congenital abnormalities of kidney and urinary tract; CMV, cytomegalovirus; CoBrazPed-RTx, Collaborative Brazilian Pediatric Renal Transplant Registry; DD, deceased donors; ESPN/ERA-EDTA, European registry of pediatric renal replacement therapy; ESRD, end-stage renal disease; FSGS, focal segmental glomerulosclerosis; IQR, interquartile range; LD, live donor; MA, mycophenolic acid; NAPRTCS, North American Pediatric Renal Trials and Collaborative Studies; OPTN, Organ Procurement and Transplantation Network; TAC, tacrolimus.

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Abstract

The Brazilian collaborative registry for pediatric renal transplantation began in 2004 as a multicenter initiative aimed at analyzing, reporting, and disseminating the results of pediatric renal transplantation in Brazil. Data from all pediatric renal transplants performed from January 2004 to May 2018 at the 13 participating centers were analyzed. A total of 2744 pediatric renal transplants were performed in the thirteen participating centers. The median age at transplantation was 12.2 years, with the majority being male recipients (56%). The main underlying diseases were CAKUT (40.5%) and glomerulopathy (28%). 1981 (72%) of the grafts were from deceased donors (DD). Graft survival at one year (censored by death) was 94% in the live donor group (LD) and 91% in the DD group (log-rank test $P < 0.01$). The patient's survival at one and 5 years was 97% and 95% for the LD group and 96% and 93% for the DD group (log-rank test $P = 0.02$). The graft loss rate was 19% (n = 517), more frequently caused by vascular thrombosis (n = 102) and chronic graft nephropathy (n = 90). DD recipients had 1.6 (1.0-2.2) times greater chance of death and 1.5 (1.2-1.8) times greater chance of graft loss compared to LD recipients. The mortality rate was 5.4% (n = 148), mainly due to infection (n = 69) and cardiovascular disease (n = 28). The results of this collaborative pediatric renal transplant record are comparable to other international registries, although we still have a high infection rate as a cause of death.

KEYWORDS
kidney transplantation, pediatric nephrology, registry

1 | INTRODUCTION

Kidney transplantation is the treatment of choice for children with ESRD, with better growth and quality of life than patients undergoing dialysis. Brazil is a continental developing country with a large number of pediatric kidney transplants. In 2017, 618 children were enrolled on the kidney transplant waiting list, and 319 had undergone kidney transplantation.[1]

Since 2004, a group of pediatric transplant physicians started a multicenter collaborative study aiming to analyze, report, and share the results of pediatric kidney transplantation in Brazil. The CoBrazPed-RTx had its results initially published in 2015.[2] The aim of this study was to update the demographic characteristics of patient and graft survival rates and the causes of death and graft loss in the last 14 years among the 13 CoBrazPed-RTx participating centers carrying out pediatric transplants in Brazil.

2 | PATIENTS AND METHODS

2.1 | Patients

This cohort consisted of 2744 consecutive kidney-transplanted children who underwent the procedure between January 2004 and May 2018 in the 15 participating centers of the CoBrazPed-RTx. Before 2014, all centers used an Excel spreadsheet for input of data. Since January 2014, the registration has been made online, using HTML, PHP, and JavaScript languages, and MySQL database for data storage. The online database allows for two fill-in options: a summary form (27 variables) or an expanded form (120 variables) that are collected on a voluntary basis, and their completeness differs per center.

2.2 | Immunosuppression

The target cyclosporine A trough blood level was 150-200 ng/mL during the first 3 months and 100-150 ng/mL thereafter. The target TAC level was 10-15 mg/L during the first 21 days, 5-10 mg/L until the month 3, and 5-6 mg/L thereafter. We do not have MA pharmacokinetic curve. In general, most of centers tapper steroids during the first 3-6 months post-Tx discontinuing the drug after patient have reached the minimal dosage established for that center.

We collected data on donor, recipient, and transplantation characteristics that have previously been reported to influence allograft survival. Patient survival was defined as the time from transplant to death or last follow-up. Death-censored graft survival was defined as the time from transplant to the earliest time of graft loss, re-transplantation, re-initiation of dialysis, or last follow-up with a functioning graft, censored by death. Demographic variables analyzed were as follows: gender, age, etiology of renal failure, transplant characteristics, donor source (living—LD or deceased—DD), etiology (FSGS

TABLE 1 Baseline characteristics of the kidney-transplanted children

Characteristics	Values	Missing
N	2744	-
Males (n; %)	1533 (56)	-
Age (years; median [IQR])	12.2 [7.9-15.4]	-
<6 y (n; %)	444 (16)	-
≥6 to <12 y (n; %)	879 (32)	-
≥12 y (n; %)	1421 (52)	-
Primary diagnosis (n; %)		-
Glomerulopathy	762 (28)	-
CAKUT	1113 (40.5)	-
Others	869 (31.5)	-
Preemptive transplantation (n; %)	299 (11)	-
Median dialysis time (months, median [IQR])	14.5 [7.7, 26.3]	2075
Delayed graft function (n; %)	477 (27)	988
Deceased donor (n; %)	1979 (72)	-
Donor age (years; median [IQR])	15 [8, 19]	1881
Donor-specific antibody class 1, n (%)		
None	628 (83)	1988
MIF < 1000	18 (2)	
MIF 1000-5000	16 (2)	
MIF > 5000	1 (0.1)	
Unknown	93 (12)	
Donor-specific antibody class 2, n (%)		
None	648 (85)	1984
MIF < 1000	3 (0.3)	
MIF 1000-5000	13 (2)	
MIF > 5000	2 (0.2)	
Unknown	94 (12.5)	
Cold ischemia time (hours, median [IQR])	20 [15, 25]	1896
Panel-reactive antibodies Class 1, n (%) (unknown n = 13)		
None	364 (47)	1964
<50%	364 (47)	
≥50%	39 (5)	
Panel-reactive antibodies Class 2, n (%) (unknown n = 14)		
None	421 (54)	1969
<50%	308 (40)	
≥50%	32 (4)	
HLA mismatches, n (%)		
HLA-A (unknown n = 7)		
0	314 (40)	1955
1	399 (51)	
2	69 (9)	
HLA-B (unknown n = 9)		
0	361 (46)	1955
1	369 (47)	
2	48 (6)	
HLA-DR (unknown n = 8)		
0	192 (24)	1955
1	441 (56)	
2	146 (19)	
Follow-up (month; median [IQR])	41.4 [16.2-82.5]	-

Abbreviations: HLA: human leukocyte antigen; MIF: mean fluorescence intensity.

vs others), immunosuppressive therapy, acute rejection, and patient and graft survival according to donor type and etiology. Three temporal cohort groups were evaluated: from 2004 to 2008, 2009 to 2012, and 2013 to 2018.

2.3 | Statistical analysis

Continuous variables were expressed as median and IQR. Groups were compared by Student's *t* test or Mann-Whitney's *U* test, if needed. Graft survival and the impact of etiology and graft source were determined. A Cox proportional hazards model was applied to evaluate the relative hazard of graft failure or death of the patient. Graft survival rate and patient survival rate were estimated by Kaplan-Meier curves and compared using log-rank test. Chi-square and Fisher's exact tests were used to determine the association between ordinal and nominal variables. A *P*-value < 0.05 was

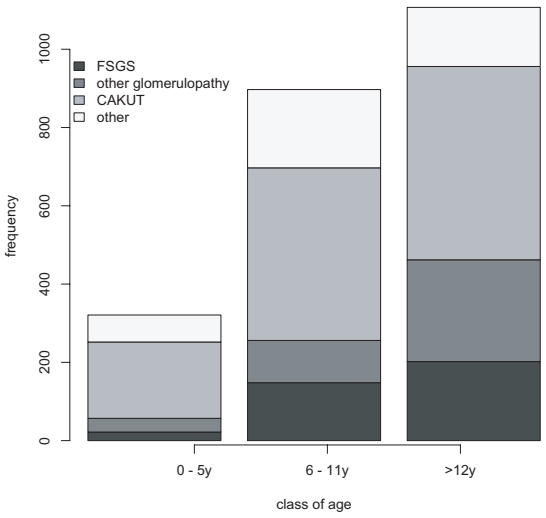

FIGURE 1 Primary cause of ESRD in pediatric kidney transplant patients by age

TABLE 2 Induction and immunosuppression in three periods of time

	2004-2008 (n = 808)	2009-2013 (n = 851)	2014-2018 (n = 1083)
Induction, n (%)			
Basiliximab	611 (76)	667 (78)	692 (64)
No induction	146 (18)	29 (3)	11 (1)
ATG	41 (5)	152 (18)	363 (34)
Other	10 (1)	3 (1)	17 (1)
Calcineurin inhibitors, n (%)			
Cyclosporine	206 (25)	113 (13)	141 (13)
TAC	571 (71)	734 (86)	908 (84)
No information	31 (4)	4 (1)	34 (3)
Antiproliferative Agents, n (%)			
MA	458 (57)	490 (58)	603 (56)
Azathioprine	341 (42)	347 (41)	435 (40)
No information	9 (1)	14 (1)	45 (4)
Prednisone, n (%)			
Yes, maintenance	705 (87)	772 (91)	1002 (92.5)
No	93 (12)	72 (8.4)	52 (5)
Only 7 d	8 (1)	6 (0.5)	12 (1)
No information	2 (0.2)	1 (0.1)	17 (1.5)

Abbreviation: ATG: antithymocyte globulin.

considered significant. Statistical analysis was conducted using R for windows version 3.5.0.

3 | RESULTS

In the cohort of 2744 transplants, patients were aged up to 18 years old with a median (IQR) age at transplantation of 12.2 years (7.9-15.4), and 10.9% were preemptive (Table 1). The percentage of males in the registry, 55.8%, was similar to our 2015 report (56%) and to the European registry (60.2%).[2,3]

The most common underlying renal etiology was CAKUT (40.5%, n = 1,113) and glomerulopathy (28%, n = 762)—FSGS accounted for 13.0% (N = 59). CAKUT accounted for the largest proportion of primary diagnosis in all ages. Glomerulopathies, of which FSGS was the most frequent (47.1%), increased with age (Figure 1).

The most common complications in the first year were infection (18.5%) and acute rejection (6.5%). The most prevalent infections were CMV (11%, n = 296), urinary infection (8%, n = 225), and pneumonia (2%, n = 65). The CMV prophylaxis was not used in 79% of recipients, and 7.5% used only ganciclovir, 4% ganciclovir and valganciclovir, and 3% only valganciclovir. In the first 3 months, 2292 (83.5%) recipients had no rejection. The most common histological changes were T cell–mediated rejection and borderline changes.

DD accounted for 72.1% (n = 1979) of all transplants. The induction of immunosuppression used in low immunologic risk patients was basiliximab (71.8% of patients). For maintenance, TAC/cyclosporine, MA/azathioprine, and prednisone were used in different combinations (Table 2). Overall, the association of TAC, MA, and steroids was the most frequent immunosuppressive therapy used.

Patient survival rate at 12, 36, and 60 months for LD patients was 97, 96, and 95, respectively, and for DD patients was 96, 95, and 93, respectively (log-rank *P*-value = 0.02). Death occurred in 148 (5.4%) recipients of all cohort, and the main causes were infection (47%) and cardiovascular diseases (19%). We observed a higher rate of death in the population under the age of 6 years (8.9%) compared to those aged 6-11 (7.1%) and older than 12 years (4.6%) ($P < 0.01$). The mortality rate showed improvement from 2004-2008 (9.5%) to 2009-2012 (4.5), and to 2013-2018 (2.9%) cohorts. The reduction in mortality rate also occurred in the age group below 6 years, which was 15.0% in the period 2004-2008 and 5.3% in the last 5 years. We had a large difference in the mortality rate (Table 3), varying from 2%

TABLE 3 Participating centers characteristics

Center	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Number of transplants	48	86	50	22	168	217	809	359	60	502	141	12	57	113	100
Pediatric center	No	Yes	No	No	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Expanded form database	Yes	No	No	No	No	Yes	No	No	No	Yes	No	No	No	Yes	No
Patients < 6 y old (%)	12.5	10.4	12.0	27.2	10.7	11.5	9.8	41.2	8.3	18.5	12.0	0	15.8	2.6	19.0
Graft loss rate (%)	31.2	20.5	13.0	9.0	16.8	25.8	22.4	9.7	11.1	18.3	45.3	16	15.7	15.5	13.0
Mortality rate (%)															
2004-2008	-	-	-	-	6.7	15.2	7.4	-	-	6.4	27.5	-	-	-	-
2009-2013	12.5	8.5	5.5	6.6	1.4	10.2	3.1	1.7	-	4.7	13.6	-	4.3	9.0	5.4
2014-2018	9.0	3.5	-	-	-	7.5	5.5	3.2	4.0	2.7	-	0	-	5.2	1.7
Vascular thrombosis (%)	2.0	11.6	2.0	0	1.8	5.0	2.9	4.4	6.6	3.2	1.4	0	0	7.9	6.0

For mortality rate: - if cell blank, there was no transplant, or number of transplants <4.

TABLE 4 Graft survival rate in all cohort, FSGS, and non-FSGS recipients adjusted by donor source

% (95% CI)	Overall cohort	FSGS	Non-FSGS	*P*
Living donor				
1 y	94 (93-96)	86 (79-94)	95 (93-97)	<0.01
3 y	91 (89-93)	78 (70-88)	93 (91-95)	<0.01
5 y	87 (85-90)	69 (60-80)	90 (87-93)	<0.01
Deceased donor				
1 y	91 (89-92)	85 (81-89)	91 (89-92)	<0.01
3 y	85 (83-86)	75 (70-82)	85 (83-87)	<0.01
5 y	78 (75-80)	58 (49-70)	80 (77-83)	<0.01

Abbreviation: 95% IC: 95% confidence interval.

to 25% in the different centers. The median time of follow-up was 41.4 (16.2-82.5) months after transplant.

Graft survival rates according to donor type at 12, 36, and 60 months were 94, 91, and 87% for LD recipients and 91%, 85%, and 78% for DD recipients, respectively (log-rank *P*-value <0.01). Graft survival rates according to etiology at 12, 36, and 60 months were 92%, 88%, and 84% for non-FSGS recipients and 86%, 77%, and 68% for FSGS recipients, respectively (log-rank *P*-value <0.01). The FSGS recipients had 26.7% of graft loss due to relapse of primary disease and the group had 1.55 (95% confidence interval: 1.23-1.95) times the hazard of graft loss compared with those of the non-FSGS group ($P < 0.01$), adjusted for donor type. A total of 517 graft losses occurred among the 2744 (18.8%) transplants. Of these, 102 (20%) losses were due to vascular thrombosis, 90 (17%) due to chronic allograft dysfunction, and 75 (15%) due to death with a functioning graft. The graft loss rate was significantly superior in the 2004-2009 cohort (30.3%) than in the 2013-2018 cohort (10.1%).

4 | DISCUSSION

This report of fourteen years of follow-up showed that patient and graft survival rates from 2744 allografts were in line with other international reports.

The leading cause of end-stage kidney disease changed with age: FSGS and glomerulonephritis were more common in older children, while CAKUT was more common in children younger than 6 years old, also in agreement with other pediatric registries.[3-7] Patients with FSGS account for 11.5% and 12.5% of transplant patients in the NAPRTCS database and in the pediatric cohort of the OPTN, respectively. These results are in accordance with our FSGS prevalence (13%), but superior to the ESPN/ERA-EDTA Registry that described 407 FSGS patients among the 5892 who received a renal transplant.[5,8,9]

Our overall mortality rate (5.4%) was similar with that of NAPRTCS database (5.3%), as well as the trend of best survival in the most recent cohorts, and was superior to the mortality rate of 23 deaths per 1000 patient-years presented by the ESPN/ERA-EDTA Registry.[5,7] In the years 2004-2009, we had a mortality rate of 9.5% which dropped to 2.9% in the last 5 years. It is noteworthy that there was a difference in mortality rates in the different centers, probably related to the experience of each site. Even so, there is a trend toward a reduction in mortality over time. This information can be used to improve the quality of care. Age is another factor that has been demonstrated to affect patient survival and that is in accordance with our findings. All over the world, advances have had a positive influence in survival as a result of improvements in technical and therapeutic knowledge.[10,11] Unfortunately, almost half of our cases of death are caused by infection (47%), surpassing the rates reported by NAPRTCS (28.4%) or by Japan (12.5%), but similar to ALANEPE.[5,12,13]

We found an overall graft loss rate of 18.8%, with a high frequency of vascular thrombosis (20%), different from NAPRTCS that found 6.6% of this cause of loss, and from Harambat et al, who found a rate of 12.7%.[5,14] Our graft survival rate was very similar to that described by Latin American (ALANEPE) Registry of Pediatric Renal Transplantation, although the Brazilian population contributed to 45% of the ALANEPE registry.[12] The recurrence of original disease as a cause of graft loss was found in 26.7% of FSGS recipients, in contrast with only 2.2% in non-FSGS patients. NAPRTCS have shown very similar results with 102/408 (25%) of graft loss in FSGS recipients, due to recurrence of original disease and only 4.2% in non-FSGS recipients.[5] Also, the ESPN/ERA-EDTA Registry found a 5-year risk of graft loss of 25.7% for FSGS recipients.[9]

Graft survival rates in non-FSGS living donor recipients were significantly higher than the other recipients (Table 4), and the long-term advantage of LD grafts was lost in this population. In 2014, in line with our findings, the NAPRTCS database showed that the 5-year LD graft survival rate was 69% for recipients with FSGS compared to 82% with no FSGS ($P < 0.01$), whereas it was 60% and 67%, respectively, in the DD groups.[5]

The large sample of pediatric kidney transplants in a continental developing country characterized by cultural and economic diversity among its regions is the major strength of this study. However, it has several limitations, including: (a) the retrospective nature of the data collected in the cohort study before 2014; (b) the voluntary basis of the Registry resulting in many missing values for the expanded form of database, which might lead to potential bias; and (c) the heterogeneity of results between the centers.

In conclusion, the results of this collaborative pediatric transplant study are comparable to international registries. Although it is difficult to maintain an updated national register in a developing country such as Brazil, with no funding, this registry is an important step to improve and homogenize national results in pediatric transplantation.

AUTHOR CONTRIBUTIONS

Vandrea Carla de Souza, Clotilde Druck Garcia, Paulo Koch Nogueira, and Mario Bernardes Wagner: Conceived and designed the study; Vandrea Carla de Souza and Mario Bernardes Wagner: Performed statistical analysis and interpreted the data; Vandrea Carla de Souza, Clotilde Druck Garcia, Ida Fernandes-Charpiot, Paulo Koch Nogueira, and Mario Abbud-Filho: Drafted and revised the manuscript; and Clotilde Druck Garcia, Jose Medina Pestana, Suelen Bianca Stopa Martins, Luciana de Fátima Porini Custódio, Viviane Bittencourt, Roberta Rohde, Izadora Simões Pires, Maria Fernanda de Camargo, Luciana de Santis Feltran, Ronaldo de Matos Esmeraldo, Rebeca Carvalho Souza Costa, Benita Schvartsman, Andreia Watanabe, Mariana Faucz Munhoz da Cunha, Romilda Santos, Liliane Cury Prates, Vera Maria Santoro Belangero, Lilian Palma, Henrique Mochida Takase, Luiz Gustavo Mondelli de Andrade, Vanda Benini, Simone Paiva Laranjo Martins, Mario Abbud-Filho, Ida Fernandes-Charpiot, Horacio Ramalho, Ana Carmen Quaresma Mendonça, Mariana Affonso Vasconcelos, Claudia Andrade Nunes, Mariana Guimaraes Penido de Paula, Carolina Moura Diniz Ferreira Leite, Enzo Ricardo Russo, and Inalda Facincani: Collected and managed the data.

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