Late Graft Loss among Pediatric Recipients of DCD Kidneys

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Summary

Background and objectives Kidney transplantation from donors after cardiac death (DCD) provides similar graft survival to donors after brain death (DBD) in adult recipients. However, outcomes of DCD kidneys in pediatric recipients remain unclear, primarily because of limited sample sizes.

Design, setting, participants, & measurements We identified 137 pediatric (<18 years old) recipients of DCD kidneys between 1994 and 2010 using Scientific Registry of Transplant Recipients data and compared outcomes with 6059 pediatric recipients of DBD kidneys during the same time period, accounting for donor, recipient, and transplant characteristics using time-varying Cox regression and matched controls. Long-term follow-up (4 years or beyond) was available for 31 DCD recipients.

Results Pediatric recipients of DCD kidneys experienced a significantly higher rate of delayed graft function (22.0% *versus* 12.3%; $P = 0.001$), although lower than reported delayed graft function rates of DCD grafts in adults. Although DCD and DBD graft survival was equal in the early postoperative period, graft loss among pediatric recipients of DCD kidneys exceeded their DBD counterparts starting 4 years after transplantation. This effect was statistically significant in a multivariate Cox model (hazard ratio = 2.03; 95% confidence interval, 1.21 to 3.39; $P = 0.007$) and matched-controls analysis (hazard ratio = 2.36; 95% confidence interval, 1.11 to 5.03; $P = 0.03$).

Conclusions A significant increase in DCD graft loss starting 4 years after transplantation motivates a cautious approach to the use of DCD kidneys in children, in whom long-term graft survival is of utmost importance.

Clin J Am Soc Nephrol 6: 2705–2711, 2011. doi: 10.2215/CJN.03760411

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Introduction

Kidney transplantation is the treatment of choice for children with ESRD, providing a significant survival advantage over dialysis (1,2). However, there is a critical shortage of deceased-donor organs available for kidney transplantation. Changes to the kidney allocation scheme with the implementation of Share-35 in 2005 gave children the highest priority for kidneys from younger deceased donors. This policy change increased both the total number of kidney transplants and the number of deceased-donor kidney transplants performed in children (3). However, over 700 pediatric candidates remain on the waiting list for a kidney transplant in the United States (4).

The use of donation after cardiac death (DCD) kidneys is one potential means to decrease the gap between the need for and availability of deceased-donor kidneys. DCD kidneys are used in a small but increasing number of pediatric recipients, and this number has continued to increase even since the implementation of Share-35 (Figure 1, A and B). In 2009, the most recent year for which all data are available, DCD kidneys were used in 6.6% of all deceased-donor pediatric kidney transplants performed.

In adults, DCD kidneys seem to result in similar graft and patient survival compared with donation after brain death (DBD) kidneys (5–12). However, DCD kidneys also have a significantly higher rate of delayed graft function (DGF) compared with DBD kidneys (5,7–12). DCD kidneys from younger donors and those with shorter cold ischemia time have the best outcomes in adult recipients (6,7,13).

In contrast to the abundant literature on DCD kidney transplantation in adult recipients, little is currently known about the outcomes of DCD kidney transplantation in pediatric recipients. The few studies completed have been limited by small sample sizes. An initial report from Japan described the successful use of DCD kidneys from pediatric donors in three pediatric recipients, although two of the patients had delayed graft function, and the third died of a pulmonary embolism despite reportedly good renal function (14). The largest series to date included 26

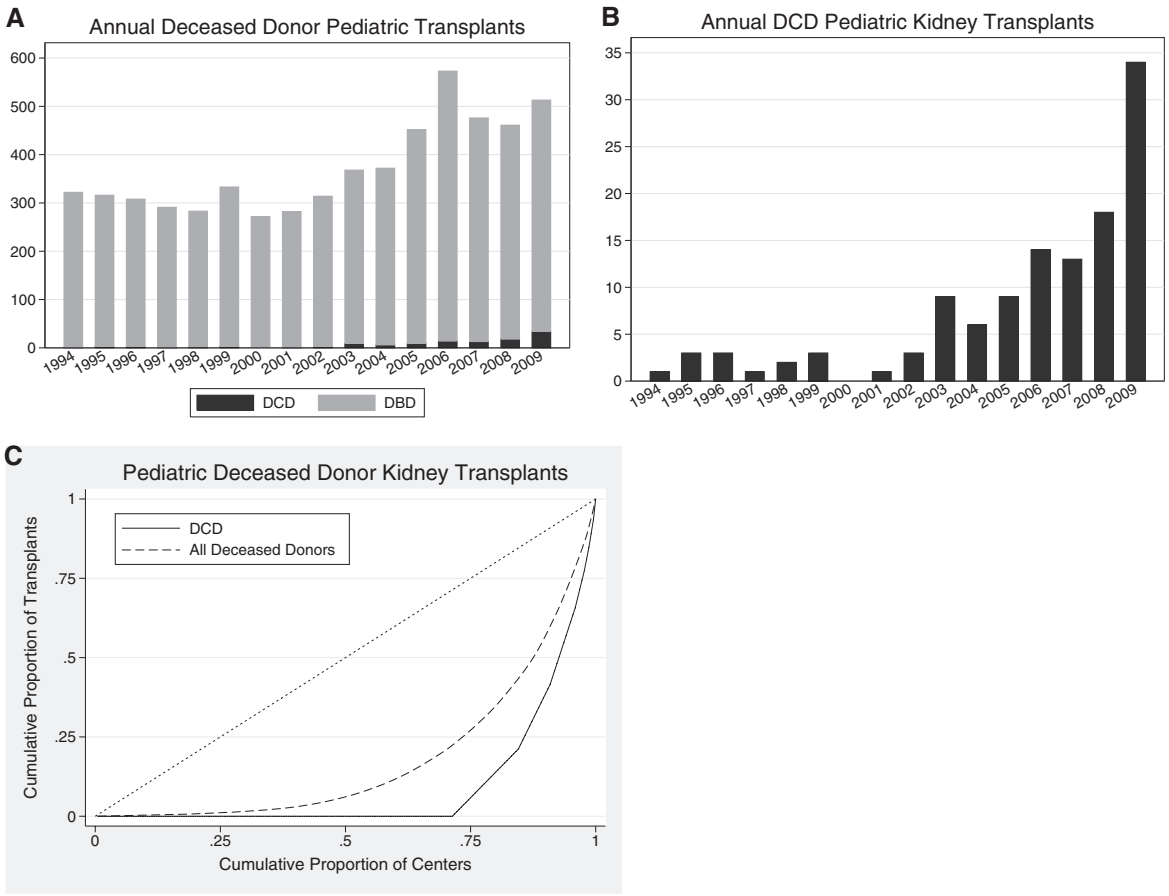

Figure 1. | Distributions of annual deceased-donor kidney transplants in pediatric recipients by donor type (A), annual donation after cardiac death (DCD) kidney transplants in pediatric recipients (B), and deceased-donor kidney transplants in pediatric recipients by donor type (C) across pediatric transplant centers. Skewing of the curve toward the bottom right of the graph indicates more clustering of a procedure (performed by fewer centers). DBD, donation after brain death.

pediatric recipients of DCD kidneys, using the United Network for Organ Sharing data, and suggested that DCD kidneys had similar graft survival (15). However, this series was limited by short follow-up and small sample size. To further examine the outcomes of DCD kidneys in pediatric recipients, we identified 137 pediatric recipients of DCD kidneys and compared their outcomes to pediatric recipients of DBD kidneys during the same period, looking particularly at longer-term outcomes and center-level practice patterns.

Materials and Methods

Study Population

After approval by the Johns Hopkins Medicine Institutional Review Board, all pediatric (recipient younger than 18 years old) deceased-donor kidney transplants between January 1994 (when DCD status was first recorded) and July 2010 were identified using the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, wait-listed candidates, and transplant recipients in the United States submitted by the members of the Organ Procurement and Transplantation Network and has been described elsewhere. The Health Resources and Services Administration of the U.S. Department of Health and Human Services provides oversight to the activities of the Organ Procurement and Transplantation Network and SRTR contractors.

Outcomes

The primary outcomes of interest were patient survival and death-censored graft survival (DCGS). Patient survival was defined as the time from transplant to death or last follow-up. DCGS was defined as the time from transplant to the earliest of graft loss, retransplantation, reinitiation of dialysis, or last follow-up with a functioning graft, censored for death. Death indicators were supplemented by linkage to the Social Security Death Master File; death and graft loss were supplemented by linkage to data from the Centers for Medicare and Medicaid Services. Both patient survival and DCGS were censored for administrative end of study. Other outcomes of interest were the rates of primary nonfunction (graft survival less than 90 days), DGF (need for dialysis within the first week post-transplantation), and rejection within 1 year.

Other Covariates

Donor age, race, history of hypertension, terminal creatinine, and cause of death were collected, as were recipient age, gender, race, peak panel reactive antibody (PRA),

hospitalization status, history of previous kidney transplantation, requirement for and length of dialysis before transplantation, primary cause of ESRD, and insurance status. Data on HLA mismatch, cold ischemia time, warm ischemia time for DCD organs, and geographic allocation type (local organ procurement organization or regional/national share) were also collected.

Center-Level Patterns

To investigate the distribution of deceased-donor transplants across pediatric transplant centers, a Lorenz curve was used to plot the cumulative percentage of deceased-donor transplants (y axis) against the cumulative percentage of transplant centers performing the transplants (x axis) as previously reported (16–18). If transplants were equally distributed across all transplant centers, a straight line at 45 degrees would be shown; increasing clustering of transplants at fewer centers increasingly skews the curve toward the bottom right of the graph. The proportion of candidates who died on the waiting list, recipient waiting times, and graft survival were also compared between those centers that did and did not perform DCD transplants.

Statistical Analyses

Comparisons of donor, recipient, and transplant characteristics were performed using t tests or Wilcoxon rank-sum tests for continuous variables and chi-squared or Fisher exact tests of independence for categorical variables. Comparisons of patient survival and DCGS between DCD and DBD recipients were explored using Kaplan-Meier survival estimates and log-rank tests. Cox models were used to adjust for donor, recipient, and transplant characteristics when comparing DCD and DBD recipients. On the basis of examination of the Kaplan-Meier curves and log-log plots, a time-varying coefficient for the DCD indicator was included in the final model to account for nonproportionality of hazards across time between DCD and DBD groups.

DCD recipients were also matched with five DBD recipients using progressive radius matching as described previously (19), on the basis of the following variables: donor age, gender, race, cause of death, history of hypertension, and terminal creatinine; recipient age, gender, race, peak PRA, history of previous transplant, and preemptive status; HLA mismatch; and year of transplant. Graft survival between matched controls was compared using a Cox model with a time-varying coefficient. Finally, a sensitivity analysis including only kidney transplants performed after the year 2000 was performed for the multivariate analysis, and inferences were similar. All of the tests were two-sided with statistical significance set at $\alpha = 0.05$. Analyses were performed using STATA 11.1/SE (College Station, TX).

Results

Study Population

Children receiving DCD kidneys ($n = 137$) were compared with children receiving DBD kidneys ($n = 6059$). Recipients of DCD kidneys were slightly older (12.8 years *versus* 11.8 years; $P = 0.03$) but otherwise similar in race, pre-emptive status, insurance, prior transplant, hospitalization at the time of transplant, PRA, and diagnosis. DCD donors were more likely to be under 35 years of age (89.1% *versus* 82.3%, $P = 0.04$), more likely to be Caucasian (76.6% *versus* 63.1%, $P = 0.005$), and less likely to have died from stroke (12.4% *versus* 23.7%, $P < 0.001$) (Table 1).

Of the 137 DCD recipients, 31 patients had at least 4 years of follow-up. The only statistically significant differences between DCD recipients with and without at least 4 years of follow-up were longer median dialysis time before transplantation (2.3 years *versus* 1.3 years; $P = 0.03$), lower prevalence of public insurance (48.4% *versus* 68.3%; $P = 0.04$), and fewer donors under 35 years of age (77.4% *versus* 92.5%; $P = 0.04$) (Table 1). At 3 years after transplantation (when coverage of immunosuppression ends), a similar percentage of DCD and DBD recipients under follow-up were over 18 years of age (34.1% *versus* 36.7%; $P = 0.7$).

Early Outcomes

DCD grafts experienced a significantly higher rate of DGF (22.0% *versus* 12.3%; $P = 0.001$). However, there was no statistically significant difference between DCD and DBD grafts in terms of primary nonfunction (4.4% *versus* 4.9%, respectively; $P = 0.8$) or acute rejection within 1 year (19.8% *versus* 22.6%, respectively; $P = 0.5$) (Table 2).

Patient Survival

The 2-, 4-, 6-, 8-, and 10-year patient survival rates were 94.2, 94.2, 86.9, 86.9, and 78.2%, respectively, in the DCD group and 97.7, 95.7, 93.3, 90.5, and 86.5%, respectively, in the DBD group (Table 2). No statistically significant difference in patient survival was found between the DCD and DBD groups ($P = 0.2$; Figure 2A).

Graft Survival

The 2-, 4-, 6-, 8-, and 10-year DCGS rates were 88.5, 74.0, 51.2, 37.3, and 29.8%, respectively, in the DCD group and 86.7, 74.8, 64.6, 55.5, and 48.7%, respectively, in the DBD group (Table 2 and Figure 2B). Using the traditional multivariate proportional hazards model, no significant difference in DCGS was detected (hazard ratio [HR] = 1.14; 95% confidence interval [CI], 0.83 to 1.59; $P = 0.4$). However, this approach was misleading because it violated the assumption of proportional hazards over the entire study period inherent in that model. Inspection of the survival differences over time revealed that the survival curves separated at 4 years (Figure 2B). When different hazard ratios were allowed over time (using a single model with a time-varying coefficient), there was no difference between DCD and DBD graft survival during the early postoperative period (HR = 0.92; 95% CI, 0.58 to 1.47; $P = 0.7$), but a two-fold increase in graft loss was seen among DCD recipients beyond 4 years post-transplant (HR = 2.03; 95% CI, 1.21 to 3.39; $P = 0.007$). Similarly, in matched-controls analysis, DCD and DBD graft survival was equal in the early postoperative period (HR = 0.95; 95% CI, 0.56 to 1.62; $P = 0.9$), but graft loss among DCD recipients exceeded their matched DBD counterparts starting 4 years after transplantation (HR = 2.36; 95% CI, 1.11 to 5.03; $P = 0.03$).

Center-Level Patterns

DCD transplants were more clustered at the center level than deceased-donor pediatric transplants in gen-

Table 1. Pediatric deceased-donor kidney transplant recipients between 1994 and 2010 stratified by donor type and length of follow-up

	DBD	DCD	
	All Patients (n = 6059)	All Patients (n = 137)	Long-term (>4 years) Follow-up (n = 31)
Recipient			
mean age (years) (SD)	11.8 (4.7)	12.8 (4.2)	12.2 (4.2)
gender (% female)	42.1%	42.3%	48.4%
race (%)			
Caucasian	43.6%	47.5%	38.7%
African American	26.4%	25.6%	38.7%
other	30.0%	27.0%	22.6%
dialysis prior to transplant (%)[a]	83.1%	85.3%	90.3%
median dialysis time (years) (IQR)	1.5 (0.7 to 2.8)	1.6 (0.6 to 3.0)	2.3 (1.5 to 5.3)
insurance (% public)[a]	66.0%	63.6%	48.4%
previous transplant (%)	14.2%	15.3%	25.8%
hospitalized at time of transplant (%)[a]	2.6%	3.0%	0.0%
peak PRA[b]			
0 to 20%	83.7%	80.7%	77.4%
20 to 80%	11.0%	10.4%	12.9%
80 to 100%	5.3%	8.9%	9.7%
diagnosis (%)[b]			
inherited/congenital[c]	45.7%	44.5%	38.7%
acquired/glomerular[d]	42.8%	46.0%	54.8%
unknown/other	11.5%	9.5%	6.5%
Donor			
mean age (years) (SD)	24.1 (12.3)	22.2 (10.5)	26.1 (13.5)
age ≤35 years (%)	82.3%	89.1%	77.4%
mean terminal creatinine (mg/dl) (SD)[a]	1.0 (1.1)	0.9 (0.4)	1.0 (0.4)
race (%)			
Caucasian	63.1%	76.6%	80.6%
African American	15.1%	8.8%	12.9%
other	21.8%	14.6%	6.5%
history of hypertension (%)	5.5%	3.6%	6.5%
cause of death (%)			
head trauma	60.9%	51.0%	61.3%
stroke	23.7%	12.4%	9.7%
anoxia	13.2%	35.0%	25.8%
Transplant			
CIT (hours)[e]	16.3 (8.6)	17.5 (6.6)	17.4 (7.1)
WIT (minutes)	n/a	16.0 (11.8)	17.4 (18.5)
HLA mismatch (%)[a]			
0	4.7%	1.5%	3.2%
1 to 3	19.4%	16.8%	19.4%
4 to 6	76.0%	81.8%	77.4%
critical or medically urgent status (%)[a]	3.0%	1.5%	0.0%

DBD, donation after brain death; DCD, donation after cardiac death; CIT, cold ischemia time; WIT, warm ischemia time; IQR, interquartile range; PRA, panel reactive antibody.
[a]Records missing in <1% of records.
[b]Records missing in <2% of records.
[c]Includes (five most common) aplasia/hypoplasia/dysplasia of kidneys, congenital obstructive uropathy, chronic pyelonephritis, polycystic kidney disease, Alport's syndrome, and others.
[d]Includes (five most common) focal segmental glomerulosclerosis, chronic glomerulonephritis, acquired obstructive uropathy, hemolytic uremic syndrome, systemic lupus erythematosus, and others.
[e]Records missing in 12.1% of records.

eral. All of the DCD transplants in pediatric recipients in the United States were performed at only 63 centers (approximately 28% of pediatric kidney transplant centers) (Figure 1C). Recipients at centers that did perform DCD transplants waited similar times for their deceased-donor transplant compared with recipients at centers that did not perform DCD transplants (median 197 days *versus* 192 days; $P = 0.3$). In addition, no statistically significant difference in waiting time was found between the DCD and DBD recipients at the 63 centers that performed DCD transplants (median 174 days *versus* 197 days; $P = 0.1$).

Table 2. Outcomes of pediatric deceased-donor kidney transplants stratified by donor type

Outcomes	DBD (n = 6059)	DCD (n = 137)	P
Delayed graft function (%)[a]	12.3%	22.0%	0.001
Primary nonfunction (%)[b]	4.9%	4.4%	0.80
Rejection within 1 year (%)[c]	22.6%	19.8%	0.50
Patient survival			0.20
2 years	97.7%	94.2%	
4 years	95.7%	94.2%	
6 years	93.3%	86.9%	
8 years	90.5%	86.9%	
10 years	86.5%	78.2%	
Death-censored graft survival			[d]
2 years	86.7%	88.5%	
4 years	74.8%	74.0%	
6 years	64.6%	51.2%	
8 years	55.5%	37.3%	
10 years	48.7%	29.8%	

DBD, donation after brain death; DCD, donation after cardiac death.
[a]Records missing in 1.1% of records.
[b]Records missing in 5.2% of records.
[c]Records missing in 9.5% of records.
[d]Allowing different hazard ratios for the periods before and after 4 years postoperatively, there was no significant difference between DCD and DBD graft survival during the early postoperative period (hazard ratio = 0.92; 95% confidence interval, 0.58 to 1.47; P = 0.7), but a two-fold increase in graft loss was seen among DCD recipients beyond 4 years post-transplant (hazard ratio = 2.03; 95% confidence interval, 1.21 to 3.39; P = 0.007).

DBD transplants performed at centers that performed DCD transplants had decreased graft survival compared with DBD transplants performed at centers that did not perform DCD transplants (univariate HR = 1.17; 95% CI, 1.07 to 1.27; P = 0.001). In addition, a higher percentage of candidates at centers performing DCD transplants died on the waiting list compared with centers that did not perform DCD transplants (3.8% *versus* 2.9%; P = 0.009). In a sensitivity analysis comparing DCD graft survival to DBD graft survival in only those transplant centers that performed DCD transplants, DCD recipients still had an increased risk of graft loss starting 4 years after transplantation (HR = 1.90; 95% CI, 1.12 to 3.20; P = 0.02).

Discussion

This national study of kidney transplantation in pediatric recipients revealed a significant increase in graft loss after 4 years in children receiving DCD kidneys compared with their counterparts who received DBD kidneys. The DCD grafts in this study by all accounts appeared to have been of high quality, predominantly having short warm ischemia time and coming from younger donors. This finding was unexpected because late graft loss in DCD kidney transplants has not been described in adult recipients (5–12), nor was it identified in a previous analysis of pediatric recipients (15). Our ability to detect this difference is likely due to a substantial increase in power (from 26 DCD recipients in the previously largest study to 137 DCD recipients in this study) and follow-up time.

This finding is particularly important given the dramatic (nearly 10-fold) increase in use of DCD kidneys for pediatric recipients over the last 10 years. Interestingly, this increase has occurred despite (and since) the implementation of Share-35 in 2005, which decreased pediatric candidates' waiting times for deceased-donor kidneys (20,21). Furthermore, the use of DCD grafts was not associated with shorter waiting times, neither in DCD recipients compared with DBD recipients nor in centers that performed DCD transplants compared with those that did not.

The DCD transplants in this study were performed within a relatively small number (28%) of all pediatric kidney transplant centers. Compared with centers that did not perform DCD transplants, these centers had decreased graft survival within DBD recipients and also a higher death rate among their candidates awaiting transplant. Although the clinical relevance of this small difference (approximately 1%) in death rate is unclear, these poorer

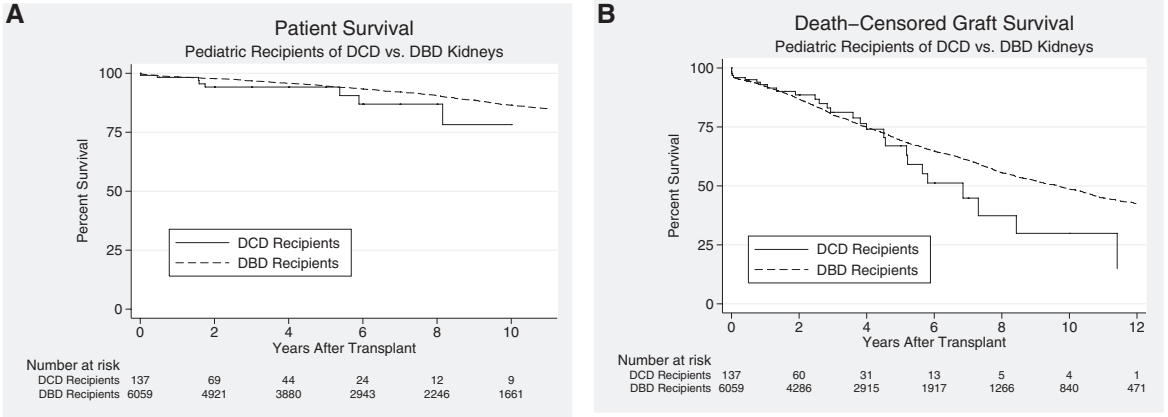

Figure 2. | Patient survival (A) and death-censored graft survival (B) in pediatric deceased-donor kidney transplant recipients stratified by donor type. DCD, donors after cardiac death; DBD, donors after brain death.

outcomes may indicate that centers performing DCD transplants have a generally more ill, higher-risk patient population. These center-level differences also highlight the importance of the sensitivity analysis comparing DCD and DBD graft survival in only those centers that performed DCD transplants, which still showed increased graft loss among DCD recipients.

Not unexpectedly, this study showed that DCD grafts experienced a significantly higher rate of DGF compared with DBD grafts. However, only 22.0% of DCD grafts in this study had DGF, a much lower rate than that reported for DCD grafts in adults (varying by study but approximately 50%). DGF has historically been closely associated with graft loss, although several recent studies have shown that the association between DGF and decreased donor graft loss may not hold true among DCD grafts in the same way that is seen among DBD grafts (6,22,23). Because of our relatively small sample size, this study lacked the power to specifically examine the effect of DGF on eventual graft failure among the DCD grafts.

Several factors may explain the increase in graft loss seen among DCD grafts examined in this study. First, DCD grafts may provide pediatric recipients with adequate nephron mass when they are smaller but may eventually become unable to meet the filtration needs of the children as they grow. Second, DCD grafts may be especially susceptible to medication noncompliance, which is known to occur commonly in adolescence (24). Indeed, both DCD and DBD recipients most frequently lost their graft during the adolescent period, with a mean age at graft loss of 16.7 years for DCD recipients and 16.4 years for DBD recipients. Similarly, inability to pay for immunosuppression may result when patients' 3-year coverage for immunosuppression ends. Theoretically this difficulty would be greatest for patients who are no longer under their parents' health insurance plans at the end of this 3-year window. However, in this study a similar percentage of DCD and DBD recipients were over age 18 (and likely off their parents' insurance) when the 3-year immunosuppression coverage ended.

Third, the difference in late graft survival between DCD and DBD recipients could also have been due to effect modification by the time period in which the transplants were performed. In other words, it is possible that early DCD recipients (for whom we have the longest follow-up time) had not only worse outcomes than the more recent DCD recipients but also, more importantly, worse outcomes *versus* early DBD recipients compared with outcomes in recent DCD recipients *versus* recent DBD recipients. However, this is somewhat unlikely given that a sensitivity analysis of only kidney transplants performed after the year 2000 showed exactly the same inferences, and our matched-controls analysis also included year of transplant. That said, additional follow-up (several years from now) of the most recent DCD transplants will best answer this question.

Finally, confounding by indication (treatment selection bias) could also explain the difference in late graft survival between DCD and DBD recipients. In other words, providers may limit the use of DCD grafts to sicker children who would then later manifest worse outcomes, and it is possible that the factors involved in this bias were not captured in SRTR data and thus not accounted for in this study. However, several observations argue against this potential bias. First, the groups had no significant difference in patient survival, yet if the groups were truly different in terms of medical urgency, one would expect to see this difference. Second, both groups were predominantly outpatients before their transplants, with very few children in either group sick enough to require hospitalization. Third, a similar percentage of patients in each group underwent preemptive kidney transplantation. Finally, a similarly low percentage of patients in each group was listed with a critical or medically urgent status at the time of their kidney transplant. Along the same lines, DCD grafts could also have been placed primarily in highly sensitized children who had had previous transplants. However, no statistically significant differences were seen between the DCD and DBD groups in peak PRA or in the percentage of patients having a repeat transplant, and both of these variables were also included in the multivariate and matched-controls analyses. Latent (unmeasured) factors still could have played a role in DCD *versus* DBD selection and thus led to biased inferences, but by all measures available to this study, the recipients in the DCD and DBD groups appeared remarkably similar.

As with all analyses of large databases, this study has some inherent limitations. The quality of the data and the conclusions on the basis of these data depend upon the accuracy of the information provided to the SRTR. Research using the SRTR database is also inherently limited by data missing from the registry. However, we chose only the most reliable and least missing variables for our models, such that only 54 of the 6196 cases had any missing data in the regression model covariates (five DCD cases and 49 DBD cases). Similarly, only two DCD recipients were excluded from the matched-controls analysis because of missing data. Finally, a multivariate model comparing a small subgroup (DCD recipients) to a large subgroup (DBD recipients) has inherent instability. This limitation was overcome by performing a matched-controls analysis that led to the same inference. In addition, among the smaller subgroup of 137 DCD recipients, only 31 remained in follow-up beyond the 4-year time point at which the difference in graft survival appeared, which could bias inferences if these 31 patients were significantly different from the larger DCD recipient population. However, few statistically significant differences in these 31 patients were identified, and any baseline differences would likely be accounted for in the multivariate Cox model and matched-controls analysis.

Despite these limitations, this analysis has several important strengths. First, the sample of 137 DCD recipients, although small compared with the sample of DBD recipients, is over five times larger than the sample of the only (to our knowledge) previous analysis on this topic. Second, this study provides a total of over 15 years of follow-up, and although only 31 DCD recipients remained in follow-up beyond the 4-year mark, even this number exceeds the entire sample of the largest prior study (26 patients). Third, compared with previous literature, our increased sample size and longer follow-up have led to a different

inference that directly impacts clinical practice. The use of DCD grafts in children is increasing exponentially, and yet the national experience using DCD kidneys in pediatric recipients suggests inferior outcomes.

In conclusion, this study suggests that in pediatric recipients, unlike adult recipients and unlike previous reports in pediatric recipients, DCD kidneys experience a statistically significant increase in graft loss compared with DBD kidneys starting 4 years after transplantation. The national experience with the use of DCD kidneys in the pediatric population is still relatively limited, but this practice has been significantly increasing over the last several years. On the basis of the data available at this time, DCD grafts do not appear to provide equivalent long-term graft survival in pediatric recipients. Although the reasons for this difference in graft survival are not yet clear, this finding motivates (or, depending on the transplant center, confirms) a cautious approach to the use of DCD kidneys in children at this time.

Acknowledgments

This research was presented in preliminary form as an oral abstract at the 2011 American Society of Transplant Surgeons State of the Art Winter Symposium and the 2011 American Transplant Congress. The data reported here have been supplied by the Minneapolis Medical Research Foundation as the contractor for the SRTR. The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy of or interpretation by the SRTR or the U.S. government.

This publication was made possible by Grant Number 5KL2RR025006 from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH), and the NIH Roadmap for Medical Research. Its contents are solely the responsibility of the authors and do not necessarily represent the official view of the NCRR or NIH. Information on NCRR is available at http://www.ncrr.nih.gov/. Information on Reengineering the Clinical Research Enterprise can be obtained from http://nihroadmap.nih.gov.

Disclosures

None.

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Received: April 20, 2011 **Accepted:** August 22, 2011

Published online ahead of print. Publication date available at www.cjasn.org.