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The “oldest and coldest” shipped living donor kidneys transplanted through kidney paired donation

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Abstract

To date, thousands of living donor kidneys have been shipped through kidney paired donation (KPD). To expand on this growing segment of living donor transplantation, we evaluated the effect of advanced age donation (“oldest kidneys”) and prolonged cold ischemia time (“coldest kidneys”) on graft function and survival using the National Kidney Registry database from February 2008 to May 2018. Donors were stratified by age at time of donation (<65 or ≥65 years) and kidneys were stratified by cold ischemia time (<16 or ≥16 hours). We evaluated delayed graft function and death-censored graft failure for up to seven post-transplant years. Of the 2,363 shipped living donor kidney transplants, 4.1% of donors were ≥65 years and 6.0% of transplanted kidneys had cold ischemia times ≥16 hours. Delayed graft function and death-censored graft failure occurred in 5.2% and 4.7% of cases. There were no significant associations between delayed graft function and donor age ($p=0.947$) or cold ischemia ($p=0.532$). Donor age and cold ischemia time were not predictive of delayed graft function ($OR=0.86, 1.20$; $p=0.8, 0.6$) or death-censored graft failure ($HR=1.38, 0.35$, $p=0.5, 0.1$). These findings may alleviate concerns surrounding the utilization of kidneys from older donors or those originating from distant transplant centers.

INTRODUCTION

2018 marked a year of record growth in living kidney transplantation and kidney paired donation (KPD) constituted its largest growing segment¹. As organ availability remains the

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rate-limiting factor preventing life-saving transplantation for many patients on the waiting list, national efforts have been made to expand the donor pool². Though historically used with reluctance, kidneys from advanced age donors and those with extended cold ischemia time (CIT) may be viable solutions to increase the living donor pool for highly sensitized patients participating in KPD.

In the setting of an aging population, an increasing proportion of older adult donors may be viable organ donors. The Organ Procurement and Transplantation Network (OPTN) reports that in the past decade, there has been a 3.5 fold increase in living kidney donation from older adult donors (65 years of age or older)¹. Despite this, the acceptability of older adult living donors remains controversial due to the association with delayed graft function (DGF)^{3,4}, and concerns about post-operative kidney function in advanced age donors. More recent studies suggest that mortality in recipients receiving older living donor kidneys is not higher than age-matched controls⁵ and improved human leukocyte antigen (HLA)-matching may offset short-term disadvantages of advanced age donation⁶.

Similar to the trend in donor age, the advent of KPD chains of living donor pairs has made the transcontinental transportation of kidneys feasible, pushing the boundaries for acceptable prolonged CIT⁷. Historically, the effect of CIT on graft function and survival has been a topic of discussion since the 1960s. While earlier studies suggest that shorter CIT is associated with a lower incidence of acute rejection and allograft failure in living donor recipients⁴, contemporary studies demonstrate that living donor kidneys can be safely shipped over long distances and transplanted with prolonged CIT^{3,8}, allowing for more optimized utilization of this valuable resource and obviating the need for donors to travel to recipient centers. Furthermore, DGF induced by prolonged CIT may have limited bearing on long-term outcomes⁹. Though performed using deceased donation kidneys, Ota and colleagues demonstrated that even with an average CIT ranging between 42–65 hours, overall graft survival 10 years after transplantation exceeded 70%¹⁰.

By reviewing the National Kidney Registry database we sought to evaluate renal allograft efficacy in KPD recipients of the very oldest of living donor kidneys, and living donor allografts that spent extended time on ice being shipped across the United States.

MATERIALS AND METHODS

The National Kidney Registry

This study used data from the National Kidney Registry (NKR), which is a nonprofit, 501(c) organization that facilitates KPDs for members of its clinical network¹¹. The NKR network currently is comprised of 85 transplant centers within the US. The core functions of the NKR are to facilitate the allocation of compatible kidney transplants across networked transplant centers and ensure that transplant programs follow prescribed OPTN protocols for the evaluation, consent, and follow-up for living donation. Participating transplant centers perform transplants in concordance with NKR and center-specific protocols. The NKR registry receives quarterly updates from participating transplant centers. The clinical and research activities of this study are consistent with the Declaration of Helsinki and Declaration of Istanbul.

National Registry Data Source

This study also used data from the Scientific Registry of Transplant Recipients (SRTR) external release made available in December 2018. The SRTR data system includes data on all donors, waitlist candidates, and transplant recipients in the US, submitted by members of the Organ Procurement and Transplantation Network (OPTN), and has been previously described (9). The Health Resources and Services Administration, U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors.

Patient selection, variable classifications, and parameters evaluated

Living donor kidney transplantations facilitated through KPD occurring from February 2008 to May 2018 were extracted from the NKR for inclusion in this study. Aliases were assigned to both donors and recipients to ensure patient confidentiality. Demographic, socioeconomic, and clinical data for both donors and recipients were collected. Specific information pertaining to the transplantation event, including CIT were cross validated by linking NKR reported data to Scientific Registry of Transplant Recipients (SRTR). We defined shipped kidneys as those that were transplanted at a different transplant center than the donor nephrectomy. Living donors were classified by age into a control group of younger than 65 years and an older adult cohort aged 65 years or older. A cut off of 65 years was chosen as the age that defines access to Medicare in the United States. Renal allografts were similarly divided into two cohorts of either less than or greater than 16 hours of CIT. Previous studies have suggested that the upper limit of permissible CIT is eight hours^{4,12}. Living donor kidneys with CIT less than 8 hours have historically been thought to have a lower incidence of acute rejection, with no impact on long-term outcomes, including allograft survival⁴. We selected our cutoff of 16 hours by doubling the standard CIT limit, in order to maximize our ability to evaluate the effect of prolonged CIT. To ensure that the 16-hour cutoff would not cause CIT to fail as a significant variable, we also evaluated the prevalence of DGF and death-censored graft failure (DCGF) at < 4 hours, 4 to < 8 hours, 8 to < 12 hours, 12 to < 16 hours and found no significant differences (Supplemental Figure 1). The associations of donor age and CIT with the incidence of DGF and DCGF up to seven post-transplant years were evaluated. DGF was ascertained from transplant center reports and SRTR, and defined as the need for dialysis within the first post-operative week following transplantation regardless of urine output. We defined DCGF as the resumption of maintenance dialysis, relisting for kidney transplantation, or re-transplantation, and was ascertained from transplant center reports, SRTR and CMS (Form 2728).

Statistical analysis

Donor, recipient and transplant characteristics, including donor and recipient age, donor and recipient gender, donor and recipient race, CIT, HLA matching, and ABO compatibility, were summarized for the entire cohort and by the categories of donor age and CIT. Incidence of DGF and DCGF were compared across donor age and CIT using Chi-square tests. For multivariate analyses, logistic regression was completed for DGF and a Cox regression for DCGF with time of follow-up calculated as years from transplant to graft failure for those that failed or to time of last follow-up, which included those that died from non-transplant

related causes. For both outcomes, donor age and CIT was included in the model and any other covariate significant at $p \leq 0.05$ from a forward selection process. Covariates entered into each model were those with $p \leq 0.20$ on univariate analysis for the respective outcome. Adjusted odds ratios (OR) for donor age and CIT for DGF are reported, and adjusted hazard ratios (HR) for DCGF. Only transplantations with a minimum of one year recorded follow-up were included for survival analysis. All statistical analyses were conducted in SAS 9.4 (Cary, NC), with $p \leq 0.05$ considered statistically significant.

RESULTS

From 2008 to 2018 2,363 living donor kidney transplants were identified in the NKR database and evaluated. Donor and recipient demographic, socioeconomic, and clinical data as well as transplant characteristics stratified by donor age and CIT is provided in Table 1. 4.1% (98) of donors were 65 years or older, with a maximum donor age of 74 years. 6.0% (141) of transplanted allografts had CIT ≥ 16 hours, with a maximum CIT of 47 hours. 24.9% (588) of recipients had received a previous kidney transplantation. 25.0% (591) of transplant events were pre-emptive. 85.6% (2,023/2,363) of living donor kidneys were shipped to different centers for transplantation.

Overall, DGF occurred in 5.2% (124/2,363) of cases (Figure 1). There were no significant differences in the incidence of DGF by donor age ≥ 65 ($p=0.947$) or CIT ≥ 16 hours ($p=0.532$). For multivariate analysis, donor race, recipient gender, race/ethnicity, body mass index (BMI), college education, insured status, diabetes, hypertension, pre-emptive transplantation, and years on dialysis were identified to enter the forward selection model based on $p \leq 0.20$. The final multivariate regression model, adjusting for the significant recipient factors (e.g. race, body mass index, education, insurance, pre-emptive transplant status, and years on dialysis) resulted in no statistically significant difference in incidence of DGF by donor age (OR=0.86, $p=0.756$) or CIT (OR=1.20, $p=0.620$) (Table 2). Increased risk of DGF was associated with African-American recipient race (OR=2.53, $p<0.001$), high recipient BMI, and insured status of the recipient (Table 2). Those transplantations which were not pre-emptive carried a 2.56-fold increased odds of DGF ($p=0.007$).

Overall incidence of DCGF was 4.74% (112). Similar to DGF, there was no statistically significant increase in the probability of DCGF with prolonged CIT ($p=0.217$) or older adult donor age ($p=0.536$) (data not shown). For multivariate analysis, donor BMI, donor estimated glomerular filtration rate (eGFR), recipient college education, insured status, previous transplant and recipient zero HLA mismatch were identified with $p \leq 0.20$ to test in the multivariate model. Final multivariate analysis identified recipient college education alone as significantly associated with DCGF (HR=1.65, $p=0.012$). There were no statistically significant associations between DCGF and advanced donor age (HR=1.376, $p=0.487$) or prolonged CIT (HR=0.353, $p=0.144$) (Table 2). Of note, there were nine transplants with advanced age donors and prolonged CIT. There were zero episodes of DGF or DCGF in this subset of recipients.

To evaluate the effects of sensitization on incidence of DGF and DCGF, we evaluated patients with panel reactive antibody > 80 (sensitized) and ≤ 80 (unsensitized). 14 patients

were missing sensitization data. 21.2 (497/2,349) patients were sensitized (panel reactive antibody [PRA] > 80). 78.8% (1,852/2,349) patients had PRA ≤ 80. Sensitized patients did not have an increased risk of DGF (p=0.966) or DCGF (p=0.902).

Further, we evaluated the three transplantations with the oldest living donors (Supplemental Table 1) and the three kidneys with the longest CIT (Supplemental Table 2). These transplantations did not overlap and constituted six unique transplant cases. Individuals aged 72, 73, and 74 years old donated at separate centers. CIT was <16 hours for each of these three cases. While DGF occurred in one of these cases, there were no episodes of DCGF amongst these oldest of donated kidneys. There was one recipient mortality that occurred secondary to unrelated causes. None of these cases were pre-emptive transplants and all three recipients were white. Similarly, we evaluated the “coldest” allografts, with cold ischemia times of 41, 47, and 39 hours, respectively. There were no DGF, DCGF, or mortality events for any of these recipients. One of these transplants was pre-emptive.

DISCUSSION

There is a substantial need to increase the supply of donated kidneys and to increase kidney life-years in transplanted allografts. Many transplant centers are reluctant to utilize living donor kidneys from older adult donors and allografts with prolonged CIT for fear of DGF, acute rejection, increased length of hospital stay and cost, and poorer long-term outcomes. However, long-term studies have not demonstrated an additional mortality risk for living kidney transplantation as donor age increases^{5,13}. A considerable body of work suggests that age^{6,14,15} and prolonged CIT¹⁶ do not portend poorer long-term living graft function or survival. These findings are unique to living donor allografts, and studies have found that the oldest living donor allografts have survival rates similar to or better than any deceased donor allografts, even in the setting of poor HLA matching^{6,14,17}.

In the nine transplants that had both advanced age donors and prolonged CIT, there were no episodes of DGF or DCGF. Interestingly, the oldest donor kidney of 74 years and the coldest kidney with nearly two days (47 hours) of cold ischemia did not demonstrate DGF or DCGF. Though studies have suggested the increasing importance of HLA matching as a predictor of graft function and survivability¹⁸, HLA mismatches were not significantly associated with DGF or DCGF in this study. Perfect HLA matching was rare, occurring in only 0.8% (18/2363) of cases.

Our study evaluated the extremes of donor age and CIT on DGF and DCGF across all living donor transplants in the NKR database. Interestingly, we found no statistically significant incidence of DGF or DCGF in kidneys from older adult donors, defined as ≥ 65 years of age, or with CIT ≥ 16 hours. This phenomenon may partially be explained by the selective nature of transplant programs to approve only the healthiest of older adult patients as candidates for donation. However, our analysis did not demonstrate a considerable difference in co-morbidities between control cohorts of younger donors or allografts with shorter CIT. All living kidney donors, especially those of advanced age, should undergo thorough pre-operative evaluation to minimize the risks of post-surgical complications.

Living donations have traditionally been thought to benefit white recipients to a great majority. In our study, while white recipients continued to represent the highest proportion of living donor recipients, ethnic minorities comprised of African-Americans, Latinos, and Asians, constituted 37% of recipients. This represents an improvement from previous reports, which cite socioeconomic and racial factors as major impediments to receiving living donor allografts^{19,20}. Interestingly, in our multivariable analysis, lack of recipient college education was independently associated with of DCGF (HR 1.65). Though this may be an incidental finding, it is possible that lower educational status may lead to poorer post-operative care from a variety of reasons, including access to care, poorer understanding of the disease process, or medication non-compliance, although without further evaluations, these statements are purely speculative.

Limitations of the present study included the use of only one national database, the NKR. Future studies will be designed to multi-faceted datasets, with larger sample sizes in order to evaluate trends between immediate and long-term graft survival and graft survival as a function of living donor age, CIT, or HLA matching between donor and recipient. Granular details regarding the use of machine perfusion technology or transplant laterality were not included in this study. Despite the use of one database, our study of over 2,000 shipped living donor kidney transplants represents the largest study to date investigating the effects of living donor age and CIT on DGF and allograft outcomes. The etiology of prolonged length of CIT may be due to shipping and transportation. However, we cannot conclude that shipping distances and time in transit are the only variables affecting CIT. Indeed, confounding variables, such as operating room or surgeon availability and recipient health concerns can affect the length of cold ischemia. The etiology of CIT is beyond the scope of this study.

A reluctance amongst transplant centers to use advanced age or extended ischemia time kidneys may be restricting the living donor pool and limiting the availability of quality organs particularly for highly sensitized candidates awaiting transplantation through KPD. We are hopeful that these findings will help alleviate concerns that some transplant centers have in accepting an 'older' or 'colder' allograft from an outside center, and that national programs within countries such as Canada, the Netherlands, and South Korea will reconsider shipping kidneys to improve donor convenience and remove the disincentives of donor travel to the recipient hospital when participating in KPD.

CONCLUSIONS

Our findings of over 2,000 shipped living donor kidneys suggest that advanced donor age (> 65 years) and extended ischemia time (> 16 hours) are not associated with increased delayed graft function or death-censored graft failure. Pre-emptive transplant status was protective against delayed graft function, but not death-censored graft failure. We hope that these findings may decrease the reluctance amongst some transplant centers in accepting an 'older' or 'colder' allograft for their highly sensitized candidates participating in KPD.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

KPD	kidney paired donation
CIT	cold ischemia time
OPTN	Organ Procurement and Transplantation Network
DGF	delayed graft function
HLA	human leukocyte antigen
DCGF	death-censored graft failure
NKR	National Kidney Registry
SRTR	Scientific Registry of Transplant Recipients
OR	odds ratio
HR	hazard ratio
PRA	panel reactive antibody
(e)GFR	(estimated) glomerular filtration rate
BMI	body mass index

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Figure 1:
Unadjusted prevalence of delayed graft function (DGF) as a function of cold ischemia time (CIT) and advanced donor age.

Figure 2:
Probability of death-censored graft failure (DCGF) by donor age and cold ischemia time (CIT) (Cox regression model after adjusting for recipient education).

Table 1:

Recipient, donor and transplant-specific characteristics.

	Donor Age				CIT	
	N=2363 % (n)	<65 n=2265 % (n)	65 n=98 % (n)	<16 n=2222 % (n)	16 n=141 % (n)	
DONOR CHARACTERISTICS						
AGE						
Median (IQR)	45.0 (35.0–53.0)	44.0 (35.0–52.0)	67.0 (66.0–69.0)	45.0 (35.0–53.0)	43.0 (35.0–53.0)	
Range	18.0–74.0	18.0–64.0	65.0–74.0	18.0–74.0	21.0–70.0	
<65	95.9 (2265)	-	-	96.0 (2133)	93.6 (132)	
65	4.1 (98)	-	-	4.0 (89)	6.4 (9)	
GENDER						
Female	62.2 (1470)	62.4 (1413)	58.2 (57)	62.2 (1381)	63.1 (89)	
Male	37.8 (893)	37.6 (852)	41.8 (41)	37.8 (841)	36.9 (52)	
RACE/ETHNICITY						
White	72.1 (1704)	71.5 (1619)	86.7 (85)	72.4 (1609)	67.4 (95)	
Hispanic or Latino	10.4 (245)	10.5 (237)	8.2 (8)	10.1 (225)	14.2 (20)	
African-American	10.0 (237)	10.3 (234)	3.1 (3)	10.0 (223)	9.9 (14)	
Asian/Pacific Islander	3.7 (87)	3.8 (85)	2.0 (2)	3.6 (80)	5.0 (7)	
Unknown	3.8 (90)	4.0 (90)	0 (0)	3.8 (85)	3.5 (5)	
BMI						
Median (IQR)	26.2 (23.3–28.9)	26.2 (23.3–28.9)	25.9 (23.0–28.3)	26.2 (23.3–29.0)	25.9 (22.8–28.0)	
Underweight	1.1 (25)	1.1 (25)	0 (0)	1.1 (25)	0 (0)	
Normal	36.6 (864)	36.5 (826)	38.8 (38)	36.1 (803)	43.3 (61)	
Overweight	41.9 (989)	41.7 (944)	45.9 (45)	41.6 (925)	45.4 (64)	
Obese	18.5 (437)	18.8 (425)	12.2 (12)	19.1 (425)	8.5 (12)	
Unknown	2.0 (48)	2.0 (45)	3.1 (3)	2.0 (44)	2.8 (4)	
CLINICAL						
eGFR (mL/min) Median (IQR)	97.6 (85.5–109)	98.5 (86.2–110)	82.6 (76.2–89.4)	97.6 (85.3–109)	99.0 (87.6–111)	
RECIPIENT CHARACTERISTICS						
AGE						
Median (IQR)	51.0 (39.0–60.0)	50.0 (38.0–59.0)	64.0 (55.0–68.0)	51.0 (39.0–60.0)	49.0 (40.0–59.0)	

	CIT			
	Donor Age		CIT	
	N=2363 % (n)	<65 n=2265 % (n)	65 n=98 % (n)	<16 n=2222 % (n)
Range	1.0–83.0	1.0–83.0	13.0–79.0	1.0–83.0
<65	85.7 (2024)	86.9 (1969)	56.1 (55)	85.6 (1901)
65	14.3 (339)	13.1 (296)	43.9 (43)	14.4 (321)
GENDER				
Female	46.3 (1094)	46.2 (1047)	48.0 (47)	46.0 (1022)
Male	53.7 (1269)	53.8 (1218)	52.0 (51)	54.0 (1200)
RACE/ETHNICITY				
White	58.8 (1390)	58.7 (1330)	61.2 (60)	58.9 (1309)
Hispanic or Latino	12.4 (294)	12.6 (285)	9.2 (9)	12.4 (275)
African-American	18.2 (430)	18.3 (414)	16.3 (16)	18.0 (400)
Asian/Pacific Islander	6.4 (152)	6.5 (147)	5.1 (5)	6.6 (146)
Unknown	4.1 (97)	3.9 (89)	8.2 (8)	4.1 (92)
BMI				
Median (IQR)	26.5 (23.2–30.9)	26.5 (23.1–30.9)	26.9 (23.9–31.1)	26.5 (23.2–30.8)
Underweight	2.5 (58)	2.5 (57)	1.0 (1)	2.5 (55)
Normal	33.9 (800)	33.9 (768)	32.7 (32)	33.7 (749)
Overweight	31.0 (733)	31.0 (702)	31.6 (31)	31.3 (696)
Obese	29.6 (699)	29.4 (666)	33.7 (33)	29.5 (655)
Unknown	3.1 (73)	3.2 (72)	1.0 (1)	3.0 (67)
GENERAL				
College Education	61.6 (1455)	61.8 (1399)	57.1 (56)	61.7 (1370)
Public Insurance	49.6 (1172)	48.9 (1108)	65.3 (64)	49.3 (1096)
CLINICAL				
Antibody Depleting Induction	64.1 (1515)	64.7 (1465)	51.0 (50)	64.2 (1427)
Antibody Non-Depleting Induction	28.9 (684)	28.5 (646)	38.8 (38)	29.2 (648)
Diabetes	18.8 (444)	18.2 (412)	32.7 (32)	18.8 (418)
Hypertension	15.8 (373)	15.8 (358)	15.3 (15)	15.9 (354)
Nadir Creatinine (mg/dL)	1.1 (0.9–1.3)	1.1 (0.9–1.3)	1.3 (1.0–1.5)	1.1 (0.9–1.3)
Transplant Median (IQR)				
PRA>80%	21.0 (497)	21.3 (482)	15.3 (15)	20.8 (462)
				24.8 (35)

	Donor Age				CIT	
	N=2363	<65 n=2265	65 n=98	>16 n=2222	<16 n=141	% (n)
Pre-emptive Transplant	25.0 (591)	25.3 (573)	18.4 (18)	25.1 (557)	24.1 (34)	
Previous Transplant	24.9 (588)	25.4 (576)	12.2 (12)	24.4 (543)	31.9 (45)	
Years on Dialysis Median (IQR)	1.3 (0.0–2.9)	1.3 (0.0–2.9)	1.6 (0.3–3.1)	1.3 (0.0–2.9)	1.3 (0.1–3.0)	
TRANSPLANT CHARACTERISTICS						
CIT (hrs)						
Median (IQR)	8.8 (5.5–12.0)	8.9 (5.6–12.0)	7.2 (2.1–12.0)	8.5 (5.0–11.0)	17.2 (16.4–19.0)	
Range	0.1–47.0	0.1–47.0	0.4–21.7	0.1–15.9	16.0–47.0	
<16	94.0 (2222)	94.2 (2133)	90.8 (89)	-	-	
16	6.0 (141)	5.8 (132)	9.2 (9)	-	-	
CLINICAL						
ABO incompatible	2.0 (48)	2.1 (47)	1.0 (1)	2.0 (45)	2.1 (3)	
Zero HLA mismatch	0.8 (18)	0.8 (17)	1.0 (1)	0.8 (17)	0.7 (1)	

Table 2:
Adjusted multivariable analysis for the incidence of delayed graft function (DGF) and death-censored graft failure (DCGF).

	DGF			DCGF		
	Odds Ratio	95% CI	P	Hazard Ratio	95% CI	P
Donor Age (<65 years old [*])			0.7562			0.4871
65 years old	0.859	0.328–2.246		1.376	0.559–3.384	
CIT (<16hrs [*])			0.6206			0.1443
16hrs	1.199	0.585–2.457		0.353	0.087–1.429	
Recipient Race (White [*])			0.0002			
Hispanic/Latino	0.971	0.517–1.823				
African-American	2.535	1.664–3.862				
Asian/Pacific Islander	1.402	0.642–3.060				
Unknown	0.840	0.255–2.767				
Recipient BMI (Normal Weight [*])			0.0388			
Underweight	1.752	0.501–6.125				
Overweight	1.900	1.139–3.170				
Obese	2.106	1.270–3.493				
Unknown	2.742	1.060–7.091				
Recipient College Education (Yes [*])						0.0116
No				1.646	1.118–2.423	
Recipient Insurance (No [*])			0.448			
Yes	1.525	1.010–2.305				
Recipient preemptive transplant (Yes [*])			0.0072			
No	2.558	1.290–5.072				
Years on Dialysis	1.069	1.019–1.121	0.0062			

^{*} Referent group