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Association of Dialysis Duration With Outcomes After Kidney Transplantation in the Setting of Long Cold Ischemia Time

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Background. There is no mechanism that matches hard-to-place kidneys with the most appropriate candidate. Thus, unwanted kidney offers are typically to recipients with long renal replacement time (vintage) which is a strong risk factor for mortality and graft failure, and in combination with prolonged cold ischemia time (CIT), may promote interactive effects on outcomes. **Methods.** Consecutive adult isolated kidney transplants between October 2015 and December 2017 were stratified by vintage younger than 1 year and CIT longer than 30 hours. **Results.** Long (n = 169) relative to short (n = 93) vintage recipients were significantly more likely to be younger (32.2 years vs 56.9 years, $P = 0.02$), black race (40.8% vs 18.3%, $P = 0.02$), have higher estimated posttransplant survival (52.6 vs 42.0, $P = 0.04$), and have a comorbid condition (45.6% vs 30.1%, $P = 0.02$); they were less likely to receive a donation after circulatory death kidney (27.8% vs 39.8%, $P = 0.05$). Long vintage was significantly associated with length of stay longer than 4 days (45.5% vs 30.1%, $P = 0.02$), and 30-day readmission (37.3% vs 22.6%, $P = 0.02$) but not additional operations (17.8% vs 15.1%, $P = 0.58$), short-term patient mortality (3.0% vs 2.2%, $P = 0.70$), or overall graft survival ($P = 0.23$). On multivariate logistic regression, long vintage remained an independent risk factor for 30-day readmission (adjusted odds ratio, 1.92; 95% confidence interval, 1.06-3.47); however, there was no interaction of vintage and CIT for this outcome ($P = 0.84$). **Conclusions.** Readmission is significantly associated with pretransplant dialysis duration; however, CIT is not a modifying factor for this outcome.

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Increasing utilization of available kidneys is an important means to address the profound gap between kidney need and availability.[1,2] Over 1000 kidneys are rescued from nonuse every year by placing them to centers throughout the United States after being rejected locally[1,3]; however, there is no mechanism in place that matches hard-to-place kidneys with the most appropriate candidate. The majority of hard-to-place kidney offers are to sensitized candidates or those with long dialysis duration.[4] Prioritizing all kidneys, even unwanted ones, to highly sensitized or long-dialyzed patients is expected because these factors strongly influence the rank score to enhance access to transplantation. However, given data suggesting that hard-to-place kidneys have been found to have inferior outcomes,[1,3] long recipient dialysis duration is a strong risk factor for mortality and graft failure,[5-8] and high priority candidates might gain greater benefit by waiting for higher quality kidneys,[9] it is unclear whether the recipient who is at the beginning of the match run specifically due to long dialysis duration is likely to realize a survival advantage from a hard-to-place kidney compared with waiting for a higher quality local offer. Nonmodifiable baseline risk factors may be compounded by using kidneys from nonlocal donor service areas because the attendant long cold ischemic times promote delayed graft function (DGF) which in turn complicates the postoperative course.[10]

Potential benefits of hard-to-place kidneys may be nuanced, especially for candidates at the beginning of match runs due to long dialysis duration. The goal of this study is to examine early posttransplant morbidity among recipients with long (relative to short) dialysis duration and analyze the potential modifying effect of cold ischemia time (CIT).

MATERIALS AND METHODS

A retrospective cohort study of consecutive adult deceased donor kidney-only recipients at Erie County Medical Center (ECMC) between October 2015 and December 2017 was performed. Two hundred sixty-three patients received a deceased donor kidney transplant during this study period. There were no exclusions and all patients were followed for a minimum of 30 days from transplant hospital discharge. Kidney transplants performed in patients with dialysis duration longer than 1 year were compared with those with shorter or no dialysis duration. The 1-year cutoff was chosen to optimize the power of the study and in addition prior studies suggest better patient and/or graft survival with transplantation performed preemptively or within 1 year of starting dialysis.[11,12] There was 1 loss to follow up.

Primary outcomes were (a) index hospitalization length of stay (LOS), (b) at least 1 unplanned readmission within 30 days after discharge from the transplant hospitalization, (c) any subsequent operation related to the transplant (d) estimated glomerular filtration rate (eGFR) at 3, 6, and 12 months calculated using Modification of Diet in Renal Disease study equation. Secondary outcomes were (1) overall patient survival, and (2) overall graft survival (defined as death, re-transplantation, return to chronic dialysis, or allograft nephrectomy). Index hospitalization LOS was calculated from the day of surgery to discharge. Creatinine levels used in eGFR calculations were ascertained as the mean of all values between posttransplant days 76 to 104, 163 to 197, and 330 to 365.

Estimated Posttransplant Survival is calculated based on time on dialysis, current diabetes diagnosis, prior solid organ transplant, and age of the candidate.[13]

Clinical data were obtained from a prospectively maintained transplant database or were collected retrospectively using standardized forms from progress notes, medical administration notes, physician and nutrition notes, and nursing documentation.

Study Environment

The ECMC is a 602-bed tertiary care teaching hospital located in Buffalo, NY. It serves a population with low socioeconomic status and high disease burden (over 50% of hospital admissions have diabetes). Erie County ranks 54th in community health rankings between the 62 counties in NY State.[14] Although ECMC is located within a single-center Organ Procurement Organization, organ availability within the donor service area dropped dramatically following organ allocation changes in December 2014 that mandated increased sharing. This relative reduced access to transplantation from deceased donors was mitigated by liberalized acceptance practices through use of nonmandatory share kidneys. Hence, prolonged CITs are common in our cohort due to inherent delays for organ allocation and transportation.

Immunosuppression consisted of antithymocyte globulin induction along with triple maintenance tacrolimus, mycophenolate mofetil, and corticosteroid taper. Basiliximab was used instead of antithymocyte globulin in patients with a history of cancer. Intraoperative placement of double J ureteral stents was performed per surgeon preference. Posttransplantation, patients were regularly reviewed by the multidisciplinary team on the following morning, daily, and at the planned time of discharge. The entire team was available during normal weekday work hours, but generally not weekends or holidays. Patients were discharged if clinical parameters were within normal limits and they were ambulatory, able to eat, had adequate pain control on oral analgesics, and after receiving adequate home support and education. No preoperative selection criteria were applied to identify those patients who might be suitable for discharge. A set criterion readmission policy was not used; each case was managed by either the surgeon or nephrologist as the clinical scenario dictated.

Statistical Analysis

Recipient, donor, and transplant covariates evaluated are depicted in Table 1. The appropriate functional form of covariates was determined by exploratory data analysis in unadjusted models and perceived impact on clinical meaningfulness. Univariate associations between exposure groups were examined using the χ^2 test or Fisher exact test for categorical variables (summarized as proportions) and Student t test for continuous variables whose distributions approximated normality (summarized as median and interquartile ranges and/or mean and standard deviation). Skewed distributions were compared with the Wilcoxon rank-sum test or dichotomized. Multivariate analyses of binary endpoints were done using logistic regression to estimate adjusted odds ratio (aOR) and 95% confidence intervals (95% CI) for exposure groups after accounting for potential confounders with an alpha less than 0.05 associated with the outcome required for entry into the model. Each model was additionally tested for an interaction between vintage and CIT. A Cox model was used to test for an interaction between vintage and CIT for the outcome of overall graft failure. This model did not include other confounders due to low event rates. Several sensitivity analyses were performed including (1) assessment of primary endpoints after cohort reduction to only recipients receiving nonmandatory share organs, (2) examination of interaction between CIT and vintage on graft survival at higher vintage cutoffs, and (3) examination of donation after circulatory death (DCD) and warm ischemia time on all endpoints. All statistical analyses were conducted using the SAS system version 9.2 (SAS Institute, Inc.). All P values were 2-sided and less than 0.05 was considered statistically significant. The study was approved by the University of Buffalo Institutional Review Board.

RESULTS

Pretransplant dialysis duration was 1 year or longer among 169 recipients (long vintage) and less than 1 year among 93 recipients (short vintage). There was no significant between-group difference in length of follow-up (463 days vs 401 days, respectively, $P = 0.07$). Long vintage recipients were significantly more likely to be younger (32.2 years vs 56.9 years, $P = 0.02$, black race (40.8% vs 18.3%, $P = 0.02$), have a higher estimated posttransplant survival (52.6 vs 42.0, $P = 0.04$), and have at least 1 comorbid condition (45.6% vs 30.1%, $P = 0.02$); they were less likely to receive a DCD kidney (27.8% vs 39.8%, $P = 0.05$). Other between-group demographic, donor, and transplant characteristics were similar (Table 1).

Primary Outcomes

Length of stay was longer by 1 day among long vintage (mean, 5.2; median, 4) compared with short vintage patients

Comparison of patient, donor, and transplant characteristics by pretransplant dialysis duration

Characteristics, n (%) or mean ± SD	Dialysis ≥1 y, n = 169	Dialysis <1 y, n = 93	P
Recipient Age, years	32.2 ± 12.3	56.9 ± 12.2	0.02
Recipient, Male	106 (62.7)	52 (55.9)	0.28
Recipient race, black	69 (40.8)	17 (18.3)	0.02
Recipient body mass index >35 kg/m^2	46 (27.2)	23 (24.7)	0.66
Recipient diabetes mellitus	76 (45.0)	35 (37.6)	0.25
Recipient, Prior Solid Organ Transplant	28 (16.6)	11 (11.8)	0.30
Recipient, EPTS	52.6 ± 29.8	42.0 ± 25.9	0.04
Recipient, ureteral double J stent placement	60 (35.5)	36 (39.1)	0.56
Recipient DR mismatch of 0	19 (11.2)	7 (7.6)	0.64
Recipient DR mismatch of 1	71 (63.4)	41 (36.6)	
Recipient DR mismatch of 2	79 (46.8)	44 (47.8)	
Recipient, antithymocyte globulin induction	135 (97.1)	83 (87.4)	0.83
Recipient comorbid condition, at least one of the characteristics below[a]	77 (45.6)	28 (30.1)	0.02
CAD or CVA	40 (24.1)	10 (10.8)	0.01
	29 (17.5)	4 (4.3)	0.02
Cancer history	23 (14.4)	15 (16.3)	0.66
Recipient, calculated panel reactive antibody level > 0%	58 (41.7)	30 (31.6)	0.12
Recipient, Index Hospitalization PRBC >2 units	15 (10.8)	14 (14.7)	0.39
Donor Age, years	39.0 ± 15.3	39.7 ± 15.3	0.73
KDPI	50.5 ± 25.0	52.0 ± 25.0	0.66
Donation after circulatory death	47 (27.8)	37 (39.8)	0.05
Kidney originated from donor in local donor service area	71 (42.0)	35 (37.3)	0.49
Kidney CIT ≥ 30 h	46 (27.2)	31 (33.3)	0.30

[a]Comorbid condition includes at least one of the following: CAD, abnormal coronary artery angiogram with ischemia identified in the same area by stress myocardial scintigraphy, or a history of myocardial infarction, coronary angioplasty or bypass surgery; CVD, defined as history of cerebrovascular accident, transient ischemic attack, or carotid endarterectomy; PAD, defined as history of lower extremity diabetic ulcer or amputation, arterial bypass surgery or stent, or diagnosis of PAD, or history of cancer confirmed by pathology.

KDPI, Kidney Donor Profile Index; PRBC, packed red blood cell; EPTS, Estimated Posttransplant Survival; CAD, coronary artery disease; PAD, peripheral artery disease.

(mean, 4.7; median, 4) predominantly due to a fewer discharges within 3 days (25.8% vs 44.1%) within the long vintage group. Long vintage was significantly associated with LOS median longer than 4 days (45.5% vs 30.1%, $P = 0.02$), and 30-day readmission (37.3% vs 22.6%, $P = 0.02$) but not additional operations during follow-up (17.8% vs 15.1%, $P = 0.58$) or eGFR (mL/min per 1.73 m^2) at 3 months (57.87 ± 22.11 vs 49.62 ± 17.07, $P = 0.06$), 6 months (57.54 ± 23.08 vs 54.57 ± 22.46, $P = 0.86$), or 12 months (59.06 ± 24.95 vs 54.62 ± 20.79, $P = 0.16$). On multivariate logistic regression, long vintage remained an independent risk factor for 30-day readmission (aOR, 1.92; 95% CI, 1.06-3.47); however, there

was no interaction of vintage and CIT ($P = 0.84$). Long vintage did not correlate significantly with LOS greater than median 4 days (aOR, 1.77; 95% CI, 0.99-3.13) after adjustment for confounders (Tables 2A and B).

Several sensitivity analyses were performed. After reducing the cohort to nonmandatory share (ie hard-to-place) kidneys only. In the reduced cohort, in which the sample size was 66 long vintage and 43 short vintage cases, the magnitude and direction of the association of long dialysis duration remained for LOS longer than 4 days (aOR, 2.42; 95% CI, 0.91-6.44) and 30-day readmission (aOR, 2.50; 95% CI, 0.99-6.35). There was no interactive effects of CIT and vintage on graft

A, B. Multivariate analysis of 30-day readmission and LOS >4 d

	30-day readmission	
A, Characteristics	Univariate, OR (95% CI)	Multivariate,[a] aOR (95% CI)
Long vintage	2.04 (1.14-3.63)	1.92 (1.06-3.47)
Comorbidity	1.83 (1.08-3.09)	1.65 (0.96-2.83)
Index hospitalization PRBC > 2 units	1.43 (1.03-1.98)	1.42 (1.02-1.98)

	LOS > 4 d	
B, Characteristics	Univariate, OR (95% CI)	Multivariate[a] aOR (95% CI)
Long vintage	1.94 (1.13-3.31)	1.77 (0.99-3.13)
Index hospitalization PRBC > 2 units	1.93 (1.38-2.69)	1.87 (1.33-2.65)
Estimated posttransplant survival	1.01 (1.00-1.02)	1.01 (1.00-1.02)
CIT >30 h	0.54 (0.31-0.95)	0.49 (0.26-0.89)

[a]$P = 0.84$ for interaction of vintage with CIT.

Multivariate analysis of variables which met criteria for inclusion in the model.

TABLE 3.

Comparison of patient outcomes by dialysis duration

| Characteristics | Long vintage | Short vintage | |
| | ≥1 y | <1 y | |
N (%) or mean ± SD	N = 169	N = 93	P
LOS ≤3 days (25th percentile)[a]	43 (25.8)	41 (44.1)	0.02
LOS = 4-5 d	49 (29.3)	19 (20.4)	
LOS ≥6 d (75th percentile)	75 (44.9)	33 (35.5)	
30-d readmission to hospital	63 (37.3)	21 (22.6)	0.02
Reoperation	30 (17.8)	14 (15.1)	0.58
eGFR (mL/min per 1.73 m²)[a]			
At 3 mo posttransplantation	57.87 ± 22.11	49.62 ± 17.07	0.06
At 6 mo posttransplantation	57.54 ± 23.08	54.54 ± 22.46	0.86
At 12 mo posttransplantation	59.06 ± 24.95	54.62 ± 20.79	0.16
Overall patient mortality	5 (3.0)	2 (2.2)	0.70
Follow-up posttransplantation	463 ± 279	401 ± 243	0.07

Multivariate analysis of variables which met criteria for inclusion in the model.
[a]Excludes patients with graft failure before the designated time point.

survival at vintage cutoffs at 2 years (n = 103; adjusted hazard ratio [aHR]; 0.88, 95% CI, 0.48-1.063) or 3 years (n = 67; adjusted hazard ratio, 0.84; 95% CI, 0.44-1.59). The terms DCD with WIT less than 30 (n = 54), DCD with warm ischemic time of 30 hours or longer (n = 30) and non-DCD (n = 178) were entered into all full models. There was no significant effect of either level of DCD on 30-day readmission (data), LOS (data), or graft survival (data).

Secondary Outcomes

Long vintage was not significantly associated with overall patient mortality (3.0% vs 2.2%, P = 0.70) or overall graft survival (P = 0.23) (Table 3). On Kaplan-Meier analysis, there were no significant differences between the 4 groups on overall graft survival (short vintage, short ischemic time, short vintage, long ischemic time, long vintage, short ischemic time, and long vintage, long ischemic time) (Figure 1). Cox model analysis showed an absence of effect of long CIT (HR, 1.01, 95% CI, 0.66-1.53), vintage longer than 1 year (HR, 0.95;
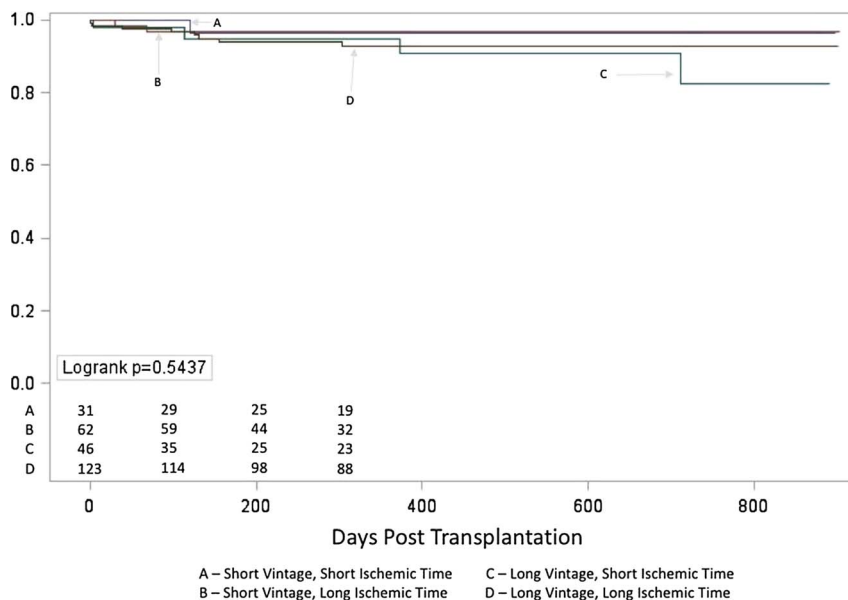
95% CI, 0.60-1.49) or the interaction of CIT and vintage (HR, 1.02; 95% CI, 0.54-1.75) on overall graft survival.

DISCUSSION

Waiting time on dialysis is a strong independent risk factor for increased patient mortality and increased graft failure after kidney transplantation.[5-8] The December 4, 2014, kidney allocation change successfully improved access of long vintage patients to all kidney offers[13] by awarding rank order points based on dialysis duration rather than waiting time but did not attempt alternate or rescue allocation for nonmandatory share kidneys which are kidneys previously turned down for local and/or regional candidates, otherwise known as hard-to-place kidneys. At our center, this allocation change resulted in some long-dialyzed candidates at the beginning of the match run to receive hard-to-place kidneys often in the setting of prolonged CIT. To provide deeper insight into the potential additive effect of prolonged CIT in the setting of long vintage we analyzed our early results.

We found that although recipient renal replacement time longer than 1 year was independently associated with 30-day readmission (aOR, 1.92), CIT was not a modifying factor for this outcome. Although for secondary endpoints low power precluded the ability to draw clear inferences there were no departures of early graft survival between the different vintage and CIT combinations nor was there an interaction between these two variables. These preliminary results are promising in that they suggest acceptable short-term allograft survival with the use of kidneys with prolonged CIT even for patients burdened by long vintage; and that the increased morbidity, ie readmissions, inherently higher among recipients with long vintage may not be potentiated by transplantation with kidneys subjected to prolonged CIT.

To enhance access to transplantation, transplant clinicians have explored ways to successfully use organs with prolonged CIT in combination with other potentially unfavorable donor characteristics such as small pediatric donors,[15] donors with acute kidney injury,[16,17] DCD,[18] expanded criteria donors,[19]

FIGURE 1. Overall graft survival stratified by dialysis duration and CIT.

A – Short Vintage, Short Ischemic Time   C – Long Vintage, Short Ischemic Time
B – Short Vintage, Long Ischemic Time   D – Long Vintage, Long Ischemic Time

and pediatric-DCD[20]; however, more research is needed to optimize donor and recipient matching not only to preserve graft longevity but also to promote organ utilization and reduce other posttransplant morbidity.

Our findings align with other reports wherein long pretransplant vintage represents a comorbidity,[21] independent of other candidate characteristics, that is associated with other morbidity such as 30-day readmission,[22] DGF,[23-25] acute rejection,[26,27] and infection.[28] However, we did not find a compounding effect of prolonged CIT with renal replacement time in our analysis, which may suggest that current allocation policy prioritizing long dialysis duration candidates for both local and nonlocal kidneys optimizes access without compromising early graft outcomes or other morbidity metrics.

Our study conclusions are limited by its retrospective nature and small sample size. It demonstrates only an association between specific recipient and transplant factors and morbidity, not cause and effect. Although we adjusted for many factors, we were unable to account for varying degrees of disease severity (ie, coronary artery disease, peripheral artery disease, different lengths of dialysis duration, etc.) and there may be other factors that are associated with posttransplant morbidity that are not included in this analysis. Generalization of our findings is limited because this is a single-center analysis wherein the majority of long cold time kidneys are imported. When considering shorter or longer dialysis period as an explanatory variable, we included preemptive kidney transplantation within the same group as those requiring less than 1 year of dialysis but were not able to adequately examine longer vintage time frames due to diminishing power. It also remains to be seen whether the combination of vintage and CIT has a synergistic association with long-term allograft survival; however, the further the time from the event, the harder it may be to draw causal inferences. We did not examine DGF because it is an endpoint that has multifactorial etiologies[29-32] and is likely to have stronger influential factors beyond CIT and vintage. CIT is a known independent risk factor for DGF,[29-31] and the consequences of DGF are difficult to overcome including increased complexity of management and readmission.[33,34] Lastly, we were unable to obtain cost data and examine the potential financial impact to the transplant center as a result of promoting transplantation utilizing long CIT organs in patients with high baseline risks for requiring extra medical care. Although our study is small, it demonstrates that such analysis is warranted and would provide useful information to transplant centers to truly determine the cost-benefit of transplanting hard-to-place kidneys in such a high-risk group of patients.

In conclusion, 30-day readmission was significantly associated with pretransplant dialysis duration; however, CIT was not a modifying factor for this outcome. In addition, overall short-term graft survival was also not influenced by cold ischemic time regardless of vintage; however, given the low even rates we consider this finding hypothesis generating. Taking together these findings suggests that improving access to transplantation using kidneys with long CIT (ie, hard-to-place) even in patients with long vintage time may be an acceptable approach and should be further explored.

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