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Running Title: Timely living donor transplants

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Abbreviations:

cPRA, calculated panel reactive antibodies; ESRD, end stage renal disease; KTx, kidney transplant; PKTx, pre-emptive kidney transplant; STAR, Standard Transplant Analysis and Research; UNOS, United Network for Organ Sharing; USRDS, United States Renal Data System

ABSTRACT

Pre-emptive kidney transplants (PKTx) and those within a year of dialysis initiation have been associated with superior outcomes. Wait-times should be minimal in those with living donors; however, there is lack of literature looking at utilization of timely kidney transplants in this population. We designed this retrospective study using data from United Network for Organ Sharing Standard Transplant Analysis and Research files from

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2000-2012 to assess the trends in utilization of PKTx and early KTx (combination of PKTx or transplant within a year of dialysis initiation) in recipients of living donor kidney transplants. Only 32.6% transplants were PKTx and 61.9% were early KTx. A significant improvement in proportion of PKTx was seen from 27.5% in 2000 to 35.4% in 2006 with no change since. Similarly, proportion of early KTx increased from 61.4% in 2000 to 63.6% in 2006 with no increase since. Similar results were seen after adjusted analysis and were independent of living donor type. Though there had been some improvement in utilization of timely transplants in early part of last decade, there has been no improvement since. Considering the benefits of timely kidney transplant, it is important to look into reasons for the same and improve their utilization.

INTRODUCTION:

Over 600,000 Americans suffer from end-stage renal disease (ESRD) (1). Dialysis and kidney transplantation are the mainstays of renal replacement therapy for these patients. Kidney transplantation is preferable to dialysis for several reasons. Patient survival is significantly greater with kidney transplantation (2). In addition, quality of life is better after a successful kidney transplant and overall healthcare costs are lower (3-5). Majority of ESRD patients wait for many years for a kidney transplant from the deceased donor pool. Living donor kidney transplantation is an alternative which is not only superior to deceased donor kidney transplantation with less acute rejections and better long-term graft survival (6) but has the potential to avoid long wait times associated with deceased donor wait-lists. Living donors also provide an opportunity for transplantation before initiation of maintenance dialysis, i.e., pre-emptive kidney transplant (PKTx).

PKTx has not only been associated with superior patient survival (7-10) but also with better death censored allograft survival (7, 9), quality of life (11), higher rate of return to work (12, 13) and overall lower medical expenditure (13) in comparison to transplants performed after starting dialysis. Though dialysis is a life-saving therapy, it is associated with significant morbidity and mortality especially related to cardiovascular disease and infections (14, 15). By avoiding chronic dialysis, PKTx can avoid such complications associated with it. Few studies have however shown that if transplantation can be performed within a year of initiating dialysis, outcomes may still be comparable to PKTx(7, 9).

PKTx have been a small proportion of transplants in the United States (16). The reasons are varied and include delayed diagnosis of chronic kidney disease (CKD), delayed referral to nephrology or transplant, lack of education/knowledge and delay in identifying and evaluating living donors (17, 18). However, for those who ultimately are transplanted by living donors, wait times for transplants should be minimal with the majority being transplanted pre-emptively. We designed this study to look at the utilization and trends of PKTx in those undergoing living donor kidney transplants. As patients who receive a kidney transplant within a year of initiation of dialysis may still have outcomes comparable to those with PKTx, we also looked at the proportion and trends of those receiving kidney transplants as a combination of pre-emptive or within a year of dialysis initiation (Early KTx).

MATERIAL AND METHODS:

Study Design

We designed a retrospective cohort study for adults undergoing living donor kidney transplants using data from United Network for Organ Sharing (UNOS) Standard Transplant Analysis and Research (STAR) files.

Study Population

We included recipients of living donor kidney transplants from January 2000-December 2012 who were 18 years or older at the time of transplant. Recipients of multiorgan

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transplants were excluded. As kidney-paired-exchange and list-exchange are primarily utilized to circumvent the issue of incompatible living donors and therefore can experience delayed transplants in comparison to those with compatible living donors, they were excluded from the study. We included those on dialysis before transplant with available dialysis initiation date before the date of kidney transplant and those with available living donor type (living related or unrelated) information.

Study Variables

Those with PKTx were identified based on missing dialysis initiation date and "No" as the response to question "Pretransplant Dialysis" in transplant recipient registration form. Pre-transplant dialysis time was calculated as the difference between transplant date and dialysis initiation date in those who responded "Yes" to the above question.

Outcomes

The primary outcome of interest was the proportion of those with PKTx among recipients of living donor kidney transplants. In addition, we calculated the proportion of those who received Early KTx, defined as, receiving a kidney transplant either pre-emptively or within a year of dialysis initiation. Trends for proportions of PKTx and Early KTx over time were also assessed. Finally we calculated odds for receiving PKTx and Early KTx over time in models adjusted for both donor and recipient characteristics.

Statistical Analysis

All statistical analyses were performed using STATA 13.1 (StataCorp, College Station, TX, USA). Chi square test was used to compare categorical variables and t-test was used to compare continuous variables. Linear regression was used to assess trends of PKTx and Early KTx over time. To allow for non-linear relationship between proportions of PKTx or Early KTx and time-period, time-period was modeled by linear splines. The knot placement for splines was estimated based on the location that yielded the lowest residual sum of squares(19). The location was then rounded off to the nearest whole number for the year of transplant. The independent effect of year of transplant on

proportions of PKTx and Early KTx was assessed using separate multivariable logistic regression models with PKTx and Early KTx as dependent variables respectively. All clinically relevant variables including both donor and recipient characteristics were used in the final multivariable models. To assess if the effect of year was different by living donor type (related vs unrelated) an interaction between living donor type and year of transplant was checked. For most variables, missing data was less than 5% except for donor BMI (7.8%), recipient functional status at the time of listing (7.8%) and recipient education (13.8%). Casewise deletion was used to handle missing data. To confirm that this method of missing data handling did not affect our results we did a sensitivity analysis using logistic regression models with missing values of each variable recoded as "missing" categories.

As calculated panel reactive antibodies (cPRA) only began to be reported in Dec 2007, separate models with cPRA were fitted for those with available cPRA data and including all the other covariates included in the initial multivariable logistic regressions to assess the odds of PKTx and Early KTx respectively over time. An interaction term between living donor type and year of transplant was checked to assess if the effect of year was different by living donor type (related vs unrelated). To assess if odds for PKTx or Early KTx differed for different cPRA categories (0, 0-20, 21-80, >80), an interaction term between cPRA and year of transplant was checked for in both models.

RESULTS:

Patient Characteristics

A total of 68,128 patients who received a living donor kidney transplant were included in the study. 63.7% of living-donor transplant recipients received transplants from a living related donor, 32.2% (21,977) recipients had available cPRA values at the time of transplant, of which 78.4% had zero cPRA.

As shown in Table 1, those who received PKTx were older (mean age 47.8±13.5 years vs 46.3±14.0 years for those without PKTx; p<0.001), more often females and whites in comparison to those who did not receive a pre-emptive transplant. Those with pre-

emptive transplants also tended to have A blood group, no history of diabetes, be first time transplant recipient, education level college or higher, have private insurance as primary payer and polycystic kidney disease as the cause for end stage renal disease (ESRD) in comparison to those who did not receive PKTx. Donors for those with preemptive transplants were older (42.1±11.1 years vs 40.2±11.3 years for those without PKTx; p<0.001), white and A blood group in comparison to those who did not receive PKTx.

Similarly, recipients who received Early KTx were younger (46.6±13.8 years vs 47.0±14.0 years for those without Early KTx; p<0.001), white, A blood group, without history of diabetes, first time transplant recipient, with highest education college or higher, have private insurance and have polycystic kidney disease as the cause for ESRD in comparison to those who did not receive Early KTx. Their donors tended to be older (41.5±11.1 years vs 39.7±11.4 years for those without Early KTx; p<0.001), white and A blood group in comparison to those who did not receive Early KTx.

Incidence and Trends of PKTx and Early KTx

Overall only 32.6% of recipients transplanted with a living donor had a PKTx. In total, 61.9% were transplanted either pre-emptively or within a year of dialysis initiation (Early KTx) and 38.1% were transplanted after a year or longer on dialysis.

A significant improvement in the proportion of PKTx was observed from 27.5% in 2000 to 35.4% in 2006, however, the proportion of PKTx has not changed significantly since then. Similarly, the proportion of Early KTx increased from 61.4% in 2000 to 63.6% in 2006 but there has been no significant change in that since (Fig 1). On adjusted analysis the odds of PKTx increased till 2006 with no significant increase since (Fig 2a). Similarly the adjusted odds of Early KTx increased till 2006 after which there was no significant increase noted (Fig 2b). Similar results were seen when missing values of each variable recoded as "missing" categories (Fig S1a and S1b). The interaction term between variable for living donor type and year of transplant was not significant in either of regression models (p=0.9 in model with PKTx as dependent variable and p=0.3 in model with Early KTx as dependent variable).

When cPRA was included in the multivariable model for regression, no significant difference was observed in odds of receiving PKTx or Early KTx over time (Fig 2c & 2d). The interaction term between the variable for living donor type and year of transplant was not significant in either models (p=0.9 in both models with PKTx or Early KTx as dependent variable). Similarly the interaction term between cPRA and year of transplant was not significant either (p=0.5 in model with PKTx as dependent variable and p=0.2 in model with Early KTx as dependent variable) suggesting similar effect of year regardless of cPRA.

DISCUSSION:

Using national data of living donor kidney transplant recipients we have shown that only one third of them have undergone PKTx and less than one-third were transplanted within a year of dialysis initiation. We have also shown that the proportion of PKTx and overall Early KTx did increase till 2006, but they have not seen any significant rise since then on both unadjusted and adjusted analysis. The effect appeared to be similar regardless of living related or unrelated donors and after adjustment for cPRA.

PKTx have been shown to be associated with improved patient survival in comparison to those staying on dialysis before transplant. Using national data from United States Renal Data System (USRDS) Meier-Kriesche et al (7) showed that being on dialysis before transplant negatively impacted patient survival in a dose-dependent manner especially for those on dialysis for longer than 6 months. Similarly favorable effects of pre-emptive kidney transplants on patient survival has been shown in a later study using USRDS data by Goldfarb-Rumyantev et al (9) and using Australian and New Zealand Dialysis and Transplantation Registry by Milton et al(10). However, Goldfarb-Rumyantev et al showed that the impact of pre-transplant dialysis on post-transplant patient survival becomes significant only after a year of chronic dialysis. The literature though seems to support that spending over a year on dialysis before transplant adversely impacts patient's post-transplant survival. Our results therefore assume greater importance and cause for

concern there appears to have been no significant improvement in proportion of both PKTx and Early kidney transplants since 2006.

It is interesting to note that though there has been a trend to provide earlier PKTx (20), based on the results of our study this does not seem to have translated into increasing proportions of PKTx. Some important reasons for lower number of pre-emptive transplants have been thought to be lack of availability of living donors, decreased number of living donors, lack of insurance, lack of education/knowledge, delayed diagnosis of CKD and delayed referral for transplant (17, 18). By restricting our sample to only those transplanted using living donors outside of kidney paired exchange we have tried to mitigate the first issue. We have seen overall decrease in living donors since 2004(21) which has been thought to contribute to low proportion of pre-emptive kidney transplants(22), however, since we only included the recipients of living donor kidney transplants, this should not have impacted our results. We controlled for presence and type of health insurance in recipients and attempted to control for overall education status of the recipient in our adjusted regression model, however, that may not be a true reflection of patient's health literacy. Lack of education/knowledge about transplant is difficult to assess in the database used as is to assess the impact of delayed diagnosis or CKD or delayed referral but by including those who were transplanted after being on almost a year on dialysis we expect that the effect of these factors would have been mitigated to some extent through education and referral provided by dialysis centers. Dialysis centers have a requirement to discuss transplants with all patients and provide referral if patient agrees. Though timing of referral for kidney transplant is not provided in the database, we found that the proportion of PKTx and Early KTx were highest in those who were not on dialysis at the time of listing and lowest in those who were on dialysis for 6 months or longer at the time of listing (Table S1). When dialysis status at the time of listing was added as a variable in regression analysis with Early KTx as the dependent variable, the odds of Early KTx were much lower in those on dialysis for less than 6 months and lowest in those on dialysis for 6 months or longer at the time of listing in comparison to those who were not on dialysis at the time of listing (Table S2). This points to the fact that earlier listing is likely associated with earlier transplants in those with living kidney donors. As earlier

referrals could lead to earlier listings, we could extrapolate these findings to say that earlier referrals can potentially results in earlier transplants. This analysis however needs to be interpreted with caution as 25.3% of those transplanted were never listed and listing time may not necessarily correlate with referral time. There are other factors such as accommodation of donor schedule that can further lead to transplant not being done pre-emptively.

The implications of lack of improvement in pre-emptive transplants are concerning. In addition to survival benefit, pre-emptive transplants have been associated with improved death censored allograft survival(7, 9), better quality of life(11) and overall lower overall medical expenses(13). These benefits further highlight the importance of directing attention towards attempts to increase pre-emptive transplants. Given the fact that these are the patients who have willing living donors who they were transplanted from, every effort should be made to increase the chances of a pre-emptive transplant or at least transplant as soon as possible after initiating chronic dialysis. It is important to note though that maintaining a fine balance between how long to wait for a transplant while not waiting for too long is important as earlier transplant may not necessarily mean better(20) and could result in premature exposure to immunosuppression.

Even though we have used a national database, our study has some limitations. This is a retrospective study and thus prone to selection bias. Even though we have attempted to adjust for confounding variables that could impact the chances of PKTx or Early KTx there are many unreported or in some cases unidentifiable characteristics which could have impacted our results. As discussed above, patient's transplant literacy, delayed diagnosis or CKD or delayed referral for transplant could not be accounted for in the study, however, we would have expected these characteristics to improve over the study period leading to increasing proportion of PKTx and Early KTx. Patients with incompatible living donors are increasing being enrolled in kidney paired exchange programs(23). We excluded these recipients as they may need to wait to find a compatible living donor which could lead to understandably increased wait times and potential loss of the opportunity for PKTx/Early KTx which may bias our results. Though few centers do enroll compatible recipient donor pairs in kidney paired exchange programs, this is practiced only by few centers. We, however, were not able to identify

patients undergoing desensitization that could lead to similarly longer wait times and potential loss of opportunities for PKTx/Early KTx. Desensitization, however, is practiced only by select centers and therefore should not have impacted our results significantly. In addition, there seemed to be similar lack of increase in adjusted odds for PKTx and Early KTx for all levels of cPRA over time, further confirming our results. As center level data is not available in the database studied, we were not able to account for the clustering due to individual center's practices in our analysis.

In summary, we have shown that the PKTx account for only about a third of total living donor kidney transplants and less than two-thirds of living donor transplants are performed pre-emptively or within a year of chronic dialysis initiation. The proportion of both PKTx and Early KTx increased in the earlier part of last decade but has been stagnant since. Further studies are needed to understand the reasons behind lack of and to improve the utilization of PKTx/Early KTx especially in those who are ultimately transplanted using living donors.

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DISCLOSURES:

The authors of this manuscript have no conflicts of interest to disclose as described by the American Journal of Transplantation.

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Figure Legends:

Figure 1: Trends for PKTx and Early KTx. Vertical dotted line at year 2006 is showing the inflection point for linear splines. PKTx, pre-emptive kidney transplant; KTx, kidney transplant.

Figure 2: Adjusted odds ratios for receiving PKTx or early KTx. (A) Adjusted odds ratios for receiving PKTx*. (B) Adjusted odds ratios for receiving early KTx*. (C) Adjusted odds ratios for receiving PKTx with model adjusted for cPRA[#]. (D) Adjusted odds ratios for receiving early KTx with model adjusted for cPRA[#].

*Adjusted for recipient age, sex, race, BMI, blood group, diabetes history, insurance, ESRD diagnosis, history of previous kidney transplants, history of any malignancy, functional status at the time of listing, highest education, donor age, sex, race, BMI, blood group, living donor type and year of transplant. *Adjusted for recipient age, sex, race, BMI, blood group, diabetes history, insurance, ESRD diagnosis, history of previous kidney transplants, history of any malignancy, functional status at the time of listing, highest education, donor age, sex, race, BMI, blood group, living donor type, cPRA and

year of transplant. PKTx, pre-emptive kidney transplant; KTx, kidney transplant; cPRA, calculated panel reactive antibodies; BMI, body mass index; ESRD, end stage renal disease.

Supporting Information

Additional Supporting Information may be found in the online version of this article.

Table S1: Proportion of pre-emptive and early kidney transplants by dialysis status at the time of listing

Table S2: Independent effect of dialysis status at the time of listing on odds of getting an Early KTx*

Supplementary Figure Legends:

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Figure S1: Adjusted odds ratios for receiving PKTx or early KTx while including missing values of each variable recoded as "missing" categories. (A) Adjusted odds ratios for receiving PKTx* while including missing values of each variable recoded as "missing" categories. (B) Adjusted odds ratios for receiving early KTx* while including missing values of each variable recoded as "missing" categories.

*Adjusted for recipient age, sex, race, BMI, blood group, diabetes history, insurance, ESRD diagnosis, history of previous kidney transplants, history of any malignancy, functional status at the time of listing, highest education, donor age, sex, race, BMI, blood group, living donor type and year of transplant.

PKTx, pre-emptive kidney transplant; KTx, kidney transplant; BMI, body mass index; ESRD, end-stage renal disease.

Table 1: Baseline characteristics of those who received PKTx and those did not receive PKTx

Characteristics		Non PKTx*	PKTx*	p value
		N=45,924(%)	N=22,204(%)	
Recipient Age	≤30	16.5	12.5	<0.001
Group (yr)	31-44	27.4	26.4	
	45-64	45.9	50.0	
\mathcal{O}	≥65	10.2	11.1	
Donor Age	≤30	23.0	17.3	<0.001
Group (yr)	31-44	40.4	39.3	
	45-64	35.4	41.7	
	≥65	1.2	1.7	
Recipient Sex	Females	38.9	41.5	<0.001
Donor Sex	Females	59.9	59.7	0.69
Recipient Race	White	62.1	79.2	<0.001
	Black	16.7	8.7	
	Hispanic	15.3	8.0	
	Others	5.9	4.1	
Donor Race	White	64.4	79.9	<0.001
	Black	15.1	8.1	
	Hispanic	15.3	8.2	
	Others	5.2	3.8	
Recipient BMI	<18.5	3.1	2.6	<0.001
	18.5-24.9	35.8	34.7	
1	25.0-29.9	31.7	33.8	
	30.0-34.4	18.7	19.4	
	≥35.0	9.4	7.7	
Donor BMI	<18.5	0.9	1.1	<0.001

	18.5-24.9	31.7	33.4	
	25.0-29.9	37.3	38.0	
	30.0-34.4	18.0	15.8	-
	≥35.0	4.4	3.4	-
Recipient ABO	A	37.1	41.0	<0.001
	В	13.2	11.9	-
	0	3.5	4.3	
	AB	46.2	42.8	-
Donor ABO	A	24.8	27.9	<0.001
S	В	7.6	7.1	-
	0	0.8	0.9	1
	AB	66.8	64.1	
Recipient with Diabetes		29.9	23.6	<0.001
Recipient with previous kidney		9.4	7.5	<0.001
transplant				
Recipient	Grade School	4.2	1.9	<0.001
Education	or less			
	High School	36.9	29.3	-
	College or	45.0	55.3	-
	Higher			
Recipient	Public	48.2	22.7	<0.001
Insurance	Private	51.0	76.1	-
	Others	0.8	1.2	-
Recipient with ma	alignancy	4.7	5.1	0.03
history				
Recipient	Good	79.5	84.3	<0.001
Functional	Impaired	12.8	7.7	
Status				
Recipient ESRD	GN ¹	27.4	27.4	<0.001
Diagnosis	Diabetes	23.5	17.8	

HTN ²	18.6	13.2	
PKD ³	7.2	17.0	
Others	22.3	23.8	

*Column percentage total may not add to 100% for missing values

¹GN – Glomerulonephritis

²HTN – Hypertension

³PKD – Polycystic Kidney Disease

Table 2: Baseline characteristics of those who received Early KTx and those did not receive Early KTx

Characteristics		Non Early KTx	Early KTx	p value
		N=25,977 (%)	N=42,151 (%)	
Recipient Age	≤30	15.6	14.9	<0.001
Group (yr)	31-44	26.3	27.6	
	45-64	47.0	47.4	
O	≥65	11.1	10.1	
Donor Age	≤30	24.4	19.0	<0.001
Group (yr)	31-44	40.6	39.8	-
	45-64	33.8	39.7	
	≥65	1.2	1.5	
Recipient Sex	Females	39.5	39.9	0.42
Donor Sex	Females	60.2	59.7	0.17
Recipient Race	White	55.5	75.2	<0.001
	Black	20.1	10.4	
	Hispanic	17.9	9.8	
	Others	6.5	4.6	
Donor Race	White	58.2	76.4	<0.001
0	Black	18.1	9.6	
	Hispanic	17.9	9.9	
	Others	5.8	4.1	
Recipient BMI	<18.5	2.9	2.9	<0.001
A	18.5-24.9	35.3	35.6	
	25.0-29.9	31.0	33.3	
	30.0-34.4	19.3	18.7	
	≥35.0	10.3	7.9	
Donor BMI	<18.5	0.9	1.0	<0.001
	18.5-24.9	31.1	32.9	

	25.0-29.9	36.9	37.9	
	30.0-34.4	18.7	16.5	-
	≥35.0	4.6	3.7	-
Recipient ABO	A	35.0	40.4	<0.001
	В	14.0	12.1	
	0	3.2	4.1	
	AB	47.8	43.4	
Donor ABO	A	23.4	27.3	<0.001
	В	7.8	7.2	
S	0	0.7	0.9	-
	AB	68.1	64.6	
Recipient with Di	abetes	30.9	25.9	<0.001
Recipient with pr	evious kidney	9.1	8.5	0.005
transplant				
Recipient	Grade School	5.2	2.3	<0.001
Education	or less			
	High School	38.9	31.6	-
	College or	41.2	52.8	
	Higher			
Recipient	Public	59.4	27.9	<0.001
Insurance	Private	39.9	71.0	
	Others	0.7	1.1	-
Recipient with ma	alignancy	5.2	4.6	0.002
history				
Recipient	Good	77.8	83.1	<0.001
Functional	Impaired	13.9	9.4	
Status				
Recipient ESRD	GN ¹	26.0	28.2	<0.001
Diagnosis	Diabetes	24.3	19.9	
	HTN ²	21.2	14.2	

PKD ³	5.8	13.3	
Others	21.7	23.5	

*Column percentage total may not add to 100% for missing values

¹GN – Glomerulonephritis

²HTN – Hypertension

³PKD – Polycystic Kidney Disease



