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FACTORS THAT IMPACT THE WILLINGNESS TO ACCEPT EXPANDED CRITERIA DONOR KIDNEYS

Zaw Maung, BS[1], Thomas Chin, MD[2], Robert Metzger, MD[2], Bobby Nibhanupudy, MD[2], Giri Vedula, MD[2] and Michael Angelis, MD[2]

[1]University of Central Florida, College of Medicine, Orlando, Florida, United States

[2]Transplant Surgery, Florida Hospital, Orlando, Florida, United States.

Abstract

Context: It is critical to develop allocation protocols that boast both equity amongst recipients and efficient utilization of scarce donor kidneys in a market of increased demand. Under current guidelines, the decision to undergo expanded criteria donor (ECD) transplantation is ultimately in the hands of the recipient. However, the utilization of recommended guidelines by physicians to guide patients in making this decision will have profound impacts.

Objective: To identify registrant characteristics associated with willingness to accept ECD kidneys and evaluate whether these associations are consistent with recommended guidelines.

Design, Setting and Patients: Single-center retrospective cohort study using data from Florida Hospital Transplantation database. The cohort included 135 patients over the age of 60 with ESRD placed on waiting-list from 2009-2010.

Main Outcome Measure: Willingness to consent for ECD kidney

Results: When compared to registrants with blood types A or AB (predicted to have lower waiting times), registrants with blood type O were 3.83 times more likely and those with type B were 6.48 times more likely to consider ECD kidney. Amongst all registrants, older patients and diabetes as primary cause of ESRD were associated with ECD willingness. When only registrants with blood types A or AB were examined, there were no significant associations. However, in patients with blood types O or B (predicted to have longer waiting times), age and diabetes as primary cause of ESRD were associated with ECD willingness while registrants with polycystic kidneys or other causes of ESRD were less likely to be ECD willing.

Conclusions: ECD listing practices at Florida Hospital Medical Center is consistent with published recommendations. Projected waiting times, indicated by an individual's blood type, takes precedence in determining whether to consent ECD organs. Secondary to waiting time is the severity of illness and increasing age. We found that gender, race, or education did not impact the consideration of ECD kidney transplantation.

1. Background

Kidney transplantation is the preferred treatment in patients with end-stage renal disease (ESRD) as it has been shown to improve survival and quality of life (1). However, the number of patients waitlisted for a kidney transplant has nearly doubled in the last decade while the total number of transplants has remained relatively steady (2). With the scarcity of organ donors in relations to the demands, most patients are placed on the waitlist and undergo dialysis until a match is made. One of the responses to organ shortages in the United States has been the implementation of an expanded criteria donor (ECD) program, using once discarded organs from older donors and donors with comorbid conditions (3). An ECD kidney is defined as any deceased donor kidneys whose relative risk of graft failure exceeded 1.7 when compared to a group of ideal donor kidneys; this meant that kidneys were considered ECD organs if the deceased donor was over 60 years of age or 50-59 years old with at least two of the three specified comorbid conditions including history of hypertension, elevated serum creatinine indicating suboptimal donor kidney function [>1.5 mg/dL], or death caused by cerebrovascular accident (3, 4).

Although the use of an ECD organ for kidney transplantation has the benefit of extra life-years, these allografts face increased risk of rejection when compared to standard criteria donor (SCD) organs (4). Nonetheless, they have been shown to prolong life when compared to the alternative of remaining on dialysis (5). The use of ECD organs has allowed survival advantages in certain recipient populations who otherwise would face increased mortality from remaining on dialysis (5, 6). On the contrary, recipient characteristics associated with no survival advantage after ECD transplantation has also been identified(7). These include patients under the age of 40, African Americans, or Asians at transplant centers where the median waiting time is less than 1350 days (7, 8). As such, identifying those that would benefit from an ECD kidney and deterring those recipients that would not reap such associated survival benefits would allow maximal utility and allocation of donor kidneys.

The decision to accept an ECD kidney is ultimately left to the patient. However, arriving at this decision is dependent on the nature of the relationship of the patient with their physicians. There have been different models published in the past few years to aid in this decision-making process (9). Merion and colleagues in 2005 identified patients that would most likely benefit from ECD kidney transplantation: patients over the age of 40 with either diabetes as primary cause of ESRD or non-Hispanic race and listing at centers with median waiting times greater than 1350 days (6). However, ECD listing practices vary throughout the country across transplant centers and has been found to be inconsistent with published recommendations (9). The goal of this study was to evaluate ECD listing practices in a single transplant center by identifying associated recipient characteristics involved in this decision making process. We analyzed patients'

characteristics including, age, sex, race, education, panel reactive antibody, and their primary cause of ESRD and their association with willingness to consent for ECD-kidney. These factors were selected based on their associations with transplantation rates, graft failure, and survival outcomes across various studies (5, 10, 11).

Of interest, even though African Americans patients with ESRD on dialysis have decreased mortality rates and as such, would benefit from avoiding acceptance of ECD kidneys, studies have shown that compared to Whites, they are more likely to be listed for and receive ECD kidneys (10). Past research has also attributed increased incidence of allograft loss amongst African American and older male recipients to immunologic and nonimmunologic factors, including HLA mismatching and ischemic time (12). Even when these factors were controlled, it was found that African Americans were 1.7 time more likely than whites to reject grafts over 9 years (12). Different studies have also attributed the significance of socioeconomic factors on disparities seen in kidney transplantation (11). Goldfarb-Rumyantzev et al found that recipients with higher education level, resident aliens, and patients with private insurance had an advantage in graft and survival outcomes that is independent of racial differences (11). However, despite these findings of the effects of socioeconomic factors on clinical outcomes, Gordon and Caicedo points out the "Hispanic paradox" in which Hispanics, as a group who rank low in socioeconomic indicators, but has superior transplant outcome (13, 14). One of the attributing factors that give rise to this paradox is that Hispanic deceased donor kidney recipients have a higher proportion of standard criteria donors than expanded criteria donors compared to Whites, Blacks, and Asians. It is stated that the decision to receive either the expanded criteria donors or standard criteria donor kidney is a matter of patient choice and they attribute the decision is likely informed cultural values and notions of risks. Undeniably, personal perceptions of risk and perceived values of outcomes will ultimately factor into determining whether to consent for ECD organs. However, a patient's decision will also be significantly influenced by their physicians. As such, we examined the interplay between personal and cultural beliefs with evidence based clinical outcomes as presented by physicians to their patients. We assessed whether the decision to consent for ECD kidneys is influenced by evidence based clinical outcomes that have been shown to benefit subset of kidney transplant recipients, including increased age and candidates with diabetes. If such associations exist, we presumed that physicians advocated and pushed their patients at risk to consider ECD kidneys. As such, the decision making process guided by physician's utilization of recommended guidelines. However, if racial differences or other socioeconomic factors were associated with willingness to consent for ECD kidneys, it is plausible that cultural differences are at play, or there is minimal influence by physicians on their patients.

2. Methods

Study population and data collection

We collected and analyzed data from the Florida Hospital Transplantation database. We adopted an inclusion and exclusion criteria to reflect ECD listing practices at this particular transplant center. Cohort included patients with end-stage renal disease placed on the waiting list from 2009-2010. We excluded patients receiving living donor renal transplants and patients under the age of 60 since ECD kidneys were primarily offered to patients over the age of 60 at Florida Hospital Transplant Center.

Outcome variable and covariates

We analyzed ECD listing status reported in the FH Transplantation database as our primary outcome. Patients who consented to accepting an ECD kidney were labeled 'ECD-willing'. Using Center-Specific Reports prepared by Scientific Registry of Transplant Recipients (SRTR), we evaluated associations between blood type and transplantation rates at 3 years after waitlisting. At 3 years, transplantation rates for blood types AB, A, O, and B are 75.9%, 71.5%, 52.3%, and 44.3% respectively. Based on this data, we used blood types as a surrogate marker of waiting time (15). Blood types A and AB were grouped together based on their high rate of transplantation at 3 year mark. Blood types B and O were grouped together for multivariate analysis because of decreased sample size for blood type B and association of both blood types with decreased transplantation rates.

Our variables of interest included age, sex, race, education level, panel reactive antibody (PRA) and primary cause of ESRD. Education level was divided into either High school or less and College or beyond. The population included five ethnic groups: White, African American, Hispanic, Asian, and Other. Panel reactive body was defined as either positive or negative. Primary causes of ESRD included as diabetes mellitus, hypertensive nephrosclerosis, polycystic kidneys, graft failure, and other causes. Other causes of ESRD include Glomerulonephritis, Focal Glomerular Sclerosis, Wegners Granulomatosis, Chronic Pyelonephritis, Sjogren's Syndrome, Alport's Syndrome, Systemic Lupus Erythematous, and IgA Nephropathy.

Statistical Analysis

Categorical variables were summarized as the percentage of total while means were used to summarize continuous variables. Comparisons between groups were made using chi-square test for the categorical variables. A multivariate logistic regression model was used to analyze associations between covariates and ECD listing status. Covariates of interest included age, sex, race, education, panel reactive antibody (PRA), and primary cause of ESRD. Analyses were performed using SPSS Statistics Version 19.

Table 1: Baseline characteristics of the study population.

	Entire study population	Willingness to consider ECD kidneys?		
		Yes	No	p-Value
N	135	93	42	
Age (mean)	66.59	67.27	65.09	
Sex (%):				0.709
Male	56.3	45.2	59.5	
Female	43.7	54.8	40.5	
Race (%):				0.66
White	48.9	46.2	54.8	
African American	27.4	26.9	28.6	
Hispanic	15.6	18.3	9.5	
Asian	6.7	6.5	7.1	
Other	1.5	2.2	0	
Education (%):				0.868
High school or less	55.6	57	52.4	
College or beyond	42.2	40.9	45.2	
Unknown	2.2	2.2	2.4	
Blood type (%):				0.007
A	32.6	23.7	52.4	
B	14.1	17.2	7.1	
O	51.1	57	38.1	
AB	2.2	2.2	2.4	
PRA Value (%):				0.653
Positive	38.5	40.9	33.3	
Negative	55.6	52.7	61.9	
Unknown	5.9	6.5	4.8	
Primary cause of ESRD (%):				0.042
Hypertensive Nephrosclerosis	26.7	25.8	28.6	
Diabetes Mellitus	36.3	41.9	23.8	
Polycystic Kidneys	8.9	6.5	14.3	
Graft Failure	7.4	9.7	2.4	
Other causes of ESRD	20.7	16.1	31	

3. Results

Baseline characteristics

We identified 135 kidney transplant registrants over age 60 that has been placed on the waiting list from 2009-2010. Of those 135 patients, 68.9% consented for ECD kidneys with the other 31.1% consenting only for the SCD kidneys. Within the entire cohort, the mean age was 66.59; 48.9% were White and 27.4% were African Americans; 56.3% were males; 55.6% had an education level of high school or below and 42.2% went to college or beyond; 51.1% had blood type O, 32.6% had blood type A, and 14.1% had blood type B; 38.5% had a positive PRA value; Primary cause of ESRD was Diabetes Mellitus in 36.3% and Hypertensive Nephrosclerosis in 26.7% (Table 1). Distribution of other baseline characteristics of the study population is presented in Table 1.

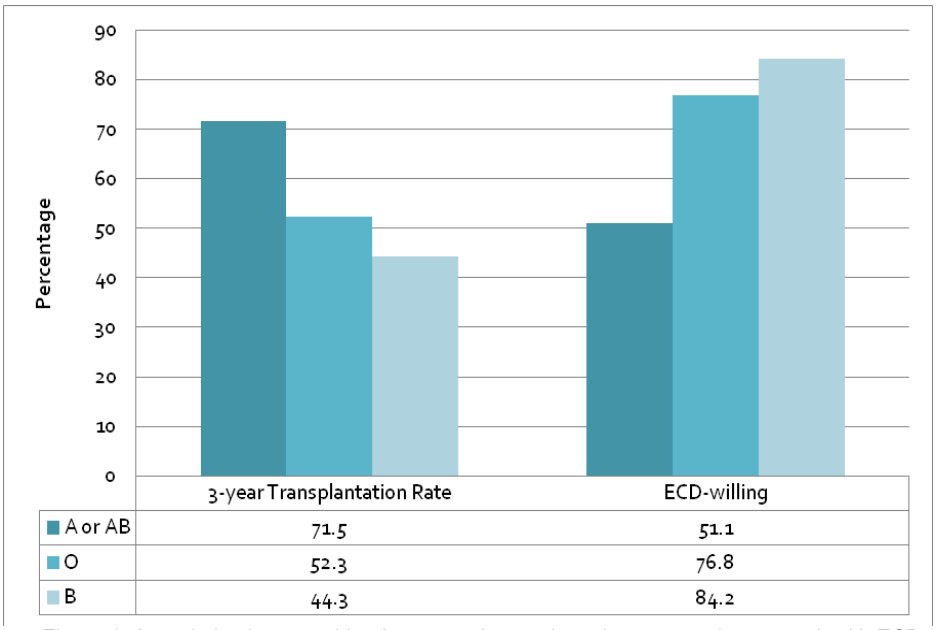

Figure 1: Association between blood types and transplantation rates at 3 year mark with ECD willingness is shown.

ECD-willing registrants

Of the 93 patients who consented for ECD kidneys, the mean age was 67.27, 54.8% were male, 46.9% were White and 26.9% were African American and 57% had an education level of high school or less ECD-registrants were more likely to have blood type B (17.2% vs 7.1%) or O (57% vs 38.1%), least likely to have type A blood (23.7% vs 52.4%). The primary cause of ESRD in ECD-willing registrants was more likely to be Diabetes Mellitus (41.9% vs 23.6%) and

least likely to be polycystic kidneys (6.5% vs 14.3%) or other causes of ESRD (16.1% vs 31%).

Predictors of ECD-willingness
51.1% of registrants with blood types A or AB were ECD-willing while 76.8% of of registrants with blood type O and 84.2% of registrants with blood type B were ECD-willing (Table-2). Comparison between blood types and transplantation rates with ECD-willingness is shown in Figure 1. Compared to patients with blood type A or AB, which is associated with the lowest waiting time (highest transplantation rates at 3 year mark), patients with blood type O (OR 6.481) or B (OR 3.825) are more likely to consent for ECD-kidneys (Table 3).

Multivariate analysis in the entire population
There is an increased likelihood of willing to accept ECD kidneys with increased age (OR 1.173 for 1 year increase in age). Patients with diabetes as a primary cause of ESRD were more likely (OR 2.31) Wwilling to accept ECD kidney. However, patients with other causes of ESRD including Glomerulonephritis, Focal Glomerular Sclerosis, Wegners Granulomatosis, Chronic Pyelonephritis, Sjogren's Syndrome, Alport's Syndrome, Systemic Lupus Erythematous, and IgA Nephropathy are associated with decreased likelihood of consenting for ECD kidney (OR .429). There were no associations between sex, race, education, or PRA levels with ECD willingness (Table 3).

Multivariate analysis within blood types A or AB
There was no significant association between any of the variables with ECD-willingness within this subset of population (Table 3).

Multivariate analysis within blood types O or B
Age is related with willingness to accept ECD kidneys (OR 1.202). Diabetes mellitus as a primary cause of ESRD is also associated with willingness to consent for ECD-kidneys. However, both polycystic kidneys and other causes of ESRD as listed prior are associated with decreased likelihood of consenting for ECD kidneys (OR.17 and OR .289 respectively). There were no associations between sex, race, education, or PRA levels with ECD willingness (Table 3).

4. Discussion

The national median time to transplant is 1522 days whereas the median time for Florida Hospital Medical Center is 569 days (15). Given the low waiting time projected at this transplant center, in order to assess waiting times in correlation with ECD willingness, we used individual blood types as markers of predicted waiting times. The median time to transplantation for Florida Hospital Medical Center correlated more with recipients with blood types A or AB in which 68% and 75.9% are transplanted at 2 year mark, and 71.5% and 75.9% at 3 year mark (15).

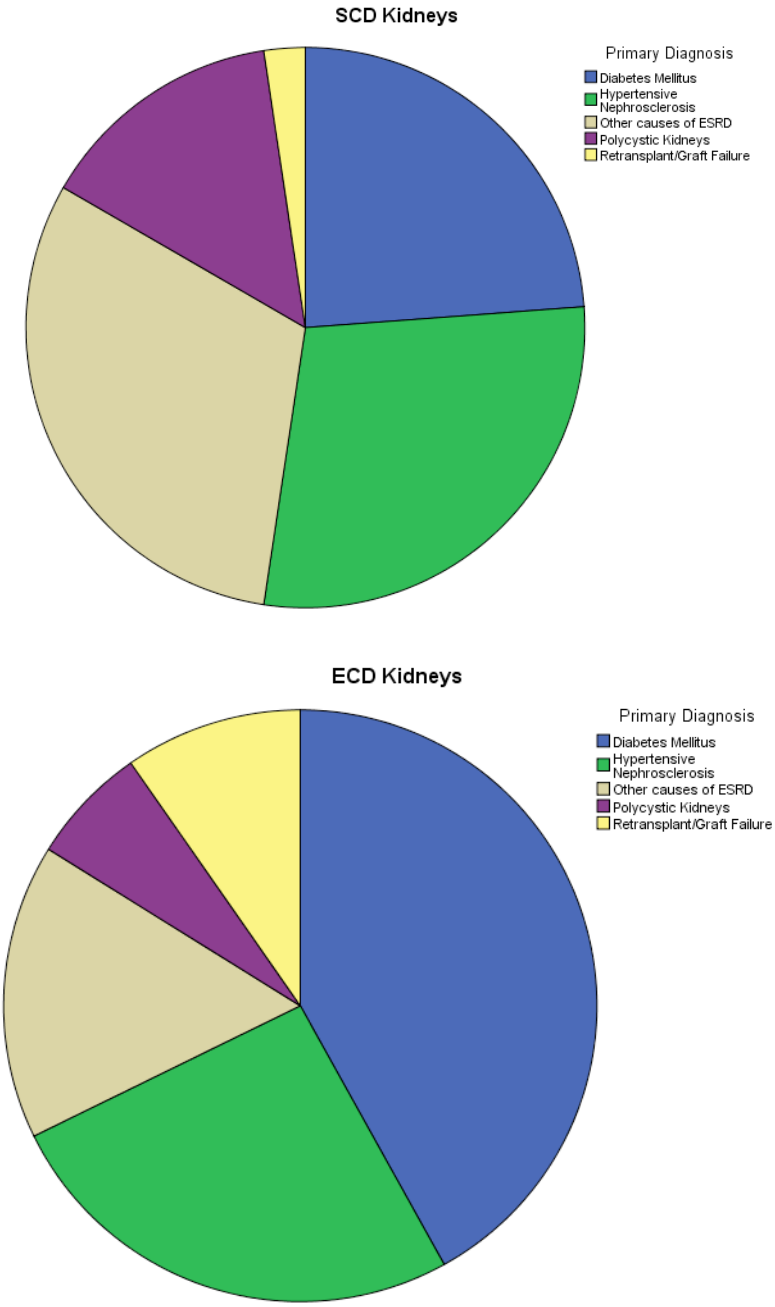

Figure 2: Pie chart comparing the percentages of primary cause of ESRD in registrants who consented for ECD kidney with registrants who only consented for SCD kidney.

Given that only 52.3% of recipients with blood type O and 44.3% with blood type B are transplanted at 3 year mark, we used blood types O and B as indicators of long waiting times (15). Using blood types as a surrogate marker for waiting times, we found that recipients were more likely to consent for ECD kidneys when associated with longer waiting times. Compared to registrants with blood type A or AB, which are shown to have decreased waiting times, registrants with blood type O and B are 6.48 and 3.83 times more as likely to be ECD-willing respectively. This is in contrast to national studies in which median waiting time of transplant centers were used to assess willingness to consider ECD kidneys and no significant association was found (9). However, consistent with national studies, we did find that older patients were more likely to be ECD-willing even after exclusion of registrants under the age of 60. Our single-center analysis also found no significant associations between men, African Americans and ECD willingness as previously reported (9, 10, 16). Also in contrast to previous studies, diabetes as the primary cause of renal failure was significantly associated with willingness to consent for ECD(9). This further elucidates the differences amongst ECD listing practices between centers.

Interestingly, when assessing ECD willingness between registrants with predicted lower waiting time as specified by blood types A or AB with predicted longer waiting times indicated by blood types O or B, we found no significant association between any of the registrants' characteristics with ECD willingness amongst registrants with blood types A or AB. However, for patients with predicted longer waiting times (blood types B or O), for 1 year age difference, there was a 1.14 times increased likelihood of consenting for ECD kidneys. Within this population, patients with diabetes as the primary cause of ESRD were 6.54 times more likely to consent for ECD kidneys whereas patients with polycystic kidneys .17 times as less likely. This finding resonated with the decreased likelihood of consenting for ECD kidneys when the primary cause of ESRD was due to polycystic kidneys or other causes. These results indicate that primary factor in considering ECD kidneys appears to be blood types, or more specifically decreased waiting times associated with blood types A or AB. Even the age of patient did not appear to impact ECD willingness in patients with expected decreased waiting times. The specific findings in patients with predicted longer waiting times are consistent with previously recommended pool of registrants expected to have survival from ECD kidney transplantation, increased age and diabetes as primary cause of ECD (6). Concurrently, there were no significant associations between ECD willingness and patient groups that have been shown to receive no improvements in patient survival; African Americans or Asians (7, 8).

Table 2: Baseline characteristics of patients grouped by their respective blood types.

	Blood type A or AB		Blood type O		Blood type B		
Willlingness to consider ECD Kidneys?	Yes	No	Yes	No	Yes	No	p-value
N	24	23	53	16	16	3	
%	51.06	48.94	76.81	23.19	84.21	15.69	0.005
Age (mean)	68.96	65.81	67.01	64.47	66.91	62.93	
Sex (%):							
Male	62.5	60.9	54.7	62.5	43.8	33.3	0.072
Female	37.5	39.1	45.3	37.5	56.3	66.7	0.071
Race/ethnicity (%):							
Whites	54.2	56.5	43.4	43.8	43.8	100	0.106
African American	25	30.4	24.5	31.3	37.5	0	0.058
Hispanic	16.7	8.7	20.8	12.5	12.5	0	0.713
Asian	4.2	4.3	7.5	12.5	6.3	0	1
Education (%):							
High school or less	50	60.9	58.5	31.3	62.5	100	0.003
College or beyond	50	34.8	37.7	68.8	37.5	0	0.215
PRA Value (%):							
Positive	37.5	34.8	39.6	25	50	66.7	0.098
Negative	54.2	56.5	56.6	75	37.5	33.3	0.13
Primary cause of ESRD(%):							
Hypertensive Nephrosclerosis	20.8	30.4	24.5	31.3	37.5	0	0.036
Diabetes Mellitus	37.5	34.8	47.2	6.3	31.3	33.3	0.002
Polycystic Kidneys	12.5	8.7	3.8	25	6.3	0	0.567
Graft Failure	16.7	4.3	9.4	0	0	0	1

Table 3: Association of registration characteristics with willingness to consent for ECD-kidneys amongst all registrant, those predicted to have lower waiting times according to associated blood types A or AB, and registrants predicted to have longer waiting times based on decreased transplantation rates with blood types O or B. Odds ratio (OR) and p-values from multivariate logistic regression model are shown.

	All registrants		**Blood type A or AB**		**Blood type O or B**	
	OR (95% CI)	p-Value	OR (95% CI)	p-Value	OR (95% CI)	p-Value
Age	1.173	0.003	1.143	0.081	1.202	0.018
Blood type:						
A or AB	Reference					
B	6.481	0.01				
O	3.825	0.002				
Sex:						
Male	0.986	0.973	1.046	0.942	0.973	0.96
Race/ethnicity:						
Whites	Reference		Reference		Reference	
African American	1.114	0.804	0.857	0.821	1.267	0.704
Hispanic	2.273	0.18	2	0.466	2.167	0.359
Asian	1.07	0.929	1	1	0.833	0.842
Education:						
High school or less	Reference		Reference		Reference	
College or beyond	0.83	0.623	1.75	0.353	0.461	0.143
PRA Value:						
Positive	1.44	0.357	1.125	0.85	1.745	0.314
Primary cause of ESRD:						
Hypertensive Nephrosclerosis	0.87	0.737	0.602	0.453	1.064	0.916
Diabetes Mellitus	2.311	0.045	1.125	0.846	6.538	0.017
Polycystic Kidneys	0.414	0.148	1.5	0.674	0.17	0.03
Graft Failure	4.393	0.167	4.4	0.201	4.80E+08	0.999
Other causes of ESRD	0.429	0.053	0.514	0.405	0.289	0.028

Patients with diabetes as primary cause of ESRD and projected longer waiting times are likely to face increased risk of death from cardiovascular incidents from prolonged dialysis (10). However, consenting for ECD kidneys increases their likelihood of transplantation and decreases time on the waiting list. As such, based on recommendations generated forth from recommended guidelines, physicians are likely to persuade their patients to consent for ECD under these scenarios(10). This is supported with the less likelihood of being ECD willing when the primary cause of ESRD was polycystic kidneys or other causes of ESRD. In these patients, they are less likely to have comorbidities and their risk of death on dialysis is decreased compared to patients with diabetes. As such, it is more beneficial for them to wait for a SCD kidney that is associated with decreased graft rejections and longer survival.

Since this was a retrospective study examining reported characteristics in the database, there were a few limitations to our study. There are many variables unaccounted for in the analysis of this study. In addition, we have no actual insight on an individual's decision to consent for an ECD kidney. The decision to accept ECD kidney is ultimately in the hands of the recipient and though we speculate physician to play a vital role in this process, it is also important to recognize the influences from their spouses and family members. Our study only provides support of ECD listing behavior at this particular transplant center that is consistent with established guidelines and recommendations for patient study characteristics that are projected to reap survival benefit from ECD transplantations. Our analysis is also not reflective of national or regional listing behaviors as we aim only to observe ECD listing patterns at this particular transplant center.

In conclusion, this study showed that projected waiting times take precedence in determining whether to consent for ECD organs. Secondary to waiting time is the severity of illness and age. We found that gender, race, or education did not impact the decision to consider ECD kidney transplantation. These findings indicate the role of physicians in identifying and advocating for patient populations that are likely to benefit from ECD transplantation as recommended by evidence based clinical outcomes. While kidney transplantation has provided a means to treat ESRD, we are still a long way from procuring transplantation as a definitive treatment for all those that requires it. The usages of ECD kidneys have provided a partial solution to the increasing demand for deceased donor kidneys. However, with its implementation also rose ethical issues given their inferiority to SCD kidneys. It is thus critical to develop allocation protocols that boast both equity amongst recipients and efficient utilization of scarce donor kidneys in a market of increased demand.

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