A Comprehensive Risk Quantification Score for Deceased Donor Kidneys: The Kidney Donor Risk Index

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Background. We propose a continuous kidney donor risk index (KDRI) for deceased donor kidneys, combining donor and transplant variables to quantify graft failure risk.

Methods. By using national data from 1995 to 2005, we analyzed 69,440 first-time, kidney-only, deceased donor adult transplants. Cox regression was used to model the risk of death or graft loss, based on donor and transplant factors, adjusting for recipient factors. The proposed KDRI includes 14 donor and transplant factors, each found to be independently associated with graft failure or death: donor age, race, history of hypertension, history of diabetes, serum creatinine, cerebrovascular cause of death, height, weight, donation after cardiac death, hepatitis C virus status, human leukocyte antigen-B and DR mismatch, cold ischemia time, and double or en bloc transplant. The KDRI reflects the rate of graft failure relative to that of a healthy 40-year-old donor.

Results. Transplants of kidneys in the highest KDRI quintile (>1.45) had an adjusted 5-year graft survival of 63%, compared with 82% and 79% in the two lowest KDRI quintiles (<0.79 and 0.79–<0.96, respectively). There is a considerable overlap in the KDRI distribution by expanded and nonexpanded criteria donor classification.

Conclusions. The graded impact of KDRI on graft outcome makes it a useful decision-making tool at the time of the deceased donor kidney offer.

Keywords: Deceased donor kidneys, Expanded criteria donors, Risk assessment modeling, Graft failure, Donor evaluation.

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The growth of the waiting list for kidney transplantation in the United States is an inevitable consequence of the increasing deficit between the number of new listings and the availability of donor organs each year. The quest to combat this problem has led to innovative solutions such as the use of the expanded criteria donor (ECD) kidneys (*1*). Deceased donor kidneys are classified as ECD if they meet either of the following conditions: (1) donor age more than or equal to 60 years or (2) donor age 50 to 59 years, with at least two of the following criteria: serum creatinine more than 1.5 mg/dL, death due to cerebrovascular accident, or history of hypertension. Kidney transplants from ECD donors have at least a 70% greater risk of graft failure than those from the lowest-risk non-ECD donors (*1*). In 2005, ECD kidneys constituted 17% of all deceased donor kidneys transplanted (*2*).

The existing ECD or non-ECD dichotomy has been useful for making decisions about accepting organ offers, counseling patients about risk, and documenting changing practices in the use of higher risk organs. Under current deceased donor kidney allocation policy in the United States, candidates are asked at the time of placement on the waiting list to specify whether they wish to receive offers of ECD kidneys. The goal of this policy has been to make kidney allocation more efficient through a reduction in the number of offers that were unlikely to be accepted.

The ECD versus non-ECD dichotomy has also permitted documentation of the substantial effects of measured differences in donor characteristics on outcomes and the recognition that these differences should be considered by doctors, patients, and policy makers. Experience with the ECD versus non-ECD classification has suggested that a more granular index of risk associated with different types of donor organs would be of value (*3–6*). To measure the spectrum of risk associated with the various factors known to influence

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graft failure, we developed a continuous kidney donor risk index (KDRI) for deceased donor kidneys using data obtained from the Scientific Registry of Transplant Recipients (SRTR). In this report, we outline the development of the KDRI, describe the proposed index, and relate it to the existing ECD definition.

METHODS

SRTR data were used for the study, including data submitted by transplant centers, organ procurement organizations, and histocompatibility laboratories to the Organ Procurement and Transplantation Network, as well as data collected by the Centers for Medicare and Medicaid Services regarding return to dialysis among transplant recipients. There were 92,102 deceased donor transplants between January 1, 1995 and December 31, 2005. By applying the exclusion criteria in sequence, we excluded recipients aged less than 18 years (3733); recipients with a previous transplant (13,122); followed by multiorgan transplant recipients (1556); ABO-incompatible patients (211); missing/invalid donor height (2481), donor weight (667), or donor creatinine (892). Therefore, the final study population consisted of n=69,440 adult (age ≥18 years) recipients of ABO-compatible primary, deceased donor, kidney-only transplants during 1995 to 2005.

Patient follow-up for graft failure started on the day of transplant. As was the case for the models used to develop the ECD definition, the outcome of interest in the current analysis was graft failure, defined as return to dialysis, retransplant, or death. Mortality information was supplemented by the Social Security Death Master File. Patients were followed up from the time of transplant until the earliest of graft failure, loss to follow-up, or the conclusion of the observation period (May 1, 2006). In total, there were 19,749 graft failure (GF) events: 11,304 returns to dialysis (57% of GF events), 179 retransplants (1% of GF events), and 8266 deaths (42%), whereas 49,691 patients (72% of total sample) had a functioning graft at end of follow-up.

Our analytic objective was to develop a continuous graft failure risk score that would capture donor and transplant characteristics. A Cox regression model was fitted to estimate the relative rate of graft failure independently associated with each donor and transplant factor, adjusted for recipient characteristics and year of transplant. Hereafter, covariate effects are described by the hazard ratio (HR), which represents the covariate-adjusted graft failure rate for the covariate of interest compared with a reference value.

The Cox model was stratified by recipient transplant center, recipient age (single year), and diabetes status, all of which are strong risk factors for death, precluding the need to prespecify the relationship of these factors (or their interaction) with graft failure rates. The variable selection for other factors used a version of stepwise variable deletion starting with every recipient and donor characteristic available in the SRTR database. All available variables potentially associated with graft failure rates were included in the initial model. Donor and transplant factors tested included donor age, race, sex, height, weight, cause of death, donation after cardiac death, serum creatinine, diabetes, hypertension, cigarette use, hepatitis C virus (HCV) positivity, pulsatile perfusion, cold ischemia time, organ sharing (local, regional, and national), human leukocyte antigen (HLA) mismatch score, year of transplant, en bloc/double transplant, and ABO compatibility. Recipient factors included age, race, sex, diagnosis, pretransplant blood transfusion, height, weight, peak panel reactive antibody level, pretransplant years of dialysis, angina pectoris, peripheral vascular disease, drug-treated chronic obstructive pulmonary disease, and HCV positivity.

Factors with nonsignificant effects were deleted from the model in sequence. The functional form of each continuous covariate was assessed by refitting the model with the continuous covariate divided into categories. We then plotted the category-specific parameter estimates against their respective category median, using the shape of the resulting plot to indicate the correct functional form. When appropriate, linear splines (straight lines of differing slopes joined at empirically determined split points) were used to approximate nonlinear effects. In cases where the functional form was too complicated to model succinctly, categories were retained. The reference values for model covariates were assigned based on the modes for categorical KDRI variables and means for continuous KDRI variables.

All analyses were performed using SAS version 9.1.3 (SAS Institute; Cary, NC). This study was approved by the Health Resources and Services Administration (HRSA) SRTR project officer. HRSA has determined that this study satisfies the criteria for the institutional review board exemption described in the "Public Benefit and Service Program" provisions of 45 Code of Federal Regulations 46.101(b)(5) and HRSA Circular 03.

RESULTS

Table 1 lists donor and transplant factors that were included in the final KDRI model. The HRs for graft failure or death are also shown compared with the reference value for each characteristic. The reference donor (KDRI=1.00) had the following characteristics: 40-year-old, non-African American race, serum creatinine 1.0 mg/dL, nonhypertensive, nondiabetic, cause of death other than cerebrovascular accident, height 170 cm, weight more than or equal to 80 kg, brain dead donor (not donation after cardiac death), and HCV negative. The reference transplant was characterized by two mismatches at the HLA-B locus and one mismatch at the HLA-DR locus and occurred after 20 hr of cold ischemia time. The HR for each factor is interpreted as "all other factors being equal," including recipient and (in particular) donor characteristics. For example, the HR for "double" compares two identical settings, except that two kidneys are transplanted, instead of one. It is quite possible that the HR for double would be in the other direction (i.e., HR >1, indicating increased risk) if no adjustment was made for other donor factors. Similar comments apply to the HR for en bloc transplant.

To compute the KDRI for a particular deceased donor kidney, start with KDRI=1.00 and then factor in each component that applies. For example, suppose the kidney in question is from a 45-year-old hypertensive male donor who weighed 65 kg, but was the same as the reference donor with respect to all other characteristics. The KDRI components that apply in this case include donor age: $1.013^{(45-40)}=1.07$, hypertension: 1.13, and donor weight: $0.98^{(65-80)/5}=1.06$. For this donor, the index is

TABLE 1. Donor and transplant factors and corresponding hazard ratios for graft failure

	Hazard ratio	95% Confidence interval	*P*
Donor parameter			
Age-40 yr; applies to all ages	1.013	1.011–1.015	<0.0001
Age-18 yr; applies only if age <18	0.98	0.97–0.99	0.0033
Age-50 yr; applies only if age >50	1.011	1.005–1.016	0.0001
African American race	1.20	1.13–1.27	<0.0001
Serum creatinine-1; applies to all Cr values	1.25	1.17–1.33	<0.0001
Serum creatinine-1.5; applies if Cr >1.5	0.81	0.74–0.89	<0.0001
Hypertensive	1.13	1.08–1.19	<0.0001
Diabetic	1.14	1.04–1.24	0.0040
Cause of death: cerebrovascular accident	1.09	1.04–1.14	0.0002
Height: per 10 cm increase	0.96	0.94–0.97	<0.0001
Weight: per 5 kg increase below 80 kg	0.98	0.97–0.99	0.0003
Donation after cardiac death	1.14	1.02–1.28	0.0246
HCV positive	1.27	1.13–1.43	<0.0001
Transplant parameter			
HLA mismatch			
0 HLA-B mismatch (ref=2 B MM)	0.93	0.87–0.98	0.0111
1 HLA-B mismatch	0.94	0.90–0.98	0.0065
0 HLA-DR mismatch (ref=1 DR MM)	0.88	0.84–0.92	<0.0001
2 HLA-DR mismatch	1.08	1.03–1.13	0.0014
Cold ischemia time: per 1 hr (ref=20 hr)	1.005	1.003–1.008	<0.0001
En bloc transplant	0.70	0.57–0.84	0.0002
Double kidney transplant	0.86	0.75–1.00	0.0494

HLA, human leukocyte antigen; Cr, creatinine; HCV, hepatitis C virus.

computed as KDRI=1.07×1.13×1.06=1.28, meaning that this organ confers an estimated graft failure risk 28% greater than the reference donor. Note that the donor's sex (male) does not factor into the KDRI computation. Other examples of KDRI calculations are given in Table 2.

The distribution of calculated KDRI values is shown in Figure 1. Although the lowest possible KDRI is 0, the minimum KDRI computed in our data set was approximately 0.5. The maximum observed KDRI was 4.2, although larger KDRI values are possible. The median KDRI was 1.05. Therefore, the KDRI can be interpreted as a measure of relative graft failure rates compared with the median donor, which has a relative failure rate of approximately 1.

TABLE 2. Calculating KDRI: examples

Donor factor	Reference donor	Example 1	Example 2	Example 3
Age (yr)	40	21	45	65
Race	Non-Black	Non-Black	Non-Black	Non-Black
Hypertensive	No	No	No	No
Diabetic	No	No	No	No
Serum creatinine (mg/dL)	1.0	1.0	1.0	1.0
Cause of death	Nonstroke	Nonstroke	Nonstroke	Nonstroke
Height (cm)	170	183	183	183
Weight (kg)	80	80	80	80
Donation after cardiac death	No	No	No	No
Hepatitis C	No	No	No	No
Number of B mismatch	2	2	2	0
Number of DR mismatch	1	2	2	0
Cold time (hr)	20	18	18	18
Enbloc kidney transplant	No	No	No	No
Double kidney transplant	No	No	No	No
KDRI	1.00	0.79	1.07	1.22

KDRI=Exp(−0.0194×I [age <18 yr]×[age−18 yr]+0.0128×[age−40 yr] + 0.0107×I [age >50 yr]×[age−50 yr]+0.179×I [race=African American]+ 0.126×I [hypertensive]+0.130×I [diabetic]+0.220×[serum creatinine−1 mg/dL]−0.209×I [serum creatinine >1.5 mg/dL]×[serum creatinine−1.5 mg/dL]+0.0881×I [cause of death=cerebrovascular accident]−0.0464×[{height−170cm}/10]−0.0199×I [weight<80kg]×[{weight−80kg}/5]+0.133×I [donation after cardiac death] +0.240×I [hepatitis C positive]−0.0766×I [HLA-B mismatch=0]−0.0610× I [HLA-B mismatch=1]−0.130×I [HLA-DR mismatch=0]+0.0765×I [HLA-DR mismatch=2]+0.00548×[cold ischemia time−20 hr]−0.364×I[en bloc transplant]−0.148×I [double kidney transplant]), where I (A) is set to 1 if condition A is applies to the donor kidney of interest (i.e., if the donor kidney of interest possesses condition A), and otherwise it is set to 0.

KDRI, kidney donor risk index.

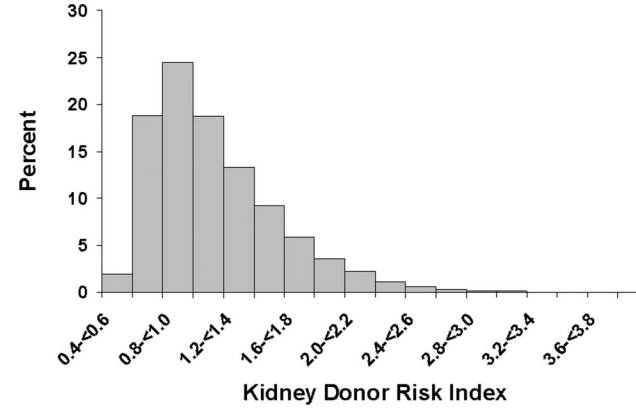

FIGURE 1. Histogram of kidney donor risk index.

Covariate-adjusted graft survival curves are presented in Figure 2 by KDRI quintile, adjusted to a reference 50-year-old, nondiabetic recipient. The decreasing trend in graft survival with increasing KDRI is apparent. Median graft survival

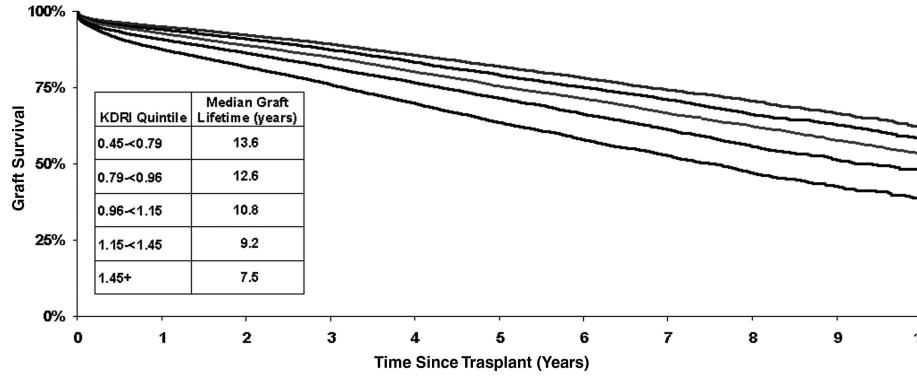

FIGURE 2. Adjusted* graft survival by kidney donor risk index (KDRI) quintile. The curves are ordered, top to bottom, as quintile 1, quintile 2, …, quintile 5. Each survival pertains to a recipient who is aged 50 years, nondiabetic, and at the reference level of all other recipient factors. Extrapolation was used for the first and second quintile. *Adjusted to a reference 50-year-old recipient.

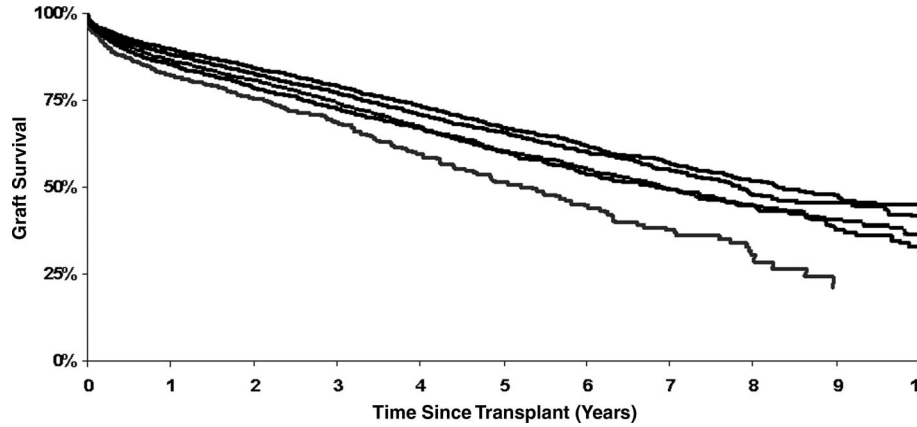

FIGURE 3. Adjusted* graft survival by kidney donor risk index (KDRI) percentile (Top Quintile only: KDRI ≥1.45). The curves are ordered, top to bottom, as: more than first percentile, more than first to less than or equal to fifth percentile, more than fifth to less than or equal to 10th percentile, more than 10th to less than or equal to 15th percentile, more than 15th to less than or equal to 20th percentile. Each survival pertains to a recipient who is aged 50 years, nondiabetic, and at the reference level of all other recipient factors. *Adjusted to a reference 50-year-old recipient.

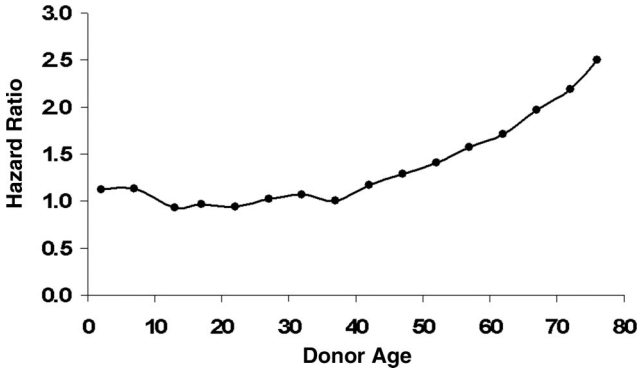

FIGURE 4. Relationship between donor age and graft survival. Based on a model that coded donor age as a categorical covariate (5-year age groups).

time (i.e., graft half-life) is presented by KDRI quintile, the estimates having been derived from the survival curves. For the first and second quintiles, observed graft survival probability did not reach 0.5, so for these quintiles the median was estimated by extrapolation, assuming that the death rate after 10 years was equal to the average death rate observed over follow-up years 7.5 to 10. In Figure 3, we plot covariate-adjusted survival within the top KDRI quintile only (KDRI ≥1.45). For kidneys within the top 1% of the KDRI distribution, 5-year graft survival was approximately 50%, compared with 67% for kidneys in the top 15% to 20%.

We compared the calculated KDRI with the ECD designation for each donor kidney. Donor age is a strong risk factor for graft failure and is categorized at ages 50 and 60 years for the ECD definition. Figure 4 is based on a model that was used to determine the nature of the relationship between donor age and graft failure rate with age-specific HR estimates plotted versus median age in each 5-year age interval. As evidenced by the plot, the HR for graft failure risk is approximately equal among all pediatric donors (age <18 years), but increases steadily with age among adult donors (age ≥18 years).

Because the KDRI considers many factors beyond those included in the ECD designation, the ECD versus non-ECD dichotomy does not correspond to a sharp cut point on the KDRI scale. In Figure 5, we plot the percentage ECD (non-ECD) by KDRI category. As would be expected, the percent ECD increases monotonically as KDRI increases. For KDRI less than 1.0, almost 0% of kidneys are ECD, whereas approximately 2% of kidneys are ECD for KDRI 1.0 to 1.2. Among kidneys with KDRI 1.4 to 1.6, 40% are ECD, whereas 63% of kidneys with KDRI 1.6 to 1.8 are ECD. In our study sample, all kidneys with KDRI more than 3 met the ECD criteria.

To further compare ECD and KDRI, we categorized the donor kidneys in the data used for analysis as being either at or below the 85th percentile of KDRI or above it, to identify the 15% highest risk donors by KDRI. The 15% cutoff was chosen because approximately 15% of transplanted deceased donor kidneys meet the ECD definition. If the two measures agreed completely, then all of the non-ECD kidneys would have KDRI at or below the 85th percentile and none would have

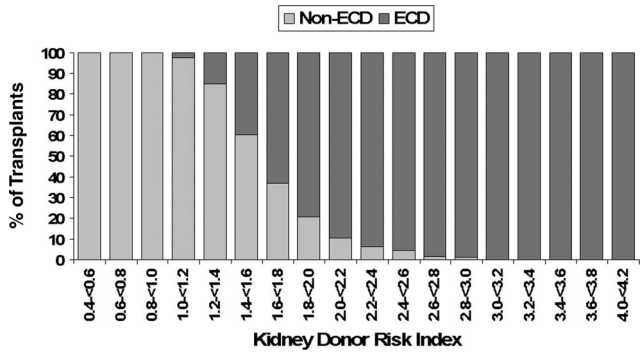

FIGURE 5. Expanded criteria donor (ECD) status by kidney donor risk index (KDRI) category. Percentages of patients in ECD and non-ECD groups, by KDRI level.

a KDRI above it; correspondingly, all ECD kidneys would have KDRI greater than the 85th percentile and none at or below. However, in fact, 32.8% of ECD kidneys had KDRI less than or equal to the 85th percentile, whereas 4.6% of non-ECD kidneys had KDRI above the 85th percentile.

Through cross-validation, we evaluated the discriminatory power of the Cox model on which the KDRI is based. We randomly split the data set five times. For each split, we fitted the model to one half of the data and computed the C statistic (i.e., index of concordance) for the other half. The C statistic considers all pairs of patients for which the ordering of the failure times is known. Specifically, C equals the fraction of times the ordering of the failure times is consistent with the ordering of the HRs. The average C statistic across the five splits was 0.62, indicating reasonable discriminatory power. Note that the C-statistic was 0.78 when based on comparing pairs of donors: one from the highest and one from the lowest quartile of KDRI. For pairs restricted to the middle two quartiles, the C-statistic was only 0.58. These last two results suggest that the KDRI is more useful for distinguishing more extreme categories of graft failure risk and of less utility for distinguishing donors from the middle ranges.

DISCUSSION

Accurate assessment of the relative risk of graft failure associated with various combinations of donor characteristics is an essential prerequisite for counseling patients, making decisions to accept kidney transplant offers, evaluating programs, and developing allocation policy. The relentless increase in the size of the kidney transplant waiting list magnifies the importance of each of these tasks. The KDRI is an easily calculated and comprehensive metric, which can be used for many of these purposes. In our analysis using national data, 10 donor and four transplant characteristics have been identified as significantly and independently associated with increased risk of failure of deceased donor kidney transplants. The prediction equation developed with these parameters offers a powerful tool for transplant physicians and candidates to assess their options when a deceased donor kidney becomes available. For incorporation into organ allocation algorithms, a reduced 13-factor KDRI that uses only donor factors and those transplant factors that are known at the time of organ offer (i.e., all except cold ischemia time) may be more appropriate, whereas for decision making regarding the acceptance of organ offers, the full 14-factor KDRI (with an estimated cold ischemia time) may be used.

The KDRI represents a substantial improvement in granularity and interpretability relative to the less accurate ECD versus non-ECD classification. Figure 5 shows that there is a considerable overlap in the KDRI distribution between non-ECD and ECD categories. Some non-ECD kidneys, in fact, have a KDRI greater than 2.0. Baskin-Bey et al. (*7*) noted similar findings in their study of deceased donors when they applied their version of a deceased donor score; 10.7% of donor kidneys predicted by their score to have worse post-transplant graft survival rates were not defined as ECD. The improved precision of the KDRI, especially among higher risk donors, is important because the percentage of older deceased donors and donors with hypertension (which increases the KDRI, but does not by itself confer ECD status) has increased over the years.

In the KDRI, higher donor age, beginning at age 18 years, was associated with a significant 1% additional risk of graft failure per year. This is important, given that the percentage of transplanted kidneys from deceased donors older than 50 years has increased from 22.1% in 1995 to 28.4% in 2005. The poorer long-term outcome of transplants of kidneys from older donors (>60 years) is well recognized (*8*, *9*). Among other donor factors, hypertension and diabetes were associated with significantly higher risks of graft failure of 13% and 14%, respectively. The increasing incidence of deceased donors with hypertension over the last decade (15.5% to 24.4%) attests to the importance of this factor.

Several transplant-related characteristics also affected graft survival. Fewer mismatches at either the HLA-B or the HLA-DR loci conferred a more favorable outcome. However, no additional benefit of zero HLA-ABDR mismatch was observed, over and above the individual effects of zero mismatch at HLA-B and HLA-DR. Despite the trend away from HLA matching as a criterion in allocation, risk assessment using these parameters is still relevant (*10*, *11*). In addition, cold ischemia time and use of the donor kidneys as double or en bloc transplants were significant determinants of graft survival. Although these transplant-related covariates cannot be considered when assessing generic donor quality, they can be included in the KDRI equation when considering a given donor kidney in an individual candidate using estimated cold ischemia time.

A few previous studies have quantified graft failure risk, with the aim of improving on the ECD versus non-ECD dichotomization. For example, Nyberg et al. (*4*) used seven donor variables to generate a donor score card, with the score ranging from 0 to 39 points. Schold et al. (*6*) used standard regression techniques to identify significant risk factors and cluster analysis to define five natural subgroups of the risk score. The model, adjusted for several recipient characteristics, showed a stepwise increase in the risk for graft loss, ranging from an increased risk of 18% for a grade 2 donor to 289% for a grade 5 donor, each compared with a grade 1 donor (*6*). The proposed continuous KDRI improves on each of these risk scores by avoiding the use of arbitrary categories and considering more donor and transplant factors.

When kidney transplant recipients were stratified by KDRI quintile, there was a monotonic "dose effect" in terms of graft survival (i.e., a higher KDRI was associated with worse

outcome) in both adjusted and unadjusted (not shown) analyses. Viewed in terms of median lifetime of the graft, the kidneys in the highest KDRI quintile (>1.45) was 7.5 years compared with 13.6 years for those in the lowest quintile (0.45 to <0.79). It is also noteworthy that the differences in long-term survival between quintiles were proportionately worse for the two highest KDRI quintiles. In addition to other short-term endpoints such as delayed graft function and hospital stay, similar long-term predictions of graft survival have been observed by Baskin-Bey et al. (*7*) using a score card to classify deceased donor kidneys.

The KDRI may be used in deceased donor kidney allocation in several ways, the simplest of which is communication of the donor-specific KDRI (i.e., the equation containing only the nine donor variables) at the time of organ offer and evaluation. For individual candidates, considerations of matching, projected cold ischemia, and dual or en bloc kidney transplant may be incorporated to more precisely define the donor risk. These distinct but related applications would not necessarily require different equations, because the graft survival model is the same; but they would require that the transplant-related factors be set to a default value (e.g., two mismatches at HLA-B and one at the HLA-DR loci, single kidney, 20 hr cold ischemia time) when calculating the donor-specific KDRI. The KDRI may also be used to calculate projected patient survival with and without transplant, or life years from transplant (LYFT), for each individual candidate on the match run. These calculations could also be communicated at the time of offer. Except for the degree of HLA matching, donor covariates do not generally influence the relative order of candidates with respect to LYFT. Therefore, the KDRI would not greatly influence the component of the allocation algorithms that uses LYFT calculations, but would be available to the clinician to assist in evaluating the offer.

Ideally, providers and patients should prospectively evaluate the risks and benefits of different types of kidneys, and candidates should predetermine the maximum degree of risk they are willing to accept from a donor kidney along a spectrum, with graft survival and LYFT estimates available for their consideration. Theoretically, the tradeoff for being willing to accept a higher risk kidney would be a greater likelihood of transplant and a shorter time to transplant. In such a system, as with the ECD system, the decisions of others would influence the expected waiting times, and, therefore, outcomes for other candidates. Hence, these estimates would not be static. Although such a system would be expected to enhance allocation efficiency, it would also require increased sophistication and attention among providers and candidates to interpret the additional information. Furthermore, additional communications and education resources at the center, organ procurement organization, and national levels might be required.

Our study is subject to the limitations associated with all observational studies. The relationships reported here between donor characteristics and failure rates do not imply that those factors cause differences in failure rates. However, our results reported do provide a description of failure rates among different types of donors. It is likely that various recipient and donor characteristics were measured with error, which can reduce the range of the estimated KDRI compared with its true range. However, the strongest risk factor, donor age, is likely to be measured with little error. There may be other unmeasured donor factors that would further improve the KDRI equation presented here. If practice were to change by accepting more high risk organs with such unmeasured high risk factors, then the KDRI reported here would underestimate the risk of using such organs. As more high risk organs are procured and used, the estimated outcomes with such organs will become more precise.

In summary, the KDRI is a useful tool that, by assessing multiple donor and transplant characteristics, calculates the profile of a renal graft and provides an estimate of posttransplant outcome. The inclusion of various significant characteristics that influence graft outcome into one metric confers major advantages over the current ECD versus non-ECD classification. The KDRI provides an additional useful tool to physicians and patients to assist them in making informed decisions about donor organ offers.

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