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Preoperative Risk Assessment of Early Kidney Graft Loss

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Background. A large proportion of potential organ donors are not utilized for kidney transplantation out of risk of early allograft loss because of donor-related characteristics. These can be summarized using kidney donor profile index (KDPI). Because KDPI affects the choice of the recipient, the predictive ability of KDPI is tied to recipient attributes. These have been questioned to explain most of the predictive ability of KDPI. This study aims to quantify the effect of the donor on early graft loss (EGL) by accounting for nonrandom allocation. **Methods.** This study included patients undergoing kidney transplantation from deceased donors between 2014 and 2020 from the Scientific Registry of Transplantation Recipients. EGL, defined as a return to dialysis or retransplantation during the first posttransplant year, was the primary endpoint. Nonrandom allocation and donor–recipient matching by KDPI necessitated the use of inverse probability treatment weighting, which served to assess the effect of KDPI and mitigate selection bias in a weighted Cox regression model. **Results.** The study comprised 89 290 transplantations in 88 720 individual patients. Inverse probability treatment weighting resulted in a good balance of recipient covariates across values of continuous KDPI. Weighted analysis showed KDPI to be a significant predictor for short-term outcomes. A comparable (in terms of age, time on dialysis, previous transplants, gender, diabetes status, computed panel-reactive antibodies, and HLA mismatches) average recipient, receiving a kidney from a donor with KDPI 40–60 had a 3.5% risk of EGL increased to a risk of 7.5% if received a kidney from a KDPI >95 donor (hazard ratio, 2.3; 95% confidence interval, 1.9-2.7). However, for all-cause survival KDPI was less influential. **Conclusions.** The predictive ability of KDPI does not stem from recipient confounding alone. In this large sample-sized study, modeling methods accounting for nonindependence of recipient selection verify graft quality to effectively predict short-term transplantation outcomes.

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Organ allocation remains a challenge for transplantation worldwide. In the United States, the introduction of the Kidney Allocation System in 2014—while aiming to improve allocation—failed to improve kidney-nonuse rates.[1,2]

The kidney donor profile index (KDPI), introduced together with Kidney Allocation System, provided clinicians with a tool to assess kidney allograft quality on a continuous scale. The loss of viable grafts remains a concern because two-thirds of the grafts with a KDPI score of 85 or more are not utilized.[3] This high nonuse rate is in direct contrast to the good outcomes published even with these high KDPI kidneys.[4]

The predictive power of KDPI is suboptimal, with c-statistics for long-term graft survival ranging from 0.56 to 0.64,[5,6] and an even more limited predictive ability for early graft loss (EGL). Matching methods and paired kidney analyses claim the effect of KDPI on EGL as being almost negligible.[7-9] Considering the nonrandom allocation of usually transplanting the frailest kidneys to the frailest recipients, some articles

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V.E., I.H., and V.S. participated in the research design. V.E. and I.H. participated in data analysis. V.E., I.H., V.S., J.S., and G.L. participated in the interpretation of the data. G.L. and J.S. contributed to the statistical methods and provided insight into the allocation system. All authors participated in the writing of the article, revised it critically, and approved the final article.

The data that support the findings of this study are available from the Scientific Registry of Transplant Recipients. Restrictions according to the Data Use Agreement apply to the availability of these data, which were used under license for the current study and therefore are not publicly available from the authors.

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TABLE 1.

Characteristics of analyzed kidney transplantations between January 1, 2014 and September 2, 2020

Variable	Median (interquartile range) or n (%); N = 89 290
Kidney donor profile index	47 (26–68)
Kidney donor risk index	1.15 (0.95–1.44)
Donor sex, male	54 975 (61.6)
Donor age, y	39 (27–51)
Donor BMI, kg/m^2	27.0 (23.3–31.8)
Donor hypertension	24 750 (28.0)
Donor diabetes	6541 (7.4)
Donor cause of death	
Anoxia	37 953 (42.5)
Stroke	21 686 (24.3)
Trauma	26 479 (30.0)
Tumor	321 (0.4)
Other	2581 (2.9)
Donor creatinine, mg/dL	0.93 (0.7–1.4)
Donor HCV positive	5471 (6.4)
DCD donor	19 770 (22.1)
Cold ischemia time, h	16.9 (11.3–22.6)
Recipient age, y	55 (44–64)
Recipient sex, male	53 694 (60.1)
Recipient time in dialysis, y	3.8 (1.5–6.2)
Recipient dialyzed before transplantation	80 678 (90.4)
Retransplantation	11 084 (12.4)
HLA mismatches	4 (3–5)
Recipient calculated panel-reactive antibodies, proportion	0 (0–0.5)
Recipient indication for transplantation[a]	
Diabetes	26 156 (31.4)
Glomerulonephritis	15 148 (18.2)
PKD	6709 (7.5)
Other	35 257 (42.3)
Recipient hypertension[b]	31 487 (35.3)
Recipient diabetes	32 876 (36.8)
Recipient BMI, kg/m^{2c}	28.0 (24.2–32.1)
Recipient DGF[d]	25 950 (29.1)

[a]Missing variables only for 6020 (6.7%) transplantations.
[b]Missing variables only for 204 (0.2%) transplantations.
[c]Missing variables only for 705 (0.8%) transplantations.
[d]Missing variables only for 2 (0.0%) transplantations.
BMI, body mass index; DCD, donation after circulatory death; DGF, delayed graft function; HCV, hepatitis C-virus; PCKD, polycystic kidney disease.

suggest that the predictive ability of KDPI is mainly explained by the recipient characteristics,[6] thus regarding KDPI as inconsequential.[7] KDPI remains, however, the main predictor for kidney nonutilization.[10]

One-year kidney transplant results excel, but a slight chance of EGL or death persists. This study aimed to quantify the actual risk for EGL or death with different KDPI donors in the hope of reducing organ-nonuse rates and the allocation process's length. Because most nonusage remains among high KDPI donors, propensity scoring this donor group compared with standard donors can help assess transplantation risks.

MATERIALS AND METHODS

Data

This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network. The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight to the activities of the Organ Procurement and Transplantation Network and SRTR contractors.

This study comprised all kidney transplantations recorded in the SRTR database in the United States between January 2014 and September 2020. A 1-y follow-up was recovered for all kidneys. Living donors were excluded.

The Institutional Review Board of Helsinki University Hospital (HUS/459/2018) and SRTR approved this study. The clinical and research activities in this study are consistent with the Principles of the Declaration of Istanbul as outlined in the "Declaration of Istanbul on Organ Trafficking and Transplant Tourism" and the Declaration of Helsinki.

Variables and Predictors

The collected data from SRTR included donor KDPI, which considers donor age, height, weight, creatinine, race, cause of death, history of hypertension, diabetes, hepatitis C, and donation after circulatory death status (Table 1). Transplantation and recipient-related factors considered for confounding included recipient age, gender, earlier transplantations, cause of end-stage kidney disease, time on dialysis before transplantation, body mass index, history of hypertension, HLA mismatches, calculated panel-reactive antibodies, graft cold ischemia time, and organ location. Kidney donor risk index (KDRI) was analyzed separately in supplemental analyses in place of KDPI because KDRI is used to calculate KDPI.

Expert opinions and reviews of predictors of graft outcome served to choose the predictors for analysis (**Figure S1, SDC**, http://links.lww.com/TXD/A652).[11,12]

Endpoints and Outcomes

EGL, in which graft failure, defined as retransplantation or return to dialysis during the first posttransplant year (early allograft failure or primary nonfunction), served as the primary-dependent outcome measure. Considering that transplantation increases the risk of death in the immediate posttransplant period and the patient dying practically constitutes a transplant failure, we augmented a secondary-dependent outcome measure of graft failure or death (all-cause graft failure) during the first posttransplant year.

Statistical Analysis

Cohort demographics present as the median and interquartile range for continuous variables and frequencies with percentages for categorical variables. Cases with missing variables were few (2.1%, Figure 1) allowing complete case analysis. Patients were censored as alive with a functioning graft at the time of center reporting for lost to follow up. Cluster-robust standard errors accounted for the correlation between kidneys donated by the same donor.

A directed acyclic graph is used to present the assumed predictors for the analysis. The directed acyclic graph (**Figure S1, SDC**, http://links.lww.com/TXD/A652) is a theory of factors affecting the analysis, deriving from expert analysis of our team and recent literature, which is statistically the preferred method of variable selection for an understood phenomenon.

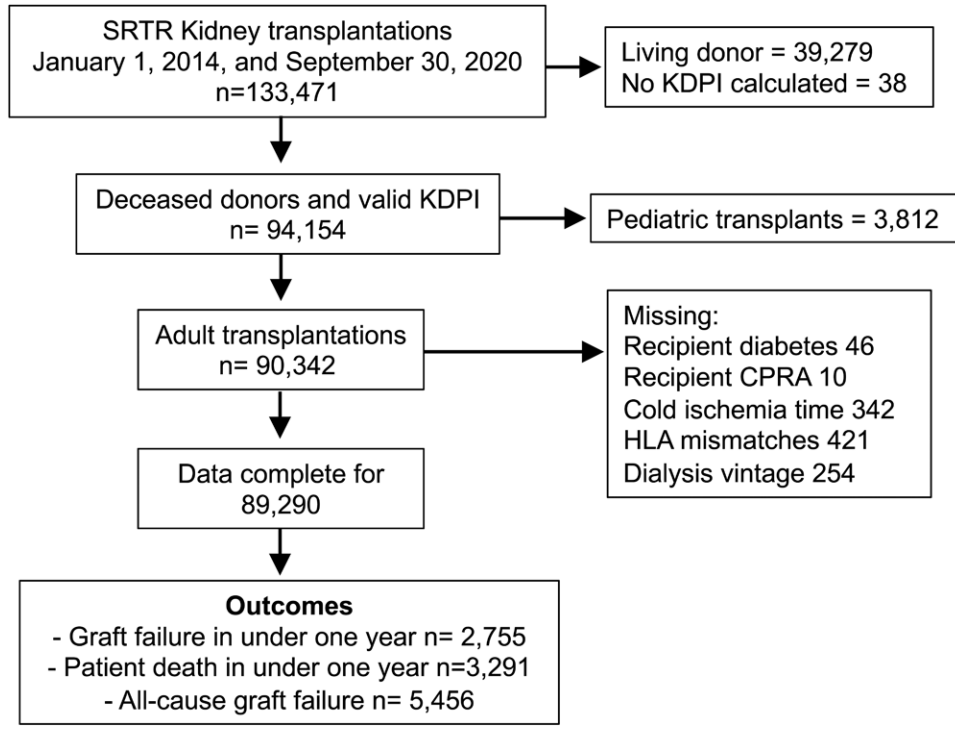

FIGURE 1. Flow chart of study inclusion and analyzed cases. Missing values of predictors and excluded cases on the right. CPRA, computed panel-reactive antibodies; KDPI, kidney donor profile index; SRTR, Scientific Registry of Transplant Recipients.

These predictors were used for weighting cases with regard to KDPI to simulate randomization of recovered kidneys at each KDPI to a representative sample of recipients. Restricted cubic splines implemented into Cox regression multivariable models served to analyze the nonlinearity of the predictors. Schoenfeld residuals served to assess the proportional hazards assumption.

The significance level was set at 5%, and analyses were carried out as two-tailed. All analyses were carried out using R software, including survival, rms, MatchIt, WeightIt, marginaleffects, cobalt, and survminer packages (R Foundation for Statistical Computing, Vienna, Austria).

Weighting for a Continuous Treatment

To account for the continuous nature of KDPI, inverse probability treatment weighting weighted all cases, regarding KDPI as a continuous treatment. Recipient age, time on dialysis, previous transplants, gender, diabetes status, CPRA, and HLA mismatches were balanced with propensity scoring using the WeightIt package, assuming a normal distribution of KDPI. Heatmaps accounted for the assessment of violations of positivity (Figure 2). Performance of the weights (balancing) was assessed numerically and graphically.

Estimating the Average Dose–Response Function

The weighted Cox regression models were displayed graphically to estimate the average dose–response function. This function connects the value of KDPI to the expected outcome across the range of KDPI. Marginal hazard ratios (HRs) were compared between nonweighted and weighted models to visualize the effect of the selection bias of allocation. Conditional HRs were plotted for realization of the outcome for different patient groups.

Matching Analysis

To validate propensity scoring with a continuous treatment, a matching analysis was conducted. Propensity score matching was used to estimate the average marginal effect of the treatment on transplantations from donors with KDPI ≥95 compared with transplantations from donors with KDPI 40–60, which accounts for confounding by the included covariates related to nonrandom donor–recipient allocation. Matching method was nearest-neighbor. Cox regression was used to estimate the effect of >95 KDPI kidney transplant on 1-y graft loss. Nonmatched transplants are not used in 1:1 nearest-neighbor matching.

RESULTS

Complete data were available for 89290 adult transplant recipients (Figure 1). The primary outcome of EGL occurred in 2755 (3.1%), more prevalently in high KDPI transplantations (Figures 2 and 3; **Figure S2, SDC**, http://links.lww.com/TXD/A652). Early death occurred after 3291 transplantations (3.7%) (**Figures S3 and S4, SDC**, http://links.lww.com/TXD/A652). Either outcome of all-cause graft failure befell 5456 (6.1%) patients.

Weighting for the Continuous Treatment of KDPI

Need for balancing presented most evident for recipient age (Figure 4). Inverse probability treatment weighting adequately balanced all covariates and their interactions with correlations to treatment of <0.1 (Figure 5; **Figure S5, SDC**, http://links.lww.com/TXD/A652). Weights settled between

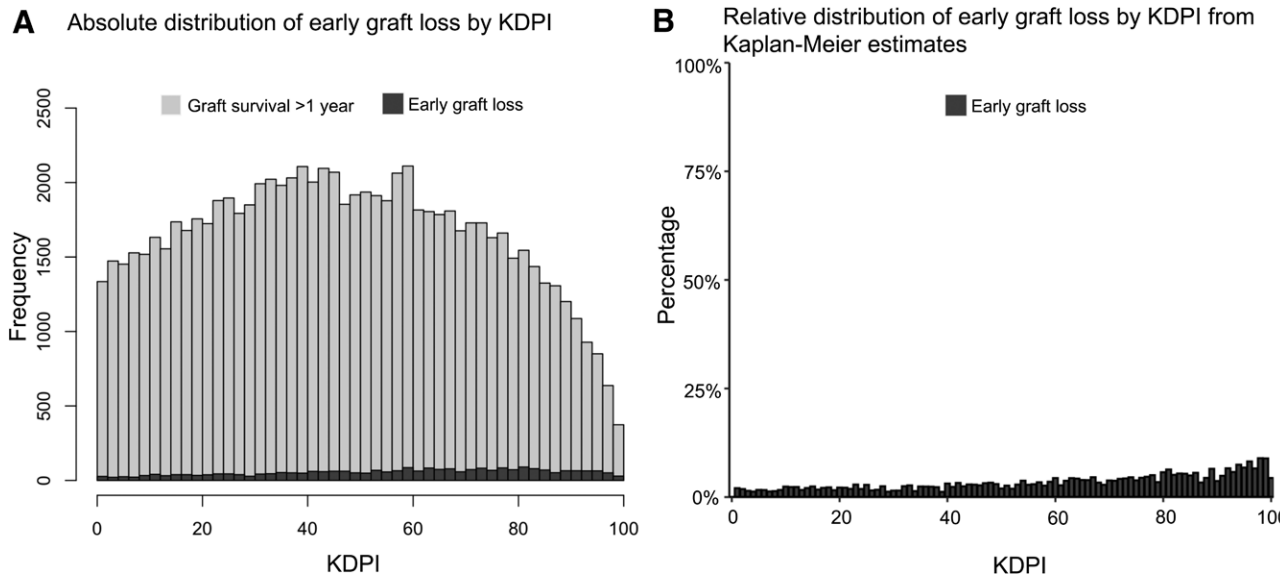

FIGURE 2. Frequency and distribution by KDPI (A) and the relative incidence of early graft loss inside a KDPI group (B). Censored patients with a follow-up or death under 1-y posttransplantation are excluded in (A). The incidence of early graft loss is slightly higher among higher KDPI transplantations. KDPI, kidney donor profile index.

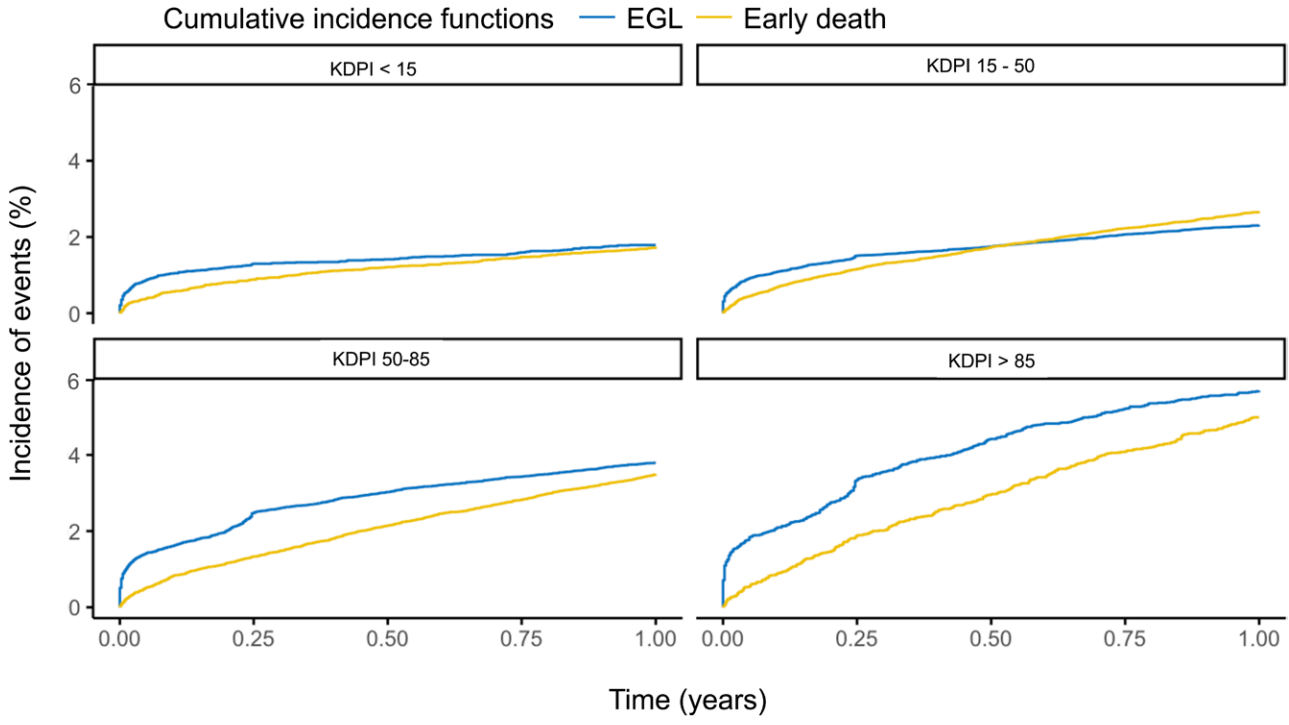

FIGURE 3. Cumulative incidence functions in competing risk analysis of early graft loss and death in the cohort by quintiles of KDPI. Higher KDPI transplantations were at higher risk of both early graft loss and death. EGL, early graft loss; KDPI, kidney donor profile index.

0.11 and 18.9. Utilizing inverse probability treatment weighting and thus simulating randomization of a similar recipient with different KDPI kidneys, the magnitude of the significant association in Cox regression analyses remained approximately the same between nonweighted and weighted models (Figure 6). For various patient groups, the conditional HRs are plotted in Figure 7. Retransplantation and high CPRA associated with a higher hazard for EGL in high KDPI transplantations.

When all-cause graft failure was chosen as the outcome, KDPI presented less influential (**Supplemental Analysis 1, SDC**, http://links.lww.com/TXD/A652). Increased hazard of graft loss was increased with KDPI starting around KDPI 70 but was relatively stable across donors with KDPI under 70 (Figure 8).

Matching Analysis

In the matching analysis, transplantations with KDPI ≥95 kidneys were matched with transplantations with an average KDPI 40–60 kidney, thus dichotomizing KDPI as a treatment compared with treating it as a continuous factor in the main analysis. The balancing of matched groups

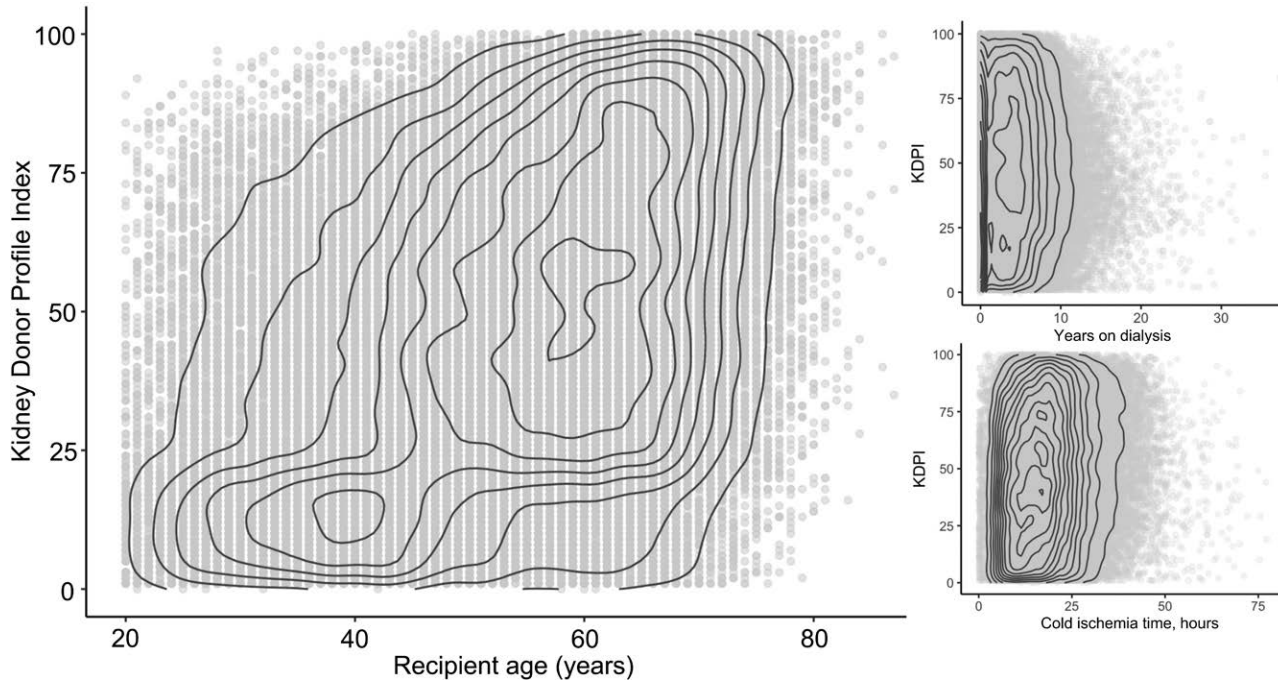

FIGURE 4. Heatmap of kidneys with certain KDPI pooling into certain recipient age groups, by years in dialysis, and by cold ischemia time. The effect of nonrandom allocation is most pronounced for recipient age. Dialysis vintage and cold ischemia time balanced better among different KDPI transplantations. KDPI, kidney donor profile index.

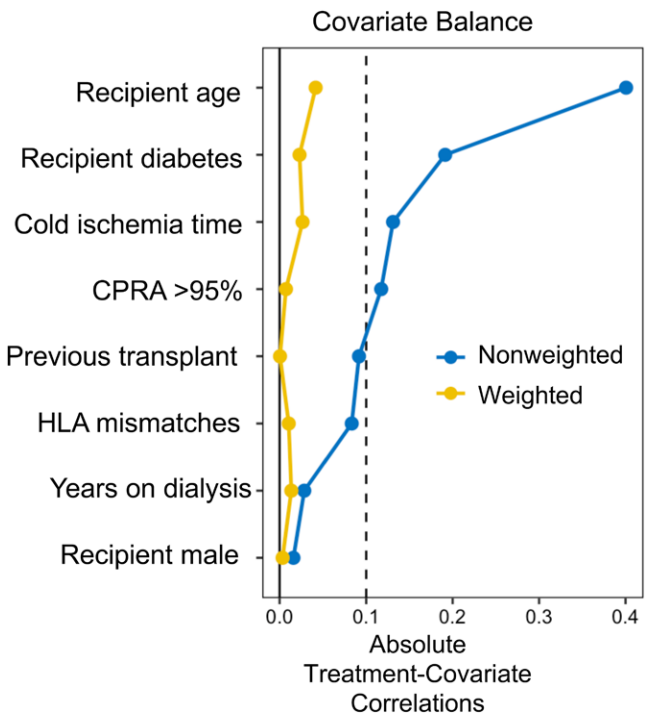

FIGURE 5. Balancing of covariates across KDPI in nonweighted and weighted analyses after inverse probability treatment weighting. Treatment correlations were low indicating adequate balancing. CPRA, computed panel-reactive antibodies; KDPI, kidney donor profile index.

was ideal (**Supplemental Analysis 2, SDC**, http://links.lww.com/TXD/A652). In this simplified propensity score analysis, a comparable recipient was exposed to a risk decrease of EGL from 7.5% to 3.5% when a marginal kidney was substituted for an average kidney (Table 2). For early death, however, effect of substitution between KDPI groups was minor (Table 2).

Supplemental Analysis

In Supplemental Analysis 3 (**SDC**, http://links.lww.com/TXD/A652), KDRI was used in place of KDPI as the treatment, with no notable differences.

DISCUSSION

The significance of allograft quality, or KDPI, has been questioned in studies arguing of KDPI's very low correlation with outcomes in propensity scoring models,[8] low or no correlation with EGL[7] and arguing that the main predictive effects of KDRI/KDPI could be explained simply by the recipient factors resulting from the nonrandom donor–recipient allocation.[6] Our results underline the importance of allograft quality and suggest caution in neglecting it.

Although sometimes higher KDPI organs are chosen for recipients with a greater ability to tolerate the suboptimal graft, the relative rarity of this occurrence enabled our analysis because these transplantations can receive more weight. KDPI clearly was associated with the risk of EGL in nonweighted and weighted analyses. The nonrandom allocation of the frailest kidneys to the frailest recipients does not seem to explain the full effect of KDPI on transplant outcomes.

When accepting a kidney offer from a deceased donor, a physician generally judges the donor and recipient as a pair. The current prediction models of graft outcome at the time of transplantation, however, have been criticized for being inaccurate and biased to disregard competing risks and the effect of allocation policy between donor and recipients.[6,13] KDPI utilization, while designed to counteract the nonuse of higher-risk transplants, has caused concern on the labeling effect of "high-KDPI" kidneys which are often at risk of nonuse.[10]

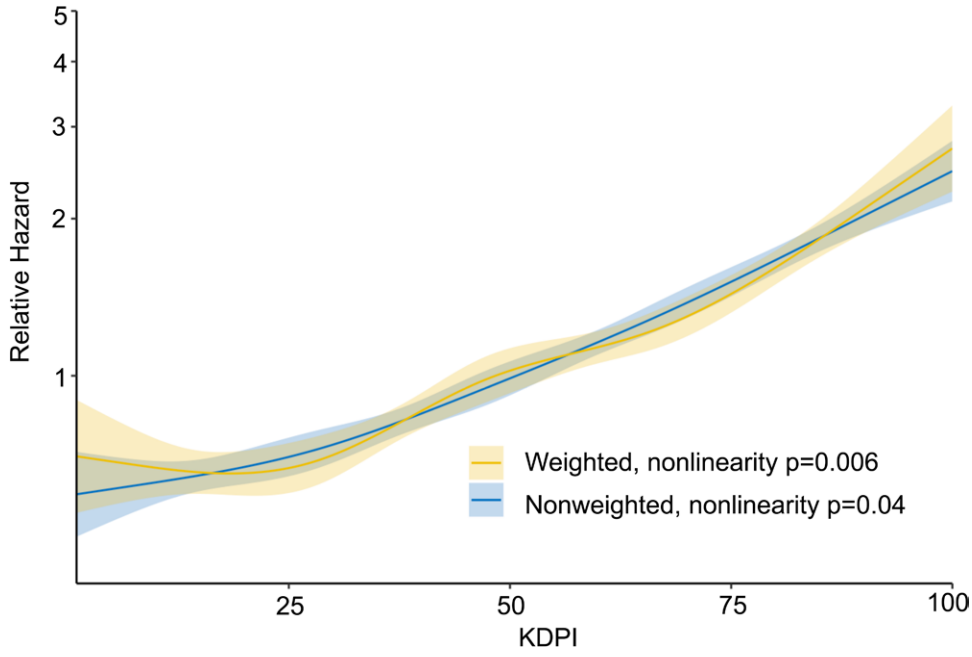

FIGURE 6. Nonweighted and weighted splined association of KDPI on early kidney graft loss from a Cox regression model. Weighting did not influence association between KDPI and early graft loss. KDPI, kidney donor profile index.

High KDPI, long cold ischemia time, high creatinine level, and unfavorable biopsy results can all lead to organ nonutilization. Still, their clinical usefulness in guiding organ acceptance is questionable because their predictive power for graft outcome is weak.[10,14-17] As an explanation, complications such as graft thrombosis, hemorrhage, and acute rejection cause most of the EGLs, and their risk is difficult to evaluate. In terms of prediction modeling for graft survival, the best c-statistics are 0.82–0.85 of the iBox-score, which considers only posttransplantation variables.[18] This score, omitting donor variables altogether as having no additional value, reflects the difficulty of predicting graft survival before transplantation. This study supports continuing the utilization of KDPI for assessing an organ offer with a high KDPI, especially for patients with very high cPRA, long time in dialysis, or retransplantation. However, the analysis accounting for also death 1-y posttransplantation assures us of the limited influence of KDPI on combined graft loss or death.

Because KDPI mainly derives from donor age, kidneys from older donors seem to function acceptably, although nephron loss with age is indisputable. Thus, KDPI shows surprisingly little concordance with graft failure. In terms of average survival, transplanting early seems beneficial compared with waiting on dialysis—even with an "inferior" graft.[2,19-24] A consensus exists on risk–benefit for transplantation 1 y after the operation for all KDPI groups, although, for high KDPI recipients with diabetes, this is controversial.[25,26] In our study, diabetes of the recipient correlated with patient mortality, although, solely graft survival was unaltered.

A short time on dialysis could negate the risks of suboptimal kidney quality[27]—recommending acceptance of the first organ offer. This is highlighted by the fact that half the patients who are offered a kidney never receive another offer[4,7] and prolonged dialysis diminishes transplant benefits.[28] In our study, dialysis vintage was an influential predictor for EGL.

This study has strengths and limitations. The large data set provided a stable ground for propensity scoring, and the achieved balance across groups was acceptable. In addition, the small number of missing observations allowed weighting across many possibly influencing factors. However, a limitation is that in a retrospective study, a chance of residual confounding remains if an overlooked variable is not included in the balancing. Propensity scoring methods can only handle measured confounders, whereas randomized controlled trials can balance measured and unmeasured confounders between groups. For the supplemental analysis, the large data set provided well-matching pairs between average and extramarginal kidneys. The aim of matching is to allow only the effect of the donor to affect the outcome. However, dichotomization can lead to information loss, which was accounted for in the main analyses for the continuous treatment of KDPI. KDPI, while intuitively easier to understand, is calculated from the relatively static KDRI. This led to supplementing the analysis with KDRI as the treatment, which revealed no major differences.

This study does not allow for extrapolation beyond the marginal kidneys that made it to transplantation; however, the probability of EGL in the kidneys used for transplant was relatively small, and the absolute risk difference of transplanting an extramarginal kidney compared with an average kidney does not seem high—at least for 1-y all-cause graft survival. For everyday practice, the notion of limited significance of KDPI for all-cause survival might help in accepting subpar grafts. In conclusion, although the focus has shifted across the recipient–donor pair, and both may contain causal effects, the occurrence of EGL is still relatively poorly understood and thus hard to prevent. Unacceptable rates of EGL, however, were not noted in any KDPI group.

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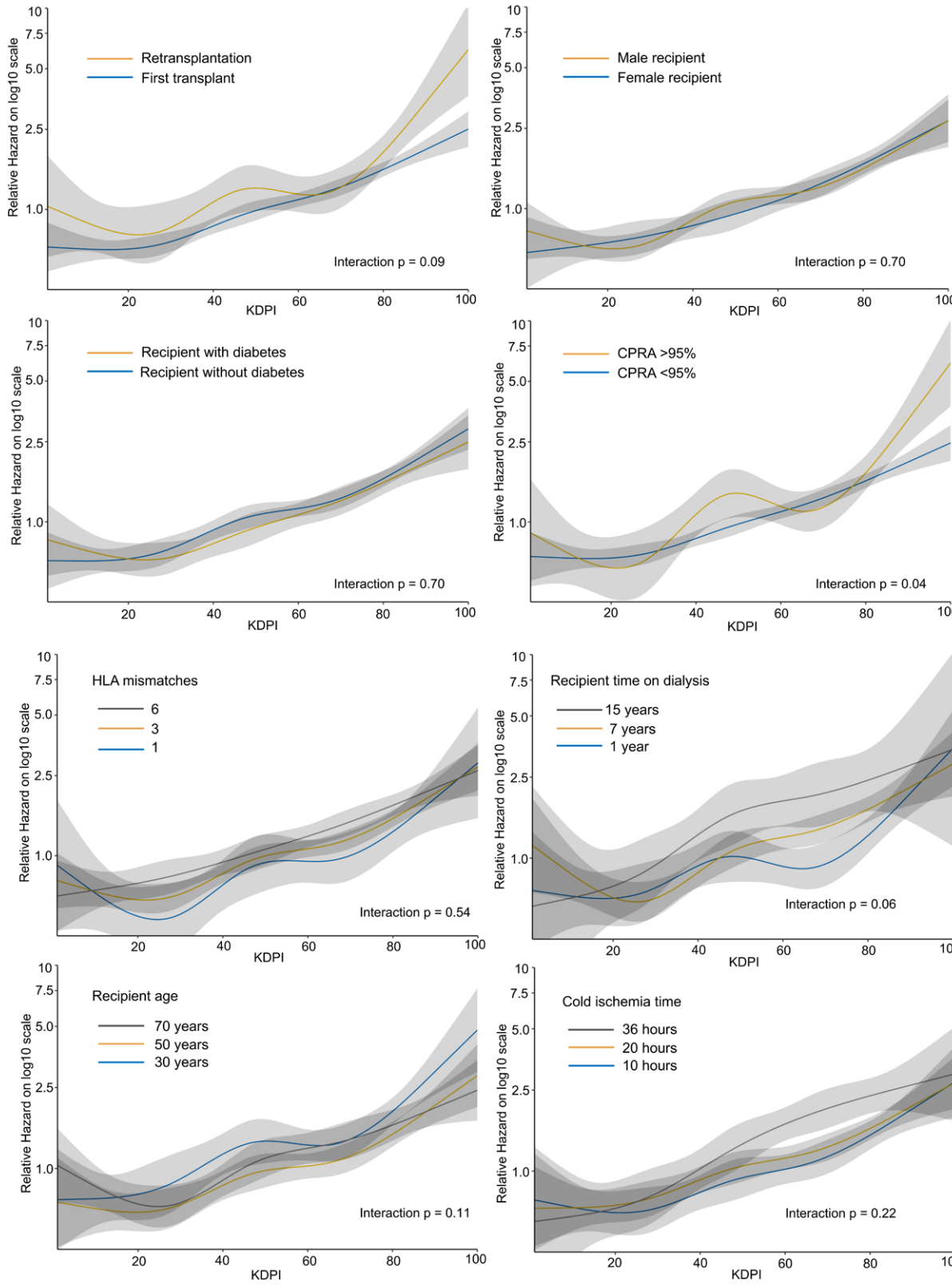

FIGURE 7. Conditional hazard ratios for different patient groups in a weighted Cox regression analysis. Weights accounted, retransplantation, immunization, time in dialysis, and cold ischemia time are harmful for early graft loss. CPRA, computed panel-reactive antibodies; KDPI, kidney donor profile index.

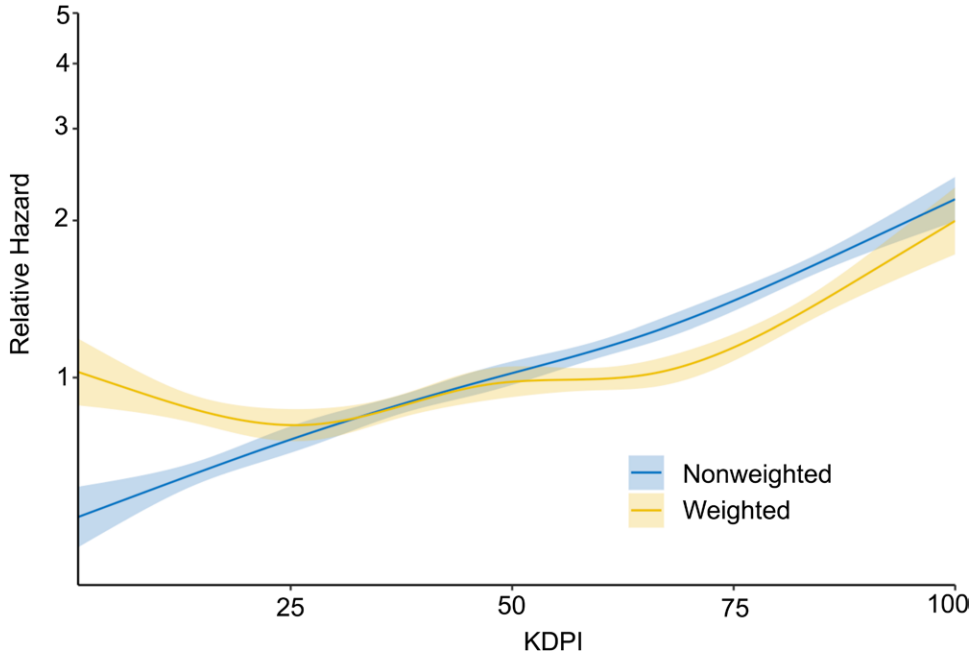

FIGURE 8. Nonweighted and weighted splined association of KDPI on all-cause graft loss in a Cox regression model. In a nonweighted model, KDPI <50 seems protective for all-cause survival. Weighted spline, however, shows hazard accumulating only after KDPI 75, with a stable hazard of graft loss or death from KDPI 0–75. KDPI, kidney donor profile index.

TABLE 2.

Early graft loss (within 1 y) and early death (within 1 y) predictions from the matched analysis, where similarly matched recipients of an average (KDPI 40–60) kidney and an extramarginal kidney (KDPI >95) were compared with Cox regression

Group	Early graft loss, HR (95%CI)		Early death, HR (95% CI)		Early graft loss estimated, % (95% CI)		Early death estimated, % (95% CI)	
KDPI	40-60	>95	40–60	>95	40–60	>95	40–60	>95
Whole cohort	1	2.2 (1.7-3.0)	1	1.2 (0.9-1.6)	3.5 (2.7-4.3)	7.5 (6.3-8.7)	4.3 (3.4-5.3)	5.2 (4.2-6.2)
Recipient diabetes								
Yes	1	1.7 (1.2-2.4)	1	0.9 (0.6-1.3)	4.6 (3.3-5.9)	7.8 (6.1-9.4)	6.1 (4.6-7.6)	5.5 (4.0-6.9)
No	1	2.3 (1.5-3.6)	1	1.5 (1.0-2.4)	3.2 (2-4.3)	7.2 (5.5-8.9)	3.2 (2.0- 4.3)	4.9 (3.5-6.3)
Time in dialysis, y								
>5	1	2.5 (1.5-4.3)	1	0.7 (0.5-1.2)	3.5 (2.0-5.0)	8.9 (6.5-11.2)	7.4 (5.2-10.0)	5.4 (3.5-7.3)
<5	1	2.9 (2.0-4.4)	1	1.7 (1.2-2.5)	2.4 (1.6-3.2)	7.0 (5.6-8.3)	3.0 (2.1-3.9)	5.1 (3.9-6.3)
Recipient age, y								
>65	1	2.5 (1.6-3.9)	1	1.4 (1.0-2.0)	2.7 (1.7-3.7)	6.6 (5.1-8.2)	5.2 (3.8-6.5)	7.2 (5.5-8.8)
<65	1	3.7 (2.3-6.0)	1	0.7 (0.4-1.1)	2.3 (1.4-3.3)	8.4 (6.6-10.2)	4.4 (3.1-5.7)	3.2 (2.0-4.3)
Cold ischemia time, h								
>20	1	2.5 (1.6-4.0)	1	1.1 (0.7-1.6)	2.7 (1.7-3.8)	6.8 (5.2-8.4)	4.7 (3.3-6.0)	5.1 (3.7-6.6)
<20	1	3.2 (2.1-5.1)	1	1.3 (0.9-2.0)	2.6 (1.6-3.6)	8.2 (6.5-9.8)	4.0 (2.8-5.2)	5.3 (3.9-6.7)

Estimates derive from Kaplan–Meier estimates. Higher KDPI transplantations resulted in higher risk of early graft loss than early death. This implies good patient selection as transplantation should not increase the risk of death, but also assure us of the usability of higher KDPI grafts.
CI, confidence interval; HR, hazard ratio; KDPI, kidney donor profile index.

The winterpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by the SRTR or the US Government.

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