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RISK OF GRAFT LOSS: SINGLE-FACTOR AND MULTIFACTOR ANALYSIS IN KIDNEY TRANSPLANTATION FROM EXPANDED CRITERIA DONORS

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Objective: to identify donor and recipient factors associated with the risk of loss of graft function in recipients of kidney grafts from expanded-criteria, brain-dead donors. **Materials and methods.** A retrospective multicenter cohort study included 254 donors who met the UNOS expanded-criteria definition and 444 corresponding recipients. Donor and recipient characteristics, perioperative parameters, and post-transplant outcomes were analyzed using single- and multivariable Cox regression models. **Results.** Mean donor age was 58.3 ± 4.8 years, and median cold ischemia time was 14.4 [12.3–17.0] hours. Mean recipient age was 51.6 ± 9.6 years. Class I anti-human leukocyte antigen (anti-HLA) antibodies (mean fluorescence intensity [MFI] >500) were detected in 40 (9.2%) recipients, and class II antibodies in 56 (12.8%). Delayed graft function occurred in 34.3% of recipients. Multivariate analysis revealed that lower donor minimum glomerular filtration rate (GFR) (HR = 0.98; 95% CI 0.965–0.997; p = 0.023) and higher combined donor ALT + AST levels (HR = 1.208; 95% CI 1.063–1.372; p = 0.004) were significantly associated with an increased risk of graft loss. Donor age was not a significant predictor. Among recipient factors, diabetes mellitus with target-organ damage (HR = 3.727; 95% CI 1.380–10.07; p = 0.009), nephropathy of unknown origin (HR = 3.816; 95% CI 1.212–12.02; p = 0.022), and elevated class II anti-HLA antibody levels (HR = 1.125 per 1000 MFI; 95% CI 1.039–1.218; p = 0.004) were the strongest predictors of graft loss. When recipient GFR at three months post-transplant was included in the model, the significance of donor-related factors (GFR, ALT, AST) was negated. **Conclusion.** Recipient-related predictors of graft loss are diabetes mellitus, unknown etiology of initial CKD, high class II anti-HLA antibody levels, and reduced GFR at three months post-transplant. Donor-related predictors of graft loss are minimum GFR during the entire period of donor hospitalization and elevated ALT/AST levels; however, these factors become statistically insignificant when recipient GFR three months after KT is included in the model.

Keywords: kidney transplantation; expanded criteria donors; brain death; graft survival.

INTRODUCTION

Expanding organ donation criteria remains one of the key strategies in addressing the persistent shortage of transplants [1–3]. The United Network for Organ Sharing (UNOS) defines expanded criteria donors (ECDs) as kidney donors aged 60 years or older, or those aged 50–59 years who meet at least two of the following conditions: a history of hypertension, death resulting from an acute cerebrovascular accident, or a serum creatinine level greater than 1.5 mg/dL [4].

According to the registry of the Russian Transplant Society, postmortem organ donation continues to develop actively in Russia [5]. However, the contribution of ECDs to the overall donor pool, as well as the outcomes of such transplants, remains insufficiently studied at the national level. Large-scale studies that not only report on immediate postoperative outcomes but also analyze factors associated with adverse transplant outcomes are particularly scarce.

It is well established that long-term transplant outcomes are influenced by a complex interplay of donor-related factors (such as age, cause of death, kidney function, and histological changes) and recipient-related factors (including age, sensitization status, and comorbidities) [6]. However, the relative impact of these risks may vary significantly depending on the population, donor conditioning practices, organ procurement and preservation techniques, and immunosuppressive strategies.

Objective: to identify donor and recipient factors associated with the risk of loss of graft function in recipients of kidney grafts from expanded criteria donors diagnosed with brain death.

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MATERIALS AND METHODS

A retrospective multicenter cohort study was conducted using data from the Moscow Organ Donation Coordination Center, Botkin Hospital. The database included 254 donors who met the UNOS expanded criteria between 2021 and 2022; in some cases, only one kidney was procured. Donor data were supplemented with information on 444 kidney transplant recipients obtained from participating transplant centers.

Statistical analysis

Descriptive statistics for qualitative variables are presented as absolute frequencies and percentages. Quantitative variables are described as the mean and standard deviation for distributions close to normal, and as the median with first and third quartiles for non-normal distributions. Normality was assessed through visual analysis of frequency histograms and quantile–quantile (Q–Q) plots.

The association between factors and the risk of graft loss was evaluated using Cox proportional hazards regression models. Effect sizes were expressed as hazard ratios (HR) with corresponding 95% confidence intervals (CI). The proportional hazards assumption was tested using Schoenfeld residuals and log(-log) survival plots. The linearity of continuous predictors with respect to the log hazard function was assessed using martingale residuals.

Residual plots and DFBETA statistics were jointly examined to identify influential observations. Multicollinearity among predictors was evaluated using correlation matrix analysis and variance inflation factors. Model comparison and selection were based on the Akaike Information Criterion (AIC), with lower values indicating better balance between model fit and complexity. The discriminative ability of the final model was quantified using Harrell's concordance index (C-index), representing the probability that, for any two randomly selected patients, the model correctly predicts which patient experiences the event first.

The sample size was not calculated and was limited by available data, including all donors who met the expanded criteria during 2021–2022.

Statistical significance was evaluated using a two-tailed test, with a p-value <0.05 considered statistically significant. All analyses were performed using R, version 4.5.1.

RESULTS

Donor factors

The mean age of donors was 58.3 ± 4.8 years (range: 50–74 years), with 155 (61%) being male. Mean body mass index (BMI) was 30.8 ± 5.9 kg/m^2 (range: 18.4–54.7 kg/m^2). A total of 37 donors (14.6%) had confirmed diabetes mellitus, and 171 (67.3%) had systemic atherosclerosis.

During hospitalization prior to organ procurement, norepinephrine was administered in 252 donors (99.2%) and epinephrine in 7 donors (2.8%). The maximum norepinephrine dose was 525 [330; 800] ng/kg/min (range: 60–3700 ng/kg/min), and the maximum epinephrine dose was 150 [75.5; 340] ng/kg/min (range: 10–1200 ng/kg/min). Successful cardiopulmonary resuscitation (CPR) was performed in 18 donors (7.1%).

GFR (CKD-EPI) in donors upon admission, at the minimum recorded value during hospitalization, and immediately before organ retrieval was 79.5 ± 21.0 mL/min/1.73 m^2 (range: 22.7–134.7), 70.2 ± 24.4 mL/min/1.73 m^2 (range: 10.1–134.7), and 73.8 ± 23.8 mL/min/1.73 m^2 (range: 10.1–134.7), respectively. Enzyme activity was also assessed upon admission and prior to organ retrieval. Alanine aminotransferase (ALT) level was 28.0 [23; 43] U/L (range: 7–406) and 28 [21; 46] U/L (range: 7–866), while aspartate aminotransferase (AST) level was 25.0 [18; 36] U/L (range: 5–413) and 24.5 [17; 36] U/L (range: 5–1090), respectively.

Multi-organ procurement was performed in 182 donors (71.7%), with a cold ischemia time of 14.4 [12.3; 17.0] hours (range: 6.9–26.0 hours).

In univariate analysis, donor gender, age, BMI, diabetes, systemic atherosclerosis, and level of vasopressor therapy (norepinephrine and epinephrine) were not significantly associated with the risk of kidney graft loss (Fig. 1). However, CPR and decreased GFR upon admission were associated with an increased risk of graft loss from any cause, as well as with loss of graft function. Additionally, minimum GFR values, maximum ALT and AST levels, and enzyme levels immediately prior to organ retrieval were associated with an increased risk of death-censored graft loss.

Recipient factors

Recipient mean age was 51.6 ± 9.6 years (range: 19–72 years), with 271 (60.2%) being male. BMI was 25.8 ± 4.5 kg/m^2 (range: 13.6–38.4 kg/m^2). A total of 337 recipients (78.4%) were undergoing maintenance hemodialysis prior to transplantation. Median duration of renal replacement therapy was 24 [12; 48] months (range: 1–240 months).

The most frequent comorbid conditions included ischemic heart disease in 73 recipients (17.0%), with a history of coronary artery stenting in 47 (10.9%), diabetes in 44 (10.2%), atrial fibrillation in 26 (6.0%), and chronic heart failure in 63 (14.7%).

Chronic kidney disease (CKD) was most commonly caused by chronic glomerulonephritis, identified in 179 recipients (41.6%). Other etiologies were considerably less frequent: autosomal dominant polycystic kidney disease in 61 (14.2%), diabetic nephropathy in 49 (11.4%), hypertensive nephropathy in 44 (10.2%),

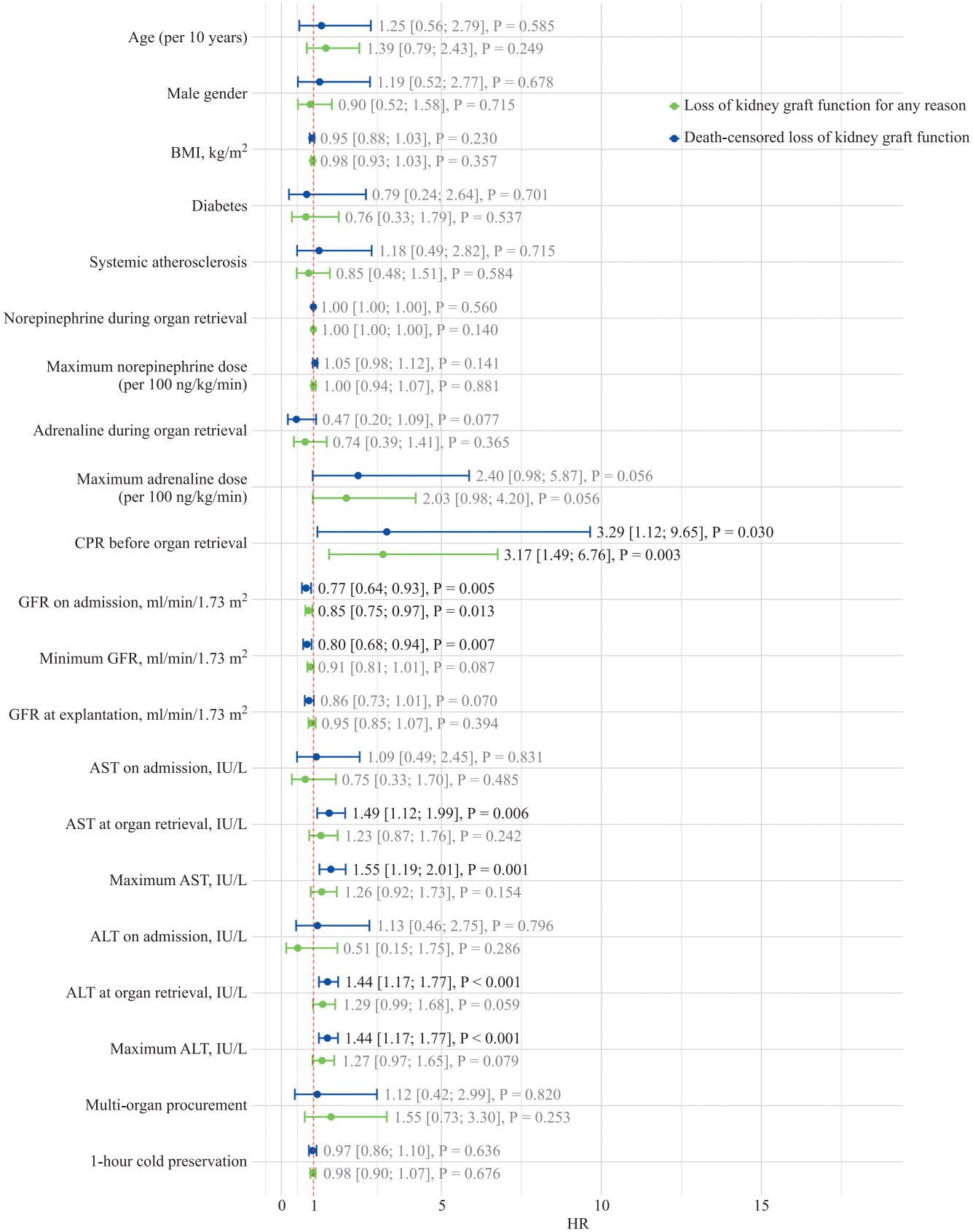

Fig. 1. Donor factors potentially associated with the risk of graft loss. BMI, body mass index; CPR, cardiopulmonary resuscitation; GFR, glomerular filtration rate (CKD-EPI); ALT, alanine aminotransferase; AST, aspartate aminotransferase. Hazard ratio (HR) estimates and 95% confidence intervals (CI) are shown. For GFR, estimates are presented per 10 mL/min/1.73 m^2; for ALT and AST – per 100 U/L

tubulointerstitial nephritis in 25 (5.6%), and secondary glomerulopathies in 22 (5.0%). Nephropathy of unknown origin was diagnosed in 55 recipients (12.2%), while other causes accounted for 15 cases (3.3%).

Class I anti- human leukocyte antigen (HLA) antibodies (mean fluorescence intensity [MFI] >500) were detected in 40 recipients (9.2%), with a median MFI of 2071.5 [1111.0; 3799.0] (range: 725–19,477 units). Class II with MFI >500 units were identified in 56 recipients (12.8%), with a median MFI of 2618 [1305.5; 7269.0] (range: 526–20,772 units).

Most patients (n = 362; 84.2%) received induction immunosuppression with basiliximab and methylprednisolone. Antithymocyte globulin combined with methylprednisolone was administered to 61 recipients (14.2%), while 4 (0.9%) received a triple combination of basiliximab, antithymocyte globulin, and methylprednisolone. Only 3 recipients (0.7%) received methylprednisolone alone.

The majority of recipients (n = 403; 93.9%) were maintained on standard triple immunosuppressive therapy, consisting of a calcineurin inhibitor, mycophenolate, and methylprednisolone.

Delayed graft function (DGF) occurred in approximately one-third of recipients (n = 147, 34.3%). Among these, the median number of hemodialysis sessions required before recovery of graft function was 3 [2; 6] (range: 1–26 sessions).

The mean eGFR (CKD-EPI) at discharge, and at 1, 3, 6, and 12 months post-transplant was 37.0 (17.9) mL/min/1.73 m^2 (range: 5.0–109.5), 40.0 (17.9) (range: 5.6–95.0), 44.8 (16.9) (range: 4.2–97.7), 46.4 (15.3) (range: 5.4–88.4), and 46.2 (15.8) mL/min/1.73 m^2 (range: 4.8–94.9), respectively.

In the univariate analysis, recipient age, ischemic heart disease, atrial fibrillation, chronic heart failure, and end-stage renal disease were associated with an increased risk of all-cause mortality but not with death-censored graft loss (Fig. 2). Nephropathy of unknown origin and elevated anti-HLA class I antibody levels were significantly associated with death-censored graft loss. In contrast, the presence of diabetes mellitus, higher anti-HLA class II antibody, DGF, a greater number of post-transplant hemodialysis sessions, and lower GFR were associated with an increased risk of both all-cause and death-censored graft loss.

In the multivariate analysis, we deliberately deviated from the commonly used but widely criticized stepwise predictor selection approach. Instead, predictors were grouped and included in the models based on the biological nature of the phenomena under study.

Tables 1–3 present the analysis of donor and recipient characteristics potentially associated with the risk of loss of graft function. Donor age, considered a key biological determinant, was not statistically significantly associated with graft function loss in any of the models (Models 1 and 2, Table 1). Successful CPR was associated with an increased risk of loss of graft function, but this association was observed only in the model that did not include donor GFR. Furthermore, ALT and AST levels, combined into a single composite variable using principal component analysis, demonstrated a significant association with the risk of loss of graft function. Among the three GFR indicators evaluated (upon admission, minimum recorded value, and before organ retrieval), the model incorporating the minimum GFR showed the best quality.

Among recipient-related factors, diabetes mellitus with target organ injury and nephropathy of unknown origin remained significantly associated with increased risk of loss of graft function, even after adjusting for MFI levels of both class I and class II anti-HLA antibodies. When evaluated separately, both class I and class II antibodies were significantly associated with the risk

Table 1

Multivariate analysis of factors potentially associated with the risk of loss of kidney graft function

Indicator	Model 1. AIC = 287.043, C-index = 0.574			Model 2. AIC = 283.788, C-index = 0.635			Model 3. AIC = 278.063, C-index = 0.630		
	HR	95% CI	P value	HR	95% CI	P value	HR	95% CI	P value
Donor age, per year	1.018	0.938; 1.105	0.668	1.011	0.931; 1.097	0.8			
Cardiopulmonary resuscitation (yes/no)	3.331	1.132; 9.800	**0.029**	2.287	0.753; 6.942	0.144			
Preservation time, per hour	0.966	0.853; 1.094	0.59	0.962	0.847; 1.093	0.554			
Minimum GFR, per mL/min/1.73 m^2				0.98	0.963; 0.997	**0.021**	0.981	0.965; 0.997	**0.023**
ALT, AST *							1.167	1.039; 1.311	**0.009**

* First principal component obtained from baseline AST and ALT values (principal component method). Reflects the total variation in AST and ALT levels. Abbreviations: GFR, glomerular filtration rate, estimated by creatinine clearance (CKD-EPI); AIC, Akaike information criterion.

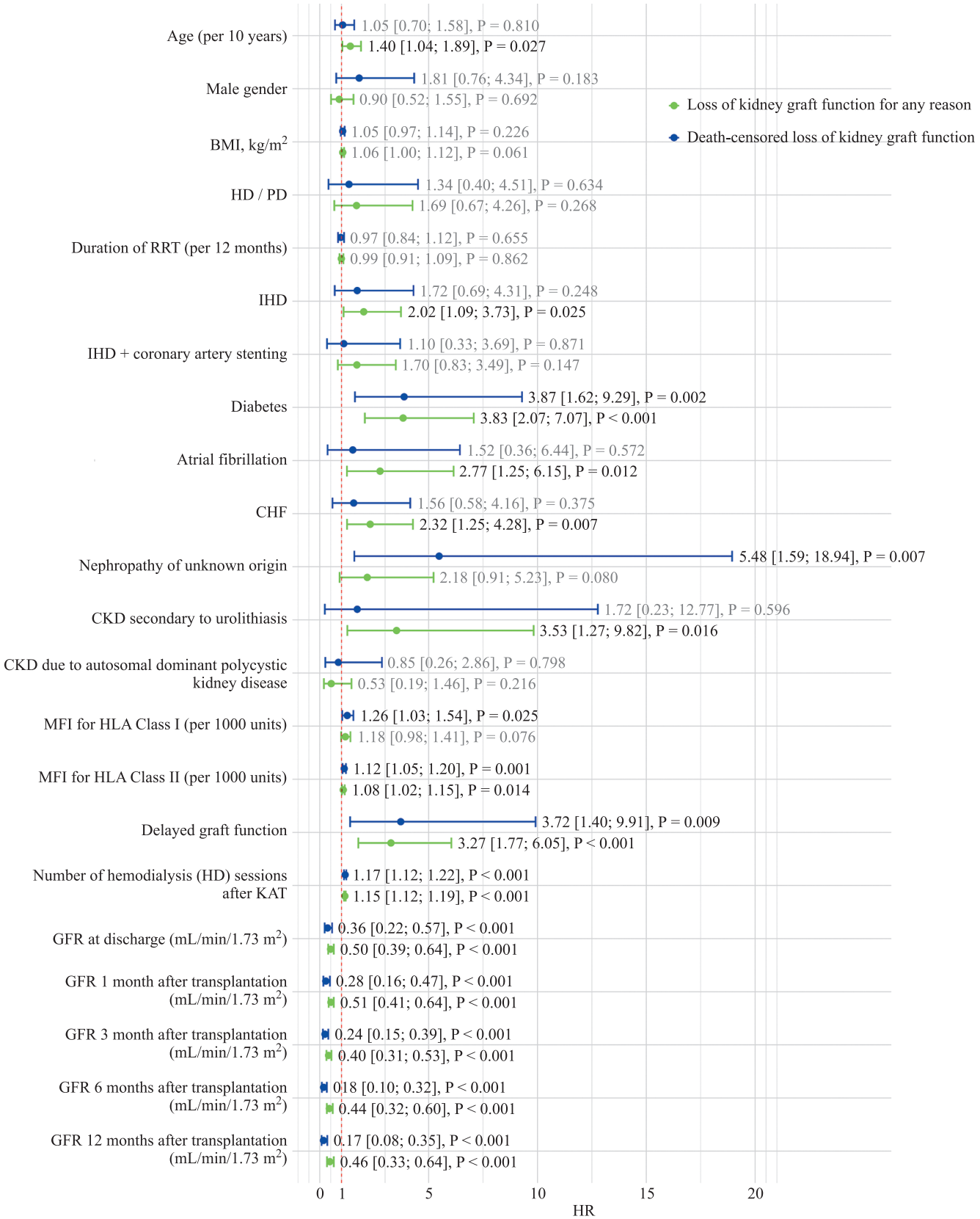

Fig. 2. Recipient factors potentially associated with the risk of kidney graft loss. HD, hemodialysis; PD, peritoneal dialysis; RRT, renal replacement therapy; IHD, ischemic heart disease; CKD, chronic kidney disease; CHF, chronic heart failure; KAT, kidney allotransplantation; GFR, glomerular filtration rate (CKD-EPI); MFI, mean fluorescence intensity; HLA, human leukocyte antigens. Hazard ratio (HR) estimates and 95% confidence intervals (CI) are presented. For GFR, estimates are provided per 10 mL/min/1.73 m^2

Table 2

Multivariate analysis of recipient characteristics potentially associated with the risk of loss of kidney graft function. Models 4 and 5

Indicator	Model 4. AIC = 279.880, C-index = 0.771			Model 5. AIC = 249.720, C-index = 0.801		
	HR	95% CI	P value	HR	95% CI	P value
Diabetes mellitus with damage to recipient's target organs (yes/no)	5.643	2.098; 15.18	**<0.001**	4.665	1.800; 12.09	**0.002**
Recipient nephropathy of unknown origin (yes/no)	4.218	1.412; 12.60	**0.01**	3.248	1.037; 10.18	**0.043**
ADPKD (yes/no)	1.601	0.433; 5.914	0.481			
Urolithiasis (yes/no)	3.134	0.395; 24.86	0.28			
MFI for HLA Class I (per 1000 units)				1.244	0.979; 1.581	0.073
MFI for HLA Class II (per 1000 units)				1.106	1.025; 1.193	**0.01**

Abbreviations: ADPKD, autosomal dominant polycystic kidney disease; MFI, mean fluorescence intensity; HLA, human leukocyte antigens; AIC, Akaike information criterion.

Table 3

Multivariate analysis of characteristics potentially associated with the risk of loss of kidney graft function (Models 6, 7, and 8)

Indicator	Model 6. AIC = 238.063, C-index = 0.830			Model 7, AIC = 147.515, C-index = 0.911			Model 8. AIC = 116.677, C-index = 0.952		
	HR	95% CI	P value	HR	95% CI	P value	HR	95% CI	P value
Minimum donor GFR, mL/min/1.73 m^2	0.982	0.965; 1.000	**0.045**	0.985	0.956; 1.016	0.344			
Donor ALT, AST*	1.208	1.063; 1.372	**0.004**	1.166	0.990; 1.373	0.066			
Diabetes mellitus with damage to recipient's target organs (yes/no)	3.727	1.380; 10.07	**0.009**	7.558	1.680; 33.99	**0.008**	6.833	2.053; 22.74	**0.002**
Recipient nephropathy of unknown origin (yes/no)	3.816	1.212; 12.02	**0.022**	7.162	1.587; 32.31	**0.01**	5.544	1.362; 22.56	**0.017**
MFI for HLA Class II (per 1000 units)	1.125	1.039; 1.218	**0.004**	1.424	1.208; 1.680	**<0.001**	1.129	1.030; 1.238	**0.01**
Delayed graft function (yes/no)				0.477	0.120; 1.895	0.293			
Recipient GFR three months after discharge, per mL/min/1.73 m^2				0.888	0.838; 0.940	**<0.001**	0.888	0.843; 0.935	**<0.001**

* First principal component obtained from baseline AST and ALT values (principal component method). Reflects the total variation in AST and ALT levels. Abbreviations: GFR, glomerular filtration rate (estimated by CKD-EPI creatinine equation); MFI, mean fluorescence intensity; HLA, human leukocyte antigens; AIC, Akaike information criterion.

of loss of graft function (data not shown in this study). However, when included in the same multivariate model, only the association with class II anti-HLA antibodies remained statistically significant (Table 2).

When the minimum donor GFR, donor ALT and AST levels, recipient diabetes mellitus with target organ damage, nephropathy of unknown origin, and class II anti-HLA antibody levels were simultaneously included in Model 6 (Table 3), all factors demonstrated a statistically significant association with the risk of off of graft function.

However, after incorporating post-transplant indicators, specifically DGF and recipient GFR at three months, the minimum donor GFR and ALT/AST levels were no longer significantly associated with risk. Moreover, simplifying the model by excluding these non-significant variables improved its overall performance

DISCUSSION

In none of the models was donor age found to be significantly associated with the risk of off of graft function. The donors in this study represented a broad age range (50–74 years). Although a decline in functional reserve is generally expected in older donors [7, 8], approximately half of the donors were between 55 and 62 years old. It is likely that the functional state of the kidneys is approximately the same in this age range [9].

One of the most important risk factors for graft loss identified in this study was minimum donor GFR, consistent with findings from previous research [10, 11].

ALT and AST levels also emerged as potentially important indicators. In multivariate models incorporating donor and recipient characteristics prior to transplantation or during the early postoperative period, elevated liver enzyme levels were associated with an increased risk of graft loss. The biological mechanisms underlying this association remain unclear. It is plausible that the relationship between enzyme levels and graft outcomes is indirect, mediated through factors such as metabolic syndrome, hepatic ischemia-reperfusion injury, or systemic inflammatory responses. Donors presenting with significantly elevated ALT and AST levels may therefore warrant more thorough assessment of kidney function prior to organ procurement. This observation needs further investigation.

Notably, after including recipient GFR measured three months post-transplant in the model, neither donor GFR nor donor ALT and AST levels remained significantly associated with the risk of graft loss. This finding suggests that recipient post-transplant GFR exerts a stronger influence on graft outcomes than donor-specific characteristics.

The associations observed between graft loss and recipient factors such as age, ischemic heart disease, atrial fibrillation, chronic heart failure, and end-stage renal disease appear to be mediated primarily through an increased risk of recipient mortality. This is supported by the observation that these factors were significantly associated only with all-cause graft loss, but not with death-censored graft loss. In this study, death-censored graft function was the most important factor as it provides an idea of the risk of losing kidney graft function at the individual. In contrast, overall graft survival, including all-cause loss due to any cause, provides information on graft outcomes at the population level but less directly captures the functional potential of the graft at the individual level.

The association between recipient diabetes and the risk of graft loss is well established [12]. Interestingly, nephropathy of unknown origin also demonstrated a statistically significant association with graft loss in multifactorial models (Models 6–8). This may be attributable to the higher incidence of recurrent graft pathology, as evidenced by the number of "on-demand" graft biopsies performed [13]. However, graft outcomes can vary widely depending on the underlying disease, such as recurrent IgA nephropathy [14] or focal segmental glomerulosclerosis [15], highlighting the critical need for accurate verification of CKD etiology in patients on the kidney transplant waiting list.

Based on these analyses, we developed an online application, accessible across platforms, designed to visualize the relationship between donor and recipient characteristics and the risk of graft loss [16].

STUDY LIMITATIONS

This study was retrospective in design. To enhance objectivity, no donors were excluded based on specific criteria; instead, all effective donors meeting the expanded criteria during the study period were included in the analysis.

The observation period in this study was limited to four years post-transplant, and therefore, the identified risk factors may primarily reflect medium-term outcomes.

When assessing graft function, we did not account for proteinuria, nor the potential overestimation of GFR due to hyperfiltration. Additionally, some potentially important factors, such as biopsy results, were not included because of limited observations, uncorrectable assumptions, or the inability to control for collider bias (Berkson's paradox).

CONCLUSION

The main risk factors for loss of kidney transplant function are recipient diabetes mellitus, nephropathy of unknown origin, and sensitization to HLA class II antigens. Donor age, although a key biological determinant, was not associated with the risk of graft loss. The effect of donor age on graft outcomes appears to be mediated through donor GFR. However, once recipient GFR measured three months post-transplant is included in the model, donor GFR no longer retains statistical significance.

The authors declare no conflict of interest.

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