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A Prognostic Index for Deceased Donor Kidneys and Criteria for Identifying Suitable Candidates for Kidney Transplantation from Expanded Criteria Donors with Prolonged Waiting Times

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Keywords
Deceased donor kidney transplantation · Expanded criteria donor · Kidney donor profile index · Prognostic index · Suitable candidate

Abstract
Introduction: The kidney donor profile index (KDPI) is a valuable prognostic tool in deceased donor kidney transplantation (DDKT), while its optimization for each country using local data is essential. It remains unclear which patients derive survival benefits from expanded criteria donor (ECD) DDKT compared to waitlist or standard criteria donor (SCD) DDKT, particularly in the context of long waiting times. This study aimed to develop a prognostic index for donor kidneys and propose criteria to identify suitable candidates for ECD DDKT in Korea. ***Methods:*** Two prediction models were developed using data from two cohorts based on national databases (the Korean Network for Organ Sharing and the National Health Insurance Data Sharing Service): cohort for the prediction of graft prognosis (n = 6,272) and cohort for the prediction of suitable candidates for ECD DDKT (n = 30,183). ***Results:*** The Korean KDPI (K-KDPI) comprises five donor factors (age, height, diabetes mellitus, serum creatinine levels, and hepatitis C virus), associated with graft failure. The discriminatory ability of the K-KDPI for graft outcomes surpassed that of the US KDPI and dichotomous ECD criteria. ECD kidneys (K-KDPI ≥70%) showed worse allograft survival compared to SCD kidneys (K-KDPI <70%). Candidates aged ≥40 years, with negative panel reactive antibody, and without diabetes mellitus had a significantly lower mortality risk with ECD DDKT than with waitlist-or-SCD DDKT, making them suitable for ECD DDKT. ***Conclusion:*** The K-KDPI and criteria for identifying suitable ECD recipients are expected to improve the quality assessment and efficient utilization of ECD kidneys in Korea with long waiting times.

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Plain Language Summary

Kidney transplants from deceased donors vary in quality, and tools like the Kidney Donor Profile Index (KDPI) help predict transplant outcome. However, these tools must be customized for each country's population and characteristics. This study created the Korean KDPI (K-KDPI), tailored to unique donor and recipient characteristics of Korean donors and recipients, using over 36,000 cases from national databases. The K-KDPI includes five donor factors: age, height, diabetes mellitus, kidney function (serum creatinine), and hepatitis C status. It performed better than the US KDPI in predicting transplant outcomes. Expanded criteria donor (ECD) kidneys, with higher K-KDPI scores (≥70%), had worse survival outcomes than standard criteria donor (SCD) kidneys (<70%). However, ECD kidney transplantation could be beneficial than waiting for SCD kidney transplantation for specific patients in the context of long waiting time. Patients aged 40 or older, who were not sensitized (negative panel reactive antibody), and who did not have diabetes mellitus, showed better patient survival rates with ECD transplants compared to staying on the waitlist or receiving SCD kidneys. These findings suggest that ECD kidneys can be effectively used for specific patients, even though they may not meet the highest quality standards. The K-KDPI and selection criteria for patients suitable for ECD kidneys are expected to improve transplant success rates and optimize the use of donor kidneys in Korea, especially given the long waiting times for transplants. This approach could lead to better matching of donors and recipients, ultimately benefiting more patients in need.

Introduction

The prevalence of end-stage kidney disease (ESKD) is rising, leading to a growing demand for kidney transplantation (KT). However, the limited supply of kidneys has led to longer waiting times and an increased number of waitlisted patients for deceased donor kidney transplantation (DDKT) [1, 2]. To address this imbalance, the criteria for deceased donor kidneys have been expanded, categorizing kidneys as expanded criteria donor (ECD) or standard criteria donor (SCD) [3]. However, these criteria may be too simplistic to the prediction of posttransplant prognosis and kidney quality [4–7]. In 2014, the Organ Procurement and Transplantation Network introduced the Kidney Donor Risk Index (KDRI) and the Kidney Donor Profile Index (KDPI) to improve donor kidney quality assessment [8–10].

Identifying suitable recipients for ECD kidneys is essential for their efficient use. A previous study proposed an allocation algorithm that defines subgroups of waitlisted patients who would benefit more from ECD DDKT than from waiting for SCD DDKT, optimizing the allocation of limited donor kidneys [11].

The incidence of ESKD is rising rapidly in Korea, where the disparity between the supply and demand for deceased donor kidneys remains severe, with waiting times for DDKT reaching up to 10 years as of 2021 [1, 2, 12]. In 2021, only 747 DDKTs were performed out of 31,055 patients on the waiting list, and a significant number of ECD kidneys were discarded [2]. Given the unique characteristics of Korea's DDKT system, developing a risk stratification system for ECD kidney allocation based on nationwide data is crucial. This study aimed to develop a Korean risk stratification scoring system for deceased donor kidneys and propose criteria for identifying suitable candidates for ECD kidneys based on nationwide Korean database.

Methods

Study Population

Two nationwide cohorts were established (1) a cohort for predicting graft prognosis (cohort 1) and (2) a cohort for identifying suitable candidates for ECD DDKT (cohort 2). Initially, a total of 34,055 patients with ESKD were registered on the waiting list for DDKT in the Korean Network for Organ Sharing (KONOS) from January 1, 2010, to December 31, 2018. Exclusions were made for patients under 18 years of age (n = 254), those with a history of KT (n = 3,214), and those with incomplete or invalid data on height, weight, or resident registration (n = 110). Finally, a total of 30,477 adult patients with ESKD remained on the KONOS waiting list. Of these, 6,566 received DDKT during this period and 6,272 DDKT received solitary DDKT, excluding who underwent multiorgan transplantation (n = 294) (designated as the cohort for predicting graft prognosis), while the remaining 23,911 patients continued to wait on the list (designated as the cohort for identifying suitable candidates for ECD DDKT) (Fig. 1).

A cohort for predicting graft prognosis included 6,272 adult DDKT recipients, while a cohort for identifying suitable candidates for ECD DDKT consisted of 12,110 patients after propensity score matching between ECD DDKT recipients and matched controls on the waiting list

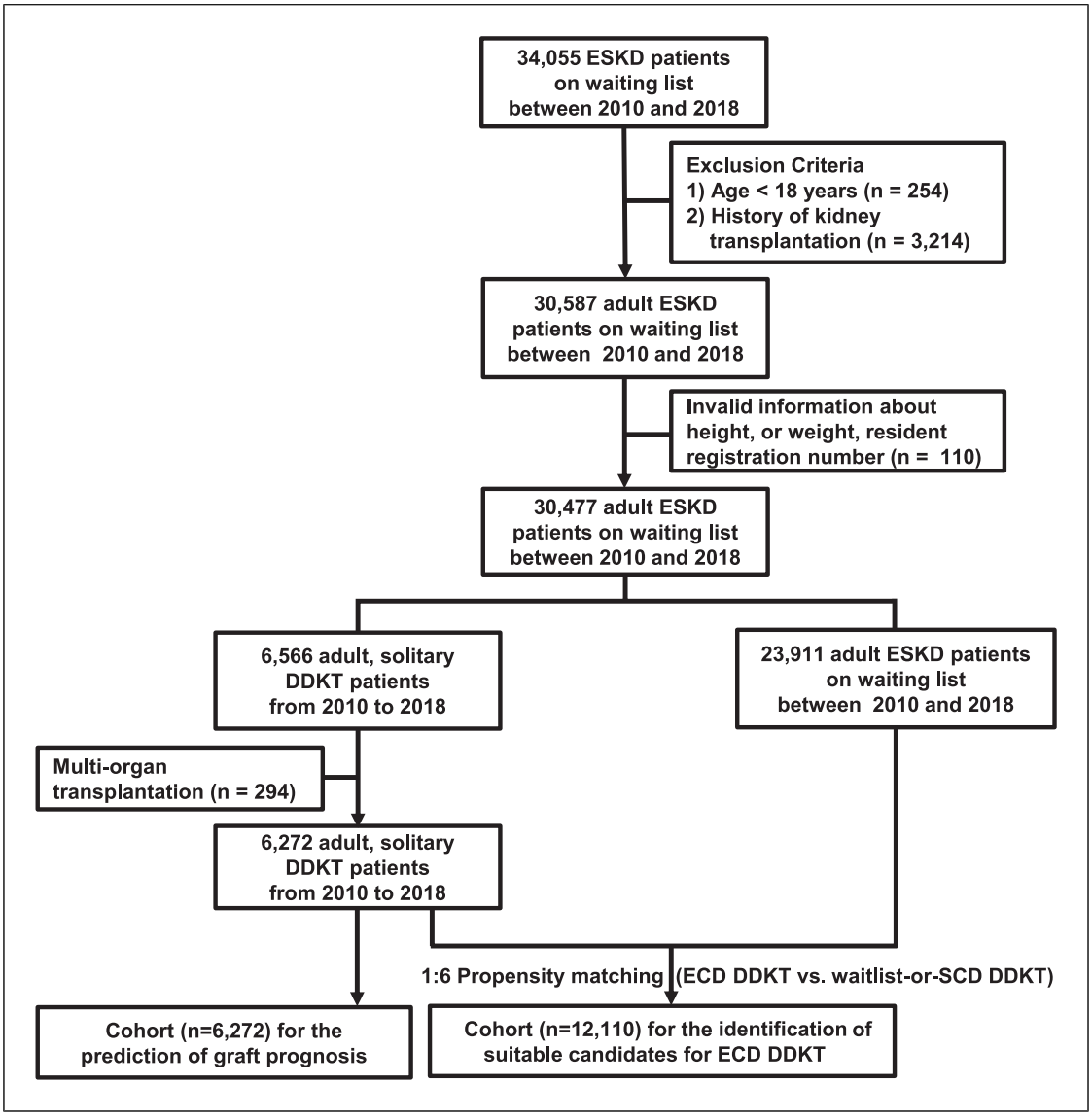

Fig. 1. Study profile. We utilized two nationwide cohorts to develop two distinct prediction models: cohort for the prediction of graft prognosis and cohort for identifying suitable candidates for ECD DDKT. BMI, body mass index; DDKT, deceased donor kidney transplantation; ECD, expanded criteria deceased donor; ESKD, end-stage kidney disease; KT, kidney transplantation; *n*, number; SCD, standard criteria deceased donor.

or receiving SCD DDKT (Fig. 1). Baseline data on recipients, donors, and comorbidities were obtained from KONOS and the National Health Insurance Data Sharing Service (NHISS), and mortality data were obtained from the Ministry of the interior and Safety.

This study was approved by the Institutional Review Board of Seoul National University Hospital (E-1906-064-1040), which waived the requirement for informed consent. The study was conducted in accordance with the Helsinki Declaration and the Declaration of Istanbul (2008).

Outcomes

(1) Cohort for the prediction of graft prognosis (cohort 1): the primary outcome was graft failure, defined as a return to dialysis or subsequent kidney transplantation. Patients were followed from the time of KT until the earliest of graft failure, loss to follow-up, or the end of the follow-up period.

(2) Cohort for identifying suitable candidates for ECD DDKT (cohort 2): the primary outcome was patient death. Patients who underwent DDKT were followed from the time

of KT until death, loss to follow-up, or the end of the follow-up period. Patients on the waiting list for KT were followed from the date of registration on the waiting list until death, loss to follow-up, or the end of the follow-up period.

Statistical Analysis

Continuous variables are reported as mean ± standard deviation, and categorical variables are reported as proportions (%) or frequencies. Analysis of variance was used for continuous variables, and chi-squared test or Fisher's exact test was used for categorical variables. Kaplan-Meier analysis with log-rank tests estimated mortality and graft loss rates, with statistical significance set at p value <0.05. Data were analyzed using a complete case approach.

A new graft prediction score was developed using the multivariable Cox proportional hazard (CPH) model. Detailed methods for the Korean risk stratification scoring system for deceased donor kidneys are provided in the online supplementary Methods (for all online suppl. material, see https://doi.org/10.1159/000544792). Model discrimination was assessed using the concordance (C) statistic, which ranges from 0.5 (no discrimination) to 1.0 (perfect discrimination) [13]. The discrimination ability of the Korean Kidney Donor Profile Index (K-KDPI) was compared with that of the United Network for Organ Sharing (UNOS) KDPI [10] and the dichotomous ECD criteria of UNOS [3] and KONOS [14] using pairwise differences and the standard error [15].

To evaluate the survival benefit of ECD DDKT in patients awaiting DDKT, we compared the mortality between ECD DDKT patients and waitlist for SCD DDKT patients using a time-varying CPH model. We performed propensity score matching between ECD DDKT recipient and matched control patients (waitlist-or-SCD DDKT group) with waiting times, as it showed an extremely substantial difference compared to other factors between those who received DDKT and those still on the waitlist. The matching ratio was set to 1:6 without discard or nonmatching of patients in the ECD DDKT group with a smaller number. Other detailed methods are provided in the online supplementary Methods.

All analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA), R version 3.6.1 (R Core Team, 2022, R Foundation for Statistical Computing, Vienna, Austria; URL: https://www.R-project.org/), and its packages, including "*MatchIt*", "*rms*", "*survival*", "*descr*", and "*tableone*", within RStudio version 2023.03.0 (RStudio Team, PBC, Boston, MA, USA; URL: http://www.rstudio.com/).

Results

Baseline Characteristics of the Cohort for the Prediction of Graft Prognosis (Cohort 1)

The cohort for the prediction of graft prognosis model consisted of 6,272 adults, first-time, solitary DDKT recipients (Fig. 1). The baseline characteristics of both recipients and donors are summarized in Table 1. The mean age of recipients at the time of transplantation was 50 years. The majority of patients were male (61.2%), with having diabetes mellitus (DM) (82.3%) and undergoing hemodialysis prior to transplantation (75.6%). The mean duration of dialysis before transplantation was 4 years. The mean donor age at transplantation was 46 years, the mean final serum creatinine level before procurement was 1.51 mg/dL and 0.3% from donation after circulatory death (DCD). The mean number of HLA mismatches at transplantation was 3.3.

Development of the Prediction Model for Graft Prognosis

Kidney graft failure occurred in 376 (6.0%) among 6,272 DDKT patients at a median follow-up of 54 months. We developed a prediction score using a multivariable CPH model. To account for the potential influence of all donor-associated, recipient-associated, and transplantation-related variables on graft outcomes, all variables were initially included in the model. The initial full model was subsequently refined to the best fit model through a backward variable selection procedure, applying an individual variable exclusion criterion of $p > 0.1$ to identify strong predictors of graft failure and minimize overfitting bias.

Ultimately, the Korean Kidney Donor Risk index (K-KDRI) was defined by five donor factors: age, height, DM, serum creatinine level before procurement, and hepatitis C virus positivity (Table 2). The median K-KDRI for patients who underwent DDKT was 1.02 (online suppl. Fig. S1a). The K-KDPI is a remapping of the K-KDRI onto a cumulative percentage scale based on the reference population [10]. We used data from the reference deceased donor population from whom kidneys were recovered between January 1, 2016, and December 31, 2018, in Korea (online suppl. Table S1). The distribution of K-KDPI among the DDKT study population is shown in online supplementary Figure S1b (median = 59.8%).

Although K-KDPI is a continuous score, it was dichotomized for practical decision-making. The optimal diagnostic performance was achieved with a cutoff value of 55%; however, a cutoff of 70% resulted in only a 0.01 difference in the concordance index (online suppl. Fig. S2). Therefore, the new Korean ECD is defined as donors with a K-KDPI ≥70%. ECDs with a K-KDPI ≥70%

Table 1. Baseline characteristics of deceased donors and their recipients in the cohort 1

Donor parameters	
Age, years	46±15
Female, *n* (%)	2,027 (32.3)
Weight, kg	64.5±13.5
Height, cm	166±12
Hypertension	1,511 (24.1)
Diabetes mellitus	607 (9.7)
Cause of death: CVA, *n* (%)	2,788 (44.5)
DCD, *n* (%)	20 (0.3)
Serum creatinine at the time of transplantation, mg/dL	1.51±1.19
HBV-positive, *n* (%)	128 (2.0)
HCV-positive, *n* (%)	18 (0.3)
Recipient parameters	
Age, years	50±11
Female, *n* (%)	2,435 (38.8)
Hypertension, *n* (%)	6,228 (99.3)
Diabetes mellitus, *n* (%)	5,163 (82.3)
Mode of dialysis, *n* (%) Hemodialysis Peritoneal dialysis	 4,742 (75.6) 1,530 (24.4)
Duration of dialysis, years	4.0±2.6
HBV-positive, *n* (%)	389 (6.2)
HCV-positive, *n* (%)	84 (1.3)
Death, *n* (%)	499 (8.0)
Graft failure, *n* (%)	376 (6.0)
Transplant parameters	
Number of HLA-A/B mismatches	2.3±1.2
Number of HLA-DR mismatches	1.1±0.7
Number of HLA mismatches	3.3±1.2
Cold ischemic time, min	258

Continuous variables are reported as mean ± standard deviation. Nominal and categorical variables are listed as total number (percentage). CVA, cerebrovascular accident; DCD, donation after cardiac death; HBV, hepatitis B virus; HCV, hepatitis C virus; HLA, human leukocyte antigen; *n*, number.

demonstrated significantly worse graft survival compared to SCDs with a K-KDPI <70% ($p < 0.001$, online suppl. Fig. S3).

Discrimination Ability and Performance of Graft Prognosis Prediction Models

The K-KDPI demonstrated a C-statistic of 0.600 (95% confidence interval [CI]: 0.578–0.617) (online suppl. Table S2). The K-KDPI outperformed the previous dichotomous ECD criteria of the UNOS ($p = 0.020$), the previous dichotomous ECD criteria of the KONOS ($p < 0.001$), and the KDPI criteria of UNOS ($p = 0.012$) in terms of discriminative ability (online suppl. Table S2). The internal validation showed that the optimism of C-statistics was 0.0103. In the calibration performed using bootstrap datasets, the mean errors were 0.006 and 0.014, and the 0.9 quantiles of errors were 0.007 and 0.008 at 2,000 days and 3,000 days, respectively.

Table 2. Relative risk of graft failure after deceased donor kidney transplantation

Donor factors	Univariate analysis		Multivariate analysis (final model)[a]		
	HR	*p* value	HR	95% CI	*p* value
Age	1.019	<0.001			
(Age – 45)	1.037	<0.001	1.034	1.026–1.042	<0.001
Female	0.839	0.016			
Weight	1.000	0.451			
Height	0.994	0.015			
(196-height)	1.015	0.005	1.006	1.001–1.011	0.047
Hypertension	1.287	0.001			
Diabetes mellitus	1.760	<0.001	1.486	1.217–1.815	<0.001
Cause of death: CVA	1.133	0.073			
DCD	1.953	0.078			
Final serum creatinine before procurement, mg/dL	1.050	<0.001			
Final serum creatinine – 2	1.348	0.092	1.110	1.023–1.203	0.011
HBV positivity	0.911	0.739			
HCV positivity	3.939	<0.001	4.244	1.899–9.482	<0.001

K-KDRI = Exp (0.033526 × [Age – 45 (years)] + 0.005575 × [196-Height (cm)] + 0.396192 × I [Diabetes] + 0.104068 × [Final serum creatinine – 2.0 (mg/dL)] + 1.445391 × I [HCV positivity]), where I (A) is set to 1 if condition A is applies to the donor kidney of interest and otherwise it is set to 0. CI, confidence interval; CVA, cerebrovascular accident; DCD, donation after circulatory death; Exp, exponential; HBV, hepatitis B virus; HCV, hepatitis C virus; HR, hazard ratio. [a]Adjusted for recipient factors (age, sex, diabetes mellitus, hypertension, mode of dialysis, duration of dialysis, HBV, HCV) and transplantation-related factor (number of HLA mismatches, cold ischemic time) in the final model.

Baseline Characteristics of the Cohort for Identifying Suitable Candidates for ECD DDKT (Cohort 2)

We next evaluated the criteria for identifying suitable candidates for ECD kidneys using this new index in Korea. The baseline characteristics of the ECD DDKT recipients and patients on the waitlist-or-SCD DDKT group before and after propensity score matching are presented in online supplementary Table S3 and Table 3, respectively. Before propensity score matching, patients in the ECD kidneys (K-KDPI ≥70%) were older compared to the SCD kidneys (K-KDPI <70%) and the waitlisted group ($p < 0.001$). Hypertension and DM were more prevalent, while positive panel reactive antibody (PRA) was less common in the ECD DDKT group compared to the waitlist-or-SCD-DDKT groups. Additionally, the waiting time for transplantation was shorter in the ECD DDKT group compared to the waitlist-or-SCD-DDKT groups ($p < 0.001$), with the waitlist group having extremely longer waiting times than the other groups. Both groups showed comparable waiting time after the matching and other factors were also comparable between the two groups, except age and blood group (Table 3), which were further adjusted in the multivariate time-varying Cox regression analysis (Fig. 2a; online suppl. Table S4).

Suitable Candidates for ECD DDKT according to ECD Subgroups

Patient death occurred in 166 (9.6%) and 308 (7.5%) in ECD and SCD DDKT patients at a median follow-up of 38 and 52 months, respectively. Mortality occurred in 1,247 waitlisted patients (19.9%) at a median follow-up of 45 months. Patients who received ECD DDKT had a significantly lower risk of mortality compared to those who were waitlisted or received SCD DDKT (hazard ratio [HR] = 0.661; 95% CI: 0.584–0.748; $p < 0.001$) (Fig. 2a, online suppl. Table S4). Hypertension was excluded from the analysis due to its very high incidence irrespective of

Table 3. Baseline characteristics of ECD DDKT and matched control group (waitlist-or-SCD DDKT) after propensity score matching in the cohort 2

Variables	ECD DDKT	SCD DDKT	Waitlist	Matched control (waitlist-or-SCD DDKT)	*p* value
Number	1,730	4,112	6,268	10,380	
Age	53±11	49±11	52±10	52±10	0.023
19–39 years, *n* (%)	191 (11.1)	822 (20.0)	940 (15.0)	1,762 (17.0)	
40–59 years, *n* (%)	990 (57.2)	2,521 (61.3)	4,005 (63.9)	6,526 (62.9)	
≥60 years, *n* (%)	549 (31.7)	769 (18.7)	1,323 (21.1)	2,092 (20.2)	
Male, *n* (%)	1,077 (62.3)	2,488 (60.5)	3,823 (61.0)	6,311 (60.8)	0.262
Hypertension, *n* (%)	1,723 (99.6)	4,083 (99.3)	6,218 (99.2)	10,301 (99.2)	0.139
Diabetes mellitus, *n* (%)	1,480 (85.6)	3,434 (83.5)	5,265 (84.0)	8,699 (83.8)	0.072
Blood type, *n* (%)					<0.001
O	399 (23.1)	987 (24.0)	1,824 (29.1)	2,811 (27.1)	
Non-O	1,331 (76.9)	3,125 (76.0)	4,444 (70.9)	7,569 (72.9)	
PRA, *n* (%)					<0.001
Positive	253 (14.6)	728 (17.7)	1,385 (22.1)	2,133 (20.4)	
Waiting time (median) since registration, days	1,398	1,441	1,363	1,402	0.192
<5 years	926 (53.5)	2,118 (51.5)	3,259 (52.0)	5,377 (51.8)	
≥5 years	804 (46.5)	1,994 (48.5)	3,009 (48.0)	5,003 (48.2)	

Continuous variables are reported as mean ± standard deviation. Nominal and categorical variables are listed as total number (percentage). DDKT, deceased donor kidney transplantation; ECD, expanded criteria donor; PRA, panel reactive antibody; SCD, standard criteria donor.

group. Survival benefits were observed in ECD DDKT patients regardless of diabetes status, blood type, and waiting time. However, patients younger than 40 years or with positive PRA did not experience significant survival benefits from ECD DDKT compared to waitlist-or-SCD-DDKT, indicating survival benefits of ECD DDKT exist only in patients aged ≥40 years and with negative PRA (Fig. 2a, online suppl. Table S4).

Interestingly, the degree of survival benefit of ECD DDKT showed a trend of difference between the DM and non-DM groups (p for interaction = 0.099) and between the short (<5 years) and long waiting (≥5 years) time groups (p for interaction = 0.021, online suppl. Table S4; Fig. 2a). Based on these findings, we further analyzed the survival benefit of ECD DDKT in the old (≥40 years), non-sensitized (negative PRA) subgroup according to DM and waiting time. When stratifying by DM, the survival benefit of ECD DDKT in the old, non-sensitized subgroup was significantly greater in the non-DM group than in the DM group (p for interaction = 0.011; HR = 0.420, 95% CI: 0.277–0.638, $p < 0.001$ in the non-DM group; HR = 0.752, 95% CI: 0.646–0.874, $p < 0.001$ in the DM group) (Fig. 2b). However, the survival benefit of ECD DDKT in the old, non-sensitized subgroup was not different between short waiting time group (<5 years) and long waiting time group (≥5 years) (p for interaction = 0.163; HR = 0.646, 95% CI: 0.549–0.759, $p < 0.001$ in short waiting time group; HR = 0.881, 95% CI: 0.644–0.947, $p = 0.011$ in long waiting time group) (Fig. 2b). Based on these findings, a decision algorithm for ECD DDKT acceptance was developed and recommends ECD kidneys to nondiabetic, non-sensitized patients aged 40 years and older (Fig. 2c). According to the proposed algorithm, 45.6% of DDKT candidates would be considered suitable for ECD kidneys.

Discussion

In this study, we developed a Korean-specific K-KDPI system and revised ECD criteria to improve kidney allocation and transplantation outcomes. We also proposed criteria for identifying suitable candidates for ECD DDKT using this new index.

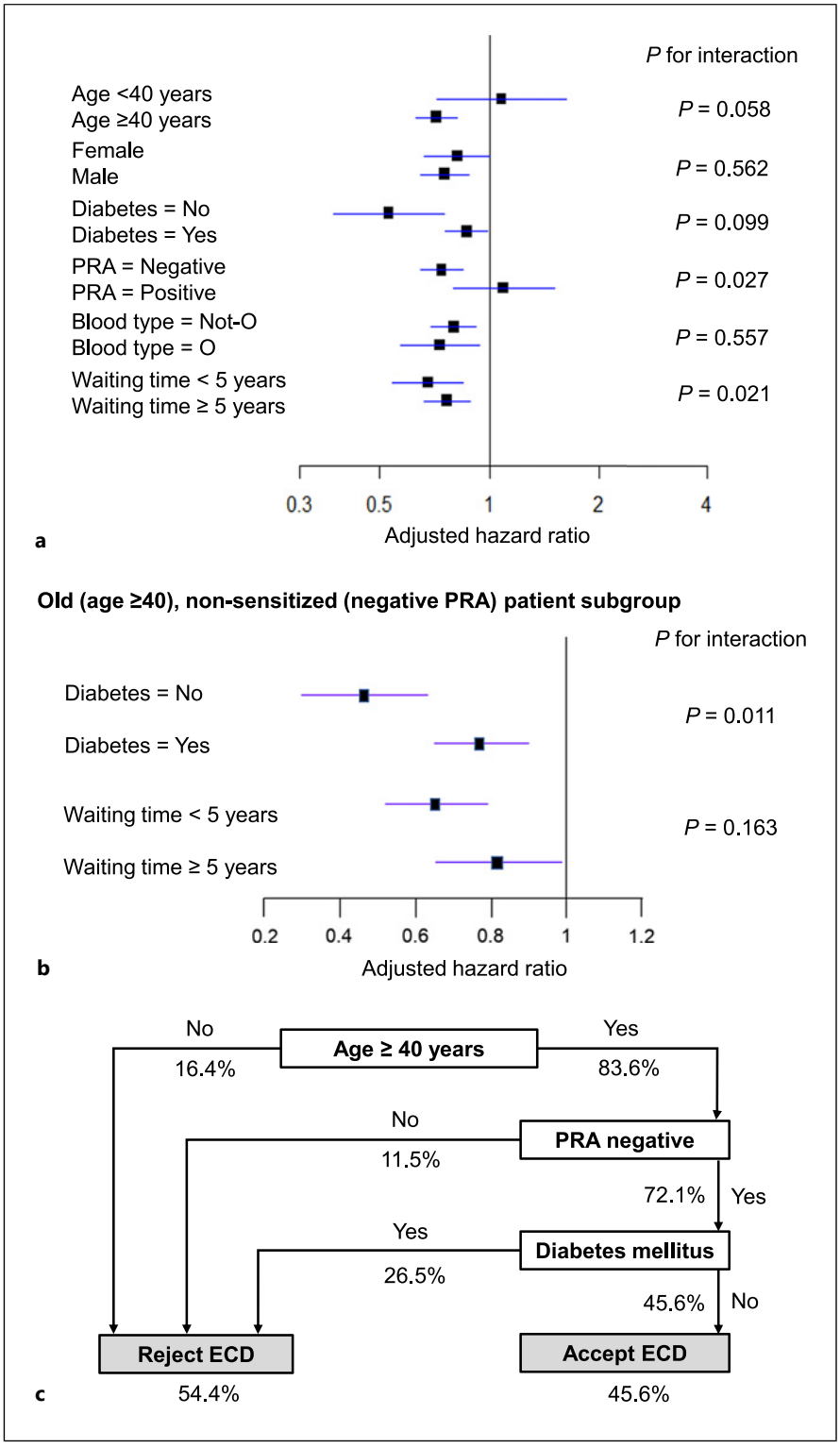

Fig. 2. Subgroup analysis and decision algorithm for ECD kidneys. **a** Subgroup analysis for relative mortality risk of ECD DDKT compared to waitlist-or-SCD DDKT. After stratifying by age, sex, DM, PRA, blood type, and waiting time, patients in the ECD DDKT group who were older or had a negative PRA had a significantly lower mortality risk compared to the waitlist-or-SCD DDKT group. **b** Subgroup analysis for DM and waiting time in the old (≥40 years), non-sensitized (negative PRA) patients. Subgroup analyses for mortality risk were conducted for DM vs. non-DM and long (≥5 years) vs. short waiting times (<5 years) in old, non-sensitized patients that showed survival benefits. Patients without DM had more benefits from ECD DDKT than patients with DM. However, there was no difference in survival benefits from ECD DDKT between long vs. short waiting time. **c** Decision algorithm for acceptance of ECD kidneys. Patients who are ≥40 years, have a negative PRA, and do not have DM, benefited from ECD DDKT (K-KDPI of 70–100%). The percentages indicate the proportion of patients at each decision point among the total waitlisted patients. DDKT, deceased donor kidney transplantation; DM, diabetes mellitus; ECD, expanded criteria donor; PRA, panel reactive antibody; SCD, standard criteria donor; K-KDPI, Korean kidney donor profile index.

Given the organ shortage, the criteria for deceased kidney donors have been relaxed, leading to increased utilization of ECD kidneys [16]. However, several Korean studies have reported no significant difference in graft survival rates following DDKT based on the dichotomous ECD criteria from UNOS [14, 17, 18] or KONOS [19–21],

suggesting that such binary criteria may not adequately predict allograft prognosis. Meanwhile, the USA developed the KDPI, a more nuanced donor prognostic stratification system that has been integrated into the new kidney allocation system [8–10]. The KDPI provides a detailed assessment of donor kidney quality and predicts posttransplant outcomes in the USA [8–10]. It has been validated in other Western countries [22–27]. When applied to Korean DDKT, the UNOS KDPI showed superior prognostic value compared to the dichotomous ECD criteria [14].

Nevertheless, some Western studies have indicated that the KDPI derived from the Scientific Registry of Transplant Recipients in the USA may not be optimal for other settings [28, 29]. The UNOS KDPI may not fully capture the unique characteristics of Korean DDKT, such as shorter cold ischemic times and longer waiting periods. Consequently, we developed a donor prognostic prediction score using Korean nationwide data. In this study, we identified five donor factors and one transplantation factor as significantly and independently associated with an increased risk of graft failure. As explained in KDRI [8], the K-KDRI was developed to improve organ allocation by using donor factors available at the time of the offer, as recipient and transplant procedure factors are typically unknown. The five-parameter K-KDRI is simpler than the UNOS KDRI, which includes ten donor-related parameters. Ethnicity and DCD factors may have minimal impact on survival in Korea, as only type IV DCD is legally allowed for transplantation, and there is a relatively homogenous ethnic background. The K-KDRI demonstrated a C-statistic of 0.600, reflecting its modest ability to discriminate risk for individual patients [13]. This value is comparable to the C-statistics of the UNOS KDRI. The results of internal validation and calibration indicate that the model exhibits low optimism and a high degree of goodness-of-fit. Graft outcomes are influenced by donor factors, recipient factors, transplant procedures, and program-specific factors, though the K-KDRI focuses solely on donor-related predictors. While incorporating additional factors could improve the C-statistics, the K-KDRI aims to summarize graft failure risk based on deceased donor characteristics, rather than account for all variations in transplant outcomes. Moreover, despite its simplicity, the K-KDPI demonstrated superior prognostic capability compared to the dichotomous ECD criteria from KONOS and UNOS, as well as the UNOS KDPI. Taken together, these findings suggest that the K-KDPI is a robust and user-friendly tool for assessing donor kidney quality and predicting subsequent kidney allograft outcomes in Korea.

In the context of a severe organ shortage, it is crucial to minimize unnecessary kidney discards and utilize ECD kidneys efficiently. To achieve optimal graft outcomes and maximize ECD utilization, it is important to identify patients who will benefit most from ECD DDKT compared to waiting for SCD kidneys. We propose a K-KDPI ≥70% as the new ECD criterion. This threshold seems reasonable, as the proportion of ECDs based on K-KDPI aligns with the ECD proportion from UNOS criteria in Korea. ECD DDKT demonstrated an overall survival benefit compared to waitlist-or-SCD DDKT across the entire study population. Subgroup analysis revealed that candidates who were aged ≥40 years, with negative PRA, and without DM experienced significant survival benefits with ECD DDKT, making them suitable candidates for ECD DDKT. Applying these criteria, ECD DDKT could be recommended to approximately 45.6% of waitlisted patients, which is similar to the 46.5% in a US study [11]. In contrast to US studies [11, 30], waiting time was not incorporated to the Korean decision algorithm. This omission may be attributed to universally lengthy waiting time in Korea, reflecting the distinct DDKT situations between the two countries.

The K-KDPI system and the revised ECD criteria were officially adopted by KONOS in 2021. Future analyses will assess the impact of this new prognostic index on kidney allocation and transplantation outcomes. The criteria for suitable candidates for ECD DDKT would be helpful for both patients and doctors faced with a DDKT offer; however, at present, it serves as a recommendation guideline rather than an obligatory allocation rule. In future studies, we could incorporate quantitatively stratified indicators into this model to enhance its predictive power.

This study has some limitations. First, comorbidity data from NHISS may be subject to over-reporting. Second, despite statistical adjustments accounting for various factors in calculating the relative mortality risk associated with ECD DDKT, cohort studies inherently carry unmeasured elements of risk that may introduce a selection bias. Third, the graft prognosis prediction model lacks external validation in independent cohorts, necessitating further validation studies to confirm these findings. Despite these limitations, this study is the first to develop a prognostic index for deceased donor kidneys using national data from an Asian country. Previous nationwide validation studies for KDPI have been conducted in Western countries [22–25], and the existing prognostic indices may not be applicable to different countries with distinct DDKT systems and cultural or ethnic characteristics. Furthermore, this nationwide study offers criteria for suitable candidates for ECD

DDKT based on the outcomes of all waitlisted candidates and DDKT patients in Korea, providing valuable insights for patients and clinicians involved in DDKT, particularly in the context of long waiting times or in countries outside the Western countries.

In conclusion, a novel K-KDPI system has been developed as a prognostic index for deceased donor kidneys, and criteria for suitable candidates for ECD DDKT in Korea based on the K-KDPI have been proposed to address the specific needs of Korea's transplant system. These tools have the potential to contribute to enhancing the efficient utilization of ECD kidneys in this area with a severe organ shortage.

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Statement of Ethics

This study was reviewed and approved by the Institutional Review Board of Seoul National University Hospital (E-1906-064-1040), which waived the requirement for written informed consent. The study was conducted in accordance with the Helsinki Declaration and the Declaration of Istanbul (2008).

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

T.Y.K., J.L., and J.Y. participated in research design. T.Y.K., J.L., O.N., and J.C.J. participated in the performance of the research. T.Y.K., J.L., Y.L., and J.Y. participated in data analysis. T.Y.K., J.L., and J.Y. participated in the writing of the manuscript.

Data Availability Statement

The data supporting the findings of this study are obtained from the National Health Insurance Service of Korea (https://nhiss.nhis.or.kr/bd/ab/bdaba000eng.do). However, access to these data is restricted, as they were used under license for this study and are not publicly available. Nonetheless, the data may be made available upon reasonable request and with the approval of the National Health Insurance Service of Korea. The data are available from the corresponding author (J.Y.) upon reasonable request.

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